SIEMENS

ACUSON X600 ACUSON X700 Diagnostic Ultrasound System Instructions for Use







ACUSON X600, Product Version 1.0 ACUSON X700, Product Version 2.0 Software Version X700 VB20, X600 VA10

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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.

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About the User and Reference Manuals

The user and reference manuals contain descriptions for the following ultrasound systems:

- ACUSON X600 diagnostic ultrasound system
- ACUSON X700 diagnostic ultrasound system

Features and options unique to an ultrasound system are identified in Chapter 1 and Appendix A of the Instructions for Use.

The user and reference manuals consist of the following publications.

Publication	Includes			
Instructions for Use	■ Intended Audience			
	 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 			
Features and Applications Reference*	 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 			
System Reference*	Description of customizable system settings			
	 Information about DICOM connectivity, network capabilities, and external devices 			
	Clinical references			
Electromagnetic Emissions and Immunity: Guidance and Manufacturer's Declaration*	 Information regarding the electromagnetic compatibility (EMC) testing of this system 			

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

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Conventions

Take a moment to familiarize yourself with these conventions.

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

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Intended Audience

The intended audience for the user and reference manuals includes the following users.

User	Interaction with Ultrasound Equipment	Expected Experience and Other Characteristics
Sonographer	 Acquires diagnostic views of anatomy, blood flow, and related pathology Performs measurements and analysis of the acquired images Prepares exam data for review and interpretation by a qualified physician 	 Ranges from novices (for example, students) to advanced practitioners with certification in multiple subspecialties Educated in anatomy, physiology, patient care, and identification of pathology in ultrasound images Many sonographers have a Bachelor's degree; some have advanced degrees in related health care subjects
Cardiologist	 Performs invasive and non-invasive ultrasound exams Interprets exam data, including echocardiography exam data Writes and assembles exam findings in a report 	 Medical doctor Expert in diagnostic imaging, including computed tomography (CT), magnetic resonance imaging (MRI), X-ray, ultrasound, and nuclear medicine Advanced training in imaging physics with typically four to six years of post-doctoral training in the field of cardiology
Maternal-fetal Medicine Obstetrician/ Perinatologist Radiologist and Internist	 Performs ultrasound exams Interprets exam data Writes and assembles exam findings in a report Performs ultrasound exams Interprets exam data Writes and assembles exam findings in a report 	 Medical doctor Manages high-risk obstetrical patients for the safe and successful delivery of the fetus Skilled in interpreting ultrasound exam data Medical doctors Expert in diagnostic imaging, including CT, MRI, X-ray, ultrasound, and nuclear medicine Advanced training in imaging physics with typically two to six years of post-doctoral training in the field of radiology
System Administrator and Customer Service Engineer	Configures the ultrasound system for use in a networked environment	 A System Administrator is an individual within your organization who is designated to set up system parameters to connect the ultrasound system or workstation to a picture archiving and communication system (PACS). Customer Service Engineers are Siemens representatives who configure the ultrasound system or workstation during software installation and support troubleshooting activities.

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1 Introduction

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System Overview

The ACUSON X600 and ACUSON X700 systems are portable, digital diagnostic ultrasound imaging systems. The systems utilize advanced imaging processing and transducer technology. The operating systems are based on Windows technology.

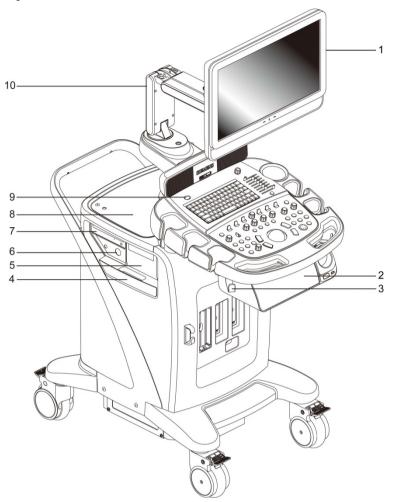
The system software supports standard applications, exam-specific imaging presets, measurements, pictograms, annotations, reports, worksheets, and system diagnostics.

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

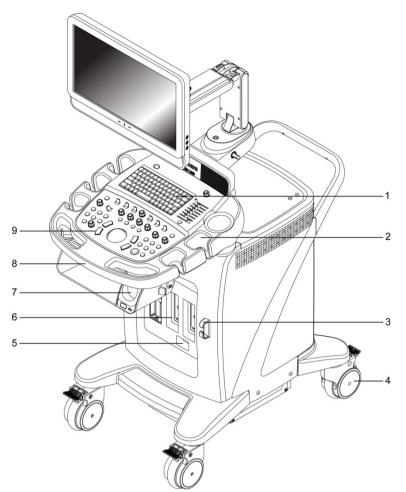
See also: Technical Description, Appendix A, Instructions for Use

System Review



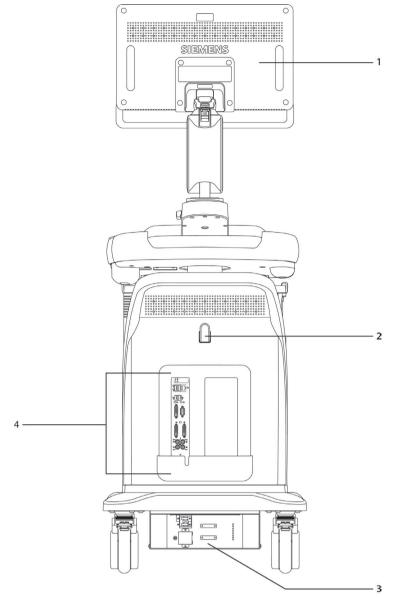
Example of the ultrasound system, left front view.

- User adjustable monitor
- 2 Storage shelf
- 3 Transducer cable hanger
- 4 Air filter
- 5 Black and white printer
- 6 Physio module (with ECG and auxiliary connectors)7 CD/DVD-R/W drive
- Rear shelf
- Power (partial) ON/OFF switch (也)
- 10 Articulating arm



Example of the ultrasound system, right front view.

- 1 Alphanumeric keyboard
- 2 Transducer holder
- 3 Transducer cable hanger
- 4 Swivel wheel with brake
- 5 Transducer port for continuous wave (pencil) transducers
- 6 Transducer ports
- 7 Integrated Gel warmer
- 8 Front handle
- 9 Back-lit control panel



Example of the ultrasound system, back view.

- Monitor 1
- 2 Cable hanger
- Power panel with circuit breaker Input/Output panel 3

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Intended Use

⚠ WARNING: The analysis of results from an ultrasound examination requires that you are trained in the interpretation of diagnostic ultrasound studies and are qualified to make clinical diagnoses.

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

ACUSON X600 Ultrasound System

The ACUSON X600 ultrasound system supports the following applications:

- Abdomen
- Aorta
- **Breast**
- Cardiac
- Cerebrovascular
- **Early Obstetrics**
- **Emergency Medicine**
- Fetal Echo
- Gynecology
- Musculoskeletal
- Obstetrics
- Obstetrics (Japan)
- Orthopedic
- Pediatric Abdomen
- Pediatric Echo
- Pelvic Floor
- Peripheral vascular
- Renal
- **Small Parts**
- Testicle
- Thyroid
- Transcranial
- Urology
- Venous

Indications for Use Statement

Product	Indications for Use Statement		
ACUSON X600 Ultrasound System	The ACUSON X600 ultrasound imaging system is intended for the following applications: Cardiac Adult, Cerebrovascular, Peripheral Vascular, Transcranial, Fetal, Abdominal, Pediatric, Small Organ, Adult Cephalic, Musculo-skeletal Conventional, Obstetrical, Gynecological (including monitoring of ovarian follicle development), and Urological applications using different ultrasound transducers for different applications.		
	The recommended use of each transducer may vary depending on the transducer design, anatomical study, patient size and imaging approach. The system also provides the ability to measure anatomical structures and supports calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.		
	⚠ Caution: Ultrasound is used as an imaging aid, but may have further restrictions specific to in-vitro fertilization (IVF), chorionic villus sampling (CVS), and percutaneous umbilical cord blood sampling (PUBS) procedures. Observe local laws and regulations.		
	The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.		
	Note: This feature can be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging."		

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Transducers and Intended Applications

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.

See Also: Electromagnetic Emissions and Immunity Guidance and Manufacturer's Declaration

Only the following transducers from Siemens are compatible with the Siemens ACUSON X600 ultrasound imaging system.

TRANSDUCER NAME	OPERATING FREQUENCY ¹	MODES OF OPERATION ²	INTENDED APPLICATIONS		
	CURVED AND LINEAR ARRAY TRANSDUCERS				
CH5-2	2D-mode: 2.5 MHz–5.0 MHz	2D, C, D, M	AbdomenEarly Obstetrics		
	Doppler: 2.0 MHz–2.7 MHz		 Emergency Medicine Fetal Echo Gynecology Obstetrics Obstetrics (Japan) Peripheral Vascular Renal Urology Venous 		
C6-2	2D-mode: 3.1 MHz–5.0 MHz Doppler: 2.5 MHz–3.3 MHz	2D, C, D, M	 Abdomen Aorta Early Obstetrics Fetal Echo Gynecology Obstetrics Obstetrics (Japan) Pediatric Abdomen Renal Venous 		
VF10-5	2D-mode: 6.2 MHz–10.0 MHz Doppler: 5.3 MHz–6.2 MHz	2D, C, D, M	 Breast Cerebrovascular Emergency Medicine Musculoskeletal Orthopedics Peripheral Vascular Testicle Thyroid Venous 		

TRANSDUCER NAME	OPERATING FREQUENCY ¹	MODES OF OPERATION ²	INTENDED APPLICATIONS
VF12-4	2D-mode:	2D, C, D, M	Breast
	6.2 MHz-11.4 MHz		Cerebrovascular
	Doppler:		Emergency Medicine
	4.0 MHz-6.7 MHz		Musculoskeletal
			Orthopedic
			Peripheral Vascular
			Small Parts
			Testicle
			Thyroid
			■ Venous
		PHASED ARRAY TR	ANSDUCERS
4V1c	2D-mode:	2D, C, D, M, SCW	■ Abdomen
	1.7 MHz-4.0 MHz		■ Cardiac
	Doppler:		Emergency Medicine
	1.8 MHz-2.5 MHz		■ Transcranial
		ENDOCAVITY TRA	NSDUCERS
EC9-4w	2D-mode:	2D, C, D, M	Early Obstetrics
	4.2 MHz-7.3 MHz		Gynecology
	Doppler:		 Obstetrics
	4.0 MHz-5.3 MHz		Obstetrics (Japan)
			 Urology
		fourSight 4D TRA	NSDUCERS
C6F2	2D-mode:	2D, C, D, M	■ Abdomen
	2.9 MHz-5.0 MHz		Early Obstetrics
	Doppler:		■ Fetal Echo
	2.5 MHz-3.1 MHz		■ Gynecology
			Obstetrics
			Obstetrics (Japan)
			■ Pelvic Floor
C8F3	2D-mode:	2D, C, D, M	■ Abdomen
	3.3 MHz-5.7 MHz		Early Obstetrics
	Doppler:		■ Fetal Echo
	2.7 MHz-3.3 MHz		■ Gynecology
			Obstetrics
			Obstetrics (Japan)
			Pelvic Floor
EV9F3	2D-mode:	2D, C, D, M	Early Obstetrics
	4.7 MHz–8.0 MHz		Gynecology
	Doppler:		Obstetrics
	4.0 MHz–5.3 MHz		Obstetrics (Japan)
			Pelvic Floor

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TRANSDUCER NAME	OPERATING FREQUENCY ¹	MODES OF OPERATION ²	INTENDED APPLICATIONS
	C	ONTINUOUS WAVE	TRANSDUCERS
CW2	2 MHz	CW	■ Cardiac
			Pediatric Echo
CW5	5 MHz	CW	Cerebrovascular
			Pediatric Echo

¹ Operating Frequency Range of selectable operating frequencies for:		
2D-mode	Fundamental and harmonic imaging, including contrast	
Doppler	Pulsed wave, continuous wave, and color imaging	

² Modes of Operation	Includes one or more of the following system operating modes	
2D (brightness mode)	2D-mode, 2D-mode with Tissue Harmonic Imaging (THI)	
C (color flow imaging)	Color Doppler, Power Doppler	
D (Doppler)	Pulsed Wave Doppler, 2D/Doppler, 2D/Doppler with Color, 2D/Doppler with Power	
M (motion mode)	M-mode, M-mode with THI, 2D/M-mode, 2D/M-mode with Color, 2D/M-mode with Power	
SCW (steerable continuous wave Doppler)	Steerable Continuous Wave Doppler (for phased array transducers)	
CW (continuous wave Doppler)	Auxiliary Continuous Wave Doppler (for continuous wave [pencil] transducers)	

ACUSON X700 Ultrasound System

The ACUSON X700 ultrasound system supports the following applications:

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

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Indications for Use Statement

Product	Indications for Use Statement		
ACUSON X700 Ultrasound System	The ACUSON X700 ultrasound imaging system, is intended for the following applications: Cardiac Adult, Cardiac Pediatric, Cardiac Transesophageal, Intracardiac Echo, Cerebrovascular, Peripheral Vascular, Transcranial, Fetal, Abdominal, Intra-operative (Specification), Pediatric, Small Organ, Neonatal Cepahalic, Adult Cephalic, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Obstetrical, Gynecological (including monitoring of ovarian follicle development), and Urological applications using different ultrasound transducers for different applications.		
	The recommended use of each transducer may vary depending on the transducer design, anatomical study, patient size and imaging approach. The system also provides the ability to measure anatomical structures and supports calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.		
	↑ Caution: Ultrasound is used as an imaging aid, but may have further restrictions specific to in-vitro fertilization (IVF), chorionic villus sampling (CVS), and percutaneous umbilical cord blood sampling (PUBS) procedures. Observe local laws and regulations.		
	The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.		
	Note: This feature can be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging."		
ACUSON AcuNav Ultrasound Catheter	The catheter is intended for intracardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.		

Transducers and Intended Applications

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.

See Also: Electromagnetic Emissions and Immunity Guidance and Manufacturer's Declaration

Only the following transducers from Siemens are compatible with the Siemens ACUSON X700 ultrasound imaging system.

TRANSDUCER NAME	OPERATING FREQUENCY ¹	MODES OF OPERATION ²	INTENDED APPLICATIONS	
CURVED AND LINEAR ARRAY TRANSDUCERS				
4C1	2D-mode:	2D, C, D, M	Abdomen	
	2.2 MHz-5.0 MHz	25, 5, 5,	Early Obstetrics	
	Doppler:		Emergency Medicine	
	2.2 MHz-3.1 MHz		Fetal Echo	
			Gynecology	
			Obstetrics	
			Obstetrics (Japan)	
			Peripheral Vascular	
			■ Renal	
			Urology	
			■ Venous	
6C2	2D-mode:	2D, C, D, M	Abdomen	
	2.5 MHz-5.7 MHz		■ Early Obstetrics	
	Doppler:		Emergency Medicine	
	2.7 MHz-3.6 MHz		■ Fetal Echo	
			Gynecology	
			Obstetrics	
			Obstetrics (Japan)	
			■ Renal	
C8-5	2D-mode:	2D, C, D, M	Cerebrovascular	
	4.2 MHz-7.6 MHz		Neonatal Head	
	Doppler:		Pediatric Abdomen	
	4.2 MHz-5.0 MHz		Pediatric Echo	
VF10-5	2D-mode:	2D, C, D, M	Breast	
	6.2 MHz-10.0 MHz		Cerebrovascular	
	Doppler:		Emergency Medicine	
	5.3 MHz-6.2 MHz		Musculoskeletal	
			Orthopedics	
			Peripheral Vascular	
			■ Testicle	
			■ Thyroid	
			■ Venous	

