

SIEMENS

ACUSON X300 Ultrasound Imaging System Instructions for Use



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Software Version 3

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CE Declaration

This product is provided with a CE marking in accordance with the regulations stated in Council Directive 93/42/EEC of June 14, 1993 concerning Medical Devices. Siemens Medical Solutions USA, Inc. is certified by Notified Body 0123 to Annex II.3 – Full Quality System.

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Contents

Chapter 1	Introduction General overview of the diagnostic ultrasound imaging system.
Chapter 2	Safety and Care Detailed information on system safety and how to care for and maintain the system, transducers, and transducer accessories.
Chapter 3	System Setup Detailed descriptions of how to transport, set up, and prepare the system for use, including transducer connection and system startup procedures.
Chapter 4	Examination Fundamentals Information on starting an examination, including instructions for entering and editing patient data and selecting an exam type, imaging mode, and transducer.
Chapter 5	Transducer Accessories and Biopsy Attachment procedures for transducer accessories and an explanation of the biopsy (puncture) function, including a procedure for needle path verification.
Chapter 6	Transesophageal Transducer Description of the transesophageal transducer, including cleaning and care information for the transducer.
Appendix A	Technical Description Technical description of the ultrasound system.
Appendix B	Control Panel Explanation of all controls and keys on the control panel, alphanumeric keyboard, and optional footswitch.
Appendix C	On-screen Controls Explanation of all on-screen controls, including menus and soft key selections.
Appendix D	Acoustic Output Reference Acoustic output reporting tables.

Note: Not all features and options described in this publication are available to all users. Please check with your Siemens representative to determine the current availability of features and options.

About the User and Reference Manuals




The user and reference manuals consist of the following publications.

Publication	Includes
<i>Instructions for Use</i>	<ul style="list-style-type: none">▪ Technical description of the ultrasound system▪ Safety and care information for the system and compatible transducers▪ Descriptions of all system controls▪ Procedures for system setup, examination fundamentals, and the biopsy function▪ Acoustic output data
<i>Features and Applications Reference*</i>	<ul style="list-style-type: none">▪ Descriptions of image acquisition and optimization, including optional imaging features▪ General and exam-specific measurements and calculations▪ Data management▪ Explanation of the clinical software programs for use on the ultrasound system
<i>System Reference*</i>	<ul style="list-style-type: none">▪ Description of customizable system settings▪ Information about DICOM connectivity, network capabilities, and external devices▪ Clinical references
<i>Electromagnetic Emissions and Immunity: Guidance and Manufacturer's Declaration*</i>	<ul style="list-style-type: none">▪ Information regarding the electromagnetic compatibility (EMC) testing of this system

*Languages supported by the user interface include a translation of this publication.

Conventions

Take a moment to familiarize yourself with these conventions.

Warnings, Cautions, and Notes	<p> WARNING: Warnings are intended to alert you to the importance of following the correct operating procedures where risk of injury to the patient or system user exists.</p> <p> Caution: Cautions are intended to alert you to the importance of following correct operating procedures to prevent the risk of damage to the system.</p> <p>Note: Notes contain information concerning the proper use of the system and/or correct execution of a procedure.</p>
Cross-References	<p>Examples:</p> <p>See also: Biohazards, Safety and Care, Chapter 2, Instructions for Use</p> <p>See also: Documentation Devices, Chapter 2, System Reference</p> <p>See also: Alphanumeric Keyboard, p. 26</p>
Customizable System Settings	<p>System settings available for customization are depicted as shown.</p> <p>Example:</p> <p> Default Settings > Automatic Freeze Response</p>
Keys and Controls	<p>Keys and controls located on the control panel are identified by uppercase, boldface type.</p> <p>Example:</p> <p>Rotate the 2D control.</p> <p>Keys located on the keyboard are identified by boldface type.</p> <p>Example:</p> <p>Press the Exam key.</p>
On-screen Objects	<p>On-screen objects such as menu selections, soft key selections, and buttons are identified by boldface type.</p> <p>Example:</p> <p>The system displays the Patient Registration form.</p>
Selection of On-screen Objects	<p>The SET key on the control panel functions as a point-and-select device (similar to a computer mouse) when used with the trackball.</p> <p>"Select" or "click" describes this action:</p> <p>Roll the trackball to position the pointer (cursor) on an on-screen object and then press the SET key.</p> <p>"Drag" describes this action:</p> <p>Roll the trackball to position the pointer (cursor) on an on-screen object and then press and hold the SET key. Roll the trackball to reposition the object and then release the SET key.</p>

1 Introduction

- System Overview 3**
 - System Review 4
- Intended Use 6**
 - Transducers and Intended Applications..... 7
- Image Screen Layout..... 8**
 - Screen Saver..... 8
 - Sample Image Screen 9
 - Status Bar..... 10
- User-Defined System Settings..... 10**
- QuickSets 10**

System Overview

The X300 system is a portable, digital diagnostic ultrasound imaging system. The system utilizes advanced imaging processing and transducer technology. The operating system is based on Windows® technology.

The system software supports standard applications, exam-specific imaging presets, measurements, pictograms, annotations, reports, worksheets, and system diagnostics.

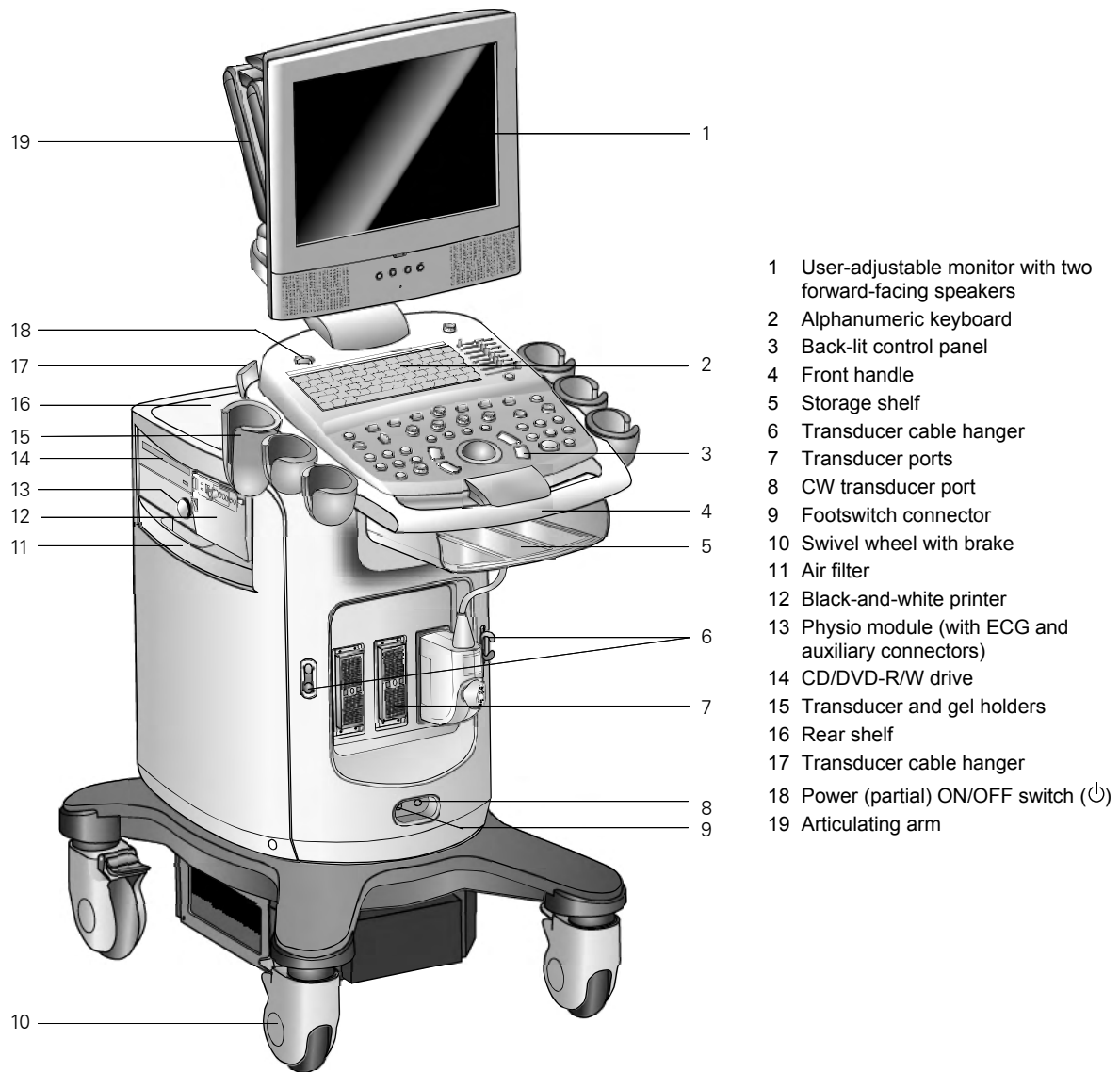
Operating modes for the system include:

- 2D-mode
- Split mode
- Dual-mode
- 4B-mode
- 2D/M-mode
- Anatomical M-mode (for Cardiac imaging)
- Pulsed Doppler
- Color Doppler
- Power Doppler
- Steerable Continuous Wave Doppler
- Auxiliary Continuous Wave Doppler

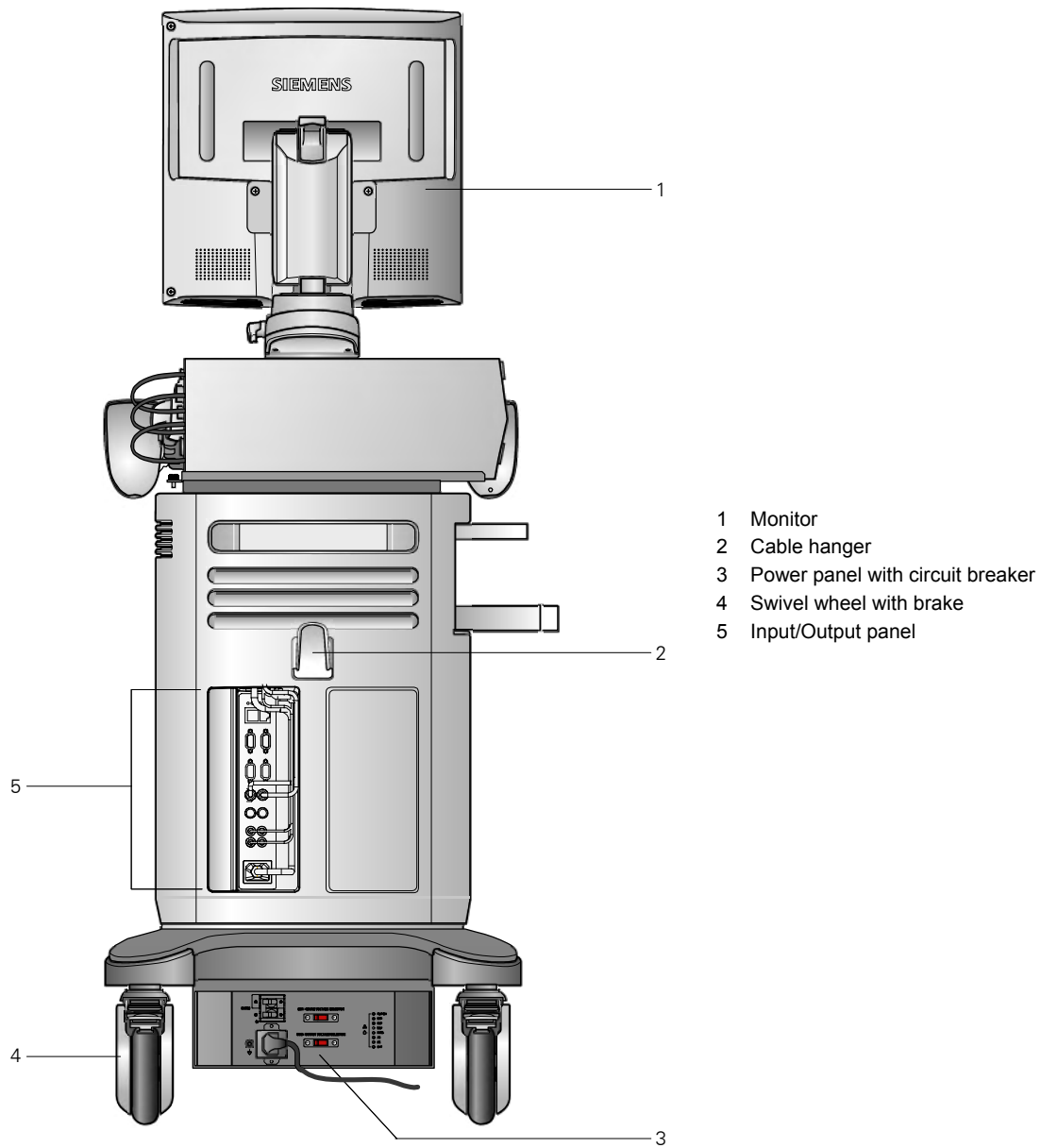
The system is equipped with a DIMAQ-IP integrated workstation. The workstation provides capabilities for digital acquisition, storage, and review of ultrasound studies. Additional system options provide integration into a networking environment.

See also: Technical Description, Appendix A, Instructions for Use

System Review




Example of the ultrasound system, left front view.



Example of the ultrasound system, back view.

Intended Use

 **Caution:** In the United States of America, federal law restricts this device to sale or use by, or on the order of, a physician.

The X300 ultrasound system supports the following applications:

- Abdomen
- Obstetrics
- Obstetrics (Japan)¹
- Early Obstetrics
- Gynecology
- Musculoskeletal
- Small Parts
- Breast
- Testicle
- Thyroid
- Urology
- Orthopedic
- Cerebrovascular
- Cardiac
- Peripheral vascular
- Venous
- Renal
- Superficial Musculoskeletal
- Pediatric Abdomen
- Pediatric Echo
- Penile
- Emergency Medicine
- Fetal Echo
- Transcranial
- Digital
- Neonatal Head
- TEE (Adult transesophageal)

¹ SONOVISTA Systems Only

Transducers and Intended Applications

Only the following transducers from Siemens are compatible with the Siemens ACUSON X300 ultrasound imaging system:

TRANSDUCER NAME	OPERATING FREQUENCY	MODES OF OPERATION	INTENDED APPLICATIONS
CURVED AND LINEAR ARRAY TRANSDUCERS			
CH5-2	2.0 – 5.0 MHz	2D, C, D, M	Obstetrics, Early Obstetrics, Gynecology, Abdomen, Renal, Urology, Fetal Echo, Emergency Medicine, Peripheral Vascular, Venous
C8-5	5.0 – 8.0 MHz	2D, C, D, M	Pediatric Abdomen, Neonatal Head, Pediatric Echo, Cerebrovascular
VF10-5	5.0 – 10 MHz	2D, C, D, M	Cerebrovascular, Peripheral Vascular, Thyroid, Testicle, Breast, Musculoskeletal, Venous, Orthopedic, Emergency Medicine
VF13-5	5.0 – 13 MHz	2D, C, D, M	Breast, Thyroid, Testicle, Musculoskeletal, Superficial Musculoskeletal, Digital, Penile, Cerebrovascular, Venous
VF13-5SP	5.0 – 13 MHz	2D, C, D, M	Cerebrovascular, Musculoskeletal, Venous, Small Parts
VF8-3	3.0 – 8.0 MHz	2D, C, D, M	Cerebrovascular, Peripheral Vascular, Venous, Musculoskeletal, Thyroid, Testicle
PHASED ARRAY TRANSDUCERS			
P4-2	2.0 – 4.0 MHz	2D, C, D, M, SCW	Cardiac, Abdomen, Renal, Gynecology, Obstetrics, Transcranial, Emergency Medicine
P8-4	4.0 – 8.0 MHz	2D, C, D, M, SCW	Pediatric Abdomen, Renal, Pediatric Echo, Neonatal Head
P5-1	1.0 – 5.0 MHz	2D, C, D, M, SCW	Cardiac, Abdomen, Obstetrics, Transcranial, Pediatric Echo
V5Ms	3.5 – 6.0 MHz	2D, C, D, M, SCW	Adult transesophageal
ENDOCAVITY TRANSDUCERS			
EC9-4	4.0 – 9.0 MHz	2D, C, D, M	Urology, Obstetrics, Early Obstetrics, Gynecology
ENDOVAGINAL TRANSDUCERS			
EV9-4	4.0 – 9.0 MHz	2D, C, D, M	Obstetrics, Early Obstetrics, Gynecology, Emergency Medicine
CONTINUOUS WAVE TRANSDUCERS			
CW2	2 MHz	CW	Cardiac, Pediatric Echo
CW5	5 MHz	CW	Pediatric Echo, Cerebrovascular

EMC Note: Operating the transducer in close proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations may lead to temporary degradation or interference visible on the monitor screen. A lightening of image background may be noticed while visualizing hypoechoic structures, or color spectral interference, or jitter, or horizontal lines in the image screen may occur. The transducer and the system have been designed and tested to withstand such interference and will not be permanently damaged. Refer to the *Electromagnetic Emissions and Immunity Guidance and Manufacturer's Declaration*.

Image Screen Layout

The monitor on the ultrasound system displays clinical images together with important operating parameters and patient data. There is a variety of on-screen overlays and graphical objects to aid in image evaluation.

Many **fields** or areas of data displayed on the screen are multi-functional. The image field can display a 2D-mode image, M-mode sweep, Doppler spectrum, and their combinations, sets of calipers, pictograms and annotation text, and CINE icons. An image can be inverted on a vertical axis and reversed on a horizontal axis to facilitate viewing and measurements.

The system displays reduced-size reference images (thumbnails) of images, clips, and volumes stored during the exam.

EMC Note: Operating the ultrasound imaging system in close proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations, may lead to interference visible on the monitor screen. However, the device has been designed and tested to withstand such interference and will not be permanently damaged.

Screen Saver

The screen saver feature automatically replaces the display with a blank screen after the system has been inactive for a specified number of minutes.

When the screen saver is activated, the system is automatically placed into freeze mode.

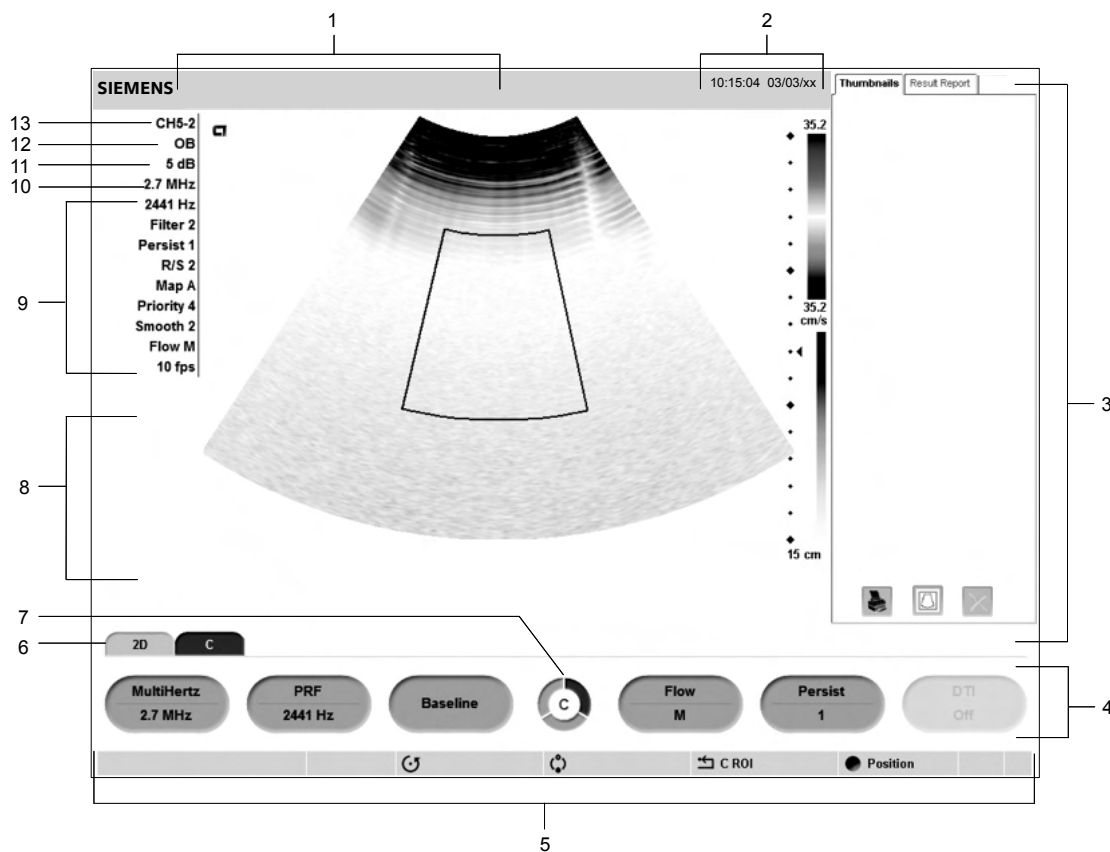
Restore the screen display by pressing any key or adjusting any control. The first key that you press will restore the view without performing a function. Press the key again to execute the command.

Use the system presets to enable the screen saver feature and to specify the delay period and the background for the blank screen.



Display > Monitor > Enable Screen Saver
Display > Monitor > Screen Saver Delay
Display > Monitor > Screen Saver Type







Sample Image Screen



Example of a typical image screen.

- 1 Information for identifying the patient, operator, and the hospital or clinic.
- 2 Time and Date
- 3 **Panels** including **Thumbnails** with controls for printing, deleting, and deselecting an image, clip, or volume and **Patient Info** for displaying patient information.
- 4 **Soft key selections** for a mode or function, including controls for image optimization, post-processing, measurement types, annotations, and playback. Use the corresponding toggle key on the control panel to activate the selection. Rotate the **PAGE** control on the control panel to access additional selections for the mode or function. Press the **PAGE** control to access soft key selections for other modes or functions.
- 5 **Page Indicator** for the soft key selections. The number of available "pages" for a specific mode or function are identified by the number of sections in the "page indicator". The highlighted section corresponds to the displayed "page" of soft key selections.
- 6 **Tab Indicator**. Identifies the mode or function for the soft key selections.
- 7 Status bar. Indicates the function currently assigned to the trackball, **SELECT** control, **UPDATE** key, **ESCAPE** key. During video recording, provides recording status and an icon to indicate microphone function is active.
- 8 During the Measurement function, the system displays the Measurement Label menu for the priority imaging mode and exam type. Use the **CALIPER** key to access the Measurement Menu. During annotation, the system displays the library of pre-defined labels for identifying body position and anatomical structures by exam type.
- 9 **Imaging Parameters**. Displays settings for parameters adjusted by the soft key selections.
Measured Results. Displays values from measurements and calculations when the Measurement function is active.
- 10 **Transducer Frequency**
- 11 **Gain** for the priority mode
- 12 **Active Exam type**
- 13 **Active transducer name**

Status Bar

Icon	Description
	Indicates recording status during video recording using a VCR or DVR. A red icon displays during recording and a white icon displays during pause or stop. The recording time also displays beside the icon.
	Indicates the function currently assigned to the SELECT control.
	Indicates the function currently assigned to the UPDATE key.
	Indicates the function currently assigned to the ESCAPE key. Press the ESCAPE key to cycle through the functions for other active modes under control of the key, if any.
	Indicates the function currently assigned to the trackball. Press the SET key to cycle through other functions under control of the trackball, if any.
	When displayed, indicates recording function with the built-in microphone is activated.

User-Defined System Settings

You can customize many features of the ultrasound system by using the system presets to designate default settings, or **presets**. The values are stored in non-volatile memory and will remain intact when the system is powered off.

Each user of the system can determine settings for imaging preferences and default settings, then store them on a disk. Those user-defined settings can then be loaded along with new system software. The disk also serves as a backup.

QuickSets

The **QuickSet™** feature allows you to capture an optimized configuration of imaging parameter settings for a combination of a specific transducer and exam.

2 Safety and Care

Operating Safety and Environment	3
System Symbols.....	3
Labels.....	7
Biohazard Considerations.....	9
Note on Fetal Examinations.....	10
Acoustic Output — Mechanical and Thermal Indices.....	10
Mechanical and Thermal Indices.....	11
Transmit Power Control.....	12
Transmit Power Display.....	13
Imaging Functions that Change Acoustic Output.....	14
Transducer Surface Temperature Limits.....	15
Electrical Safety.....	15
Level of Protection Against Electrical Shock — Transducers.....	17
Defibrillators.....	17
Pacemakers.....	17
Possible Combinations with Other Equipment.....	17
Ultrasound System — Care	18
Daily Checklist.....	18
Maintenance.....	19
Repair.....	19
Siemens Authorized Care.....	19
Cleaning and Disinfecting.....	21
Cleaning and Disinfecting the System.....	21
Cleaning an Air Filter.....	23
Caring for the Battery Pack.....	25
Battery Pack Location.....	25
Battery Pack Replacement and Disposal.....	26
Battery Pack Disposal.....	27
Documentation and Storage Devices — Care	28
Transducers — Care	28
Cleaning and Disinfecting Transducers.....	29
IPX8 Immersion Levels.....	31
Approved List of Pre-Cleaners and Low-Level Disinfectants.....	32
Approved List of Disinfectants.....	33
Sterilizing Transducers — VF13-5SP.....	34
Storage.....	34
Repair.....	34
Protective case.....	34



















Transducer Accessories — Care	35
Transducer Sheaths	35
Storage.....	35
Gel Pad.....	36
Storage.....	36
Needle Guide Bracket Kits.....	36
Storage and Transportation.....	36
Cleaning, Disinfecting, and Sterilizing — Needle Guide Bracket Kits...	36
Universal Needle Guide, Stainless	37
Storage.....	37
Product Recycling and Disposal	38























Operating Safety and Environment













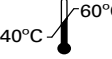





Do not operate the ultrasound imaging system until you fully understand the safety considerations and procedures presented in this manual.

System Symbols


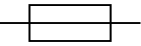




The table below is provided for your identification of important symbols located in labels on the ultrasound imaging system and transducers.

Symbol	Explanation
	Alternating Current
V~	AC (alternating current) voltage source
	Caution: Risk of electric shock
	Type BF Defibrillator-proof Patient Connection
	Type BF Applied Part
	Type CF Patient Connection
	Consult Operator's Manual
	Control Panel Task Light Indicator Light
	Monitor Menu Control
	Monitor Menu Control, left (decrease)
	Monitor Menu Control, right (increase)
	Monitor Picture menu icon
	Monitor Function menu icon
	Monitor OSD menu icon
	Monitor menu Exit icon
	Monitor Contrast
	Monitor Brightness
	Protective Earth Ground
	Signal Earth Ground

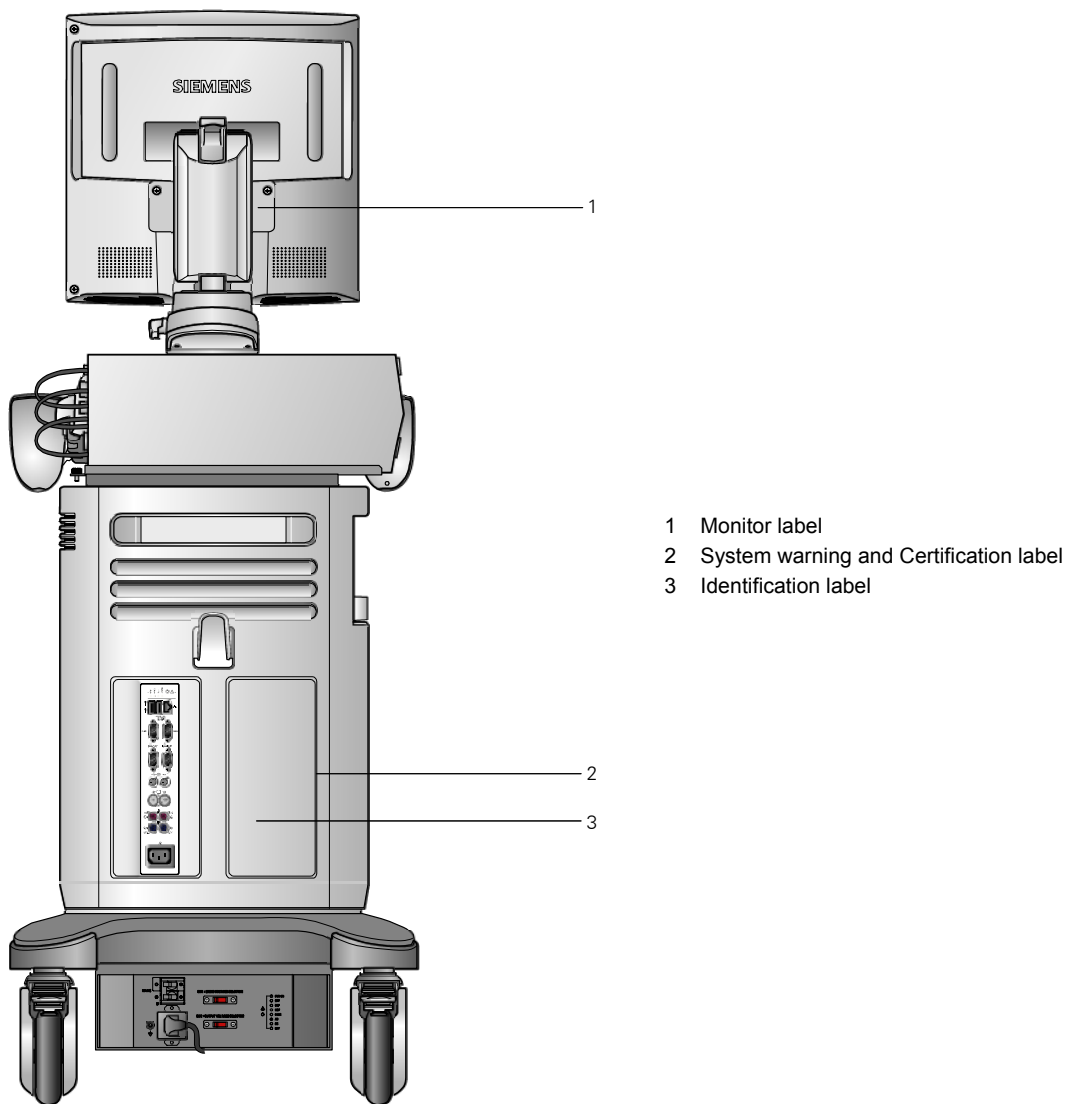
Symbol	Explanation
	Signal Input
	Signal Output
	Video Connection (monochrome video signals)
	Start (of action for equipment)
	Digital Interface, RS-232-C connection
	USB Connection
	Ethernet 10/100BaseT Connection
	Equipotential Connection
	Footswitch Connector
	Printer Connection
B/W	Black and White Printer Connection
	Video Luma/Color
	Video Red, Green, Blue
	VGA
	Electronic Array Transducer Port
	Continuous Wave Doppler Transducer Port
	Unlocked position
	Locked position
	Audio
	Shelf Weight Restriction
	ON only for MAINS control
	OFF only for MAINS control
	Power "On" standby switch

Symbol	Explanation
	ECG Socket
IPX8	Protected against the effects of continuous immersion in water
	Do not open. Refer servicing to qualified service personnel
	Danger: Risk of explosion if used in the presence of flammable anesthetics
	Manufacturer's declaration of product compliance with applicable EEC directive(s) and the European Notified Body
	Manufacturer's declaration of product compliance with applicable EEC directive(s)
	UL symbol for listing as recognized components for Canada and United States of America
	Gost-R symbol indicates that this product is certified for conformity to the safety requirements of Russian state standards
IVK	(Installierte Volumen Komponente) Identifier of selected system components or parts for product traceability
	UL classified symbol for Canada and United States of America
	Bar Code
 2006	Date of Manufacture symbol with the date below
	Do not install wet
	Location of air filter
 -40°C — 60°C	Storage temperature range (example)
	Indicates this side up
	Do not stack
 140 kg	Shipping weight (example)
	Do not allow to get wet
	Fragile. Handle with care

2 Safety and Care

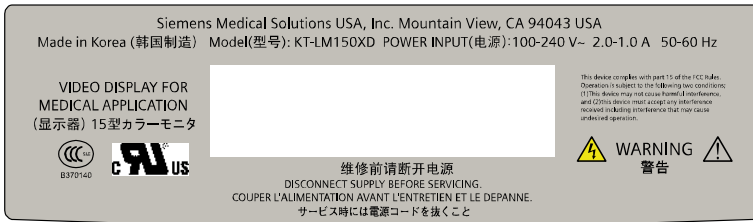
Symbol	Explanation
	Do not dispose of by dumping in garbage. Use a separate collection for electrical and electronic equipment.
	Fuse
	Pinch hazard.
	Control panel height adjustment
  DO NOT LEAN	Do not lean against the monitor.

Labels



Location of labels.

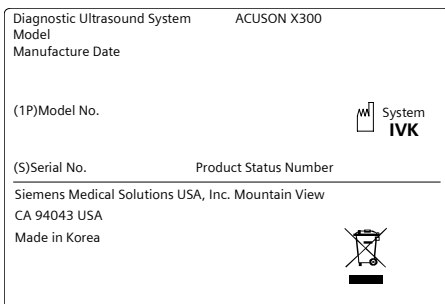
2 Safety and Care



Example of monitor label.



Example of system warning label with certification labels.



Example of identification label.

Biohazard Considerations

- ⚠ **WARNING:** This equipment is not suitable for intracardiac use or direct cardiac contact.
- ⚠ **WARNING:** For neonatal head imaging, Siemens recommends that you exercise special care during neonatal cephalic scanning to avoid possible damage to the posterior region of the eye. The ultrasound energy emitted by the transducer easily penetrates the fontanelles of the infant.
- ⚠ **WARNING:** Siemens makes every effort to manufacture safe and effective transducers. You must take all necessary precautions to eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials. These precautions should be considered in the use of any application that may indicate the need for such care, and during endocavity or intraoperative scanning; during biopsy or puncture procedures; or when scanning patients with open wounds.
- ⚠ **WARNING:** To eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials, always dispose hazardous or infectious materials according to medical regulations for biohazardous waste.
- ⚠ **WARNING:** There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex-sensitive patients and to be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.
- ⚠ **WARNING:** Ultrasound energy is transmitted more effectively through water than through tissue. When using a standoff device of any kind, for example, a gel pad, the actual mechanical and thermal indices, MI and/or TI, may be higher than indicated in the output display on the system.

The assessment of the biological effects of diagnostic ultrasound on humans is a subject of ongoing scientific research. This system, and all diagnostic ultrasound procedures, should be used for valid reasons, for the shortest possible period of time, and at the lowest mechanical and thermal indices necessary to produce clinically acceptable images.

According to the ALARA (As Low As Reasonably Achievable) principles, acoustic output should be set to the **lowest level required to satisfactorily perform the examination**.

The ultrasound imaging system complies with the standards of the American Institute of Ultrasound in Medicine (AIUM), the National Electrical Manufacturer's Association (NEMA), the guidelines of the United States Food and Drug Administration (FDA), and the guidelines of the International Electrotechnical Commission (IEC) in terms of safety and acoustic output levels. The ultrasound output levels are stated to permit the user to critically evaluate the system settings in the event of new research findings being announced.

Note on Fetal Examinations

The following recommendation is excerpted from the National Institute of Health in the United States of America. *Consensus Statement on the Use of Ultrasound Imaging During Pregnancy*, Volume 5, No. 1, based on the recommendation issued at the Health Consensus Development Conference, February, 1984:


Ultrasound examination in pregnancy should be performed for a specific medical indication. The data on clinical efficacy and safety do not allow a recommendation for routine scanning at this time.

Ultrasound examination performed solely to satisfy the family's desire to know the fetal sex, to view the fetus, or to obtain a picture of the fetus should be discouraged. In addition, visualization of the fetus solely for educational or commercial demonstrations without medical benefit should not be performed.

In August 1994, the Food and Drug Administration (FDA) notified the medical community and the ultrasound industry regarding its concerns about the misuse of diagnostic ultrasound equipment for non-medical purposes, and to discourage patients from having sonograms for non-medical reasons.

The American Institute of Ultrasound in Medicine (AIUM) has also advocated the responsible use of diagnostic ultrasound for all fetal imaging (August 2005).

Acoustic Output — Mechanical and Thermal Indices

 **WARNING:** Ultrasound procedures should be used for valid reasons, for the shortest period of time, and at the lowest mechanical/thermal index setting necessary to produce clinically acceptable images.

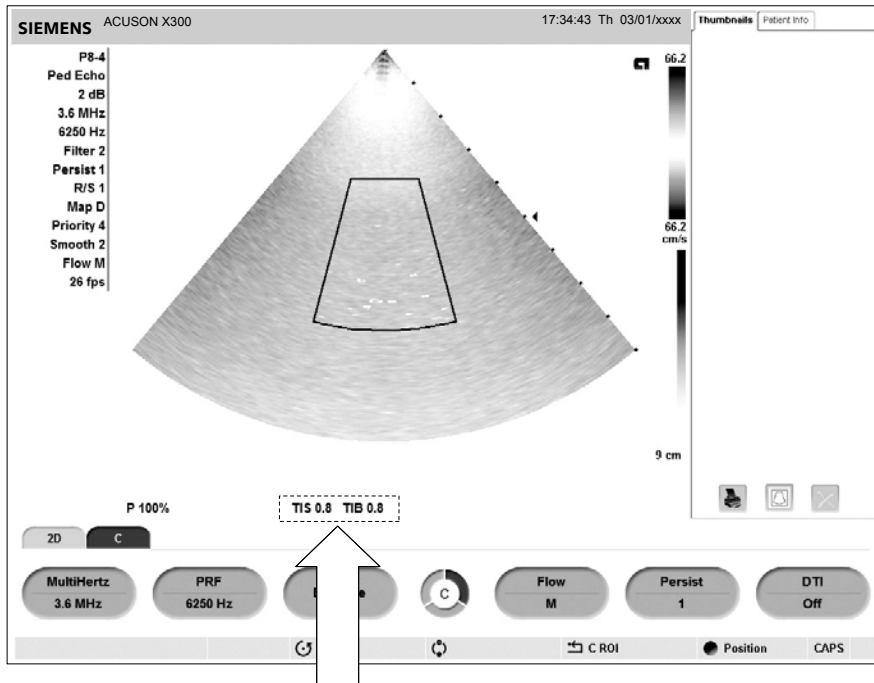
The ultrasound system incorporates an output display of Mechanical and Thermal Indices to allow you to monitor, and to limit, the amount of ultrasound energy that is transferred to the patient.

Note: For systems distributed in the United States of America, refer to the *Medical Ultrasound Safety* ultrasound education program brochure produced by the AIUM that is shipped with the ultrasound system.

See also: Acoustic Output Reference, Appendix D, Instructions for Use

Mechanical and Thermal Indices

The system displays the Mechanical and Thermal Indices during real-time imaging, in all imaging modes, when the Mechanical Index or the Thermal Indices are equal to or exceed a value of 0.4.



Location of mechanical and thermal indices on the image screen.

Indices display in the abbreviated form shown below:

- **MI:** Mechanical Index
- **TIB:** Bone Thermal Index (fetal application)
- **TIS:** Soft Tissue Thermal Index
- **TIC:** Cranial Thermal Index

Transmit Power Control

Adjust the transmit power and the corresponding acoustic pressure delivered through the transducer to the patient by using the designated control on the system. It is the main system function that determines the transmitted intensity of ultrasound for all transducers and imaging modes during real-time imaging, though it is not the only function that affects the mechanical and thermal indices. The range and especially the maximum level of the mechanical and thermal indices differ depending on the transducers. In addition, each diagnostic exam type has preset values for mechanical and thermal indices.

See also: Imaging Functions that Change Acoustic Output, p. 2-14

Note: Maximum transmit acoustic intensity and the mechanical index for each exam type are limited in accordance with the United States Food and Drug Administration's (FDA) recommendations and guidelines. System default transmit intensity and mechanical index values are always below the FDA recommendations for each exam type. Although some exam types may default to a condition of maximum allowable transmit power, there are other system controls or functions that could raise acoustic output levels.

To increase the transmit power:

- During real-time imaging, press the toggle key for **P** upward to increase transmit power.

To decrease the transmit power:

- During real-time imaging, press the toggle key for **P** downward to decrease transmit power.

Transmit Power Display

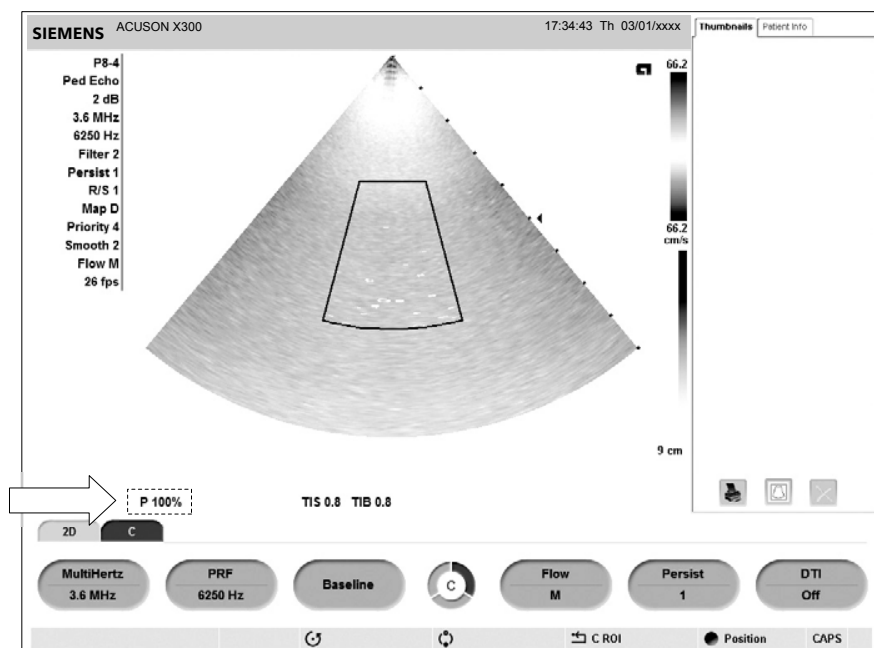
The transmit power range is from 0% to 100%. Selecting 100%, in combination with other system controls or functions, generates the maximum acoustic intensity and mechanical index for each transducer, where:

$$I_{SPTA,3} : \leq 720 \text{ mW/cm}^2 \text{ and MI} \leq 1.9$$

Percentage (%)	Decibels (dB)	Percentage (%)	Decibels (dB)
100%	0 dB	4.0%	-28 dB
79%	-2 dB	3.2%	-30 dB
63%	-4 dB	2.5%	-32 dB
50%	-6 dB	2.0%	-34 dB
40%	-8 dB	1.6%	-36 dB
32%	-10 dB	1.3%	-38 dB
25%	-12 dB	1.0%	-40 dB
20%	-14 dB	0.79%	-42 dB
16%	-16 dB	0.63%	-44 dB
13%	-18 dB	0.40%	-46 dB
10%	-20 dB	0.50%	-48 dB
7.9%	-22 dB	0.32%	-50 dB
6.3%	-24 dB	0.25%	-52 dB
5.0%	-26 dB	0.20%	-54 dB


Comparison of decibels to percentages.

When the power level is changed, the system briefly highlights the power value to indicate the change.



Location of power display on the image screen.

Imaging Functions that Change Acoustic Output

 **WARNING:** Observe the real-time display of mechanical and thermal indices (MI/TI) at all times.

In addition to the adjustment of the transmit power, adjustment of the following imaging functions and/or controls may affect the acoustic output:

- Automatic Time-out
- M-mode cursor
- Color and Power ROI Position and Size; Steering Angle for linear array transducers
- Doppler Gate Position and Size; Steering Angle for linear array transducers
- Doppler PRF
- Color PRF
- Exam Type
- Field of View (Scan Angle); 2D Steering Angle for linear array transducers
- Focus
- Zoom
- Frame Rate
- Freeze
- Image Depth
- Imaging Mode
- Multi-Frequency
- Power On/Off
- System Presets and QuickSets
- THI
- Resolution/Speed
- Simultaneous/Update
- Transducer
- Gel pad use

Transducer Surface Temperature Limits

The following table provides the maximum surface temperature of the transducers compatible with the system.

Maximum surface temperatures are in accordance with IEC 60601-2-37.

Note: The systemic uncertainty of the transducer surface temperature is estimated as 1.39° C.

Transducer	Maximum Temperature	
	TMM	Still Air
CH5-2	<41.4° C	<42.5° C
C8-5	<33.1° C	<43.5° C
VF8-3	<33.5° C	<46.2° C
VF10-5	<41.1° C	<42.7° C
VF13-5	<41.4° C	<42.7° C
VF13-5SP	<41.2° C	<42.5° C
EV9-4	<42.3° C	<43.6° C
EC9-4	<41.7° C	<43.8° C
P4-2	<42.2° C	<44.1° C
P5-1	<41.5° C	<46.0° C
P8-4	<41.2° C	<42.1° C
V5Ms	<41.6° C	<44.3° C
CW2	<31.5° C	<35.5° C
CW5	<27.0° C	<32.0° C

TMM = Tissue Mimicking Material

Electrical Safety

- ⚠ **WARNING:** For systems used in the U.S.A.: To ensure grounding reliability, only connect the system to a hospital-grade power outlet.
- ⚠ **WARNING:** The AC power connector plug for the ultrasound system is a three-prong grounded plug (in the U.S.A.) and should never be adapted to any two-prong (non-grounded) outlet, either by modifying the plug or by using an adapter. In the U.S.A., proper grounding requires the AC power connector plug to be plugged into a hospital-grade power outlet.
- ⚠ **WARNING:** To avoid electrical shock, never modify the ultrasound system's AC power connector plug, as doing so may overload your facility's power circuits. To ensure grounding reliability, connect the system only to an equivalent outlet.
- ⚠ **WARNING:** To avoid electrical shock, never use equipment or a MAINS power cord that shows signs of wear or tampering, or whose ground plug has been bypassed using an adapter.
- ⚠ **WARNING:** Equipment connected to the ultrasound system and in the patient zone must be powered from a medically-isolated power source or must be a medically-isolated device. Equipment powered from a non-isolated source can result in chassis leakage currents exceeding safe levels. Chassis leakage current created by an accessory or device connected to a non-isolated outlet may add to the chassis leakage current of the ultrasound system.

- ⚠ WARNING:** Using an extension cord or multi-socket outlet setup to provide power to the imaging system, or to the system's peripheral devices may compromise the system grounding and cause your system to exceed leakage current limits.
- ⚠ WARNING:** To avoid electrical shock and damage to the ultrasound system, power off and unplug the equipment from the AC power outlet before cleaning and disinfecting.
- ⚠ WARNING:** Do not pour any fluid onto the ultrasound system surfaces, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure.
- ⚠ WARNING:** To ensure proper grounding and leakage current levels, it is the policy of Siemens to have an authorized Siemens representative or Siemens-approved third party perform all on-board connections of documentation and storage devices to the ultrasound system.
- ⚠ WARNING:** To maintain the safety and functionality of the ultrasound system, maintenance must be performed every 12 months. Electrical safety tests must also be performed at regular intervals as specified by local safety regulations, or as needed.
- ⚠ Caution:** To avoid the possibility of static shock and damage to the system, avoid the use of aerosol spray cleaners on the monitor screens.
- ⚠ Caution:** Do not use spray cleaners on the ultrasound system, as this may force cleaning fluid into the system and damage electronic components. It is also possible for the solvent fumes to build up and form flammable gases or damage internal components.
- ⚠ Caution:** To reduce the risk of fire and subsequent equipment damage, use only 26 gauge (0.14 mm²) or heavier wire for the cable connecting to the Ethernet port located on the ultrasound system.

EMC Note: Operating the ultrasound system in close proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations, may lead to interference visible on the monitor screen. However, the device has been designed and tested to withstand such interference and will not be permanently damaged.

Level of Protection Against Electrical Shock — Transducers

⚠ WARNING: Only use Type BF transducers with the ultrasound system to maintain a level of protection against electrical shock.

According to EN 60601-1 and IEC 60601-1, the assemblies for the linear, curved, and phased array transducers provide a "Level of Protection Against Electrical Shock" of "Type BF."



The Type BF icon is located on the transducer label.

Defibrillators

⚠ WARNING: The ECG function is designed to withstand the effects of defibrillation. However, when possible, disconnect the ECG leads during defibrillation since a malfunction of the safety controls could otherwise result in electrical burns for the patient.

For patient safety, be sure to use defibrillators that do not have grounded patient circuits.

Pacemakers

⚠ WARNING: Pacemakers may be susceptible to the high frequency electrical signal generated by ultrasound equipment. Use precautions when using ultrasound equipment on or near someone with a pacemaker. If there is interference, immediately discontinue the examination and power off the ultrasound system.

Possible Combinations with Other Equipment

⚠ WARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (for example, EN 60950 and IEC 60950 for data processing equipment and EN 60601-1 and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standards EN 60601-1-1 and IEC 60601-1-1. Anyone who connects additional equipment to any of the signal input or signal output ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standards EN 60601-1-1 and IEC 60601-1-1. Siemens can only guarantee the performance and safety of the devices listed in the *Instructions for Use*. If in doubt, consult the Siemens service department or your local Siemens representative.

The ultrasound system supports three on-board documentation devices. The ultrasound system can support two on-board documentation devices at one time.

On-board peripheral devices must be installed by an authorized Siemens representative or by a Siemens-approved third party. Devices installed by other people will be at the user's risk and may void the system warranty.

Ultrasound System — Care

It is the responsibility of the user to verify that the ultrasound system is safe for diagnostic operation on a daily basis. Each day, prior to using the system, perform each of the steps in the Daily Checklist.

All exterior parts of the system, including the control panel, keyboard, and transducers, should be cleaned and/or disinfected as necessary or between uses. Clean each component to remove any surface particles. Disinfect components to kill vegetative organisms and viruses.

The air filter on the ultrasound system must be cleaned regularly to maintain proper system cooling. Remove and check the air filter weekly, and clean as needed.

Daily Checklist

Perform the following each day before using the ultrasound system:

- Visually inspect all transducers. Do not use a transducer which has a cracked, punctured, or discolored casing or a frayed cable.

⚠ WARNING: To avoid electrical shock, you must visually inspect a transducer prior to use. Do not use a transducer that has a cracked, punctured, or discolored casing or a frayed cable.

Discoloration Exception: The use of the approved disinfectants, Cidex OPA and Gigasept FF, may cause discoloration of transducer housings, including the face of the transducer. You can continue to use a transducer if it is discolored due to the use of these specific disinfectants only.


See also: Approved List of Disinfectants, p. 2-33.

- Visually inspect all power cords. Do not turn on the power if a cord is frayed or split, or shows signs of wear.
If your system's power cord is frayed or split, or shows signs of wear, contact your Siemens service representative for power cord replacement.
- Visually inspect the ECG connector and the cable. Do not use the ECG function if the connector or cable is damaged or broken.
- Verify that the trackball, DGC slide controls, and other controls on the control panel are clean and free from gel or other contaminants.

Once the system is powered on:

- Visually check the on-screen displays and lighting.
- Verify that the monitor displays the current date and time.
- Verify that the transducer identification and indicated frequency are correct for the active transducer.

Maintenance

 **WARNING:** To maintain the safety and functionality of the ultrasound system, maintenance must be performed every 12 months. Electrical safety tests must also be performed at regular intervals as specified by local safety regulations, or as needed.

Repair

For questions regarding repair or replacement of any equipment parts on your system, contact your Siemens service representative.

Siemens Authorized Care

Installers and operators must observe any statutory regulations that govern the installation, operation, inspection, and maintenance of this equipment.

To ensure the safety of patients, operators, and third parties, the equipment must be inspected every 12 months, and the replacement of parts is performed as necessary. This maintenance must be performed by a qualified Siemens authorized representative. It is important to inspect the equipment more frequently if it is operated under extraordinary conditions.


Perform inspections and maintenance at the prescribed intervals to avoid worn and hazardous parts due to wear. Contact the Siemens service department for information regarding the required maintenance. As manufacturers and installers of ultrasound equipment, Siemens cannot assume responsibility for the safety properties, reliability, and/or performance of the equipment, if:

- Installations, extensions, readjustments, modifications, additions, or repairs are carried out by persons not specifically authorized by Siemens.
- Components that affect the safe operation of the system are replaced by parts not authorized by Siemens.
- The electrical installation of the room where the equipment is located does not meet the power and environmental requirements stated in this manual.
- The equipment is not used in accordance with the operating instructions.
- The system is operated by personnel not adequately educated or trained.

Siemens suggests that you request any person who performs maintenance, or repairs, to provide you with a certificate showing:

- The nature and extent of the work performed
- Changes in rated performance
- Changes in working ranges
- Date of service
- Name of person or firm performing the service
- Signature of person performing the service

Technical documentation pertinent to the ultrasound system is available at an additional charge. However, this does not in any way constitute an authorization to conduct repairs or maintenance. Siemens refuses all responsibility whatsoever for repairs that are performed without the express written consent of the Siemens service department.







 **WARNING:** Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (for example, EN 60950 and IEC 60950 for data processing equipment and EN 60601-1 and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standards EN 60601-1-1 and IEC 60601-1-1. Anyone who connects additional equipment to any signal input or signal output ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standards EN 60601-1-1 and IEC 60601-1-1. Siemens can only guarantee the performance and safety of the devices listed in the *Instructions for Use*. If in doubt, consult the Siemens service department or your local Siemens representative.

Cleaning and Disinfecting

You must take all necessary precautions to eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials. Use universal precautions when cleaning and disinfecting. You should treat all portions of the imaging system that come in contact with human blood or other body fluids as if they were known to be infectious.

All exterior parts of the system, including the control panel, and transducers, should be cleaned and/or disinfected as necessary or between uses. Clean each component to remove any surface particles. Disinfect the components to kill vegetative organisms and viruses.

Cleaning and Disinfecting the System

-  **WARNING:** To avoid electric shock and damage to the system, always power off and disconnect the equipment from the AC power source before cleaning and disinfecting.
-  **WARNING:** Contents of some disinfecting agents are known to be health hazards. Their concentration in the air must not exceed an applicable specified limit. Comply with the manufacturer's instructions when using these agents.
-  **Caution:** To avoid the possibility of static shock and damage to the ultrasound system, avoid the use of aerosol spray cleaners on the monitor screens.
-  **Caution:** Do not clean the system with chlorinated or aromatic solvents, acidic or basic solutions, isopropyl alcohol or strong cleaners such as ammoniated products, as these can damage the surface of the system. **Isopropyl alcohol exception:** It is acceptable to use isopropyl alcohol only when recommended for cleaning the trackball assembly. Use the recommended cleaning procedure.
See also: Trackball Cleaning, p. 2-22
-  **Caution:** Do not use spray cleaners on the ultrasound system, or pour fluid onto the system surfaces, as fluid can seep into the system and damage electronic components. It is also possible for the solvent fumes to build up and form flammable gases or damage internal components.
-  **Caution:** Do not pour any fluid onto the ultrasound system surfaces, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure.

System Surfaces

The following instructions describe cleaning the surface of the ultrasound system, including the trackball and transducer holder.

To clean the surface of the ultrasound system:

1. Power off (⏻) the ultrasound system and unplug the power cord from the power outlet.
2. Use a clean gauze pad or lint-free cloth, lightly moistened with a mild detergent, to wipe the surface of the ultrasound system.

Take particular care to clean the areas near the trackball and the slide controls. Ensure these areas are free of gel and any other visible residue.

Ensure that cleaning solution does not seep into the control panel, keyboard, or any other openings.


3. After cleaning, use a clean, lint-free cloth to dry the surface.
4. After cleaning, reconnect the ultrasound system power cord into the power outlet.


To clean the liners of the transducer holders:

1. Use the tab to remove the liner from the transducer holder.
2. Clean the liner under running water, using a mild detergent and dry with a lint-free cloth.
3. Reinsert the liner into the transducer holder.

See also: System Setup, Chapter 3, Instructions for Use

To clean the trackball:

 **Caution:** Do not drop or place foreign objects inside the trackball assembly. This may affect the trackball's operation and damage the system.

 **Caution:** Do not submerge the front bezel and Teflon seal in isopropyl alcohol - this may damage the adhesive bond between the two components.

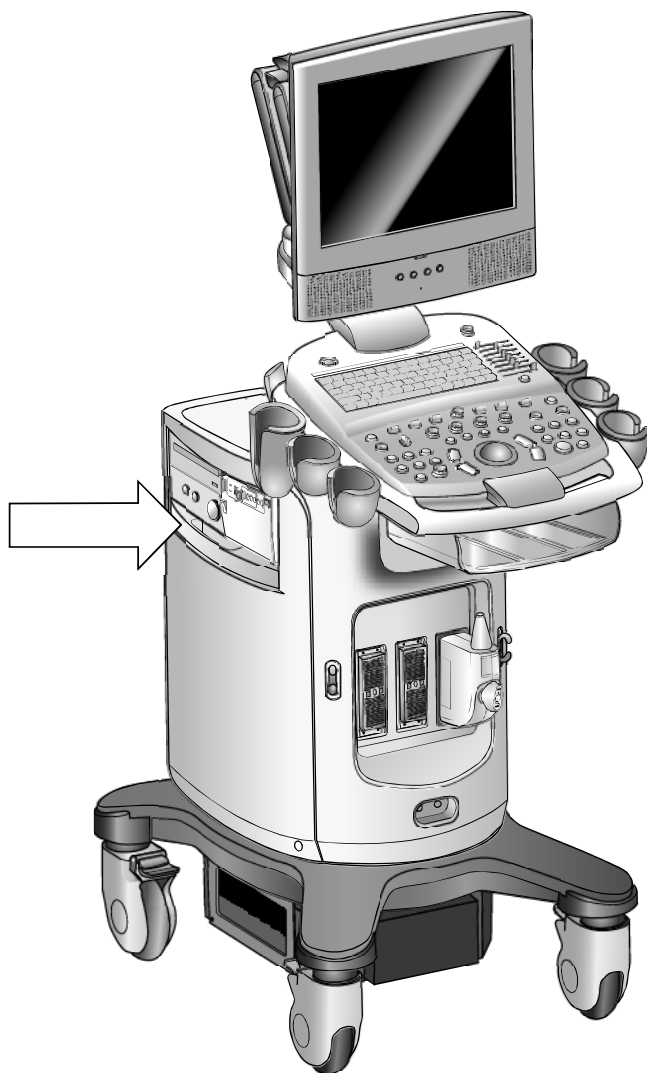
1. Remove the trackball front panel bezel by rotating the bezel counterclockwise.
2. Remove the ball.
3. Clean the ball with tissue and isopropyl alcohol.
4. Clean the Teflon seal (located in the front panel bezel) with a tissue and isopropyl alcohol.
5. Clean the inside of the trackball assembly with a cotton swab and isopropyl alcohol.
6. Allow the assembly parts to completely dry before reassembly.
7. Replace the ball and front panel bezel.

Cleaning an Air Filter

The air filter on the ultrasound system must be cleaned regularly to maintain proper system cooling. Remove and check the air filter weekly, and clean as needed.



The filter location is marked with the air filter symbol.

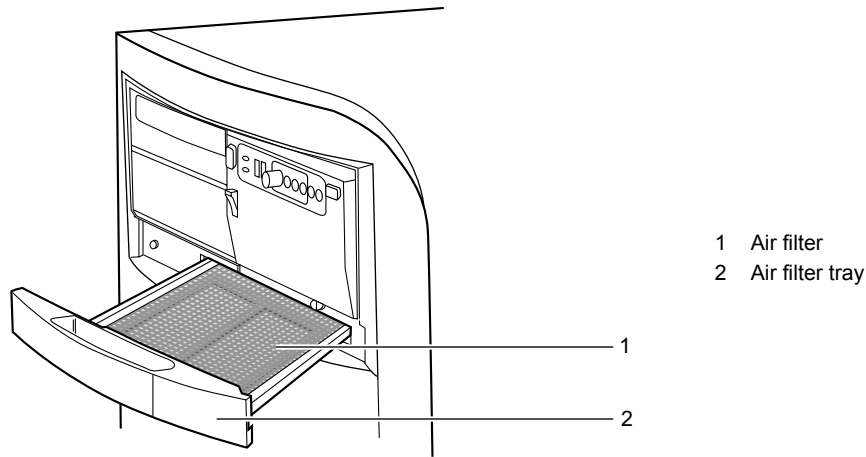


Location of air filter.

To remove and clean the air filter:

⚠ Caution: Do not scrub, stretch, or bend the filter, or apply heat to the filter, as doing so could damage the filter.

1. Power off and unplug the power cord from the power outlet.
2. Grasp the air filter tray and pull it out of the system.



Removing the air filter tray.

3. Remove the filter.
4. Rinse the air filter with running water and allow the filter to completely dry.
To hasten drying, you may gently shake the filter, or blot the filter with a clean, lint-free cloth.

⚠ Caution: Do not insert a wet filter as this can damage the system.

5. Reinsert the filter into the filter tray.
6. Slide the air filter tray back into the ultrasound system.
7. Plug the power cord into the power outlet.

Caring for the Battery Pack

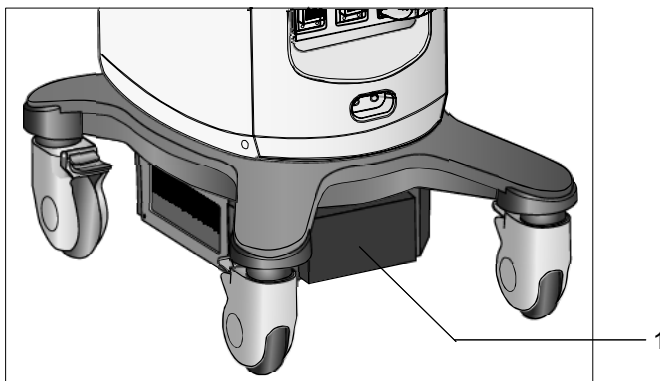
- ⚠ **WARNING:** Do not strike or drop the battery pack because this can cause heat generation, bursting, or fire. Compromising the structural integrity of the battery pack can result in leakage or explosion and the potential for personal injury.
- ⚠ **WARNING:** Do not use the battery pack if it leaks fluid or has changed shape. If skin or clothing comes in contact with fluid from the battery pack, thoroughly wash the area immediately with clean water. If any fluid comes in contact with a user's eyes, immediately flush their eyes with water and seek medical attention.
- ⚠ **WARNING:** Do not allow the battery pack to contact water. Compromising the structural integrity of the battery pack can result in leakage or explosion and the potential for personal injury.
- ⚠ **WARNING:** Do not disassemble the battery pack. Compromising the structural integrity of the battery pack can result in leakage or explosion and the potential for personal injury.

The battery pack is designed to maintain system memory for a maximum of forty minutes.

The length of the charge time is three hours.

Battery Pack Location

The battery pack is located on the front side of the ultrasound system, where the power is located. The battery pack cover must be removed to access the battery pack.



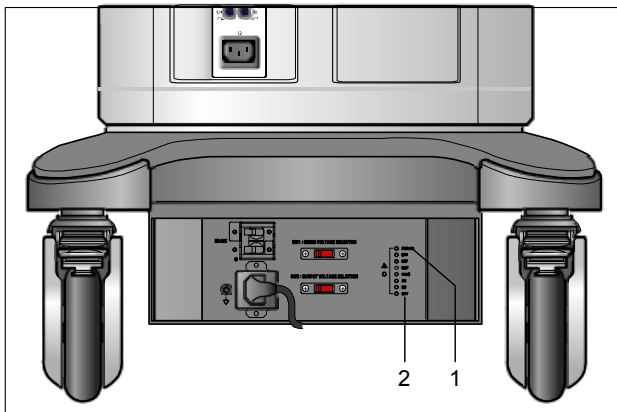
1 Battery pack location

Battery pack location.

Battery Pack Replacement and Disposal

Replace the battery pack when it is no longer able to hold a charge.

- When the system is used with the Mobile QuickStart option and frequently disconnected from the AC power (for a duration of greater than 20 minutes), replace the battery every 6 months.
- When the system is used with the Mobile QuickStart option and only occasionally disconnected from the AC power (for a duration of approximately 20 minutes), replace the battery every year.





- 1 AC OK indicator LED
- 2 Battery pack charge indicator LED

Example of an AC Tray panel with the battery pack charge indicator LED.

The battery pack charge indicator LED is located at the rear of the system, on the AC Tray panel. A green blinking LED indicates that the battery is actively charging. A solid green LED indicates that the battery pack is fully charged. If the LED is not illuminated, then there is a problem with the battery pack, or the battery pack may be missing.

Battery Pack Disposal

 **Caution:** Never dispose of a battery pack by burning or by flushing into any waste water system, for example, a lavatory. Compromising the structural integrity of the battery pack can result in leakage or explosion and the potential for personal injury.

 **Caution:** Collect and dispose of used battery packs separate from other waste. Do not throw into trash.

The battery pack should be recycled according to local, state and federal regulations. Use a battery collection program available in your country to dispose of the battery pack. The following agencies may be contacted for further collection information:

- Australia – Australian Battery Recycling Program (AMTA)
- Austria – UFB
- Belgium – Bebat
- Canada – Rechargeable Battery Recycling Corporation (RBRC)
- Denmark – Batteriforeningens
- European Union – European Portable Battery Association
- France – Societe de Collecte et de Recyclage des Accumulateurs (SCRA)
- Finland – (NBA)
- Germany – Stiftung Gemeinsames Rucknahmesystem Batterien (GRS)
- Italy – COBAT
- Japan – Battery Association of Japan
- Netherlands – Stibat
- Norway – REBATT AS
- Portugal – AGEFE
- Sweden – CT
- Switzerland – Batterieentsorgungs-Selbsthilfeorganisation (BESO)
- United Kingdom – REBAT
- United States of America – Rechargeable Battery Recycling Corporation (RBRC)

Note: If a local battery recycling program does not exist then return used batteries to the address below. When returning batteries, label the package: "Attn.: Battery Recycling".

Siemens AG
 Medical Engineering
 TD ML RE
 Betr.: Battery Recycling
 Am Pestalozziring 3
 D-91058 Erlangen
 GERMANY

Documentation and Storage Devices — Care

For information on the care of an optional documentation or storage device, please refer to the manufacturer's operating instructions that accompanied the device.

Transducers — Care

- ⚠ **WARNING:** Always place a sterile, non-pyrogenic transducer sheath on a transducer used in procedures requiring sterility.
- ⚠ **WARNING:** To minimize the risk of cross-contamination and infectious diseases, intraoperative transducers must be cleaned and high-level disinfected after each use. A sterile, non-pyrogenic transducer sheath must be in place during procedures requiring sterility.
- ⚠ **WARNING:** There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex-sensitive patients and to be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.
- ⚠ **WARNING:** During neurosurgical procedures, if a transducer becomes contaminated with tissue or fluids of a patient known to have Creutzfeld-Jacob disease, the transducer should be destroyed, as it cannot be sterilized.
- ⚠ **WARNING:** When using an endocavity or intraoperative transducer with a CF type applied part, the patient leakage currents may be additive.
- ⚠ **WARNING:** The outer surfaces of an endocavity or intraoperative transducer should be checked to ensure there are no unintended rough surfaces, sharp edges, or protrusions that may cause a safety hazard.
- ⚠ **Caution:** Transducers are sensitive instruments – irreparable damage may occur if they are dropped, knocked against other objects, cut, or punctured. Do not attempt to repair or alter any part of a transducer.
- ⚠ **Caution:** To avoid cable damage, do not roll the system over transducer cables.
- ⚠ **Caution:** To avoid damage to the transducer, do not use transducer sheaths containing an oil-based coating or petroleum- or mineral oil-based ultrasound coupling agents. Use only a water-based ultrasound coupling agent.
- ⚠ **Caution:** Follow all instructions provided by manufacturers of sterile goods (transducer sheaths) to ensure proper handling, storage, and cycling of all sterile goods.

Take extreme care when handling or storing transducers. They must not be dropped, jarred, or knocked against other objects. Do not allow transducers to come into contact with any sharp-edged or pointed object.

Cleaning and Disinfecting Transducers

- ⚠ **WARNING:** To avoid electrical shock and damage to the system, disconnect the transducer prior to cleaning or disinfecting.
- ⚠ **WARNING:** Disinfectants and cleaning methods listed are recommended by Siemens for compatibility with product materials, not for biological effectiveness. Refer to disinfectant label instructions for guidance on disinfection efficacy and appropriate clinical uses.
- ⚠ **Caution:** Do not sterilize transducers using hot steam, cold gas, or Ethylene Oxide (ETO) methods. Before applying any other methods which might be recommended by manufacturers of sterilization equipment, please contact your Siemens representative.
- ⚠ **Caution:** To avoid damage to the transducer, observe the immersion levels indicated for each transducer type. Do not immerse or allow the cable or connector of a transducer to become wet.
- ⚠ **Caution:** The transducers have been designed and tested to be able to withstand high-level disinfection as recommended by the manufacturer of the disinfectant product. Carefully follow the disinfectant manufacturer's instructions. Do not immerse for more than one hour.
- ⚠ **Caution:** Do not use abrasive cleaning agents, organic solvents such as benzene, isopropyl alcohol, or phenol-based substances, or cleaning agents containing organic solvents to clean or disinfect transducers. These substances can damage the transducers.
- ⚠ **Caution:** Do not use a spray cleaner on a transducer, as this may force cleaning fluid inside the housing and damage the transducer.

All transducers should be cleaned and disinfected prior to their use on each patient. Endocavity and intraoperative transducers require high-level disinfection prior to use.

See also: Transesophageal Transducer, Chapter 6, Instructions for Use

To clean a transducer:

1. Disconnect the transducer from the system.
2. Moisten a clean gauze pad with water and wipe the transducer to remove any gel or particles remaining on the transducer. If water is not effective, then you can use an approved pre-cleaner or low-level disinfectant.
3. Carefully wipe the entire transducer, including the cable and connector.
4. After cleaning or disinfecting, use a clean cloth to dry the transducer.

To disinfect or high-level disinfect a transducer:

1. Disconnect the transducer from the system.
2. Thoroughly clean, rinse, and dry the transducer.
3. Take care to keep the cable strain relief and connector of the transducer dry while immersing the transducer in an approved disinfectant to the level indicated in the following illustration.
4. Carefully follow the disinfectant manufacturer's instructions for disinfection or high-level disinfection.
5. After disinfecting or high-level disinfecting, use a clean cloth to dry the transducer.

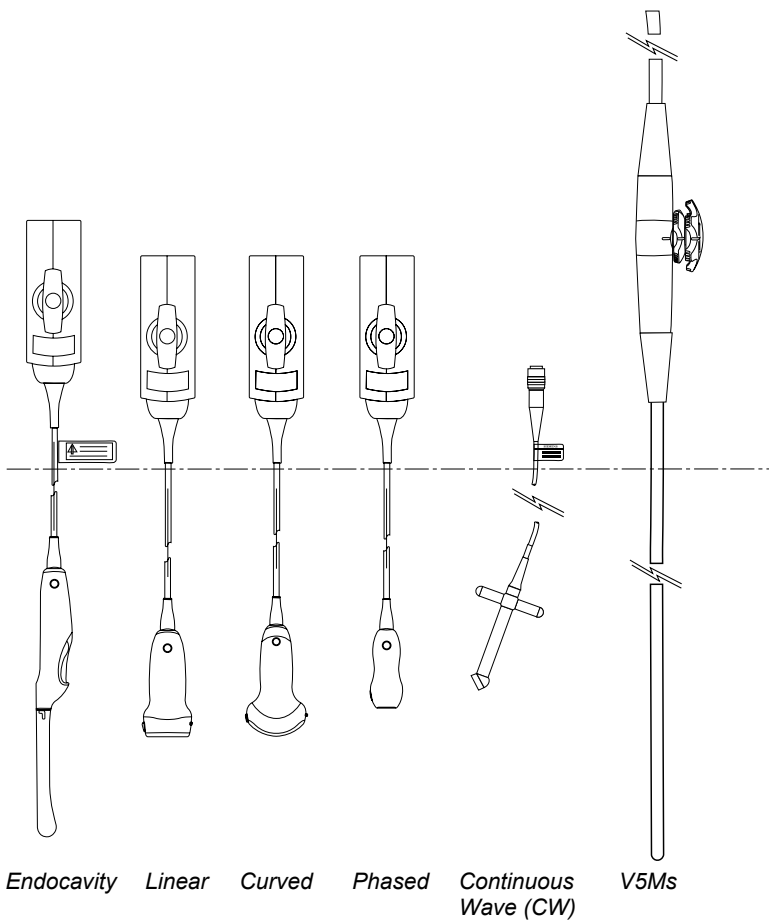
IPX8 Immersion Levels

⚠ Caution: To avoid damage to the transducer, observe the immersion levels indicated for each transducer type. Transducers with the protection level IPX8 are indicated by the presence of the "IPX8" symbol on the connector of the transducer.

Transducers meet Ingress Protection level IPX8 of EN 60539 and IEC 60539 to the depth of the immersion line shown in the illustration only for transducers with the "IPX8" symbol on the connector of the transducer.



Example of transducer labels with IPX8 symbol.



IPX8 Immersion Levels.

⚠ Caution: Do not immerse the label located on the cable of the CW transducer.

Note: Intraoperative transducers are immersible up to the strain relief on the connector.

Approved List of Pre-Cleaners and Low-Level Disinfectants

The following matrix provides a list of approved pre-cleaners and low-level disinfectants for all transducers.

	Enzol	Transeptic	Hi-Tor Plus	Theracide Plus	T-Spray II	Super SaniCloth
CH5-2	✓	✓	✓	✓	✓	✓
C8-5	✓	✓	✓	✓	✓	✓
VF8-3	✓	✓	NC	✓	✓	NC
VF10-5	✓	✓	✓	✓	✓	✓
VF13-5	✓	✓	✓	✓	✓	✓
VF13-5SP	✓	✓	✓	✓	✓	✓
EV9-4	✓	✓	✓	✓	✓	✓
EC9-4	✓	✓	✓	✓	✓	✓
P4-2	✓	✓	✓	✓	✓	✓
P5-1*	NC	NC	NC	NC	NC	NC
P8-4	✓	✓	✓	✓	✓	✓
V5Ms	✓	✓	NA	NA	✓	NA
CW2	✓	✓	✓	✓	✓	✓
CW5	✓	✓	✓	✓	✓	✓

✓ = compatible

NC = not compatible

NA = not applicable (not tested)

* = Compatible pre-cleaners and low-level disinfectants for the P5-1 transducer include: T-Spray, ANIOS, Wavicide-01, MetriZyme, and Klenzyme.

Approved List of Disinfectants

The following matrix provides a list of approved disinfectants for all transducers.

Note: The approved disinfectants, Cidex OPA and Gigasept FF, may discolor transducer housings, including the face of the transducer. There is no associated degradation of imaging performance or transducer reliability.


	Cidex	Cidex Plus	Cidex OPA	Milton	Virkon	Gigasept FF
CH5-2	✓	✓	✓	✓	NC	✓
C8-5	✓	✓	✓	✓	✓	✓
VF8-3	✓	✓	✓	✓	✓	✓
VF10-5	✓	✓	✓	✓	✓	✓
VF13-5	✓	✓	✓	✓	✓	✓
VF13-5SP	✓	✓	✓	✓	✓	✓
EV9-4	✓	✓	✓	✓	✓	✓
EC9-4	✓	✓	✓	✓	✓	✓
P4-2	✓	✓	✓	✓	NC	✓
P5-1	NC	✓	✓	NC	✓	✓
P8-4	✓	✓	✓	✓	NC	✓
V5Ms	NC	✓	✓	✓	NC	✓
CW2	✓	✓	✓	✓	✓	✓
CW5	✓	✓	✓	✓	✓	✓

✓ = compatible

NC = not compatible

NA = not applicable (not tested)

Sterilizing Transducers — VF13-5SP

 **Caution:** The transducers have been designed and tested to be able to withstand sterilization as recommended by the manufacturer of the sterilization system. Carefully follow the sterilization manufacturer's instructions.

The STERRAD® sterilization system, a hydrogen peroxide gas plasma sterilization system, is approved for use with the listed intraoperative transducer(s).

- VF13-5SP

To sterilize a transducer with the STERRAD system:

Note: This procedure applies to the VF13-5SP transducer only.

1. Disconnect the transducer from the system.
2. Thoroughly clean, rinse, and dry the transducer.
3. Carefully follow the manufacturer's instructions for sterilization.

Storage

Store transducers in a clean and dry environment. Extreme temperatures or humidity may damage a transducer.

See also: Technical Description, Appendix A, Instructions for Use

Repair

Do not attempt to repair or alter any part of the transducer. Contact your service representative at Siemens immediately if a transducer appears to be damaged or malfunctions in any way.

Protective case

Due to the mechanical sensitivity of transducers, Siemens recommends that you always use the transducer case when you ship a transducer or transport it from one place of examination to another. The case is specially designed to protect the sensitive parts of the transducer. Be sure that all parts of the transducer are properly placed inside the case before you close the lid.

Transducer Accessories — Care

- ⚠ **WARNING:** Ensure the accessories for a transducer are properly cleaned, sterilized, or disinfected as appropriate before each use to avoid possible patient contamination.

Transducer Sheaths

- ⚠ **WARNING:** There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex-sensitive patients and to be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.
- ⚠ **WARNING:** To minimize the risk of cross-contamination and infectious diseases, endocavity or intraoperative transducers must be cleaned and high-level disinfected after each use. A sterile, non-pyrogenic transducer sheath must be in place during procedures requiring sterility.
- ⚠ **WARNING:** Only a sterile transducer sheath provides the sterile barrier required for surgical procedures. To ensure sterility of a procedure, always place a sterile sheath on a transducer, as transducers cannot be sterilized using hot steam, cold gas, or Ethylene Oxide (ETO) methods.
- ⚠ **Caution:** Siemens recommends that you follow all instructions provided by manufacturers of sterile goods (transducer sheaths) to ensure proper handling, storage, and cycling of all sterile goods.

Transducer sheaths are single-use items used to ensure proper acoustic coupling and provide a prophylactic barrier for the intended ultrasound application. Sheaths are available for all transducers. Siemens recommends the use of market-cleared transducer sheaths.

Using a disposable latex transducer sheath on a transducer reduces the possibility of cross-contamination. Always use a protective transducer sheath for endocavity exams, and when scanning an open wound or an area where the skin is not intact.

Storage

- ⚠ **Caution:** Do not store transducer sheaths in direct sunlight, as ultraviolet damage can result.

Latex products have a limited shelf life, and should be stored in a cool, dry, dark place with an ambient temperature between -5°C and $+40^{\circ}\text{C}$ and up to 80% relative humidity at $+40^{\circ}\text{C}$. Before use, examine these products for any material flaws. Some packaging may list an expiration date. Any product showing flaws, or whose expiration date has passed, should not be used.

Gel Pad


Before use, examine the gel pad for any material flaws. Thinning, bulging, or brittleness of the material indicates damage. Any product showing flaws should not be used.

See also: Transducer Accessories and Biopsy, Chapter 5, Instructions for Use

Storage

Do not store gel pads below 5°C nor above 57°C. Gel pads have a limited shelf life. Before use, examine these products for any material flaws. Some packaging may list an expiration date. Any product showing flaws, or whose expiration date has passed, should not be used.

Needle Guide Bracket Kits

 **WARNING:** If a needle guide becomes contaminated with tissue or fluids of a patient known to have Creutzfeld-Jacob disease, then the needle guide should be destroyed. Sterilization is not effective against Creutzfeld-Jacob contamination.

Needle guide bracket kits are available for biopsy and puncture procedures for specific transducers.


See also: Transducer Accessories and Biopsy, Chapter 5, Instructions for Use

Storage and Transportation

Always clean and sterilize or high-level disinfect components used in a needle puncture or biopsy procedure after each use.


Cleaning, Disinfecting, and Sterilizing — Needle Guide Bracket Kits

EC9-4 Disposable Endocavity Needle Guide

 **WARNING:** The needle guide is packaged sterile and is a single-use item. Do not use if the packaging indicates signs of tampering or if the expiration date has passed.

The disposable endocavity needle guide is a single-use item. Refer to the in-box instructions for disposal instructions.

EC9-4 Stainless Steel Endocavity Needle Guide

 **WARNING:** Needle Guide Bracket kits are packaged non-sterile. Sterilize these products prior to their first use.

The stainless steel endocavity needle guide is a reusable item. Refer to the in-box instructions for attachment and care procedures, including cleaning and sterilization.

CH4-1, SG-4, and SG-3 Needle Guide Bracket Kits

Disposable Needle Guide

⚠ WARNING: The needle guide is packaged sterile and is a single-use item. Do not use if the packaging indicates signs of tampering or if the expiration date has passed.

The needle guide for use with the CH4-1, SG-4 and SG-3 bracket kit is a single-use item. Refer to the in-box instructions for disposal instructions.

Reusable Bracket

⚠ WARNING: Needle Guide Bracket kits are packaged non-sterile. High-level disinfect these products prior to their first use.

Refer to the in-box instructions for attachment and care procedures, including cleaning and high-level disinfecting procedures for the bracket.

Universal Needle Guide, Stainless

⚠ WARNING: Needle Guide Bracket kits are packaged non-sterile. Sterilize these products prior to their first use. Refer to the sterilization procedures for the Universal Needle Guide in the following pages.

Prior to sterilization, clean the universal needle guide bracket and insert(s) using an enzymatic cleaner.

To clean:

1. Rinse the bracket and insert(s) with water.
2. Soak the bracket and insert(s) in an enzymatic cleaner.
Carefully follow the manufacturer's instructions.
3. Rinse the bracket and insert(s) with water to remove any debris and remaining cleaner.


To sterilize:

- Sterilize the bracket and needle guide insert(s) using a wrapped, gravity-displacement steam sterilization at a temperature of 121°C to 123°C for an exposure time of 15 to 30 minutes.

Storage

Always clean and sterilize components used in a needle puncture or biopsy procedure after each use.

Product Recycling and Disposal

Symbol	Explanation
	<p>Products bearing this symbol are subject to the European Community directive 2002/96/EC on waste electrical and electronic equipment (WEEE), amended by directive 2003/108/EC. For take-back and disposal of the product, its components or accessories, please contact Siemens Medical Solutions Customer Service or your Siemens regional office.</p>

Batteries and packaging may be required by local laws and regulations to be taken back and disposed at no cost to the customer. Disassembly instructions applicable to this device are prepared for treatment facilities to properly and safely remove electronic components for appropriate treatment and recycle.

For more information on the take-back and disposal of batteries and packaging, or on disassembly instructions, please contact Siemens Medical Solutions Customer Service or your Siemens regional office.

3 System Setup

Initial Setup	3
Moving the System	3
Swivel Locking Brake	4
Front Swivel Locking Brake	4
Back Swivel Locking Brake	5
Prior to the Move	6
During the Move	8
Shipping the System	9
After the Move	9
System Startup	10
Plugging in the System	10
Supplying Power to the System	11
QuickStart Feature (Battery-Powered Standby Mode)	13
Adjusting Controls on the Monitor	14
Controls on the Monitor	14
Adjusting Brightness and Contrast	15
Adjusting the Monitor with the Monitor Menu Selections	16
Audio and Microphone Volume	17
Connecting and Disconnecting Transducers	18
Array Transducers	19
Continuous Wave Transducers	21
Protective Transducer Holder	22
Transducer Cable Management	23
Connecting System Accessories	23
Footswitch	23
ECG (EKG) Cables	24
Input/Output Panel Connections	24
Connecting Peripheral Equipment	26
Serial Port	27
System Ergonomics	28
General System Settings	30
Modifying Hospital or Clinic Name	30
Setting System Date and Time	30
Configuring the Documentation Controls	33
Software Installation	34
Software-Based Option Installation	35


Initial Setup


The ultrasound system is initially unpacked and installed by a Siemens representative. Your Siemens representative will verify the operation of the system. Any transducers, documentation and storage devices, accessories, and options delivered with your system are also connected and installed for you.


Each day before you use the ultrasound system, perform the Daily Checklist.


See also: Daily Checklist, Safety and Care, Chapter 2, Instructions for Use


Moving the System


 **WARNING:** Preparations before moving the system are important to minimize potential damage to sensitive components and to avoid safety hazards. Review the moving instructions before moving the system.

 **WARNING:** To avoid damage to the monitor and the potential for personal injury to the user, ensure the monitor does not swivel during transport. Lock the vertical position of the flat panel monitor prior to moving the ultrasound system according to the directions provided in this section of the instructions.

 **Caution:** Do not push the flat panel monitor to move the system. Pushing on the flat panel monitor can cause loss of control over the system and damage to the moving parts of the flat panel monitor.

 **Caution:** Do not lean on the flat panel monitor. Subjecting the flat panel monitor to heavy loads or extreme pressure can damage the ultrasound system.

 **Caution:** Do not park, or leave unattended, on a slope. Even when the rear brakes are engaged, the system may slide down a ramp.

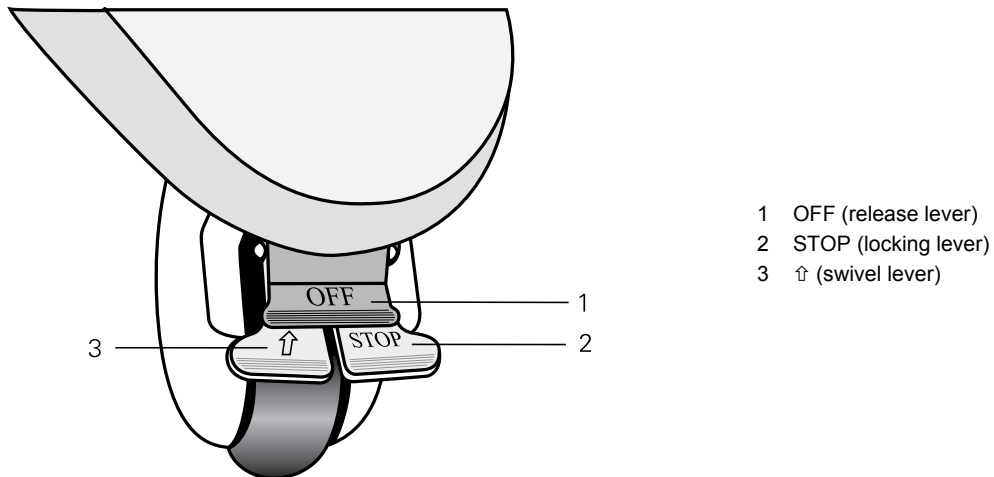
 **Caution:** To prevent damage to the system during a move, retract or close any doors and trays on the documentation devices or components on the ultrasound system. Ensure components do not protrude from the system.

The ultrasound system is designed to be a mobile unit. Before moving the system to another location, you must prepare for the move by powering off and securing the system.

Swivel Locking Brake

The ultrasound system has four swivel locking brakes. The two front brakes each have a locking lever, a swivel lever, and a release lever. The two back brakes each have a locking lever, and a release lever. Set the swivel locking brakes with the levers on each wheel.

Front Swivel Locking Brake



Example of wheel with locking brake (unlocked).

To lock the brake:

- Press the **STOP** lever down with your foot into the locked position.

To release the brakes:

- Press the **Off** lever down with your foot to release the brake.

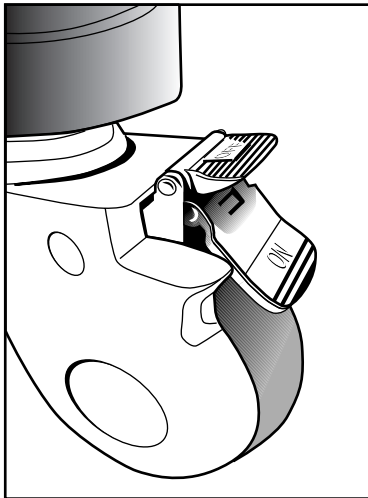
To lock the swivel:

- Press the ↑ lever with your foot until the swivel brake locks into place.

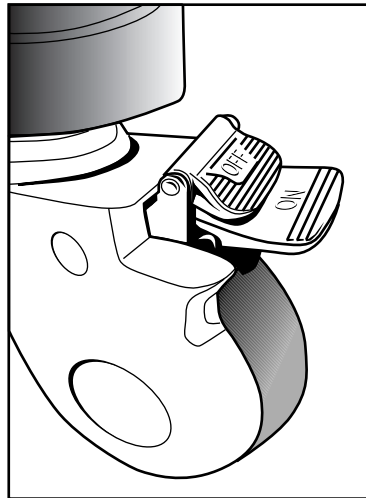
To release the swivel:

- Press the **OFF** lever down with your foot until the brake unlocks and the ↑ lever releases.

Back Swivel Locking Brake



Example of wheel with locking brake (locked).



Example of wheel with locking brake (unlocked).

To lock the brake and the swivel for each wheel:

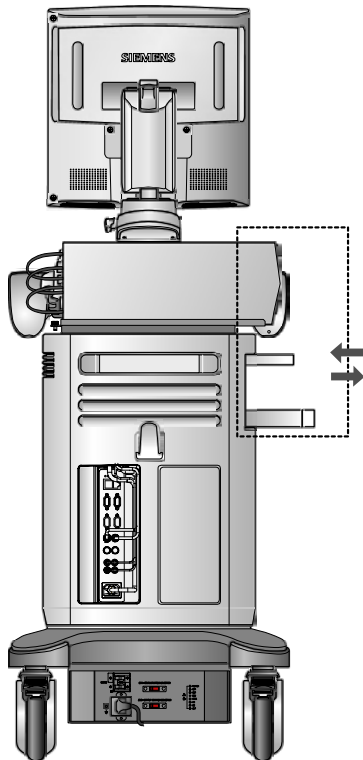
- Using your foot, press the "ON" lever into the lowest position (locked).

To release the brakes and the swivel:

- Using your foot, press the "OFF" lever to release the brake.

Prior to the Move

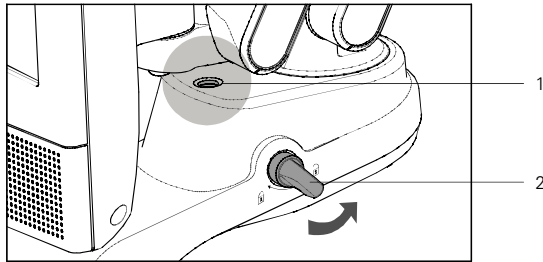
1. Power off the ultrasound system. The power (partial) on/off (⏻) switch is located on the upper left of the control panel.
2. Unplug the power cord from the wall outlet. Pull on the plug, not the cord.
3. Secure the power cord to avoid rolling the system wheels over the cord.
4. To ensure that the transducers are transported safely, remove each transducer and place it in its protective carrying case.
5. Retract or close any doors or trays of the documentation devices or components on the ultrasound system.



Retracting open doors or trays.

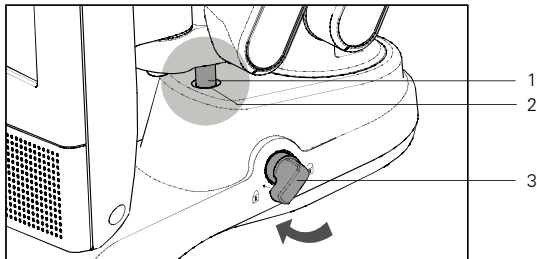
6. Disconnect off-board documentation devices from the system.
7. Transport gel, video tapes, and CD/DVD disks separately.
8. Disconnect the optional footswitch.

9. Lock the position of the flat panel monitor for transport:
 - a. Align the flat panel monitor to the front, center of the ultrasound system.
 - b. Push and rotate the transport lock into the locked position. Ensure the locking pin engages with the hole on the articulating arm.



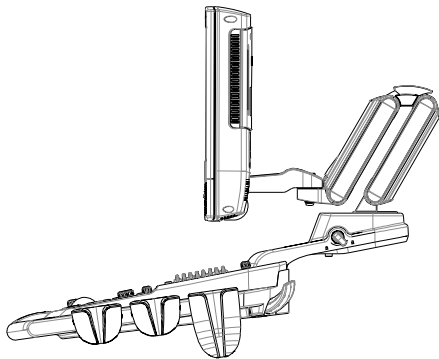
- 1 Pin hole
- 2 Transport lock

Example of transport lock in the unlocked position.



- 1 Pin
- 2 Pin hole
- 3 Transport lock

Example of transport lock in the locked position.



Example of monitor in vertical position for transport.

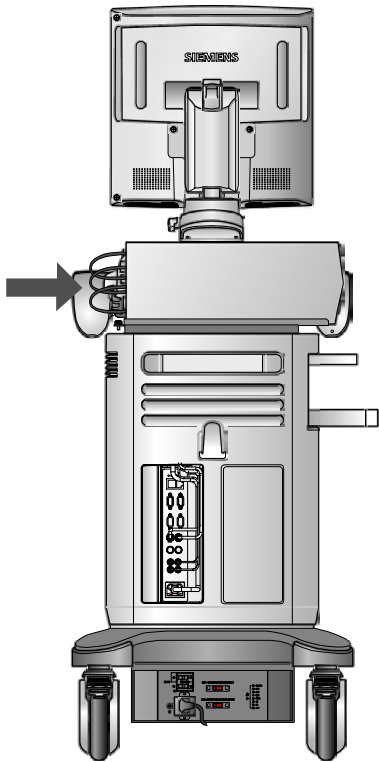
10. Release both the front and rear brakes.

During the Move

- ⚠ **Caution:** When moving the ultrasound system, protect it from environmental changes including: moisture, winds, dirt and dust, and extreme heat or cold exposure.
- ⚠ **Caution:** Avoid moving the ultrasound system on outside surfaces with loose dirt, contaminants, or standing liquids.
- ⚠ **Caution:** Care should be taken to minimize shock and vibration of the ultrasound system. Avoid uneven surfaces that contain an abrupt height change or jarring surface irregularities.
- ⚠ **Caution:** For systems installed with an on-board documentation device located on the rear shelf of the ultrasound system, avoid damage to cables and connectors protruding from the documentation device, particularly when moving the system around corners or through doorways.

See also: Supplying Power to the System, p. 3-11

See also: Transducers — Care, Safety and Care, Chapter 2, Instructions for Use



Protruding cables and connectors.

You can move the ultrasound system from room to room within a facility and easily reposition the system during an examination. Be careful on inclines and uneven surfaces. The ultrasound system can be moved across pavement and other hardened parking lot surfaces.

Note: The wheels of the ultrasound system must be locked when transporting by vehicle. The ultrasound system must be sufficiently anchored to the vehicle floor or walls such that it does not shift or move during transport.

Shipping the System

When shipping the system, perform the following tasks, as appropriate.


To prepare the system for shipment over long distances or rough terrain:


1. Repack the system in the factory packaging and crate.
2. Load the system into a vehicle using a lift gate.


To prevent lateral movement of the system, secure the system with cargo straps.


To prevent sudden jarring of the system during transport, provide shock cushions beneath the system.

After the Move

 **Caution:** Make sure the ultrasound system has proper ventilation during operation. Do not position the system against walls or hard surfaces that would impede free ventilation around the system.

 **Caution:** Do not allow linens, bedding, and/or hanging curtain partitions to block the ultrasound system's ventilation.

 **Caution:** Obstructed fans can cause potential system overheating, system performance degradation, or failure.

 **Caution:** Brakes are most effective on a level surface. Never park the system on an incline greater than five degrees.

See also: Swivel Locking Brake, p. 3-4

See also: Daily Checklist, Safety and Care, Chapter 2, Instructions for Use

1. Position the system: Make sure the system is not placed against walls or fabrics that obstruct perimeter air flow to the system cooling fans.
2. Set the brakes: Set the front and rear brakes.
3. Plug in the cord: Plug the power cord into a hospital-grade or local equivalent wall outlet.
4. Power on: Power on (⏻) the ultrasound system.
5. Check the display: After the boot-up sequence is complete, verify that the image display is stable, that you can select a transducer, and that the system responds to selections made on the control panel.

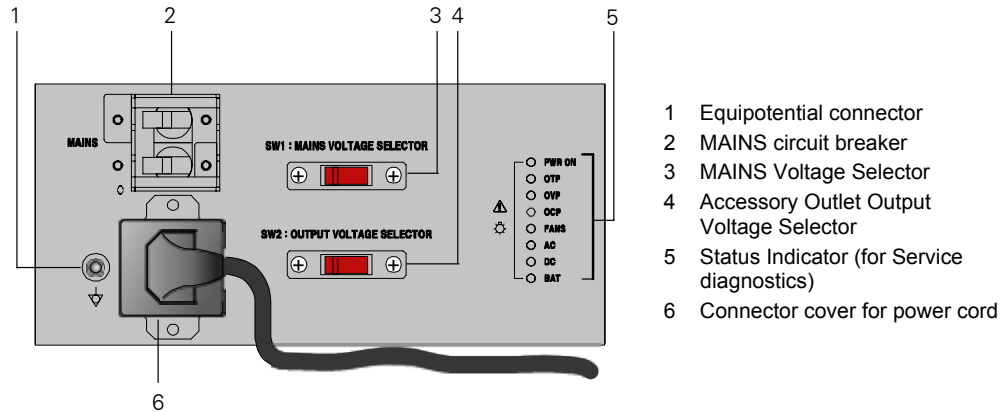
System Startup

The first step to operating the ultrasound system is to connect the system to a power source.

Plugging in the System

⚠ WARNING: For systems used in the U.S.A.: To ensure grounding reliability, only connect the system to a hospital-grade power outlet.

The ultrasound system has a non-detachable power cord.



Example of power panel.

To plug in the system:

- Connect the power cord to the MAINS supply:
 - 200V~ to 240V~ systems: connect the power cord to a standard MAINS receptacle. For example, a "Schuko" receptacle (CEE 7-7 standard).
 - 100V~ to 120V~ systems used in the U.S.A.: connect the power cord to a hospital-grade MAINS receptacle.
 - 100V~ to 120V~ systems outside the U.S.A.: connect the power cord to a standard MAINS receptacle.

Supplying Power to the System

The ultrasound system is powered on and off using the partial power on/off switch (⏻) located on the upper left of the keyboard.

Note: This switch does not completely shut down or disconnect the system from the power mains. This switch only powers on, or off, a portion of the ultrasound system. To completely disconnect the system from the power mains, the circuit breaker located on the back panel must be switched from On to Off.

⚠ Caution: Wait approximately 20 seconds between powering the system off and then on again. This allows the system to complete its shutdown sequence.

Power on/off button display	System status:
Blue	Powered on
Amber	Stand-by mode
Off (not lit)	Powered off

To power on the system:

1. Before using the system, perform the Daily Checklist.
See also: Daily Checklist, Safety and Care, Chapter 2, Instructions for Use
2. Verify the power cord is plugged into the system and then into the power supply.
3. Power on (⏻) the ultrasound system.

When powered on, the system runs through a series of self-diagnostic and calibration tests. The tests last a few minutes, after which the system is ready for use.

Note: The system will not run through the complete power-on routine if a problem occurs. Instead, an error code or message appears on the screen to indicate the problem. Please note the message and call your local Siemens service representative.

The system is factory-configured to display initially in 2D-mode.

4. Visually check the on-screen displays and lighting indicated in the Daily Checklist.

To power off the system:

Note: To cancel the power off procedure, select the **Cancel** button in the **System Shut Down** dialog box.

1. Briefly press the partial power on/off (⏻) button on the upper left of the ultrasound system.

The system displays the **System Shut Down** dialog box.

2. Select the **Power off** button.

Wait approximately 30 seconds before powering on the ultrasound system.

Note: In case the system is down, use the compulsory shutdown by pressing and holding the power on/off (⏻) button for at least five seconds.

To restart the system:

1. Briefly press the partial power on/off (⏻) button on the upper left of the ultrasound system.

The system displays the **System Shut Down** dialog box.

2. Select the **Restart** button.

The system will power off and restart.

To enter Standby mode:

Note: The system preserves patient data when in standby mode. To avoid the possibility of data loss, Siemens recommends that you close the current patient study, activate 2D-mode, and wait until the system finishes writing data to external storage media before entering standby mode.

1. Briefly press the partial power on/off (⏻) button on the upper left of the ultrasound system.

2. Select **Stand-by** from the displayed dialog box.

The system enters standby mode.

3. If you are using the QuickStart battery-powered feature, wait approximately 20 seconds after the system powers off before unplugging the ultrasound system.

To exit Standby mode:

Note: You must wait approximately 20 seconds after the system powers off before powering on (⏻) the ultrasound system.

1. If you are using the QuickStart feature, verify the power cord is plugged into the system and into the power supply.
2. Press the partial power on/off (⏻) button on the upper left of the ultrasound system.

The system is ready for use in less than 15 seconds.

3. To re-enter standby mode, wait approximately 20 seconds after powering on the system.

QuickStart Feature (Battery-Powered Standby Mode)

The QuickStart feature for portable studies decreases the time required to power the system on or off by using the installed battery to place the ultrasound system in a standby status.

The system can maintain the standby status for approximately 40 minutes when the system's power cord is not plugged into the power supply.

When the system is in standby status running on battery power, the power on/off (⏻) button functions as a battery power indicator.

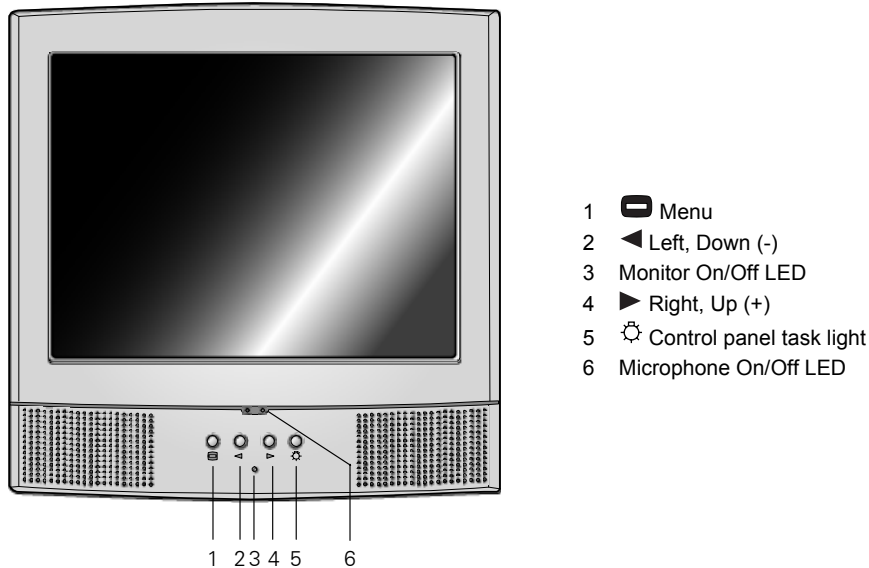
Power on/off button display	Battery status:
Steady amber	More than 60% charge remaining.
Flashing amber (slow)	More than 30% charge remaining.
Flashing amber (fast)	Battery power is low.
Flashing amber (fast) with audible beep	Battery power is very low. If the system is not plugged in, it will shut down automatically within 5 minutes.

Adjusting Controls on the Monitor

Use the controls located on the underside of the monitor to directly adjust the brightness and contrast settings of the monitor. Additional settings are available as menu selections from the monitor.






See also: Monitor Menu Selections, p. 3-16

Note: The language setting for the monitor menu is separate from the language setting of the ultrasound system.



Example of monitor.

Controls on the Monitor

Monitor button	Description
 Menu	Briefly press to step cycle through: <ul style="list-style-type: none"> ▪ Contrast control ▪ Brightness control ▪ Off Press and hold Menu and  (for at least 8 seconds) to display the monitor menu with additional controls.
 Left (-)	Decreases the values of a control, or moves to the left or down.
 Right (+)	Increases the values of a control, or moves to the right or up.
 Light Intensity	Turns the control panel task light on or off. (Cycles through settings: off , low , mid and high intensity.)

Adjusting Brightness and Contrast




Note: Factory-defined imaging presets were created using default settings of the brightness and contrast controls of the monitor. Adjusting the brightness and contrast controls on the monitor may affect the image optimization intended by the factory-defined imaging presets.

For consistency in image reproduction, adjustments to the brightness and contrast of the viewing monitor should be made prior to adjusting the print quality of installed documentation devices.

These processes assure consistent quality in the image display and reduces the potential for image quality issues.




To adjust the brightness or contrast of the monitor:

Note: Always begin adjusting your monitor with the controls set to the factory defaults, and then adjust each control separately to suit your preference and the lighting conditions in the room.



1. Press the  control on the monitor to display the setting for Contrast or press twice to display the setting for Brightness.
2. Press the  control to decrease the setting or press the  control to increase the setting.

Decrease the setting for darker images or lower contrast; increase the setting for lighter images or higher contrast.

To restore and lock the factory default monitor settings for brightness and contrast:

1. Press the  control on the monitor to display the setting for Contrast or press twice to display the setting for Brightness.
2. Press the  control and the  control simultaneously.

The system restores the factory default settings for the selection.

3. Press and hold the  control or the  control (for at least 5 seconds) simultaneously.





The system displays the OSD Main Menu is locked message.

4. To unlock the monitor settings, repeat step 3.















Adjusting the Monitor with the Monitor Menu Selections

You can adjust the monitor controls through the monitor menu.

Monitor Menu Selections

Menu Icon	Menu Selection
	Picture Contrast Brightness Color Mode Exit
	Function Scale Information Memory Recall SBC Exit
	OSD Language Half Tone Exit
	Exit

To adjust monitor controls from the monitor menu:

1. Press and hold  and  simultaneously on the monitor to display the monitor menu.
2. Press  or  to highlight a selection.
3. Press  to select a Menu Icon.
4. Press  or  to select a menu selection and press  to adjust the setting.
5. Press  or  to change the setting.
6. Select the **EXIT** button or press  to confirm the setting and return to the main Selection screen.
7. To exit the monitor menu, allow the menu to time out (for 10 seconds), or press  or  to select **EXIT**, and then press  again.

Monitor Error Messages

Message	Action
NO SIGNAL	Check the signal cable
OUT OF FREQUENCY	Check if the operating frequency is out of range
SBC ERROR (blank dialog box)	Exchange the Monitor

Audio and Microphone Volume

You can adjust the volume of the speakers. Use the system presets to set a default volume level.

 **General 1 > Audio**

You can also adjust the volume using the volume control on the control panel located above the DGC controls.



Example of the volume control.

To adjust the volume during Doppler:

- Rotate the volume control on the control panel.

To activate the microphone during recording:

1. Press the volume control to activate the microphone.
The system illuminates the LED located on the front of the monitor.
2. To adjust the volume, rotate the volume control.

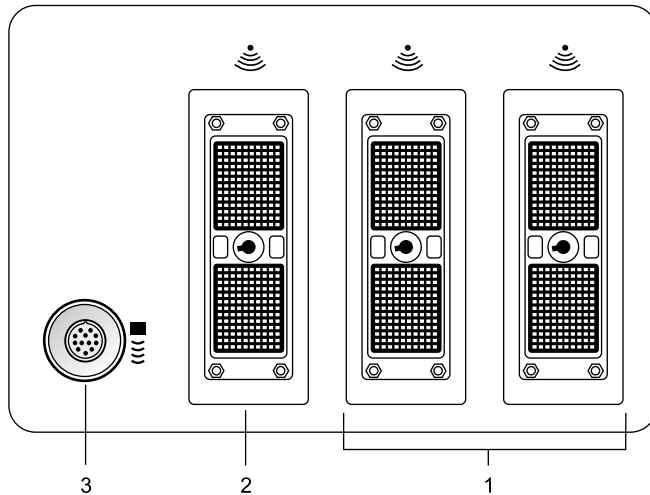
Connecting and Disconnecting Transducers

⚠ Caution: Ensure that the system is in freeze before connecting and disconnecting transducers. If a transducer is disconnected before the image is frozen, the system will display an error message, and it will be necessary to reset the system before continued use.

You can connect multiple transducers to the ultrasound system, with one transducer being the **active** transducer.

Press the **TRANSDUCER** key on the control panel to change the active transducer.

Note: When three transducers are connected to the system, the names of the transducers display as soft key selections.



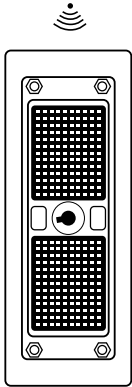
Example of transducer ports.

- 1 Two 260-pin ports for standard array transducers
- 2 One 260-pin port for standard and specialty array transducers
- 3 Continuous Wave (CW) Doppler port for CW Doppler pencil transducers

Array Transducers

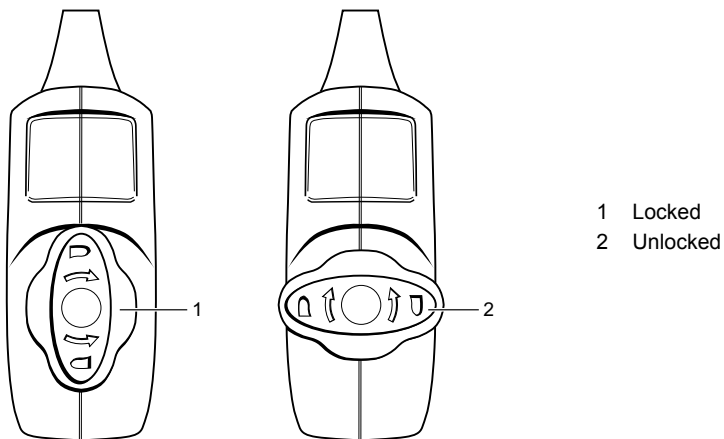
⚠ Caution: You must freeze the system before connecting or disconnecting a transducer.

Connect an array transducer to any of the available array ports.



Example of array transducer port.

Note: When transducer connectors are being attached to or disconnected from the system, resistance may be encountered due to the special shielding material inside the connectors. This is normal for these transducers.



Example of locked and unlocked positions of the connector.


To connect an array transducer:

1. Hold the transducer connector with the cable extending upward from the connector.
2. Insert the connector pins into the system port. Adjust the connector until you can turn the lever on the transducer connector clockwise to lock it in position.

This secures the connector in position and ensures the best possible contact.

3. Place the transducer in the transducer holder and drape the cable through the cable hangers.

To disconnect an array transducer:

 **Caution:** To avoid damaging the transducer cable, do not pull on the cable to disconnect the transducer. Use the following instructions.

1. Turn the lock on the connector housing counterclockwise until it unlocks.
2. Firmly grasp the transducer connector and carefully remove it from the system port.
3. Store each transducer in its protective carrying case.

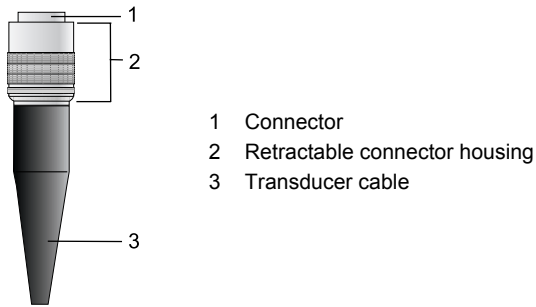
Continuous Wave Transducers

⚠ Caution: You must freeze the system before connecting or disconnecting a CW transducer.

Connect a continuous wave transducer to the round sector port located to the left of the array ports.



Continuous wave transducer port.



Example of CW transducer connector.

To connect a continuous wave transducer:

1. Align the connector key until it fits smoothly into the port.
2. Insert the connector into the system port until it locks into position.

To disconnect a continuous wave transducer:

⚠ Caution: To avoid damaging the transducer cable, do not pull on the cable to disconnect the transducer. Use the following instructions.

1. Pull on the connector housing ring to disengage the locking mechanism and remove the connector from the system port.
2. Store each transducer in its protective carrying case.

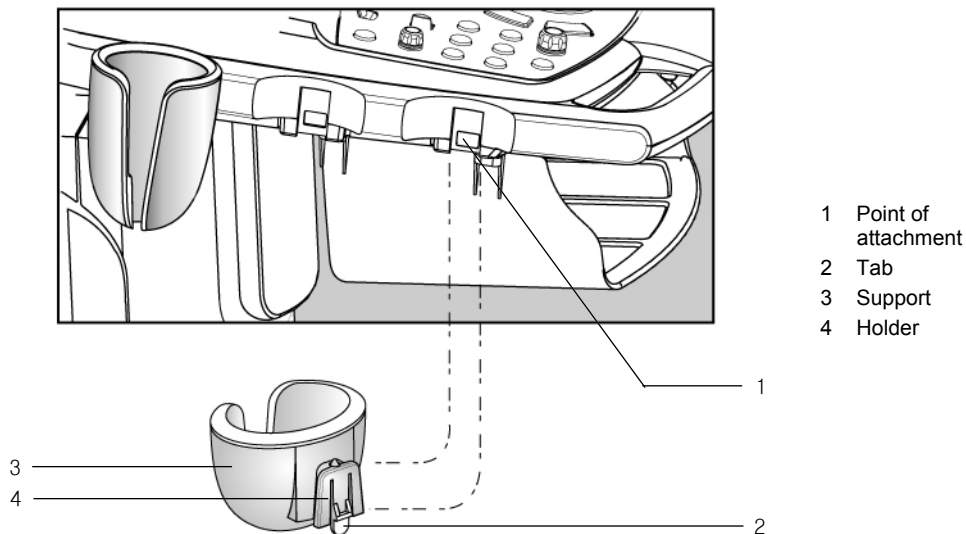
Protective Transducer Holder

⚠ Caution: Transducer holders have variable sizes both in depth and diameter. To avoid transducer damage, you must use the holder and/or insert provided for transducers that have small or large diameter handles or for specialty transducers.

After connecting a transducer to the system, place the transducer in the protective holder attached to the control panel platform. A holder can also be used for the coupling agent (gel).

Transducer Holders

The transducer holders on the sides of the control panel are interchangeable and replaceable.



Example of transducer holders.

To remove a transducer holder:

1. Locate the tab underneath the holder.
Note: The tab extends below the point of attachment to the ultrasound system.
2. Press the tab against the holder and pull the holder downward.

To install a transducer holder:

1. Press the tab against the holder.
2. Align the support on the holder with the attachment slot on the system and slide the holder upwards until it snaps into place.

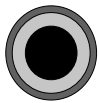
Transducer Cable Management

⚠ WARNING: To avoid injury to the patient or operator, use the cable hooks located on the ultrasound system to manage one or more transducer cables. Entanglement with the transducer cables could result in injury.

After you have connected and secured a transducer, drape the transducer cable through one of the cable hangers located on the back of the control panel.