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TRANSDUCER NAME	OPERATING FREQUENCY ¹	MODES OF OPERATION ²	INTENDED APPLICATIONS
VF12-4	2D-mode:	2D, C, D, M	Breast
	6.2 MHz-11.4 MHz		Cerebrovascular
	Doppler:		Emergency Medicine
	4.0 MHz-6.7 MHz		Musculoskeletal
			 Orthopedics
			Peripheral Vascular
			Small Parts
			■ Testicle
			■ Thyroid
			■ Venous
VF16-5	2D-mode:	2D, C, D, M	Breast
	8.0 MHz-13.3 MHz		Cerebrovascular
	Doppler:		Emergency Medicine
	5.3 MHz-6.2 MHz		■ Penile
			Superficial Musculoskeletal
			■ Testicle
			■ Thyroid
	PHAS	ED ARRAY TRANS	-
4V1c	2D-mode:	2D, C, D, M,	Abdomen
	1.7 MHz-4.0 MHz	SCW	■ Cardiac
	Doppler:		Emergency Medicine
	1.8 MHz-2.5 MHz		Transcranial
P8-4	2D-mode:	2D, C, D, M,	Neonatal Head
	3.8 MHz-6.7 MHz	SCW	Pediatric Abdomen
	Doppler:		Pediatric Echo
	3.6 MHz-4 MHz		■ Renal
V5Ms	2D-mode:	2D, C, D, M,	Transesophageal Echo
	4.0 MHz-5.7 MHz	SCW	
	Doppler:		
	3.6 MHz		
AcuNav 8F/	2D-mode:	2D, C, D, M,	Cardiac Adult
SoundStar eco 8F	5.0 MHz-8.9 MHz	SCW	Cardiac Pediatric
	Doppler:		■ Intra-Cardiac
	4.0 MHz-5.0 MHz		
AcuNav 10F/	2D-mode:	2D, C, D, M,	Cardiac Adult
SoundStar 10F/	5.0 MHz-8.9 MHz	SCW	Cardiac Pediatric
SoundStar eco 10F	Doppler:		■ Intra-Cardiac
	4.0 MHz-5.0 MHz		

TRANSDUCER NAME	OPERATING FREQUENCY ¹	MODES OF OPERATION ²	INTENDED APPLICATIONS
	END	OCAVITY TRANSDI	UCERS
EC9-4w	2D-mode: 4.2 MHz-7.3 MHz	2D, C, D, M	Early ObstetricsGynecology
	Doppler: 4.0 MHz-5.3 MHz		ObstetricsObstetrics (Japan)Urology
MC9-4	2D-mode: 4.2 MHz-7.3 MHz Doppler: 4.0 MHz-5.3 MHz	2D, C, D, M	 Early Obstetrics Gynecology Obstetrics Obstetrics (Japan) Urology
	four	Sight 4D TRANSDU	ICERS
C6F2	2D-mode: 2.9 MHz-5.0 MHz Doppler: 2.5 MHz-3.1 MHz	2D, C, D, M	 Abdomen Early Obstetrics Fetal Echo Gynecology Obstetrics Obstetrics (Japan) Pelvic Floor
C8F3	2D-mode: 3.3 MHz-5.7 MHz Doppler: 2.7 MHz-3.3 MHz	2D, C, D, M	 Abdomen Early Obstetrics Fetal Echo Gynecology Obstetrics Obstetrics (Japan) Pelvic Floor
EV9F3	2D-mode: 4.7 MHz-8.0 MHz Doppler: 4.0 MHz-5.3 MHz	2D, C, D, M	 Early Obstetrics Gynecology Obstetrics Obstetrics (Japan) Pelvic Floor
	CONTIN	UOUS WAVE TRAN	SDUCERS
CW2	2 MHz	CW	Cardiac Pediatric Echo
CW5	5 MHz	CW	Pediatric EchoCerebrovascular

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¹ Operating Frequency	Range of selectable operating frequencies for:
2D-mode	Fundamental and harmonic imaging, including contrast
Doppler	Pulsed wave, continuous wave, and color imaging

² Modes of Operation	Includes one or more of the following system operating modes
2D (brightness mode)	2D-mode, 2D-mode with Tissue Harmonic Imaging (THI)
C (color flow imaging)	Color Doppler, Power Doppler
D (Doppler)	Pulsed Wave Doppler, 2D/Doppler, 2D/Doppler with Color, 2D/Doppler with Power
M (motion mode)	M-mode, M-mode with THI, 2D/M-mode, 2D/M-mode with Color, 2D/M-mode with Power
SCW (steerable continuous wave Doppler)	Steerable Continuous Wave Doppler (for phased array transducers)
CW (continuous wave Doppler)	Auxiliary Continuous Wave Doppler (for continuous wave [pencil] transducers)

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.

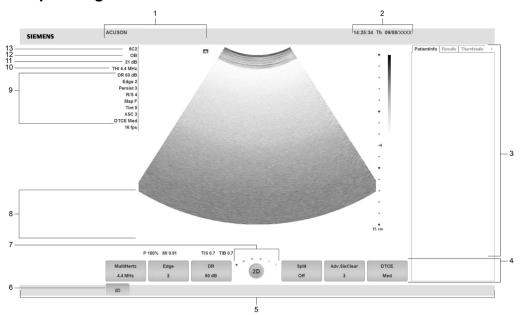
Restore the screen display by pressing any key or adjusting any control. The first key that you press will restore the view without performing a function. Press the key again to execute the command.

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

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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, Patient Info for displaying patient information and Results for displaying measurement results.
- 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 Status bar. Indicates the function currently assigned to the trackball, SELECT control, UPDATE key, ESCAPE key.

Provides an indication of the following functions: video recording or paused recording, signal strength of the wireless connection signal, and insert text or overwrite text for annotations.

- 6 Tab Indicator. Identifies the mode or function for the soft key selections.
- 7 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.
- 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.
- 9 Imaging Parameters. Displays settings for parameters adjusted by the soft key selections.
- 10 Transducer Frequency
- 11 Gain for the priority mode
- 12 Active Exam type
- 13 Active transducer name

Status Bar

Icon	Description
\odot	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.
00	Indicates recording status during video recording using a DVR. A red icon displays during recording and a white icon displays during pause. The recording time also displays beside the icon.
Q	When displayed, indicates recording function with the built-in microphone is activated.
*	Indicates strength of wireless connection signal.

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.

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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

Refer to this table to identify important symbols located on the ultrasound imaging system and transducers.

Symbol	Explanation
\sim	Alternating Current
V~	AC (alternating current) voltage source
A	Caution: Risk of electric shock
- ^	Type BF Defibrillator-proof Patient Connection
★	Type BF Applied Part
•	Type CF Patient Connection
	Consult Instructions for Use
	Operating Instruction – Mandatory Action
	(blue illustration)
\wedge	Caution
	(black illustration)
	Note: For systems and transducers shipped from the factory prior to 1 October 2010, the symbol means "Caution, consult accompanying documents."
\wedge	General Warning
<u> </u>	(yellow and black illustration)
	Monitor Menu Control
<u> </u>	Monitor Menu Control, up (increase)
▼	Monitor Menu Control, down (decrease)
	Monitor Picture menu icon
p	Monitor Function menu icon

Symbol	Explanation
	Monitor OSD menu icon
3 1	Monitor menu Exit icon
<u></u>	Protective Earth Ground
Ţ	Signal Earth Ground
⊕	Signal Input
\rightarrow	Signal Output
	Video Connection (monochrome video signals)
()	Start (of action for equipment)
Ŷ	USB Connection
**	Ethernet 10/100BaseT Connection
\bigvee	Equipotential Connection
	Printer Connection
B/W	Black and White Printer Connection
VGA	VGA
	Digital Video Interface (DVI)
	Intentional transmitter of non-ionizing radiation.
۱	Electronic Array Transducer Port
-	Continuous Wave Doppler Transducer Port

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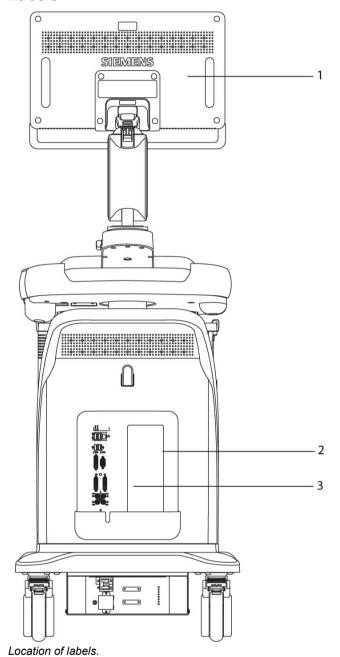
Symbol	Explanation
El .	Unlocked position
£	Locked position
)	Audio
DO NOT LEAN	Do not lean against the monitor.
20 kg MAX 44 lbs MAX	Shelf Weight Restriction
	ON only for MAINS control
0	OFF only for MAINS control
Ů	Power "On" standby switch
1	ECG Socket
IPX8	Protected against the effects of continuous immersion in water
	Do not open. Refer servicing to qualified service personnel.
(A-P)	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
CE	Manufacturer's declaration of product compliance with applicable EEC directive(s)
c Al us E170920	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
	(Installierte Volumen Komponente)
IVK	Identifier of selected system components or parts for product traceability
C UL US	UL classified symbol for Canada and United States of America
	Bar Code

Symbol	Explanation
50	Environmentally friendly use period
	Manufacturer
20XX	Date of Manufacture symbol with the date below
8	Do not install wet
<u> </u>	Location of air filter
-40°C 60°C	Storage temperature range (example)
11	Indicates this side up
1	Do not stack
140 kg	Shipping weight (example)
聋	Do not allow to get wet
Ţ	Fragile. Handle with care.
	Refer to the operator's manual for information about compatible needle guides.
	Do not dispose of by dumping in garbage. Use a separate collection for electrical and electronic equipment.
X	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 collection and disposal of the product, its components, or its accessories, contact your local Siemens representative.

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Symbol	Explanation
	Fuse
WARNING PINCH POINT WATCH YOUR HAND	Pinch hazard
	WARNING: PINCH POINT
	WATCH YOUR HAND
\	Control panel swivel
↑ ↓	Control panel height adjustment
SW1 SW5 OFF DVI/D-SUB NTSC ON S-Video PAL	External input/output converter box

Labels

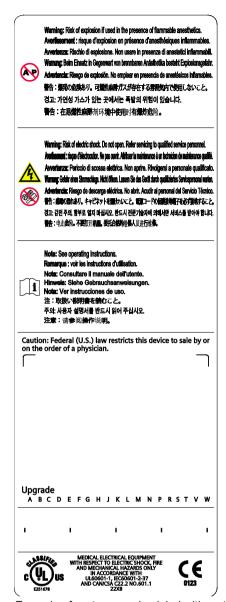


- 1 Monitor label
- 2 System warning and Certification label
- 3 Identification label

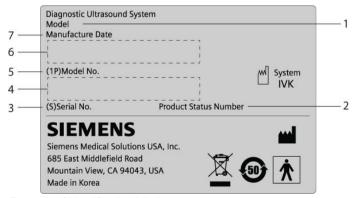


Example of monitor label.

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Example of system warning label with certification labels.



Example of identification label.

- 1 Product name
- 2 Product status number
- 3 Serial number
- 4 Serial number barcode
- 5 Model number
- 6 Model number barcode
- 7 Manufacturing date

Biohazard Considerations

▲ WARNING: With the exception of systems licensed to use the ACUSON AcuNav catheter, this equipment is not suitable for intracardiac use or direct cardiac contact.

See also: For additional information on the AcuNay catheter, refer to the user manual for the catheter.



▲ 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 of hazardous or infectious materials according to local, state, and regional regulations.



▲ 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.

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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.

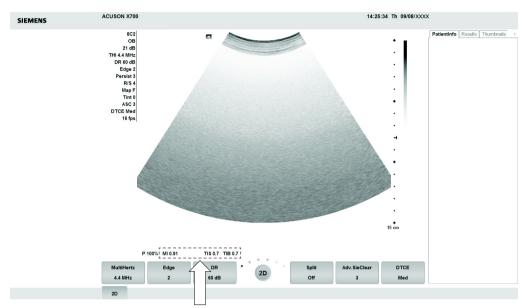
Note: For systems distributed in the United States of America, refer to the Medical Ultrasound Safety ultrasound education program brochure produced by the AIUM that is shipped with the ultrasound

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

Mechanical and Thermal Indices

The system displays the Mechanical Index during real time imaging, in all imaging modes. The system displays the Thermal Indices during real-time imaging when the value is equal to or exceeds 0.4.

Note: During exams using Contrast Agent Imaging (CAI), the system always displays values for the Mechanical Index (MI) and the Maximum of Mechanical Indices measured at the active focal zones (MIF).



Location of mechanical and thermal indices on the image screen.

Indices display in the abbreviated form shown below:

- MI: Mechanical Index
- MIF: Maximum of the Mechanical Indices measured at the active focal zones (displayed during CAI exams only)
- TIB: Bone Thermal Index (fetal application)
- TIS: Soft Tissue Thermal Index
- TIC: Cranial Thermal Index

2 - 12 Instructions for Use

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. 2-15

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

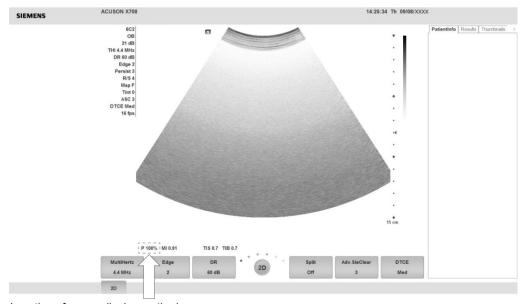
The transmit power range is from 0.20% to 100%. Selecting 100%, in combination with other system controls or functions, generates the maximum acoustic intensity and mechanical index for each transducer, where:

 $I_{\text{SPTA.3}}$: \leq 720 mW/cm² 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.

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Imaging Functions that Change Acoustic Output

MARNING: 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 1.41%.

	Maximum Temperature				
Transducer	ТММ	Still Air			
4C1	<32.1° C	<41.6° C			
CH5-2	<31.2° C	<42.7° C			
6C2	<32.7° C	<43.5° C			
C6-2	<31.4° C	<42.1° C			
C8-5	<28.9° C	<38.8° C			
VF10-5	<33.2° C	<44.5° C			
VF12-4	<32.0° C	<44.8° C			
VF16-5	<28.8° C	<41.7° C			
C6F2	<28.8° C	<40.2° C			
C8F3	<26.4° C	<39.4° C			
EV9F3	<28.3° C	<43.2° C			
EC9-4w	<30.7° C	<44.3° C			
MC9-4	<30.7° C	<44.3° C			
4V1c	<32.8° C	<45.5° C			
P8-4	<29.4° C	<39.3° C			
V5Ms	<30.3° C	<43.2° C			
AcuNav 8F	<29.5° C	<36.5° C			
AcuNav 10F	<29.8° C	<36.4° C			
SoundStar 10F	<29.8° C	<36.4° C			
SoundStar eco 8F	<29.5° C	<36.5° C			
SoundStar eco 10F	<29.8° C	<36.4° C			
CW2	<30.6° C	<40.2° C			
CW5	<29.4° C	<38.1° C			

TMM = Tissue Mimicking Material

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Electrical Safety

A

▲ WARNING: To avoid electric shock, use a protective earth connection to connect the ultrasound system to the mains power supply. The protective earth connection ensures that the mains circuit breaker will disconnect the power supply in the event of a short circuit.

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:** To avoid electrical shock and damage to the control panel resulting from ingress of liquid, place the gel and gel warmer on the side of the system closest to the patient.

⚠ **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 prevent excessive leakage current from contacting the patient, do not touch a user-accessible connector on the system while touching or scanning the patient. Useraccessible connectors include the ECG connector, a USB connector, and any other audio, video, or data transmission connectors.

▲ WARNING: Connecting peripheral devices to accessory outlets on the ultrasound system effectively creates a medical electrical system, resulting in a reduced level of safety.

WARNING: Do not modify this equipment without authorization from Siemens.

△ Caution: To maintain the safety and functionality of the ultrasound system, maintenance must be performed every 24 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.

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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.

Defibrillator Use and the ACUSON AcuNay Ultrasound Catheter



MARNING: The catheter is designed to withstand the effects of defibrillation. However, when possible, disconnect the connector from the ultrasound system during defibrillation because a malfunction of the safety controls could otherwise result in electrical burns for the patient.

The catheter 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.

Recovery Time After Defibrillation During a Catheter Procedure

If you disconnect the SwiftLink catheter connector from the ultrasound system before defibrillation, the recovery time after defibrillation is equal to the time required to reconnect the connector to the ultrasound system.

The recovery time after defibrillation for the ultrasound system:

Three (3) minutes if defibrillation is performed with the ultrasound system on.

Implantable Devices



⚠ WARNING: Ultrasound systems, like other medical equipment, use high-frequency electrical signals that can interfere with implantable devices such as pacemakers and implantable cardioverter-defibrillators (ICDs). If the patient has such an implantable device, you should be aware of any interference in its operation and immediately 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 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.

Barcode Reader



▲ WARNING: To avoid electrical shock, do not connect the barcode reader to the system when more than two on-board documentation devices are connected to the system.



▲ WARNING: Do not stare into the beam of the barcode reader. This action can create a risk for injury to the user.

You can connect a Siemens-approved barcode reader directly to a USB port on the ultrasound system. The barcode reader provides direct entry of patient information in the registration form, for example, patient name, patient identifier, or physician identifier.