These hangers provide support for the transducer cables, keep cables off the floor, and help to prevent tangling of the cables when more than one transducer is connected to the system.

Connecting System Accessories



Footswitch label identifying the connector socket.

Footswitch

The ultrasound system has an optional dual-pedal, watertight footswitch.

Ingress Protection

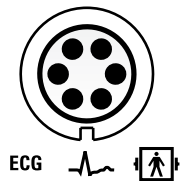
With the exception of the connector on the footswitch, the footswitch meets Ingress Protection level IPX8 of EN 60539 and IEC 60539.

To connect the footswitch to the system:

- Insert the footswitch connector housing into the socket located on the front of the system.

ECG (EKG) Cables

The ECG feature allows the system to display a scrolling ECG waveform on the image screen.



ECG label identifying the connector socket.

To connect the ECG cables:

- Insert the six-pin ECG connector into the socket labeled ECG on the left side of the system.

Input/Output Panel Connections

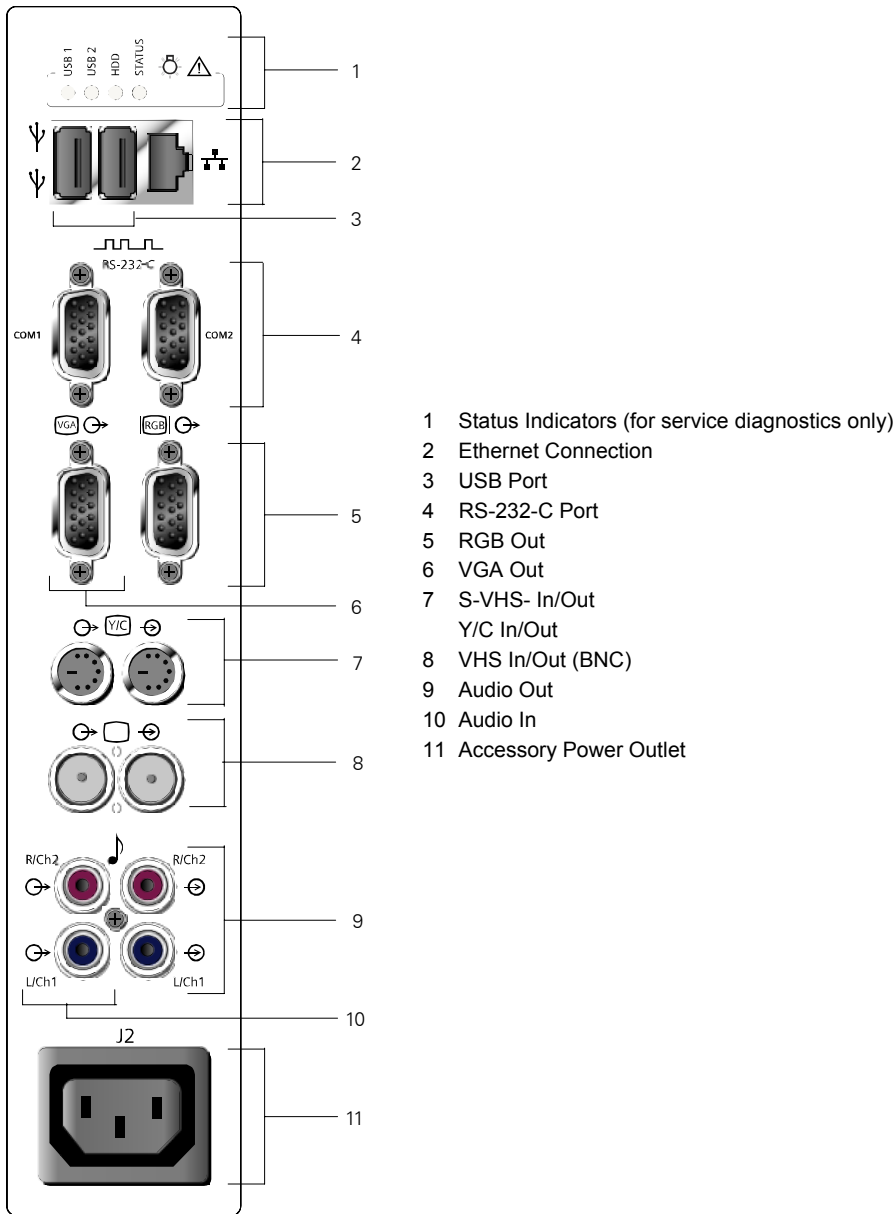
Audio and video connections are located on the Input/Output (I/O) panel.

⚠ WARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (e.g., EN 60950 and IEC 60950 for data processing equipment and EN 60601-1 and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard EN 60601-1-1 and IEC 60601-1-1. Anyone who connects additional equipment to the signal input or signal output ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standard EN 60601-1-1 and IEC 60601-1-1. Siemens can only guarantee the performance and safety of the devices listed in the *Instructions for Use*. If in doubt, consult the Siemens service department or your local Siemens representative.

See also: Accessories and Options, Technical Description, Appendix A, Instructions for Use

⚠ Caution: To ensure proper grounding and leakage current levels, it is the policy of Siemens to have an authorized Siemens representative or approved third party perform all on-board connections of documentation and storage devices to the ultrasound system. The *Instructions for Use* lists the peripheral devices specified for use with the ultrasound system.

⚠ Caution: To reduce the risk of fire and subsequent equipment damage, use only 26 gauge (0.14 mm²) or heavier wire for the cable connecting to the Ethernet port located on the ultrasound system.



Input/output panel connections.

 ACCESSORY OUTLETS ISOLATED / SWITCHED TOTAL(J1,J2) 200VA MAX ~ (50/60Hz)	MAINS VOLTAGE	ACCESSORY OUTLET VOLTAGE
	100-120 V~	100-120 V~
	200-240 V~	200-240 V~

Accessory outlet label.

The impedance of the video input to the ultrasound system must be matched to the output impedance of the peripheral device using the video impedance control. Standard video devices have an output impedance of 75 ohms, so the video impedance control is normally set to the 75 ohm position.

Connecting Peripheral Equipment

See also: Documentation Devices, Chapter 2, System Reference

On-board peripheral devices must be installed by an authorized Siemens representative or by a Siemens approved third party. Any use of other devices with the system will be at the user's risk and may void the system warranty.

In order to fulfill EN 60601-1-1 and IEC 60601-1-1 (Medical Electrical Equipment, Part 1: General Requirements for Safety) requirements, connection of peripheral equipment to your ultrasound imaging system must adhere to one of the following conditions:

- The peripheral equipment itself is a medical device approved according to EN 60601-1 and IEC 60601-1, or
- Non-medical peripheral equipment approved according to any other EN or IEC standard (EN XXXXX or IEC XXXXX, e.g., equipment complying with EN 60348 and IEC 60348, EN 60950 and IEC 60950, etc.) must use the following setup for connection:

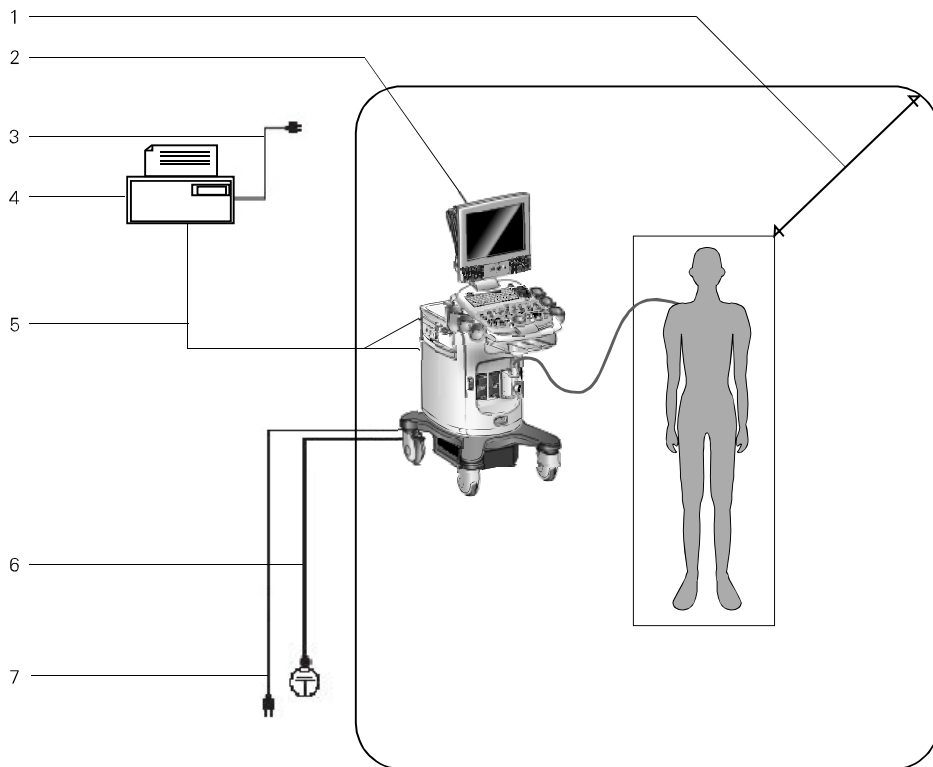


Equipotential connector located on power panel of imaging system.

- Connect the imaging system to an independent protective earth terminal, with a ground wire connection to the ultrasound systems equipotential connector. Ensure that the protective earth wire is connected to a qualified protective earth connection independent of the existing systems earth connection (via the power cable).
- The peripheral equipment is located at least 1.5 meters (1.8 meters [6 feet] in Canada and the U.S.A.) outside of the patient environment. A patient environment is defined as the area in which medical examination, monitoring, or treatment of the patient takes place.
- The peripheral equipment is connected to a main outlet outside the patient environment but still within the same room as the imaging system.

For additional information and other possible combinations, please refer to the Medical Electrical Equipment Standard EN 60601-1-1 or IEC 60601-1-1, Annex BBB.7, Scenario 3c.

Note: The above information is based on current EN 60601-1-1 and IEC 60601-1-1 standards, dated 2000-12. If your country's regulatory standards for medical equipment do not correspond to EN 60601-1 and IEC 60601-1 as well as EN 60601-1-1 and IEC 60601-1-1, your local requirements may be different.



Example of a peripheral equipment connection and patient environment.

- | | |
|--|---|
| <p>1 Patient environment (represented by dot pattern, extending exactly 1.5 meters (1.8 meters [6 feet] in Canada and the U.S.A.) around patient and ultrasound system)</p> <p>2 Ultrasound system</p> <p>3 Peripheral equipment power</p> | <p>4 Peripheral equipment (EN XXXXX and IEC XXXXX)</p> <p>5 RS-232C cable or video in/out</p> <p>6 Additional Protective Earth (refer to 3-26)</p> <p>7 Ultrasound system power</p> |
|--|---|

Serial Port

The system has a serial port for connecting to a PC. This port is located on the Input/Output panel.



Peripheral > External RS-232C Port #1
Peripheral > External RS-232C Port #2

Configuring the Serial Port

Use the system presets to select the destination for data sent through the serial port on the ultrasound system.

- ⚠ Caution:** Should you disconnect the RS-232C cable from peripheral equipment, always connect the termination cap to the cable connector. The termination cap protects the pins on the connector and protects the system from potential image degradation due to radio wave interference.

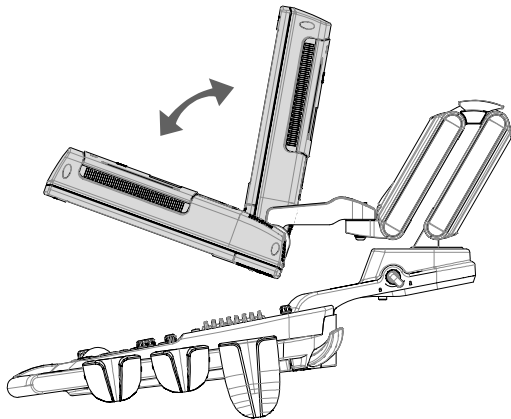
System Ergonomics

⚠ WARNING: Do not lean on the monitor. Doing so might cause the system to tilt over and may result in the potential for personal injury to the user or patient and/or damage to the system.

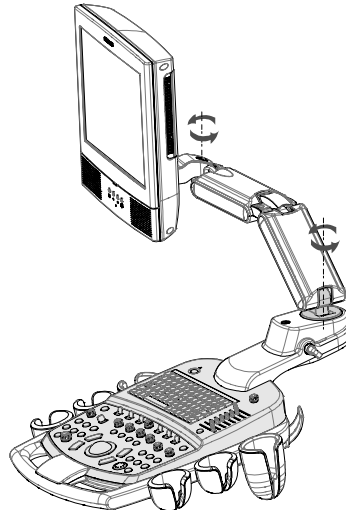
You can make the following adjustments to the system:

Monitor – Tilt the monitor for optimal viewing while scanning.

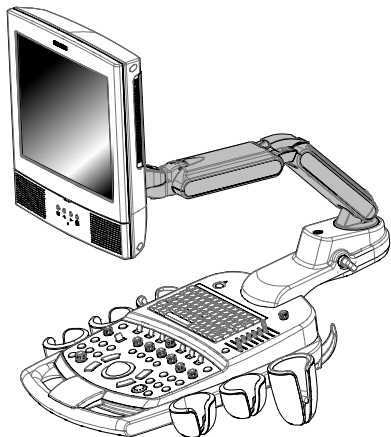
Monitor Arm – Use the monitor arm to extend the monitor forward over the control panel, and swivel the monitor right or left or swivel the monitor arm right or left.



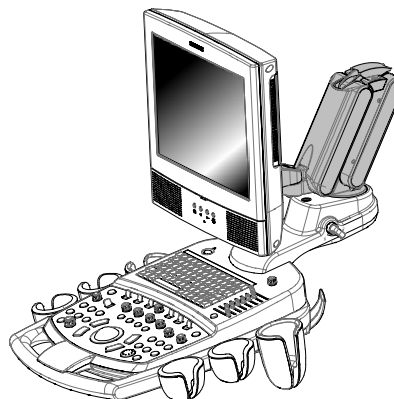
Example of monitor in tilted and upright positions.



Example of monitor swivel and monitor arm swivel.



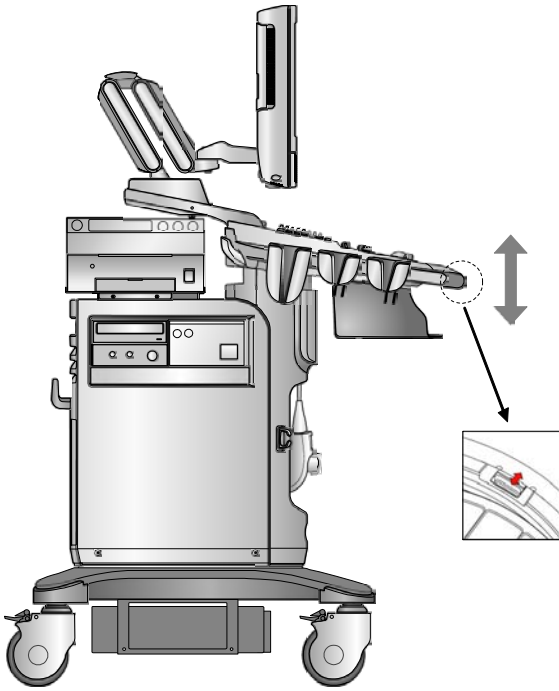
Example of monitor arm in forward, extended position.



Example of monitor in non-extended position.

Lighting – A task light is available under the monitor to illuminate the keyboard.

Control Panel – Use the button located under the control panel to adjust the height of the control panel.



Example of the location of the button for adjusting the height of the control panel.

General System Settings

You can change general system settings such as the on-screen display of the date, time, and hospital name using the system presets. These settings display on the image screen as well as on patient reports.



General 1 > Organization > Hospital Name

Modifying Hospital or Clinic Name

To change the hospital or clinic name, enter a new name into the system preset.

To change the hospital name:

1. Press the **Presets** key on the keyboard to access the system presets.
2. Roll the trackball to **General 1** on the left of the screen and then press the **SET** key on the control panel.
3. Roll the trackball to **Hospital Name**, and then press the **SET** key.
4. Enter a name. You can enter up to 25 characters.
5. Roll the trackball to **Save** and then press the **SET** key to store the new settings and exit the system presets.

Setting System Date and Time

The date is displayed numerically on the upper right of the image screen. You can enter a new date and time, and you can select the format in which the date displays on-screen.

Use the system presets to select a date format and to set the date and time.



General 1 > Format > Date Format
General 1 > Format > Date & Time Settings

Note: You cannot change the date and time during an active study. Close the active study before changing date and time.

To select the date format:

1. Press the **Presets** key on the keyboard to access the system presets.
2. Roll the trackball to **General 1** on the left of the screen and then press the **SET** key on the control panel.
3. Roll the trackball to **Month/Day/Year**, **Day/Month/Year** or **Year/Month/Day** in the **Date Format** area, then press the **SET** key on the control panel.
4. Roll the trackball to **Save** and then press the **SET** key to store the new settings and exit the system presets.

To change the system date:

1. Press the **Presets** key on the keyboard to access the system presets.
2. Roll the trackball to **General 1** and then press the **SET** key on the control panel.
3. Roll the trackball to **Date & Time Settings** and press the **SET** key.

The system displays the **Date and Time Properties** screen.

4. Enter the date by completing the Date fields:
 - a. Select a month from the list of months.
 - b. Select a year from the list of years.
 - c. Select a day from the calendar.
5. Roll the trackball to the **OK** button or to the **Apply** button and then press the **SET** key.

Note: Selecting **OK** applies the change and closes the window; selecting **Apply** applies the change and leaves the window open.

To change the system time:

1. Press the **Presets** key on the keyboard to access the system presets.
2. Roll the trackball to **General 1** and then press the **SET** key on the control panel.
3. Roll the trackball to **Date & Time Settings** and press the **SET** key.

The system displays the **Date and Time Properties** screen.

4. Enter the time by completing the **Hour**, **Minute**, and **Second** fields.

Use the **Tab** key to advance to the next field. Use the trackball to reposition the text cursor if you need to make a correction.
5. Roll the trackball to the **OK** button or to the **Apply** button and then press the **SET** key.

Note: Selecting **OK** applies the change and closes the window; selecting **Apply** applies the change and leaves the window open.

To adjust the time for Daylight Savings:

1. Press the **Presets** key on the keyboard to access the system presets.
2. Roll the trackball to **General 1** and then press the **SET** key on the control panel.
3. Roll the trackball to **Date & Time Settings** and press the **SET** key.
The system displays the **Date and Time Properties** screen.
4. Roll the trackball to the **Time Zone** tab and then press the **SET** key on the control panel.
5. Select the time zone from the list.
If Daylight Savings time is used by that time zone, then a check box displays at the bottom of the window.
6. To adjust for Daylight Savings time, select the check box.
7. Roll the trackball to the **OK** button or to the **Apply** button and then press the **SET** key.

Note: Selecting **OK** applies the change and closes the window; selecting **Apply** applies the change and leaves the window open.

To set the time using an Internet time server:

Note: To use the time server option, the system must be configured with access to the Internet.

1. Press the **Presets** key on the keyboard to access the system presets.
2. Roll the trackball to **General 1** and then press the **SET** key on the control panel.
3. Roll the trackball to **Date & Time Settings** and press the **SET** key.
The system displays the **Date and Time Properties** screen.
4. Roll the trackball to the **Internet Time** tab and then press the **SET** key on the control panel.
5. Select the check box to synchronize with an internet time server.
6. Enter the Internet server name in the **Server** field.
7. To update the time immediately, roll the trackball to the **Update Now** button, and then press the **SET** key.
8. To update the time at the next interval, roll the trackball to the **OK** button or to the **Apply** button and then press the **SET** key.

Note: Selecting **OK** applies the change and closes the window; selecting **Apply** applies the change and leaves the window open.

Configuring the Documentation Controls

You can configure the documentation controls for printing and storing. The system stores images, patient reports, and CINE data to its hard disk.



Customize Keys > Print/Store 1 Key
Customize Keys > Print/Store 2 Key

To configure the documentation controls:

1. Press the **Presets** key on the keyboard to access the system presets.
2. Select **Peripheral** on the left of the screen.
3. For each documentation control (**PRINT/STORE1** or **PRINT/STORE2**, or **CLIP STORE**), select the required option:

Note: The **PC Printer** and **Disk Store & PC Printer** selections are available when you select a **PC printer** on the **Printer** screen.

To configure the documentation control to:	Select an option:
Store images and patient reports	Disk Store
Store Clip data	Clip Capture
Store 3D volume data	Volume Store
Print images and patient reports	<ul style="list-style-type: none"> ▪ B/W Print ▪ Color Print ▪ PC Printer ▪ USB B/W ▪ USB Color ▪ DICOM B/W Print ▪ DICOM Color Print
Store and print images and patient reports	<ul style="list-style-type: none"> ▪ Disk Store & B/W Print ▪ Disk Store & Color Print ▪ Disk Store & PC Printer ▪ Disk Store & USB B/W ▪ Disk Store & UBS Color

4. Select the **Save** button to store the new settings and exit the system presets.

Software Installation

You can install new software or you can re-install existing software. When you install or re-install, you can choose to retain user-defined settings (system presets and QuickSets) or you can remove the user-defined settings. Retaining user-defined settings allows you to use the new software without having to reconfigure the system. Removing user-defined settings allows you to completely reset the system for another purpose or to reset the system in order to re-load all user-defined settings from a back-up.

See also: Software-Based Option Installation, p. 3-35

- To install software and retain all existing user-defined settings, follow the procedure to install system software.
- To install new software and remove existing user-defined settings, follow the procedure to reset system software. Removing user-defined settings also removes any installed software-based options.

Note: Siemens recommends that you retain user-defined settings. Whether you retain or remove user-defined settings, you should make a backup copy of system presets and QuickSets before installing software.

Refer to the software installation procedure that accompanies your system software disks.

Software-Based Option Installation

You can install a software-based option on the ultrasound system using a software-based option media.

To install a software-based option:

1. Prepare the system for the software load:
 - a. Press the **Presets** key to display the **Presets** screen.
 - b. Select **Service** on the left of the screen.
 - c. Select **Service**.
 - d. Delete **none** from the text box and then click **OK**.
 - e. Select **Configuration**.
 - f. Select **Licensing & Components** on the left of the screen.
2. Install the software:
 - a. Press the eject button on the CD/DVD drive on the left side of the ultrasound system to eject the CD/DVD tray, insert the license disk, and then press the eject button again to load the disk.
 - b. Select **Select New License File** on the upper right of the screen.
The system displays the **License File to be set** section.
 - c. Select the license file from **Browse** or from **History**.
 - d. Click **Save**.
The system displays a status dialog box.
 - e. Click **OK**.
The software-based options are displayed in the **Available Features** section.
3. Click **OK** when the system displays a reboot dialog box.
The system restarts and confirms the installation of the options.

4 Examination Fundamentals

Entering Patient Data	3
Retrieving Patient Data for Registration	4
Using the Patient Data Form	4
Calendar Tool.....	5
Fields in the Patient Data Form	5
Patient — Original	6
Patient — e-entry	7
History (All Examinations)	7
History (OB, Early OB, GYN, Fetal Echo, or EM) — Original Method ...	8
History (C-Vascular, P-Vascular, and Venous).....	9
History (Urology)	9
Institution	9
Exam	9
Selecting a Scheduled Procedure	9
Searching the Worklist.....	10
Worklist and Procedure Screen.....	11
Selecting Another Procedure.....	12
Editing Patient Data	12
Changing the Exam Type	13
Exam Type Abbreviations.....	14
Activating a Transducer	15
Changing a Transducer Frequency	15
Selecting an Operating Mode	16
2D-Mode and M-Mode Imaging	17
Example Screen Layout.....	17
2D-Mode with Color	18
Example Screen Layout.....	18
Doppler	19
Example Screen Layout.....	19
2D-Mode/Doppler Formats	19
Optimizing Images	20
Creating and Viewing Thumbnails	20
Viewing Patient Information in the PatientInfo Tab	22
Measurement Function — Overview	23
General and Exam-Specific Measurements	23
Examination Completion	24

Entering Patient Data

Before beginning a patient examination, you can use the keyboard to enter general patient information into the **Patient Data** form.

- You can retrieve previously entered patient information.
- You can also automatically register a new patient by pressing one of the documentation controls configured for disk storage when no patient is registered. The system opens a new study, identifying the **Patient Name** as an asterisk (*) and the **Patient ID** as the opening date and time. You can then change the patient information for the current study while the study remains open.
- You can automatically register a new patient by using the Worklist search function.


See also: Searching the Worklist, p. 4-10

Use the system presets to select the registration method (patient registration form and data entry requirements):

- **Original** uses the standard patient registration form with conventional requirements for data entry.
- **e-entry** displays an overlay of patient identification fields on the Image screen.

 **General 2 > Common Mode > Patient Registration**

Use the system presets to select the order that the tab key moves from field to field on the **New Patient Data** form.

 **General 2 > Patient ID > Customize Entry Order**

To enter new patient information:

1. Press the **NEW PATIENT** key located on the control panel.

The system displays the **New Patient Data** form with a text entry cursor positioned in the **Last Name** field.

Note: You can also review and edit an existing form by pressing the **Patient Data** key on the keyboard.

2. Enter the patient information using the instructions on the following pages.
3. Select **OK** at the bottom of the form to confirm your entries or select **Cancel** to discard your entries.
 - To confirm your entries, roll the trackball to the **OK** button and then press the **SET** key to enter the patient information.
The system displays the Image screen with the new patient information.
 - To exit the form without saving the entries, select **Cancel** at the bottom of the form.
The system redisplay the Image screen with the previous patient's information and discards the entries on the New Patient Data form.

Retrieving Patient Data for Registration

You can retrieve previously entered patient data for registration from the ultrasound system's hard disk or external media.

To retrieve previously entered patient data:

1. Press the **Patient Browser** key on the keyboard.
If a patient is currently registered, then the system displays the DIMAQ-IP Image screen. If a patient is not currently registered, then the system displays the DIMAQ-IP Study screen.
2. To display the Study screen (from the Image screen), select the **Study Screen** button on the left of the screen.
3. Select the location of the patient data from the **Disk** section of the Study screen.
4. Select the required study at the top of the screen and then select the **New** button in the **Study** section of the Study screen.

The system transfers the patient data into the **New Patient Data** form.

5. Use the keyboard to edit or enter data.
6. To begin the study, select **OK**.

Using the Patient Data Form

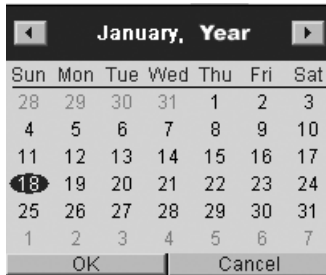
The **Patient Data** form contains general and exam-specific information.

To:	Perform this action:
Move the text cursor to the beginning position of the next entry field	Press the Tab key on the keyboard. You can also roll the trackball to the next field and then press the SET key on the control panel.
Delete characters	Press the Backspace key on the keyboard.
Select a button or object on the form	Roll the trackball to the button or object and then press the SET key.
Save the new patient data, exit viewing/editing of the patient form, and redisplay the Image screen	Roll the trackball to the OK button and then press the SET key or press the Enter key on the keyboard. Or, press the 2D control.
Exit viewing/editing of the patient form, and redisplay the Image screen without saving the new patient data	Roll the trackball to the Cancel button and then press the SET key, or press the ESCAPE key on the control panel.

Calendar Tool

You can display a calendar tool in the **Patient Data** form for use with the following exam types: OB, Early OB, GYN, Fetal Echo, and EM.

The calendar tool is available for date fields in the **History** section of the **Patient Data** form.



Example of Calendar Tool.

To use the calendar tool:

1. Roll the trackball to select the down arrow (▼) on a date field of the **Patient Data** form and press the **SET** key to access the calendar.
2. To scroll through the months of the calendar, select either the back arrow (◀) or the forward arrow (▶).
3. Roll the trackball pointer to a date and then press the **SET** key.


The system exits the calendar tool and places the selected date in the **Patient Data** form.

4. To exit the calendar without saving changes, select the **Cancel** button below the calendar.

Fields in the Patient Data Form

The **Patient Data** form includes the following sections: **Patient**, **History**, **Institution**, and **Exam**.

Use the system presets to select the following formats: date, height, and weight.

 **General 1 > Format**

Patient — Original

In this field:	Enter the...
Last Name	Patient's last name.
First Name	Patient's first name.
Prefix	Dr., Miss, Mrs., Ms., Mr., Prof.
Suffix	Jr., Sr., I, II, III
MI	Patient's middle initial(s).
Patient ID	<p>Identification code for the patient.</p> <p>If an identification (ID) is not entered, then the system generates a unique identifier starting with the system date and time.</p> <p>This ID code displays on the Image screen. If there is not enough space for the entire code to display on the Image screen, a portion of the code is displayed followed by three dots (...).</p>
Date of Birth	<p>Patient's date of birth using the date format selected in the system presets.</p> <p>When you enter or change this value, the system calculates and displays values for Age.</p>
Age	The system automatically calculates and displays the patient's age based on the Date of Birth , if entered.
Sex	<p>Patient's sex.</p> <p>If Male or Female is not selected, then the system selects Unknown.</p>
Height	<p>Patient's height using the measurement system selected in the system presets:</p> <p>Metric or U.S.</p>
Weight	<p>Patient's weight using the measurement system selected in the system presets:</p> <p>Metric or U.S.</p>
BP [mmHg]	Patient's blood pressure.
BSA	<p>Patient Body Surface Area in m². The system automatically calculates the BSA (based on Height and Weight entries) and transfers the value to the patient report.</p> <p>BSA is calculated with one of the following two formulas:</p> <p>For height in centimeters and weight in kilograms:</p> $BSA = 0.007184 \times (\text{weight})^{0.425} \times (\text{height})^{0.725}$ <p>For height in feet/inches and weight in pounds:</p> $BSA = 0.007184 \times (\text{weight} \times 0.454)^{0.425} \times (\text{height} \times 2.54)^{0.725}$

Patient — e-entry

Note: To move the cursor, press the **Tab** key on the keyboard. To confirm your entries, press the **SET** key on the control panel. Or, press the **2D** control.

OB, Early OB, Fetal Echo and EM Exams

Note: The **EDC** and gestational age display at the top of the screen during imaging. These values also display in the patient report.

In this field:	Enter the...
ID	Identification code for the patient. If an identification (ID) is not entered, then the system generates a unique identifier starting with the system date and time.
Name	Patient's last and first name.
Age	Fetal age in weeks (w) and days (d). The system automatically calculates and displays the fetal age in weeks and days if a value already exists for LMP .
LMP	Start date of the patient's Last Menstrual Period (LMP) using the date format displayed on the screen. When you enter or change this value, the system calculates and displays values for Age and EDC .
EDC	Estimated Date of Confinement (EDC) using the date format displayed on the screen. The system automatically calculates and displays the Estimated Date of Confinement (EDC) if a value already exists for LMP and/or Age . When you enter or change this value, the system calculates and displays values for LMP and Age .

Other Exams

In this field:	Enter the...
ID	Identification code for the patient. If an identification (ID) is not entered, then the system generates a unique identifier starting with the system date and time.
Name	Patient's last and first name.
Birth	Patient's date of birth using the date format displayed on the screen. When you enter or change this value, the system calculates and displays values for Age .
Age	The system automatically calculates and displays the patient's age based on the Date of Birth , if entered.
Sex	Patient's sex. If Male or Female is not selected, then the system selects Unknown . To select the sex, press the right or left arrow key on the keyboard.

History (All Examinations)

In this field:	Enter...
Additional Info	Additional information.

History (OB, Early OB, GYN, Fetal Echo, or EM) — Original Method

See also: Obstetrical Measurements and Calculations, Chapter B2, Features and Applications Reference

In this field:	Enter...	History				
		OB	Early OB	Gyn	Fetal Echo	EM
Date LMP/IVF	Select either LMP or IVF . For the LMP , enter the start date of the patient's Last Menstrual Period (LMP) using the date format selected in the system presets. For IVF , enter the date of in-vitro fertilization using the date format selected in the system presets. When you enter or change this value, the system calculates and displays values for Age[wks/days] and EDC . The system automatically enters the year when you enter the month and day (if a compatible Date Format option [Day/Month/Year or Month/Day/Year] is selected in the system presets).	✓	✓	✓	✓	✓
EDC	The system automatically calculates and displays the Estimated Date of Confinement (EDC) if a value already exists for Date LMP/IVF and/or Age[wks/days] . Enter the Estimated Date of Confinement (EDC) using the date format selected in the system presets. When you change a value (other than zero) for EDC , the system recalculates and displays values for Date LMP/IVF and Age[wks/days] .	✓	✓		✓	✓
Age[wks/days]	The system automatically calculates and displays the fetal age in weeks and days if a value already exists for Date LMP/IVF . Enter the fetal age in weeks and days. When you enter or change this value, the system calculates and displays values for Date LMP/IVF and EDC . The system automatically calculates the EDC , but not the Date LMP/IVF , when you enter only the fetal age. If you enter the Date LMP/IVF and then change the fetal age, the system recalculates both the Date LMP/IVF and EDC according to the fetal age.	✓	✓		✓	✓
Gravida Para Aborta Ectopics	Patient's history of pregnancies. The entries in these fields are transferred to the Patient Report, but do not display on the Image screen.	✓	✓	✓	✓	✓

History (C-Vascular, P-Vascular, and Venous)


In this field:	Enter...	History		
		C-Vascular	P-Vascular	Venous
BP(Left)	Blood pressure of the left arm, using the systole over diastole measurement in mmHg.	✓	✓	✓
BP(Right)	Blood pressure of the right arm, using the systole over diastole measurement in mmHg.	✓	✓	✓
ABI [Left/Right]	Ankle Brachial Index.		✓	

History (Urology)

In this field:	Enter...
PSA (ng/ml)	Prostate specific antigen level.

Institution

Use the system presets to display physician identification on the patient report.

 **M & R Configuration 1 > Measurement and Report Preset > Display Item**

In this field:	Enter the...
Referring MD	Identifying information for the referring physician.
Performing MD	Identifying information for the performing physician.
Sonographer	Identifying information for the sonographer.

Exam

Field:	Description:
Transducer	Lists the available transducers.
Exam	Lists the exam types available for the selected transducer.
Accession No	Identification code indicating the sequence of the current study as related to other studies for this patient. Used for billing purposes. Typically generated by a HIS/RIS (Worklist) server.
Indication	Information describing the symptom or particular circumstance that indicates the advisability or necessity of a specific medical procedure.

Selecting a Scheduled Procedure

(Requires the DICOM option and the DICOM Modality Worklist option)

You can select a scheduled procedure using the Worklist search method.

Searching the Worklist

You can use the Worklist search function to select a scheduled procedure for a new study.

 **DICOM > Worklist Server > Streamlined Search**

To search the Worklist server and begin a scheduled procedure:

1. Press the **NEW PATIENT** key on the control panel.

The system displays the **New Patient Data** form with a text entry cursor positioned in the **Last Name** field.

2. Enter patient information for the search and then select the **Worklist** button located at the upper left side of the form.

The system displays the **Worklist Search** screen containing data entered on the **New Patient Data** form. If streamlined search is enabled, then the system begins searching procedures scheduled for the next 24 hours using data entered on the **New Patient Data** form.

3. If streamlined search is not enabled, you must first select the **Search** button before entering additional search criteria.

- a. Enter additional search criteria using the keyboard.
 - To access the next field, press the **Tab** key on the keyboard.
 - To remove data from all fields, select **Clear**.
- b. Select **Search** to begin the search.

Note: Select **US Only** to search for procedures scheduled on all ultrasound systems; select **This system only** to confine the search to procedures scheduled on this ultrasound system.

The system displays the search results at the top of the **Worklist Search** screen and activates the **Scheduled Procedures** field and the **Select** button.

4. To sort patient data:
 - Select a column heading to sort the files in ascending order by heading.
 - Select the column heading again to sort in descending order.

5. To begin a new study:

- a. Select a study from the top of the **Worklist Search** screen.

Note: When the Worklist server assigns different accession numbers to procedures within a study, the system lists each procedure separately at the top of the **Worklist Search** screen.

- b. Select (click) the **Select** button.

The system transfers the patient data into the **New Patient Data** form.

- c. Use the keyboard to edit or enter data and then select **OK** to begin the study.

Note: The following fields cannot be edited for patient data transferred from the Worklist server: **Patient Name, Patient ID, Accession Number, DOB/Age, Sex**.

Worklist and Procedure Screen

In this field:	Displays...
Worklist	
Patient Name	Name of patient.
Patient ID	Identification code for the patient. Searching for the ID requires an exact match.
Study Description	Description of the study.
Accession Number	Accession number. Searching for the accession number requires an exact match.
Date/Time	Dates and times for the scheduled study.
Scheduled Procedures	Lists available procedures for the selected study. Procedures are identified by study code and description.
Code Value	Value of the code.
Scheduled Procedure Description	Description of the scheduled procedure.
State	Procedure status.
Code	
Value	Value of the code.
Meaning	Meaning of the code.

Search Dialog Box

In this field:	Enter...
Patient Name	
Last	Last name of patient. Use an asterisk (*) to indicate partially known values. For example, to search for the last name "Miller", you can enter "Mil*" or "*ler".
First	First name of patient. Use an asterisk (*) to indicate partially known values. For example, to search for the first name "Christopher", you can enter "Chris*" or "*pher".
Middle	Middle initial of patient.
Patient ID	Identification code for the patient. Searching for the ID requires an exact match.
Date	Dates for the search.
Accession Number	Accession number. Searching for the accession number requires an exact match.
Requested Procedure ID	Requested procedure ID. Searching for the requested procedure ID requires an exact match.
Scope	Select US Only to search for procedures scheduled on all ultrasound systems; select This system only to confine the search to procedures scheduled on this ultrasound system.
Performing Physician	
Last	Last name of physician. Use an asterisk (*) to indicate partially known values. For example, to search for the last name "Miller", you can enter "Mil*" or "*ler".
First	First name of physician. Use an asterisk (*) to indicate partially known values. For example, to search for the first name "Christopher", you can enter "Chris*" or "*pher".
Middle	Middle initial of physician.

Selecting Another Procedure

When MPPS is set up, you can select another procedure for the currently registered patient.

To select another procedure for the currently registered patient:

1. Press the **REVIEW** key on the control panel to display the Image screen.
2. Select the **Procedure Screen** button on the left of the screen to display the **Choose procedure** screen.

Note: This selection is available when a connected DICOM Worklist server contains multiple procedures for the currently registered patient.

3. Select the procedure from the **Scheduled Procedure(s)** section and then select the **Select** button on the right of the screen.

The system displays a confirmation message.

4. Select **Select** to confirm the closing of the current procedure and the starting of the selected procedure.
5. To complete the closed procedure, select **Completed**.
6. To discontinue the closed procedure, select **Discontinued**.
7. Select the **Live Screen** button to display the Image screen and begin the selected procedure.

To append another procedure for the currently registered patient:

Note: You can append a procedure to another procedure in progress.

- Select **<Click here to append...>** from the **Scheduled Procedure(s)** section and then select the **Append** button.

The new procedure displays in the Scheduled Procedure(s) section.

Editing Patient Data

You can edit entries on the **Patient Data** form at any time during the patient examination.

Note: The following fields cannot be edited for patient data transferred from the Worklist server: **Patient Name, Patient ID, Accession Number, Date of Birth/Age, Sex.**

To display the Patient Data form:

1. Press the **Patient Data** key on the keyboard.

The system displays the **Patient Data** form.

2. Use the keyboard to update your entries.

Changes to the **Patient Data** form are also updated on the Image screen and in the report for exams with a patient report.

Changes to fields used in calculations cause the system to update previously measured results.

3. Roll the trackball to the **OK** button and then press the **SET** key to save the revisions to the patient information and redisplay the Image screen. To restore the current **Patient Data** form and redisplay the Image screen without saving the revisions, roll the trackball to the **Cancel** button and then press the **SET** key.

Changing the Exam Type

You can change the exam type at any time by making a selection from the **Exam and QuickSet List**. System-defined exam types and user-defined QuickSets display on this list. A QuickSet is an optimized configuration of imaging parameter settings for a specific transducer, exam, and operating mode.

See also: Imaging Functions, Chapter A1, Features and Applications Reference

Use the system presets to select the names of the exam types to display in the **Exam and QuickSet List**.

Note: You cannot disable the display of the currently active exam type.



User-Defined Exam List > Enable Exam

To select or change the exam type or QuickSet:

1. Access the **Exam and QuickSet List** by pressing the **Exam** key on the keyboard.
The system displays the names of the connected transducers as "button" selections, a list of system-defined exam types, and a list of QuickSets.
Note: If the transducer associated with a QuickSet is not connected to the system, the QuickSet is not selectable.
2. Roll the trackball to select the button for a transducer and then press the **SET** key on the control panel.
The system displays the exams related to the selected transducer.
3. Roll the trackball to the name of the required exam type or the QuickSet and then press the **SET** key.
The system highlights the selected item and then displays the name of the selected exam type or QuickSet in the upper left of the image screen.
4. To redisplay the image screen without selecting an exam type or QuickSet, select the **Cancel** button.

Exam Type Abbreviations

The system displays an abbreviation that indicates the active exam type in the upper left of the Image screen. The system-defined exams are abbreviated as follows:

- **Abdomen** Abdominal
- **OB** Obstetrics
- **OB(J)** Obstetrics (Japan)¹
- **Early OB** Early Obstetrics
- **Breast** Breast
- **Thyroid** Thyroid
- **Testicle** Testicle
- **GYN** Gynecology
- **Orthopedic** Orthopedics
- **Cardiac** Cardiac
- **Urology** Urology
- **Renal** Renal
- **MSK** Musculoskeletal
- **C-Vascular** Cerebrovascular
- **P-Vascular** Peripheral Vascular
- **Venous** Venous
- **Sup MSK** Superficial Musculoskeletal
- **Ped Abd** Pediatric Abdomen
- **Ped Echo** Pediatric Echo
- **Penile** Penile
- **EM** Emergency Medicine
- **Fetal Echo** Fetal Echo
- **TCD** Transcranial
- **Digital** Digital
- **Neo Head** Neonatal Head
- **Small Parts** Small Parts
- **TEE** Adult transesophageal

¹ SONOVISTA Systems Only

Activating a Transducer

Although multiple transducers can be connected to the ultrasound system, only one transducer can be active.

Use the system presets to select the transducer port that will be active at system power-on.



General 1 > Boot Up > Active Transducer

To activate a transducer connected to the system:

1. Press the **TRANSDUCER** key located on the control panel.
The name of the active transducer displays on the upper left of the screen.
2. To activate another transducer connected to the system, press the **TRANSDUCER** key again.

To activate a transducer when three (or more) transducers are connected to the system:

Note: When three (or more) transducers are connected to the system, the names of the transducers display as soft key selections.

- Press the toggle key for the required transducer.
The name of the active transducer displays on the upper left of the screen.

Changing a Transducer Frequency

You can change the operating frequency of an active transducer for the active imaging mode.

The system displays the operating frequency on the upper left of the screen.

During THI imaging, the system displays "THI" next to the gain value on the upper left of the screen.


To change the transducer frequency for the active imaging mode:

- Press the toggle key for **MultiHertz**.
The system applies the selection and displays the current setting in the Imaging Parameters on the upper left of the screen.

Selecting an Operating Mode

When powered on, the system automatically displays in 2D-mode. You can change modes by pressing the appropriate control or key located on the control panel.

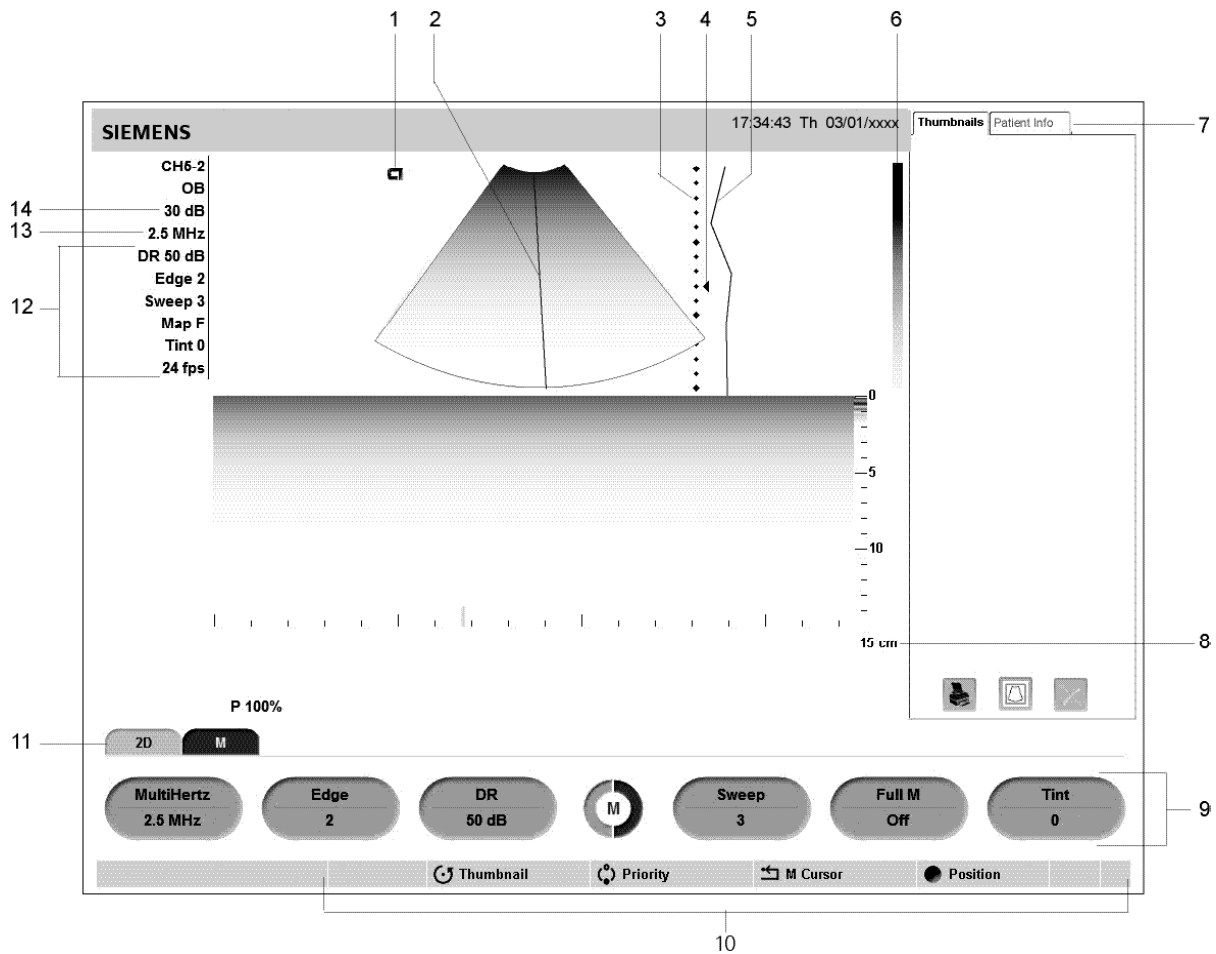
Use the system presets to display the 2D image simultaneously with the M-mode sweep or Doppler spectrum when M-mode or Doppler is selected. If you do not activate the bypass cursor display selection in the system presets, the system displays the 2D image with the cursor when M-mode or Doppler is selected and you must select the control a second time to display the sweep or spectrum.

 **Display > Doppler/M-Mode > Bypass M/D Cursor Display**

Mode	Selection
2D-mode	Press the 2D control on the control panel.
Split mode	During 2D-mode imaging, press the toggle key for Split .
Dual-mode	Press the left or right DUAL/SELECT key on the control panel. A 2D image displays in the respective half of the image area. Press the other DUAL/SELECT key to display an image in the other half of the display area. The last DUAL/SELECT key pressed (left or right) establishes the active image. Press either key twice to display the image full-screen. Return to dual displays by pressing the key once again.
4B-mode	During 2D-mode imaging, press the toggle key for 4B .
2D/M-mode	Press the M control on the control panel two times while in 2D-mode.
M-mode	Press the M control on the control panel two times while in 2D-mode and then select Full M from the M-mode on-screen menu on the left of the screen.
2D-mode with Doppler	Press the D control on the control panel two times while in 2D-mode.
Doppler	Press the D control on the control panel two times while in 2D-mode and then select Full D from the D-mode on-screen menu on the left of the screen.
Steerable Continuous Wave Doppler	Connect a phased array transducer to an array port and then press the CW key.
Auxiliary Continuous Wave Doppler	Connect a continuous wave (pencil) transducer to the CW port.
Color	Press the C control on the control panel.
Power	Press the POWER control on the control panel.

2D-Mode and M-Mode Imaging

Example Screen Layout

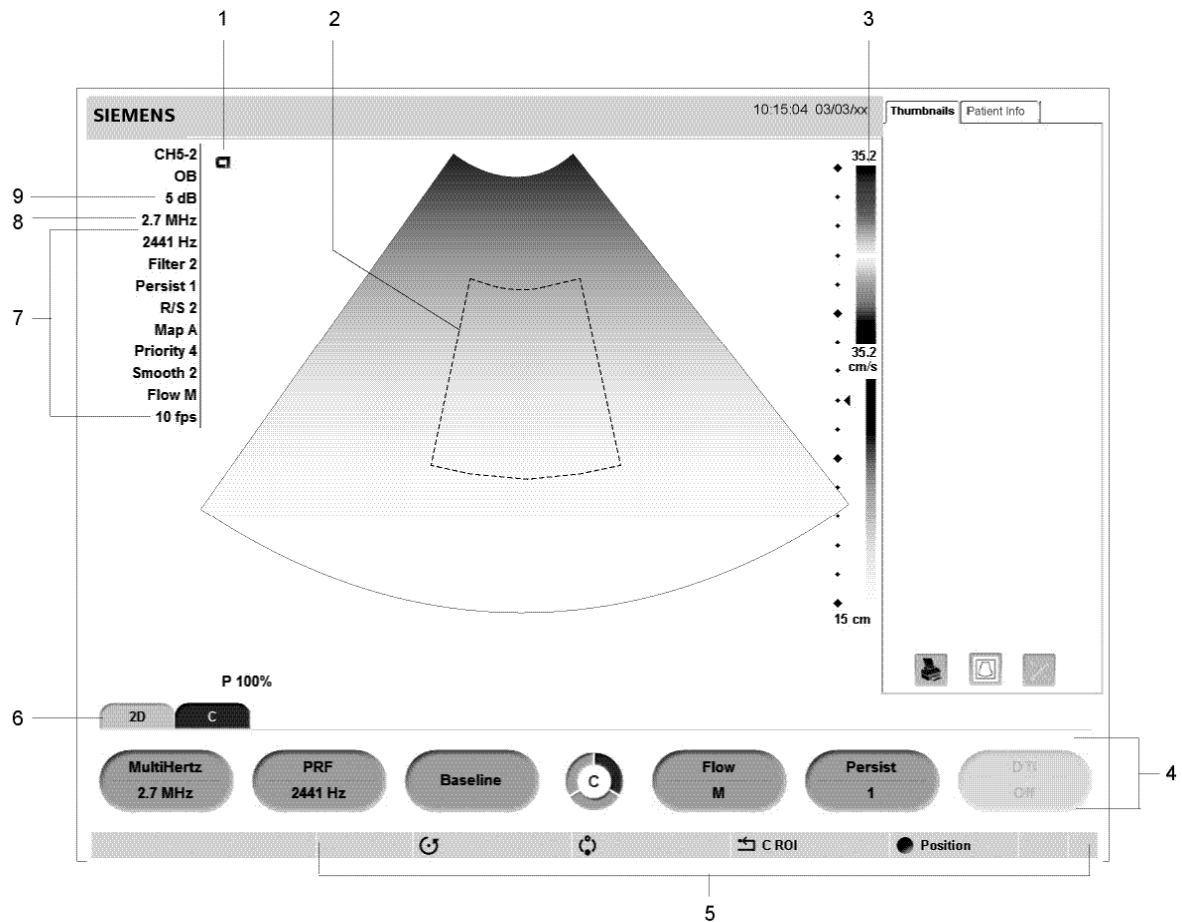


Example of screen layout in 2D/M-mode.

- 1 Image orientation and active image indicator
- 2 M-mode cursor
- 3 Depth scale
- 4 Focal zone marker
- 5 DGC curve
- 6 Gray bar
- 7 Panels, including thumbnails and patient information.
- 8 Image status (Depth in cm, Zoom, and Frame rate)
- 9 Soft key selections and Page Indicator
- 10 Status bar. Indicates the function currently assigned to the trackball, **SELECT** control, **UPDATE** key, and **ESCAPE** key. During video recording, provides recording status and an icon to indicate microphone function is active.
- 11 Tab indicator. Identifies the mode or function for the soft key selections.
- 12 Imaging Parameters (Dynamic Range, Edge Enhance, Sweep, Map and Tint)
- 13 Transducer Frequency
- 14 Gain

2D-Mode with Color

Example Screen Layout

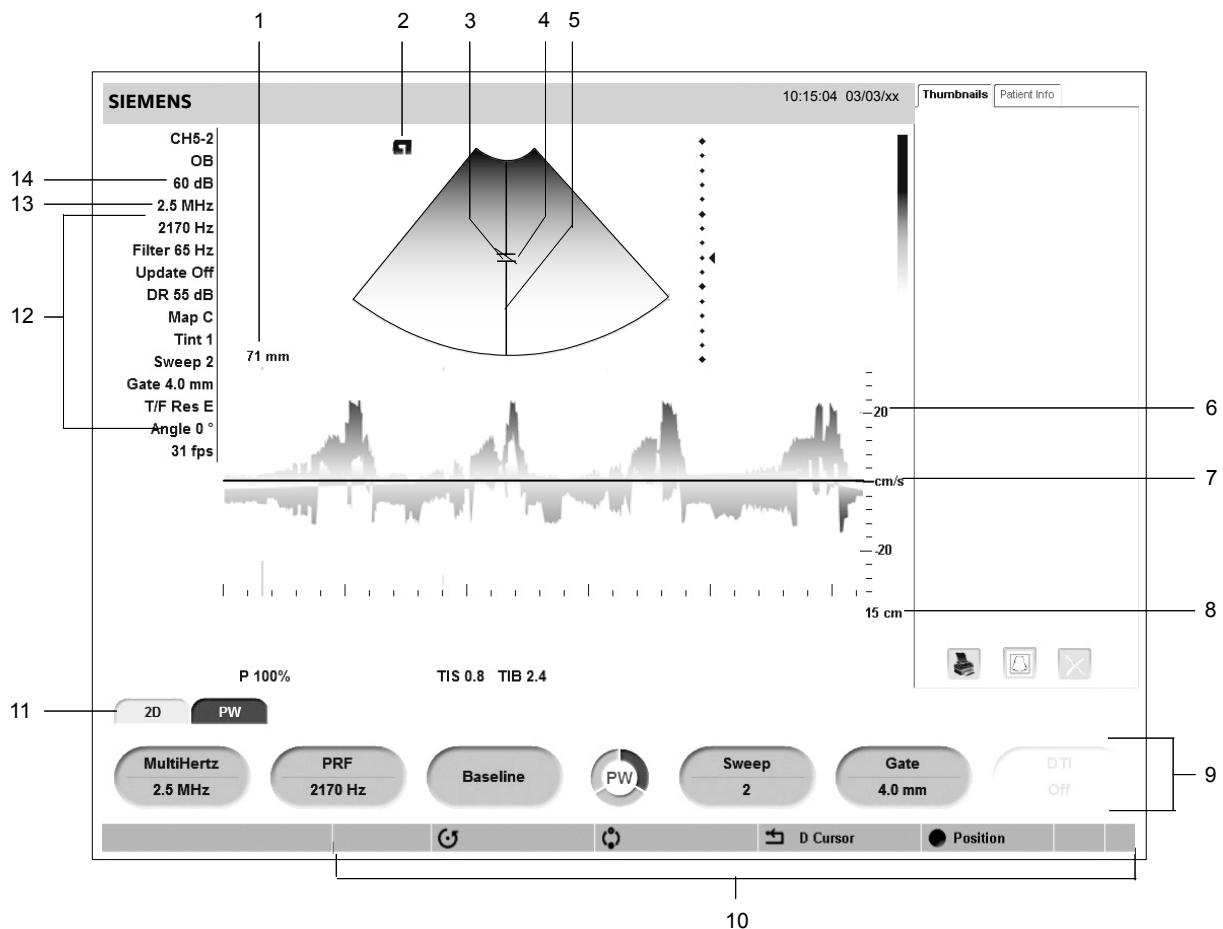


Example of a Color Flow imaging screen.

- 1 Image orientation and active image indicator
- 2 Color ROI or Power Window
- 3 Color or Power Bar and Color Flow Velocity Range (toward transducer)
- 4 Color or Power soft key selections and Page Indicator
- 5 Status bar. Indicates the function currently assigned to the trackball, **SELECT** control, **UPDATE** key, and **ESCAPE** key. During video recording, provides recording status and an icon to indicate microphone function is active.
- 6 Tab indicator. Identifies the mode or function for the soft key selections.
- 7 Color Flow Imaging Parameters (PRF, Persistence, Filter, R/S, Map, Priority, and Smooth); Power mode Imaging Parameters (PRF, Persistence, Filter, R/S, Map, Priority, and Smooth)
- 8 Transducer Frequency
- 9 Gain

Doppler

Example Screen Layout



Example of a pulsed Doppler imaging screen in 2D-mode/Doppler.

- 1 Doppler gate depth
- 2 Image orientation and active image indicator
- 3 Flow angle indicator
- 4 Doppler gate (sample volume)
- 5 Doppler cursor
- 6 Velocity scale (cm/s) or frequency scale (kHz)
- 7 Baseline
- 8 Image status (Depth in cm, Zoom, and Frame rate)
- 9 Doppler soft key selections and Page Indicator
- 10 Status bar. Indicates the function currently assigned to the trackball, **SELECT** control, **UPDATE** key, **ESCAPE** key. During video recording, provides recording status and an icon to indicate microphone function is active.
- 11 Tab Indicator. Identifies the mode or function for the soft key selections.
- 12 Doppler Imaging Parameters (PRF, Filter, Update, DR, Map, Angle, Gate, and T/F Res)
- 13 Transducer frequency
- 14 Gain

2D-Mode/Doppler Formats

Use the system presets to select your Doppler format preference.



Exam Configuration > 2D/M & 2D/Doppler Display Format

Optimizing Images

During imaging, the system displays mode-dependent parameters that you can use to optimize images. Some parameters, such as depth, gain, focus, and zoom, are changed using the controls on the control panel. Other parameters, such as dynamic range, edge enhancement, maps, and tint, are adjusted using mode-specific on-screen controls and soft key selections.


Creating and Viewing Thumbnails

Thumbnails are reduced-size versions of images (including an image of a patient report), clips, and volumes, which are stored during an exam. After you have configured a documentation control in the system presets for the storage function (disk or volume) or for clip capture, the system automatically creates thumbnails when you press the assigned key.

Stored thumbnails display in the **Thumbnails** tab on the right of the screen.

The system assigns a number to each thumbnail and displays a total for each type of stored thumbnails at the bottom of the tab.

Use the system presets to enable and disable the **Thumbnails** display, and to customize the number of columns and rows in the **Thumbnails** tab layout.

 **DIMAQ Utility > Panel**

Note: You cannot create a thumbnail during clip playback or during Stress Echo.

To create a thumbnail:

- Press the documentation control (**PRINT/STORE1**, **PRINT/STORE2**, or **CLIP STORE**) that is configured in the system presets for the storage function (disk or volume) or for clip capture.

The system creates a thumbnail and displays it in the **Thumbnails** tab.

To activate the Thumbnails tab:

- Press the **SELECT** control on the control panel during real-time imaging.
The system displays a trackball pointer.
- Press the **FREEZE** key on the control panel and then press the toggle key for **Thumbnail**.

The system displays a trackball pointer.

To view an image, clip, or volume referenced by a thumbnail:

Note: When multiple thumbnails exist, the system displays a scrollbar to navigate through the thumbnails.

1. To select a thumbnail:
 - Roll the trackball to position the trackball marker on the required thumbnail and then press the **SET** key.
 - Rotate the **SELECT** control on the control panel to scroll through the available thumbnails on the **Thumbnails** tab and then press the **SELECT** key to select the identified thumbnail.

The system outlines the current thumbnail with a white box and confirms the thumbnail in a blue box when selected.
2. To select additional thumbnails, repeat step 1.
3. To de-select a thumbnail:
 - Roll the trackball to position the cursor on a selected thumbnail, and then press the **SET** key.
 - Rotate the **SELECT** control to position the cursor on a selected thumbnail, and then press **SELECT**.
4. Double-click the thumbnail to display the selected images, clips, and volumes on the Review screen with either the **SELECT** control or the **SET** key.
5. Press the **REVIEW** key or **ESCAPE** key on the control panel to exit the Review screen.
6. To print a selected thumbnail, select the **Print** icon at the bottom of the **Thumbnails** tab.
7. To delete selected thumbnails, select the **Delete** icon at the bottom of the **Thumbnails** tab.

Viewing Patient Information in the PatientInfo Tab

You can view the data and study information registered in the patient data form at any time without viewing the form. The patient data and study information display during a current examination or during review of a saved examination in the **PatientInfo** section of the screen next to the **Thumbnails** tab.

Use the system presets to enable and disable the display of the Patient Info tab.



DIMAQ Utility > Panel

Note: To view data during system freeze in a current examination, the function of the **FREEZE** key must be assigned to activate the CINE function.



Exam Configuration > Automatic Freeze Response > Cine

To view the PatientInfo tab:

1. Activate the **PatientInfo** tab.
 - During system freeze, press the **FREEZE** key on the control panel and then press the toggle key for **Thumbnail**.
 - During real-time imaging, press the **SELECT** control on the control panel.
 - During review of a saved study, proceed to step 2.
2. Select the **PatientInfo** tab next to the **Thumbnail** tab.

The tab displays the patient data and study information entered during patient registration.
3. To expand or close a section of the patient data or study information, roll the trackball to the maximize/minimize icon at the right side of the data and then press the **SELECT** key.
4. To scroll through the stored studies and display the related patient data or study information in the **PatientInfo** tab, rotate the **SELECT** control.

Measurement Function — Overview

The measurement function contains the measurements and calculations available for each exam type and imaging mode. You can use the measurement function during a patient examination or on images stored in CINE Review. You can also make measurements on stored images.

When the measurement function is active:

- The soft key selections list measurement methods for the active exam type and imaging mode.
- The trackball controls the placement of measurement markers (calipers) and selection of measurement labels.
- The Measurement Menu displays selectable labels along the left side of the image screen. When available, a report uses these labels to identify measurement values.
- The Measured Results display results of the measurements and calculations at the bottom of the image screen.

General and Exam-Specific Measurements

The ultrasound system contains measurements and calculations that are either **General** – standard for all exam types – or **Exam-specific** – particular to one exam type.

Calculations use formulas that require specific measurements. The system automatically performs a calculation when the required measurements have been completed.

Examination Completion

When you complete a patient examination, the system removes the patient information from the Image screen.

Note: The system automatically completes the patient examination when you shut down the ultrasound system.

To complete a patient examination, choose a method:

- Press **Patient Browser** on the keyboard or press **REVIEW** to display the DIMAQ-IP Image screen and then click **Close Study**.

Note: To complete a patient examination from the DIMAQ-IP Study screen, select the **Close** button in the **Study** box.

- Begin another examination: Press the **NEW PATIENT** key on the control panel to begin a new examination, enter patient data and then select the **OK** button at the bottom of the form.
- Press **NEW** on the keyboard when **Close Study** is assigned to the key.



Customize Keys > NEW Key

5 Transducer Accessories and Biopsy

Transducer Accessories	3
Transducer Sheaths	3
General Information — Sheaths	3
Application — Sheaths	4
Disposal — Sheaths	5
Gel Pad	5
Preparation for Use	5
Disposal — Gel Pad	5
Needle Guide Brackets	6
EV9-4/EC9-4 Disposable Needle Guide Kit	6
EV9-4/EC9-4 Stainless Steel Needle Guide Kit	6
CH4-1 Needle Guide Bracket Kit	6
SG-3 Needle Guide Bracket Kit	6
SG-4 Needle Guide Bracket Kit	6
Universal Needle Guide S	7
Biopsy (Puncture) Guideline Function	11
Activating the On-screen Guidelines	11
System Biopsy Safeguards	12
Needle Path Verification	12

Transducer Accessories

Attachment procedures for the following accessories are presented in this chapter or are shipped separately with the device. Accessories are arranged by transducer type in the following table:

Accessory	Curved Array	Linear Array
Transducer Sheath	All	All
Gel Pad	---	VF10-5 VF13-5
EV9-4/EC9-4 Disposable Needle Guide Kit	EC9-4 EV9-4	---
EV9-4/EC9-4 Stainless Steel Needle Guide Kit	EC9-4 EV9-4	---
Needle Guide Bracket Kit, SG-3	---	VF10-5
Needle Guide Bracket Kit, SG-4	---	VF13-5
Needle Guide Bracket Kit, CH4-1	CH5-2	---
Universal Needle Guide, S	---	VF8-3

See also: Transducer Accessories — Care, Safety and Care, Chapter 2, Instructions for Use

Transducer Sheaths

Siemens makes every effort to manufacture safe and effective transducers. You must take all necessary precautions to eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials. These precautions should be considered in the use of any application that may indicate the need for such care, and during endocavity or intraoperative scanning; during biopsy or puncture procedures; or when scanning patients with open wounds.

General Information — Sheaths

⚠ WARNING: There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex-sensitive patients and to be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.

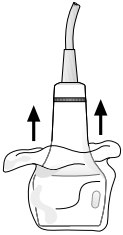
⚠ WARNING: Only a sterile transducer sheath provides the sterile barrier required for surgical or puncture procedures. To ensure sterility of a procedure, always place a sterile sheath on a transducer as transducers cannot be sterilized using hot steam, cold gas, or Ethylene Oxide (ETO) methods.

Transducer sheaths are single-use items used to ensure proper acoustic coupling and provide a prophylactic barrier for the intended ultrasound application. Sheaths are available for all transducers. Siemens recommends the use of market-cleared transducer sheaths.

Application — Sheaths

⚠ WARNING: After placing the sheath over the transducer, visually inspect the sheath to ensure there are no defects. Do not use the sheath if it has any holes or tears.

Step-by-step instructions are provided for both non-sterile and sterile procedures.



Example of placing a sheath over a transducer.

To place the transducer in a sheath for non-sterile use:

Before applying any coupling agent (gel) to the sheath, remove any powder in the sheath by rinsing with water.

1. Remove the packaging and unfold the transducer sheath.
2. Apply a water-based coupling agent (gel) to the inside of the sheath and onto the face of the transducer.
3. Hold the transducer by the cable relief and unroll the sheath onto the transducer.
4. Pull the transducer sheath tightly over the face of the transducer to remove wrinkles.
5. Secure the sheath to the transducer housing or cable relief with the adhesive tapes or elastic bands provided.

To place the transducer in a sheath for sterile use:

Before applying any sterile coupling agent (gel) to the sheath, remove any powder in the sheath by rinsing with sterile water.


1. Using sterile technique, remove the packaging and unfold the transducer sheath.
2. Taking care not to contaminate the sheath, apply a sterile water-based coupling agent (gel) to the inside of the sheath and onto the face of the transducer.
3. Using sterile technique, hold the transducer by the cable relief and unroll the sheath onto the transducer and cable.
4. Pull the transducer sheath tightly over the face of the transducer to remove wrinkles.
5. Secure the sheath to the transducer cable with the adhesive tapes or elastic bands provided.

Disposal — Sheaths

While wearing protective gloves, remove the transducer sheath from the transducer and dispose of it according to medical regulations for biohazardous waste.

Gel Pad

The gel pad is a disposable bacteriostatic standoff. It is used when superficial imaging requires an appropriate standoff for utilizing the focal zone of the transducer. The gel pad provides a fixed distance between the transducer face and the body surface.

 **WARNING:** Ultrasound energy is transmitted more efficiently through the gel pad than through tissue. When using a standoff device of any kind, for example a waterpath or gel pad, the actual mechanical and thermal indices, MI and/or TI, may be higher than indicated in the output display on the system.


Preparation for Use

Before use, examine the gel pad for any material flaws. Any product showing flaws should not be used.

Disposal — Gel Pad

While wearing protective gloves, remove the gel pad from the transducer and dispose of it according to medical regulations for biohazardous waste.

Needle Guide Brackets

 **WARNING:** Percutaneous procedures always involve heightened risk to the patient and to the operator handling biopsy needle guides. Clinicians using Siemens recommended biopsy devices under ultrasound guidance should be trained and must observe proper needle insertion sequencing with the needle guide in order to avoid undue discomfort and unnecessary risk and injury to the patient.

EV9-4/EC9-4 Disposable Needle Guide Kit

Refer to the in-box instructions for attachment and care procedures.

EV9-4/EC9-4 Stainless Steel Needle Guide Kit

Refer to the in-box instructions for attachment and care procedures, including cleaning and sterilization.

CH4-1 Needle Guide Bracket Kit

Refer to the in-box instructions for attachment and care procedures.

SG-3 Needle Guide Bracket Kit

Refer to the in-box instructions for attachment and care procedures.

SG-4 Needle Guide Bracket Kit

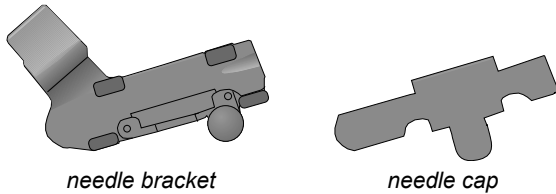
Refer to the in-box instructions for attachment and care procedures.

Universal Needle Guide S

The Universal Needle Guide is a stainless steel transducer accessory used for biopsy and needle puncture procedures.

The Universal Needle Guide S consists of a needle bracket and three (3) needle caps. The needle caps are designed for quick release.

Components of the Universal Needle Guide S



The needle bracket and needle cap have a single angle. When the needle cap is attached to the bracket, a needle channel is created. This channel secures needles in the needle guide.

The needle caps are labeled with the needle size. Needle caps are provided for the following needle sizes:

- 0.9 mm (20 gauge)
- 1.2 mm (18 gauge)
- 1.8 mm (15 gauge)

Note: The Universal Needle Guide S supports *only* the needle sizes in the above list.

Preparation for Use — Universal Needle Guide

⚠ WARNING: Do not attempt to use the needle guide until you have read the following instructions. The needle guide should only be used after proper training and after verifying the path of the needle.

⚠ WARNING: The needle guide kit is packaged non-sterile. Sterilize these components prior to the first use.

⚠ WARNING: Ensure that the needle guide components are properly cleaned and sterilized before each use to avoid possible patient contamination.

See also: Transducer Accessories — Care, Safety and Care, Chapter 2, Instructions for Use

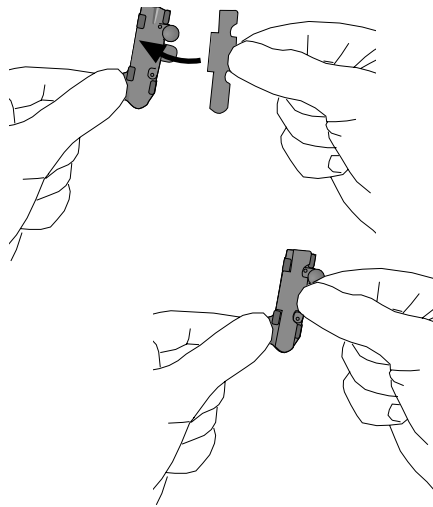
⚠ WARNING: Before attaching the needle guide to the transducer, place the transducer in a sterile transducer sheath.

⚠ WARNING: There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex-sensitive patients and to be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.

⚠ Caution: Use only a water-based ultrasound coupling agent (gel) with this kit. Petroleum- or mineral oil-based materials can harm the transducer.

To attach the needle cap to the needle bracket:

1. Place a sterile transducer sheath over the transducer.
2. Select the needle cap that matches the size of the needle to be used in the procedure. The needle size is marked on each needle cap.
3. Place the needle cap into the raised edge on the needle bracket, and then snap the needle cap onto the bracket. This secures the cap to the bracket and forms the needle channel.



Attaching the needle cap to the needle bracket.

To attach the needle guide to the transducer:

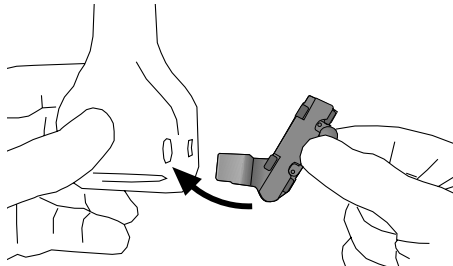
After the needle cap is attached to the needle bracket, attach the needle guide to the transducer.

Using sterile technique:

1. Loosen the thumb screw on the needle guide.

Attach the needle guide to the grooves on the side of the transducer housing.

Note: For illustration purposes only, the transducer is shown without a transducer sheath. Always place a sterile transducer sheath over the transducer.



Attaching the needle guide to the transducer.

2. Gently tighten the thumb screw to firmly secure the needle guide.

⚠ Caution: Excessive force could harm the transducer.

3. Insert the needle into the channel on the needle guide.

The needle must be the correct size for the needle guide.

4. Before performing any patient procedure, verify the needle path.

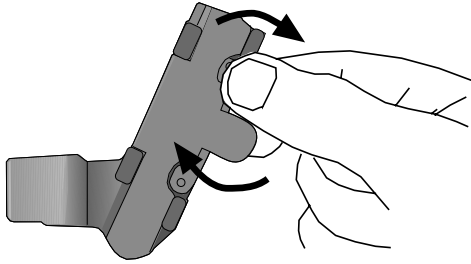
See also: Needle Path Verification, p. 5-12

Detachment Procedure — Universal Needle Guide S

Before you remove the needle guide from the transducer, remove the needle cap from the needle bracket.

To remove the needle cap from the needle bracket:

1. Push down with the thumb and up with the index finger on the tabs to release the needle cap.
2. Pull the needle cap away from the bracket.





Detaching the needle cap from the needle bracket.

To remove the needle guide from the transducer:

1. Loosen the thumb screw on the needle guide.
2. Lift the needle guide up and away from the transducer.

Biopsy (Puncture) Guideline Function

 **WARNING:** Percutaneous procedures always involve heightened risk to the patient and to the operator handling biopsy needle guides. Clinicians using Siemens recommended biopsy devices under ultrasound guidance should be trained and must observe proper needle insertion sequencing with the needle guide in order to avoid undue discomfort and unnecessary risk and injury to the patient.

 **WARNING:** The biopsy guidelines that display on the system monitor are not intended as an absolute reference. It is the user's responsibility to verify correct positioning of the needle during a biopsy or puncture procedure.

You can display on-screen guidelines for use with transducers compatible with needle guide attachments.

See also: Transducer Accessories, p. 5-3

Activating the On-screen Guidelines

The biopsy function is activated only during real-time imaging in the following modes:

- 2D-mode full FOV
- 2D-mode with color
- 2D-mode with power

Should you attempt to activate the biopsy function from an incompatible mode or with an incompatible transducer, the system displays a message.

Use the system presets to assign the biopsy function to the **UD 1** or **TGO/UD 2** key.



Customize Keys > Key Function > User-Defined 1 Key
Customize Keys > Key Function > User-Defined 2 Key

To activate the Guideline function:

1. Press the **Biopsy** key on the keyboard.

The system displays the following message as a precaution:

Please verify that the physical needle guide matches your angle selection.

2. Select the **OK** button on the displayed message box.

The system displays needle guide angle **A**.

3. Before performing any patient procedure, verify the needle path.

4. To display needle guide angle **B**, press the **Biopsy** key again.

Note: Angle **B** is not available for the following transducers: VF13-5, VF8-3, EV9-4, EC9-4.

5. To exit the function, press the **Biopsy** key again.

Note: Alternatively, you can press the **ESCAPE** key on the control panel.

System Biopsy Safeguards

While using the biopsy function, you can switch to a different acceptable mode or freeze the image. When you freeze the image, the color of the guidelines change from yellow to white.

Should you request an action that is not allowed during the biopsy function, the system displays a message indicating that the action is not allowed. The message remains on the screen for a few seconds before it is removed.

Disconnecting the active transducer while in biopsy causes the system to exit the biopsy function. The system displays a message prompting you to connect a transducer and then it displays a message indicating that the biopsy function has ended.

Needle Path Verification


Before performing any patient procedure using a needle guide, you must verify that the path of the needle is accurately indicated by the on-screen guidelines.


The needle guide is ready for patient use **only after the path of the needle has been verified**.

Checklist of Items Required for Needle Path Verification:

- Transducer with attached needle guide
- Water-based coupling agent (gel)
- Sterile transducer cover
- New, straight, biopsy needle
- Sterilized container of sterilized and degassed water

To verify the path of the needle:

 **WARNING:** The biopsy guidelines that display on the system monitor are not intended as an absolute reference. It is the user's responsibility to verify correct positioning of the needle during a biopsy or puncture procedure.

 **WARNING:** Do not use a needle guide if the path of the needle is not accurately indicated by the on-screen guidelines. The path of the needle must display within the guideline. Contact your Siemens service representative if the needle path is not accurately indicated.

1. Attach the needle guide to the transducer.
2. Connect the transducer to the system and activate the transducer.
3. Set the system to the depth of the intended puncture procedure.
4. Press the **Biopsy** key on the keyboard.

The system displays the following message as a precaution:

Please verify that the physical needle guide matches your angle selection.

5. Select the **OK** button on the displayed message box.
The system displays needle guide angle **A**.
6. Before performing any patient procedure, verify the needle path.
7. To display needle guide angle **B**, press the **Biopsy** key again.
Note: Angle **B** is not available for the transducers VF13-5, VF8-3, EV9-4 or EC9-4.
8. Immerse the head of the transducer into the degassed water and insert the needle into the needle guide.
9. Verify that the path of the needle displays according to the guidelines shown on the image screen.
After verification, the needle guide is ready for use.

6 Transesophageal Transducer

About the V5Ms Transducer	3
Transducer Articulation Controls	5
Array Rotation Control	5
Flex Controls	6
Friction Brakes	7
Preparation for Use	9
Prior to First Use	9
Prior to Each Use	9
Inspecting the Transducer	10
Using a Transducer Cover	11
Using Protective Drapes	11
Electrical Safety Considerations	12
Pacemakers	12
Defibrillators	12
Punctures or Cracks	13
Electrosurgical Units	13
Using the Micro-Pinless Adapter	14
Imaging with the V5Ms Transducer	15
Changing the Imaging Scan Plane	16
Temperature Controls and Safeguards	17
Temperature Sensor Failure	18
Exam Considerations	19
Bite Guards	19
Exam Procedures	19
Transesophageal Transducer — Care	20
Cleaning and Storage	21
Approved Cleaning and Disinfection Agents for the V5Ms Transducer	21
Cleaning and Disinfecting the Transducer	21
Cleaning and Disinfecting the Bite Guard	23
Storing and Handling	23
Service and Repair	23
Summary — Patient and Equipment Safety	24
Technical Description — V5Ms	26

About the V5Ms Transducer

- ⚠ **WARNING:** Do not use this transducer unless you are thoroughly trained in transesophageal echocardiography and are familiar with the orientation of cardiac images obtained through a TEE procedure. The V5Ms should be used only by a licensed physician.
- ⚠ **WARNING:** Before attempting to use this transducer, you should be thoroughly familiar with the safe operation of the ultrasound imaging system and this transducer. Refer to the content of this chapter and to the Safety and Care chapter in the Instructions for Use manual for safety-related information.
- ⚠ **WARNING:** The leakage current test for transesophageal transducers must be done prior to each use in order to reduce the likelihood of harm to the patient. Refer to the manufacturer's instructions included with the tester.

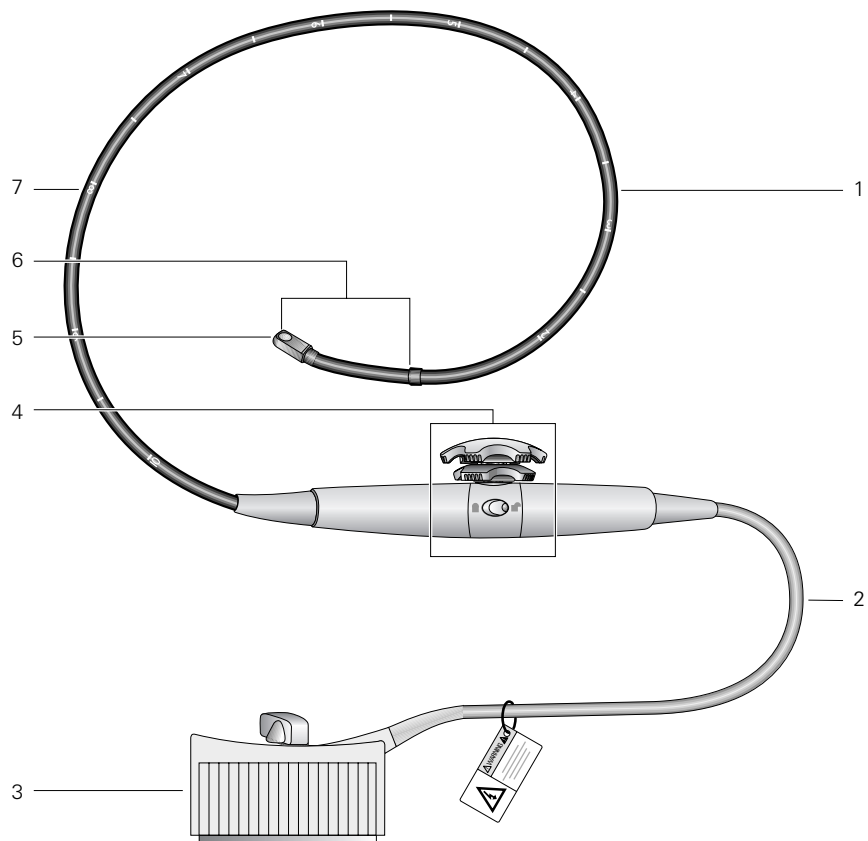
See also: Safety and Care, Chapter 2, Instructions for Use

The V5Ms is a multi-frequency, multi-plane, phased sector array transducer. The transducer can be introduced into the esophagus of the patient to obtain images of the heart structure. This procedure, known as transesophageal echocardiography (TEE), can provide virtually unobstructed views of the heart and surrounding tissue.

The V5Ms transducer supports the following modes:

- 2D-mode
- M-mode
- Pulsed Wave Doppler
- Steerable Continuous Wave Doppler
- Color Doppler
- Color DTI
- Pulsed Wave DTI

6 Transesophageal Transducer



Controls located on the handle of the V5Ms transducer allow anterior/posterior and left/right deflection of the distal tip and 180° rotation of the transducer array.

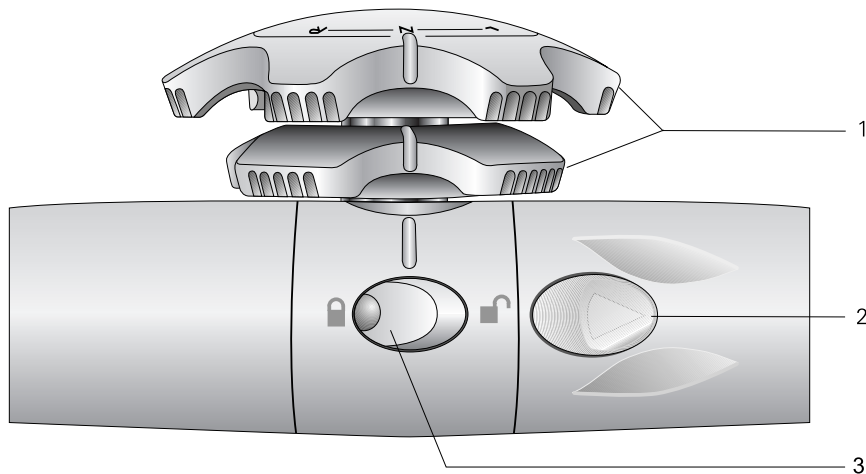
- 1 Flexible shaft
- 2 Cable
- 3 Transducer connector
- 4 Transducer controls
- 5 Distal tip (Contains rotating array)
- 6 Articulating section
- 7 Depth markings (in centimeters)

Transducer Articulation Controls

⚠ WARNING: When you insert or withdraw the transducer, ensure that the flex controls are in the neutral alignment position, without the friction brakes applied. Failure to do so can result in patient injury and damage to the transducer.

⚠ Caution: Do not use your hands or fingers to bend or manipulate the articulating section of the V5Ms transducer. To avoid severe damage to the articulating mechanism, use only the transducer controls to change the articulation angle.

The Array Rotation Control, Flex Controls, and Friction Brakes are located on the handle of the transducer.



Transducer controls.

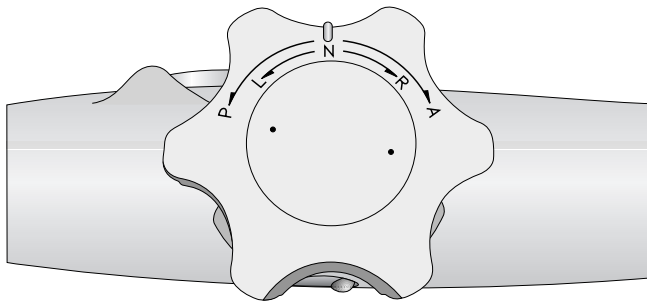
- 1 **Flex Controls**
Bend the articulating section of the transducer shaft
- 2 **Array Rotation Control**
Rotates the transducer array
- 3 **Friction Brakes** (one on each side of the transducer)
Locks the flex controls

Array Rotation Control

The array rotation control rotates the array within the distal tip of the transducer. The position of the array corresponds to the imaging **scan plane**. The scan plane is adjustable from 0° to 180°.

Flex Controls

The flex controls manipulate the movement of the distal tip.



The Flex Controls are located on the handle of the transducer.

Anterior/Posterior Deflection

For anterior deflection (anteflexion) of the distal tip, rotate the anterior/posterior flex control toward the **A** marking to move the tip anteriorly.

For posterior deflection (retroflexion) of the distal tip, rotate the anterior/posterior flex control toward the **P** marking to move the tip posteriorly.

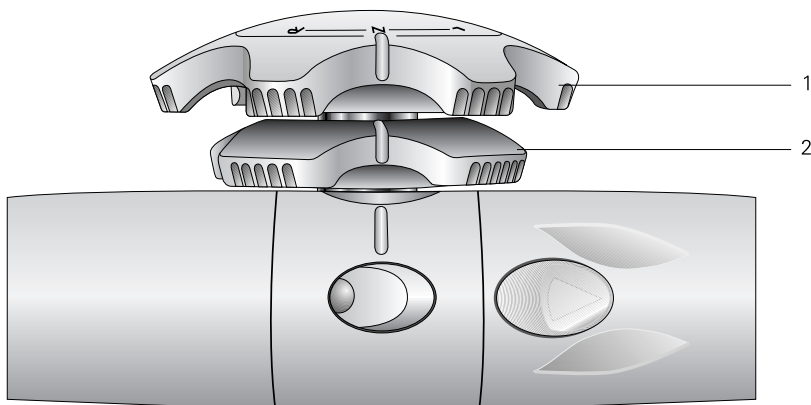
Right/Left Deflection

For right deflection of the distal tip, rotate the left/right flex control toward the **R** marking to move the tip right.

For left deflection of the distal tip, rotate the left/right flex control toward the **L** marking to move the tip left.

Neutral Position

To place the distal tip in the neutral position, rotate the anterior/posterior flex control and the right/left flex control to align the **N** marking and raised reference lines with the raised reference line on the handle of the transducer.



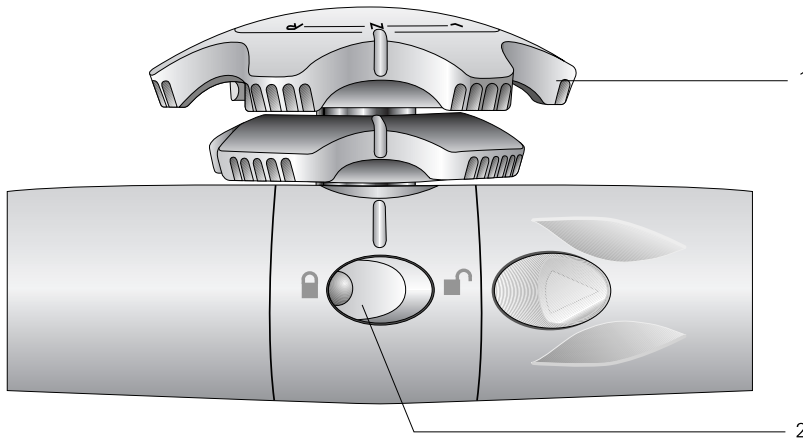
Flex controls in the neutral alignment.

- 1 Anterior/Posterior flex control
- 2 Left/Right flex control

Friction Brakes

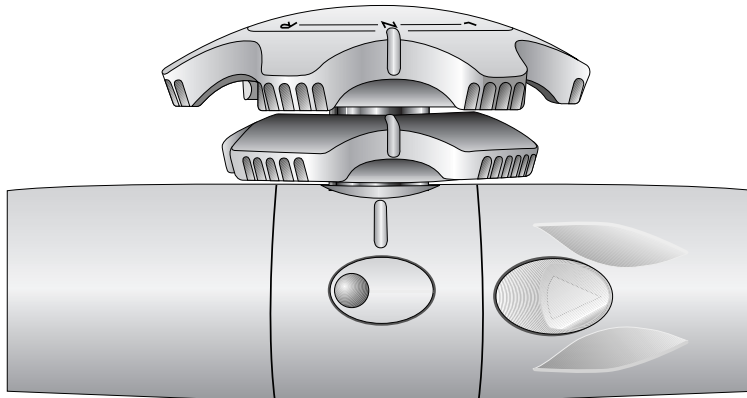
The friction brakes lock the deflection positions of the distal tip. When the brakes are engaged, you can change the imaging scan plane without losing acoustical contact.

A friction brake is located on each side of the transducer handle. The friction brakes are color-coded to match their corresponding flex control.



*Example of transducer with locked/unlocked icons.
Brake for Anterior/Posterior flex control is in the locked position.*

- 1 Anterior/Posterior flex control (light gray)
- 2 Brake for Anterior/Posterior flex control (light gray)



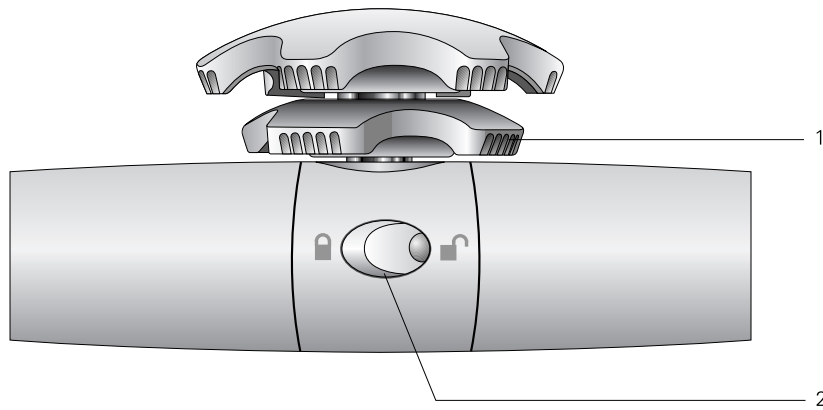
*Example of transducer without locked/unlocked icons.
Brake for Anterior/Posterior flex control is in the unlocked position.*

To lock the anterior/posterior deflection position of the distal tip:

- Press the raised tactile indicator located on the button of the corresponding brake.

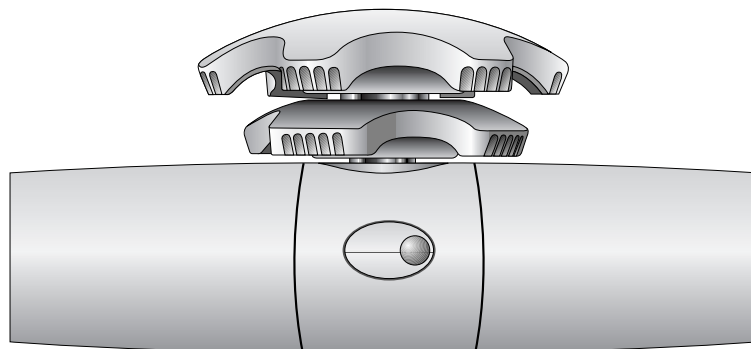
To unlock a brake:

- Press the flat portion on the button of the corresponding brake.



*Example of transducer with locked/unlocked icons.
Brake for Left/Right flex control is in the locked position.*

- 1 Left/Right flex control (dark gray)
- 2 Brake for Left/Right flex control (dark gray)



*Example of transducer without locked/unlocked icons.
Brake for Left/Right flex control is in the unlocked position.*

To lock the left/right deflection position of the distal tip:

- Press the raised tactile indicator located on the button of the corresponding brake.

To unlock a brake:

- Press the flat portion on the button of the corresponding brake.

Preparation for Use

- ⚠ **WARNING:** When using an endocavity or intraoperative transducer with a CF type applied part, the patient leakage currents may be additive.
- ⚠ **WARNING:** The leakage current test for transesophageal transducers must be done prior to each use in order to reduce the likelihood of harm to the patient. Refer to the manufacturer's instructions included with the tester.
- ⚠ **WARNING:** Prior to each use, inspect the V5Ms transducer to ensure that it is functioning properly and that it has no cuts, tears, or rough edges. A failure to do so can result in harm to the patient or damage to the device.
- ⚠ **WARNING:** The outer surfaces of an endocavity or intraoperative transducer should be checked to ensure there are no unintended rough surfaces, sharp edges, or protrusions that may cause a safety hazard.

Prior to First Use

Proper precautions reduce risks to the patient and the equipment.

- Review the Safety and Care section.
- Thoroughly understand the features and operation of the V5Ms transducer, particularly the use of the flex controls and friction brakes.
- Clean and high-level disinfect the V5Ms transducer prior to its first use.
- Perform a leakage current test on the transducer. Refer to the manufacturer's instructions included with the tester.


Prior to Each Use


Review this checklist before each use of the V5Ms transducer to ensure patient safety, comfort, and confidence.

- Review patient history to ensure contraindications do not apply.
- Thoroughly inspect the transducer for mechanical damage.
- Familiarize yourself with the articulation controls.
- Ensure that the transducer has been properly cleaned and has been high-level disinfectant, if disinfection is necessary.
- Perform a leakage current test on the transducer. Refer to the manufacturer's instructions included with the tester.
- Place a cover on the transducer, if indicated.
- If necessary, place a drape over the transducer handle, cable, connector and the ultrasound system.

See also: Safety and Care, Chapter 2, Instructions for Use

Inspecting the Transducer


 **WARNING:** Prior to each use, inspect the V5Ms transducer to ensure that it is functioning properly and that it has no cuts, tears, or rough edges. A failure to do so can result in harm to the patient or damage to the device.

 **WARNING:** The outer surfaces of an endocavity or intraoperative transducer should be checked to ensure there are no unintended rough surfaces, sharp edges, or protrusions that may cause a safety hazard.

To inspect the transducer before use:

1. Examine by look and touch the entire surface of the flexible shaft all the way to the distal tip for cuts, scrapes, protrusions, holes, dents, or cracks.
If you discover the surface of the transducer has been compromised, do not use the transducer. Contact your local Siemens representative.
2. Test the array rotation control to ensure a smooth rotation.
3. Rotate the flex controls through the full range of motion and observe that the control movement is smooth and easy.
If the range of motion is tight or binding, or if the transducer controls make an unusual noise, do not use the transducer. Contact your local Siemens representative.
If the distal tip appears to sag slightly when the flex controls are in the neutral position, this may be a sign of stretched or damaged control cables. Do not use the transducer. Contact your local Siemens representative.
4. Engage the brakes (deflection locking mechanism) by pressing each ratchet button.
The brakes hold the distal tip at the appropriate articulation angle when locked.

Using a Transducer Cover

 **WARNING:** There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex-sensitive patients and be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.

For greatest patient and operator safety, cover a transducer with a transducer cover. Siemens recommends that you use market-cleared transducer covers specifically designed for TEE applications. Follow the instructions provided by the manufacturer of the transducer cover.

Disposal

While wearing protective gloves, remove the transducer cover from the transducer and dispose of it according to the medical regulations for biohazardous waste.

Using Protective Drapes

Follow your hospital's guidelines regarding equipment use in the presence of infectious disease.

Electrical Safety Considerations

For safe use of this device, ensure an electrical safety procedure is in place for periodically inspecting the grounding system in the examination area and that this procedure is performed routinely.

Pacemakers

⚠ WARNING: Pacemakers are susceptible to the high frequency electrical signal generated by ultrasound equipment and other surgical equipment. When using the V5Ms transducer on a patient who has a pacemaker, pay special attention to pacemaker operation. Stop the examination if there is interference.

Defibrillators

⚠ WARNING: The V5Ms transducer is designed to withstand the effects of defibrillation. However, when possible, disconnect the transducer during defibrillation since a malfunction of the safety controls could otherwise result in electrical burns for the patient.

The V5Ms transducer is designed to withstand the effects of defibrillation. There are no exposed conductive surfaces distal to the handle. Within the flexible shaft, a chassis ground shield covers all active circuits and conductors. The shield runs along the entire length of the transducer.

V5Ms transducers with this label are certified as type BF defibrillator proof per IEC 60601-1 Standard for Safety of Medical Equipment:



Type BF Defibrillator-proof Patient Connection.

V5Ms transducers with this label are not certified as defibrillation proof:




Type BF Applied Part.

Punctures or Cracks

Punctures or cracks in the outer layer of the transducer could expose the patient's esophagus to chassis leakage current and cause the patient to be at the chassis ground potential. If this occurs, the transducer will no longer meet the requirements of a type BF classification. The transducer would no longer be a "floating" part and would fail a dielectric test. Provided that the internal grounding mechanism within the ultrasound system's power cord is intact and the cord is connected to a properly grounded wall outlet, there is little hazard to the user or patient from the system's leakage current. However, since the patient would now be at ground potential, leakage currents from other devices within the patient's environment could travel through the patient, compromising the safety to the patient or operator. If punctures or cracks in the outer layer of the transducer are observed, contact your local Siemens representative.

Electrosurgical Units

 **WARNING:** Use only isolated output electrosurgical units with the V5Ms transducer and disconnect the transducer when it is not in use. Failure to follow these procedures can result in esophageal burns for the patient, damage to the equipment, and unreliable data.

Use only electrosurgical units that have isolated outputs. If possible, use return-aolt/ground-fault detection circuits, which provide extra protection.

Electrosurgical units and other operating room devices that do not have isolated outputs can introduce radio frequency electromagnetic fields or currents into the patient. The transducer is susceptible to these radio frequencies, which can interfere with the 2D-mode image and can completely override the color flow image, making it useless for diagnostic purposes.

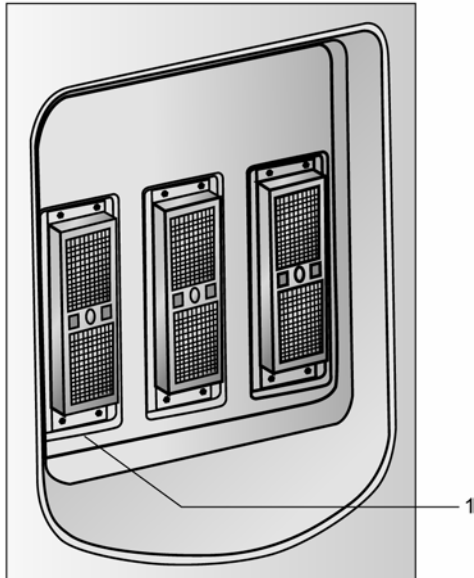
In addition, any failure to an electrosurgical unit or other device, including the V5Ms transducer, could cause electrosurgical currents to return along the transducer's conductors. As a result, the patient could suffer from burns to the esophageal membranes. This arcing could also damage the transducer. To reduce the risk of leakage currents and electrosurgical interference, disconnect the V5Ms transducer from the ultrasound system when it is not in use.

Where isolation of electrosurgical units is in question, consult the manual for each electrosurgical unit or contact the biomedical engineering group.

Using the Micro-Pinless Adapter

⚠ Caution: To avoid damaging the V5Ms transducer, the micro-pinless adapter, or the ultrasound system, you must use the V5Ms transducer with the micro-pinless adapter connected only to the second (middle) array transducer port on the ultrasound system.

The micro-pinless adapter is required for connecting the V5Ms transducer to the ultrasound system.



Transducer ports.

- 1 Valid transducer port for use with the micro-pinless adapter

To connect the micro-pinless adapter to the ultrasound system:

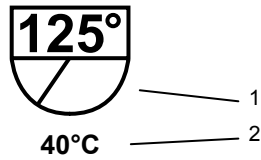
1. Insert the adapter into the leftmost array transducer port.
2. Rotate the lever on the adapter clockwise to lock it in position.
3. Connect the micro-pinless transducer to the adapter.

To disconnect the micro-pinless adapter from the ultrasound system:

1. Disconnect the micro-pinless transducer from the adapter.
2. Rotate the lock on the adapter counterclockwise until it unlocks.
3. Remove the adapter from the ultrasound system.

Imaging with the V5Ms Transducer

During imaging with the V5Ms transducer, information displays on the image screen regarding the rotation angle of the transducer array and regarding an indication of temperature at the lens surface of the transducer array.

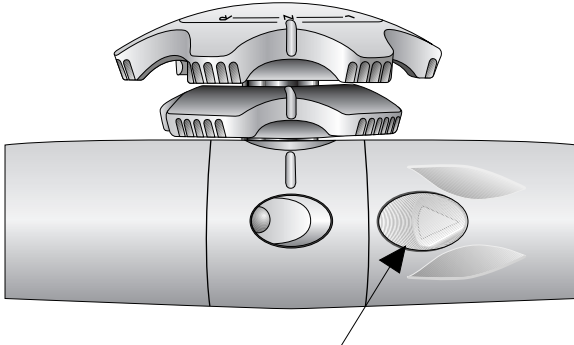


The **Scan Plane Icon** indicates the approximate rotation angle of the imaging scan plane.

- 1 **Rotation Angle** of the transducer array.
- 2 **Temperature Indicator**
Should normally display as <40°C.

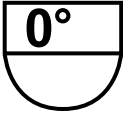
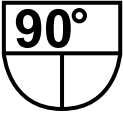

Changing the Imaging Scan Plane

You can change the imaging plane of the V5Ms transducer by using the array rotation control to rotate the transducer crystal within the distal tip of the transducer in a 0° to 180° range. The starting position for the transducer is 0°.



The array rotation control is located on the handle of the transducer.

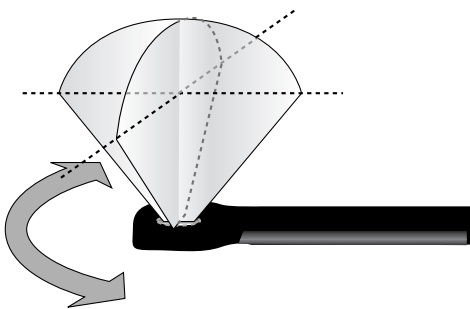
As the array orientation changes, the on-screen scan plane icon updates to indicate the relative direction of the array and the numerical value of the rotation angle.

The angle of 0° is equivalent to the transverse imaging scan plane.	The angle of 90° is equivalent to the longitudinal imaging scan plane.	The angle of 180° provides the mirrored transverse imaging scan plane.
 0° <40°C	 90° <40°C	 180° <40°C

Examples of the **scan plane icon**. The array rotation angle is displayed numerically at the top of the icon.

To change the array orientation:

- Press the array rotation control to increase or decrease the array rotation angle. Press and hold the control to rapidly change the angle.



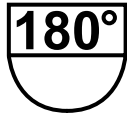
Temperature Controls and Safeguards

Because some concerns have been raised about possible thermal injury to the esophagus due to the local buildup of heat during transesophageal echocardiography, the V5Ms transducer incorporates a shut-off mechanism in the interest of patient safety in the unlikely event overheating should occur. For additional information on temperature limitation, refer to EN 60601-2-37 and IEC 60601-2-37.

A temperature sensor mounted in the distal tip of the transducer monitors the temperature of the scanning array and displays the temperature on the screen.

When the temperature is **40°C** or below, the temperature indicator displays **<40°C**.

Once the temperature is above 40°C, the system displays the actual temperature.



41.5°C

A temperature indicator is displayed below the scan plane icon.

The color of the temperature indicator changes when the temperature changes.

Range of Lens Temperature	Color of Indicator
40.0°C to 40.9°C	Yellow
41.0°C to 42.9°C	Orange
43.0°C or higher	Red

Screen Message	Cause	User Action
Transducer Approaching Temperature Limit of 43°C. Automatically Reduce Transmit Power?	The temperature reached 42°C during the exam when the setting for transmit power is not at its <i>minimum setting</i> .	Select YES to lower the transmit power in one-step increments. If the setting is High it will go to Medium; if it is Medium it will go to Low.
Transducer Approaching Temperature Limit of 43°C.	Reaches 42°C during the exam when the Transmit Power setting is already at its <i>minimum setting</i> . This message remains on the image screen until the temperature at the array of the transducer reaches a safe level (41°C) or the user selects OK to continue.	Note: Imaging can continue without lowering the Transmit Power while the temperature indicator displays a temperature below 43°C.
Transducer exceeded Temperature Limit of 43°C. Allow Transducer to Cool to Continue. Current Transducer Temperature: ≥ 43°C.	Reaches 43°C during the exam.	The system automatically freezes the image. This turns off the transmitted power to the transducer. This message remains on the image screen until the temperature at the lens surface of the transducer array reaches a safe level (41°C). The transducer temperature shown in the message will continually update the real-time temperature of the array, allowing you to monitor the actual temperature. Once the temperature is below 43°C, you can begin to image again by selecting OK and then pressing the 2D control

Temperature Sensor Failure

If the system detects a temperature sensor failure, the system stops imaging and displays the following message:

*Temperature Monitor Failure
Temperature monitor failure. Disconnect transducer.*

The message remains on the image screen until the user selects **OK** or the transducer is removed.

Exam Considerations

Bite Guards

Bite guards are provided with the transducer for use with patients who will be awake during the exam. These guards are also available from third-party providers.

Do not use the provided bite guard with anesthetized patients. Use a separately purchased bite guard that has a space for taping an endotracheal tube to the guard.

Exam Procedures

- ⚠ **WARNING:** When you insert or withdraw the transducer, ensure that the flex controls are in the neutral alignment position, without the friction brakes applied. Failure to do so can result in patient injury and damage to the transducer.
- ⚠ **WARNING:** To reduce the risk of pressure necrosis, put the transducer in the neutral position when inserting or withdrawing it. Minimize pressure applied to the articulating section and distal tip. Do not let the distal tip displace tissue for more than five minutes.
- ⚠ **WARNING:** Do not use the V5Ms transducer for any procedure requiring hyperextension of the neck. Improper patient positioning can cause paralysis of the vocal cord.
- ⚠ **WARNING:** Always use a bite guard to prevent damage to the transducer from the patient's teeth, which could, as a result, create potential mechanical and electrical hazards for the patient. Using a bite guard also protects the patient's teeth.

To use the V5Ms transducer during a transesophageal echocardiogram:

1. Remove dentures, if present, and place them in a protected area until after the procedure.
2. Place a transducer cover on the transducer, if needed.
3. Place a bite guard around the distal end of the transducer.
4. Ensure that both friction brakes are unlocked and both flex controls are in the neutral alignment position before inserting the transducer so that the transducer can bend to accommodate the path of the esophagus.
5. Place the transducer in the patient's mouth, and secure the bite guard into place before further advancing the transducer.
6. When the transducer has been inserted, press the array rotation control to change the imaging scan plane.
7. As necessary, adjust the anterior/posterior and the left/right deflection using the flex controls. Position the transducer for optimal acoustical contact and the required viewing scan plane.
8. When the required scan plane is achieved and good acoustical contact is made, engage both the anterior/posterior and the left/right friction brakes.
9. Unlock both friction brakes and move both flex controls to the neutral position to acquire new echocardiographic views, which necessitate further advancement or withdrawal of the transducer, or change in the deflection.
10. Unlock both friction brakes and move both flex controls to the neutral position to remove the transducer.

Transesophageal Transducer — Care

- ⚠ **WARNING:** To minimize the risk of cross-contamination and infectious diseases, endocavity and intraoperative transducers must be cleaned and high-level disinfected after each use. A sterile, non-pyrogenic transducer sheath must be in place during procedures requiring sterility.
- ⚠ **WARNING:** There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex-sensitive patients and to be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.
- ⚠ **WARNING:** During neurosurgical procedures, if a transducer becomes contaminated with tissue or fluids of a patient known to have Creutzfeld-Jacob disease, the transducer should be destroyed, as it cannot be sterilized.
- ⚠ **WARNING:** When using an endocavity or intraoperative transducer with a CF type applied part, the patient leakage currents may be additive.
- ⚠ **WARNING:** The outer surfaces of an endocavity or intraoperative transducer should be checked to ensure there are no unintended rough surfaces, sharp edges, or protrusions that may cause a safety hazard.
- ⚠ **Caution:** Transducers are sensitive instruments – irreparable damage may occur if they are dropped, knocked against other objects, cut, or punctured. Do not attempt to repair or alter any part of a transducer.
- ⚠ **Caution:** To avoid cable damage, do not roll the system over transducer cables.
- ⚠ **Caution:** To avoid damage to the transducer, do not use transducer sheaths containing an oil-based coating or petroleum- or mineral oil-based ultrasound coupling agents. Use only a water-based ultrasound coupling agent.
- ⚠ **Caution:** Follow all instructions provided by manufacturers of sterile goods (transducer sheaths) to ensure proper handling, storage, and cycling of all sterile goods.

Take extreme care when handling or storing transducers. They must not be dropped, jarred, or knocked against other objects. Do not allow transducers to come into contact with any sharp-edged or pointed object.

Cleaning and Storage

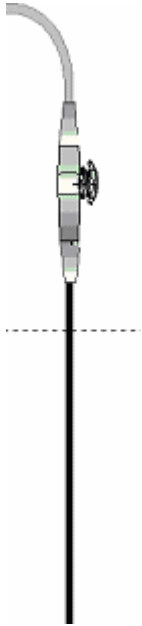
Each time the transducer is used, it must be properly cleaned and disinfected.

Approved Cleaning and Disinfection Agents for the V5Ms Transducer

- ⚠ **WARNING:** The use of any disinfectants other than those specified here may damage the transducer and, as a result, may create electrical hazards for patients and/or users.
- ⚠ **WARNING:** Disinfectants and cleaning methods listed are recommended by Siemens for compatibility with product materials, not for biological effectiveness. Refer to disinfectant label instructions for guidance on disinfection efficacy and appropriate clinical uses.
 - Cidex
 - Cidex Plus
 - Cidex OPA
 - Milton
 - Gigasept FF

Cleaning and Disinfecting the Transducer

- ⚠ **WARNING:** To avoid electrical shock and damage to the system, disconnect the transducer prior to cleaning or disinfecting.
- ⚠ **WARNING:** Never use Steam Heat or Ethylene Oxide for disinfecting the V5Ms transducer. These disinfection methods may damage the jacketing material, the transducer array, or the articulation controls, making the device unsafe to use on a patient.
- ⚠ **WARNING:** Never use iodine or solutions containing iodine for cleaning or disinfecting the V5Ms transducer. Iodine will cause degradation of the shaft material and of the distal tip resulting in a dangerous electrical hazard.
- ⚠ **Caution:** Never clean the transducer with bleach. Cleaning with bleach will damage the flexible shaft jacketing material, which will invalidate the manufacturer's warranty and could increase leakage current.
- ⚠ **Caution:** The distal tip is very sensitive to pressure. Care must be taken not to damage the tip while cleaning it.
- ⚠ **Caution:** Do not bend the flexible shaft into a curve of less than 30.5 cm in diameter.
- ⚠ **Caution:** The transducers have been designed and tested to be able to withstand high-level disinfection as recommended by the manufacturer of the disinfectant product. Carefully follow the disinfectant manufacturer's instructions.
- ⚠ **Caution:** Never immerse the entire V5Ms transducer in any solution. Immersion of the transducer handle could introduce fluid into the housing and cause damage to the controls or steering cables.
- ⚠ **Caution:** Do not immerse the transducer above 100-cm from the distal tip; doing so may damage the controls.



Submerge only to the 100-cm mark.

To clean the V5Ms transducer:

1. Disconnect the transducer from the system.
2. Wearing protective gloves, remove the transducer cover, if appropriate. Dispose of it in accordance with medical regulations for biohazardous waste.
3. Clean the distal tip and flexible shaft of the transducer with gauze pads that have been soaked in approved cleaning agents or immerse the tip and shaft up to the 100-cm mark in an approved cleaning solution.
4. Use gauze pads dipped in a mild, soapy solution to wipe off any parts of the transducer that cannot be immersed.
5. Rinse the distal tip and shaft up to the 100-cm mark with warm tap water. Wipe off the soapy solution from the remaining portion of the transducer with gauze pads moistened with tap water.
6. Clean the transducer handle with a pad moistened in 70% isopropyl alcohol. Do not use ethanol.
7. Disinfect the transducer.

To disinfect the V5Ms transducer:

1. Immediately after cleaning, submerge the distal tip and the flexible shaft up to the 100-cm mark in one of the approved disinfectant agents.
2. Carefully follow the disinfectant manufacturer's instructions for high-level disinfection.
3. Dry the transducer with gauze pads. Do not use heated air.
4. Store the disinfected transducer in the original shipping case only after disinfecting. The transesophageal transducer is fragile and should not be stored in the transducer holders on the system.

Cleaning and Disinfecting the Bite Guard

To clean the bite guard:

1. Wearing protective gloves, wash the bite guard in mild, soapy water, being sure to remove all debris.
2. Thoroughly rinse the guard in flowing tap water.

To disinfect the bite guard:

1. Thoroughly clean the bite guard.
2. Soak the guard in one of the approved disinfecting agents listed above and follow the disinfectant manufacturer's directions for high-level disinfection.
3. Rinse the guard thoroughly to remove the disinfectant.
4. Dry with a paper towel or air dry.