2 - 20 Instructions for Use

Maintaining Data Integrity

Important Information

To ensure data integrity:

- To prevent the loss of data that results from power failures and other system "down" occurrences, you must archive important data, such as patient records, onto an external recording media, such as a CD or a network.
- Loss of data is to be expected and its retrieval is not normally possible under the following conditions: loss of power to the ultrasound system, hard disk failure, CPU failure, system lockup, and other similar causes.
- Should an abnormal system shutdown occur, retrieval of data not saved to the hard disk or not archived to an external recording media is not normally possible.
 - An abnormal system shutdown occurs if you do not power off the ultrasound system using the partial power on/off switch (0) located on the control panel. Other examples of abnormal system shutdown include: equipment malfunction, loss of power, or pressing and holding the partial power on/off switch longer than 4 seconds.
- Should an abnormal system shutdown occur, the system may initially require additional time to reboot or to respond to user input. This is due to the operating system performing a background scan of the hard disk to detect and segregate any truncated or corrupted files.

Caring for the Ultrasound System

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



⚠ **WARNING**: To minimize the risk of cross-contamination and infectious diseases, a sterile, non-pyrogenic transducer sheath must be in place during procedures requiring sterility.



⚠ 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. 2-36

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.
- 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.

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Maintenance

riangle Caution: To maintain the safety and functionality of the ultrasound system, maintenance must be performed every 24 months. Electrical safety tests must also be performed at regular intervals as specified by local safety regulations, or as needed.

Repair

▲ WARNING: Do not modify this equipment without authorization from Siemens.

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 24 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:

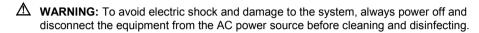
- The nature and extent of the work performed
- Changes in rated performance
- Changes in working ranges
- Date of service
- Name of person or firm performing the service
- Signature of person performing the service

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.

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: 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.

★ 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.

▲ WARNING: The use of any disinfectants other than those specified in the instructions for use may damage the ultrasound system and accessory surfaces and, as a result, may create electrical hazards for the patients and/or users.

⚠ 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. 2-25

⚠ 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.

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System Surfaces

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

After cleaning system surfaces, including the trackball and transducer holder, you can disinfect the surface with an approved disinfectant wipe.

To clean the surface of the ultrasound system:

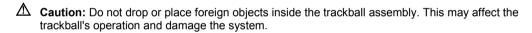
- Power off (⁽¹⁾) the ultrasound system and unplug the power cord from the power outlet.
- 2. Use a clean gauze pad or lint-free cloth, lightly moistened with a mild detergent, to wipe the surface of the ultrasound system.
 - Take particular care to clean the areas near the trackball and the slide controls.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

Approved Disinfectant Wipes for the Ultrasound System Surfaces

The following matrix provides a list of approved disinfectant wipes for use on the ultrasound system and surfaces of the listed components.

	Sani-Cloth AF	Sani-Cloth AF3	Sani-Cloth Bleach Wipe*	Sani-Cloth HB	Sani-Cloth Plus	Super Sani-Cloth
Ultrasound System	✓	✓	✓	✓	✓	✓
Transducer Liners	✓	✓	✓	✓	✓	✓
Trackball Assembly	✓	✓	✓	✓	✓	✓

^{*}or any bleach wipe with <1% sodium hypochlorite and no other active ingredients

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^{√ =} compatible

NC = not compatible

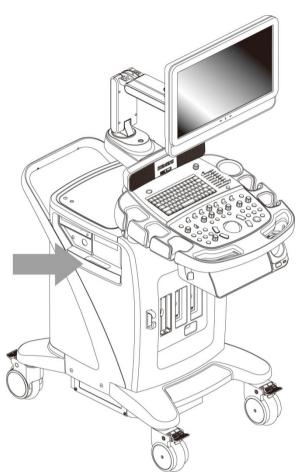
NA = not applicable (not tested)

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.

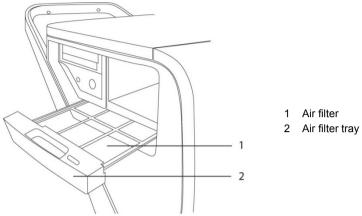


Location of air filter.

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.

- Rinse the air filter tray with running water and allow the filter to completely dry.
 To hasten drying, you may gently shake the air filter tray, or blot the filter with a clean, lint-free cloth.
- ⚠ Caution: Do not insert the air filter tray into the ultrasound system with a wet filter as this can damage the system.
- 4. Slide the air filter tray back into the ultrasound system.
- 5. 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.

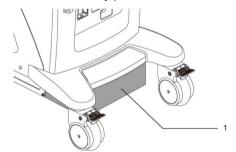
⚠ **WARNING:** Do not disassemble the battery pack. Compromising the structural integrity of the battery pack can result in leakage or explosion and the potential for personal injury.

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



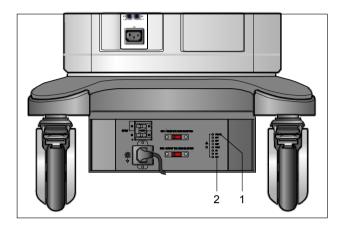
1 Battery pack location

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 QuikStart 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 QuikStart 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.

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Caring for Documentation and Storage Devices

△ Caution: Computer viruses on a USB-compatible device can infect the ultrasound system. Check for viruses before connecting the device to the system.

Note: Study data stored directly to a USB device can be lost. Do not use a USB device for permanent data storage.

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

Caring for Transducers



⚠ 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.



⚠ **WARNING:** Prior to each use, inspect the endocavity or intraoperative transducer for signs of mechanical damage such as cracks, cuts, tears, perforations, or protrusions. Do not use the transducer if the transducer appears damaged in any way. Any damage could cut the patient and compromise the electrical safety of the transducer, causing possible patient or user injury. Contact your local Siemens representative.



⚠ **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.



△ 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.

▲ 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 (EO) 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

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To clean a transducer:

- 1. Disconnect the transducer from the system.
- 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.
- 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.
- Thoroughly clean, rinse, and dry the transducer.
- 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.
- After disinfecting or high-level disinfecting, use a clean cloth to dry the transducer.

IPX8 Immersion Levels

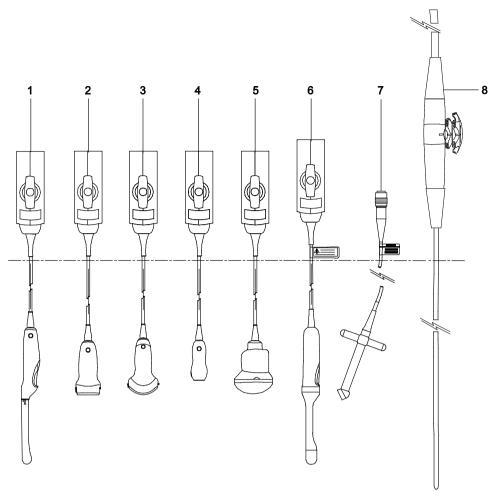
△ Caution: To avoid damage to the transducer, observe the immersion levels indicated for each transducer type. Transducers with the protection level IPX8 are indicated by the presence of the "IPX8" symbol on the connector of the transducer.

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.

- 1 Endocavity
- 2 Linear
- 3 Curved
- 4 Phased
- 5 fourSight 4D
- 6 fourSight 4D (endocavity)
- 7 Continuous Wave (CW)
- 8 V5Ms

⚠ 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.

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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
4C1	✓	✓	✓	✓	✓	✓
CH5-2	✓	✓	✓	✓	✓	✓
6C2	✓	✓	✓	✓	✓	✓
C6-2	✓	✓	NA	✓	✓	✓
C8-5	✓	✓	NA	✓	✓	✓
VF10-5	✓	✓	✓	NA	✓	✓
VF12-4	✓	NC	NA	NA	✓	NC
VF16-5	✓	✓	NA	NA	✓	✓
C6F2	NA	NA	NA	NA	✓	NA
C8F3	NA	NA	NA	NA	✓	NA
EV9F3	NA	✓	NA	NA	NA	✓
EC9-4w	✓	✓	✓	✓	✓	✓
MC9-4	✓	✓	NA	✓	✓	✓
4V1c	✓	✓	✓	✓	✓	✓
P8-4	✓	✓	✓	✓	✓	✓
V5Ms	✓	✓	NA	NA	✓	✓
CW2	✓	✓	✓	✓	✓	✓
CW5	✓	✓	✓	✓	✓	✓

^{√ =} compatible

NC = not compatible

NA = not applicable (not tested)

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	Resert XL HLD
4C1	✓	✓	✓	✓	✓	✓	✓
CH5-2	✓	✓	✓	✓	✓	✓	✓
6C2	✓	✓	✓	✓	✓	✓	✓
C6-2	✓	✓	✓	✓	✓	✓	NA
C8-5	✓	✓	✓	✓	✓	✓	NA
VF10-5	✓	✓	✓	NA	NA	NA	NA
VF12-4	✓	✓	✓	NA	✓	NA	✓
VF16-5	NA	NA	✓	✓	✓	NA	NC
C6F2	✓	✓	✓	NA	NA	NA	NA
C8F3	✓	✓	✓	NA	NA	NA	NA
EV9F3	NA	✓	✓	✓	✓	NA	NA
EC9-4w	✓	✓	✓	✓	✓	✓	NA
MC9-4	✓	✓	✓	✓	✓	✓	NA
4V1c	✓	✓	✓	✓	✓	✓	✓
P8-4	✓	✓	✓	✓	✓	✓	✓
V5Ms	✓	✓	✓	✓	NA	✓	NA
CW2	✓	✓	✓	✓	✓	✓	NA
CW5	✓	✓	✓	✓	✓	✓	NA

^{✓ =} compatible

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NC = not compatible

NA = not applicable (not tested)

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.

Caring for Transducer Accessories

Instructions are provided for the following accessories for transducers:

- Transducer Sheaths
- Gel Pads
- Needle Guide Bracket Kits

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

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.



MARNING: To minimize the risk of cross-contamination and infectious diseases, a sterile. non-pyrogenic transducer sheath must be in place during procedures requiring sterility.



MARNING: 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 (EO) 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

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



⚠ **WARNING:** Before use, examine sterile goods, such as sheaths, 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.

△ 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°C and up to 80% relative humidity at +40°C.

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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.

Refer to the in-box instructions for storage and transportation information.

Cleaning, Disinfecting, and Sterilizing Transducer Accessories

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

Needle Guide Bracket Kits

Needle guide bracket kits are available for specific transducers. Instructions follow for the cleaning, disinfecting, and sterilization of each kit. Bracket assemblies should be cleaned and sterilized or high-level disinfected after each use.

See also: For a list of transducers compatible with the needle guide accessories, refer to Chapter 5 in this manual.

CH4-1, SG-3, SG-5, and Infiniti Plus 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 quide for use with the CH4-1, SG-3, SG-5, and Infiniti Plus bracket kit is a singleuse 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.

EV9F3 Reusable Needle Guide Bracket Kit (Stainless Steel)



▲ 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.

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EC9-4w Disposable Needle Guide Bracket Kit

⚠ **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.

EC9-4w Reusable Needle Guide Bracket Kit (Stainless Steel)

⚠ **WARNING:** The needle guide is packaged non-sterile. Sterilize this product prior to its 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.

VF12-4 Reusable Needle Guide Bracket Kit

⚠ **WARNING**: The needle guide is packaged non-sterile. Sterilize this product prior to its first use.

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

Universal Reusable Needle Guide Bracket Kit S (Stainless Steel)

⚠ **WARNING**: Needle Guide Bracket kits are packaged non-sterile. Sterilize these products prior to their first use. Refer to the sterilization procedures for the Reusable Needle Guide Bracket Kit S (Stainless Steel) in the following pages.

Prior to sterilization, clean the Universal Reusable 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.

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Environmental Protection

Product Recycling and Disposal

Dispose of this product according to local, state, and regional regulations.

Batteries and electrical and electronic equipment can contain hazardous substances. If released, the hazardous substances can harm people and the environment.

Siemens provides disassembly instructions to treatment facilities for the safe and proper removal and recycling of electrical and electronic components in this product. For more information, contact your local Siemens representative.

To the extent required by local laws and regulations, Siemens has programs for the return of used products. For more information, contact your local Siemens representative.

Hazardous Substances

▲ WARNING: This product consists of devices that may contain mercury, which must be recycled or disposed of in accordance with local, state, or federal laws.

Hazardous Substance	Included in the Product?	Location
Mercury	Yes	A small amount of mercury (maximum 5.0 mg/lamp) is included in the backlight of the flat panel monitor.

Caring for Batteries

▲ WARNING: Do not strike or drop batteries, allow batteries to contact water or other fluids, disassemble batteries, allow conductive object to contact a battery's terminals, cause a battery to become short circuited, heat batteries, or expose batteries to fire. Any of these actions can compromise the structural integrity of a battery. Compromising the structural integrity of a battery can result in battery leakage, heat generation, fire, or explosion, causing possible personal injury.

▲ WARNING: Do not use a battery if it leaks fluid or has changed shape. If skin or clothing comes in contact with fluid from the battery, 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: Replace batteries with the same or equivalent type. Use of incompatible batteries can result in battery leakage, heat generation, fire, or explosion, causing possible personal injury.



⚠ **WARNING**: Do not attempt to recharge non-rechargeable batteries, such as the batteries included on printed circuit boards. Recycle non-rechargeable batteries according to local, state, and regional regulations.

For maximum battery life, observe all of the following steps when the system is not in use:

- Keep the system plugged into the power outlet.
- Ensure the mains circuit breaker is in the on position (I = ON).
- Store the system in an environment with low humidity and a temperature range between 0°C and 21°C, where possible.

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Recycling Batteries

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

⚠ **WARNING:** Do not throw batteries into the trash. Collect and recycle used batteries separate from other waste.

Item	Estimated Use Period	Handling Instructions
Lithium batteries	1.5 years	See also: Caring for Batteries, p. 2-44
		The battery is expected to hold a sufficient charge for 1.5 years from the start of service if:
		The system is never plugged into the power outlet.
		 The system is plugged into the power outlet, but the mains circuit breaker is in the off position (O = OFF) for the entire 1.5 years.
		If the system clock no longer keeps time, it could be time to replace the battery. Contact your local Siemens representative.
Battery packs (lithium-ion battery)	6 months	See also: Caring for the Battery Pack, p. 2-29
		The battery is rechargeable.

Recycle batteries according to local, state, and regional regulations. Use a battery collection program available in your country to recycle batteries.

To the extent required by local laws and regulations, Siemens will collect and recycle batteries for this product at no charge. Contact your local Siemens representative for battery shipment instructions.

Disposing of the Packaging Materials

Dispose of or recycle the packaging materials according to local, state, and regional regulations.

To the extent required by local laws and regulations, Siemens will collect and dispose of packaging materials for this product. For more information, contact your local Siemens representative.

Disposing of Components and Accessories

▲ WARNING: Observe local, state, and regional regulations for the disposal of the ultrasound system components and accessories.

Component or Accessory	Handling Instructions
air filter tray	See also: Cleaning an Air Filter, p. 2-27
	The air filter tray is reusable.
	Replace the air filter tray if the air filter is damaged in any way. For example, the air filter has a hole, or the air filter tray will not fit in the air filter tray slot.

Energy Conservation

See also: Supplying Power to the System, Chapter 3, Instructions for Use

For moderate energy conservation when the system is not in use, place the system in standby status.

For improved energy conservation when the system is not in use, power off the system. Keep the system plugged into the power outlet. Ensure the mains circuit breaker is in the on position (I = ON).

For maximum energy conservation when the system is in storage, power off and unplug the system from the power outlet or switch the mains circuit breaker to the off position (O = OFF).

Note: Unplugging the system from the power outlet or switching the mains circuit breaker to the off position (O = OFF) for long periods of time can shorten the life of the system batteries.

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3 System Setup

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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.



MARNING: 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.



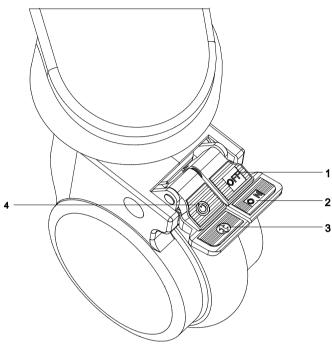
Caution: To prevent damage to the system during a move, retract or close any doors and travs on the documentation devices or components on the ultrasound system. Ensure components do not protrude from the system.

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 and locking release lever and a swivel and swivel 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



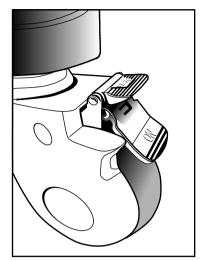
Example of wheel with locking brake (unlocked).