Storing and Handling

The V5Ms transducer is a mechanically sensitive device. The distal tip is especially sensitive to bumps, scrapes, and jarring. Take extreme care when handling and storing the transducer. Never move the distal tip by hand. Always use the flex controls.

When you store the V5Ms transducer, ensure that both friction brakes are off, the distal tip is straight, and the cables and flexible shaft are free of kinks.

Store the disinfected transducer in the original shipping case only after disinfecting. The transesophageal transducer is fragile and should not be stored in the transducer holders on the system.

Transporting the Transducer

Use the case for shipping or for moving the transducer from one site to another. Take care that the distal tip is straight and that the cable is free of kinks as you carefully place the transducer in the foam padding. Before you close the lid, ensure that nothing protrudes from the case.

Service and Repair

Do not attempt to repair or alter any part of the V5Ms transducer. Contact your local Siemens service representative office immediately if your transducer appears to be damaged or malfunctions in any way.



Summary — Patient and Equipment Safety

Following the preventive measures outlined below will help ensure patient safety.

Preventive Measure	Problem	Potential Harm to Patient/Potential Damage
Place both V5Ms flex controls in the neutral alignment position, without the friction brakes applied, when you insert or withdraw it. Do not force the transducer.	Improper insertion or withdrawal	Esophageal cuts, bruising, bleeding, ligament damage, perforations
Inspect the V5Ms transducer prior to each use to ensure that it is functioning properly and that it has no cuts, tears, fraying, loose parts, or rough edges.	Mechanical damage, electrical damage, leakage current	Severe trauma, esophageal cuts, bleeding, perforation, electrical burns, serious electrical hazards
Use only isolated output electro-surgical units with the V5Ms transducer. Disconnect the transducer when it is not in use.	Non-isolated electro-surgical units	Electrical burns
Adjust the Transmit Voltage (dB or %) as low as clinically useful. Observe the on-screen temperature warning messages and respond accordingly.	Improper transducer temperature and/or acoustic output	Esophageal burns
For maximum safety (where possible), disconnect the V5Ms transducer from the system prior to defibrillation rather than relying on the transducer's built-in safeguards.	Defibrillation	Electrical burns
Maintain a regimen of electrical safety checks.	Electrical damage, leakage current	Esophageal burns, electrical damage
Put the transducer in the neutral position, without either friction brake applied, when inserting or withdrawing it. Minimize pressure applied to the articulating section and distal tip. Do not let the distal tip displace tissue for more than five minutes.	Pressure necrosis	Permanent damage to esophageal lining
Do not use the V5Ms transducer if a patient has esophageal varices or masses or strictures are present.	Esophageal Varices	Excessive bleeding
Do not use the V5Ms transducer for any procedure requiring hyperextension of the neck.	Improper patient position	Paralysis of the vocal cord

Preventive Measure	Problem	Potential Harm to Patient/Potential Damage
Be aware that a patient with a loose tooth could lose the tooth in a TEE procedure.	Improper assessment of dental risk	Tooth loss
Use a bite guard.	No dental protection, leakage current	Dental damage, electrical damage
Never use Steam Heat or Ethylene Oxide for disinfecting the V5Ms transducer. Do not use any disinfectants other than those specified. Do not use iodine or solutions containing iodine for cleaning or disinfecting the V5Ms transducer.	Improper cleaning resulting in electrical damage	Esophageal burns
Immerse the V5Ms transducer no longer than the time required by the manufacturer for high-level disinfection. Never immerse transducer controls or the system connector in liquids.	Improper disinfection, exposing electrical workings to liquids	Nosocomial infection, electrical damage affecting image quality, electrical safety, or mechanical operation
Do not force distal tip articulation. Always use the controls to alter articulation.	Forcing the deflection control	Stretching or breaking deflection controls
When the V5Ms transducer is not in use, store it in the original case or suspend it from a wall rack. Do not store the transducer in a tight coil.	Improper storage	Damage to array elements, cuts and abrasions to the flexible shaft

Technical Description — V5Ms

Transducer Type:	Phased Array, multiplane											
Elements:	64											
Array Rotation Angle:	0° – 180°											
Distal Tip Articulation:	120° anterior, 90° posterior 45° right, 45° left											
2D-mode Transmit Frequencies:	4 MHz, 5.7 MHz, 2.7 MHz (THI)											
PW Doppler and Color Frequency:	3.6 MHz											
CW Doppler Frequency:	3.6 MHz											
Imaging Modes:	2D-mode, PW Doppler, Steerable CW Doppler, Color mode, M-mode, Color DTI, Pulsed Wave DTI											
Maximum Image												
Field of View:	90°											
Image:	Sector											
Operating Environment												
Temperature:	10°C to +40°C											
Relative Humidity:	10% to 80%											
Storage Environment												
Temperature:	-10°C to +50°C											
Relative Humidity:	10% to 95%											
Degree of protection against electrical shock:		V5Ms transducers with this label are certified as type BF defibrillator proof per IEC 60601-1 Standard for Safety of Medical Equipment										
		V5Ms transducers with this label are certified as type BF (not defibrillator proof) per IEC 60601-1 Standard for Safety of Medical Equipment										
Degree of protection against ingress of fluid:	IPX8											
Measurement Accuracy												
Rotation angle of the transducer array:	≤3°											
Temperature:	<table border="1"> <thead> <tr> <th>Temperature</th> <th>Accuracy</th> </tr> </thead> <tbody> <tr> <td>>41°C</td> <td>40.1 ≤ 41°C</td> </tr> <tr> <td>>=41°C</td> <td>40.1 ≤ 41°C</td> </tr> <tr> <td>>=42°C</td> <td>41.1 ≤ 42°C</td> </tr> <tr> <td>>=42°C and system freeze</td> <td>41.9 ≤ 43°C</td> </tr> </tbody> </table>	Temperature	Accuracy	>41°C	40.1 ≤ 41°C	>=41°C	40.1 ≤ 41°C	>=42°C	41.1 ≤ 42°C	>=42°C and system freeze	41.9 ≤ 43°C	
Temperature	Accuracy											
>41°C	40.1 ≤ 41°C											
>=41°C	40.1 ≤ 41°C											
>=42°C	41.1 ≤ 42°C											
>=42°C and system freeze	41.9 ≤ 43°C											

MC Note: Operating the transducer in close proximity to sources of electromagnetic fields, such as radio transmitters, may lead to temporary degradation or interference visible on the image monitor screen. A lightening of image background may be noticed while visualizing hypoechoic structures, or color spectral interference, or jitter, or horizontal lines in the image screen may occur. The transducer and system have been designed and tested to withstand such interference and will not be permanently affected.

Appendix A Technical Description

Standard Features	3
Operator Control Panel.....	3
Multi-Lingual System Operating Software.....	3
Processing Power.....	3
High Resolution Color Monitor.....	3
Mobility	4
Transducer Compatibility.....	4
User-Accessible Connections.....	4
Operating Modes	5
Single Modes.....	5
Mixed Modes.....	5
Image Display Formats.....	5
Imaging Functions	6
2D-mode.....	6
M-mode	7
Pulsed Wave Doppler.....	7
Steerable Continuous Wave Doppler	8
Continuous Wave Doppler.....	9
Color Doppler	9
Power Doppler.....	10
Accessories and Options	11
Language-Specific Operating System	11
Options	12
Transducer Options	14
Documentation Devices.....	15
Consumables.....	15
Measurements, Calculations, and Reports	16
General Functions	16
General 2D-Mode Measurements and Calculations.....	16
General M-Mode Measurements and Calculations	16
General Doppler Measurements and Calculations	16
Exam-Specific Measurements and Calculations.....	17
Abdominal	17
Obstetrics	17
OB (J) Exams	18
Cerebrovascular	18
Peripheral Vascular	19
Venous	19
Gynecology	19
Cardiac.....	19
TEE	19

Thyroid	20
Urology	20
Orthopedic.....	20
Musculoskeletal.....	20
Breast.....	20
Testicle.....	20
Renal.....	20
Superficial Musculoskeletal	20
Pediatric Echo	20
Penile	21
Emergency Medicine.....	21
Fetal Echo	21
Transcranial.....	21
Digital	21
Neonatal Head	21
Measurement Accuracy.....	22
Image Display	23
System Requirements	24
Power Supply Requirements	24
Possible Combinations with Other Equipment.....	24
Leakage Currents.....	24
Audio, Video, and Data Transmission Connections — Input and Output Signals.....	25
Video Standard.....	25
Environmental Requirements	26
Protective Measures.....	26
Maximum Physical Dimensions.....	26
System Classifications.....	27
Standards Compliance.....	28

Standard Features

Operator Control Panel

- Adjustable height and swivel
- Trackball
- Backlit controls and keys
- Language-specific control panel overlays
- High-resolution Liquid Crystal Display (LCD) with dedicated function keys
- Alphanumeric keyboard with special function keys

Multi-Lingual System Operating Software

- All digital system architecture
- Windows®-based operating software
- Multi-language capability, selectable during software installation
- User-modifiable system presets, including libraries of annotations and pictograms
- QuickSet feature for defining up to 32 sets of specific exam, transducer, and image parameter settings

Processing Power

- DIMAQ-IP integrated workstation
- Pathway for future performance expansion and technological innovations
- SynAps synthetic aperture technology for improved image quality at depth
- Signal processing hardware for parallel and quad signal processing

High Resolution Color Monitor

- 38 cm (15-inch), Flat Panel Display Monitor
- Active Matrix Liquid Crystal Display with 1024 x 768 display matrix
- Tilt of 10° up and 65° down
- Swivel of monitor by 180°, swivel of arm by 180°
- Brightness, contrast, and degauss controls
- Built-in stereo speakers
- Energy savings compliant per VESA Display Power Management Signaling standard

Mobility

- Mobile console with swivel wheels and brakes for transport
- Large front steering handle for ease in mobility
- QuickStart Option

Transducer Compatibility

- 2.0 to 13.0 MHz imaging range capability
- Wideband MultiHertz multiple frequency imaging
- Hanafy Lens transducer technology
- Virtual format imaging
- Transducer Ports:
 - Three 260-pin ports for standard array transducers
 - One auxiliary continuous wave transducer port
- Transducer and gel holders with removable liners
- Transducer cable management
- microCase transducer miniaturization technology for increased user comfort and reduced fatigue
- Lightweight, ergonomic transducer design with SuppleFlex cables

User-Accessible Connections

- Compact disk CD-RW/DVD-RW drive for user presets, system software updates and upgrades, and patient data and image storage/retrieval and for use with the DIMAQ-IP integrated ultrasound workstation
- On-board location for up to two image recording devices (analog output)
- RS-232C port for data transfer to a personal computer (PC)
- USB port for off-board printer connectivity
- Ethernet port
- User-programmable, dual-pedal footswitch (optional)

Operating Modes

The following modes are available on the system:

Single Modes

- 2D-mode, Dual mode, and Split mode in fundamental and harmonics
- M-mode
- Color Doppler
- Power Doppler
- Pulsed Wave Doppler
- Steerable Continuous Wave Doppler
- Continuous Wave Doppler (non-steerable)

Mixed Modes

- 2D/M-mode
- 2D/Doppler
- 2D-mode with color (2D-mode with power)
- Dual-mode with color (Dual-mode with power)
- Split-mode with color (Split-mode with power)
- 2D-mode with color/Doppler (update and triplex)
- 2D-mode with power/Doppler (update and triplex)
- 4B with color (4B-mode with power)
- M-mode with color

Image Display Formats

- 2D/M-mode
 - 1/3, 2/3
 - 1/2, 1/2
 - 2/3, 1/3
 - Side-by-side
 - Full screen M-mode
- 2D/Doppler
 - 1/3, 2/3
 - 1/2, 1/2
 - 2/3, 1/3
 - Side-by-side
 - Full screen Doppler spectrum

Imaging Functions

2D-mode

Parameters	Settings	Increment
Transmit Frequencies	Transducer-dependent	—
Transmit power	0 dB to -54 dB Displayed in percentage (%)	2 dB
2D-mode Gain	0 dB to 60 dB	1 dB
Dynamic Range	30 dB to 70 dB	5 dB
DGC controls	20 dB (+/-10 dB) to 26 dB (+/-13 dB)	—
Depth	20 mm to 300 mm	Transducer-dependent
Focal zones	Up to 4	—
CINE	128 gray scale frames 64 frames for Dual mode	—
Zoom	Up to 10x	—
Gray maps	A, B, C, D, E, F, G, H, I, 1, 2, 3	—
Color maps (tint)	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15	—
Edge Enhancement	0, 1, 2, 3	—
Persistence	0, 1, 2, 3, 4	—
Resolution/Speed	0, 1, 2, 3, 4, 5	—
TGO	On/Refresh/Off	—
Synthetic Aperture	On/Off	—
Clarify VE	On/Off	—
Clarify VE Levels	1, 2, 3, 4, 5, 6, 7	—
SieClear	On, 1, 2	—
THI Tissue Harmonic Imaging Technology	Ensemble Tissue Harmonic Imaging (THI) is available with the following transducers and THI frequencies:	—
<ul style="list-style-type: none"> ▪ Enhances visualization, particularly in difficult-to-image patients ▪ Improves image contrast and spatial resolution; reduces noise 	<ul style="list-style-type: none"> ▪ CH5-2: 1.8 MHz, 2.2 MHz ▪ C8-5: 2.7 MHz, 3.1 MHz ▪ P4-2: 1.5 MHz, 1.7 MHz, 1.8 MHz, 2.0 MHz ▪ P4-2: 1.3 MHz, 1.5 MHz (for TCD exam only) ▪ P5-1: 1.5 MHz, 1.7 MHz (for TCD exam only) ▪ P5-1: 1.7 MHz, 1.8 MHz, 2.0 MHz, 2.2 MHz (for Cardiac and Ped Echo exams) ▪ P5-1: 1.7 MHz, 2.0 MHz (for Abdomen exam only) ▪ V5Ms: 2.7 MHz ▪ VF8-3: 2.7 MHz, 3.6 MHz ▪ VF10-5: 4.0 MHz, 4.7 MHz ▪ VF13-5: 4.4 MHz, 5.3 MHz ▪ VF13-5SP: 5.0 MHz, 5.7 MHz ▪ P8-4: 2.7 MHz, 3.1 MHz ▪ EV9-4: 2.9 MHz, 3.3 MHz ▪ EC9-4: 2.9 MHz, 3.3 MHz 	

M-mode

Parameters	Settings	Increment
Transmit Frequencies	Transducer-dependent	—
Transmit power	0 dB to -54 dB Displayed in percentage (%)	2 dB
M-mode Gain	0 dB to 60 dB	1 dB
Dynamic Range	30 dB to 70 dB	5 dB
Depth	20 mm to 300 mm	Transducer-dependent
Focal zones	1	—
CINE	128 gray scale frames	—
Zoom	Up to 10x	—
Gray maps	A, B, C, D, E, F, G, H, I	—
Color maps (tint)	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15	—
Edge Enhancement	0, 1, 2, 3	—
Sweep speed	1, 2, 3, 4, 5	—

Pulsed Wave Doppler

Parameters	Settings	Increment
Transmit Frequencies	Transducer-dependent	—
Transmit power	0 dB to -54 dB Displayed in percentage (%)	2 dB
Doppler Gain	0 dB to 90 dB	1 dB
PRF scale Range	100 Hz to 34,700 Hz	Transducer-dependent
Dynamic Range	30 dB to 60 dB	5 dB
Depth	20 mm to 300 mm	Transducer-dependent
Focal zones	1	—
CINE	Available	—
Zoom	Up to 10x	—
Velocity scale range (0° angle correction)	±1.5 cm/s to 350 cm/s	—
Transducer Steering	VF10-5, VF13-5, VF13-5SP	—
Flow angle correction	0° to 89°	1°
Gate size	Transducer-dependent	—
Baseline shift	1 to 17	8 above baseline 8 below baseline
Doppler Search Mode	On/Off	—
Sweep Speed Selections	1, 2, 3, 4, 5	—
T/F Resolution	A, B, C, D, E, F, G, H, I	—
Post-processing gray map	A, B, C, D, E, F, G, H	—
Doppler colorization maps	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	—

Parameters	Settings	Increment
Auto-Doppler trace functions		—
Off		
Above	Maximum, Mean	
Below	Maximum, Mean	
Both	Maximum, Mean	
Spectral Invert	On/Off	—
Wall filter selections	Up to 8 selections	Transducer-dependent
Triplex (simultaneous)	On/Off	—
Spectral DTI™ (Doppler tissue imaging capability)	On/Off	—
High PRF	Transducer-dependent	—
Update Rate	Off, 1sec, 2sec, 4sec, 8sec, EOS	

Steerable Continuous Wave Doppler

Parameters	Settings	Increment
Transmit Frequencies	Transducer-dependent	—
Transmit power	0 dB to -54 dB Displayed in percentage (%)	2 dB
Doppler Gain	0 dB to 90 dB	1 dB
PRF scale Range	100 Hz to 34,700 Hz	Transducer-dependent
Dynamic Range	30 dB to 60 dB	5 dB
Depth	20 mm to 300 mm	Transducer-dependent
Focal zones	1	—
CINE	Available	—
Zoom	Up to 10x	—
Velocity scale range (0° angle correction)	±0.8 cm/s to 650 cm/s	—
Flow angle correction	0° to 89°	1°
Baseline shift	1 to 17	8 above baseline 8 below baseline
Doppler Search Mode	On/Off	—
Sweep Speed Selections	1, 2, 3, 4, 5	—
T/F Resolution	A, B, C, D, E, F, G, H, I	—
Post-processing gray map	A, B, C, D, E, F, G, H	—
Doppler colorization maps	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	—
Spectral Invert	On/Off	—
Wall filter selections	Up to 8 selections	Transducer-dependent

Continuous Wave Doppler

Parameters	Settings	Increment
Transmit Frequencies	Transducer-dependent	—
Transmit power	0 dB to -54 dB Displayed in percentage (%)	2 dB
Doppler Gain	0 dB to 90 dB	1 dB
PRF scale Range	100 Hz to 34,700 Hz	Transducer-dependent
Dynamic Range	30 dB to 60 dB	5 dB
CINE	Available	—
Baseline shift	1 to 17	8 above baseline 8 below baseline
Doppler Search Mode	On/Off	—
Sweep Speed Selections	1, 2, 3, 4, 5	—
T/F Resolution	A, B, C, D, E, F, G, H, I	—
Post-processing gray map	A, B, C, D, E, F, G, H	—
Doppler colorization maps	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	—
Spectral Invert	On/Off	—
Wall filter selections	Up to 5 selections	Transducer-dependent

Color Doppler

Parameters	Settings	Increment
Transmit Frequencies	Transducer-dependent	—
Transmit power	0 dB to -54 dB Displayed in percentage (%)	2 dB
Color Gain	-20 dB to 20 dB	1 dB
PRF scale	100 Hz to 19,500 Hz Transducer-dependent	—
Depth	20 mm to 300 mm	Transducer-dependent
Focal zones	1	—
CINE	128 image frames	—
Zoom		—
2D-mode with Color	Up to 10x	
2D-mode with Color Doppler	Up to 10x	
Velocity scale	±1.5 cm/s to 350 cm/s	—
Color ROI adjustments	Position Size	—
Transducer Steering	VF10-5, VF13-5, VF13-5SP	—
Baseline shift	1 to 13	6 above baseline 6 below baseline
Color maps	A, B, C, D, E, F, G, H	—
Color smoothing	0, 1, 2, 3	—
Tissue/Color priority	0, 1, 2, 3, 4	—
Color persistence	0, 1, 2, 3, 4	—
Color Peak Hold	Off, 1sec, 2sec, 3sec	—
Color invert	On/Off	—

Parameters	Settings	Increment
Resolution/Speed	0, 1, 2, 3, 4, 5	—
Wall filter	0, 1, 2, 3	—
Velocity Tag		—
Single	On/Off	
User-defined Range	On/Off	
Display	On/Off	—
Color DTI	On/Off	—

Power Doppler

Parameters	Settings	Increment
Transmit Frequencies	Transducer-dependent	—
Transmit power	0 dB to -54 dB Displayed in percentage (%)	2 dB
Power Gain	-20 dB to 20 dB	1 dB
PRF scale Range	100 Hz to 19,500 Hz (transducer-dependent)	—
Dynamic Range	-20 dB to 20 dB	1 dB
Depth	20 mm to 300 mm	Transducer-dependent
Focal zones	Up to 4	—
CINE	128 image frames	—
Zoom	Up to 10x	—
Transducer Steering	VF10-5, VF13-5	—
Power ROI adjustments	Position Size	—
Power Doppler color maps	A, B, C, D, E, F, G, H	—
Color maps	1, 2, 3, 4, 5, 6	—
Color line density	1, 2, 3, 4, 5, 6	—
Power smoothing	0, 1, 2, 3	—
Tissue/Color priority	0, 1, 2, 3, 4	—
Color persistence	0, 1, 2, 3, 4	—
Wall filter selections	0, 1, 2, 3	—
Resolution/Speed	0, 1, 2, 3, 4, 5	—
Directional Power	On/Off	—

Accessories and Options

Note: Not all features and options described in this publication are available to all users. Please check with your Siemens representative to determine the current availability of features and options.

The only Siemens-authorized accessories and options for the ACUSON X300 ultrasound system are described in this chapter.

Note: The system software, DIMAQ-IP integrated workstation with a CD/DVD combination drive, power cord, transducer holders, and one bottle of coupling agent (gel) are included with the ultrasound system.

⚠ WARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (e.g., EN 60950 and IEC 60950 for data processing equipment and EN 60601-1 and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard EN 60601-1-1 and IEC 60601-1-1. Anyone who connects additional equipment to the signal input or signal output ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standard EN 60601-1-1 and IEC 60601-1-1. Siemens can only guarantee the performance and safety of the devices listed in the *Instructions for Use*. If in doubt, consult the Siemens service department or your local Siemens representative.

Note: To ensure compliance with the Medical Device Directive, use only the devices listed in this chapter with your ultrasound imaging system.

Language-Specific Operating System

Includes an overlay for the control panel and system user and reference manuals.

- English Language Operating System
- German Language Operating System
- French Language Operating System
- Spanish Language Operating System
- Italian Language Operating System
- Chinese Language Operating System

Options

Options	Description
3-Scope Real-Time 3D Imaging Option	<ul style="list-style-type: none"> ▪ Compatible transducer and exam types: <ul style="list-style-type: none"> – CH5-2 – OB, Early OB, OB(J) – EV9-4 – Gynecology, OB, Early OB, OB(J) ▪ The 3D Imaging feature is a system option that allows the acquisition of three-dimensional ultrasound images. Multiplanar Reformatting (MPR) provides a view of each segment of the volume as an arbitrary slice ▪ Real-time reconstruction after free-hand acquisition ▪ Multiplanar rendering demonstrates imaging planes not accessible with normal scanning techniques
Axis Edge-Assisted Ejection Fraction Option	<ul style="list-style-type: none"> ▪ Assists in detecting borders used in automated measurements of left ventricular volume, ejection fraction, stroke volume, and cardiac output
Clarify Vascular Enhancement (Clarify VE) Technology Option	<ul style="list-style-type: none"> ▪ Available for the CH5-2 and linear array transducers ▪ Available in combination with 2D-mode, the 2D-mode image in Doppler, SieClear compounding, THI, and TGO
Doppler Tissue Imaging (DTI)	<ul style="list-style-type: none"> ▪ Includes spectral DTI ▪ Includes color DTI
SieClear Multi-View Spatial Compounding Option	<ul style="list-style-type: none"> ▪ Available for curved and linear array transducers
SieScope Panoramic Imaging Option	<ul style="list-style-type: none"> ▪ Available for linear array and curved array transducers ▪ SieScope images may be created up to 60 cm in length and up to 360° when the depth is less than the radius of the target area being scanned ▪ CINE display of frame-by-frame review of individual data frames within the SieScope image ▪ On-screen reference and speed indicators enhance imaging technique ▪ Reverse during acquisition ▪ Zoom and pan capabilities
TGO Tissue Grayscale Optimization Option	<ul style="list-style-type: none"> ▪ Available on all transducers ▪ Automatically optimizes the overall field of view (FOV) image brightness uniformity
AcuNav ICE Option	<ul style="list-style-type: none"> ▪ SwiftLink catheter connector (includes instructions for use) ▪ Sterile Sheaths
syngo Arterial Health Package Option	<ul style="list-style-type: none"> ▪ AHP is compatible only with 2D-mode images and clips acquired with a linear array transducer
syngo Auto Left Heart	<ul style="list-style-type: none"> ▪ Automatically traces an outline of the endocardial border of the left ventricle or the left atrium for the end-diastolic and end-systolic images on an apical two-chamber or four-chamber view of the heart ▪ Generates calculation data and measurements for end-diastolic volume and end-systolic volume, ejection fraction, and heart rate

Options	Description
syngo Velocity Vector Imaging Option	<ul style="list-style-type: none"> ▪ Tracks and estimates tissue velocity and other motion and deformation parameters at selected points on a user-defined outline of a structure ▪ Assists analysis of rotation, displacement, and radial strain of the left ventricle ▪ Assists evaluation of fetal to adult cardiac contraction by analyzing the systolic and diastolic ventricular strain and rotation
Cardio-Vascular Option	<ul style="list-style-type: none"> ▪ Includes the Physio Module ▪ Includes steerable continuous wave Doppler
Stress Echo Option	<ul style="list-style-type: none"> ▪ Requires the Cardio-Vascular Option ▪ Requires a phased array transducer
DICOM 3.0 Connectivity Option	<ul style="list-style-type: none"> ▪ Software license for use of networking software ▪ Provides digital image transfer using a DICOM network for both printing and storage. When the option is installed, the ultrasound system is a "DICOM Print Class User" (for printing to a networked DICOM printer) and a "DICOM Storage Class User" (for storage to a networked DICOM workstation and/or archive device).
DICOM Modality Worklist Option	<ul style="list-style-type: none"> ▪ Requires the DICOM Connectivity Option ▪ Software license for querying and directing the download of a patient work schedule from a HIS/RIS system (Hospital Information System/Radiology Information System) to the ultrasound system ▪ Automatically populates the patient registration form with patient demographic information
DICOM MPPS Option	<ul style="list-style-type: none"> ▪ Requires the DICOM Connectivity Option ▪ Requires the DICOM Modality Worklist Option
DICOM Structured Reporting for Obstetrics/Gynecology	<ul style="list-style-type: none"> ▪ Requires the DICOM Connectivity Option
DICOM Structured Reporting for Cardiac	<ul style="list-style-type: none"> ▪ Requires the DICOM Connectivity Option
DICOM Structured Reporting for Vascular	<ul style="list-style-type: none"> ▪ Requires the DICOM Connectivity Option
Dual-pedal footswitch	
Physio Module Option	<ul style="list-style-type: none"> ▪ Includes the ECG function, which contains ECG cable and leads
QuickStart Option	<ul style="list-style-type: none"> ▪ For portable studies ▪ Decreases the time required to power the system on or off by using the installed battery to place the ultrasound system in a standby status.
Pocket Accessory	<ul style="list-style-type: none"> ▪ Storage for a transducer connectors or supplies
ECG leads	<ul style="list-style-type: none"> ▪ ECG leads, standard European ▪ ECG leads, special European ("banana" plug) ▪ ECG leads, compatible with 115-volt systems

Transducer Options

Options	Description
Transducers, Curved Array	<ul style="list-style-type: none"> ▪ C8-5 ▪ CH5-2 ▪ EV9-4 ▪ EC9-4
Transducers, Linear Array	<ul style="list-style-type: none"> ▪ VF8-3 ▪ VF10-5 ▪ VF13-5 ▪ VF13-5SP
Transducers, Phased Array	<ul style="list-style-type: none"> ▪ P4-2 ▪ P5-1 ▪ P8-4 ▪ V5Ms with micro-pinless adapter (requires the Cardio-Vascular Option)
Transducers, Continuous Wave (Requires the Cardio-Vascular Option)	<ul style="list-style-type: none"> ▪ CW2 ▪ CW5
Transducer Accessories	<ul style="list-style-type: none"> ▪ Transducer Sheaths: <ul style="list-style-type: none"> – Non-sterile, EC9-4 – Sterile, EV9-4, EC9-4 ▪ Biopsy Protective Sleeves, sterile, VF10-5, CH5-2 ▪ Standoff Gel Pad, disposable, VF10-5 ▪ CH4-1 Needle Guide Bracket Kit, CH5-2 ▪ SG-3 Needle Guide Bracket Kit, VF10-5 ▪ SG-4 Needle Guide Bracket Kit, VF13-5 ▪ Needle Guide Bracket Kit, disposable, EV9-4, EC9-4 ▪ Needle Guide Bracket Kit, stainless steel, EV9-4, EC9-4 ▪ Universal Needle Guide S, VF8-3 ▪ Leakage Current Tester (compatible with the V5Ms transducer) ▪ Micro-pinless (MP) adapter (compatible with the V5Ms transducer)

Documentation Devices

Options	Description
Documentation Devices	<ul style="list-style-type: none"> ▪ DVR, BD-X201 MS, JVC
USB Documentation Devices	<ul style="list-style-type: none"> ▪ B&W Video Printer, P93DW, Mitsubishi ▪ B&W Video Printer, UP-D897, Sony ▪ Color Printer, CP30DW, Mitsubishi ▪ Color Printer, UP-D23MD, Sony

Consumables

Options	Description
Consumables	<ul style="list-style-type: none"> ▪ Contact Scan Gel, 0.25 liter ▪ Contact Scan Gel, 5 liter ▪ Contact Scan Gel, Sterile Packets ▪ Paper, Black and White Video Printer ▪ Cleaning Sheets, Black and White Video Printer ▪ CD-R 650MB (10) ▪ Disposable ECG Electrodes ▪ DVD-RW 4X (1) ▪ Stress Echo External/Adapter Cable ▪ ACUSON AcuNav 8F ultrasound catheter ▪ ACUSON AcuNav 10F ultrasound catheter

Measurements, Calculations, and Reports

Two categories of measurements and calculations are available on the ultrasound system: general and exam-specific.

General Functions

- 2D-mode and M-mode imaging have up to eight (8) distance sets of caliper measurements per image
- Area and circumference: up to eight Ellipse and Trace measurements per image
- Doppler has up to eight (8) points available on the waveform display
- Ratio Calculations
- Summary feature available for Cardiac (including Pediatric Echo and TEE), C-Vascular, P-Vascular, Venous, and TCD

General 2D-Mode Measurements and Calculations

- Angle
- Distance/Depth
- Circumference (using a Trace or Ellipse method)
- Area (using a Trace or Ellipse method)
- Volume (using a 1 Distance, 2 Distances, 3 Distances, 1 Ellipse, 1 Ellipse+1 Distance, Disk, or Thyroid method)
- Area % Stenosis
- Diameter % Stenosis
- Flow Volume (using an Area or Diameter method with a Doppler measurement)

General M-Mode Measurements and Calculations

- Distance
- Time
- Heart Rate
- Slope

General Doppler Measurements and Calculations

- Velocity (Frequency)
- Heart Rate
- Time
- Acceleration/Deceleration
- Diameter Flow Volume
- Area Flow Volume
- Resistive Index
- Pulsatility Index
- Velocity Ratio

Exam-Specific Measurements and Calculations

The measurement function is arranged by exam type and is available for use with all exam types.

Abdominal

- All general measurements and calculations

Obstetrics

- All general measurements and calculations
- Amniotic Fluid Index measurement
- Early OB and Standard OB parameter labels
- Early OB and Standard OB measurement labels
- Calculations for parameters and estimated fetal weight (EFW)
- Calculations for both clinical and ultrasound menstrual age, and estimated date of confinement
- Menstrual Age parameter labels
- User defined:
 - Menstrual Age formulas or tables
 - Ratio or parameter formulas
 - Growth Analysis formulas or tables
 - Measurement labels for 2D-mode
 - Measurement labels for Doppler
 - Estimation of fetal weight (EFW) formulas
- One table and one formula per parameter for menstrual age, and estimated date of confinement
- Two formulas for composite ultrasound menstrual age calculation: Average, user-defined
- Growth Analysis Graphs
- Early Obstetric patient report and Standard Obstetric patient report include a worksheet for viewing the progress of the report during the exam process and to edit the report, along with multiple fetus reporting capabilities

OB (J) Exams

(SONOVISTA Systems Only)

- All general measurements and calculations
- User-selectable formula sets for Tokyo, Osaka, and JSUM exams:
 - Estimation of menstrual age
 - Estimation of fetal weight
 - Calculation of growth ratios
- Obstetric-specific calculations:
 - Amniotic Fluid Index
 - Cardio-Thoracic Area Ratio
 - Fetal Heart Rate
- Obstetric-specific parameter, measurement, and calculation labels
- User-selectable primary and secondary references for the **User1** and **User2** formula sets
- User-selectable measurement methods for X, Y, and Z measurements
- Supports multiple gestation studies
- Clinical menstrual age calculated by user-entered **LMP/EDC** or direct user input in **Fetal Age** field on patient registration form
- Display of clinical menstrual age (**AGE**) and estimated date of confinement (**EDC**) at top of image screen
- Measurement menu displays labels with values and a date indicating estimation of US MA
- Measured Results display lists the values, standard deviation (SD), and resulting estimations of dates for US MA (**AGE**) and US EDC (**EDC**)
- Editable patient report
- Growth Analysis Graphs

Cerebrovascular

- All general measurements and calculations
- Right and left measurements
- CCA, Pre ICA1, ICA1, Post ICA1, Pre ICA1, ICA2, Post ICA2, Pre ICA3, ICA3, Post ICA3, ECA, and VA measurements
- User-defined labels
- Cerebrovascular patient report
- Customizable summary feature

Peripheral Vascular

- All general measurements and calculations
- Right and left extremity measurements
- User-defined labels
- Peripheral vascular patient report
- Customizable summary feature

Venous

- All general measurements and calculations
- Right and left measurements
- Venous patient report
- Customizable summary feature

Gynecology

- All general measurements and calculations
- User defined:
 - Measurement Labels for 2D-mode
 - Measurement Labels for Doppler
 - Measurement type for Follicle measurement
- Right and left follicle, uterus, and right and left ovary measurements
- Gynecology patient report

Cardiac

- All general measurements and calculations
- Volume formulas for Left Ventricular function assessment
- 2D-mode, M-mode, and Doppler calculations
- M-mode Slope, Heart Rate, Time, and Distance measurements
- Doppler Acceleration, Deceleration, Trace, Heart Rate, Time, and Velocity measurements
- Cardiac worksheet and patient report
- Customizable summary feature

TEE

- All features of the Cardiac exam are available for the TEE exam.

Thyroid

- All general measurements and calculations

Urology

- All general measurements and calculations
- Micturated volume
- Prostate dimensions
- Prostate and urology patient report

Orthopedic

- All general measurements and calculations
- Right and Left Hip Angle measurement
- Graf Sonometer
- Orthopedic (hip angle) patient report

Musculoskeletal

- All general measurements and calculations

Breast

- All general measurements and calculations

Testicle

- All general measurements and calculations

Renal

- All general measurements and calculations

Superficial Musculoskeletal

- All general measurements and calculations

Pediatric Echo

Note: You can use the Cardiac measurements and calculations with the Ped Echo exam.

- All general measurements and calculations
- Volume formulas for Left Ventricular function assessment
- 2D-mode, M-mode, and Doppler calculations
- M-mode Slope, Heart Rate, Time, and Distance measurements
- Doppler Acceleration, Deceleration, Trace, Heart Rate, Time, and Velocity measurements
- Ped Echo worksheet and patient report
- Customizable summary feature

Penile

- All general measurements and calculations
- Anatomy and Vessels measurement labels
- Penile patient report

Emergency Medicine

The Emergency Medicine (EM) package includes measurements, calculations, and patient reports for assessing:

- Dimensions of abdominal organs: Gall bladder wall, bile duct, and aorta
- Cardiac function: End-diastolic and end-systolic volumes and the derived ejection fraction
- Fetal Growth: Gestational sac, crown-rump length, and biparietal diameter
- Bladder dimensions for the transverse and sagittal planes

Fetal Echo

- Fetal Echo measurement labels for 2D-mode for left and right heart structures, cardiothoracic area, and arteries
- Fetal Echo measurement labels for M-mode for left and right heart structures
- Fetal Echo measurement labels for Doppler for valves, ventricles, arteries, and veins
- Fetal Echo measurement ratios for 2D-mode LV percentage of fractional shortening and for Doppler mitral valve E/A and Tei Index
- Fetal Heart Rate
- Fetal Echo patient report

Transcranial

- All general measurements and calculations

Digital

- All general measurements and calculations

Neonatal Head

- All general measurements and calculations

Measurement Accuracy

The following table describes the variability in accuracy for each parameter:

Parameter	Ranges	Accuracy
Image Depth Scale	30 to 280 mm	< ± 3% of full scale
Two-dimensional Measurements		
– Distance/Depth	up to 240 mm	< ± 3% or < 1 mm, if below 33 mm
– Area	up to 999 cm ²	< ± 6% or < 66 mm ² , if below 11 cm ²
– Trace (Ellipse)	up to 999 cm ²	< ± 6% or < 66 mm ² , if below 11 cm ²
– Angle	0° to 180°	< ± 3% on ½ segment
– Ratio (A/B)		
Result B/A & (A-B)/A	up to 1.0	< ± 10% of A
Result A/B	1.0 to 99.9	< ± 10% of A
Time Motion (TM) Measurements		
– Depth	up to 280 mm	< ± 3% or < 0.5 mm, if below 17 mm
– Time	up to 16 sec.	< ± 2%
– Heart Rate	15 to 999 bpm	< ± 5%
– Velocity	up to 999 mm/sec.	< ± 5%
Volume Measurements		
– Volume (Area, Length, Diameter)	up to 999 cm ³	< ± 9% or < 3.2 cm ³ , if below 36 cm ³
Distance using SieScape extended field of view	0 - 60 cm	Linear transducer: 5% of the distance or 2.5 mm whichever is greater assuming 1540 m/sec speed of sound. Curved transducer: 8% of the distance or 2.5 mm whichever is greater assuming 1540 m/sec speed of sound.
Trace Area using SieScape extended field of view	0 - 560 cm ²	10% of the area or 1.5 cm ² , whichever is greater, assuming minimal operator error in acquiring the image and in tracing the desired object, and assuming 1540 mm/sec speed of sound.

Image Display

Video Standards:	EIA/NTSC and CCIR/PAL	
Monitor:	Color 38 cm (15"), non-interlaced, MultiSync (SVGA)	
Gray Scale:	256 levels	
Color:	Up to 16.7 million colors	
Image polarity:	Positive (black on white) or negative (white on black)	
Date/Time display:	System displays current date and time above the imaging area. Clock freezes in frozen image. Daylight saving time changes available in system presets.	
Image field size: (by frequency)	3.5 MHz = 30 to 280 mm 5.0 MHz = 30 to 280 mm 7.5 MHz = 30 to 160 mm 10.0 MHz = 30 to 120 mm 12.0 MHz = 30 to 120 mm The depth is selectable in increments of 10 mm. Minimum and maximum depth values for each frequency are transducer dependent.	
Image Orientation:	Left-to-right or right-to-left orientation for 2D, Split, and Dual modes; 2D image in mixed 2D/M-mode and Doppler. Active image indicator designates direction of scan. 180-degree rotation for 2D, Split, and Dual modes; 2D image in 2D/D-mode and 2D/M-mode.	
Image Screen Display:	<ul style="list-style-type: none"> ▪ Information for identifying the patient, operator, and hospital or clinic ▪ Panel for thumbnails ▪ Panel for patient information ▪ Date and Time ▪ Active transducer and transmit frequency ▪ Imaging Parameters ▪ Exam type ▪ Active image indicator ▪ Focal zone marker: number, position ▪ DGC curve ▪ Trackball arbitration ▪ Depth Scale ▪ Zoom indicator ▪ Frame rate ▪ Error messages ▪ Gray bar 	<ul style="list-style-type: none"> ▪ Color bar ▪ Color flow velocity range ▪ Color ROI ▪ Power bar ▪ Power ROI ▪ M-mode cursor ▪ Doppler cursor ▪ Doppler scales: Velocity, Frequency ▪ Doppler gate: location, depth ▪ Doppler flow angle indicator ▪ Doppler angle ▪ Doppler invert ▪ Measurement menu ▪ Measured Results ▪ Active measurement method ▪ Soft key selections ▪ On-screen menu ▪ TGO mark
Patient Data Form:	Fields for identification of the patient and physician.	
Text Annotation:	Customize phrase libraries for patient reports and on-screen annotation. You can directly enter text on the image screen using the keyboard.	
Pictograms:	Standard and exam-specific graphics representing anatomical structures are user selectable. Transducer position and orientation are also available for positioning on the pictograms.	

System Requirements

This section describes the power and environmental requirements for the ultrasound imaging system.

Power Supply Requirements

MAINS Voltage	Range	Maximum Current	Frequency
100V~ to 120V~	90V~ to 132V~	5.5 amps	50/60 Hz
200V~ to 240V~	180V~ to 264V~	3.0 amps	50/60 Hz

Possible Combinations with Other Equipment

Only the peripheral devices listed in the *Instructions for Use* are approved for use with the ultrasound system. Any use of other devices with the system will be at the user's risk and may void the system warranty.

On-board peripheral devices must be installed by an authorized Siemens representative or approved third party.

⚠ WARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (e.g., EN 60950 and IEC 60950 for data processing equipment and EN 60601-1 and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standards EN 60601-1-1 and IEC 60601-1-1. Anyone who connects additional equipment to the signal input or signal output ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standards EN 60601-1-1 and IEC 60601-1-1. Siemens can only guarantee the performance and safety of the devices listed in the *Instructions for Use*. If in doubt, consult the Siemens service department or your local Siemens representative.

Leakage Currents

⚠ WARNING: Connecting peripheral products and accessories from non-isolated sources may result in chassis leakage current exceeding safe levels.

Audio, Video, and Data Transmission Connections — Input and Output Signals

Input/Output	Connector
Composite Video	BNC-type (1 input, 1 output)
Y/C Video	S-terminal (1 input, 1 output)
2 Channel Audio (Right, Left)	RCA-type (1 input, 1 output)
USB	Series A type (2 ports)
Ethernet (10BaseT/100BaseT)	RJ45 (1 port)

Output	Connector
VGA	26-pin, HDMI (1 port)
RGB/Composite Synchronous	15-pin D-sub high density (1 port)
RS-232-C	9-pin, D-sub (2 active ports)
Remote printer connector	Mini-jack (stereo) (1 jack)
B/W Video	BNC-type (1 output)

Video Standard

MAINS Voltage	Video Standard
100V~ to 120V~	NTSC (525 lines)
200V~ to 240V~	PAL (625 lines)

Environmental Requirements

EMC Note: Operating the ultrasound imaging system in close proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations may lead to interference visible on the monitor screen. However, the device has been designed and tested to withstand such interference and will not be permanently damaged.

	During Operation	Ambient (During Storage or Transportation)
Maximum Altitude:	Operation up to 3,000 meters (700 hPa to 1060 hPa)	Up to 5,050 meters (500 hPa to 1060 hPa)
Relative humidity:	10% to 80%, non-condensing	< 95% non-condensing
Temperature:		
System	+10°C to +40°C	-20°C to +55°C
Array Transducers		
C8-5	+10°C to +40°C	-10°C to +60°C
CH5-2	+10°C to +40°C	-10°C to +60°C
EV9-4	+10°C to +40°C	-10°C to +60°C
EC9-4	+10°C to +40°C	-10°C to +60°C
P4-2	+10°C to +40°C	-10°C to +60°C
P5-1	+10°C to +40°C	-10°C to +60°C
P8-4	+10°C to +40°C	-10°C to +60°C
V5Ms	+10°C to +40°C	-10°C to +60°C
VF8-3	+10°C to +40°C	-10°C to +60°C
VF10-2	+10°C to +40°C	-10°C to +60°C
VF13-5	+10°C to +40°C	-10°C to +60°C
VF13-5SP	+10°C to +40°C	-10°C to +60°C
Pencil CW Transducers		
CW2	+10°C to +40°C	-10°C to +60°C
CW5	+10°C to +40°C	-10°C to +60°C

Protective Measures

Explosion protection: This product is not designed for operation in areas subject to explosion hazards.

Maximum Physical Dimensions

Width: 886 mm
Height: 1659 mm
Depth: 880 mm
Weight: 98 kg without documentation devices

System Classifications

The X300 ultrasound imaging system has the following classifications:

- Type of protection against electrical shock:
Class I
- Degree of protection against electrical shock:
Type B applied part
Type BF for ECG connection
- Degree of protection against harmful ingress of water:
Ordinary equipment (transducers & footswitch: IPX8)
- Degree of safety of application in the presence of a flammable anesthetic material with air or with oxygen or nitrous oxide:
Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Mode of operation:
Continuous operation

Standards Compliance

The X300 ultrasound imaging system is in compliance with the following standards, including all applicable amendments at the time of product release.

Quality Standards

- FDA QSR 21 CFR Part 820
- ISO 9001:2000
- ISO 13485:2003
- EN 46001:1996

Design Standards

- UL 60601 2003
- CSA C22.2 No. 601.1
- EN 60601-1 and IEC 60601-1
- EN 60601-1-1 and IEC 60601-1-1
- EN 60601-1-2 and IEC 60601-1-2 (Class B)
- EN 60601-2-18 and IEC 60601-2-18
- EN 60601-2-37 and IEC 60601-2-37
- EN 60601-2-25 and IEC 60601-2-25
- EN 60601-1-4 and IEC 60601-1-4

Acoustic Output Standards

- IEC 61157 (Declaration of Acoustic Power)
- AIUM/NEMA UD-2, 1998 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- AIUM/NEMA UD-3, 1998 Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

CE Declaration

This product is provided with a CE marking in accordance with the regulations stated in Council Directive 93/42/EEC of June 14, 1993 concerning Medical Devices. Siemens Medical Solutions USA, Inc., is certified by Notified Body 0123 to Annex II.3 – Full Quality System.

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Appendix B Control Panel

Control Panel	3
Control Panel Overlays	4
Control Panel Lighting	4
Control Panel Audio Signal	4
Trackball	5
Set	6
Update, View	6
Escape, Timer	7
Caliper	8
Select	9
Freeze	10
Patient Information Keys	10
New Patient	10
2D-Mode and M-Mode Imaging Controls	11
2D	11
THI	11
Dual/Select	11
M	12
3D/4D	12
Doppler and Color Flow Operation Keys	13
D	13
CW	13
C	14
Power	14
Triplex	14
Angle	15
Steer	15
Invert	15
Image Parameter Controls	16
DGC	16
TGO	16
Transducer	16
Depth/Zoom	17
Focus	18
Pictograms and Annotation	19
Text	19
Pictogram	19

Documentation Controls	20
Print/Store1	20
Print/Store2	20
Clip Store.....	20
VCR/DVR	21
Review.....	21
Volume Control.....	21
Toggle Keys and Page Control.....	22
Toggle	22
Page	22
Special Function Controls.....	23
Applications	23
UD 1 (User Defined 1).....	23
TGO / UD2 (User Defined 2)	23
Alphanumeric Keyboard	24
Shortcut Keys	24
Special Characters	25
Function Keys.....	26
Other Alphanumeric Keys.....	27
Footswitch.....	28

Control Panel

The controls and keys for all imaging modes, parameters, documentation, and on-screen selections are designed to promote quick learning and recognition of the controls and keys on the control panel.





Example of the control panel on the ultrasound imaging system.

Control Panel Overlays

Language overlays for the control panel are available. The locations and functions of the keys and controls are not impacted by the overlay.

The following keys are assigned two labels: a label for the primary function of the key and a label for the function of the key during Stress Echo.

Key	Primary Label	Stress Echo Label
	UPDATE	VIEW
	ESCAPE	TIMER

The following controls are assigned two labels: a label for the primary function of the control and a label for the function of the control during 3D imaging.

Primary Label	3D Label
D	X
C	Y
M	Z

Control Panel Lighting

The system provides two levels of lighting on the control panel: when the ultrasound imaging system is in use, the control panel is back-lit, and when a control or key is active, the lighting intensity of the active control or key is increased.

The alphanumeric keyboard on the control panel is also back-lit.

Controls and keys not available for the active function are not back-lit.

A lamp located under the monitor provides additional lighting for the keyboard.

Control Panel Audio Signal

Use the system presets to deactivate or adjust the volume of the beep, enable a beep when a key is pressed, and enable a beep when storage is completed.



General 1 > Audio > Beep on Key Press
 General 1 > Audio > Beep after store completes
 General 1 > Audio > Beep Volume

Trackball



The trackball positions image graphics, measurement markers, and text. You can use the trackball in conjunction with the keys and controls located on the control panel.

When a particular function is active, the system assigns the trackball to a specific task. The assignment of the trackball displays next to the status icon at the bottom of the screen. On-screen objects under trackball control are indicated by the color green.



Example of status icon.

To select an on-screen object (such as a thumbnail or a measurement label), roll the trackball to position the pointer (cursor) on the object and then press the **SET** key on the control panel.



Example of trackball pointer.

Use the system presets to adjust the trackball travel speed.



General 1 > Trackball Travel Speed

Set



The **SET** key confirms the selection of a specific function or command. For example, you can use it to anchor calipers, select a menu item or image graphic, include a measurement value in a patient report, or delete a measurement from the worksheet.

Press the **SET** key to toggle the size and position options for the ROI. The trackball status at the lower right of the screen indicates the active option.

Press **ESCAPE** on the control panel to toggle 2D FOV with ROI.

When used with the trackball, the function of the **SET** key is similar to a mouse click in the system's Windows®-based technology.

Use the system presets to assign the functionality of the **SET** key to the location of the **ESCAPE** key.



Exchange Key Functionality > Exchange Functionality of Set and Escape keys

Update, View



Note: This key is assigned two labels: a label for the primary function of the key and a label for the function of the key during Stress Echo.

Toggles a real-time display with a frozen display during mixed-mode imaging.

For example, if a 2D-mode image is frozen while the Doppler spectrum is in real-time, pressing the **UPDATE** key causes the system to display the 2D-mode image in real-time while freezing the spectrum.

When performing a measurement, pressing the **UPDATE** key cycles through the measurement markers for editing. When measurements are complete, pressing the **UPDATE** key accesses an editing function for measured results.

During text annotation, pressing the **UPDATE** key cycles through the annotation labels assigned to the image. You can then roll the trackball to reposition the label and confirm the new location by pressing the **SET** key.

During 3D imaging, pressing the **UPDATE** key starts or cancels the acquisition process. After acquisition, pressing **UPDATE** toggles the Pan function with the Rotate function for the active quadrant.

During Stress Echo, pressing the **VIEW** key excludes a view or stage during acquisition of Stress Echo loops.

The active function displays next to the status icon at the bottom of the screen.



Example of the status icon.

Escape, Timer



Note: This key is assigned two labels: a label for the primary function of the key and a label for the function of the key during Stress Echo.

Exits the currently displayed mode, function, or page and reactivates the previous mode, function, or page. Pressing the **ESCAPE** key, while in the Measurement function, exits the function and erases all measurements. During Stress Echo, the **TIMER** key is assigned to the timer function. When the trackball is assigned to a function or task (indicated by the trackball status icon at the bottom of the screen), pressing the **ESCAPE** key changes the on-screen object currently under the control of the trackball.

During...	When the trackball is assigned to:	Pressing the ESCAPE key:
2D mode	2D FOV	No function.
M-mode or Mixed modes	M cursor	Toggles control of the M cursor with the 2D FOV.
Color Flow or Power mode	C ROI	Toggles control of the C ROI with the 2D FOV.
Doppler	D cursor	Toggles control of the D cursor with the 2D FOV.
Doppler with mixed modes	D cursor	Cycles through control of the D cursor, 2D FOV, and C ROI.
3D imaging	3D ROI	Toggles control of the 3D ROI with the 2D FOV.
Steerable continuous wave Doppler	D cursor	Toggles control of the D cursor with the 2D FOV.

The active function of the **ESCAPE** key displays next to the status icon at the bottom of the screen.



Example of the status icon.

Use the system presets to assign the functionality of the **ESCAPE** key to the location of the **SET** key.

 **Exchange Key Functionality > Exchange Functionality of Set and Escape keys**

Caliper



Activates the measurement function.

When you activate the measurement function, the system displays measurement selections for the selected imaging mode and exam type.

During the measurement function, pressing the **CALIPER** key toggles the measurement marker with the Measurement Menu.

Press the **ESCAPE** key to exit the measurement function.

The measurement function can generate a patient report for exam types with a report.

Use the system presets to automatically activate the measurement function each time you press the **FREEZE** key.

 **Exam Configuration > Automatic Freeze Response**

Select



A dualfunction control that activates one function when the control is pressed and another function when the control is rotated.

Use the **SELECT** control to make selections from the screen. Rotating the **SELECT** control either highlights a selection or cycles through available selections; pressing the **SELECT** control either adjusts the setting for the highlighted selection or activates the highlighted selection.

When this is active...	Rotating SELECT	Pressing SELECT
Measurement function	Cycles through the available selections on the measurement menu.	Selects the highlighted label.
Trace measurement	Deletes the line, one dot at a time.	Not available.
Editing of Measured Results	Cycles through the values in the Measured Results.	Selects the value and activates the most recently used marker for the selected measurement data.
Pictogram with a transducer marker	Changes the direction of the transducer marker.	Confirms the current direction of the transducer marker.
Annotation arrow	Changes the direction of the arrow.	Confirms the current direction of the arrow.
Review of patient data in the Study screen	Highlights a study.	Displays the study's images in the Image screen.
Review of patient data in the Image screen	Cycles through the stored images.	Toggles the full-screen display format of the selected image (indicated by an outline) with the most recently selected display format.
Thumbnail	Cycles through the available thumbnails.	Selects the highlighted thumbnail(s). Double-clicking SELECT displays the image, clip, or volume represented by the thumbnail on the Review screen.
Stress Echo	Selects the Phase (Stage)/View in the Imaging Screen.	Activates the ROI.

The active function displays next to the status icon at the bottom of the screen.



Example of the status icon.

Freeze



Freezes the image, sweep, or spectrum on the screen. If an image or sweep is already frozen, pressing the **FREEZE** key restores real-time imaging.

Use the system presets to change the response of the **FREEZE** key to activate another function or to assign the freeze function to a footswitch pedal.



Exam Configuration > Automatic Freeze Response
Customize Keys > Left Pedal
Customize Keys > Right Pedal

During 3D imaging, pressing the **FREEZE** key during volume acquisition completes the acquisition.

During SieScape imaging, pressing the **FREEZE** key stops image acquisition. After acquiring an image, pressing the **FREEZE** key opens the setup screen.

Patient Information Keys

Use the patient information keys to input and edit patient data.

New Patient



Displays the **New Patient Data** form.

2D-Mode and M-Mode Imaging Controls

Use the imaging controls to activate an operating mode, change the image orientation, or modify the sweep display.

2D



A dual-function control that activates one function when the control is pressed and another function when the control is rotated.

Pressing the **2D** control activates 2D-mode for grayscale imaging. If a mixed mode or imaging function is active, pressing **2D** causes the system to exit the mode or function and return to 2D-mode.

Rotating the **2D** control changes the overall gain for 2D-mode. Rotating the **2D** control clockwise increases the gain; a counterclockwise rotation decreases the gain.

The range for gain settings is from 0 dB to 60 dB. When combined with the DGC control, the gain range is -13 dB to 73 dB. (The DGC control range is -13 dB to +13 dB). The gain value displays in the Imaging Parameters on the upper left of the screen.

THI



Activates Tissue Harmonic Imaging.

Tissue Harmonic Imaging (THI) is a system feature that can enhance contrast resolution with fine tissue differentiation, benefiting difficult-to-image patients.

Dual/Select



Activates Dual-mode, which displays two separately acquired images, side-by-side.

The **DUAL/SELECT** control consists of a set of two keys. The left key displays an image on the left side of the screen. The right key displays an image on the right side of the screen. Use either key to initiate Dual-mode.

Only one image can be active at any one time. The active image is indicated by the lighting intensity of the selected key and by the brightened on-screen icon that displays on the image screen.



On-screen icon to indicate image orientation and to identify the active image.

The **DUAL/SELECT** control can be used to toggle the active image. Pressing the left key activates the left image and freezes the right image. Pressing the right key activates the right image and freezes the left image.

Note: The system displays a full-screen image when the key for the active image is pressed. The system restores the side-by-side display when this key is pressed again.

After acquiring both images, you can set imaging parameters independently for each image.

Use the system presets to activate seamless display of dual and split images.



Exam Configuration > Seamless Dual

M



A dual-function control that activates one function when the control is pressed and another function when the control is rotated.

Pressing the **M** control displays an M-mode cursor in a 2D image. You can then roll the trackball to place the cursor in the area of interest. Pressing **M** a second time displays 2D/M-mode.

Rotating the **M** control changes the overall gain for M-mode. Rotating the **M** control clockwise increases the gain, and counterclockwise rotation decreases the gain. The range for gain settings is from 0 dB to 60 dB. The gain value displays in the Imaging Parameters on the upper left of the screen.

During 3D imaging, this control rotates the volume around the "z" axis.

3D/4D



Note: 4D is reserved for future use.

Activates the 3-Scape Real-Time 3D Imaging mode.

Doppler and Color Flow Operation Keys

Use these controls and keys to operate the Doppler and Color Flow functions.

D



A dual-function control that activates one function when the control is pressed and another function when the control is rotated.

Pressing the **D** control displays a Doppler cursor and Doppler gate for placement in the 2D-mode image. Depending on the system presets, pressing the **D** control the first time can also initiate display of the Doppler spectrum.



Display > Doppler/M-Mode > Bypass M/D Cursor Display

For pulsed Doppler, pressing the **D** control a second time causes the system to display 2D-mode with Doppler and to transmit an audible Doppler signal.

Doppler Search mode enables transmission of an audible Doppler signal the first time you press the **D** control. Pressing the **D** control a second time changes the display to 2D-mode with Doppler. Use the system presets to activate Doppler Search mode.



Display > Doppler/M-Mode > Doppler Search Mode

Rotating the **D** control clockwise increases the gain; counterclockwise rotation decreases the gain. The range for gain settings is from 0 dB to 90 dB. The gain value displays in the Imaging Parameters on the upper left of the screen.

During 3D imaging, this control rotates the volume around the "x" axis.

CW



Activates the steerable continuous wave (SCW) Doppler function for phased array transducers.

Activates the auxiliary continuous wave Doppler function for the continuous wave (pencil) transducer.

C



A dual-function control that activates one function when the control is pressed and another function when the control is rotated.

Pressing the **C** control initiates Color Flow imaging.

Rotating the **C** control clockwise increases the gain; counterclockwise rotation decreases the gain. The range for gain settings is from -20 dB to 20 dB. The gain value displays in the Imaging Parameters on the upper left of the screen.

Note: In Power mode, rotating the **C** control changes the overall gain for Power mode.

During 3D imaging, this control rotates the volume around the "y" axis.

Power



Activates Power mode.

During Power mode, rotating the **C** control clockwise increases the Power gain; counterclockwise rotation decreases the Power gain. The range for gain settings is from -20 dB to 20 dB. The gain value displays in the Imaging Parameters on the upper left of the screen.

Triplex



Allows mixed-mode imaging to display simultaneously, in real-time.

An example of mixed mode imaging is 2D-mode with color and Doppler.

Angle



A dual-function control that activates one function when the control is pressed and another function when the control is rotated.

Rotating the **ANGLE** control during Doppler (with the angle function active) adjusts the Doppler angle.

The value of the angle displays in the Imaging Parameters on the upper left of the screen.

The system also displays the values of angles greater than 1° on the image screen. When the angle is 65° or greater, the system highlights the value of the angle in green.

Rotating the **ANGLE** control after pressing the **M** control (when bypass is not selected in the system presets) activates Anatomical M-mode.

Pressing the **ANGLE** control in Anatomical M-mode resets the angle of the Anatomical M-mode cursor to the angle of the M-mode cursor.

Steer



For linear array transducers, steers the 2D image. The amount of steering is dependent on the type of transducer.

For other transducers, positions the M-Mode or Doppler cursor or the color ROI.

Invert



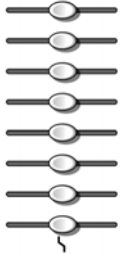
During pulsed wave Doppler, pressing **INVERT** flips the Doppler spectrum vertically on the baseline.

During Color Flow or directional Power mode, transposes the colors depicting forward and reverse flow in the color ROI and the color bar.

Image Parameter Controls

Use the image parameter controls to acquire and view an image.

DGC



DGC Control.

Increases or decreases the received gain for the depth of view. The receiver gain range is depth-dependent for the active transducer frequency.

The system can display a graphic representing the DGC curve on the image screen.

Use the system presets to select the length of time that the DGC graphic displays on the image screen. The **2D** control also affects system gain.



Display > DGC Curve Display
Display > DGC Invert with Image Invert

TGO



Automatically optimizes the overall FOV image brightness uniformity.

Transducer



Activates a transducer.

Press **TRANSDUCER** repeatedly to cycle through the transducers connected to the system. The name of the active transducer displays on the screen.

Note: When three or more transducers are connected to the system, the names of the transducers display as soft key selections.

Depth/Zoom



A dual-function control that activates one function when the control is rotated and another function when the control is pressed and then rotated.

Rotating the **DEPTH/ZOOM** control changes the imaging depth.

Rotate the **DEPTH/ZOOM** control clockwise to decrease depth and counterclockwise to increase depth.

Use the system presets to assign the direction of rotation to the **DEPTH/ZOOM** control for increasing the depth.



Customize Keys > Depth

The depth scale displays in centimeters (cm), and the current depth setting displays on the lower right of the image screen.

Pressing **DEPTH/ZOOM** activates a zoom window in the image, initiating the magnification process. Zoom is available in real-time or when the image is frozen. Pressing **DEPTH/ZOOM** again exits zoom.

Note: The zoom window appears highlighted in green when active.

Rolling the trackball positions the zoom window over the region of interest (ROI). Rotating **DEPTH/ZOOM** adjusts the size of the window. Pressing **DEPTH/ZOOM** again magnifies the selection. To exit zoom, press the **2D** control. Pressing **DEPTH/ZOOM** again exits zoom.

During the zoom function, rotating **DEPTH/ZOOM** changes the magnification level.

Rotate the **DEPTH/ZOOM** control clockwise to increase magnification and counterclockwise to decrease magnification.

Use the system presets to assign the direction of rotation to the **DEPTH/ZOOM** control for increasing the magnification factor.



Customize Keys > Zoom

During SieScape imaging, rotating the **DEPTH/ZOOM** control pans the image.

During Auto Left Heart, rotating **DEPTH/ZOOM** toggles the zoomed image and the image in its original size.

Focus



A dual-function control that activates one function when the control is rotated and another function when the control is pressed and then rotated.

Pressing the **FOCUS** control changes the number of transmit focal zones in the image.

Rotating the **FOCUS** control positions the transmit focal zones in the image.

Rotate the **FOCUS** control clockwise to increase the depth of focal zone markers (to the far field) and counterclockwise to decrease the depth of focal zone markers (to the near field).

Use the system presets to assign the direction of rotation to the **FOCUS** control for decreasing the depth of the focal zone marker (to the near field).



Customize Keys > Focus

Note: When more than one focal zone is used, a reduction in frame rate occurs. The amount of reduction depends on the depth of view and the transducer in use.

Pictograms and Annotation

Use the pictogram and annotation controls to display text and graphics depicting anatomical structures on-screen.

Text



Activates the annotation feature and places the text cursor on the image screen. Either use the keyboard to enter text or select a term from the list of annotations.

Use the system presets to display a list of annotations when you activate the annotation feature, to customize the text libraries, to automatically delete on-screen annotation each time you unfreeze an image, and to select a library (anatomy or position) for initial display.



General 2 > Common Mode > Default Annotation Library
General 2 > Common Mode > Font Size
General 2 > Common Mode > Delete Text on Unfreeze
Text Annotation

Pictogram



Pictograms are on-screen anatomical graphics that indicate the anatomy under evaluation and the orientation of the transducer. Pressing the **PICTOGRAM** key displays the first available pictogram for the selected exam type.

Press the toggle key for **Pictogram Select** to cycle through the available pictograms.

Use the system presets to customize the pictograms assigned to an exam type, to change the location of the pictogram on the image, and to delete the pictogram when the image is unfrozen.



Pictogram List
General 2 > Common Mode > Pictogram Location
General 2 > Common Mode > Delete Pictogram on Unfreeze

Press the **ESCAPE** key to remove the pictogram displayed on the screen.

Some pictograms contain a transducer marker. Use the **SELECT** control to rotate the transducer marker. To reposition the marker, roll the trackball.

Documentation Controls

Use the documentation controls to access recording devices for printing, storing, or retrieving images and imaging parameters.

Print/Store1



Stores or prints the displayed image or report to the destination configured in system presets.

Use the system presets to assign functionality to this control. For example, you can configure the control to:

- Send on-screen information to an installed documentation device, such as the black and white printer.



Customize Keys > Print/Store 1 Key

Print/Store2



Stores or prints the displayed image or report to the destination configured in system presets.

Use the system presets to assign functionality to this control. For example, you can configure the control to:

- Send on-screen information to an installed documentation device, such as the black and white printer.



Customize Keys > Print/Store 2 Key

Clip Store



Sends the image or report on the screen to a patient file on disk. Use the system presets to indicate the destination of the data when the **CLIP STORE** key is pressed.

Use the system presets to assign functionality to this control. For example, you can configure the control to:

- Store a volume, clip or image.
- Begin Stress Echo acquisition.



Customize Keys > Clip Store Key

VCR/DVR



Toggles the record function with the pause or stop function if the video recorder (VCR/DVR) is on and media is inserted.

Use the system presets to assign functionality to this control. For example, you can configure the control to:

- Use the record/pause function or the record/stop function.



Peripheral > VCR/DVR > Key Function

Review



Accesses the DIMAQ-IP integrated ultrasound workstation for image and data management, either during a patient examination or from saved studies.

Volume Control



Example of the volume control.

A dual-function control that activates one function when the control is pressed and another function when the control is rotated.

Rotate the volume control located on the upper right of the control panel to adjust the volume Doppler signal.

Press the volume control to activate the microphone function during video recording (VCR/DVR).

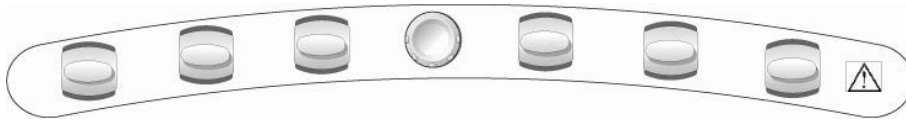
Use the system presets to adjust the volume during video playback (VCR/DVR).



General 1 > Audio > Line-in Volume

Toggle Keys and Page Control

The toggle keys and the **PAGE** control provide functionality for interacting with the soft key selections displayed at the bottom of the screen.



Toggle keys and **PAGE** control.

Toggle



Toggle key.

Activates or adjusts the corresponding (highlighted) soft key selection.

Page



Rotate the **PAGE** control to access the "pages" of soft key selections for a mode or function. Press the **PAGE** control to access soft key selections for other modes or functions. For example, during 2D-mode/Doppler with color, repeatedly pressing the **PAGE** control cycles through the soft key selections for 2D-mode, Doppler, and Color Flow.

Special Function Controls

Applications



Activates and displays selections for optional features requiring the DIMAQ-IP integrated workstation. An example of a DIMAQ-IP based optional feature is the Stress Echo option.

To activate Stress Echo, SieScape, or Axius EF, press the **APPLICATIONS** key.

UD 1 (User Defined 1)



Use the system presets to assign functionality to this control. For example, you can configure the control to:

- Activate the biopsy function, 4B-mode, or the ECG function.
- Activate growth analysis graphs



Customize Keys > User-Defined 1 Key

TGO / UD2 (User Defined 2)



The update function for the TGO feature is assigned to this control by default.

Use the system presets to assign functionality to this control. For example, you can configure the control to:

- Activate the biopsy function, 4B-mode, or the ECG function.
- Activate growth analysis graphs



Customize Keys > User-Defined 2 Key

Alphanumeric Keyboard

Use the alphanumeric keyboard for entering patient data, selecting an exam type, annotating clinical images, and configuring the system presets.

The keyboard is arranged like a standard computer keyboard. A description of the function keys and other special keys follows.



Example of the system keyboard.

Shortcut Keys

The system supports "shortcuts" through combining keys on the keyboard.

To use a shortcut, press and hold the first key and then press the second key. For example, to use the shortcut **Ctrl+P**, press and hold the **Ctrl** key and then press the **P** key.

Shortcut (Key Combination)	Function
Ctrl+H	Hides or displays the border on the top and on the left of the image during image review.
Ctrl+P	Hides or displays patient information on the screen.
Ctrl+Q	Logs out of the DIMAQ integrated workstation.

Use the system presets to activate functions without using shortcuts (not available for all functions).



General 1 > Hide Patient Information

Special Characters



The **ALT** key located on the left or right side of the keyboard accesses the special characters located on the upper right of a key.

















The **SHIFT** key located on the left or right side of the keyboard accesses the special characters located on the upper left of a key.

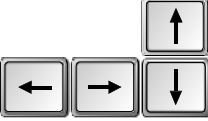












German		French	
Character	Key Combination	Character	Key Combination
Ä	ALT p	Ç	ALT n
ä	ALT -	ç	ALT j
ö	ALT 0 (zero)	à	ALT z
Ü	ALT [è	ALT x
ü	ALT =	é	ALT s
ß	ALT '	ù	ALT b
Spanish		Italian	
Character	Key Combination	Character	Key Combination
í	ALT 1	à	ALT z
¿	ALT /	è	ALT x
Ñ	ALT l	é	ALT s
ñ	ALT 9	ì	ALT c
á	ALT a	ò	ALT v
é	ALT s	ù	ALT b
í	ALT d		
ó	ALT f		
ú	ALT g		
Scandinavian		Other	
Character	Key Combination	Character	Key Combination
Æ	ALT m	Œ	ALT u
æ	ALT k	œ	ALT 8
Ø	ALT . (period)	α	ALT q
ø	ALT ;	β	ALT w
Å	ALT ,	μ	ALT e
å	ALT l	θ	ALT r

Function Keys

The keys located in a row across the top of the alphanumeric keyboard are called **function keys**. These keys are used to access patient data and reports, select an exam type, configure presets, define a QuickSet, activate a biopsy (puncture) procedure, and activate the annotation function.

Function Keys	Description
Report 	Displays the patient report if one is available for the current exam type. You can view, edit, or print the report.
Patient Data 	Displays the Patient Data form currently in use. You can view or edit the page.
Patient Browser 	Accesses the DIMAQ-IP integrated ultrasound workstation for image and data management, either during a patient examination or from saved studies.
Exam 	Displays a list of available system-defined exam types and user-defined QuickSets.
Presets 	Displays the first page of the Presets screen. Use the system presets to modify and customize the system, including general settings, QuickSets, image annotation, and calculation settings.
Help 	Displays operating instructions.
QuickSet 	Accesses the screen for saving, deleting, renaming and overwriting QuickSets (a configuration of imaging settings for a specific transducer and exam type).
Arrow 	Places an arrow on the screen. Roll the trackball to reposition the arrow. Press the SET key to anchor the arrow's position. To change the direction of the arrow, rotate the SELECT key on the control panel.
Home 	Places the text cursor in the Home position (as defined with the Home Set key) when the Annotation function is active.
Home Set 	Sets the default location of the text cursor. After pressing the TEXT key on the control panel, roll the trackball to place the text cursor on the image screen in the desired location and then press the Home Set key. When the Home key on the keyboard is pressed, the system places the text cursor in the position defined with the Home Set key.
Delete Word 	Removes the selected term from the screen. Select the term by rolling the trackball to position the cursor on the term.
Hide Text 	Hides or displays annotations and arrows.
Clear Screen 	Removes all annotations, arrows, and pictograms from the screen.
Biopsy 	Displays biopsy/puncture guidelines on the image screen for specific transducers.

Other Alphanumeric Keys

Other Alphanumeric Keys	Description
Arrows 	Repositions the text cursor in the direction shown on the arrow key.
Alt 	Accesses special characters on the upper right of the keys located on the keyboard.
Backspace 	Deletes one character at a time from right to left during text entry. Deletes lines of completed text, one at a time.
Caps Lock 	Locks all keyboard letter keys in upper case.
Ctrl 	Accesses special characters. When used in a shortcut (key combination), activates the related function.
Enter 	Accepts entered data. Moves the cursor to the beginning of the next line of text or entry field.
Shift 	Accesses the upper-case letters and the character on the upper left of a key located on the keyboard.
Space Bar 	Inserts a blank space.
Tab 	Moves the cursor to the beginning of the next available entry field.
Video I/O 	Displays a video signal that originates from an outside source, such as a VCR, on the system monitor.
NEW 	Closes and saves the current study, and begins a new study without requiring patient registration. Use the system presets to customize the functionality of the NEW key.  Peripheral > NEW Key > Enable NEW Key
Blank 	No function.

Footswitch

Use the optional footswitch as an alternative to operating keys on the control panel.

Use the system presets to assign each footswitch pedal to a function:

- Print to a black and white printer.
- Print to a color printer.
- Store to the system's hard disk.
- Freeze or unfreeze the image, sweep, or spectrum on the screen.
- Capture clips.



Customize Keys > Left Pedal
Customize Keys > Right Pedal

Appendix C On-screen Controls

Soft Key Selections	3
Soft Key Selections for 2D-Mode.....	5
Modify Map Screen	6
Soft Key Selections for M-Mode	7
Soft Key Selections for Anatomical M-Mode.....	8
Soft Key Selections for Doppler.....	9
Soft Key Selections for Color Flow	10
Soft Key Selections for Power Mode	11
Soft Key Selections for Clip Capture	13
Soft Key Selections for CINE.....	14
Soft Key Selections for SieScape Panoramic Imaging Option.....	15
Soft Key Selections for 3D Imaging	15
3D Soft Key Selections — Set Up	15
3D Soft Key Selections — Acquisition.....	17
3D Soft Key Selections — Editing Selections.....	19
3D Soft Key Selections — Animation Selections.....	19
Soft Key Selections for ECG.....	20
Soft Key Selections for Video Recording.....	21
Selections Used in the Stress Echo Feature	22
Select Protocol to Load Dialog Box	22
Protocol Window	22
Stress Echo Screen.....	23
Soft Key Selections for All Measurements and Calculations	25
Soft Key Selections for 2D-Mode Measurements and Calculations.....	25
Soft Key Selections for M-Mode Measurements and Calculations	26
Soft Key Selections for Doppler Measurements and Calculations.....	26
Selections for Summary.....	27
Soft Key Selections for the Summary.....	27
Screen Selections for the Summary	27
Soft Key Selections for Annotations	27
Soft Key Selections for Arrows	28
Soft Key Selections for Pictograms	28
Soft Key Selections for Transducers	28
Soft Key Selections for the Applications Key	28
Soft Key Selections for Review.....	28
Soft Key Selections for Study Screen.....	28
Soft Key Selections for Image Screen – Review Tab	29
Soft Key Selections for Image Screen – Applications Tab.....	29

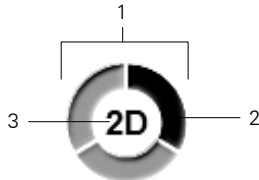
Selections during Review of Patient Data	30
Study Screen — DIMAQ-IP	30
Image Screen — DIMAQ-IP	32
Options Dialog Box.....	33
Clip Edit Dialog Box.....	34
Teaching File Dialog Box.....	34
DICOM Screen Selections	35
Study Screen	35
Image Screen	35
DICOM Screen	36
Printer Layout Pages.....	36
Print and Store Queues	37
Selections for Auto Left Heart	38
<i>syngo</i> Auto Left Heart Controls.....	38
Soft Key Selections for Auto Left Heart	39
<i>syngo</i> VVI Controls.....	40
Strain/Velocity Measurement Window	42
Global Measurements Window.....	43
M-mode, R-waves, Crop Window	43
Dyssynchrony Analysis Window	44
Selections used in the Axius-EF Feature	46
Axius-EF Screen.....	46
Specify View Dialog Box.....	46
Heart Cycle Buttons	46
Soft Key Selections for Axius-EF	47
Screen Controls — AHP	48
AHP Screen – Navigation Panel.....	48
Image Quality Panel	48
IMT Editing Tools Panel.....	49
Far Wall Tools	49
Near Wall Tools	49
Trace Editing Tools	50
Soft Key Selections for <i>syngo</i> Arterial Health Analysis Package	50
Soft Key Selections for Intima-Media Thickness (IMT) Reports	50

Soft Key Selections

Soft key selections are located on the screen and are available for image optimization and activation of specific functions. Soft key selections are arranged on "pages" by mode or function. The active tab indicator identifies the mode or function for the available soft key selections. Selections vary by mode or function, depending on real-time imaging or system freeze.

Note: Other controls for optimizing an image or activating a function are located on the control panel.

See also: Control Panel, Appendix B, Instructions for Use



Page indicator located in the middle of the soft key selections.

- 1 Number of available "pages" for a specific mode or function identified by the number of sections in the "page indicator."
- 2 Highlighted section corresponds to the displayed "page" of soft key selections.
- 3 Mode or function for the soft key selections.



Tab indicators display above the soft key selections. The highlighted tab corresponds to the displayed soft key selections.

To use the soft key selections:

1. To adjust or activate a soft key selection, press the toggle key on the control panel corresponding to the soft key selection at the bottom of the screen.

For soft key selections with adjustable settings, the system displays the current setting in the Imaging Parameters at the left of the screen.

2. To access another "page" of related soft key selections, rotate the **PAGE** control on the control panel.

The system displays additional "pages" of the available soft key selections for the related mode or function.

3. To access soft key selections for another mode or function, press **PAGE** to highlight the required tab indicator.





Active Mode or Function	Tab Labels
2D-mode	2D
M-mode	M
Anatomical M-mode	AMM
Doppler	PW
Color	C
Power	P
ECG	Phy
Text	General Anatomy Position
Review	Review Applications

Soft Key Selections for 2D-Mode

Selection	Description	Settings
Thumbnail	Accesses the thumbnail panel on the right of the screen. Note: This selection displays only when the system is frozen.	—
P	Adjusts the transmit power.	0.20%, 0.25%, 0.32%, 0.40%, 0.50%, 0.63%, 0.79%, 1%, 1.3%, 1.6%, 2%, 2.5%, 3.2%, 4.0%, 5.0%, 6.3%, 7.9%, 10%, 12%, 15%, 19%, 25%, 31%, 39%, 50%, 63%, 79%, 100%
MultiHertz	Changes the transducer frequency.	Transducer-dependent
Edge (Edge Enhance)	Distinguishes the contours of a structure during real-time imaging.	0, 1, 2, 3
DR (Dynamic Range)	Controls the overall contrast resolution of the image.	30, 35, 40, 45, 50, 55, 60, 65, 70 (in dB units)
Split	Creates side-by-side images from one 2D-mode image. The two images are simultaneously frozen or real-time.	On, Off
2D Size	Resizes the field of view. Note: Not available for linear transducers with the sector format.	—
Full Size	Maximizes the field of view. Note: Not available for linear transducers with the sector format.	—
Map	Selects a processing curve that assigns echo amplitudes to gray levels.	A, B, C, D, E, F, G, H, I, 1, 2, 3
Tint	Changes the color of the image.	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15
Persist (Persistence)	Increasing persistence creates a visible smoothing effect by maintaining lines of image data for each frame of imaging.	0, 1, 2, 3, 4
U/D Flip	Vertically flips the image (top-to-bottom or bottom-to-top).	U, D
L/R Flip	Horizontally flips the image (right-to-left or left-to-right).	L, R
Sector	Activates the sector transducer format for linear transducers. Note: This selection is available for the following transducers: VF10-5, VF13-5, VF13-5SP.	On, Off
R/S (Resolution/Speed)	Adjusts the balance between the image line density (resolution) and the frame rate.	0, 1, 2, 3, 4, 5
4B	Activates 4B-mode which displays four separately acquired images.	—

Selection	Description	Settings
SynAps	Extends the focal zone. This selection is available for curved and linear array transducers.	On, Off
TGO Set	Saves a TGO gain offset for the current 2D-mode imaging feature.	—
ClarifyVE	Activates Clarify VE. (For systems installed with the Clarify VE option)	On, Off
ClarifyVE Levels	When Clarify VE is active, selects the level of flow information to add to the image. (For systems installed with the Clarify VE option)	1 to 7
SieClear	Activates SieClear multi-view spatial compounding.	Off, 1, 2
Modify Map	When Clarify VE is not active, activates Modify Map to change the shape of the current Gray Map.	—
Clip Capture	Displays capture options for cardiac cycles. Use the system presets to assign default settings to the clip capture options. Note: You must assign a documentation control to the clip capture function in the system presets.	—
DTO	Activates Dynamic Tissue Optimization for user-selectable levels of gain compensation.	
LVO Contrast	Adjusts the contrast for left ventricular opacification imaging.	

Modify Map Screen

Button	Tool Tip	Description	Settings
	Save	Displays the User Map box.	—
	Exit	Closes the Modify Map screen.	—
	Undo	Removes the most recent modification.	—
	Redo	Restores the most recent modification.	—
---	Inflection points (drop-down list)	Select the number of inflection points displayed on processing curve.	4, 8, 16, 32
---	XY (check box)	Displays the coordinates of the inflections points.	on, off
---	User Map (drop-down list)	Select the destination to save map settings.	User Map 1 User Map 2 User Map 3

Soft Key Selections for M-Mode

Selection	Description	Settings
Thumbnail	Accesses the thumbnail panel on the right of the screen. Note: This selection displays only when the system is frozen.	—
MultiHertz	Changes the transducer frequency.	Transducer-dependent
Edge (Edge Enhancement)	Distinguishes the contours of a structure during real-time imaging.	0, 1, 2, 3
DR (Dynamic Range)	Adjusts the overall contrast resolution of the M-mode sweep.	30, 35, 40, 45, 50, 55, 60, 65, 70 (in dB units)
Sweep	Adjusts the scrolling speed of the M-mode sweep.	1, 2, 3, 4, 5
Full M	Displays a full-screen M-mode sweep.	On, Off
Map	Selects a processing curve that assigns echo amplitudes to gray levels.	A, B, C, D, E, F, G, H, I
Tint	Changes the color of the sweep.	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15
P	Adjusts the transmit power.	0.20%, 0.25%, 0.32%, 0.40%, 0.50%, 0.63%, 0.79%, 1%, 1.3%, 1.6%, 2%, 2.5%, 3.2%, 4.0%, 5.0%, 6.3%, 7.9%, 10%, 12%, 15%, 19%, 25%, 31%, 39%, 50%, 63%, 79%, 100%
Clip Capture	Displays capture options for cardiac cycles. Use the system presets to assign default settings to the clip capture options. Note: You must assign a documentation control to the clip capture function in the system presets.	—

Soft Key Selections for Anatomical M-Mode

Selection	Description	Settings
P	Adjusts the transmit power.	0.20%, 0.25%, 0.32%, 0.40%, 0.50%, 0.63%, 0.79%, 1%, 1.3%, 1.6%, 2%, 2.5%, 3.2%, 4.0%, 5.0%, 6.3%, 7.9%, 10%, 12%, 15%, 19%, 25%, 31%, 39%, 50%, 63%, 79%, 100%
MultiHertz	Changes the transducer frequency.	Transducer-dependent
DR (Dynamic Range)	Adjusts the overall contrast resolution of the M-mode sweep.	30, 35, 40, 45, 50, 55, 60, 65, 70 (in dB units)
Sweep	Adjusts the scrolling speed of the M-mode sweep.	1, 2, 3, 4, 5
Map	Selects a processing curve that assigns echo amplitudes to gray levels.	A, B, C, D, E, F, G, H, I
Persist (Persistence)	Increasing persistence creates a visible smoothing effect by maintaining lines of image data for each frame of imaging.	0, 1, 2, 3, 4
Tint	Changes the color of the sweep.	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15
Edge (Edge Enhance)	Distinguishes the contours of a structure during real-time imaging.	0, 1, 2, 3
U/D Flip	Vertically flips the image (top-to-bottom or bottom-to-top).	U, D
L/R Flip	Horizontally flips the image (right-to-left or left-to-right).	L, R

Soft Key Selections for Doppler

Selection	Description	Settings
Thumbnail	Accesses the thumbnail panel on the right of the screen. Note: This selection displays only when the system is frozen.	—
MultiHertz	Changes the transducer frequency.	Transducer-dependent
PRF	Adjusts the scale factor of the Pulsed Repetition Frequency (PRF).	Transducer-dependent
Baseline	Shifts the spectral baseline position.	—
Sweep	Adjusts the scrolling speed of the Doppler spectrum.	1, 2, 3, 4, 5
Gate (Gate Size)	Adjusts the size of the Doppler gate.	Transducer-dependent
DTI	Activates the DTI Doppler Tissue Imaging feature.	On, Off
Map	Allows changes to the shape of the current map.	A, B, C, D, E, F, G, H
Tint	Colorizes a Doppler spectrum.	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11
DR (Dynamic Range)	Controls the overall contrast resolution of the image.	30, 35, 40, 45, 50, 55, 60 (in dB)
Filter (Wall Filter)	Rejects low frequency signals, for example, signals generally caused by tissue clutter.	Up to eight levels, transducer-dependent
Full D	Activates a full-screen format for Doppler spectrum.	On, Off
Auto Stat	Displays graphical traces to track mean and/or maximum velocities or frequencies. Blw displays a trace below the baseline. Abv displays a trace above the baseline.	Blw, Abv, Both, Off
P	Adjusts the transmit power.	0.20%, 0.25%, 0.32%, 0.40%, 0.50%, 0.63%, 0.79%, 1%, 1.3%, 1.6%, 2%, 2.5%, 3.2%, 4.0%, 5.0%, 6.3%, 7.9%, 10%, 12%, 15%, 19%, 25%, 31%, 39%, 50%, 63%, 79%, 100%
T/F Res (Time/Frequency Resolution)	Adjusts Time/Frequency resolution for finer detail in either the time data or the frequency data.	A, B, C, D, E, F, G, H, I
Update Rate	Defines the interval for refreshing the 2D-mode image.	Off, 2 sec, 4 sec, 8 sec, EOS Note: In simultaneous (triplex) format, the system automatically displays Sim (simultaneous).
Clip Capture	Displays capture options for cardiac cycles. Use the system presets to assign default settings to the clip capture options. Note: You must assign a documentation control to the clip capture function in the system presets.	—

Soft Key Selections for Color Flow

Selection	Description	Settings
Thumbnail	Accesses the thumbnail panel on the right of the screen. Note: This selection displays only when the system is frozen.	—
MultiHertz	Changes the transducer frequency.	Transducer-dependent
PRF	Adjusts the scale factor of the Pulsed Repetition Frequency (PRF).	Transducer-dependent
Baseline	Adjusts the relative baseline position upward and downward. A shift in the baseline adjusts the range of displayed flow velocities without changing the system PRF.	—
Flow	Optimizes hemodynamic flow conditions. The system automatically adjusts the parameters for wall filter and pulse repetition frequency (PRF) for the selected Flow state. <ul style="list-style-type: none"> ▪ Low — allows maximum sensitivity to low velocity flows. The system achieves this by incorporating the lowest possible filter settings and lower PRFs. You may experience increased flash. ▪ Medium — produces an optimal balance between flash (motion artifacts) suppression and maximum sensitivity by using an adaptive wall filter. ▪ High — optimizes the system for the high arterial flow common to pulsatile vessels and stenotic conditions. 	L, M, H
Persist (Persistence)	Determines how long the colors corresponding to blood flow velocity remain in the Color ROI before decaying or being replaced by another color.	0, 1, 2, 3, 4
DTI	Activates the DTI Doppler Tissue Imaging feature.	On, Off
Map	Selects a processing curve that assigns the velocity range to a range of colors.	A, B, C, D, E, F, G, H
Priority (Tissue Reject)	Adjusts the threshold for choosing to display Color or 2D-mode data for any pixel.	0, 1, 2, 3, 4
R/S (Resolution/Speed or Line Density)	Adjusts the balance between the image line density (resolution) and the frame rate. Increasing the line density increases resolution and decreases frame rate.	0, 1, 2, 3, 4, 5
Filter (Wall Filter)	Activates and deactivates the adaptive wall filter.	0, 1, 2, 3
Smooth (Smoothing)	Adjusts the level of spatial (both axial and lateral) averaging used to smooth the flow pattern display.	0, 1, 2, 3
P	Adjusts the transmit power.	0.20%, 0.25%, 0.32%, 0.40%, 0.50%, 0.63%, 0.79%, 1%, 1.3%, 1.6%, 2%, 2.5%, 3.2%, 4.0%, 5.0%, 6.3%, 7.9%, 10%, 12%, 15%, 19%, 25%, 31%, 39%, 50%, 63%, 79%, 100%

Selection	Description	Settings
Peak	Designates the period of time that peak color velocities of blood flow are collected.	Off, 1 sec, 2 sec, 3 sec
VelTag	Designates or tags a specific blood flow velocity or a range of blood flow velocities in a real-time or frozen image or during CINE Review.	Off, Sngl, Rng
Display	Activates the Color information in the ROI.	On, Off
4B	Activates 4B-mode which displays four separately acquired images.	—
Clip Capture	Displays capture options for cardiac cycles. Use the system presets to assign default settings to the clip capture options. Note: You must assign a documentation control to the clip capture function in the system presets.	—

Soft Key Selections for Power Mode

Selection	Description	Settings
Thumbnail	Accesses the thumbnail panel on the right of the screen. Note: This selection displays only when the system is frozen.	—
MultiHertz	Changes the transducer frequency.	Transducer-dependent
PRF	Adjusts the scale factor of the Pulsed Repetition Frequency (PRF).	Transducer-dependent
Background Flow	Activates a background enhancement of solid color. Optimizes hemodynamic flow conditions. The system automatically adjusts the parameters for wall filter and pulse repetition frequency (PRF) for the selected Flow state. <ul style="list-style-type: none"> ▪ Low — allows maximum sensitivity to low velocity flows. The system achieves this by incorporating the lowest possible filter settings and lower PRFs. You may experience increased flash. ▪ Medium — produces an optimal balance between flash (motion artifacts) suppression and maximum sensitivity by using an adaptive wall filter. ▪ High — optimizes the system for the high arterial flow common to pulsatile vessels and stenotic conditions. 	On, Off L, M, H
Persist (Persistence)	Adjusts the time over which power data are processed in calculating the power amplitude display.	0, 1, 2, 3, 4

Selection	Description	Settings
Dir Power (Directional Power)	Select a map to identify direction of flow in relationship to the transducer. Directional power mode detects and assigns color to the energy and direction generated by the reflections of blood flow.	Off, On
Filter (Wall Filter)	Balances low flow sensitivity with flash suppression.	0, 1, 2, 3
R/S (Resolution/Speed or Line Density)	Adjusts the balance between the image line density (resolution) and the frame rate. Increasing the line density increases resolution and decreases frame rate.	0, 1, 2, 3, 4, 5
Map	Selects a processing curve that assigns flow amplitudes to color levels.	A, B, C, D, E, F, G, H
Priority (Tissue Reject)	Adjusts the threshold for the amplitude of the Power display.	0, 1, 2, 3, 4
Smooth (Smoothing)	Adjusts the level of spatial (both axial and lateral) averaging used to smooth the flow pattern display.	0, 1, 2, 3
P	Adjusts the transmit power.	0.20%, 0.25%, 0.32%, 0.40%, 0.50%, 0.63%, 0.79%, 1%, 1.3%, 1.6%, 2%, 2.5%, 3.2%, 4.0%, 5.0%, 6.3%, 7.9%, 10%, 12%, 15%, 19%, 25%, 31%, 39%, 50%, 63%, 79%, 100%
Display	Activates the Power information in the ROI.	On, Off
4B	Activates 4B-mode which displays four separately acquired images.	—
Clip Capture	Displays capture options for cardiac cycles. Use the system presets to assign default settings to the clip capture options. Note: You must assign a documentation control to the clip capture function in the system presets.	—

Soft Key Selections for Clip Capture

Selection	Description	Settings
Trigger Type Time Capture Beat Capture Rwave Capture	Select clip capture over a period of seconds or heart beat cycles.	—
sec	Specify the duration of each clip in seconds. Note: Available when Time Capture is selected for Trigger Type .	1, 2, 3, 4, 8*, 60*, 120*
beats	Specify the duration of each clip in heart beat cycles. Note: Available when Beat Capture is selected for Trigger Type .	1, 2, 3, 4, 8*, 60*, 120*
beats	Specify the duration of each clip in heart beat cycles. The system captures only the frames with R-waves into the clip. Note: Available when R-wave Capture is selected for Trigger Type .	1, 2, 3, 4, 5, 6, 7, 8, 9, 10
Chronology Retrospective Prospective	Retrospective selects a clip of previous images. Prospective selects a clip of succeeding images.	—
Compression High (13:1) Low (8:1)	Select level of image resolution and file size.	—
Preset	Display the system presets.	—
Exit	Returns to the active image.	—

* Available when **Prospective** is selected for **Chronology**.

Soft Key Selections for CINE

Selection	Description
Edit Start	(Not available for M-mode or Doppler data) Defines new beginning point of a loop of CINE data.
Edit End	(Not available for M-mode or Doppler data) Defines new ending point of a loop of CINE data.
Edit Reset	(Not available for M-mode or Doppler data) Resets the beginning and ending points to their originally acquired positions.
Rate	(Not available for M-mode or Doppler data) Changes the speed of CINE review while in motion review. Note: The signal of a Doppler spectrum is not audible when the review speed has been adjusted with the Rate selection.
U/D Flip	(Available only for 2D-mode) Vertically flips the image (top-to-bottom or bottom-to-top).
L/R Flip	(Available only for 2D-mode) Horizontally flips the image (right-to-left or left-to-right).
Map	Selects a processing curve that assigns flow amplitudes to color levels.
DR (Dynamic Range)	(Not available for Color flow) Controls the overall contrast resolution of the image, sweep, or spectrum. Controls the overall contrast resolution of the image.
Priority (Tissue Reject)	(Available only for Color flow) Adjusts the threshold for the amplitude of the Color or Power display.
Baseline	(Available only for Doppler data) Adjusts the relative baseline position of the spectrum upward and downward. A shift in the baseline adjusts the range of displayed flow velocities without changing the system PRF.
Tint	(Not available for Color flow) Changes the color of the image, sweep, or spectrum by adding blue, red, yellow, or green to the gray in a gray map.
Sweep	(Not available for 2D-mode or Color flow) Adjusts the scrolling speed of the sweep or spectrum.
Display	(Available only for Color flow) Activates the Color information in the ROI.
VelTag	(Available only for Color flow) Designates or tags a specific blood flow velocity or a range of blood flow velocities in a real-time or frozen image or during CINE Review.
T/F Res (Time/Frequency Resolution)	(Available only for Doppler data) Adjusts Time/Frequency resolution for finer detail in either the time data or the frequency data.
Modify Map	(Available only for 2D-mode) Changes the shape of the current gray map.
Full M	(Available only for M-mode) Displays a full screen M-mode sweep.
Full D	(Available only for Doppler data) Activates a full screen format for a Doppler spectrum.
Thumbnail	Accesses the thumbnail panel on the right of the screen. Note: This selection displays only when the system is frozen.

Soft Key Selections for SieScape Panoramic Imaging Option

Selection	Description
Restore	In Setup or CINE Review, reactivates the Review screen. In Review , scales the SieScape image to the original display of the frozen image.
Redisplay	In Review , redisplay the SieScape image in the size and rotation selected prior to entering CINE (or previous size and rotation prior to re-accessing Setup).
Setup	In Review or CINE Review, reactivates the Setup screen.
Cine	In Review , activates CINE Review.
Scale Display	In Review or CINE Review, displays a flexible ruler with markers along the skin line.
Full	In Review , scales the image to its full acquisition size.
Best Fit	In Review , automatically scales the image to fit the image area.

Soft Key Selections for 3D Imaging

The system displays 3D imaging selections as soft key selections for viewing, displaying, selecting, editing, and animating the 3D data set(s).

3D Soft Key Selections — Set Up

These selections are available after activating 3D imaging before image acquisition.

Selection	Description	Settings
Scan	Selects the scan method for volume acquisition.	Linear, Rocked
Angle/Length	Selects the scan length or scan angle for volume acquisition.	Length: 5, 10, 15, 20, 30, 40 (in cm units) Angle: 30°, 45°, 60°, 90°, 120°, 150°
Speed	Selects the scan speed or quality setting for volume acquisition.	Speed: Slow, Medium, Fast
ROI (Region of Interest)	Activates display of the 3D ROI.	On, Off

For 2D FOV adjustments, you also have the following selections:

Selection	Description	Settings
P	Adjusts the transmit power.	0.20%, 0.25%, 0.32%, 0.40%, 0.50%, 0.63%, 0.79%, 1%, 1.3%, 1.6%, 2%, 2.5%, 3.2%, 4.0%, 5.0%, 6.3%, 7.9%, 10%, 12%, 15%, 19%, 25%, 31%, 39%, 50%, 63%, 79%, 100%
MultiHertz	Changes the transducer frequency.	Transducer-dependent
Edge (Edge Enhance)	Distinguishes the contours of a structure during real-time imaging.	0, 1, 2, 3
DR (Dynamic Range)	Controls the overall contrast resolution of the image.	30, 35, 40, 45, 50, 55, 60, 65, 70 (in dB units)
2D Size	Resizes the field of view. Note: Available for linear transducers with the sector format.	—
Full Size	Maximizes the field of view. Note: Available for linear transducers with the sector format.	—
Map	Selects a processing curve that assigns echo amplitudes to gray levels.	A, B, C, D, E, F, G, H, I
Tint	Changes the color of the image.	
Persist (Persistence)	Increasing persistence creates a visible smoothing effect by maintaining lines of image data for each frame of imaging.	0, 1, 2, 3, 4
U/D Flip	Vertically flips the image (top-to-bottom or bottom-to-top).	U, D
L/R Flip	Horizontally flips the image (right-to-left or left-to-right).	L, R
R/S (Resolution/Speed)	Adjusts the balance between the image line density (resolution) and the frame rate.	0, 1, 2, 3, 4, 5
SieClear	Activates SieClear multi-view spatial compounding.	Off, 1, 2

3D Soft Key Selections — Acquisition

These selections are available after image acquisition.

The system applies opacity and shading settings to the volume quadrant only.

Selection	Description	Settings
Quadrant	Selects (activates) a quadrant.	A, B, C, D
Rotate	Rotates the volume to the selected angle (in degrees).	0, 90, 180, 270
Render	Selects a display method for the volume quadrant: <ul style="list-style-type: none"> ▪ Slice — Displays a one-voxel-thick slice in its three-dimensional context. The displayed slice (within the volume) corresponds to the most recently selected slice (Multi-Planar Reformatting, or MPR) quadrant. ▪ Opacity — Smooths image contours, creating a soft, sculptured appearance for highlighting surface features. Uses the mode-specific selections for opacity percentage and thresholds. ▪ Surf. Shading — Heightens contrast, creating a textured appearance for highlighting internal features. Uses the mode-specific selected shading in addition to the mode-specific selected opacity percentage and thresholds. ▪ MPR Only — Increases the rendering speed by displaying the MPRs (arbitrary slices) only. 	Slice, Opacity, Surf. Shading, MPR Only
Format	Selects a display format: <ul style="list-style-type: none"> ▪ 1:1 — Displays the selected quadrant only, ▪ 4:1 — Displays all four quadrants on the screen. ▪ 2:1 — Displays two quadrants on the screen. ▪ 1-3 — Displays the volume on the left of the screen and the other three quadrants on the right. 	1:1, 4:1, 1-3, 2:1
Cut Plane	Enables or disables the cut plane for 2D-mode data in the volume. When enabled, the volume does not display any 2D-mode data beyond the cut plane. Enables or disables the specified cut plane (A or B) for 2D-mode data in the volume. When enabled, the volume does not display any 2D-mode data beyond the cut plane.	Off, A, B
Wireframe	Enables or disables the display of the wireframe in the volume quadrant.	On, Off
VOI	Defines content of the volume (Volume of Interest).	On, Off
Reset Center	Adjusts the orientation of quadrants on each slice, repositions the focal point to the center of the quadrant.	—
Reset Sync. (Reset Synchronize)	Aligns slice and volume orientations. When the selected quadrant is a slice, aligns the orientation of the volume quadrant to that of the slice quadrant. When the selected quadrant is the volume quadrant, aligns the orientation of all slice quadrants to that of the volume quadrant.	—
Reset Ori. (Reset Orientation)	Restores the default orientation for all quadrants.	—

Selection	Description	Settings
Reset All	Restores the default orientation and display format for all quadrants; also restores the default (or user-defined) settings of other parameters for all quadrants. User-defined settings are those that were in effect when the current volume was first displayed.	—
Reset Flip	Reverses the render direction.	
Map	Not available for Quadrant D. Selects a processing curve that assigns echo amplitudes to gray levels. Applies the selected curve to the selected quadrant. If a slice (MPR) quadrant is selected, applies the selected curve to all slices. If the selected rendering method is Slice or Opaque , applies the selection to all quadrants.	A, B, C, D, E, F, G, H, I
DR (Dynamic Range)	Controls the overall contrast resolution. Applies the selected resolution to the selected quadrant. If a slice (MPR) quadrant is selected, applies the selected resolution to all slices. If the selected rendering method is Slice or Opaque , applies the selection to all quadrants.	30, 35, 40, 45, 50, 55, 60, 65, 70 (in dB units)
Tint	Applies the selected tint to the selected quadrant. If a slice (MPR) quadrant is selected, applies the tint to all slices. If the selected rendering method is Slice or Opaque applies the selection to all quadrants.	0 to 15
Low Th (Low Threshold)	Available for Opacity and Surf. Shading (Surface Shading) rendering methods only. Sets the low threshold for the opacity curve. Removes 2D-mode data (voxels) that have values lower than the selected threshold. Lower settings create a more saturated image.	0 to 255
High Th (High Threshold)	Available for Opacity and Surf. Shading (Surface Shading) rendering methods only. Sets the high threshold value for the opacity curve. Removes 2D-mode data (voxels) that have values higher than the selected threshold.	0 to 255
Opacity	Available for Opacity and Surf. Shading (Surface Shading) rendering methods only. Adjusts the percentage of opacity in the volume to smooth image contours.	0% to 100% (in increments of 2)
Smooth	Adjusts the percentage of smoothing to smooth the data in the volume quadrant.	0% to 100% (in increments of 5)
Brightness	Available for Opacity and Surf. Shading (Surface Shading) rendering methods only. Adjusts the percentage of brightness in the 2D-mode data of the volume. An increase in brightness increases the saturation of voxels that have a higher voxel value and increases the brightness of voxels that have a lower voxel value.	0% to 100%
Contrast	Adjusts the percentage of contrast.	0% to 100%
Editing	Displays the Editing soft key selections.	—
Animation	Displays the Animation soft key selections.	—

3D Soft Key Selections — Editing Selections

Selection	Description	Settings
Polygon	Defines an irregular area from a drawn outline and then removes all the voxels inside or outside of that area.	—
Trace	Defines an area from a free-form drawn outline and then removes all the voxels inside or outside that area.	—
Parallel Cut	Selects a plane (layer) within the volume and then removes all the voxels outside the selected plane. Displays the wireframe on the volume.	—
Niche	Removes all the voxels from the nearest corner of the volume to a selected depth inside the volume. Activated for Quadrant D.	—
Undo Last Edit	Removes the most recent edit.	—
Undo All Edits	Removes all edits.	—
Cancel	Returns to 3D Imaging mode.	—

3D Soft Key Selections — Animation Selections

Selection	Description	Settings
Animation	Automatically rotates the volume according to the selected range, speed, and axis. Note: The system dithers the Editing selections and the general selections from the 3D Parameter menu (except Wireframe) while the volume is automatically rotating.	On, Off
Angle	For the 360 selection, the volume continuously rotates in one direction around the selected axis (for Axial , to the right; for Lateral , downward). For other selections, the volume rotates in both directions around the selected axis (for Axial , first right, then left; for Lateral , first downward, then upward).	15, 30, 60, 90, 120, 180, 240, 300, 360
Speed	Selects rotation speed.	Slow Med Fast
Axis	Selects rotation axis: <ul style="list-style-type: none"> ▪ Axial — Rotates around the Axial axis. ▪ Lateral — Rotates around the Lateral axis. 	Axial Lateral
Clip Time	Selects the storing time for clip store.	3, 4, 5, 6, 7, 8, 9, 10 (sec)
Cancel	Returns to 3D Imaging mode.	—

Soft Key Selections for ECG

Use the system presets to enable the ECG function (or the external ECG function) to automatically activate when an exam type is selected.



Exam Configuration > Physio Management

Note: The **ECG** selections display when the ECG function is active.

Selection	Description	Settings
ECG	Activates (On) the ECG function.	On, Off
Ch 1 Delay	Selects the channel 1 trigger point in the cardiac cycle where the system updates the image from ventricular depolarization, or the 'R' value of the ECG tracing.	0 ms to 990 ms in increments of 10
Ch 2 Delay	Selects the channel 2 trigger point in the cardiac cycle where the system updates the image from ventricular depolarization, or the 'R' value of the ECG tracing.	0 ms to 990 ms in increments of 10
Position	Adjusts the vertical position of the ECG trace on the image screen.	0 to 29 in increments of 1
Gain	Increases or decreases the trace amplitude.	0 to 63 in increments of 1
Invert	Vertically inverts the ECG trace.	On, Off
Trigger	Enables ECG-triggered acquisition of 2D-mode data.	On, Off
Trigger Type	Selects Single or Dual trigger within one cardiac cycle.	Single, Dual

Soft Key Selections for Video Recording

A VCR/DVR counter is displayed on the upper right of the playback screen.

Note: The installed video recorder (such as **DVR** or **VCR**) is identified in the middle of the "page indicator" for the soft key selections.

Selection	Description
REW (Rewind)	When playback is stopped, this selection plays the media in a backward direction at a high speed while displaying the content on the image screen. During playback, this selection plays the media in a backward direction at low speed while displaying the content on the image screen.
Eject	Opens and closes the disk tray on the recording device.
Play	Starts playback.
Pause	Pauses playback or recording.
FF (Fast Forward)	When playback is stopped, this selection plays the media in a forward direction at high speed while displaying the contents on the image screen. During playback, this selection plays the media in a forward direction at low speed while displaying the content on the image screen.
Stop	Stops playback or recording.
Shuttle	Uses the trackball to play the media in a forward or backward direction, at low or high speed. When you select Shuttle , a shuttle indicator displays at the top of the screen. Before you move the trackball in either direction, the shuttle indicator displays only a vertical line, indicating the playback of the media is paused. To play the media in a forward direction, roll the trackball to the right. To play the media in a backward direction, roll the trackball to the left. To play the media at a low speed, move the trackball slowly in the required direction. To play the media at a high speed, move the trackball quickly in the required direction.
Step Frame	Displays the frames one at a time in the selected direction. To move to the next frame, roll the trackball to the right; to move to the previous frame, roll the trackball to the left.
Search Index	Searches in the specified direction for the specified index marker (1 to 99) you entered using the Write Index function. <i>For example, if 10 is entered into the dialog box and Backward is selected, the media searches 10 index markers backward from the current display.</i>
Counter Search	Searches the recording media in the selected direction for the specified counter value and displays the corresponding frame. Note: VCRs can accept negative numbers.

Only DVRs have the following selections:

Selection	Description
Write Index	Enters an index marker (bookmark) at the location of the displayed frame. You can enter any number from 01 to 99.
Prev Study	Plays the previous study.
Begin of Study	Restarts the current study.
Next Study	Plays the next study.
Study List	Displays the list of studies recorded on the media.

Selections Used in the Stress Echo Feature

When you use the Stress Echo feature, you use selections from several windows, dialog boxes, and screens.

Select Protocol to Load Dialog Box

The **Select Protocol to load** dialog box lists all the available protocols. The default list includes the following protocols:

- **Dobutamine Stress Echo**
- **Ergometric Stress Echo**
- **Treadmill**
- **Ergometric continuous**
- **Treadmill continuous**
- **Ergometric continuous R-R**
- **Treadmill continuous R-R**
- **Dobutamine Stress Echo Auto Review**
- **Ergometric Stress Echo Auto Review**
- **Treadmill Stress Echo Prospective**
- **Treadmill Stress Echo Retrospective**

Protocol Window

















Continuous stages, unlike non-continuous stages, do not display views in the **Protocol** window. The system responds as follows for non-continuous stages. (Phases are stages.) The **Protocol** window lists the phases and views of the selected protocol. At the beginning of acquisition, the system expands the first phase to list its constituent views; all other phases are contracted. The system expands the next phase in the sequence once images have been acquired for each view in the current phase. When the last phase is completed, the system activates **STOP** for your selection.

Stress Echo Screen

Selections used in the Stress Echo screen include toolbar buttons and the buttons available during each Stress Echo mode.

Toolbar Buttons — Stress Echo

During all Stress Echo modes except Acquire mode, the following toolbar buttons display at the top of the Stress Echo screen.

Toolbar button	Description
	Acquire Mode Exits the Stress Echo screen and redisplay the real-time imaging screen. This button is available only when acquisition of Stress Echo loops is not yet complete.
	Select Mode Enables Select Mode .
	Review Mode Enables Review Mode .
	Wall Motion Scoring Mode Enables Wall Motion Scoring Mode .
	LV Mode Enables LV Mode .
	Indication Displays the Indication dialog box.
	Save Examination Saves the Stress Echo data with all loops (all loops acquired for each view or continuous stage).
	Save Examination (only selected loops) Saves the Stress Echo data with loops selected as "preferred" only (one representative loop for each view).
	Report Preview Displays the report for the current mode when available. Reports are available for Wall Motion Scoring Mode and LV Mode .
	Print Prints the report for the current mode when available. Reports are available for Wall Motion Scoring Mode and LV Mode .
	Maintenance Displays the Maintenance dialog box.
	Exit Closes the Stress Echo screen and exits the Stress Echo feature; redisplay the real-time imaging screen. The current patient examination remains active.
	Toggle Play When enabled (highlighted), plays back the loops. When disabled (not highlighted), displays one frame for each loop.
	Start of sequence Displays the first frame of each loop.
	Step backward Displays the previous frame of each loop.
	Step forward Displays the next frame of each loop.

Toolbar button	Description
	End of sequence Displays the last frame of each loop.
	Decrease Speed Decreases the speed of loop playback.
	Increase Speed Increases the speed of loop playback.
	Sweeping play Plays back loops in both directions, forward from beginning systole to end systole and then reversed from end systole to beginning systole. The system initially plays back the displayed loops in one direction, from beginning systole to end systole. When the last frame is played, the system reverses the playback direction, playing back the displayed loops from end systole to beginning systole. You can change the beginning and end points for playback.
	Labels on/off Removes labels from loops.
—	Loop segment Specifies the loop segment for display. Drop-down list. Available settings: <ul style="list-style-type: none"> ▪ Full heartbeat — displays the complete loop (all loops). ▪ Systole — displays the systole segment only (all loops). ▪ Diastole — displays the diastole segment only (all loops). ▪ User-defined — allows manual repositioning of review markers on the loop bar to exclude frames from review (selected loop only). ▪ Fixed range — displays the – and + buttons for repositioning of review markers on the loop bar to exclude frames from review (all loops).
	Decrement left marker position (Displayed when you select Fixed range from the Loop Segment drop down list.) Repositions the left review marker on the loop bar one frame to the left.
	Increment left marker position (Displayed when you select Fixed range from the Loop Segment drop down list.) Repositions the left review marker on the loop bar one frame to the right.
	Decrement right marker position (Displayed when you select Fixed range from the Loop Segment drop down list.) Repositions the right review marker on the loop bar one frame to the left.
	Increment right marker position (Displayed when you select Fixed range from the Loop Segment drop down list.) Repositions the right review marker on the loop bar one frame to the right.
—	(text box) (Displayed when you select Fixed range from the Loop Segment drop down list.) Indicates the frame number of the review marker.

Soft Key Selections for All Measurements and Calculations

The following soft key selections display during the measurement function when you press the **UPDATE** key on the control panel to modify previous measurements.

Selection	Description
Delete	Removes the currently selected set of measurement markers from the screen. Note: This selection does not remove measured results from the screen, worksheet, or report.
Delete All	Removes all sets of measurement markers from the screen. Note: This selection does not remove measured results from the screen, worksheet, or report.

Soft Key Selections for 2D-Mode Measurements and Calculations

Selection	Description
Distance	Simple linear measurement between two points.
Area	Calculate the area using Ellipse or Trace method.
Ellipse	Elliptical measurement. The system determines one diameter using the end points of the ellipse and calculates the second diameter.
Trace	Free hand trace method. Roll the trackball to delineate an area. The system determines the circumference and area using the trace segments.
Angle	Determines the angle using two lines you place on the image. The lines must connect or intersect.
Ellipse	Elliptical measurement. The system determines one diameter using the end points of the ellipse and calculates the second diameter.
%Stenosis	Performs a % stenosis calculation based on the area or diameter of the same vessel.
A-% Stenosis	Calculate area % stenosis, comparing cross-sectional areas of the same vessel.
D-% Stenosis	Calculate diameter % stenosis, comparing diameters of the same vessel.
Volume	Performs a volume measurement.
1 Dist	Calculate a volume by measuring one distance.
2 Dist	Calculate a volume by measuring two distances.
3 Dist	Calculate a volume by measuring three distances: length and depth in one plane, and width in another plane.
1 Ellipse + 1 Dist	Calculate a volume by measuring an area with an ellipse on one plane and measuring a distance on another plane.
1 Ellipse	Calculate a volume by measuring an area with an ellipse, identifying the axis common to both planes.
Disk	Calculate a volume by using the trackball to trace a structure and then positioning an axis line along which the disks will be calculated.
Thyroid	Calculate a volume by measuring three distances: length and depth in one plane, and width in another plane.
Flow Volume	Measures distance or area to calculate an estimate of blood flow volume.
A-Flow Vol	Calculate an estimate of blood flow volume based on area, requiring measurements in 2D-mode and Doppler.
D-Flow Vol	Calculate an estimate of blood flow volume based on diameter, requiring measurements in 2D-mode or M-mode and Doppler.