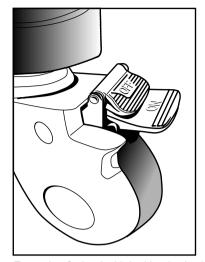
- 1 Locking release lever
- 2 Locking lever
- 3 Swivel lock lever
- 4 Swivel release lever

То	Do This	Symbol
Lock the brake	 Press the locking lever down with your foot into the locked position. 	ON (on)
Release the brake	 Press the locking release lever down with your foot to release the brake. 	OFF (off)
Lock the swivel	 Press the swivel lock lever with your foot until the swivel brake locks into place. 	Û
Release the swivel	 Press the swivel release lever with your foot until the brake unlocks and the lock swivel lever releases. 	C

3 - 4 Instructions for Use

Back Swivel Locking Brake





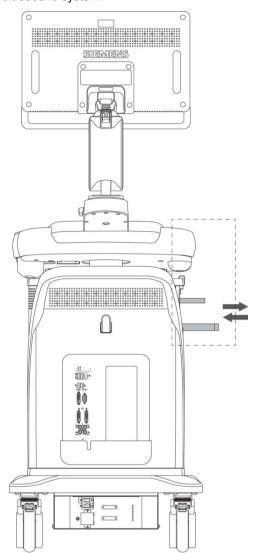
Example of wheel with locking brake (locked).

Example of wheel with locking brake (unlocked).

То	Do This	Symbol
Lock the brake	 Press the locking lever down with your foot into the lowest (locked) position 	ON (on)
Release the brake	 Press the locking release lever down with your foot to release the brake. 	OFF (off)

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.
- Retract or close any doors or trays of the documentation devices or components on the ultrasound system.

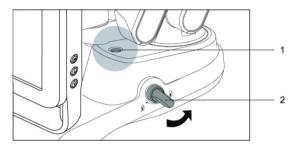


Retracting open doors or trays.

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

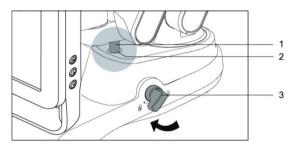
3 - 6 Instructions for Use

- 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.



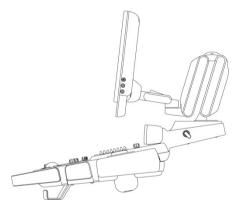
Example of transport lock in the unlocked position.

- 1 Pin hole
- 2 Transport lock



Example of transport lock in the locked position.

- 1 Pin
- 2 Pin hole
- 3 Transport lock



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, contaminates, or standing liquids.

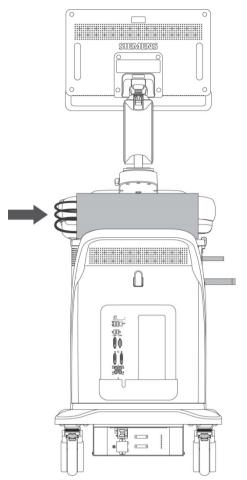
△ Caution: Care should be taken to minimize shock and vibration of the ultrasound system. Avoid uneven surfaces that contain an abrupt height change or jarring surface irregularities.

⚠ 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. 3-12

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

3 - 8 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

⚠ 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.
- Set the brakes: Set the front and rear brakes.
- Plug in the cord: Plug the power cord into a hospital-grade or local equivalent wall outlet.
- Power on: Power on $(^{\circlearrowleft})$ the ultrasound system.
- 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.

3 - 10 Instructions for Use

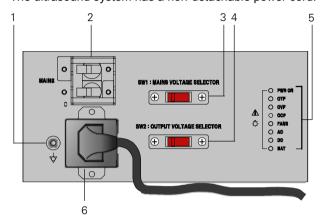
System Startup

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

Plugging in the System

⚠ **WARNING**: Before connecting the ultrasound system to a power supply, you must read and understand the Electrical Safety section of Chapter 2, Instructions for Use.

The ultrasound system has a non-detachable power cord.



- Equipotential connector
- MAINS circuit breaker
- MAINS Voltage Selector
- Accessory Outlet Output Voltage Selector
- Status Indicator (for Service diagnostics)
- Connector cover for 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 hospitalgrade 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 $({}^{\circlearrowleft})$ 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 (0) 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 Shut Down System dialog box.

- 1. Briefly press the partial power on/off ($^{\circlearrowleft}$) button on the upper left of the ultrasound system. The system displays the Shut Down System dialog box.
- Select the **Shut Down** 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 (0) button for at least five seconds.

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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 **Shut Down System** dialog box.
- 2. Select the **Restart** button.

The system will power off and restart.

Entering and Exiting Standby Mode

The standby function is not available during video playback or use of an application. Examples of applications include: Stress Echo, Axius EF, and SieScape.

To enter Standby mode:

Use the system presets to automatically close the current study when standby mode is activated.

■ General 1 > Close Study on System Standby

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 ($^{\circlearrowleft}$) button on the upper left of the ultrasound system.
- 2. Select **Stand by** from the displayed dialog box.

The system enters standby mode.

3. To use the QuikStart battery-powered feature in standby mode, wait approximately 20 seconds before unplugging the ultrasound system.

To exit Standby mode:

Note: You must wait approximately 20 seconds after the system powers off before powering on $(^{\cup})$ the ultrasound system.

- If you are using the QuikStart feature in standby mode, plug the power cord into a power outlet before exiting standby mode.
- 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.

QuikStart Feature (Battery-Powered Standby Mode)

The QuikStart 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 30 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 $(^{\circlearrowleft})$ 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.

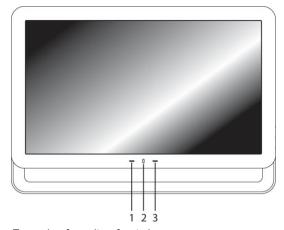
3 - 14 Instructions for Use

Adjusting Controls on the Monitor

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

See also: Monitor Menu Selections, p. 3-17

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





Example of monitor, front view.

- 1 Monitor On/Off LED
- 2 Microphone
- 3 Microphone On/Off LED

Example of monitor, side view.

- 1 🖼 Menu
- 2 ▲ Up (+)
- 3 ▼ Down (-)

Controls on the Monitor

Monitor button	Description
☐ Menu	Press Menu to activate and deactivate the brightness control.
	Press and hold Menu and Down ▼ (for at least 8 seconds) to display the monitor menu with additional controls.
▲ Up (+)	Press Up to increase the settings for a control or to move the selection to the right or up.
▼ Down (-)	Press Down to decrease the settings for a control or to move the selection to the left or down.

Adjusting Brightness

Note: Factory-defined imaging presets use a default setting for the brightness of the monitor. Adjusting the brightness setting on the monitor may affect the image optimization intended by the factory-defined imaging presets.

For consistency in image reproduction, adjustments to the brightness 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 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 Brightness.
- 2. Press the ▼ control to decrease the setting or press the ▲ control to increase the setting. Decrease the setting for darker images; increase the setting for lighter images.

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

- 1. Press the control on the monitor to display the setting for Brightness.
- Press and hold the ▼ control or the ▲ control (for at least 3 seconds).
 The system displays the OSD Main Menu is locked message.
- 3. To unlock the monitor settings, repeat step 2.

3 - 16 Instructions for Use

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
	Brightness
	Sharpness
	Color Mode
	Exit
	Function
	Scale
	Information
	Memory Recall
	SBC
	Exit
	OSD
	Language
	OSD H-Position
	OSD V-Position
	Half Tone
	Exit
50	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 is 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

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.



фф)

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:

Use the system presets to adjust the volume during video playback (DVR).

■ General 1 > Audio > Line-in Volume

- 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.

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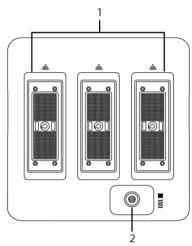
Connecting and Disconnecting Transducers

⚠ 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.

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

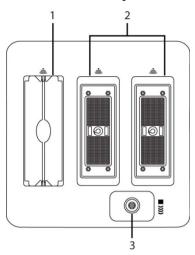
ACUSON X600 System



Example of transducer ports.

- Three 260-pin ports for standard array transducers
- 2 Continuous Wave (CW) Doppler port for CW Doppler pencil transducers

ACUSON X700 System



Example of transducer ports.

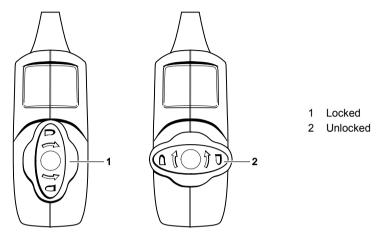
- 1 One 192-element port for micro-pinless transducers
- 2 Two 260-pin ports for standard array transducers
- 3 Continuous Wave (CW) Doppler port for CW Doppler pencil transducers

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Array Transducers

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

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. (260-pin array transducers) Insert the connector pins into the system port. (Micro-pinless transducers) Insert the connector 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.
- 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.

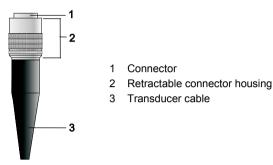
Continuous Wave Transducers

⚠ 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.

- 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.

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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).

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

Transducer Cable Management



MARNING: 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

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 into the USB port located on the back 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.

Auxiliary Inputs

.

⚠ **WARNING:** The Aux 1 input is not intended for direct connection to the patient. To reduce the risk of electrical shock while using this connection, ensure that the external source (peripheral equipment) is properly set up and is designed for direct patient connection.

Aux 1



Aux 1 connector socket.

To connect an external auxiliary cable:

- Connect the one-pin external auxiliary cable to the socket labeled "Aux 1" on the front of the system.
- 2. To connect the external auxiliary cable to a device (external source), see the device manufacturer's operating instructions.

Wireless Network Connections

(Requires the wireless option license)

The ultrasound system can send data, such as studies, images, and clips, to a network location over a wireless network.

Use the system presets to configure wireless network connections.

■ Wireless

When the ultrasound system is connected to a wireless network, the system displays an icon indicating the connection to the wireless network and the signal strength on the status bar.

Note: Siemens recommends connecting the ultrasound system to wireless networks that use only the 5 GHz frequency bandwidth to reduce potential radio interference from the 2.4 GHz frequency bandwidth.

Approved Wireless Adapters



△ Caution: Use of wireless adapters not tested for use and approved by Siemens can damage the ultrasound system. Do not connect any wireless adapters to the system except the wireless adapters listed below.

Note: Use of an unapproved wireless adapter may cause loss of data transferred over a wireless network.

The following wireless adapters have been tested for use and approved by Siemens.

- Linksys AE1000
- ASUS USB-N53

For information on the transmission and reception frequencies used by the wireless adapter, refer to the manufacturer's operating instructions included with the wireless adapter.

You must abide by the regulatory requirements of your country to use a wireless adapter. Refer to the manufacturer's operating instructions for information regarding certified use of the wireless adapter in your country.

△ Caution: Maintain a distance of at least 25 cm of radius between the wireless adapter and possible sources of interference. Possible sources of interference can be other medical devices and systems, including devices and systems in compliance with CISPR emission standards.



⚠ Caution: Ultrasound systems operate in the range of radio frequencies (RF) and are susceptible to electromagnetic interference generated by other RF energy sources. To prevent this interference, increase the distance between the ultrasound system and the interfering RF energy source.

Siemens recommends connecting the wireless adapter to the leftmost USB port on the Input/Output panel of the ultrasound system.

Informational Icons for the Wireless Adapter

Icon	Explanation
	Connected to a wireless network, strong signal strength
*	Connected to a wireless network, good signal strength
*	Connected to a wireless network, weak signal strength
	Connected to a wireless network, poor signal strength
***	Cannot connect to a wireless network, no signal

3 - 26 Instructions for Use

Input/Output Panel Connections

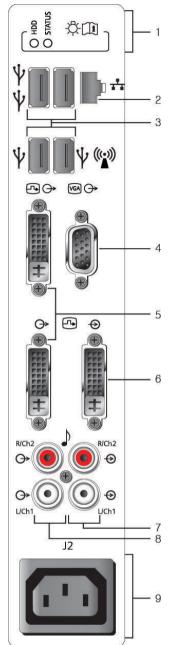
Audio and video connections are located on the Input/Output (I/O) panel.

▲ WARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (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.

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.



- 1 Status Indicators (for service diagnostics only)
- 2 Ethernet Connection
- 3 USB Port
- 4 VGA Out
- 5 DVI Out
- 6 DVI In
- 7 Audio In
- 8 Audio Out
- 9 Accessory Power Outlet

Input/output panel connections.

	MAINS VOLTAGE	ACCESSORY OUTLET VOLTAGE
ACCESSORY OUTLETS ISOLATED / SWITCHED TOTAL(J1,J2) 200VA MAX ~ (50/60Hz)	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.

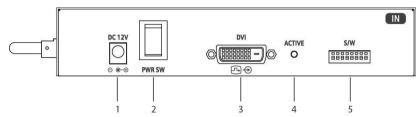
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Input/Output Converter Box (Video Converter)

The external input/output (I/O) video converter box converts:

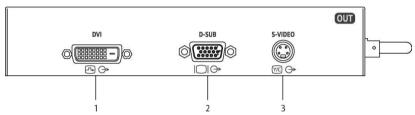
- Digital video input signals to analog video output signals.
- Video signals from the ultrasound system for display on an external display device.

The I/O converter box supports one digital input video format (DVI) and three digital output video formats (DVI, D-sub, and S-Video).



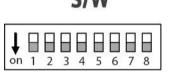
Example of the input/output converter box, left view (input ports).

- 1 Power cable outlet
- 2 Power switch
- 3 DVI In
- 4 LED status indicator
- 5 DIP switch



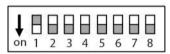
Example of the input/output converter box, right view (output ports).

- 1 DVI Out
- 2 VGA Out
- 3 S-Video Out



Example of the DIP switch with the switches off.

S/W



Example of the DIP switch with the first switch on.

То	Do This
Use the DVI or D-SUB (VGA) output ports	Push the first switch upwards (off).
Use the S-video output port to display NTSC format	Push the first switch downwards (on).
Use the S-video output port to display PAL format	Push the first and fifth switches downwards (on).

See also: Documentation Devices, Chapter 2, System Reference

⚠ WARNING: Equipment connected to the ultrasound system and in the patient environment 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: Non-medical grade report printers cannot be used within a patient environment.



MARNING: During use of a non-medical grade report printer or when a non-medical grade report printer is connected to the ultrasound system, the ultrasound system cannot in any way be in contact with a patient.

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.

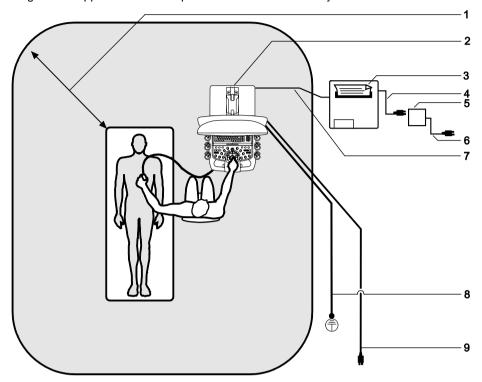
- Connect the imaging system to an independent protective earth terminal, with a ground wire connection to the ultrasound systems equipotential connector. Ensure that the protective earth wire is connected to a qualified protective earth connection independent of the existing systems earth connection (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.

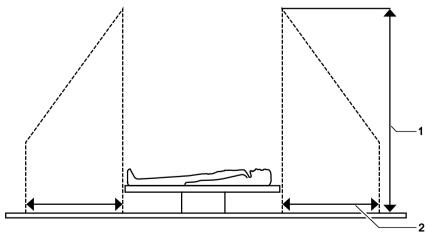
3 - 30Instructions for Use During normal operation, the ultrasound system is designed to display ultrasound images without noise, artifacts, or distortion that cannot be attributed to physiological effects.

Observe the peripheral equipment connections and patient environment shown in the following diagram to support the normal operation of the ultrasound system.



Example of a peripheral equipment connection and patient environment.

- Patient environment represented by shading, extending exactly 1.5 meters (1.8 meters [6 feet] in Canada and in the U.S.A.) around patient and ultrasound system
- 2 Ultrasound system
- 3 Peripheral equipment (EN XXXXX and IEC XXXXX)
- 4 Peripheral equipment power cord
- 5 Medically-approved isolation transformer
- 6 Medically-approved isolation transformer power cord
- 7 Printer data cable
- 8 Additional protective ground
- 9 Ultrasound system power cord



Example of a peripheral equipment connection and patient environment.

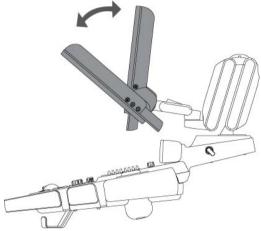
- 1 2.5 meters (typical)
- 2 1.5 meters (1.8 meters [6 feet] in Canada and the U.S.A.)