Selection	Description
Trace Length	Trace distance measurement between two points.
A/B Ratio	Ratio of measurements. The system calculates the ratios A/B, B/A and (A-B)/A from the 2D-mode measurements: distance, area or volume.
Dist Ratio	Calculate ratios A/B, B/A, and (A-B)/A for distance.
Area Ratio	Calculate ratios A/B, B/A, and (A-B)/A for area.
Vol Ratio	Calculate ratios A/B, B/A, and (A-B)/A for volume.
Auto EFW	(SONOVISTA systems only) Advances through the required parameters (measurement labels) for calculating an estimated fetal weight (EFW).

Soft Key Selections for M-Mode Measurements and Calculations

Selection	Description
Slope	Distance over time. The measurement is determined by two distance measurement markers.
Distance	Vertical distance between two points in the M-mode sweep.
HR	Heart rate determined over one heart cycle in 2D/M-mode.
Time	Interval in seconds between two measurement markers.
A/B Ratio	Ratio of measurements. The ratios are A/B, B/A and (A-B)/A. Ratios can be determined for Distance, Heart Rate or Time measurements.
Dist Ratio	Calculate ratios A/B, B/A, and (A-B)/A for distance.
Time Ratio	Calculate ratios A/B, B/A, and (A-B)/A for time.

Soft Key Selections for Doppler Measurements and Calculations

Selection	Description
Acceleration	Acceleration or Deceleration of speed over the time traveled determined by two measurement markers.
Velocity (Frequency)	Distance over time. The measurement is determined by a measurement marker placed along a vertical plane.
RI (Resistance Index)	Pourcelot's Ratio: $RI = [PS-ED] / [PS]$
HR	Heart rate determined over one heart cycle.
Time	Interval in milliseconds between two measurement markers.
PI Auto	Use an automatic trace of the spectrum to determine a pulsatility index.
PI Manual	Use a manual trace of the spectrum to determine a pulsatility index.
Flow Volume	Selects methods for estimating blood flow volume.
A-Flow Vol	Area Flow Volume requires measurements in two modes: an area measurement in 2D-mode using an ellipse, circle, or trace, and a TAV (time averaged velocity) measurement from Doppler.
D-Flow Vol	Diameter Flow Volume requires measurements in two modes: a 2D-mode diameter or two M-mode diameter measurements, and a TAV measurement from Doppler. TAMx is the TAV measurement default.
Velocity Ratio	Calculate a ratio of two velocity measurements.
VTI	Automatically selects the default method to determine a Velocity-time Integral.

Selections for Summary

Soft Key Selections for the Summary

Selection	Description
Export to USB	Stores the Summary on a USB-compatible device in both PDF and RTF format.
Print	Prints the Summary to a USB printer connected to the system.
Exit	Exits the Summary feature.

Screen Selections for the Summary

Selection	Description
Letter Header	Displays a logo or text at the top of the summary. Use the system presets to define the logo or text.
Patient Data	Displays general information entered on the Patient Data form.
Exam Specific Data	Displays specific exam data, depending on the exam type.
Result	Displays measurements and calculation results, depending on the exam type and the measurements and calculations performed during the exam.
Image	Insert up to four images from the displayed thumbnails. Note: If you select a thumbnail for a clip, the system inserts the displayed frame.
Summary	Insert pre-defined comments or enter comments directly in the form.
Recommendations	Enter recommendations.
Signature	Displays a signature line which can be included in the printed Summary.

Soft Key Selections for Annotations

Selection	Description
Library	Displays or hides the list of annotations for the current exam type.
Arrow	Places an arrow on the screen. (Performs the same function as the Arrow key on the keyboard.)
Delete Word	Removes the selected term from the screen. Select the term by rolling the trackball to position the cursor on the term. (Performs the same function as the Delete Word key on the keyboard.)
Hide Text Show Text	Hides or displays annotations and arrows. (Performs the same function as the Hide Text key on the keyboard.)
Home	Places the text cursor in the Home position (as defined with the Home Set key or the Home Set soft key selection) when the Annotation function is active. (Performs the same function as the Home key on the keyboard.)
Home Set	Sets the default location of the text cursor. (Performs the same function as the Home Set key on the keyboard.)
Clear Screen	Removes all annotations and pictograms from the screen. (Performs the same function as the Clear Screen key on the keyboard.)
Delete Line	Removes all annotations and pictograms on the same line where the cursor is located.

Soft Key Selections for Arrows

Selection	Description
Next	Activates the next arrow on the screen if there are multiple arrows on the screen.
Select	Cycles through the confirmed arrows displayed on the screen.
Arrow Size	Cycles through the available sizes for arrows.
Rotate 30°	Rotates the arrow 30° in the clockwise direction.
Rotate 90°	Rotates the arrow 90° in the clockwise direction.
Delete	Removes the activated arrow.
Delete All	Removes all the arrows displayed on the screen.

Soft Key Selections for Pictograms

Selection	Description
Pictogram Select	Displays the previous or next pictogram.

Soft Key Selections for Transducers

Selection	Description
LC1	Displays the name of the transducer connected to the corresponding transducer port.
LC2	Displays the name of the transducer connected to the corresponding transducer port.
LC3	Displays the name of the transducer connected to the corresponding transducer port.
AUX	Displays the name of the CW transducer connected to the corresponding transducer port.

Soft Key Selections for the Applications Key

Selection	Description
Stress Echo	Activates the Stress Echo feature.
Axius EF	Activates the Axius EF feature.
SieScape	Activates the SieScape feature.
Auto Left Heart	Activates the Auto Left Heart feature.

Soft Key Selections for Review

These soft key selections display when the DIMAQ IP Study screen or Image screen is active.

Soft Key Selections for Study Screen

Selection	Description
Show Archive	Displays the archival history for the selected study.
Image Screen	Displays the DIMAQ image screen.
Live Screen	Displays the live image screen.

Soft Key Selections for Image Screen – Review Tab

Selection	Description
Hide Controls	Displays only the images.
Show Controls	Displays the DIMAQ-IP controls.
Show All	Exits simultaneous display and displays all images in the study.
Show Selected	Displays the selected images in a new Image screen.
Unselect Image	De-selects the image.
Select Image	In the Image screen, selects the image.
Clear Selected	In the Image screen, clears all selected images. Displays when Unselect Image is selected.
Teaching File	Displays a dialog box for combining images from multiple patient studies into a single teaching file. Displays when Unselect Image is selected.
Delete	Deletes the selected clip, image, or report.
Close	Closes the current study.
Study Screen	Displays the study screen.
Live Screen	Displays the live image screen.
Rate 1/1	Defines the rate of playback for the selected clip. Displays when a clip is selected.
Rate 2/1	
Rate 1/8	
Rate 1/4, Rate 1/2	

Soft Key Selections for Image Screen – Applications Tab

Selection	Description
VVI	Activates the VVI function.
Axius EF	Activates the Axius EF function.
Auto Left Heart	Activates the Auto Left Heart function.
IMT	Activates the IMT function.

Selections during Review of Patient Data

Study Screen — DIMAQ-IP

In the upper half of the Study screen, the system displays all studies that are saved on the currently selected disk in the **Disk** section of the screen. The columns displayed in the upper half of the screen include **Patient Name**, **Patient ID**, **Date/Time**, **Clips**, **Images**, **Archived**, and **MBytes**.

You can select multiple studies for export, import, or deletion.

If the DICOM option is installed on the ultrasound system, then additional selections display on this screen.

At the top of the Study screen, the system indicates the file size of the selected studies (when multiple studies are selected), the number of studies displayed, and the total number of studies. The system also displays the utilized capacity and the total capacity of the selected disk (**HD**, **CD/DVD** or **USB**).

In the **Export/Import** section of the Study screen, the system indicates the recognition (for example: **Ready**) and the used space of the inserted media.

Use the system presets to indicate the status of network connection in the **Network** section of the Study screen.

Network

Study Screen Selection	Description
Hide Studies	Limits the display of studies to those newer than the age (of the study) selected in the drop-down list (for studies on hard disk only).
Screen	
Image Screen	Displays the Image screen with the images from the selected study.
Worklist Screen	(Requires the DICOM option) Displays the Worklist screen.
Procedure Screen	Activates when DICOM MPPS is installed.
Live Screen	Exits the Study screen and the Review function; redisplay the real-time imaging screen.
DICOM Screen	(Requires the DICOM option) Displays the DICOM screen.
Search for Studies	
Search...	Displays a dialog box for entry of patient name, ID, and/or study date and then searches the currently selected disk for matching studies.
Show All	Displays all studies that are stored on the currently selected disk.

Study Screen Selection	Description
Disk	
HD	Lists studies on the system's hard disk.
CD/DVD	Lists studies on the inserted disk media.
USB	Lists studies on the connected USB-compatible storage device.
Export/Import	
Export	Copies the selected study from the system's hard disk to the inserted disk media. This selection is available when the Disk selection is HD and a completed study is selected.
Import	Copies the selected study from the inserted disk media to the system's hard disk. This selection is available when the Disk selection is CD/DVD and a completed study is selected. Note: Select the name of the connected USB device from the drop-down list next to the USB selection.
Eject	Ejects the disk media.
Load	Closes the disk media tray.
Finalize	Prevents additional storage to the inserted disk media.
Export Format (displayed for HD only)	Specifies the format(s) of exported images: <ul style="list-style-type: none"> ▪ TIFF/Avi exports images in the "Tagged Image File Format" (TIFF) format. ▪ DICOM exports images in the DICOM (Digital Images and Communications in Medicine) format.
Study	
New	Creates a new study by re-registering the patient listed in the selected study. If a patient is already registered, the system first prompts you to close the current study.
Close	Closes the selected study.
Delete	Removes the selected study from the hard disk. Studies on disk media cannot be deleted using the DIMAQ-IP Study screen.
Network	
Send	(Requires the DICOM option) Copies the images from the selected study to the destination selected from the drop-down list.
(drop-down list)	Lists the available destinations, such as printers and servers.

Image Screen — DIMAQ-IP

Note: In this chapter, the term "Image screen" refers to a screen with the DIMAQ-IP option. In other chapters of the operating instructions, the use of "image screen" refers to a typical image screen that displays real-time images as they are acquired.

At the top of the Image screen, the system displays the **Patient Name**, **Patient ID**, and **Date/Time** of the study containing the displayed images.

If the DICOM option is installed on the ultrasound system, then additional selections display on this screen.

The system indicates the current page number and the total number of pages on the upper right of the screen. For example, "1/2" indicates that the system is displaying the first of two pages.








Image Screen Selection	Description
Options	Accesses a dialog box for enabling simultaneous image playback and configuring sequential viewing (slide show capability).
1 x 1, 2 x 2, 3 x 3, 4 x 4, 5 x 5	Specifies the layout format, which determines the number of images per page.
	When enabled (checked), locks the selected layout format until system shutdown. When this selection is disabled (unchecked), the system optimizes the display format (layout format) to fit the number of images contained in the selected study onto one page.
	Displays the Select Printer dialog box.
BW Print	(Requires the DICOM option) Sends the selected image to the DICOM BW Printer Layout page.
Color Print	(Requires the DICOM option) Sends the selected image to the DICOM Color Printer Layout page.
Delete	Removes the selected image from storage.
Close Study	Completes the current patient examination and displays the Study screen.
Procedure Screen	Activates when DICOM MPPS is installed.
Study Screen	Displays the Study screen.
Live Screen	Exits the Image screen and the Review function; redisplay the real-time imaging screen.
Previous	Displays the previous page of images and automatically selects the last image on that page.
Next	Displays the next page of images and automatically selects the first image on that page.
Clip Edit	Select a range of frames to save to a new clip.
Clip Speed	Defines the playback speed of the clip.
—	Moves the slider. Or, click in the slider bar to select a frame.






Image Screen Selection	Description
	Goes to the first frame in the displayed clip.
	Goes to the previous frame.
	Goes to the next frame.
	Plays the clip.
	Stops playing the clip.

Options Dialog Box

The system displays the **Options** dialog box when you select **Options** from the Image screen.

Selection	Description
Clip Playback	—
Play Only Selected Clip	Disables simultaneous playback of all clips in the currently displayed study.
Play All Clips	Enables simultaneous playback of all clips in the currently displayed study.
Loop aligned	Begins each playback cycle at the same time. Note: This selection is available only when Play All Clips is selected.
Slide Show	—
Slide Show on	Configures clips and images for sequential viewing in the currently displayed study.
Image Period (sec)	Specifies the length of display for each image.
Clip Play Loops	Specifies the number of times each clip is played back.

Clip Edit Dialog Box

Button	Description
Start Frame	Selects the first frame for the new clip.
End Frame	Selects the last frame for the new clip.
Clear All	Clears all the frame settings.
Create	Creates and saves a new clip from the selected frames.
Close	Closes the Clip Edit dialog and redisplay the Image screen.
—	Moves the slider. Alternatively, click in the slider bar to select a frame.
	Goes to the first frame in the displayed clip.
	Goes to the previous frame.
	Goes to the next frame.
	Plays the clip.
	Stops playing the clip.

Teaching File Dialog Box

Button/Selection	Description
Select Teaching File	—
Teaching File Name	Lists existing teaching files.
Appending Status	Displays a progress bar during modification of an existing teaching file.
Append	Adds the selected images and clips to an existing teaching file study. Use the trackball to select the teaching file study to which you want to add the images and clips.
Add Teaching File	—
New Teaching File Name	Text field for user entry of a file name. Note: The system applies a unique identifier to the file name ("TF" followed by the date and time of file creation).
New	Creates a new teaching file with the selected images and clips
Close	Exits the DIMAQ-IP Image Screen.

DICOM Screen Selections

The following descriptions for the Study, Image, and DICOM screens are specific to the DICOM Connectivity option. DIMAQ-IP Study and Image screen selections are also available for use with this option.

In the **Network** section of the Study screen, the system indicates the connection status (for example: **Ping OK**).

Study Screen

Study Screen Selections	Description
Screen	
DICOM Screen	Displays the DICOM screen for access to printer layout pages and print and store queues.
Worklist Screen	(Requires DIMAQ-IP support and the DICOM 3.0 connectivity option) Displays the Worklist screen for automatic entry of patient data on the New Patient Data form. Systems with the Worklist option installed and the Worklist server configured display a Worklist button on the screen.
Procedure Screen	Activates when DICOM MPPS is installed.
Network	
Send	Copies the images from the selected study to the destination selected from the drop-down list.
(drop-down list)	Lists the available destinations, such as printers and servers.

Image Screen

For each print selection (such as **BW Print**), the system indicates the number of images on the printer layout page and the number of images required to fill the page. For example, "1/4" indicates that one image has been sent to the printer layout page and that four images are required to fill the layout page.

Image Screen Selections	Description
BW Print	Sends the selected image to the DICOM BW Printer Layout page.
Color Print	Sends the selected image to the DICOM Color Printer Layout page.

DICOM Screen

The DICOM screen displays layout pages for the black and white and color printers and queue status pages for the DICOM print and store functions.

Printer Layout Pages

Page tabs displayed along the top of the DICOM screen include:

- **DICOM BW Printer Layout**
- **DICOM Color Printer Layout**

The selections available for the printer layout pages are described below. The system also lists the following settings at the top of each page: setup alias, film size, number of copies, and film orientation (Portrait or Landscape); these settings are only selectable in the system presets.

The system indicates the current page number and the total number of pages on the upper right of the screen. For example, "1/2" indicates that the system is displaying the first of two pages.

Selection	Description
Delete	Removes the image outlined in green from the layout page.
Cut	Marks the image outlined in green for rearranging. The image outline changes to yellow.
Paste	First select a new image as the paste location. The paste location image outline changes to blue. Then select the Paste button to insert the cut image in place of the image outlined in blue.
1x1 3x3	Identifies the columns and rows needed to assemble a full page of print images. This setting (Display Layout) is selected separately in the system presets for each type of printer and cannot be changed from a layout page.
1x2 3x5	
2x2 4x5	
2x3 4x6	
3x2 5x6	
Print Page	Sends the current page of images to the DICOM Print Queue . The Display Layout requirements do not need to be filled to print the page.
Print All Pages	Sends all pages of images to the DICOM Print Queue .
Back	Displays the Study screen.
Change	Displays a dialog box for change of printer selection, film size, number of copies, and print orientation.
Previous	Displays the preceding page of print images.
Next	Displays the next page of print images.

Print and Store Queues

Page tabs displayed along the top of the DICOM screen include:

- **DICOM Print Queue**
- **DICOM Store Queue**

The system lists the following items for each queue entry on the **DICOM Print Queue** page:

Item	Description
Patient Name	Patient name.
Printer	AE Title of printer.
No of Copies	Number of copies.
No of Sheets	Number of pages.

The system lists the following items for each queue entry on the **DICOM Store Queue** page:

Item	Description
Type	Type of operation: <ul style="list-style-type: none"> ▪ Store (storage) ▪ Commit (storage commitment)
Patient Name	Patient name.
Server	AE Title of server.
MBytes	For storage operations, indicates size of entry.
State	For storage operations, indicates archive status: <ul style="list-style-type: none"> ▪ None ▪ Stored ▪ Committed

The selections available for the print and store queue pages are described below:

Selection	Description
Delete Job	Deletes the highlighted queue entry. You can select and delete multiple queue entries.
Back	Displays the Study screen.
Retry Job	Attempts to resend the selected queue entry.
Time Sent	Time at which the entry was sent.
Status	Queue status indicator.
Details	Error description.

Selections for Auto Left Heart

syngo Auto Left Heart Controls









Selection	Description
Flip Left/Right	Reorients the image view selection from left-to-right to right-to-left to match the orientation of the clip.
LV	Selects the left ventricle as the active chamber.
LA	Selects the left atrium as the active chamber.
A4C	Selects the apical four-chamber image view (non-contrast) for the displayed clip.
A2C	Selects the apical two-chamber image view (non-contrast) for the displayed clip.
A4C Contrast	Selects the contrast apical four-chamber image view for the displayed clip.
A2C Contrast	Selects the contrast apical two-chamber image view for the displayed clip.
Arrow key	When pressed, starts or stops play of the clip in the active view (ED or ES).
Left or right arrow key	Displays prior or next frame of the clip.
Up or down arrow key	Changes the gamma curve (brightness) of the active image.
Stop	Stops play of the clip.
<div style="display: flex; flex-wrap: wrap; gap: 5px;"> <div style="border: 1px solid black; padding: 2px 5px;">1</div> <div style="border: 1px solid black; padding: 2px 5px;">2</div> <div style="border: 1px solid black; padding: 2px 5px;">3</div> <div style="border: 1px solid black; padding: 2px 5px;">4</div> <div style="text-align: center;">⋮</div> <div style="text-align: center;">⋮</div> </div>	Indicates the selected heart cycle from multiple-cycle clips.
DEPTH/ZOOM control	Toggles between zoom factors for the 2-D images.
Show Trace	Hides or displays the outlines and their long axes, including any markers on the images. Calculation data and measurement values continue to display at the bottom of the screen.
Auto/Manual	Toggles the automatic trace method with the manual trace method for generating an outline. Note: If you create a trace and toggle between Auto and Manual before saving the trace, the program deletes the trace so you can start over.
Guided/ Manual	Available for contrast studies only. Toggles the guided trace method with the manual trace method for generating an outline. Note: If you create a trace and toggle between Guided and Manual before saving the trace, the program deletes the trace so you can start over.
Apply	Available for non-contrast studies only, when a trace is displayed on both the ED and ES frames and after changes to the border are made. Applies the <i>syngo</i> Auto Left Heart algorithm to all frames in the clip.














Selection	Description
SET ED	Selects the currently displayed frame as the representative frame for the End Diastole image.
SET ES	Selects the currently displayed frame as the representative frame for the End Systole image.
Backup	Erases the most recent segment or marker of a user-created outline. Available during tracing of a new outline and before the outline is complete.
Mark	Activates the mark function for creating an outline from positioned points along the border.
Draw	Activates the trace drawing function for creating an outline.
End Trace	Completes the manual marking of LV or LA border points and calculates the results.
Change Units	Toggles the units displayed in calculations and the volume graph. Units available are ml and ml/m ² .
Close	Exits the Volume Range Selector or BSA Calculator dialog box without saving changes.
Save&Close	Exits the Volume Range Selector or BSA Calculator dialog box and saves changes.
Save	Saves the calculation data and measurements to a findings record on the <i>syngo</i> US Workplace desktop.
Exit	Exits <i>syngo</i> Auto Left Heart.

Soft Key Selections for Auto Left Heart



Selection	Description
Softkey1	Activates the first function box.
Softkey2	Activates the second function box.
Softkey3	Activates the third function box.
Softkey4	Activates the fourth function box.

syngo VVI Controls

Icon	Selection	Description
—	Exit	Exits the module.
	Strain/Velocity Measurement Window	Displays velocity, strain, and strain rate information in the Strain/Velocity Measurement window.
	Global Measurements Window	Displays ejection fraction (EF), Dmin, Dmax, volume, and segmental volume information in the Global Measurement window. Note: This selection may not be available for traces processed using the Generic Curve processing algorithm.
	Dyssynchrony analysis	Displays peak and timing information (such as time-to-peak values) related to strain, strain rate, velocity, or displacement in the Dyssynchrony window. Note: This selection may not be available for traces processed using the Generic Curve processing algorithm.
—	Long Axis	Selects the Long Axis algorithm for processing the trace.
—	Short Axis	Selects the Short Axis algorithm for processing the trace.
—	Generic Curve	Selects the Generic Curve algorithm for processing the trace.
—	Average Heart Cycle	When selected (enabled), calculates and displays the motion parameters for the average heart cycle by averaging the values from the multiple R-R intervals. Note: This selection is available for multiple-cycle clips, after processing only.
—	Endo+Epi	When selected (enabled), displays a second trace outside the endocardium trace. Required to calculate radial strain and radial strain rate.
	—	Restores the original gamma image setting.
—	Gamma	Adjusts the gamma image setting (changes both brightness and contrast).
	Process Images	Calculates velocity vector data for the selected trace.
	New Trace	Activates the tracing (outlining) function and removes the displayed trace (if any) from the window.
	—	Increases or decreases the distance between the endo/epi traces. Only visible when creating or editing endo/epi traces.
	Bkg MMode display	Adds or removes the M-mode display from graphs.

Icon	Selection	Description
	Toggle Pan/Zoom	Changes the size of the displayed clip.
	Edit trace	Activates or deactivates the editing function. When the editing function is active, points within the trace are available for repositioning.
	Shorter Arrows	Decreases the length of the velocity vectors in two-pixel increments.
	No Arrows	Cycles through display settings for velocity vectors: <ul style="list-style-type: none"> ▪ Display velocity vectors ▪ Hide velocity vectors ▪ Display trajectory of segments of tissue over time ▪ Hide velocity vectors and trace (contour)
	Longer Arrows	Increases the length of the velocity vectors in two-pixel increments.
	Restore the Graphs Aspect	Displays all curves on the curve plot.
	Toggle Original Border Points to Equispaced Points x4	Toggles display of the user-defined trace points with display of the program-generated trace points.
	M-mode, R-waves, Crop	Displays the M-mode, R-Waves, Crop window where you can: <ul style="list-style-type: none"> ▪ View clip in M-mode ▪ Add, move, or delete R-wave indicators ▪ Crop long clips
	Toggle Filtered/Unfiltered Plots	Adjusts the smoothing in curves on all curve plots (all windows).
	Export	Exports an image or clip to a storage device, network destination, or to the system's hard disk.
—	(slider at lower left)	Positions the clip frame within the clip window.
—	Slow	Slows playback of a clip.
	Play/Stop	Starts and stops playback of a clip. This is a toggle control.
	Next Frame	Displays the next frame of a clip.
	Previous Frame	Displays the previous frame of a clip.
—	History	Displays a button for each trace.
—	Delete	Removes the displayed trace from the window.

Strain/Velocity Measurement Window






Icon	Selection	Description
—	Row by Row	Displays curves for all points in the parametric M-mode graphs.
—	Delete Stored Points	Removes all selected points from the parametric M-mode graphs and associated curves.
—	Zoom	Magnifies the selected curve plots to a full-screen display.
—	Velocity	Selects the velocity curve plot for magnification.
—	Strain	Selects the strain curve plot for magnification.
—	Strain Rate	Selects the strain rate curve plot for magnification.
—	3D	Displays the 3-D window including the 3-D rendering of information in the related parametric M-mode graph.
	Toggle Filtered/Unfiltered Plots	Adjusts the smoothing in curves on all curve plots (all windows).
	Export	Saves an image or clip to a storage device, network destination, or to the system's hard disk.
—	Close	Exits the displayed window and redisplay the VVI window.

3D Window and Magnification Window


The following selections are displayed on the 3D window and the magnification window accessed from the Strain/Velocity Measurement window.

Selection	Description
Export	Exports an image or clip to a storage device, network destination, or to the system's hard disk.
Close	Exits the displayed window and redisplay the VVI window.

Global Measurements Window



Icon	Selection	Description
—	All the Curves	When selected (enabled), displays curves for all traces. When unselected, displays curves for the current trace only.
	Toggle Filtered/Unfiltered Plots	Adjusts the smoothing in curves on all curve plots (all windows).
	Export	Exports an image or clip to a storage device, network destination, or to the system's hard disk.
	Play/Stop	Starts and stops playback of a clip. This is a toggle control.
	Next Frame	Displays the next frame of a clip.
	Previous Frame	Displays the previous frame of a clip.
—	LAX Calc Area	Displays only if Long Axis is select on the VVI window. When selected (enabled), calculates the area enclosed by the trace.
—	Close	Exits the displayed window and redisplay the VVI window.

M-mode, R-waves, Crop Window

Icon	Selection	Description
—	Gamma	Adjusts the gamma image setting (changes both brightness and contrast).
	—	Restores the original gamma image setting.
—	Reset	Removes the currently displayed free-form M-mode trace.
—	Reverse Colors	Toggles black-on-white display with white-on-black display.
—	Bpm	Displays beats per minute. Changes as you add or delete an R-wave.
—	Period Selector	Displays R-waves. Displays selected M-mode background for viewing on plots, behind curves. Time bars on either end are used to crop the clip.
—	Close	Exits the displayed window and redisplay the VVI window.

Dyssynchrony Analysis Window

Icon	Selection	Description
—	Time To Peak	Identifies the highest point on each curve for all parameters except strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential. Identifies the lowest point on each curve for these parameters: strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential.
—	Time to 75%	Identifies the point that is 75% of the highest point on each curve for all parameters except strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential. Identifies the point that is 75% of the lowest point on each curve for these parameters: strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential.
—	Time to 50%	Identifies the point that is 50% of the highest point on each curve for all parameters except strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential. Identifies the point that is 50% of the lowest point on each curve for these parameters: strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential.
—	Reverse Peak	For all parameters except strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential, identifies the lowest point, the point that is 75% of the lowest point, or the point that is 50% of the lowest point as determined by the "Time To" selection. For parameters strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential, identifies the highest point, the point that is 75% of the highest point, or the point that is 50% of the highest point as determined by the "Time To" selection.
—	R-R	Moves from beat to beat with each click in a continuous cycle. Disabled if only one beat is captured.
—	Velocity	Computes and displays values for the selected parameter: <ul style="list-style-type: none"> ▪ Longitudinal (longitudinal velocity). Long axis and generic curve views only. ▪ Rotation (rotation rate). Counterclockwise rotation is positive. Short axis views only. ▪ Radial (radial velocity).
—	Strain	Computes and displays values for the selected parameter: <ul style="list-style-type: none"> ▪ Longitudinal (strain longitudinal). Long axis and generic curve views only. ▪ Circumferential (strain circumferential). Short axis views only. ▪ Radial (radial strain). Requires endo/epi traces.

Icon	Selection	Description
—	Strain Rate	Computes and displays values for the selected parameter: <ul style="list-style-type: none"> ▪ Longitudinal (strain rate longitudinal). Long axis and generic curve views only. ▪ Circumferential (strain rate circumferential). Short axis views only. ▪ Radial (radial strain rate). Requires endo/epi traces.
—	Displacement	Computes and displays values for the selected parameter: <ul style="list-style-type: none"> ▪ Longitudinal (longitudinal displacement) Long axis and generic curve views only. ▪ Rotation (Rotation). Short axis views only. ▪ Radial (radial displacement)
—	All Curves	When selected (enabled), displays all curves. When cleared (disabled), displays selected curves only. Note: Data on the window includes values for the displayed curves only.
	Toggle Filtered/Unfiltered Plots	Adjusts the smoothing in curves on all curve plots (all windows).
—	Zoom	Magnifies the graph. Click Close to return to the Dyssynchrony Analysis window.
	Export	Exports an image or clip to a storage device, network destination, or to the computer's hard disk.
—	Close	Exits the displayed window and redisplay the VVI window.

Selections used in the Axius-EF Feature

Axius-EF uses selections on the Axius-EF screen.

Axius-EF Screen

Selections on the Axius-EF screen include options in the **Specify View** dialog box and heart cycle buttons on the lower left of the screen.

Specify View Dialog Box

The system displays the **Specify View** dialog box when you activate Axius-EF. This dialog box contains the following selections:

- **A4C**: Apical four-chamber view of the heart.
- **A2C**: Apical two-chamber view of the heart.

Heart Cycle Buttons

The system displays up to five heart cycle buttons on the lower left of the screen, depending on the number of heart cycles that the system detects in the clip. You can select a heart cycle button to view its clip frames.

Each heart cycle button is labeled with a number, representing a heart cycle in the clip. For example, the heart cycle button labeled **1** represents the first heart cycle, which begins with the first frame of the clip.

The heart cycle buttons are initially gray. When the Axius-EF measurements for a heart cycle are transferred to the patient report, the related heart cycle button becomes white.

The system retains the frame number of each frame in the clip; each heart cycle begins with the frame after the last frame in the previous heart cycle. For example, in a clip containing two heart cycles, if the first heart cycle ends with frame 14, then the second heart cycle begins with frame 15. The last heart cycle ends with the last frame in the clip.

Soft Key Selections for Axius-EF

Selection	Description
A4C	Selects the apical four-chamber view of the heart. Displayed when you activate Axius-EF.
A2C	Selects the apical two-chamber view of the heart. Displayed when you activate Axius-EF.
Set ED	Selects the displayed frame as the new representative frame for the End Diastolic image.
Set ES	Selects the displayed frame as the new representative frame for the End Systolic image.
Recall ED	Retrieves for display the currently selected representative frame for the End Diastolic image.
Recall ES	Retrieves for display the currently selected representative frame for the End Systolic image.
Manual	For Trace , traces the left ventricle using your drawn depiction. For Mark , traces the left ventricle using your specified changes of direction.
Guided	Traces the left ventricle using your specified mitral annulus boundaries and apex.
Mark	Creates or modifies the selected element (long axis or border).
Trace	Creates or modifies the selected element (long axis or border).
Undo	Removes the outline (border and long axis) on the selected image, or removes the border adjustment in progress.
Redo	Cancels the previous removal of border adjustment action.
End	Anchors the marker as an end point of the border or border adjustment.
Delete	Removes the outline (border and long axis) on the selected image, or removes the border adjustment in progress.
Axis	Activates the long axis for modification.
Border	Activates the border for creation or modification.
Enter	Transfers the detected heart rate and the calculation values displayed at the bottom of the screen into the patient report.
Exit	Exits Axius-EF.

Screen Controls — AHP

Controls consist of on-screen selections, keys on the alphanumeric keyboard, and keys on the system control panel.

AHP Screen – Navigation Panel

The navigation panel displays on the upper right of the AHP screen.















Icon	Selection (Tool Tip)	Description
	IMT Border	Displays the IMT screen with the Image Quality Panel and the IMT Editing Tools Panel.
	Distensibility/ Elasticity	Displays the screen for determining distensibility and elasticity only when the currently displayed clip or image contains an ECG trace.
	Reports	Displays the IMT report and report selections.
	Setup	Displays the AHP Setup screen.
	Exit	Exits the AHP program.

Image Quality Panel

The image quality panel displays on the right of the screen.

Icon	Selection (Tool Tip)	Description
	Prior	Displays the previous frame of the clip.
	Run	Starts playback of the displayed clip.
	Stop	Stops playback of the displayed clip.
	Next	Displays the next frame of the clip.
	Zoom +	Magnifies the current clip or frame.
	Zoom -	Minimizes the current clip or frame.
	Pan	Positions the current clip or frame in the window.
	Contrast (slider)	Adjusts the difference between the light and dark shades.
	Brightness (slider)	Lightens or darkens shades.





IMT Editing Tools Panel

Tools for editing the borders of the IMT display on the right of the screen and are available after establishing the IMT ROI.





Selections

Selection	Description	Settings
Wall (drop-down list)	Specify the default setting of the first wall for evaluation.	Far Near




Far Wall Tools

Button	Tool Tip	Description
	Edit lumen-intima	Activates the edit function for the far lumen-intima boundary. Note: This button is also available as a selection for determining distensibility and elasticity.
	Edit media-adventitia	Activates the edit function for the far media-adventitia boundary. Note: This button is also available as a selection for determining distensibility and elasticity.
	Manual trace lumen-intima	Activates the manual trace function for the far lumen-intima boundary.
	Manual trace media-adventitia	Activates the manual trace function for the far media-adventitia boundary.

Near Wall Tools

Button	Tool Tip	Description
	Edit lumen-intima	Activates the edit function for the near lumen-intima boundary. Note: This button is also available as a selection for determining distensibility and elasticity.
	Edit media-adventitia	Activates the edit function for the near media-adventitia. Note: This button is also available as a selection for determining distensibility and elasticity.
	Manual trace lumen-intima	Activates the manual trace function for the near lumen-intima boundary.
	Manual trace media-adventitia	Activates the manual trace function for the near media-adventitia boundary.

Trace Editing Tools

Button	Tool Tip	Description
	Clear borders	Deletes the current border and the IMT ROI. Note: This button is also available as a selection for determining distensibility and elasticity.
	Toggle exclude frame	Exclude or include a specific frame from analysis and quantification.
	Undo Edit	Discards the most recent edit. Note: This button is also available as a selection for determining distensibility and elasticity.
—	Save IMT	Saves data into the report.

Soft Key Selections for *syngo* Arterial Health Analysis Package

Selection	Description
IMT	Activates the <i>syngo</i> Arterial Health Analysis software program (AHP).
Exit	Exits the <i>syngo</i> Arterial Health Analysis software program (AHP).

Soft Key Selections for Intima-Media Thickness (IMT) Reports

Selection	Description
[Exit]	Closes the report page and activates 2D-mode.
[Export]	Exports the report and worksheet to a connected USB storage device.
[Print Preview]	Displays the report in a printing format.
[Print]	Prints the report.

Appendix D Acoustic Output Reference

Display Resolution and Measurement Accuracy	3
Default Displayed MI and TI Values by Transducer.....	4
IEC 61157 Acoustic Output Reporting	5
Legend.....	5
Track 3, FDA 510(k) and IEC 60601-2-37 Acoustic Output Reporting	13
Summary Table for Acoustic Output.....	13
Definitions.....	14
Legend.....	15

Display Resolution and Measurement Accuracy

For any transducer capable of exceeding a mechanical or thermal index value of 1.0, the ultrasound imaging system displays indices starting from 0.4. The resolution of the display is 0.1 for all displayed values of MI. For all TI values, the resolution of the display is 0.2.

It is important to note that displayed indices are obtained through measurement, and are subject to measurement errors. Specific measurement uncertainties for acoustic power, pressure, and center frequency are 3.7%, 8.5%, and 2.0% respectively. Measurement precision for ultrasonic power, peak rarefactional pressure, and center frequency from a standard test transducer/driver combination is 5.1%, 4.8%, and 0.2% respectively. The reported values assume 90% population (P) at 90% confidence level (γ). Definitions for these parameters can be found in the 1998 AIUM/NEMA document entitled Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment – Revision 1 (also known as the Output Display Standard).

Default Displayed MI and TI Values by Transducer

(Per transducer/mode that exceeds default MI or TI value of 0.4)

Transducer	Mode											
	B		M		PwD		SCw		Color		CwD	
	MI	TI	MI	TI	MI	TI	MI	TI	MI	TI	MI	TI
CH5-2	-	-	-	-	-	0.8(S ¹) 2.5(B ²)	-	-	-	-	-	-
C8-5	0.9	-	-	0.4(S ¹)	-	0.6(S ¹) 1.3(B ²)	-	-	-	-	-	-
VF8-3	0.7	-	-	0.4(S ¹)	-	1.5(B ²)	-	-	-	-	-	-
VF10-5	0.8	-	-	1.4(S ¹) 1.3(B ²)	-	0.9(B ²)	-	-	0.4 (S ¹ , B ²)	-	-	-
VF13-5	0.5	-	-	-	-	0.6(B ²)	-	-	-	-	-	-
VF13-5SP	0.4	-	-	1.2(S ¹) 1.1(B ²)	-	1.6(S ¹) 2.0(B ²)	-	-	-	2.0 (S ¹ , B ²)	-	-
EV9-4	0.7	-	-	-	-	0.6(S ¹) 1.4(B ²)	-	-	-	-	-	-
EC9-4	1.1	-	-	0.4 (S ¹ , B ²)	-	0.5(S ¹) 1.5(B ²)	-	-	-	-	-	-
P4-2	0.8	-	-	0.6 (S ¹ , B ²)	-	0.8(S ¹) 3.5(B ²)	-	1.3(S ¹) 3.8(B ²)	-	0.9 (S ¹ , B ²)	-	-
P5-1	1.2	-	-	0.7(S ¹) 0.8(B ²)	-	1.0(S ¹) 2.8(B ²)	-	1.0(S ¹) 1.5(B ²)	-	1.0(S ¹) 2.6(B ²)	-	-
P8-4	0.8	-	-	0.6 (S ¹ , B ²)	-	0.8(S ¹) 2.1(B ²)	-	0.7(S ¹) 1.9(B ²)	-	0.8 (S ¹ , B ²)	-	-
V5Ms	0.7	-	-	0.4(S ¹) 0.4(B ²)	-	0.6(S ¹) 2.1(B ²)	-	0.4(S ¹) 0.8(B ²)	-	0.5(S ¹) 0.5(B ²)	-	-
CW2	-	-	-	-	-	-	-	-	-	-	-	0.4(S ¹) 1.2(B ²)
CW5	-	-	-	-	-	-	-	-	-	-	-	0.7(B ²)

S¹: Soft Tissue Thermal Index, B²: Bone Thermal Index

IEC 61157 Acoustic Output Reporting

Legend

English	Translations for languages other than English
Acoustic Output Reference	n/a
IEC 61157 Acoustic Output Reporting	n/a
Acoustic output information for the Siemens ACUSON X300 ultrasound imaging system.	n/a
Phased Array Transducer	n/a
Curved Array Transducer	n/a
Linear Array Transducer	n/a
Continuous Wave Transducer	n/a
Type	n/a
Manufacturer:	n/a
Parameter	n/a
Mode	n/a
System settings	n/a
Frequency	n/a
Output Power	n/a
Output beam dimensions	n/a
Maximum power	n/a
Power-up Mode	n/a
Initialization Mode	n/a
Acoustic Output Freeze	n/a
n/a (not applicable)	n/a
Inclusive modes	n/a
a Acoustic power-up fraction	n/a
b Acoustic initialization fraction	n/a
Acoustic output information is presented according to the recommendations of the International Electrotechnical Commission (IEC) as expressed in IEC 61157.	n/a

Acoustic output information for the Siemens ACUSON X300 ultrasound imaging system. **Curved Array Transducer. Type: CH5-2**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		3.7	3.4	3.9	3.2	4.5	1.6	4.0	3.4
I_{spta} (mW/cm ²)		58	543	447	763	188	1505	47	485
System settings:	Frequency(MHz)	2.5	3.6	2.7	2.7	3.6	2.5	2.5	3.6
	Focus(Cm)	4.0	16	16	16	13	8.0	13	16
	Output Power (%)	100	100	100	100	100	100	100	100
I_p (mm)		39	139	136	136	123	67	112	139
W_{pbs}	() (mm)	1.9	4.0	4.7	4.7	2.9	2.0	4.0	4.0
	(⊥) (mm)	4.3	6.0	5.7	5.7	5.4	2.8	5.0	6.0
prr (kHz)						3.4	4.9	3.3	4.1
srr (Hz)		48	48	4	225				
Output beam dimensions (mm)		10 x 14	31 x 14	31 x 14	31 x 14	26 x 14	19 x 14	28 x 14	31 x 14
f_{awf} (MHz)		2.8	3.0	2.4	2.4	3.3	2.4	2.5	3.0
APF ^a (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
ALF ^b (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Maximum power (mW)		37	83	21	30	45	69	8.1	69
I_{ob} (mW/cm ²)		27	19	5.0	7	12	26	2.1	16
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes						B+D	B+D	B+M	B+M
						B+C+D	B+C+D		
a Acoustic power-up fraction									
b Acoustic initialization fraction									

Acoustic output information for the Siemens ACUSON X300 ultrasound imaging system. **Curved Array Transducer. Type: C8-5**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		4.4	2.4	4.0	1.8	4.0	1.2	4.7	4.2
I_{spta} (mW/cm ²)		24.8	89.6	59.2	198.1	175.9	1078.7	65.3	123.0
System settings:	Frequency(MHz)	5.7	4.7	4.2	4.2	4.2	4.2	5.7	4.7
	Focus(Cm)	2.0	3.0	2.0	4.0	2.0	3.0	2.0	3.0
	Output Power (%)	100	100	100	100	100	100	100	100
I_p (mm)		14	20	19	31	19	26	14	20
W_{pbs}	() (mm)	1.1	1.7	0.87	1.7	0.86	1.2	1.1	1.7
	(⊥) (mm)	0.8	1.1	1.1	1.8	1.1	1.6	0.8	1.1
prr (kHz)						0.1	12.0	4.5	4.5
srr (Hz)		46	120	96	587				
Output beam dimensions (mm)		5.0 x 5.0	7.7 x 5.0	10.2 x 5.0	10.2 x 5.0	10.2 x 5.0	10.2 x 5.0	5.0 x 5.0	7.7 x 5.0
f_{awf} (MHz)		5.8	4.9	4.4	4.3	4.3	4.3	5.8	4.9
APF ^a (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
ALF ^b (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Maximum power (mW)		16.8	13.2	5.3	10.7	3.9	33.9	2.6	7.2
I_{ob} (mW/cm ²)		67.8	34.3	10.3	20.9	7.6	66.1	10.3	18.8
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes						B+D	B+D	B+M	B+M
						B+C+D	B+C+D		
a Acoustic power-up fraction									
b Acoustic initialization fraction									

Acoustic output information is presented according to the recommendations of the International Electrotechnical Commission (IEC) as expressed in IEC 61157.

Acoustic output information for the Siemens ACUSON X300 ultrasound imaging system. **Linear Array Transducer. Type: VF8-3**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		3.7	2.9	3.4	2.9	3.1	2.0	4.1	2.7
I_{spta} (mW/cm ²)		57.4	137.1	62.6	411.2	72.4	1123.7	57.2	176.2
System settings:	Frequency(MHz)	4.0	4.0	4.0	3.1	3.1	4.0	4.0	4.0
	Focus(Cm)	2.0	5.0	3.0	7.0	3.0	4.0	3.0	4.0
	Output Power (%)	100	100	100	100	100	100	100	100
I_p (mm)		16	39	23	59	20	27	21	28
W_{pb6}	() (mm)	1.3	1.8	1.3	1.7	1.6	1.7	1.5	1.8
	(⊥) (mm)	1.2	2.1	1.4	4.2	1.5	1.5	1.2	1.5
prf (kHz)						0.1	2.8	12.2	12.2
srr (Hz)		41	30	49	82				
Output beam dimensions (mm)		5.0 x 6.2	12.6 x 6.2	10.0 x 6.2	18.8 x 6.2	7.0 x 6.2	9.7 x 6.2	7.6 x 6.2	10.0 x 6.2
f_{awf} (MHz)		4.4	4.0	3.9	3.0	3.1	3.9	4.3	4.1
APF ^a (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
AIF ^b (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Maximum power (mW)		21.0	21.2	5.4	13.2	2.1	28.2	2.9	4.1
I_{ob} (mW/cm ²)		68.1	27.1	8.8	11.3	4.7	47.0	6.2	6.6
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes						B+D	B+D	B+M	B+M
						B+C+D	B+C+D		
a	Acoustic power-up fraction								
b	Acoustic initialization fraction								

Acoustic output information for the Siemens ACUSON X300 ultrasound imaging system. **Linear Array Transducer. Type: VF10-5**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		4.4	3.5	4.8	3.9	3.7	1.9	4.6	3.7
I_{spta} (mW/cm ²)		33	559	326	1373	943	1701	34	175
System settings:	Frequency(MHz)	4.7	4.0	6.2	6.2	5.3	6.2	6.2	8.0
	Focus(Cm)	2.0	7.0	5.0	5.0	5.0	4.0	4.0	5.0
	Output Power (%)	100	100	100	100	100	100	100	100
I_p (mm)		15	62	46	46	37	27	36	46
W_{pb6}	() (mm)	0.92	1.1	0.8	0.8	1.4	1.5	0.86	0.73
	(⊥) (mm)	0.95	4.0	2.8	2.8	2.0	1.3	2.3	3.3
prf (kHz)						2.8	13	12	10
srr (Hz)		31	86	49	238				
Output beam dimensions (mm)		4.4 x 5.0	13 x 5.0	11 x 5.0	11 x 5.0	7.8 x 5.0	6.2 x 5.0	6.6 x 5.0	8.2 x 5.0
f_{awf} (MHz)		5.5	4.3	6.1	6.1	5.3	6.1	6.5	6.7
APF ^a (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
AIF ^b (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Maximum power (mW)		9.5	162	9.4	23	23	22	7.3	117
I_{ob} (mW/cm ²)		43	253	17	41	59	72	22	283
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes						B+D	B+D	B+M	B+M
						B+C+D	B+C+D		
a	Acoustic power-up fraction								
b	Acoustic initialization fraction								

Acoustic output information is presented according to the recommendations of the International Electrotechnical Commission (IEC) as expressed in IEC 61157.

Acoustic output information for the Siemens ACUSON X300 ultrasound imaging system. **Linear Array Transducer. Type: VF13-5**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		3.7	2.8	4.9	3.8	4.9	3.0	3.2	2.9
I_{spta} (mW/cm ²)		159	366	286	866	52	2411	18	204
System settings:	Frequency(MHz)	5.3	5.3	7.3	7.3	7.3	7.3	7.3	11.4
	Focus(Cm)	3.0	4.0	4.0	4.0	4.0	4.0	1.0	4.0
	Output Power (%)	100	100	100	100	100	100	100	100
I_p (mm)		26	35	37	37	37	37	6	35
W_{pbs}	() (mm)	0.8	0.9	0.7	0.6	0.7	0.7	0.7	0.7
	(⊥) (mm)	2.3	3.1	2.8	2.8	2.8	2.8	0.8	2.0
prr (kHz)						0.1	13	12	9.1
srr (Hz)		41	94	51	258				
Output beam dimensions (mm)		9.9 x 2.5	9.9 x 2.5	13 x 2.5	13 x 2.5	13 x 2.5	13 x 2.5	2.4 x 2.5	9.9 x 2.5
f_{awf} (MHz)		6.0	5.5	7.3	7.3	7.3	7.3	8.7	9.6
APF ^a (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
ALF ^b (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Maximum power (mW)		9.9	14	6.7	19	1.5	54	0.2	4.8
I_{ob} (mW/cm ²)		40	44	20	57	4.4	163	4.0	19
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes						B+D	B+D	B+M	B+M
						B+C+D	B+C+D		
a	Acoustic power-up fraction								
b	Acoustic initialization fraction								

Acoustic output information for the Siemens ACUSON X300 ultrasound imaging system. **Linear Array Transducer. Type: VF13-5SP**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		2.7	2.5	4.3	3.4	4.6	1.3	2.7	2.5
I_{spta} (mW/cm ²)		28	78	61.3	349	66	1158	12	13
System settings:	Frequency(MHz)	7.3	7.3	7.3	6.2	7.3	7.3	7.3	7.3
	Focus(Cm)	1.5	3.0	4.0	4.0	4.0	2.0	3.0	2.0
	Output Power (%)	100	100	100	100	100	100	100	100
I_p (mm)		9	23	37	38	38	15	23	13
W_{pbs}	() (mm)	1.0	1.0	0.8	0.8	0.7	0.9	1.0	1.0
	(⊥) (mm)	0.9	1.7	2.6	2.9	2.6	1.3	1.7	1.1
prr (kHz)						0.1	20	9.3	9.3
srr (Hz)		58	47	33	190				
Output beam dimensions (mm)		3.8 x 2.5	7.6 x 2.5	13 x 2.5	13 x 2.5	13 x 2.5	6.6 x 2.5	7.6 x 2.5	5.0 x 2.5
f_{awf} (MHz)		8.4	7.9	7.2	6.4	7.2	7.3	7.9	8.2
APF ^a (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
ALF ^b (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Maximum power (mW)		39	56	20	85	9.3	115	3.0	1.8
I_{ob} (mW/cm ²)		407	295	63	266	29	700	15	14
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes						B+D	B+D	B+M	B+M
						B+C+D	B+C+D		
a	Acoustic power-up fraction								
b	Acoustic initialization fraction								

Acoustic output information is presented according to the recommendations of the International Electrotechnical Commission (IEC) as expressed in IEC 61157.

Acoustic output information for the Siemens ACUSON X300 ultrasound imaging system. **Curved Array Transducer. Type: EV9-4**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		3.5	2.5	4.2	2.6	4.3	1.3	4.3	2.2
I_{spta} (mW/cm ²)		19	58	3.3	307	3.4	1051	64	85
System settings:	Frequency(MHz)	5.0	5.0	5.0	4.0	5.0	5.3	5.0	5.0
	Focus(Cm)	2.0	6.0	4.0	6.0	2.0	3.0	2.0	4.0
	Output Power (%)	100	100	100	100	100	100	100	100
I_p (mm)		15	201	30	42	15	21	15	30
W_{pb6}	() (mm)	1.3	2.1	1.9	2.3	1.1	1.4	1.1	1.9
	(⊥) (mm)	1.6	1.2	1.9	2.1	1.9	1.1	1.9	1.9
ρ_{rr} (kHz)						15	14	7.3	12
s_{rr} (Hz)		35	95	7	232				
Output beam dimensions (mm)		4.0 x 8.0	5.3 x 8.0	4.8 x 8.0	13 x 8.0	5.1 x 8.0	7.7 x 8.0	5.0 x 8.0	10 x 8.0
f_{avef} (MHz)		4.8	4.7	5.0	3.9	5.0	5.1	5.0	4.8
APF ^a (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
AIF ^b (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Maximum power (mW)		24	17	6.6	19	7.6	15	2.7	22
I_{ob} (mW/cm ²)		75	40	17	19	19	25	6.8	27
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{ti} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes						B+D	B+D	B+M	B+M
						B+C+D	B+C+D		
a	Acoustic power-up fraction								
b	Acoustic initialization fraction								

Acoustic output information for the Siemens ACUSON X300 ultrasound imaging system. **Curved Array Transducer. Type: EC9-4**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		3.6	2.3	4.2	2.0	4.2	1.4	4.2	2.3
I_{spta} (mW/cm ²)		35	99	8.4	328	8.7	1095	30	93
System settings:	Frequency(MHz)	5.0	5.0	5.0	5.3	5.0	5.3	5.0	5.0
	Focus(Cm)	2.0	4.0	2.0	4.0	2.0	3.0	2.0	4.0
	Output Power (%)	100	100	100	100	100	100	100	100
I_p (mm)		14	31	14	28	14	22	14	31
W_{pb6}	() (mm)	1.2	2.1	1.2	1.8	1.2	1.4	1.2	2.1
	(⊥) (mm)	1.7	1.8	1.7	1.2	1.7	1.0	1.7	1.8
ρ_{rr} (kHz)						15	14	6.8	12
s_{rr} (Hz)		35	95	7	521				
Output beam dimensions (mm)		5.1 x 8.0	10 x 8.0	2.9 x 8.0	9.8 x 8.0	5.1 x 8.0	7.8 x 8.0	5.1 x 14	10 x 8.0
f_{avef} (MHz)		4.8	4.7	4.8	5.1	4.9	5.2	4.8	4.7
APF ^a (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
AIF ^b (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Maximum power (mW)		27	38	8.7	11	14	18	3.3	34
I_{ob} (mW/cm ²)		65	45	38	15	34	29	8.0	40
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{ti} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes						B+D	B+D	B+M	B+M
						B+C+D	B+C+D		
a	Acoustic power-up fraction								
b	Acoustic initialization fraction								

Acoustic output information is presented according to the recommendations of the International Electrotechnical Commission (IEC) as expressed in IEC 61157.

Acoustic output information for the Siemens ACUSON X300 ultrasound imaging system. **Phased Array Transducer. Type: P4-2**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi	SCWp	SCWi
p_- (MPa)		3.0	2.0	3.8	1.9	4.1	2.0	4.0	2.6	0.2	0.2
I_{spta} (mW/cm ²)		73	397	19	64	41.9	1284	38	361	918	918
System settings: Frequency(MHz)		2.5	3.6	3.1	2.5	3.1	2.7	3.1	3.6	2.0	2.0
	Focus(Cm)	3.0	15.0	5.0	18.0	5.0	7.0	5.0	11.0	9.0	9.0
	Output Power (%)	100	100	100	100	100	100	100	100	100	100
I_p (mm)		25	79	51	67	51	54	49	79	44	44
W_{pbe}	() (mm)	1.3	4.4	1.4	4.6	1.4	1.7	1.3	2.6	4.4	4.4
	(⊥) (mm)	7.7	3.6	5.8	2.8	5.8	3.2	5.8	3.2	3.0	3.0
ρ_{rr} (kHz)						7.6	2.6	3.6	3.7	3.7	3.7
s_{rr} (Hz)		62	37	6	213						
Output beam dimensions (mm)		15.0x14.0	17.0x14.0	17.0x14.0	17.0x14.0	17.0x14.0	17.0x14.0	17.0x14.0	17.0x14.0	7.5x14.0	7.5x14.0
f_{awf} (MHz)		2.6	3.1	2.8	2.4	2.8	2.6	2.8	3.1	2.0	2.0
APF ^a (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
AIF ^b (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Maximum power (mW)		87	57	53	74	34	80	14	50	137	137
I_{ob} (mW/cm ²)		41	24	23	32	14	34	5.9	22	129	129
Power-up mode		B	B	B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{ti} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes						B+D	B+D	B+M	B+M		
						B+C+D	B+C+D				
a Acoustic power-up fraction b Acoustic initialization fraction											

Acoustic output information for the Siemens ACUSON X300 ultrasound imaging system. **Phased Array Transducer. Type: P5-1**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi	SCWp	SCWi
p_- (MPa)		3.2	1.5	1.4	1.4	2.4	0.9	4.1	4.1	0.1	0.1
I_{spta} (mW/cm ²)		5.3	25.2	7.0	7.0	511	1087	76.6	76.6	350.3	388.0
System settings: Frequency(MHz)		4.0	2.2	2.2	2.2	2.2	2.7	2.7	2.7	2.2	2.2
	Focus(Cm)	15.0	13.0	4.78	4.78	6.48	5.00	9.0	9.0	15.0	5.5
	Output Power (%)	100	100	100	100	100	100	100	100	100	100
I_p (mm)		78	64	47	47	59	50	57	57	64	47
W_{pbe}	() (mm)	3.96	3.42	1.83	1.83	2.22	2.03	2.23	2.23	4.53	1.83
	(⊥) (mm)	2.36	2.81	3.81	3.81	3.08	3.39	3.28	3.28	3.36	3.81
ρ_{rr} (kHz)						0.10	9.77	0.38	0.38	8.68	8.68
s_{rr} (Hz)		45	70	139	139						
Output beam dimensions (mm)		15.4x14.0	15.4x14.0	12.0x14.0	12.0x14.0	15.4x14.0	12.5x14.0	15.4x14.0	15.4x14.0	15.4x14	12.5x14.0
f_{awf} (MHz)		3.45	2.31	2.13	2.13	2.16	2.57	2.64	2.64	2.12	2.13
APF ^a (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
AIF ^b (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Maximum power (mW)		74.19	47.28	55.26	55.26	14.58	84.92	30.24	30.24	93.57	93.47
I_{ob} (mW/cm ²)		34.5	21.98	32.9	32.9	6.78	48.61	14.06	14.06	43.51	53.50
Power-up mode		B	B	B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{ti} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes						B+D	B+D	B+M	B+M		
						B+C+D	B+C+D				
a Acoustic power-up fraction b Acoustic initialization fraction											

Acoustic output information is presented according to the recommendations of the International Electrotechnical Commission (IEC) as expressed in IEC 61157.