⚠ 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.

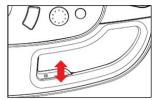


Example of monitor arm in forward, extended position.



Example of monitor in non-extended position.

3 - 32 Instructions for Use **Control Panel** – Use the button located on the inner side of the handle on the control panel to adjust the height or position of the control panel.



Example of the location of the button for adjusting the height or position 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 **Presets** on the keyboard.
- 2. Click General 1.
- 3. Enter the name of your institution in the Hospital Name field.
- 4. Click Save.

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 Presets on the keyboard.
- 2. Click General 1.
- 3. Select a date format from the **Date Format** section, and then click **Save**.

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To change the system date or time:

- 1. Press **Presets** on the keyboard.
- 2. Click General 1.
- 3. Click Date & Time Settings.
- 4. Change the date or time:
 - Click Change date and time to display a calendar screen.
 - To change the date, select a year, month, and day and then click OK.
 - To change the time, enter an hour, minute, and second value and then click **OK**.
- 5. Change the time zone:
 - To change the time zone, click Change time zone, select a time zone, and then click OK.

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 **Presets** on the keyboard.
- 2. Click General 1.
- 3. Select the Internet Time tab and click Change settings.
- 4. Select the check box to synchronize with the server.
- 5. Enter the Internet server name in the **Server** field.
- 6. To update the time immediately, click ${\bf Update\ Now}.$

To update the time at the next interval, click **OK**.

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.

- **E** Customize Keys > Print/Store 1 Key
- **E** 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 Customize Keys on the left of the screen.
- 3. Select the required option for the **PRINT/STORE1** or **PRINT/STORE2** control:

To configure the documentation control to:	Select an option:
Store images and patient reports	Disk Store
Store clip data or 3D volume data	Clip/Volume Store
Store 3D volume data	Volume Store
Print images and patient reports	PC Printer
	■ USB B/W
	 USB Color
	 DICOM B/W Print
	 DICOM Color Print
Store and print images and patient reports	 Disk Store & PC Printer
	 Disk Store & USB B/W
	 Disk Store & USB Color

4. Select the required option for the **CLIP STORE** control:

To configure the documentation control to:	Select an option:
Store images and patient reports	Disk Store
Store clip data or 3D volume data	Clip/Volume Store

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

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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. 3-39

- 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.

See also: Storing and Retrieving System Presets and QuickSets, Documentation Devices, Chapter 2, System Reference

Use the system presets to verify the system software version.

≡ Service

To install the system software:

- 1. Power on $(^{\circlearrowleft})$ the ultrasound system.
- 2. Insert the installation media into the CD/DVD drive.
- 3. Briefly press the partial power on/off (⁽¹⁾) button and then select **Restart** in the **Shut down System** dialog box.
- 4. Press any key on the keyboard when the Siemens logo displays.

The system displays a software installation screen.

- 5. Click **Next**, and select an installation method:
 - To install software and retain all existing user-defined settings, select UPGRADE/UPDATE INSTALLATION.
 - To install software and remove existing user-defined settings, select CLEAN INSTALLATION.
 - To cancel the installation, click **Cancel**.
- 6. Follow the instructions presented on the screen.

The system displays the status of the installation.

When the system displays the completion message, remove the installation media from the CD/DVD drive and click FINISH.

The system restarts automatically.

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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 and Components on the left of the screen.
- 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.

3 System Setup

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Patient Registration

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. (Required for use with a barcode reader.)
- e-entry displays an overlay of patient identification fields on the Image screen.

■ General 2 > Patient ID > Customize Entry Order

То	Do This			
Enter or edit patient	1. Press NEW PATIENT on the control panel. Or, press Patient Data on the keyboard.			
information and start an	2. Enter the required information in the registration form.			
exam	See also: Using the Patient Data Form, p. 4-4			
	3. Click OK . Or, click Cancel to discard entries.			
Enter patient information scanned with a barcode	Note: Use the system presets to identify the information in the barcode used by your facility. The barcode reader must be mapped to your barcode system.			
reader	■ Peripheral > Barcode Reader			
	1. Press NEW PATIENT on the control panel. Or, press Patient Data on the keyboard			
	Position the text cursor in the first entry field defined in the system presets.			
	3. Scan the barcode.			
	You can separately scan the barcodes for the patient name and ID, the performing physician, and the sonographer.			
	4. Complete the entries in the registration form.			
	5. Click OK . Or, click Cancel to discard entries.			
Register a new patient using the Worklist search function	See also: Searching the Worklist, p. 4-11			
Retrieve patient information using the query/retrieve function	See also: Querying and Retrieving Studies, p. 4-10			
Retrieve patient	Press Patient Browser on the keyboard.			
information from the ultrasound system's hard disk or external media	The system displays the Image screen if a patient is currently registered; if not, the system displays the Study screen.			
	Click Study Screen, if necessary, and then select the location of the patient data from the Archive Source section.			
	3. Select the required study and then click New .			
	The system transfers the patient data into patient registration form.			
	4. Use the keyboard to edit or enter data.			
	5. To begin the study, click OK .			
Immediately begin the	 Press the control panel key assigned to the store function. 			
examination without registering the patient	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 change the patient information until you end the exam.			

Using the Patient Data Form

Use the system presets to select the order that the tab key moves from field to field on the patient data form.

■ General 2 > Patient ID > Customize Entry Order

The patient data form contains general and exam-specific information.

То	Do This	
Move the text cursor to the beginning position of the next entry field	Press the Tab key on the keyboard. Or, click the next entry field.	
Delete characters	Press the Backspace key on the keyboard.	
Save the new patient data, exit	Choose a method:	
viewing/editing of the patient form, and redisplay the Image screen	• Click OK .	
	 Press Enter on the keyboard. 	
	Press 2D on the control panel.	
Exit viewing/editing of the patient form, and redisplay the Image screen without saving the new patient data	Click Cancel. Or, press ESCAPE on the control panel.	

4 - 4 Instructions for Use

Fields in the Patient Data Form

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

■ General 1 > Format

Patient — Original

Entry Field	Description		
Last Name	Patient's last name.		
	Note: You can use a barcode reader for direct entry of this information.		
	Note: You can enter the first three letters of the last name to display a list of the saved patient information.		
First Name	Patient's first name.		
Note: You can use a barcode reader for direct entry of this information.			
Prefix	Dr., Miss, Mrs., Ms., Mr., Prof.		
Suffix	Jr., Sr., I, II, III		
MI	Patient's middle initial(s).		
Patient 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.		
	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 ().		
	Note: You can use a barcode reader for direct entry of this information.		
	Note: You can enter the first three characters of the patient ID to display a list of the saved patient information.		
Date of Birth	Patient's date of birth using the date format selected in the system presets.		
	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.		
Height	Patient's height using the measurement system selected in the system presets: Metric or U.S.		
Weight	Patient's weight using the measurement system selected in the system presets: Metric or U.S.		
BP [mmHg]	Patient's blood pressure.		
BSA	Patient Body Surface Area in m ² . The system automatically calculates the BSA (based on Height and Weight entries) and transfers the value to the patient report.		
	BSA is calculated with one of the following two formulas:		
	For height in centimeters and weight in kilograms:		
	BSA = $0.007184 \text{ x (weight)}^{0.425} \text{ x (height)}^{0.725}$		
	For height in feet/inches and weight in pounds:		
	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 estimated date of confinement (EDC) and gestational age display at the top of the screen during imaging. These values also display in the patient report.

Entry Field	Description				
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 or 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 ${\bf LMP}$ and ${\bf Age}.$				
Other Exams					
Entry Field	Description				
ID	Identification code for the patient.				
	If an identification (ID) is not entered, then the system generates a unique identifier				

Entry Field	Description		
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.		

4 - 6 Instructions for Use

History (All Examinations)

Entry Field	Description
Additional Info	Additional information.

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. Click the down arrow (▼) on a date field of the patient data form to access the calendar.
- To scroll through the months of the calendar, click either the back arrow (◄) or the forward arrow (►).
- Click a date on the calendar.
 The system exits the calendar tool and places the selected date in the patient data form.
- 4. To exit the calendar without saving changes, click Cancel.

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

See also: Obstetrical Measurements and Calculations, Chapter B3, Features and Applications Reference

Entry Field	Description	ОВ	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	Patient's history of pregnancies.	✓	✓	✓	✓	✓
Para	The entries in these fields are transferred to the					
Aborta	Patient Report, but do not display on the Image screen.					
Ectopics	Solden.					

4 - 8 Instructions for Use

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

Entry Field	Description	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)

Entry Field	Description
PSA (ng/ml)	Prostate specific antigen level.

Institution

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

■ M & R Configuration > Measurement and Report Preset > Display Item

Note: Enter names in the following fields in this sequence: last name, first name, middle name, prefix, suffix (each separated by a comma). If you omit the commas, the system recognizes the entry as the last name only.

Entry Field	Description
Referring MD	Identifying information for the referring physician.
Performing MD	Identifying information for the performing physician.
	Note: You can use a barcode reader for direct entry of this information.
Sonographer	Identifying information for the sonographer.
	Note: You can use a barcode reader for direct entry of this information.

Exam

Entry 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.

Querying and Retrieving Studies

You can import studies from an information system server to the ultrasound system's hard disk.

Note: The imported studies from the Query server do not support the measurement function, report, teaching files, structured reporting, or software applications.

To retrieve patient information using the query/retrieve function:

Prerequisite: Your information system administrator has configured a server for the query/retrieve function.

1. Press Patient Browser on the keyboard.

The system displays the Image screen if a patient is currently registered; if not, the system displays the Study screen.

- Click Study Screen, if necessary, and then select the name of the server from the Archive Source section.
- 3. Enter the required patient information in the search fields.

Search Field	Description
Last Name	Patient's last name.
First Name	Patient's first name.
Patient ID	Identification code for the patient. Searching for the ID requires an exact match.
Date	Dates for the search.
Accession No.	Accession number. Searching for the accession number requires an exact match.
Referring MD	Identifying information for the referring physician.
Modality	Only US (Ultrasound) is available for searching scheduled procedures.
Sex	Patient's sex.

4. Click Query.

The system displays the studies that match your query criteria.

- 5. To view additional information about a study, for example, exam type or quantity of images, click the study name.
- 6. Select the required studies and then click Retrieve.

The system imports the selected studies to the system hard disk.

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 patient data form with a text entry cursor positioned in the **Last Name** field.

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 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 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 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**, **Date of Birth/Age**, **Sex**.

Worklist and Procedure Screen

Entry Field	Description
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	Study code for the procedure.
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

Entry Field	Description
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.

4 - 12 Instructions for Use

Selecting a Scheduled Procedure

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

To select a scheduled procedure for the currently registered patient:

- 1. Press the **REVIEW** key on the control panel to display the Image screen.
- Click Procedure Screen 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 click **Select** on the right of the screen.

The system displays a confirmation message.

- Click Select to confirm the closing of the current procedure and the starting of the selected procedure.
- 5. To close both the current procedure and close the study, click **Completed**.
- 6. To temporarily discontinue the current procedure and close the study, click **Discontinued**.
- 7. Click Live Screen to display the Image screen and begin the selected procedure.

To append a scheduled procedure for the currently registered patient:

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

 Select <Click here to append...> from the Scheduled Procedure(s) section and then click Append.

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.
- 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.
- Click OK to save the revisions and redisplay the Image screen. To restore the current entries in the form and redisplay the Image screen without saving the revisions, click Cancel.

Changing the Exam Type or QuickSet

You can change the selected system-defined exam type or user-defined QuickSet at any time. 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 list of exams and QuickSets.

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:

Press Exam/QuickSet on the keyboard. Or, press EXAM on the control panel.
 The system displays the names of the connected transducers, 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. Click the required transducer to display the exams associated with the selected transducer.
- 3. Select the required exam type or QuickSet.
- 4. To redisplay the image screen without selecting an exam type or QuickSet, click Close.

4 - 14 Instructions for Use

Exam Type Abbreviations

The system displays an abbreviation that indicates the active exam type in the upper left of the Image screen.

Abbreviation	Exam Type
Abdomen	Abdominal
Aorta	Aorta
Breast	Breast
Cardiac	Cardiac
C-Vascular	Cerebrovascular
Early OB	Early Obstetrics
EM	Emergency Medicine
Fetal Echo	Fetal Echo
GYN	Gynecology
MSK	Musculoskeletal
Neo Head	Neonatal Head
ОВ	Obstetrics
OB(J)	Obstetrics (Japan)
Orthopedic	Orthopedics
Ped Echo	Pediatric Echo
Ped Abd	Pediatric Abdomen
Pelvic Floor	Pelvic Floor
Penile	Penile
P-Vascular	Peripheral Vascular
Renal	Renal
Small Parts	Small Parts
Super MSK	Superficial Musculoskeletal
TEE	Adult Transesophageal
Testicle	Testicle
Thyroid	Thyroid
TCD	Transcranial
Urology	Urology
Venous	Venous

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.

E General 1 > Boot Up > Active Transducer

Use the systems presets to assign a key on the control panel that will activate another connected transducer.

- E Customize Keys > Key Function > User-Defined 1 Key
- **E** Customize Keys > Key Function > User-Defined 2 Key
- **E** Customize Keys > Key Function > User-Defined 3 Key

To activate a transducer connected to the system:

- Press the user-defined key assigned to activating the transducer.
 The name of the active transducer displays on the upper left of the screen.
- To activate another transducer connected to the system, press the user-defined key assigned to activating the transducer 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.

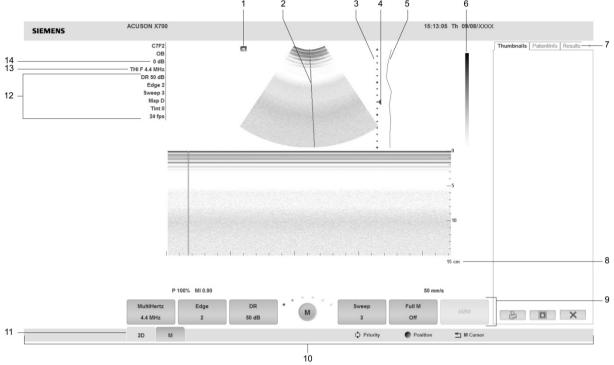
Use the system presets to display the 2D image simultaneously with the M-mode sweep or Doppler spectrum when M-mode or Doppler is selected. If you do not activate the bypass cursor display selection in the system presets, the system displays the 2D image with the cursor when M-mode or Doppler is selected 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 DUAL key on the control panel to display the 2D image on the left side of the screen.
	Press the DUAL key again to display an image on the right side of the screen. To change the active image, press DUAL . To exit dual mode, press the 2D key.
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

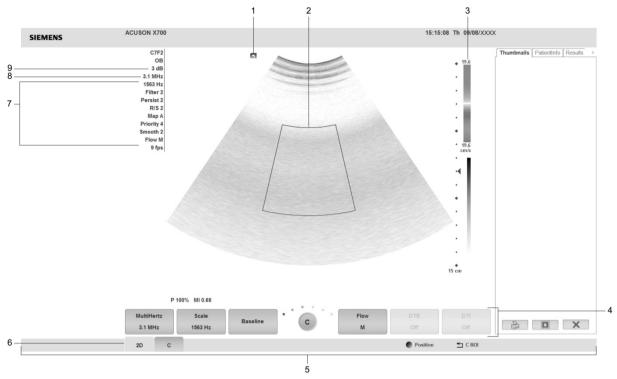


Example of screen layout in 2D/M-mode.

- 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, patient information, and measurement results.
- 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.
- 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

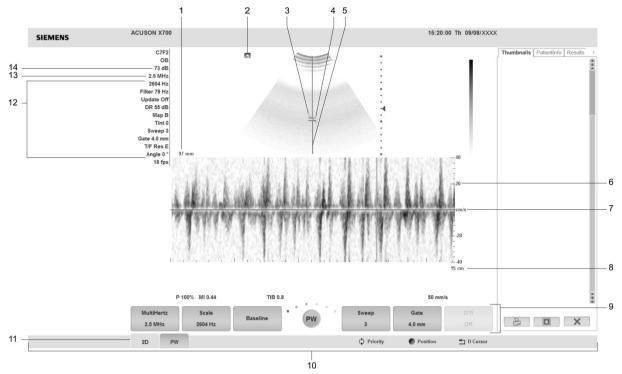


Example of a Color Flow imaging screen.

- 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.
- 6 Tab indicator. Identifies the mode or function for the soft key selections.
- 7 Color Flow Imaging Parameters (Scale, Persistence, Filter, R/S, Map, Priority, and Smooth); Power mode Imaging Parameters (Scale, 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.
- 11 Tab Indicator. Identifies the mode or function for the soft key selections.
- 12 Doppler Imaging Parameters (Scale, Filter, Update, DR, Map, Angle, Sweep, 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.

Note: You can also create thumbnails during review of a saved examination.

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 SELECT on the control panel during real-time imaging.
 - The system displays a trackball pointer.
- Press FREEZE 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:
 - Click the required thumbnail.
 - 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:
 - Click the required thumbnail
 - Rotate the SELECT control to position the cursor on a selected thumbnail, and then press SELECT.
- 4. To display the selected images, clips, and volumes on the Review screen, double-click the thumbnail with either the **SELECT** control or the **SET** key on the control panel.
- 5. To exit the Review screen, press the **REVIEW** key or **ESCAPE** key on the control panel.
- 6. To print a selected thumbnail, click the **Print** icon at the bottom of the **Thumbnails** tab.
- 7. To delete selected thumbnails, click 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 **PatientInfo** 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 FREEZE on the control panel and then press the toggle key for Thumbnail.
 - During real-time imaging, press **SELECT** 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, position the pointer on the maximize/minimize icon at the right side of the data and then press **SELECT**.
- To scroll through the stored studies and display the related patient data or study information in the **PatientInfo** tab, rotate the **SELECT** control.

Viewing Measurement Results in the Results Tab

You can view measurement results at any time without accessing the patient report.

Use the system presets to enable and disable the display of the **Results** tab and rearrange the display of the tabs on the panel.

■ DIMAQ Utility > Panel

То	Do This
View Results tab during live imaging	Press SELECT.
View Results tab during system freeze	 Press the toggle key for Thumbnail.

Overview of the Measurement Function

The measurement function includes 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 Measurement Menu displays the activated exam type.
- The Measured Results display results of the measurements and calculations for OB, Early OB, and Fetal Echo exams below the measurement labels.
- 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.

4 - 24 Instructions for Use

Recording Patient Data

You can record data to a video recorder connected to the ultrasound system during CINE when a single frame or image is displayed, during stress echo acquisition, or during Review when stored images are displayed.

Use the user-defined key assigned to the DVR function to send examination data to the video recorder. Standard video signals are provided in digital video interface (DVI) format.

- **E** Customize Keys > User-Defined 1 Key
- **E** Customize Keys > User-Defined 2 Key
- **E** Customize Keys > User-Defined 3 Key

öö

Video status icon indicates recording status: a red icon displays during recording, and a white icon displays during pause. The recording time also displays beside the icon.

To record patient data using a video recording device:

Note: Use the slide show capability to record all images in a study.

- Insert the media into the video recorder and then press the user-defined key assigned to the DVR function to begin recording.
- To pause recording, press the user-defined key assigned to the DVR function. To resume recording, press the key again.
- To end the recording session, press the VIDEO I/O key to display playback soft key selections.
 - The system automatically stops recording.
- 4. To eject the video media, press the toggle key for **Eject**.
 - The video recorder powers off when the system is turned off.

Using Video Playback

During video playback, an image can be paused and then printed through a connected printing device.

To play back a recorded image:

- Insert the media into the video recorder and then press the VIDEO I/O key on the control
 panel.
 - Communication between the video recorder and the imaging system is opened. The system displays soft key selections for controlling the operation of the video recorder during video playback.
- 2. Use the soft key selections to control the video playback.
 - See also: Soft key selections are described in Appendix C of this manual.
- 3. To discontinue communication between the video recorder and the ultrasound system and resume real-time imaging, press **VIDEO I/O** again or press the **ESCAPE** key.

4 - 26 Instructions for Use

Examination Completion

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

The system automatically completes the patient examination when you shut down the ultrasound system. You can use the system presets to configure the system to enter standby mode.

■ General 1 > Close Study on System Standby

You can close the current examination at any time using the **NEW** key. Use the system presets to configure the function of the **NEW** key.

E Customize Keys > NEW Key

To end the current patient examination when an image or clip is stored:

- Press Patient Browser on the keyboard or press REVIEW on the control panel to display the Image screen.
 - If an image or clip is stored, the image screen displays.
- 2. Click Close Study on the left of the Image screen or select the Close Study soft key.

To end the current patient examination when image or clip is not stored:

- Press Patient Browser on the keyboard or, press REVIEW on the control panel to display the Study screen.
 - If an image or clip is not stored, the study screen displays.
- 2. Click Close in the Study field.

To end the current patient examination and to begin a new examination:

- 1. Press **NEW PATIENT** on the control panel.
- 2. Enter patient data to register a new patient, and then click **OK**.

The system automatically ends the current patient examination and begins a new examination.

4 Examination Fundamentals

4 - 28 Instructions for Use

5 Transducer Accessories and Biopsy

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5 Transducer Accessories and Biopsy

5 - 2 Instructions for Use

Transducer Accessories

⚠ **WARNING:** Before using the transducer accessories, you must read and understand the Caring for Transducer Accessories section of Chapter 2, Instructions for Use.

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	fourSight 4D
Transducer Sheath	All	All	All
Gel Pad		VF10-5	
SG-3 Needle Guide Bracket Kit		VF10-5	
SG-5 Needle Guide Bracket Kit	6C2		
CH4-1 Needle Guide Bracket Kit	4C1		
	CH5-2		
VF12-4 Reusable Needle Guide Bracket Kit		VF12-4	
Infiniti Plus Needle Guide Bracket Kit		VF16-5	
Universal Reusable Needle Guide Bracket Kit S (Stainless Steel)	C6-2		
EV9F3 Reusable Needle Guide Bracket Kit (Stainless Steel)			EV9F3
EC9-4w Reusable Needle Guide Bracket Kit	EC9-4w		
(Stainless Steel)	MC9-4		
EC9-4w Disposable Needle Guide Bracket Kit	EC9-4w		
	MC9-4		

Instructions for Use 5 - 3 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.



MARNING: 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 (ET) 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.

5 - 4 Instructions for Use

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.
- 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.
- Secure the sheath to the transducer housing or cable relief with the adhesive tapes or elastic bands provided.

Instructions for Use 5 - 5

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.

- Using sterile technique, remove the packaging and unfold the transducer sheath.
- 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.
- 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. Dispose of the transducer sheath according to local, state, and regional 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.

5 - 6 Instructions for Use

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.

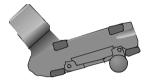
Refer to the in-box instructions for attachment and care procedures for all needle guide accessories except as provided in this chapter.

Universal Reusable Needle Guide S (Stainless Steel)

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

The Universal Reusable 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 Reusable Needle Guide S





Example of a needle bracket.

Example of a needle cap

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 Reusable Needle Guide S supports only the needle sizes in the above list.

Instructions for Use 5 - 7

Preparing the Universal Needle Guide S for Use



★ 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.



MARNING: 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.

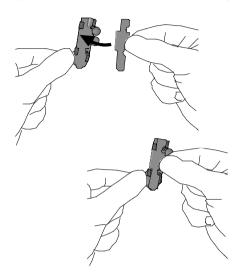


△ Caution: Use only a water-based ultrasound coupling agent (gel) with this kit. Petroleum- or mineral oil-based materials can harm the transducer.

5 - 8 Instructions for Use

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.



Example of 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.

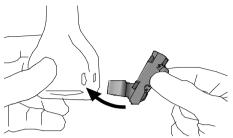
Instructions for Use 5 - 9

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.



Example of 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.

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.

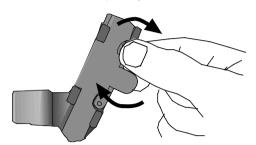
See also: Needle Path Verification, p. 5-13

Detaching the Universal Reusable 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:

- 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.



Example of 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.

Instructions for Use 5 - 11

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 quidelines for use with transducers compatible with needle quide attachments.

See also: Transducer Accessories, p. 5-3

Note: The biopsy guideline function is not available for the following transducers: VF16-5.

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, UD 3, or TGO/UD 2 key.

- **□** Customize Keys > Key Function > User-Defined 1 Key
- **E** Customize Keys > Key Function > User-Defined 2 Key
- E Customize Keys > Key Function > User-Defined 3 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.
- To display needle guide angle **B**, press the **Biopsy** key again.

Note: Angle B is not available for the following transducers: 6C2, C6-2, EV9F3, EC9-4w, MC9-4, VF12-4.

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

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

5 - 12Instructions for Use

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

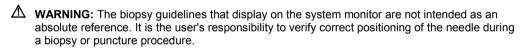
Before performing any patient procedure using a needle guide, you must verify that the path of the needle is accurately indicated by the on-screen guidelines.

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:** 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.
- 6. To change the needle guide angle, press the **Biopsy** key again.

Note: Angle **B** is not available for the following transducers: 6C2, C6-2, EV9F3, EC9-4w, MC9-4, VF12-4.

- 7. Immerse the head of the transducer into the degassed water and insert the needle into the needle guide.
- 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.

Instructions for Use 5 - 13

5 Transducer Accessories and Biopsy

5 - 14 Instructions for Use

6 Transesophageal Transducer

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6 Transesophageal Transducer

6 - 2 Instructions for Use

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.

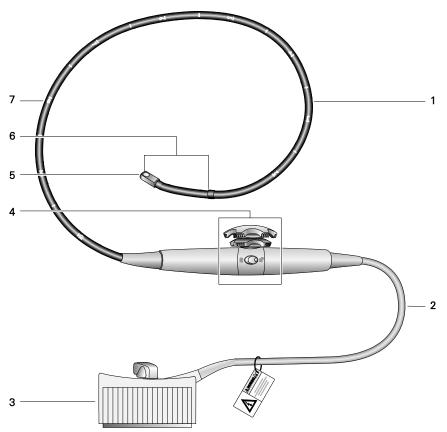
See also: Safety and Care, Chapter 2, Instructions for Use

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
- Anatomical M-mode
- Pulsed Wave Doppler
- Steerable Continuous Wave Doppler
- Color Doppler
- Color DTI
- Pulsed Wave DTI

Instructions for Use 6 - 3



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)

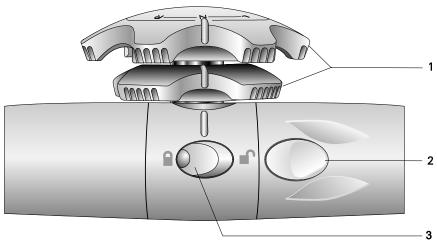
6 - 4 Instructions for Use

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

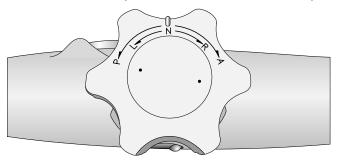
Array Rotation Control

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° .

Instructions for Use 6 - 5

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.

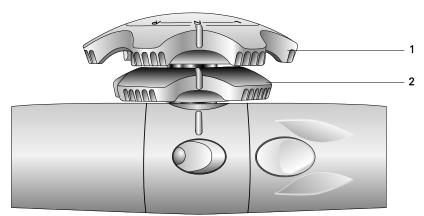
Right/Left Deflection

For right deflection of the distal tip, rotate the left/right flex control toward the ${\bf R}$ marking to move the tip right.

For left deflection of the distal tip, rotate the left/right flex control toward the ${\bf L}$ 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 ${\bf N}$ marking and raised reference lines with the raised reference line on the handle of the transducer.



Flex controls in the neutral alignment.

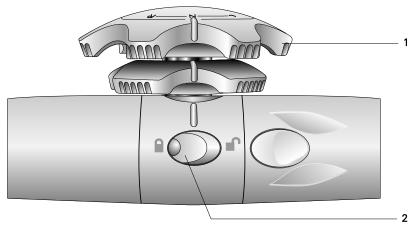
- 1 Anterior/Posterior flex control
- 2 Left/Right flex control

6 - 6 Instructions for Use

Friction Brakes

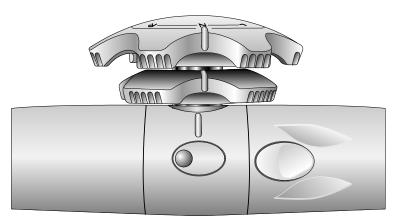
The friction brakes lock the deflection positions of the distal tip. When the brakes are engaged, you can change the imaging scan plane without losing acoustical contact.

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.

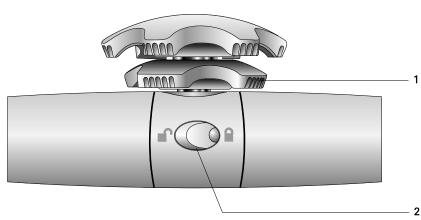
To lock the anterior/posterior deflection position of the distal tip:

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

To unlock a brake:

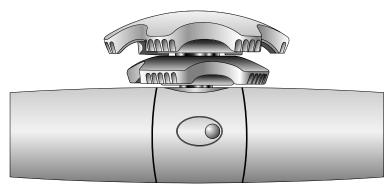
Press the flat portion on the button of the corresponding brake.

Instructions for Use 6 - 7



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.

6 - 8 Instructions for Use

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 disinfected, 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

Instructions for Use 6 - 9

⚠ 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:

- 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.
- Test the array rotation control to ensure a smooth rotation.
- 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 vour 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

MARNING: 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.

6 - 10Instructions for Use

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.

Instructions for Use 6 - 11

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-fault/groundfault 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.

6 - 12 Instructions for Use

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.



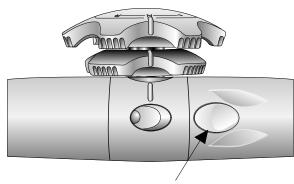
The **Scan Plane Icon** indicates the approximate rotation angle of the imaging scan plane.

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

Instructions for Use 6 - 13

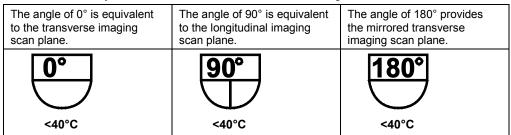
Changing the Imaging Scan Plane

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.

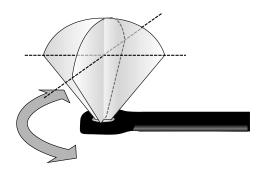
As the array orientation changes, the on-screen scan plane icon updates to indicate the relative direction of the array and the numerical value of the rotation angle.



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.



6 - 14 Instructions for Use

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.



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	

Instructions for Use 6 - 15

Screen Message	Cause	User Action	
Transducer Approaching Temperature Limit of 43°C.	during the exam when the setting for transmit power is not	Select YES to lower the transmit power in one-step increments.	
Automatically Reduce Transmit Power?		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> .	Note: Imaging can continue without lowering the Transmit Power while the temperature indicator displays a temperature below 43°C.	
	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.		
Transducer exceeded Temperature Limit of 43°C.	Reaches 43°C during the exam.	The system automatically freezes the image. This turns off the transmitted power to the transducer.	
Allow Transducer to Cool to Continue.		This message remains on the image screen	
Current Transducer Temperature: ≥ 43°C.		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 Failure.

Please Contact your Siemens Service Representative.

The message remains on the image screen until the user selects \mathbf{OK} or the transducer is removed.

6 - 16 Instructions for Use

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.



MARNING: Do not use the V5Ms transducer for any procedure requiring hyperextension of the neck. Improper patient positioning can cause paralysis of the vocal cord.



MARNING: Always use a bite quard 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.
- 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.

Instructions for Use 6 - 17

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.

6 - 18Instructions for Use

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.

Instructions for Use 6 - 19



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.
- 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.
- 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:

- 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.

6 - 20 Instructions for Use

Cleaning and Disinfecting the Bite Guard

To clean the bite guard:

- 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.

Instructions for Use 6 - 21

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 electrosurgical units with the V5Ms transducer. Disconnect the transducer when it is not in use.	Non-isolated electrosurgical 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

6 - 22 Instructions for Use

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.	Improper cleaning resulting in electrical damage	Esophageal burns
Do not use any disinfectants other than those specified.		
Do not use iodine or solutions containing iodine for cleaning or disinfecting the V5Ms transducer.		
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

Instructions for Use 6 - 23

Technical Description — V5Ms

Transducer Type: Phased Array, multiplane

Elements: 64
Array Rotation Angle: $0^{\circ} - 180^{\circ}$

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,

Anatomical M-mode, Color DTI, Pulsed Wave DTI

Maximum Image Field of View: 87° 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 85%

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

≤3°

Measurement Accuracy

Rotation angle of the transducer array:

Temperature:

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

EMC 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.

6 - 24 Instructions for Use

7 Specialty Transducers

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7 Specialty Transducers

7 - 2 Instructions for Use

EV9F3 Transducer

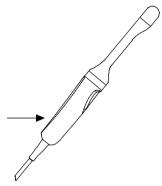
▲ WARNING: Before attempting to use endocavity transducers, you should be trained in ultrasonography and endocavity scanning techniques, and you should be thoroughly familiar with the safe operation of the ultrasound imaging system.