Acoustic output information for the Siemens ACUSON X300 ultrasound imaging system. **Phased Array Transducer. Type: P8-4**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi	SCWp	SCWi
p_- (MPa)		2.9	1.6	4.7	1.9	4.8	1.7	4.8	3.6	0.2	0.2
I_{spta} (mW/cm ²)		3.5	26	0.1	59	0.2	1201	21	43	806	856
System settings: Frequency(MHz)		5.3	3.8	5.3	3.6	5.3	4.4	5.3	3.8	3.6	3.6
	Focus(Cm)	3.0	9.0	4.0	8.0	4.0	4.0	4.0	7.0	5.0	3.0
	Output Power (%)	100	100	100	100	100	100	100	100	100	100
I_p (mm)		27	36	30	36	30	30	30	34	24	24
W_{pb6}	(l) (mm)	1.0	3.2	1.4	2.7	1.4	1.4	1.4	2.5	2.3	2.3
	(⊥) (mm)	2.5	2.1	2.2	2.0	2.2	2.1	2.2	2.0	2.2	2.2
ρ_{rr} (kHz)						8.7	12	6.0	6.0	8.2	8.2
s_{rr} (Hz)		34	58	2	467						
Output beam dimensions (mm)		9.6 x 8.0	9.6 x 8.0	9.6 x 8.0	9.6 x 8.0	9.6 x 8.0	9.6 x 8.0	9.6 x 8.0	9.6 x 8.0	4.4 x 8.0	4.4 x 8.0
f_{awf} (MHz)		4.3	3.7	4.3	3.6	4.3	4.2	4.3	3.7	3.6	3.6
APF ^a (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
AIF ^b (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Maximum power (mW)		46	27	35	41	54	47	12	13	42	42
I_{ob} (mW/cm ²)		60	35	45	54	70	61	16	17	120	120
Power-up mode		B	B	B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{ti} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes						B+D	B+D	B+M	B+M		
						B+C+D	B+C+D				
a Acoustic power-up fraction b Acoustic initialization fraction											

Acoustic output information for the Siemens ACUSON X300 ultrasound imaging system. **Phased Array Transducer. Type: V5Ms**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bi	Bp	Ci	Cp	Di	Dp	Mi	Mp	SCWp	SCWi
p_- (MPa)		1.9	1.4	1.4	1.3	0.9	0.8	3.2	2.3	0.1	0.1
I_{spta} (mW/cm ²)		2.4	9.4	0.7	9.0	481.2	521.3	2.1	14.5	122.9	122.9
System settings: Frequency(MHz)		5.7	4.0	3.6	3.6	3.6	3.6	4.0	4.0	3.6	3.6
	Focus(Cm)	11.0	9.0	2.50	4.97	4.46	3.0	2.0	9.0	7.0	7.0
	Output Power (%)	100	100	100	100	100	100	100	100	100	100
I_p (mm)		47	37	30	37	38	30	19	37	13	13
W_{pb6}	(l) (mm)	2.72	2.45	1.34	1.73	0.9	1.35	0.85	2.45	2.41	2.41
	(⊥) (mm)	1.24	1.48	2.31	1.80	3.88	2.32	4.00	1.48	3.33	3.33
ρ_{rr} (kHz)						0.10	13.02	0.38	0.38	0.10	0.10
s_{rr} (Hz)		67	209	331	331						
Output beam dimensions (mm)		9.6 x 7.7	9.6 x 7.7	9.6 x 7.7	9.6 x 7.7	9.6 x 7.7	9.6 x 7.7	9.6 x 7.7	9.6 x 7.7	9.6 x 7.7	9.6 x 7.7
f_{awf} (MHz)		5.64	4.28	3.74	3.78	3.68	3.65	4.28	4.28	3.62	3.62
APF ^a (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
AIF ^b (%)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Maximum power (mW)		18.24	23.07	5.61	19.45	19.40	30.48	5.39	5.4	19.25	19.25
I_{ob} (mW/cm ²)		24.68	31.21	7.59	26.32	26.25	41.23	7.29	7.3	26.05	26.05
Power-up mode		B	B	B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{ti} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		-	-	-	-	B+D	B+D	B+M	B+M		
						B+C+D	B+C+D				
a Acoustic power-up fraction b Acoustic initialization fraction											

Acoustic output information is presented according to the recommendations of the International Electrotechnical Commission (IEC) as expressed in IEC 61157.

Acoustic output information for the Siemens ACUSON X300 ultrasound imaging system. **Continuous Wave Transducer. Type: CW2**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	cwD
p_- (MPa)		0.1
I_{spta} (mW/cm ²)		189.7
System settings		
	Focus in mm	100
	Output in dB	0
I_p (mm)		12
W_{pbe}	() (mm)	5.3
	(⊥) (mm)	3.0
prr (kHz)		-
srr (Hz)		-
Output beam dimensions (mm)		8.8 x 8.7
f_{awf} (MHz)		2.0
APF ^a (%)		n/a
AIF ^b (%)		n/a
Maximum power (mW)		36.7
I_{ob} (mW/cm ²)		48.1
Power-up mode		CW
Initialization mode		n/a
Acoustic output freeze		Yes
I_{tt} (mm)		n/a
I_{ts} (mm)		Contact
Inclusive modes		-
a Acoustic power-up fraction		
b Acoustic initialization fraction		

Acoustic output information for the Siemens ACUSON X300 ultrasound imaging system. **Continuous Wave Transducer. Type: CW5**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	cwD
p_- (MPa)		0.1
I_{spta} (mW/cm ²)		536.0
System settings		
	Focus in mm	90
	Output in dB	0
I_p (mm)		23
W_{pbe}	() (mm)	1.3
	(⊥) (mm)	1.7
prr (kHz)		-
srr (Hz)		-
Output beam dimensions (mm)		5.9 x 5.4
f_{awf} (MHz)		5.0
APF ^a (%)		n/a
AIF ^b (%)		n/a
Maximum power (mW)		8.0
I_{ob} (mW/cm ²)		25.1
Power-up mode		CW
Initialization mode		n/a
Acoustic output freeze		Yes
I_{tt} (mm)		n/a
I_{ts} (mm)		Contact
Inclusive modes		-
a Acoustic power-up fraction		
b Acoustic initialization fraction		

Acoustic output information is presented according to the recommendations of the International Electrotechnical Commission (IEC) as expressed in IEC 61157.

Track 3, FDA 510(k) and IEC 60601-2-37 Acoustic Output Reporting

Data presented in Track 3 and IEC 60601-2-37 format represents the average MI/TI values for five transducers of each transducer model measured under worst-case acoustic output conditions. The on-screen MI/TI values are based on measurements on one transducer under worst-case acoustic output conditions – rounded up to the nearest display increment. It is possible that the values displayed on screen may exceed the MI/TI values presented in the Track 3 and IEC 60601-2-37 format.

Summary Table for Acoustic Output

An "X" indicates that either the MI index or TI indices is greater than 1.0 for each transducer/mode. A Track 3 and IEC 60601-2-37 format acoustic output table is supplied for each transducer/mode combination marked with an "X."

Operating Mode	Transducer Model													
	CH5-2	C8-5	VF8-3	VF10-5	VF13-5	VF13-5SP	EV9-4	EC9-4	P4-2	P5-1	P8-4	V5MS	CW2	CW5
B-mode (2D)	X	X	X	X	X	X	X	X	X	X	X			
M-mode	X			X	X	X	X	X	X		X			
Pulsed Doppler	X	X	X	X	X	X	X	X	X	X	X	X		
Color Flow or Power	X		X	X	X	X	X	X	X	X	X			
SCW									X	X	X			
CW Doppler													X	X

The following rules apply to the summary table:

B-mode (2D)	No other mode active. Only MI (when larger than 1.0) is reported for this mode.
M-mode	Includes simultaneous B-mode.
PW-Doppler	In duplex modes, the largest displayed TIS (scanned or non-scanned) is reported if it is larger than 1.0.
Color Flow or Power	Includes simultaneous color flow M-mode, B-mode, and Doppler. In combined modes, the largest displayed TIS (scanned or non-scanned) is reported if it is larger than 1.0.
Other	The output is reported as a separate mode if the largest formulation of TIS, TIB, or TIC (if an intended use) is greater than the corresponding value reported for all constituent modes. TIC is reported if the transducer is intended for transcranial or neonatal cephalic use.

Definitions

Symbol		Definition		Units
FDA	IEC	FDA	IEC	
MI	<i>MI</i>	Mechanical Index	Same as FDA	n/a
TIS _{scan}	<i>TIS Scan</i>	Soft Tissue Thermal Index in autoscanning mode	Same as FDA	n/a
TIS _{non-scan}	<i>TIS Non-scan</i>	Soft Tissue Thermal Index in non-autoscanning mode	Same as FDA	n/a
TIB	<i>TIB</i>	Bone Thermal Index	Same as FDA	n/a
TIC	<i>TIC</i>	Cranial Thermal Index	Same as FDA	n/a
A _{aprt}	<i>A_{aprt}</i>	Area of the active aperture	-12dB output beam area	cm ²
P _{r,3}	<i>p_{ra}</i>	Derated peak rarefactional pressure	Attenuated peak-rarefactional acoustic pressure	MPa
W _o	<i>P</i>	Ultrasonic power, except for TIS _{scan} in which case it is the ultrasonic power passing through a one centimeter window	Output power	mW
W _{.3(z₁)}	<i>P_o(z_s)</i>	Derated ultrasonic power at axial distance z ₁	Attenuated output power at z _s	mW
I _{TA,3(z₁)}	<i>I_{ta,α}(z_s)</i>	Derated spatial-peak, temporal-average intensity at axial distance z ₁	Attenuated temporal-average intensity at z _s	mW/cm ²
z ₁	z _s	Axial distance corresponding to the location of the max [min (W _{.3(z)} , I _{TA,3(z)} × 1 cm ²)], where z > z _{bp}	Depth for TIS	cm ²
z _{bp}	z _{bp}	1.69 (A _{aprt}) ^{1/2}	Break-point depth	cm
z _{sp(MI)}	z at max. <i>I_{pl,α}</i>	For MI: axial distance at which P _{r,3} is measured	Depth at the point where the free-field, attenuated pulse intensity integral is a maximum	cm
z _{sp(TIB)}	z _b	For TIB: axial distance at which TIB is a maximum (i.e., z _{sp} = z _{B,3})	Depth for <i>TIB</i>	cm
d _{eq(z)}	<i>d_{eq}(z)</i>	Equivalent beam diameter as a function of axial distance z, and is equal to $\left[\frac{4}{\pi} \left(\frac{W_o}{I_{TA}(z)} \right) \right]^{0.5}$ where I _{TA(z)} is the temporal-average intensity as a function of z	Equivalent beam diameter at axial distance z	cm
f _c	<i>f_{awf}</i>	Center frequency	Acoustic working frequency	MHz
Dim. of A _{aprt}	Dim. of A _{aprt}	Active aperture dimensions for the azimuth and elevational planes	Same as FDA	cm
PD	<i>t_d</i>	Pulse duration	Same as FDA	μs
PRF	<i>prr</i>	Pulse repetition frequency	Pulse repetition rate	Hz
p _{r@PII_{max}}	<i>p_r</i> at max. <i>I_{pi}</i>	Peak rarefactional pressure at the point where the free-field, spatial-peak pulse intensity integral is a maximum	Same as FDA	MPa
d _{eq@PII_{max}}	<i>d_{eq}</i> at max. <i>I_{pi}</i>	Equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum	Same as FDA	cm
FL	<i>FL</i>	Focal Length, or azimuthal and elevational lengths, if different	Same as FDA	cm
I _{PA,3@MI_{max}}	<i>I_{pa,α}</i> at max. <i>MI</i>	Derated pulse-average intensity at the point of global maximum reported MI	Same as FDA	W/cm ²

Legend

English Text	Translations for languages other than English
Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37	n/a
(Per transducer/mode that exceeds MI or TI value of 1.0)	n/a
Transducer Model	n/a
Operating Mode	n/a
Associated Acoustic Parameters	n/a
Index label	n/a
scan	n/a
non-scan	n/a
units	n/a
Maximum Value	n/a
Other Information	n/a
Operator Control	n/a
TX Level (transmit level)	n/a
Focal length	n/a
Focus	n/a
PRF (Pulsed Repetition Frequency)	n/a
a This Index is not relevant to this operating mode.	n/a
b This transducer is not intended for transcranial or neonatal cephalic uses.	n/a
c This formulation for TIS is less than that for an alternate formulation in this mode.	n/a
# No data is provided for this operation condition since the maximum index value is not reported for the reason listed.	n/a

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CH5-2**Operating mode: **2D-mode**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			1.5	(a)	-	-	-	(a)
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	2.5					
W_o	P	(mW)		#	-		-	#
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \text{max. } I_{pl,\alpha}$	(cm)	3.9					
$d_{\text{eq}}(z_{sp})$	$d_{\text{eq}}(z_b)$	(cm)					-	
f_c	f_{awt}	(MHz)	2.8	#	-	-	-	#
Dim. of A_{aprt}		X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	0.45					
PRF	prr	(Hz)	8828					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	4.7					
$d_{\text{eq}} @ \text{PII max}$	$d_{\text{eq}} @ \text{max. } I_{pi}$	(cm)					-	#
Focal Length	FLx	(cm)		#	-	-		#
	FLy	(cm)		#	-	-		#
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	183					

Operator Control

TX-Level (dB)	0						
Focus (mm)	40						
PRF(prr) (Hz)							

- a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CH5-2**Operating mode: **M-mode**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	1.3	-	-	-	2.3
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		88	-		-	198
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-	
f_c	f_{awt}	(MHz)	#	3.2	-	-	-	3.2
Dim. of A_{aprt}			X (cm)	2.5	-	-	-	2.5
			Y (cm)	1.4	-	-	-	1.4

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	p_{rr}	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$	(cm)					-	2.9
Focal Length	FLx	(cm)		10	-	-		10
	FLy	(cm)		5.0	-	-		5.0
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#				-	-	0
Focus (mm)	#				-	-	100
PRF(prr) (Hz)							

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CH5-2**Operating mode: **Pulsed Doppler**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$	Non-scan	
Maximum Value			(a)	-	-	1.19	3.13	3.69
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		-	-		72.36	344.40
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]		Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)			118.44		
z_1	z_s	(cm)				8.20		
z_{bp}	z_{bp}	(cm)				3.09		
z_{sp}	z_b	(cm)					1.0	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					2.33	
f_c	f_{awt}	(MHz)	#	-	-	2.11	2.14	2.08
Dim. of A_{aprt}		X (cm)		-	-	2.39	0.48	3.05
		Y (cm)		-	-	1.40	1.40	1.40

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	prr	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$	(cm)					0.45	0.73
Focal Length	FLx	(cm)		-	-	10.00		13.00
	FLy	(cm)		-	-	5.00		5.00
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#			0	0	0
Focus (mm)	#			100.00	20.00	130.00
PRF(prr) (Hz)				6250	17361	4883

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CH5-2**

Operating mode: **Color / Power**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			(a)	<1	-	-	-	2.81
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		#	-		-	262.27
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)					-	
z_1	z_s	(cm)					-	
z_{bp}	z_{bp}	(cm)					-	
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \max. I_{pl,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-	
f_c	f_{awt}	(MHz)	#	#	-	-	-	2.44
Dim. of A_{aprt}		X (cm)		#	-	-	-	3.05
		Y (cm)		#	-	-	-	1.40

Other information

FDA	IEC	Units						
PD	t_d	(μ sec)	#					
PRF	prr	(Hz)	#					
$P_r @ PII \max$	$P_r @ \max. I_{pl}$	(MPa)	#					
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pl}$	(cm)					-	3.55
Focal Length	FLx	(cm)		#	-	-		16.00
	FLy	(cm)		#	-	-		5.00
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#			-			-	0
Focus (mm)	#			-			-	160.00
PRF(prr) (Hz)				-			-	3552

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **C8-5**

Operating mode: **2D-mode (includes THI)**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			1.5	(a)	-	-	-	(a)
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	3.2					
W_o	P	(mW)		#	-		-	#
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)					-	
z_1	z_s	(cm)					-	
z_{bp}	z_{bp}	(cm)					-	
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \max. I_{pl,\alpha}$	(cm)	1.3					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-	
f_c	f_{awt}	(MHz)	5.0	#	-	-	-	#
Dim. of A_{aprt}		X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#

Other information

FDA	IEC	Units						
PD	t_d	(μ sec)	0.48					
PRF	prr	(Hz)	8908					
$P_r @ PII \max$	$P_r @ \max. I_{pl}$	(MPa)	5.1					
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pl}$	(cm)					-	#
Focal Length	FLx	(cm)		#	-	-		#
	FLy	(cm)		#	-	-		#
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm^2)	545					

Operator Control

TX-Level (dB)		0			-			-
Focus (mm)		20			-			-
PRF(prr) (Hz)					-			-

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **C8-5**Operating mode: **Pulsed Doppler**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	-	<1	-	2.4	<1
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		-	#		26.2	#
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					3.1	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					0.3	
f_c	f_{awt}	(MHz)	#	-	#	-	4.3	#
Dim. of A_{aprt}		X (cm)		-	#	-	1.0	#
		Y (cm)		-	#	-	0.5	#

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	prf	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$	(cm)					0.3	#
Focal Length	FLx	(cm)		-	#	-		#
	FLy	(cm)		-	#	-		#
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#		-	-	0	#
Focus (mm)	#		-	-	40	#
PRF(prf) (Hz)			-	-	10416	#

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF8-3**Operating mode: **2D-mode (includes THI)**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			1.5	(a)	-	-	-	(a)
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	2.9					
W_o	P	(mW)		#	-		-	#
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)					-	
z_1	z_s	(cm)					-	
z_{bp}	z_{bp}	(cm)					-	
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \text{max. } I_{pl,\alpha}$	(cm)	2.2					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-	
f_c	f_{awt}	(MHz)	3.7	#	-	-	-	#
Dim. of A_{aprt}		X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	0.4					
PRF	prr	(Hz)	12407					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pl}$	(MPa)	2.8					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pl}$	(cm)					-	#
Focal Length	FLx	(cm)		#	-	-		#
	FLy	(cm)		#	-	-		#
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	349.0					

Operator Control

TX-Level (dB)		0						
Focus (mm)		30						
PRF(prr) (Hz)								

- a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF8-3**Operating mode: **Pulsed Doppler**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	-	-	1.3	2.8	(c)
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		-	-		18.5	#
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]		Min. of [$P_o(z_s)$, $I_{a,\alpha}(z_s)$]	(mW)			70.9		
z_1	z_s	(cm)				2.2		
z_{bp}	z_{bp}	(cm)				1.7		
z_{sp}	z_b	(cm)					1.5	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					0.2	
f_c	f_{awt}	(MHz)	#	-	-	3.9	3.9	#
Dim. of A_{aprt}		X (cm)		-	-	1.7	0.1	#
		Y (cm)		-	-	0.6	0.6	#

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	prf	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$	(cm)					0.2	#
Focal Length		FL_x	(cm)		-	-	7.0	#
		FL_y	(cm)		-	-	2.1	#
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#		-	0	0	#
Focus (mm)	#		-	70	5	#
PRF(prf) (Hz)			-	2790	19531	#

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF8-3**

Operating mode: **Color / Power**

Associated Acoustic Parameters

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			(a)	1.3	-	-	(b)	
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		90.8	-	-	#	
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_o(z_s)$, $I_{a,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)				-		
z_{sp}	$z @ \max. I_{pl,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)				-		
f_c	f_{awt}	(MHz)	#	3.0	-	-	#	
Dim. of A_{aprt}		X (cm)		1.9	-	-	#	
		Y (cm)		0.6	-	-	#	

Other information

FDA	IEC	Units					
PD	t_d	(μ sec)	#				
PRF	prf	(Hz)	#				
$P_r @ PII \max$	$P_r @ \max. I_{pl}$	(MPa)	#				
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pl}$	(cm)				-	#
Focal Length	FLx	(cm)		7.4	-	-	#
	FLy	(cm)		2.1	-	-	#
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm^2)	#				

Operator Control

TX-Level (dB)	#			-		-	#
Focus (mm)	#			-		-	#
PRF(prf) (Hz)				-		-	#

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF10-5**Operating mode: **2D-mode**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			1.46	(a)	-	-	(a)	
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	3.46					
W_o	P	(mW)		#	-	-	#	
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)				-		
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	1.1					
$d_{\text{eq}}(z_{sp})$	$d_{\text{eq}}(z_b)$	(cm)				-		
f_c	f_{awt}	(MHz)	5.62	#	-	-	#	
Dim. of A_{aprt}		X (cm)		#	-	-	#	
		Y (cm)		#	-	-	#	

Other information

FDA	IEC	Units					
PD	t_d	(μsec)	0.25				
PRF	prr	(Hz)	8300				
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	4.29				
$d_{\text{eq}} @ \text{PII max}$	$d_{\text{eq}} @ \text{max. } I_{pi}$	(cm)				-	#
Focal Length	FLx	(cm)		#	-	-	#
	FLy	(cm)		#	-	-	#
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	26.69				

Operator Control

TX-Level (dB)	0					
Focus (mm)	15					
PRF(prr) (Hz)						

- a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF10-5**Operating mode: **M-mode**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	3.9	-	-	-	6.0
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		102	-		-	136
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-	
f_c	f_{awt}	(MHz)	#	8.0	-	-	-	7.3
Dim. of A_{aprt}			X (cm)	1.2	-	-	-	0.50
			Y (cm)	0.50	-	-	-	0.50

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	p_{rr}	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$	(cm)					-	2.9
Focal Length	FL_x	(cm)		7.0	-	-		3.0
	FL_y	(cm)		1.8	-	-		1.8
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#				-	-	0
Focus (mm)	#				-	-	30
PRF(prr) (Hz)							

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF10-5**Operating mode: **Pulsed Doppler**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC	
				Scan	Non-scan		Non-scan		
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$			
Maximum Value			(a)	-	1.09	-	-	1.08	
FDA	IEC	Units							
$P_{r,3}$	p_{ra}	(MPa)	#						
W_o	P	(mW)		-	37.16		-	27.22	
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-			
z_1	z_s	(cm)				-			
z_{bp}	z_{bp}	(cm)				-			
z_{sp}	z_b	(cm)					-		
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#						
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-		
f_c	f_{awt}	(MHz)	#	-	6.16	-	-	6.10	
Dim. of A_{aprt}			X (cm)		-	1.09	-	-	0.62
			Y (cm)		-	0.50	-	-	0.50

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	prr	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$	(cm)					-	0.28
Focal Length	FLx	(cm)		-	6.97	-		4.00
	FLy	(cm)		-	1.80	-		1.80
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#				-	-	0
Focus (mm)	#				-	-	69.70
PRF(prr) (Hz)					-	-	2790.18

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF10-5**Operating mode: **Color / Power**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	1.34	-	-	-	2.45
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		45.05	-	-	-	88.71
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \text{max. } I_{pl,\alpha}$	(cm)	#					
$d_{\text{eq}}(z_{sp})$	$d_{\text{eq}}(z_b)$	(cm)					-	
f_c	f_{awt}	(MHz)	#	6.25	-	-	-	6.25
Dim. of A_{aprt}			X (cm)	1.29	-	-	-	1.29
			Y (cm)	0.50	-	-	-	0.50

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	prr	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{\text{eq}} @ \text{PII max}$	$d_{\text{eq}} @ \text{max. } I_{pi}$	(cm)					-	0.89
Focal Length	FLx	(cm)		7.00	-	-		7.00
	FLy	(cm)		1.80	-	-		1.80
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#			-			-	0
Focus (mm)	#			-			-	70.00
PRF(prr) (Hz)				-			-	1099

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF13-5**Operating mode: **2D-mode**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			1.25	(a)	-	-	-	(a)
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	3.04					
W_o	P	(mW)		#	-		-	#
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	0.5					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-	
f_c	f_{awt}	(MHz)	5.91	#	-	-	-	#
Dim. of A_{aprt}		X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	0.22					
PRF	prr	(Hz)	10574					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	3.37					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$	(cm)					-	#
Focal Length	FLx	(cm)		#	-	-		#
	FLy	(cm)		#	-	-		#
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	280					

Operator Control

TX-Level (dB)	0						
Focus (mm)	10						
PRF(prr) (Hz)							

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF13-5**Operating mode: **M-mode**

Associated Acoustic Parameters

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			(a)	0.55	-	-	0.53	
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		13.31	-	-	12.82	
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)				-		
z_{sp}	$z @ \max. I_{pl,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)				-		
f_c	f_{awt}	(MHz)	#	8.68	-	-	8.68	
Dim. of A_{aprt}		X (cm)		0.99	-	-	0.99	
		Y (cm)		0.25	-	-	0.25	

Other information

FDA	IEC	Units					
PD	t_d	(μ sec)	#				
PRF	prr	(Hz)	#				
$P_r @ PII \max$	$P_r @ \max. I_{pi}$	(MPa)	#				
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pi}$	(cm)				-	0.36
Focal Length	FLx	(cm)		4.0	-	-	4.0
	FLy	(cm)		1.2	-	-	1.2
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm^2)	#				

Operator Control

TX-Level (dB)	#				-	-	0
Focus (mm)	#				-	-	40
PRF(prr) (Hz)							

- a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF13-5**Operating mode: **Pulsed Doppler**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	-	1.86	-	1.82	1.88
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		-	53.51		37.98	48.70
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					0.8	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					0.65	
f_c	f_{awt}	(MHz)	#	-	7.30	-	7.21	7.30
Dim. of A_{aprt}		X (cm)			1.32	-	0.99	1.32
		Y (cm)			0.25	-	0.25	0.25

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	prr	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$	(cm)					0.31	0.33
Focal Length	FLx	(cm)		-	4.0	-		4.0
	FLy	(cm)		-	1.2	-		1.2
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#				-	0	0
Focus (mm)	#				-	30	40
PRF(prr) (Hz)					-	2790	13021

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF13-5**Operating mode: **Color / Power**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	1.19	-	-	-	1.36
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		34.42	-	-	-	35.27
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \text{max. } I_{\text{pl},\alpha}$	(cm)	#					
$d_{\text{eq}}(z_{sp})$	$d_{\text{eq}}(z_b)$	(cm)					-	
f_c	f_{awt}	(MHz)	#	7.26	-	-	-	7.26
Dim. of A_{aprt}			X (cm)	1.32	-	-	-	1.32
			Y (cm)	0.25	-	-	-	0.25

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	p_{rr}	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{\text{pl}}$	(MPa)	#					
$d_{\text{eq}} @ \text{PII max}$	$d_{\text{eq}} @ \text{max. } I_{\text{pl}}$	(cm)					-	0.39
Focal Length	FL_x	(cm)		4.0	-	-		4.0
	FL_y	(cm)		1.2	-	-		1.2
$I_{\text{pa},3} @ \text{MI max}$	$I_{\text{pa},\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#			-			-	0
Focus (mm)	#			-			-	40
PRF(prr) (Hz)				-			-	5208

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF13-5SP**Operating mode: **2D-mode**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			1.01	(a)	-	-	(a)	
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	2.60					
W_o	P	(mW)		#	-	-	#	
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)				-		
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	1.10					
$d_{\text{eq}}(z_{sp})$	$d_{\text{eq}}(z_b)$	(cm)				-		
f_c	f_{awt}	(MHz)	6.50	#	-	-	#	
Dim. of A_{aprt}		X (cm)		#	-	-	#	
		Y (cm)		#	-	-	#	

Other information

FDA	IEC	Units					
PD	t_d	(μsec)	0.21				
PRF	prr	(Hz)	18195				
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	2.50				
$d_{\text{eq}} @ \text{PII max}$	$d_{\text{eq}} @ \text{max. } I_{pi}$	(cm)				-	#
Focal Length	FLx	(cm)		#	-	-	#
	FLy	(cm)		#	-	-	#
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	267.96				

Operator Control

TX-Level (dB)	0					
Focus (mm)	15					
PRF(prr) (Hz)						

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF13-5SP** Operating mode: **M-mode**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	-	0.16	-	0.06	0.15
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		-	3.90		0.40	3.39
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					0.90	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					0.31	
f_c	f_{awt}	(MHz)	#	-	8.62	-	8.42	8.62
Dim. of A_{aprt}			X (cm)	-	1.00	-	0.38	1.00
			Y (cm)	-	0.25	-	0.25	0.25

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	prf	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$	(cm)					0.31	1.21
Focal Length	FLx	(cm)		-	4.00	-		4.00
	FLy	(cm)		-	1.20	-		1.20
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#				-	0	0
Focus (mm)	#				-	15.00	4.00
PRF(prf) (Hz)							

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF13-5SP** Operating mode: **Pulsed Doppler**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	-	6.00	-	3.84	5.10
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		-	201.67		29.40	130.25
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					1.10	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					0.26	
f_c	f_{awt}	(MHz)	#	-	6.25	-	7.30	6.25
Dim. of A_{aprt}	X (cm)			-	1.28	-	0.50	1.28
		Y (cm)		-	0.25	-	0.25	0.25

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	prr	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$	(cm)					0.26	1.08
Focal Length	FL_x	(cm)		-	4.00	-		4.00
	FL_y	(cm)		-	1.20	-		1.20
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)		#			-	0	0
Focus (mm)		#			-	15.00	40.00
PRF(prr) (Hz)					-	2790.18	13020.80

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF13-5SP** Operating mode: **Color / Power**

Associated Acoustic Parameters

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			(a)	3.15	-	-	5.97	
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		89.76	-	-	95.29	
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)				-		
z_{sp}	$z @ \max. I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)				-		
f_c	f_{awt}	(MHz)	#	7.37	-	-	7.37	
Dim. of A_{aprt}			X (cm)	0.50	-	-	0.50	
			Y (cm)	0.25	-	-	0.25	

Other information

FDA	IEC	Units					
PD	t_d	(μ sec)	#				
PRF	prf	(Hz)	#				
$P_r @ PII \max$	$P_r @ \max. I_{pi}$	(MPa)	#				
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pi}$	(cm)				-	1.77
Focal Length	FLx	(cm)		1.50	-	-	1.50
	FLy	(cm)		1.20	-	-	1.20
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm^2)	#				

Operator Control

TX-Level (dB)	#		-		-	0
Focus (mm)	#		-		-	15.00
PRF(prf) (Hz)			-		-	1099

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **EV9-4**

Operating mode: **2D-mode**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			1.4	(a)	-	-	-	(a)
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	2.7					
W_o	P	(mW)		#	-		-	#
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_o(z_s)$, $I_{a,\alpha}(z_s)$]	(mW)					-	
z_1	z_s	(cm)					-	
z_{bp}	z_{bp}	(cm)					-	
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \max. I_{pi,\alpha}$	(cm)	1.6					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-	
f_c	f_{awt}	(MHz)	3.6	#	-	-	-	#
Dim. of A_{aprt}		X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#

Other information

FDA	IEC	Units						
PD	t_d	(μ sec)	0.46					
PRF	prr	(Hz)	14655					
$P_r @ PII \max$	$P_r @ \max. I_{pi}$	(MPa)	2.7					
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pi}$	(cm)					-	#
Focal Length	FLx	(cm)		#	-	-		#
	FLy	(cm)		#	-	-		#
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm^2)	376					

Operator Control

TX-Level (dB)		0						
Focus (mm)		20						
PRF(prr) (Hz)								

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **EV9-4**Operating mode: **M-mode**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	1.5	-	-	-	1.3
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		49	-		-	55
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]		Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-	
z_1	z_s	(cm)					-	
z_{bp}	z_{bp}	(cm)					-	
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-	
f_c	f_{awt}	(MHz)	#	6.6	-	-	-	6.6
Dim. of A_{aprt}		X (cm)		1.0	-	-	-	1.0
		Y (cm)		0.80	-	-	-	0.80

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	prr	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$	(cm)					-	2.9
Focal Length	FLx	(cm)		4.0	-	-		4.0
	FLy	(cm)		2.2	-	-		2.2
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#				-	-	0
Focus (mm)	#				-	-	40
PRF(prr) (Hz)							

- a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **EV9-4**Operating mode: **Pulsed Doppler**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	-	-	<1	1.96	1.75
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		-	-		28.95	25.67
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				#		
z_1	z_s	(cm)				#		
z_{bp}	z_{bp}	(cm)				#		
z_{sp}	z_b	(cm)					1.30	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#					
$d_{\text{eq}}(z_{sp})$	$d_{\text{eq}}(z_b)$	(cm)					0.62	
f_c	f_{awt}	(MHz)	#	-	-	#	3.97	3.97
Dim. of A_{aprt}		X (cm)		-	-	#	0.37	0.13
		Y (cm)		-	-	#	0.80	0.80

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	prr	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{\text{eq}} @ \text{PII max}$	$d_{\text{eq}} @ \text{max. } I_{pi}$	(cm)					0.23	0.42
Focal Length	FL_x	(cm)		-	-	#		0.50
	FL_y	(cm)		-	-	#		0.80
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#		-			0	0
Focus (mm)	#		-			15.00	5.00
PRF(prr) (Hz)			-			2790	19531

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **EV9-4**Operating mode: **Color / Power**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	<1	-	-	-	1.30
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		#	-		-	60.31
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-	
f_c	f_{awt}	(MHz)	#	#	-	-	-	3.88
Dim. of A_{aprt}		X (cm)		#	-	-	-	1.32
		Y (cm)		#	-	-	-	0.80

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	prr	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$	(cm)					-	1.74
Focal Length	FLx	(cm)		#	-	-		8.00
	FLy	(cm)		#	-	-		2.20
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#				-	-	0
Focus (mm)	#				-	-	80.00
PRF(prr) (Hz)					-	-	1953

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **EC9-4**

Operating mode: **2D-mode**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			1.3	(a)	-	-	(a)	
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	3.0					
W_o	P	(mW)		#	-	-	#	
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)				-		
z_{sp}	$z @ \max. I_{pl,\alpha}$	(cm)	1.2					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)				-		
f_c	f_{awt}	(MHz)	5.0	#	-	-	#	
Dim. of A_{aprt}		X (cm)		#	-	-	#	
		Y (cm)		#	-	-	#	

Other information

FDA	IEC	Units					
PD	t_d	(μ sec)	0.35				
PRF	prr	(Hz)	14812				
$P_r @ PII \max$	$P_r @ \max. I_{pi}$	(MPa)	4.4				
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pi}$	(cm)				-	#
Focal Length	FLx	(cm)		#	-	-	#
	FLy	(cm)		#	-	-	#
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm^2)	352				

Operator Control

TX-Level (dB)	0					
Focus (mm)	15					
PRF(prr) (Hz)						

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **EC9-4**

Operating mode: **M-mode**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			(a)	<1	-	-	-	1.1
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		#	-		-	26
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]		Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-	
z_1	z_s	(cm)					-	
z_{bp}	z_{bp}	(cm)					-	
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \max. I_{pl,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-	
f_c	f_{awt}	(MHz)	#	#	-	-	-	4.9
Dim. of A_{aprt}		X (cm)		#	-	-	-	0.37
		Y (cm)		#	-	-	-	0.80

Other information

FDA	IEC	Units						
PD	t_d	(μ sec)	#					
PRF	prr	(Hz)	#					
$P_r @ PII \max$	$P_r @ \max. I_{pi}$	(MPa)	#					
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pi}$	(cm)					-	0.83
Focal Length	FLx	(cm)		#	-	-		1.5
	FLy	(cm)		#	-	-		1.9
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#				-	-	0
Focus (mm)	#				-	-	15
PRF(prr) (Hz)							

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **EC9-4** Operating mode: **Pulsed Doppler**

Associated Acoustic Parameters

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			(a)	1.07	-	-	1.35	
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		55.76	-	-	54.07	
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)				-		
z_{sp}	$z @ \max. I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)				-		
f_c	f_{awt}	(MHz)	#	4.03	-	-	4.02	
Dim. of A_{aprt}		X (cm)		1.09	-	-	0.98	
		Y (cm)		0.80	-	-	0.80	

Other information

FDA	IEC	Units					
PD	t_d	(μ sec)	#				
PRF	prr	(Hz)	#				
$P_r @ PII \max$	$P_r @ \max. I_{pi}$	(MPa)	#				
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pi}$	(cm)				-	1.04
Focal Length	FLx	(cm)		8.00	-	-	4.00
	FLy	(cm)		1.90	-	-	1.90
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm^2)	#				

Operator Control

TX-Level (dB)	#			-	-	0
Focus (mm)	#			-	-	40.00
PRF(prr) (Hz)				-	-	100

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **EC9-4**Operating mode: **Color / Power**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	<1	-	-	-	1.10
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		#	-		-	39.20
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \text{max. } I_{pl,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-	
f_c	f_{awt}	(MHz)	#	#	-	-	-	4.02
Dim. of A_{aprt}		X (cm)		#	-	-	-	0.78
		Y (cm)		#	-	-	-	0.80

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	prr	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$	(cm)					-	1.12
Focal Length	FLx	(cm)		#	-	-		3.00
	FLy	(cm)		#	-	-		1.90
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#			-			-	0
Focus (mm)	#			-			-	30.00
PRF(prr) (Hz)				-			-	1953

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P4-2**

Operating mode: **2D-mode**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			1.42	(a)	-	-	-	(a)
FDA	IEC	Units						
$P_{r,3}$	P_{ra}	(MPa)	2.28					
W_o	P	(mW)		#	-		-	#
min of [$W_s(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{r,\alpha}(z_s)$, $I_{f,\alpha}(z_s)$]	(mW)					-	
z_1	z_s	(cm)					-	
z_{bp}	z_{bp}	(cm)					-	
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \max. I_{pi,\alpha}$	(cm)	2.70					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-	
f_c	f_{awf}	(MHz)	2.58	#	-	-	-	#
Dim. of A_{aprt}			X (cm)	#	-	-	-	#
			Y (cm)	#	-	-	-	#

Other information

FDA	IEC	Units						
PD	t_{ci}	(μ sec)	0.66					
PRF	prr	(Hz)	8304					
$P_r @ PII \max$	$P_r @ \max. I_{pi}$	(MPa)	2.90					
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pi}$	(cm)					-	#
Focal Length	FL_x	(cm)		#	-	-		#
	FL_y	(cm)		#	-	-		#
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm^2)	265.37					

Operator Control

TX-Level (dB)		0						
Focus (mm)		30.00						
PRF(prr) (Hz)								

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P4-2**Operating mode: **M-mode**

Associated Acoustic Parameters

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	1.00	-	-	1.71	
FDA	IEC	Units						
$P_{r,3}$	p_a	(MPa)	#					
W_o	P	(mW)		66.88	-	-	117.83	
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)				-		
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#					
$d_{\text{eq}}(z_{sp})$	$d_{\text{eq}}(z_b)$	(cm)				-		
f_c	f_{awt}	(MHz)	#	3.14	-	-	3.10	
Dim. of A_{aprt}			X (cm)	1.51	-	-	1.66	
			Y (cm)	1.40	-	-	1.40	

Other information

FDA	IEC	Units					
PD	t_d	(μsec)	#				
PRF	p_{rr}	(Hz)	#				
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#				
$d_{\text{eq}} @ \text{PII max}$	$d_{\text{eq}} @ \text{max. } I_{pi}$	(cm)				-	1.16
Focal Length	FL_x	(cm)		3.00	-	-	7.00
	FL_y	(cm)		6.20	-	-	6.20
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#				

Operator Control

TX-Level (dB)	#			-	-	0
Focus (mm)	#			-	-	70.00
PRF(prr) (Hz)						

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P4-2**Operating mode: **Pulsed Doppler**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan			
Maximum Value			(a)		1.87	$A_{aprt} \leq 1$	$A_{aprt} > 1$	-
FDA	IEC	Units						
$P_{r,3}$	P_{ra}	(MPa)	#					
W_o	P	(mW)		204.53	-		-	203.49
min of [$W_s(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)					-	
z_1	z_s	(cm)					-	
z_{bp}	z_{bp}	(cm)					-	
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \max. I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-	
f_c	f_{awf}	(MHz)	#	1.92	-	-	-	1.92
Dim. of A_{aprt}	X (cm)			1.51	-	-	-	1.25
	Y (cm)			1.40	-	-	-	1.40

Other information

FDA	IEC	Units						
PD	t_d	(μ sec)	#					
PRF	prr	(Hz)	#					
$P_r @ PII \max$	$P_r @ \max. I_{pi}$	(MPa)	#					
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pi}$	(cm)					-	1.52
Focal Length	FL_x	(cm)		3.00	-	-		5.00
	FL_y	(cm)		6.20	-	-		6.20
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm^2)	#					

Operator Control

TX-Level (dB)		#				-	-	0
Focus (mm)		#				-	-	50.00
PRF(prr) (Hz)						-	-	100

- | | |
|---|---|
| a | This Index is not relevant to this operating mode. |
| b | This transducer is not intended for transcranial or neonatal cephalic uses. |
| c | This formulation for TIS is less than that for an alternate formulation in this mode. |
| # | No data is provided for this operation condition since the maximum index value is not reported for the reason listed. |

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P4-2**Operating mode: **SCW**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	-	-	1.32	3.96	3.40
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		-	-		32.00	157.71
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				138.60		
z_1	z_s	(cm)				3.80		
z_{bp}	z_{bp}	(cm)				1.74		
z_{sp}	z_b	(cm)					4.40	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#					
$d_{\text{eq}}(z_{sp})$	$d_{\text{eq}}(z_b)$	(cm)					0.29	
f_c	f_{awt}	(MHz)	#	-	-	2.00	2.00	2.00
Dim. of A_{aprt}			X (cm)	-	-	0.75	0.75	0.75
			Y (cm)	-	-	1.40	1.40	1.40

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	prr	(Hz)	#					
$P_r @ \text{PII max}$	$P @ \text{max. } I_{pi}$	(MPa)	#					
$d_{\text{eq}} @ \text{PII max}$	$d_{\text{eq}} @ \text{max. } I_{pi}$	(cm)					0.29	0.63
Focal Length	FLx	(cm)		-	-	11.00		11.00
	FLy	(cm)		-	-	6.20		6.20
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#			0	0	0
Focus (mm)	#			11.00	9.00	11.00
PRF(prr) (Hz)				-	-	-

- a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P4-2**Operating mode: **Color / Power**

Associated Acoustic Parameters

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	1.10	-	-	2.41	
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		98.05	-	-	166.07	
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)				-		
z_{sp}	$z @ \text{max. } I_{\text{pl},\alpha}$	(cm)	#					
$d_{\text{eq}}(z_{sp})$	$d_{\text{eq}}(z_b)$	(cm)				-		
f_c	f_{awt}	(MHz)	#	2.40	-	-	1.91	
Dim. of A_{aprt}		X (cm)		1.66	-	-	1.66	
		Y (cm)		1.40	-	-	1.40	

Other information

FDA	IEC	Units					
PD	t_d	(μsec)	#				
PRF	p_{rr}	(Hz)	#				
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{\text{pl}}$	(MPa)	#				
$d_{\text{eq}} @ \text{PII max}$	$d_{\text{eq}} @ \text{max. } I_{\text{pl}}$	(cm)				-	4.15
Focal Length	FL_x	(cm)		8.74	-	-	17.62
	FL_y	(cm)		6.20	-	-	6.20
$I_{\text{pa},3} @ \text{MI max}$	$I_{\text{pa},\alpha} @ \text{max. MI}$	(W/cm^2)					

Operator Control

TX-Level (dB)	#		-		-	0
Focus (mm)	#		-		-	176
PRF(prf) (Hz)			-		-	1099

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P5-1** Operating mode: **2D-mode**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			1.2	(a)	-	-	-	(a)
FDA	IEC	Units						
$P_{r,3}$	P_{ra}	(MPa)	1.9					
W_o	P	(mW)		#	-		-	#
min of [$W_s(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_a(z_s)$, $I_{a,\alpha}(z_s)$]	(mW)					-	
z_1	z_s	(cm)					-	
z_{bp}	z_{bp}	(cm)					-	
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	2.7					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-	
f_c	f_{awf}	(MHz)	2.8	#	-	-	-	#
Dim. of A_{aprt}			X (cm)	#	-	-	-	#
			Y (cm)	#	-	-	-	#

Other information

FDA	IEC	Units						
PD	t_{ci}	(μsec)	0.84					
PRF	p_{rr}	(Hz)	8356					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	3.16					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$	(cm)					-	#
Focal Length	FL_x	(cm)		#	-	-		#
	FL_y	(cm)		#	-	-		#
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	145.17					

Operator Control

TX-Level (dB)		0						
Focus (mm)		30						
PRF(prr) (Hz)								

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P5-1** Operating mode: **Pulsed Doppler**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			(a)	-	-	1.04	2.78	(b)
FDA	IEC	Units						
$P_{r,3}$	P_{ra}	(MPa)	#					
W_o	P	(mW)		-	-		28.7	#
min of [$W_s(z_1)$, $I_{TA,3}(z_1)$]		Min. of [$P_a(z_s)$, $I_{sa,3}(z_s)$]	(mW)			84.92		
z_1	z_s	(cm)				5.00		
z_{bp}	z_{bp}	(cm)				2.23		
z_{sp}	z_b	(cm)					4.80	
z_{sp}	$z @ \max. I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					0.47	
f_c	f_{awf}	(MHz)	#	-	-	2.57	2.57	#
Dim. of A_{aprt}			X (cm)	-	-	1.25	1.49	#
			Y (cm)	-	-	1.40	1.40	#

Other information

FDA	IEC	Units						
PD	t_{ci}	(μ sec)	#					
PRF	p_{rr}	(Hz)	#					
$P_r @ PII \max$	$P_r @ \max. I_{pi}$	(MPa)	#					
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pi}$	(cm)					0.47	#
Focal Length	FL_x	(cm)		-	-	5.00		#
	FL_y	(cm)		-	-	8.00		#
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#				0	0	#
Focus (mm)	#				50	30	#
PRF(prr) (Hz)					100	100	#

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P5-1** Operating mode: **SCW**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			(a)	-	<1	-	1.5	(b)
FDA	IEC	Units						
$P_{r,3}$	P_{ra}	(MPa)	#					
W_o	P	(mW)		-	#		9.3	#
min of [$W_s(z_1)$, $I_{TA,3}(z_1)$]		Min. of [$P_a(z_s)$, $I_{a,\alpha}(z_s)$]	(mW)			-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					1.0	
z_{sp}	$z @ \max. I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					0.29	
f_c	f_{awf}	(MHz)	#	-	#	-	5.00	#
Dim. of A_{aprt}			X (cm)	-	#	-	1.54	#
			Y (cm)	-	#	-	1.40	#

Other information

FDA	IEC	Units						
PD	t_{ci}	(μ sec)	#					
PRF	p_{rr}	(Hz)	#					
$P_r @ PII \max$	$P_r @ \max. I_{pi}$	(MPa)	#					
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pi}$	(cm)					0.29	#
Focal Length	FL_x	(cm)		-	#	-		#
	FL_y	(cm)		-	#	-		#
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm^2)	#					

Operator Control

TX-Level (dB)		#			-	0	#
Focus (mm)		#			-	70	#
PRF(prr) (Hz)					-	8681	#

- a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P5-1** Operating mode: **Color / Power**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			(a)	1.04	-	-	-	(b)
FDA	IEC	Units						
$P_{r,3}$	P_{ra}	(MPa)	#					
W_o	P	(mW)		93.48	-		-	#
min of [$W_s(z_1)$, $I_{TA,3}(z_1)$]		Min. of [$P_a(z_s)$, $I_{a,\alpha}(z_s)$]		(mW)			-	
z_1	z_s	(cm)					-	
z_{bp}	z_{bp}	(cm)					-	
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$		(cm)	#				
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$		(cm)				-	
f_c	f_{awf}	(MHz)	#	2.34	-	-	-	#
Dim. of A_{aprt}			X (cm)		1.54	-	-	#
			Y (cm)		1.40	-	-	#

Other information

FDA	IEC	Units						
PD	t_{ci}	(μsec)	#					
PRF	p_{rr}	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$		(MPa)	#				
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$		(cm)				-	#
Focal Length	FL_x	(cm)		17.41	-	-		#
	FL_y	(cm)		8.00	-	-		#
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$		(W/cm^2)	#				

Operator Control

TX-Level (dB)		#			-	-	#
Focus (mm)		#			-	-	#
PRF(prr) (Hz)					-	-	#

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P8-4**

Operating mode: **2D-mode**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			1.05	(a)	-	-	-	(a)
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	1.84					
W_o	P	(mW)		#	-		-	#
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)					-	
z_1	z_s	(cm)					-	
z_{bp}	z_{bp}	(cm)					-	
z_{sp}	z_b	(cm)					-	
z_{sp}	$z @ \max. I_{pl,\alpha}$	(cm)	1.8					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					-	
f_c	f_{awt}	(MHz)	3.06	#	-	-	-	#
Dim. of A_{aprt}		X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#

Other information

FDA	IEC	Units						
PD	t_d	(μ sec)	0.84					
PRF	prr	(Hz)	8722					
$P_r @ PII \max$	$P_r @ \max. I_{pi}$	(MPa)	2.22					
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pi}$	(cm)					-	#
Focal Length	FLx	(cm)		#	-	-		#
	FLy	(cm)		#	-	-		#
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm^2)	109					

Operator Control

TX-Level (dB)	0						
Focus (mm)	20						
PRF(prr) (Hz)							

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P8-4**

Operating mode: **M-mode**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			(a)	1.02	-	-	<1	<1
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		37.78	-		#	#
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					#	
z_{sp}	$z @ \max. I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					#	
f_c	f_{awt}	(MHz)	#	5.67	-	-	#	#
Dim. of A_{aprt}		X (cm)		0.96	-	-	#	#
		Y (cm)		0.8	-	-	#	#

Other information

FDA	IEC	Units						
PD	t_d	(μ sec)	#					
PRF	prf	(Hz)	#					
$P_r @ PII \max$	$P_r @ \max. I_{pi}$	(MPa)	#					
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pi}$	(cm)					#	#
Focal Length	FLx	(cm)		2.0	-	-		#
	FLy	(cm)		5.0	-	-		#
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm ²)	#					

Operator Control

TX-Level (dB)	#				-	#	#
Focus (mm)	#				-	#	#
PRF(prf) (Hz)							

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P8-4**Operating mode: **Pulsed Doppler**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	-	1.25	-	2.35	1.58
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		-	62.06		43.91	62.51
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					1.9	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					0.99	
f_c	f_{awt}	(MHz)	#	-	4.23	-	3.54	4.23
Dim. of A_{aprt}			X (cm)		0.96	-	0.96	0.96
			Y (cm)		0.8	-	0.8	0.8

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	prf	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{eq} @ \text{PII max}$	$d_{eq} @ \text{max. } I_{pi}$	(cm)					0.27	0.27
Focal Length	FLx	(cm)		-	4.0	-		4.0
	FLy	(cm)		-	5.0	-		5.0
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#				-	0	0
Focus (mm)	#				-	20	40
PRF(prf) (Hz)					-	17361	2790

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P8-4**Operating mode: **SCW**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$		
Maximum Value			(a)	-	0.72	-	1.99	1.57
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		-	41.80		15.90	41.81
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					2.40	
z_{sp}	$z @ \text{max. } I_{pi,\alpha}$	(cm)	#					
$d_{\text{eq}}(z_{sp})$	$d_{\text{eq}}(z_b)$	(cm)					0.21	
f_c	f_{awt}	(MHz)	#	-	3.62	-	3.62	3.62
Dim. of A_{aprt}	X (cm)				0.43	-	0.43	0.43
	Y (cm)				0.80	-	0.80	0.80

Other information

FDA	IEC	Units						
PD	t_d	(μsec)	#					
PRF	prr	(Hz)	#					
$P_r @ \text{PII max}$	$P_r @ \text{max. } I_{pi}$	(MPa)	#					
$d_{\text{eq}} @ \text{PII max}$	$d_{\text{eq}} @ \text{max. } I_{pi}$	(cm)					0.21	0.34
Focal Length	FL_x	(cm)		-	3.00	-		3.00
	FL_y	(cm)		-	5.00	-		5.00
$I_{pa,3} @ \text{MI max}$	$I_{pa,\alpha} @ \text{max. MI}$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#				-	0	0
Focus (mm)	#				-	30	30
PRF(prr) (Hz)					-	-	-

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P8-4**Operating mode: **Color / Power**

Associated Acoustic Parameters

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			(a)	1.24	-	-	1.61	
FDA	IEC	Units						
$P_{r,3}$	p_{ra}	(MPa)	#					
W_o	P	(mW)		63.36	-	-	63.70	
min of [$W_{.3}(z_1)$, $I_{TA,3}(z_1)$]	Min. of [$P_{\alpha}(z_s)$, $I_{\alpha,\alpha}(z_s)$]	(mW)				-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)				-		
z_{sp}	$z @ \max. I_{pl,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)				-		
f_c	f_{awt}	(MHz)	#	4.11	-	-	4.11	
Dim. of A_{aprt}			X (cm)	0.96	-	-	0.96	
			Y (cm)	0.8	-	-	0.8	

Other information

FDA	IEC	Units					
PD	t_d	(μ sec)	#				
PRF	prf	(Hz)	#				
$P_r @ PII \max$	$P_r @ \max. I_{pi}$	(MPa)	#				
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pi}$	(cm)				-	1.33
Focal Length	FLx	(cm)		7.0	-	-	7.0
	FLy	(cm)		5.0	-	-	5.0
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm ²)	#				

Operator Control

TX-Level (dB)	#		-		-	0
Focus (mm)	#		-		-	70
PRF(prf) (Hz)			-		-	7062

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **V5Ms** Operating mode: **Pulsed Doppler**

Associated Acoustic Parameters

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value			(a)	-	<1	-	2.08	(b)
FDA	IEC	Units						
$P_{r,3}$	P_{ra}	(MPa)	#					
W_o	P	(mW)		-	#		15.1	#
min of [$W_s(z_1)$, $I_{TA,3}(z_1)$]		Min. of [$P_a(z_s)$, $I_{sa,3}(z_s)$]	(mW)			-		
z_1	z_s	(cm)				-		
z_{bp}	z_{bp}	(cm)				-		
z_{sp}	z_b	(cm)					2.00	
z_{sp}	$z @ \max. I_{pi,\alpha}$	(cm)	#					
$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)					0.26	
f_c	f_{awf}	(MHz)	#	-	#	-	3.62	#
Dim. of A_{aprt}			X (cm)	-	#	-	0.96	#
			Y (cm)	-	#	-	0.77	#

Other information

FDA	IEC	Units						
PD	t_{ci}	(μ sec)	#					
PRF	p_{rr}	(Hz)	#					
$P_r @ PII \max$	$P_r @ \max. I_{pi}$	(MPa)	#					
$d_{eq} @ PII \max$	$d_{eq} @ \max. I_{pi}$	(cm)					0.26	#
Focal Length	FL_x	(cm)		-	#	-		#
	FL_y	(cm)		-	#	-		#
$I_{pa,3} @ MI \max$	$I_{pa,\alpha} @ \max. MI$	(W/cm^2)	#					

Operator Control

TX-Level (dB)	#				-	0	#
Focus (mm)	#				-	20	#
PRF(prr) (Hz)					-	100	#

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k)

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CW2**

Operating mode: **Continuous Wave Doppler**

Associated Acoustic Parameters

Index Label	MI	TIS				TIB	TIC
		Scan	Non-scan		Non-scan		
			$A_{aprt} \leq 1$	$A_{aprt} > 1$			
Maximum Value	---	-	---	0.35	#	1.02	0.93
$P_{r,3}$	(MPa)	-					
W_o	(mW)		#	36.74		5.30	36.69
min of [$W_s(z_1)$, $I_{TA,3}(z_1)$]	(mW)				#		
z_1	(cm)				#		
z_{bp}	(cm)				#		
z_{sp}	(cm)	-				1.20	
$d_{eq}(z_{sp})$	(cm)					0.20	
f_c	(MHz)	-	#	2.00	#	2.00	2.00
Dim. of A_{aprt}	X (cm)		#	0.88	#	0.88	0.88
	Y (cm)		#	0.87	#	0.87	0.87

Other information

PD	(μ sec)	-					
PRF	(Hz)	-					
$P_r@ PII$ max	(MPa)	-					
$d_{eq}@ PII$ max	(cm)					0.20	0.54
Focal Length	FLx (cm)		#	10.00	#		10.00
	FLy (cm)		#	10.00	#		10.00
$I_{pa,3}@ MI$ max	(W/cm ²)	-					

Operator Control

TX-Level	(dB)	-		0		0	0
Focus	(mm)						
PRF	(Hz)						

a	This Index is not relevant to this operating mode.
b	This transducer is not intended for transcranial or neonatal cephalic uses.
c	This formulation for TIS is less than that for an alternate formulation in this mode.
#	No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k)

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CW5** Operating mode: **Continuous Wave Doppler**

Associated Acoustic Parameters

Index Label	MI	TIS				TIB	TIC
		Scan	Non-scan		Non-scan		
			$A_{aprt} \leq 1$	$A_{aprt} > 1$			
Maximum Value	---	-	-	0.19	#	0.56	0.31
$P_{r,3}$	(MPa)	-					
W_o	(mW)		#	7.98		5.4	7.90
min of [$W_3(z_1)$, $I_{TA,3}(z_1)$]	(mW)				#		
z_1	(cm)				#		
z_{bp}	(cm)				#		
z_{sp}	(cm)	-				2.30	
$d_{eq}(z_{sp})$	(cm)					0.17	
f_c	(MHz)	-	#	5.00	#	5.00	5.00
Dim. of A_{aprt}	X (cm)		#	0.59	#	0.59	0.59
	Y (cm)		#	0.54	#	0.54	0.54

Other information

PD	(μ sec)	-					
PRF	(Hz)	-					
$P_r@ PII$ max	(MPa)	-					
$d_{eq}@ PII$ max	(cm)					0.16	0.20
Focal Length	FLx (cm)		#	9.00	#		9.00
	FLy (cm)		#	9.00	#		9.00
$I_{pa,3}@ MI$ max	(W/cm ²)	-					

Operator Control

TX-Level (dB)	-		0		0	0
Focus (mm)						
PRF (Hz)						

- a This index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