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

The EV9F3 transducer is a fourSight 4D (curved array) transducer. The EV9F3 transducer is designed for endovaginal imaging of the general pelvic region, such as during the early stages of pregnancy, for detection of ectopic pregnancies, and for examination of the follicles, ovaries, fallopian tubes, inner cavities, bladder, and uterus.

Transducer Markings

The EV9F3 transducer is designed with an orientation indicator on the handle of the transducer.



Example of orientation indicator on transducer handle.

The EV9F3 transducer supports all of the functions and controls that are available in 2D-mode, M-mode, Color, Power, Pulsed Doppler, and during volume acquisition.

The EV9F3 transducer samples a 143° \pm 1° maximum sector angle. You can select a structure of interest between 10° \pm 1° and 143° \pm 1° within the scan plane. You can also adjust the scan angle.

То

Do This

Select a steering angle for the EV9F3 transducer

Press the toggle key for Steer Angle.

The steering angle increases or decreases relevant to the scan angle. An on-screen graphic indicates the steering angle of the transducer when the steering angle is greater or less than 0° .



Example of the on-screen symbol for the EV9F3 transducer during 2D-mode imaging.



Example of the on-screen symbol for the EV9F3 transducer during volume acquisition.

Note: During *four*Sight imaging or 3-Scape imaging (when using **Auto Sweep**), the range of settings depends on the selected angle.

Select a scan angle (to determine the amount of data for volume acquisition) for the EV9F3 transducer Press the toggle key for Angle.

During 3-Scape imaging, the system computes the scan duration based on the selected angle, acquisition speed, and the current frame rate and displays the steering angle and acquisition time on the image screen.

7 - 4 Instructions for Use

EV9F3 Technical Data

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

Transducer type: Mechanically-driven curved array

Number of Elements: 128

Focus: 35 mm \pm 5%

Minimum Depth: 3 cm

Maximum Depth: 14 cm

Operating modes: 2D-mode, M-mode, 2D/M-mode, 2D/Doppler, Color, Power, Pulsed Doppler

Maximum displayable

field of view: 143°±1°

Maximum scan angle

(wobble angle): $\pm 45^{\circ}$

Radius of Curvature: 10 mm

Orientation: On-screen graphical icon indicates steering angle

7 Specialty Transducers

7 - 6 Instructions for Use

8 Physiologic Function Physiologic Function

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8 Physiologic Function

8 - 2 Instructions for Use

Physiologic Function

The physiologic function includes the ECG function (which contains the ECG input) and physiologic inputs. The system can display auxiliary physiologic traces (DC input signals such as pressure waveforms) from medically approved, properly isolated devices. The Aux 1 input can be used for either the external ECG function or auxiliary physiologic traces.

Note: You can simultaneously display an ECG trace and an auxiliary physiologic trace (excluding the auxiliary ECG trace) by activating the ECG function (internal or external) and the auxiliary physiologic trace display. You can also simultaneously display the auxiliary signal and the respiration trace by turning off the ECG function. Since the respiration signal is obtained from the internal ECG function, you must ensure that the ECG leads are attached to the patient to display both the auxiliary signal and the respiration trace.

ECG Function

The ECG function includes an ECG cable and three leads, along with a start-up kit of ECG electrode patches.

⚠ **WARNING:** Do not use the ECG option in conjunction with electrosurgery or diathermy equipment.

⚠ **WARNING:** Use ECG for timing purposes only. It is not intended for diagnostic usage or patient monitoring.

The ECG trace is used to place *triggers*, or timing markers, which update the 2D-mode image at specific point(s) in the cardiac cycle. The electrical activity controlling the heart muscle is detected by placing ECG electrode patches in specific locations on the patient and amplifying the electrical signals that produce the ECG trace display on the system monitor. The respiratory trace also displays on the system monitor.

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.

Connecting ECG Cables and Leads

▲ WARNING: To reduce risk of electric shock and burns, use only the cable and patient leads supplied with the physiologic function. Use of other ECG cables could defeat the current-limiting and electrical safety features of the physiologic function.



ECG connector socket.

To connect the ECG cable:

Connect the six-pin ECG cable to the socket labeled "ECG" on the left side of the system.

⚠ Caution: To avoid possible damage to the ECG cables, do not pull on the cables when disconnecting the ECG connector. Always grasp the connector housing.

Connecting Leads to the Patient

In keeping with existing international standards, the ECG leads for systems that operate at 115V (for example, North and South America) are red, white, and black. They are labeled RA (right arm), LA (left arm), and LL (left leg). Leads for systems that operate at 230V (for example, Europe) are green, red, and yellow. They are labeled R (right arm), L (left arm), and F (left leg).

Patient Location	100V	115V	230V
Left leg	Green	Red	Green
Right arm	Red	White	Red
Left arm	Yellow	Black	Yellow

Only use ECG leads that comply with the requirements of your country.

To connect the leads to the patient:

- 1. Attach the ECG electrode patches to the patient in the locations specified above.
- 2. Connect each lead to the appropriate patch.

Use the system presets to select the lead type for tracing the voltage between the electrodes (right arm and left arm or right arm and left leg).

Exam Configuration > Physio Management

Using the External ECG Cable

MARNING: The Aux 1 input is not intended for direct connection to the patient. To reduce the risk of electrical shock while using this connection, ensure that the external source (peripheral equipment) is properly set up and is designed for direct patient connection.

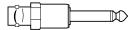
The external ECG cable kit contains a BNC cable and connector adapters used to attach various peripheral equipment to the ultrasound system.

See also: Connecting Peripheral Equipment, System Setup, Chapter 3, Instructions for Use

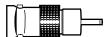
Connector Adapters to Peripheral Equipment



Phone adapter



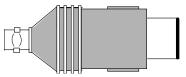
Phone plug (mono)



BNC to Phono plug adapter

Assemble one end of the external ECG cable with the connector adapter that attaches to the ultrasound system. Assemble the other end of the cable with a connector adapter appropriate for the peripheral equipment.

Connector Adapters to the Ultrasound System



ECG connector adapter



Auxiliary connector adapter

Τо	Do	Т	hi	5

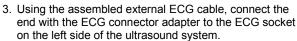
Connect the external ECG cable to the ultrasound sytem and the peripheral equipment using the ECG connector adapter

 Attach the ECG connector adapter to one end of the external ECG cable.

This end of the cable attaches to the ultrasound system.

2. Attach the appropriate connector adapter to the other end of the cable.

Use the manufacturer's operating instructions for the peripheral equipment to determine which connector adapter to use.



 To connect the external ECG cable to the peripheral equipment (external source), see the manufacturer's operating instructions.

Connect the external ECG cable to the ultrasound sytem and the peripheral equipment using the auxiliary connector adapter Attach the auxiliary connector adapter to one end of the external ECG cable.

This end of the cable attaches to the ultrasound system.

2. Attach the appropriate connector adapter to the other end of the cable.

Use the manufacturer's operating instructions for the peripheral equipment to determine which connector adapter to use.

- Using the assembled external ECG cable, connect the end with the auxiliary connector adapter to the Aux 1 connector socket on the left side of the ultrasound system.
- To connect the external ECG cable to the peripheral equipment (external source), see the manufacturer's operating instructions.



ECG connector socket.

Activating the ECG Function

Use the system presets to automatically activate the ECG function and an R-wave indicator when an exam type is selected.

Exam Configuration > Physio Management

Use the system presets to assign the ECG function to a user-defined key.

- Customize Keys > Key Function > User Defined 1 Key
- **E** Customize Keys > Key Function > User Defined 2 Key
- **■** Customize Keys > Key Function > User Defined 3 Key

To display an ECG trace:

Note: If baseline wander in the ECG trace becomes a problem, the cause may be respiratory movement (ventilatory excursions). Minimize this artifact by making certain that the ECG leads or cable are not needlessly draped over the patient. Secure the leads and cable off to the side of the patient.

- 1. Connect the ECG cable to the system and the ECG leads to the patient.
- Press the PAGE control to access the soft key selections for the ECG function.
 The system displays Phy (Physiological) in the middle of the "page indicator" to identify the soft key selections for the ECG function.
- Press the toggle key for ECG to select On.
 The system displays the ECG trace on the image screen.
- 4. If required, adjust the position of the ECG trace on the image screen.
 - To adjust the vertical position of the ECG trace, press the toggle key for Position.
 - To vertically invert the ECG trace, press the toggle key for Invert.
- 5. To remove the trace, press the toggle key for **ECG** to select **Off**.

Activating the Trigger Function

During 2D-mode and Split (B+B) mode imaging, you can enable one or two trigger markers for positioning at specific points in the cardiac cycle. Each trigger defines when the system updates (refreshes) the 2D image.

The trigger function is not compatible with the following modes or features:

- M-mode
- Dynamic Tissue Contrast Enhancement (DTCE)
- Advanced SieClear

To enable trigger(s):

- 1. Activate the ECG function.
- 2. Press the toggle key for Trigger.
- 3. Press the toggle key for **Trigger Type** to display either one or two triggers.
 - Ch 2 Delay displays when Dual is selected from Trigger Type.

The system detects the R-wave and displays each trigger as a white, vertical line on the ECG trace. The image is refreshed at the position(s) of the trigger(s), which each indicate a point in the cardiac cycle. If Split (B+B) Mode is active, each 2D image is refreshed at the position(s) of the trigger(s). During Cine, the system displays a yellow, vertical line to indicate the relationship of the specific phase of the ECG to the 2D-mode image.

- 4. If required, reposition the triggers.
 - To reposition the first (or single) trigger, press the toggle key for Ch 1 Delay.
 - To reposition the second (or dual) trigger, press the toggle key for **Ch 2 Delay**.

Each time you press the toggle key, the position of the trigger advances by ten milliseconds.

8 - 8 Instructions for Use

Setting the Trigger Delay

Use a trigger delay to evaluate the function of the valves, wall motion, and dynamics of blood flow. This delay relates the 2D-mode image to the specific phases of the ECG. Use the **Ch 1 Delay** and **Ch 2 Delay** selections when the ECG function is active to select the point(s) in the cardiac cycle at which the system updates the 2D image.

The Ch 1 Delay and Ch 2 Delay Physio selections each range from 0 to 990 milliseconds.

Note: When you change a trigger delay, a "lag" period occurs before the new trigger position is activated.

When the ECG function is turned off and back on, the system retains the "last known" position(s) of the trigger(s).

To position the first (or single) trigger when the trigger function is activated:

Press the toggle key for Ch 1 Delay.

Each press of the toggle key visibly advances the position of the trigger by ten milliseconds.

To position the second trigger when the trigger function is activated and two triggers have been selected:

Press the toggle key for Ch 2 Delay.

Each press of the toggle key visibly advances the position of the trigger by ten milliseconds.

Note: If you select two triggers and the triggers have identical values, then the system derives the second update time from the frame rate. For example, if the Single Physio selection is set to Dual, the Ch 1 Delay and Ch 2 Delay Physio selections are both set to 300, and the frame rate is five seconds, then the system updates the 2D image at 300 and 500 milliseconds — 300-millisecond intervals for the first trigger, and 200 milliseconds after each first-trigger update for the second trigger. (The update time for the second trigger is derived by dividing 1000 milliseconds, or one second, by the frame rate. In this example, 1000 milliseconds divided by 5 frames-per-second is 200 milliseconds.) If you then change the Ch 2 Delay Physio selection to 310, then the system updates the 2D image at 300 and 310 milliseconds.

Activating Capture

Use the system presets to set the capture options for cardiac cycles when a documentation control assigned to the clip capture function is pressed.

To display the Clip Capture preset screen:

1. Press Presets on the keyboard.

The system displays the preset screen for configuring clip capture options.

- 2. Configure the capture options.
 - Select **Time Capture** from **Trigger Type** to enable the Time Trigger capture method.
 Select or enter the time to specify the duration of the clip capture in seconds.
 - Select Beat Capture from Trigger Type to enable the Beat Trigger capture method.
 Select or enter the number of beats to specify the duration of the clip capture. Select the R-Wave Delay from the drop-down box to specify the delay of R-Wave in milliseconds.
- 3. Select **Save** to confirm the changed settings.

The system displays the ECG image screen.

8 - 10 Instructions for Use

ECG Troubleshooting Guide

Symptom	Possible Cause
ECG trace is not present,	The ECG cable is not properly attached to the system.
or cannot detect an R-wave	 Leads are poorly connected to the cable.
IX-wave	 Leads are poorly connected to the patient.
	 Leads are incorrectly placed on the patient. Remove the ECG patch, clean the skin, and attach a new ECG patch to the patient.
	• ECG gain is set too low. Press the toggle key for Gain to increase the gain.
Cannot position a trigger	■ No R-wave present (see above).
	■ Too much movement by the patient.
ECG trace is noisy,	• ECG gain is set too high. Press the toggle key for Gain to decrease the gain setting.
ragged, or erratic	 A lead or leads may be detecting muscle movement. Inspect the ECG patch placement and reposition the lead(s) on the patient as necessary.
	 The conductive gel pad of an ECG patch has evaporated (dried out). Replace the ECG patch with a new one (check the expiration date of the new patch).
Trigger is not visible on the	A trigger may be superimposed on the R-wave.
trace	 If dual triggers are used, the first and second trigger may be superimposed. Press the toggle key for Ch 1 Delay or Ch 2 Delay to reposition a trigger.

Potential ECG Error Messages

Message on the Image Screen	Possible Cause
Erratic ECG detected. Please check ECG leads.	 Leads are poorly connected to the patient. Remove the ECG patch, clean the skin, and attach a new ECG patch to the patient.
	Too much movement by the patient.

Respiratory Traces

Use the system presets to automatically activate the respiratory trace when an exam type is selected.

Exam Configuration > Physio Management

To display the respiratory trace:

- 1. Press PAGE to highlight the Phy tab indicator.
- 2. Rotate **PAGE** to display the respiration trace selections.
- 3. Press the **Resp** soft key to select **On**.

Auxiliary Physiologic Traces

Use the system presets to automatically activate the auxiliary physiologic function when an exam type is selected.

Exam Configuration > Physio Management

To display the auxiliary physiologic trace from the Aux 1 input:

- Press PAGE to highlight the Phy tab indicator and then rotate PAGE to display the soft key selections.
- 2. To activate the ECG function press the **Aux ECG** soft key.
- 3. To activate the auxiliary signal press the Aux Signal soft key.

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Appendix A Technical Description

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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 128 sets of specific exam, transducer, and image parameter settings

Processing Power

- Integrated workstation
- Pathway for future performance expansion and technological innovations
- Signal processing hardware for parallel and quad signal processing

High Resolution Color Monitor

- 50 cm (20-inch) Flat Panel Display Monitor
- Active Matrix Liquid Crystal Display with 1600 x 900 display resolution
- Tilt of 15° up and 90° down
- Swivel of monitor by 160°, swivel of arm by 180°
- Brightness control
- 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

Transducer Compatibility

- 2.0 to 13.0 MHz imaging range capability
- Wideband MultiHertz multiple frequency imaging
- Hanafy Lens transducer technology
- Virtual format imaging
- ACUSON X600 Transducer Ports:
 - Three 260-pin ports for standard array transducers
 - One auxiliary continuous wave transducer port
- ACUSON X700 Transducer Ports:
 - Two 260-pin ports for standard array transducers
 - One 192-element port for micro-pinless transducers
 - One auxiliary continuous wave transducer port
- Transducer and gel holders with removable liners
- Transducer cable management
- ACUSON X700 only:
 - microCase transducer miniaturization technology for increased user comfort and reduced fatigue
- Lightweight, ergonomic transducer design with SuppleFlex cables or the equivalent

User-Accessible Connections

- Compact disk CD-RW/DVD-RW drive for user presets, system software updates and upgrades, patient data storage and retrieval
- On-board location for up to two image recording devices
- USB port for off-board printer connectivity
- Ethernet port
- User-programmable, dual-pedal footswitch (optional)

A - 4 Instructions for Use

Operating Modes

The following modes are available on the system:

Category Available modes and display formats	
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	2 dB
	Displayed in percentage (%)	
2D-mode Gain	-30 dB to 30 dB	1 dB
Dynamic Range	Transducer-dependent	_
DGC controls	0 dB to 40 dB	_
Depth	10 mm to 300 mm	Transducer-dependent
Focal zones	Up to 4	_
CINE	256 gray scale frames	_
	128 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 Gain	-5, -4, -3, -2, -1, 0, 1, 2, 3, 4, 5	_
Clarify VE	On/Off	_
Clarify VE Levels	1, 2, 3, 4, 5, 6, 7	_
SieClear	Off, 2	_
Advanced SieClear	3, 5, 7*	_
(Not available for phased array transducers)	* Not available for curved array transducers	

A - 6 Instructions for Use

Parameters	Settings	Increment
THI Tissue Harmonic Imaging Technology	Ensemble Tissue Harmonic Imaging (THI) is available with the following transducers and THI frequencies:	_
 Enhances visualization, 	 4C1: 3.6 MHz, 4.4 MHz 	
particularly in difficult-to- image patients	 4C1: 3.1 MHz, 3.6 MHz, 4.4 MHz (supported exams: Abdomen, Emergency Medicine) 	
 Improves image contrast and 	■ CH5-2: 3.6 MHz, 4.4 MHz	
spatial resolution; reduces noise	■ 6C2: 4.4 MHz, 5.3 MHz	
	C6-2: 4.0 MHz, 5.0 MHz	
	C8-5: 6.7 MHz, 7.6 MHz	
	VF10-5: 8.0 MHz, 9.4 MHz	
	VF12-4: 8.0 MHz, 10.7 MHz	
	 VF16-5: 10.7 MHz, 12.3 MHz 	
	 4V1c: 3.0 MHz, 3.4 MHz, 3.7 MHz, 4.0 MHz 	
	 4V1c: 2.7 MHz, 3.1 MHz, 3.6 MHz (supported exams: Abdomen, Emergency Medicine) 	
	 4V1c: 2.7 MHz, 3.1 MHz (supported exams: TCD) 	
	■ P8-4: 5.3 MHz, 6.1 MHz	
	■ V5Ms: 5.3 MHz	
	■ EC9-4w: 5.7 MHz, 6.7 MHz	
	MC9-4: 5.7 MHz, 6.7 MHz	
	 C6F2: 3.6 MHz, 4.4 MHz, 5.0 MHz 	
	 C8F3: 4.4 MHz, 5.0 MHz, 5.7 MHz 	
	EV9F3: 5.7 MHz, 7.2 MHz	

M-mode

Parameters	Settings	Increment
Transmit Frequencies	Transducer-dependent	_
Transmit power	0 dB to -54 dB	2 dB
	Displayed in percentage (%)	
M-mode Gain	-30 dB to 30 dB	1 dB
Dynamic Range	Transducer dependent	5 dB
Depth	10 mm to 300 mm	Transducer-dependent
Focal zones	1	_
CINE	256 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, 6, 7, 8	_

Pulsed Wave Doppler

Parameters	Settings	Increment
Transmit Frequencies	Transducer-dependent	_
Transmit power	0 dB to -54 dB	2 dB
	Displayed in percentage (%)	
Doppler Gain	0 dB to 90 dB	1 dB
Scale Range	100 Hz to 19.5 kHz	Transducer-dependent
Dynamic Range	■ 30 dB to 70 dB	5 dB
	 30 dB to 90 dB (for Cardiac exams with the 4V1c transducer) 	_
Depth	10 mm to 300 mm	Transducer-dependent
Focal zones	1	_
CINE	Available	_
Zoom	Up to 10x	_
Velocity scale range	±1.5 cm/s to 350 cm/s	_
(0° angle correction)		
Transducer Steering	VF10-5, VF12-4, VF16-5	_
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, 6, 7, 8	_
T/F (Time/Frequency) Resolution	A, B, C, D, E, F, G, H, I	_
Post-processing gray map	A, B, C, D, E, F, G, H	_
Doppler color maps (tint)	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	_
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	_

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Parameters	Settings	Increment
Spectral DTI (Doppler tissue imaging capability)	On/Off	_
Compatible transducers and exam types:		
 4V1c: Cardiac 		
V5Ms: TEE		
 AcuNav: Cardiac 		
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	2 dB
	Displayed in percentage (%)	
Doppler Gain	0 dB to 90 dB	1 dB
Scale Range	100 Hz to 34,700 Hz	Transducer-dependent
Dynamic Range	■ 30 dB to 70 dB	5 dB
	 30 dB to 90 dB (for Cardiac exams with the 4V1c transducer) 	_
Depth	10 mm to 300 mm	Transducer-dependent
Focal zones	1	_
CINE	Available	_
Zoom	Up to 10x	_
Velocity scale range	±0.8 cm/s to 650 cm/s	_
(0° angle correction)		
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, 6, 7, 8	_
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 color maps (tint)	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	_
Spectral Invert	On/Off	<u> </u>
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	2 dB
	Displayed in percentage (%)	
Doppler Gain	0 dB to 90 dB	1 dB
Scale Range	100 Hz to 34,700 Hz	Transducer-dependent
Dynamic Range	30 dB to 70 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, 6, 7, 8	
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

Color Doppler

Parameters	Settings	Increment
Transmit Frequencies	Transducer-dependent	_
Transmit power	0 dB to -54 dB	2 dB
	Displayed in percentage (%)	
Color Gain	-20 dB to 20 dB	1 dB
Scale Range	100 Hz to 52,083 Hz	Transducer-dependent
Depth	10 mm to 300 mm	Transducer-dependent
Focal zones	1	_
CINE	256 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 107.4 cm/s	_
Color ROI adjustments	Position	_
	Size	
Transducer Steering	VF10-5, VF12-4, VF16-5	
Baseline shift	1 to 13	6 above baseline
		6 below baseline
Color maps	A, B, C, D, E, F, G, H, I	
Color smoothing	0, 1, 2, 3	
Tissue/Color priority	0, 1, 2, 3, 4	_

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Parameters	Settings	Increment
Color persistence	0, 1, 2, 3, 4	_
Color Peak Hold	Off, 1sec, 2sec, 3sec	_
Color invert	On/Off	-
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	_
Compatible transducers and exam types:		
 4V1c: Cardiac 		
 V5Ms: TEE 		
 AcuNav: Cardiac 		

Power Doppler

Parameters	Settings	Increment
Transmit Frequencies	Transducer-dependent —	
Transmit power	0 dB to -54 dB	2 dB
	Displayed in percentage (%)	
Power Gain	-20 dB to 20 dB	1 dB
Scale Range	100 Hz to 19,500 Hz	_
	(transducer-dependent)	
Depth	10 mm to 300 mm	Transducer-dependent
Focal zones	1	_
CINE	256 image frames	_
Zoom	Up to 10x	_
Transducer Steering	VF10-5, VF12-4, VF16-5 —	
Power ROI adjustments	Position	_
	Size	
Power Doppler color maps	A, B, C, D, E, F, G, H	_
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.

MARNING: 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.

MARNING: You must only use the transducers, accessories, cables, and replacement parts for internal components specified by Siemens to reduce the risk of increased RF (radio frequency) emissions or decreased immunity of the ultrasound system.

The Siemens-authorized accessories and options for your ultrasound system are listed in this chapter.

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

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

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Options

Note: For information about the combinations of options available for purchase, contact your Siemens representative.

Options

3-Scape Imaging Option

(Standard feature on the ACUSON X700 system; available as an option on the ACUSON X600 system)

Description

WARNING: To avoid technique-related artifacts, you must be thoroughly familiar with the techniques of 3D and 4D imaging. Read the entire 3D and 4D imaging chapter before using the 3-Scape real-time 3D imaging or fourSight 4D ultrasound imaging technology.

- Included with fourSight 4D Imaging Option
- Compatible transducers and exam types:
 - 4C1: OB, Early OB, OB(J), Abdomen, GYN, Renal
 - CH5-2: OB, Early OB, OB(J), Abdomen, GYN, Renal
 - 6C2: OB, Early OB, OB(J), Abdomen, GYN, Renal
 - C6-2: OB, Early OB, OB(J), Abdomen, GYN, Renal
 - EC9-4w: OB, Early OB, OB(J), GYN
 - MC9-4: OB, Early OB, OB(J), GYN
 - C6F2: OB, Early OB, OB(J), Abdomen, GYN, Pelvic Floor
 - C8F3: OB, Early OB, OB(J), Abdomen, GYN, Pelvic Floor
 - EV9F3: OB, Early OB, OB(J), GYN, Pelvic Floor
- The 3D Imaging feature is a system option that allows the acquisition of three-dimensional ultrasound images.
 Multiplanar rendering (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

Options	Description
fourSight 4D Imaging Option	Compatible transducers and exam types:
	 C6F2: OB, Early OB, OB(J), Abdomen, GYN, Pelvic Floor
	 C8F3: OB, Early OB, OB(J), Abdomen, GYN, Pelvic Floor
	 EV9F3: OB, Early OB, OB(J), GYN, Abdomen, Pelvic Floor
	 fourSight 4D imaging ultrasound technology provides a comprehensive real-time image of anatomical structures and pathological conditions displayed simultaneously in all spatial dimensions
	 MultiPlanar rendering demonstrates imaging planes not accessible with normal scanning techniques
Advanced four Sight 4D Imaging Option	★ WARNING: To avoid technique-related artifacts, you must be thoroughly familiar with the techniques of 3D and 4D imaging. Read the entire 3D and 4D imaging chapter before using the 3-Scape real-time 3D imaging or fourSight 4D ultrasound imaging technology.
	 Requires fourSight 4D Imaging Option
	 Provides advanced features for 4D Imaging
	 MultiSlice
	 Thick slice imaging (TSI)
	 Curved multiplanar rendering (MPR)
fourSight TEE View Option	⚠ WARNING: This application utilizes ultrasound data
(Available only on the ACUSON X700 system)	collected prior to analysis. The quality of the data collected and used as input could have an effect on the output of this application. Variability in ultrasound system performance, operator technique, patient characteristics, and other factors may affect the output. At all times, the clinician is advised to carefully review the output and confirm the information presented with clinical judgment and any other relevant sources of data.
	Compatible transducers and exam types:
	 V5Ms: Transesophageal Echo (TEE)
	 Acquires and displays 3D volume datasets
	 Available to facilitate evaluation of cardiac diseases such as valvular disease and detection of embolic sources

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Options	Description
Mitral Valve Assessment (Available only on the ACUSON X700 system)	⚠ WARNING: This application utilizes ultrasound data collected prior to analysis. The quality of the data collected and used as input could have an effect on the output of this application. Variability in ultrasound system performance, operator technique, patient characteristics, and other factors may affect the output. At all times, the clinician is advised to carefully review the output and confirm the information presented with clinical judgment and any other relevant sources of data.
	 Compatible transducers and exam types: V5Ms: Transesophageal Echo (TEE) Requires fourSight TEE View Option Provides a guided workflow for measuring and locating structures of mitral valve
Axius Edge-Assisted Ejection Fraction Option (Standard feature on the ACUSON X700 system; available as an option on the ACUSON X600 system)	 Compatible transducers and exam types: 4V1c: Cardiac 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 (Standard feature on the ACUSON X700 system; available as an option on the ACUSON X600 system)	 Available on all transducers Available in combination with 2D-mode, the 2D-mode image in Doppler, SieClear compounding, THI, and TGO

Options Description **SieScape Panoramic Imaging Option** WARNING: To avoid technique-related artifacts and (Standard feature on the ACUSON X700 system; measurement inaccuracies, read the entire SieScape available as an option on the ACUSON X600 imaging chapter before using the SieScape feature. system) MARNING: To ensure accuracy, measurements should only be made on SieScape images that are acquired in a single scan plane. MARNING: Technique-related artifacts unique to SieScape imaging can occur. Before using the SieScape imaging feature, be sure to read and understand the technique tips in the SieScape imaging chapter. Available for linear array and curved array transducers SieScape 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 SieScape image On-screen reference and speed indicators enhance imaging technique Reverse during acquisition Zoom and pan capabilities **Contrast Agent Imaging Option** WARNING: At the time of publication, the United States Food and Drug Administration has cleared ultrasound contrast agents only for use in LVO (left ventricular opacification). Check the current regulation for the country in which you are using this system for contrast agent clearance. ⚠ **WARNING:** Carefully follow manufacturers' instructions for use, including indications and contraindications, when administering ultrasound contrast agents. Compatible transducers and exam types: 4C1: Abdomen CH5-2: Abdomen Real time, low mechanical index, non-linear imaging technique

for contrast agent examination

Options	Description
syngo Arterial Health Package Option	Available for linear transducers
	 Compatible with clips or images that contain only 2D-mode data and clips or images acquired with a linear transducer
	 Provides a method of quantifying Carotid Intima-Media Thickness (CIMT)
	 Uses semi-automated border detection to determine the maximum and average thickness of the intima-medial layer of the carotid artery
syngo Auto Left Heart	★ WARNING: This application utilizes ultrasound data collected prior to analysis. The quality of the data collected and used as input could have an effect on the output of this application. Variability in ultrasound system performance, operator technique, patient characteristics, and other factors may affect the output. At all times, the clinician is advised to carefully review the output and confirm the information presented with clinical judgment and any other relevant sources of data.
	Compatible transducers and exam types:
	- 4V1c: Cardiac
	- V5Ms: TEE
	 AcuNav: Cardiac
	 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
syngo Velocity Vector Imaging Option (Available only on the ACUSON X700 system)	⚠ WARNING: This application utilizes ultrasound data collected prior to analysis. The quality of the data collected and used as input could have an effect on the output of this application. Variability in ultrasound system performance, operator technique, patient characteristics, and other factors may affect the output. At all times, the clinician is advised to carefully review the output and confirm the information presented with clinical judgment and any other relevant sources of data.
	Compatible transducers and exam types:
	- 4V1c: Cardiac
	- V5Ms: TEE
	- AcuNav: Cardiac
	 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

Options	Description
syngo Auto OB	Available for OB and Early OB exam types.
	 Provides automatic measurements of bi-parietal diameter (BPD), occipital frontal diameter (OFD), head circumference (HC), abdomen circumference (AC), femur length (FL), and humerus length (HL)
syngo Auto Follicle	 Available for GYN exam type.
(Available only on the ACUSON X700 system)	 Provides semi-automatic measurements of follicle diameter or area
Stress Echo Option	 Requires the Cardio-Vascular Option
	 Requires a phased array transducer
	 Optional Stress Echo External/Adapter Cable
eSie Touch Elasticity Imaging Option (Available only on the ACUSON X700 system)	 Provides a qualitative representation of relative tissue stiffness for the region of interest
(Compatible transducers and exam types:
	VF10-5: Breast, Thyroid
	 VF12-4: Breast, Thyroid
	VF16-5: Breast, Thyroid

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Options	Description		
DICOM Structured Reporting for Obstetrics/Gynecology			
DICOM Structured Reporting for Cardiac			
DICOM Structured Reporting for Vascular			
Dual-pedal footswitch	Attaches to the ultrasound system with a USB connector		
Cardio-Vascular Option	 Includes the Physio Module 		
	 Includes CW board or CW functionality 		
Physio Module Option	■ Includes Physio Module		
	 Includes the ECG function 		
	 Requires ECG cable and leads 		
	 Provides the ability to configure ECG capabilities for specialty applications that require display and monitoring of physiologic traces 		
Integrated Gel Warmer			
ECG leads	 ECG leads, standard U.S.A. 		
	 ECG leads, standard European 		
ICE Option	 Compatible with AcuNav 8F and AcuNav 10F transducers 		
(Available only on the ACUSON X700 system)	 SwiftLink catheter connector (includes instructions for use) 		
	 Sterile Sheaths 		
SwiftLink catheter connector	 Connects the AcuNav ultrasound catheter to the ultrasound 		
(Available only on the ACUSON X700 system)	system		
Barcode Reader	 Provides direct entry of patient information in the registration form, for example, the patient name and ID, the performing physician, or the sonographer 		
QuikStart Option	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 		
Wireless Option	 Sends data, such as studies, images, and clips to a network location over a wireless network 		
	 Requires approved wireless adapter, purchased separately 		
CARTOSOUND Communication	 Includes external input/output converter (I/O) box 		
(Available only on the ACUSON X700 system)	 Enables Ethernet communication between the ultrasound system and the CARTOSOUND™ system 		
Input/Output converter box	 Includes AC/DC adapter 		
	 Converts the digital video input signals to analog video output signals 		
	 Converts the video signals from the ultrasound system for display on an external display device 		

ACUSON X600 Transducer Options

Options	Description
Transducers, Curved Array	■ CH5-2
	■ C6-2
	■ EC9-4w
Transducers, fourSight 4D	■ C6F2
	■ C8F3
	■ EV9F3
Transducers, Linear Array	■ VF10-5
	■ VF12-4
Transducers, Phased Array	■ 4V1c
Transducers, Continuous Wave	(Requires the Cardio-Vascular Option)
	■ CW2
	■ CW5
Transducer Accessories	Transducer Sheaths
	 Biopsy Protective Sleeves, sterile, C6-2, CH5-2, VF10-5
	 Standoff Gel Pad, disposable, VF10-5
	 SG-3 Needle Guide Bracket Kit, VF10-5
	 CH4-1 Needle Guide Bracket Kit, CH5-2
	 VF12-4 Reusable Needle Guide Bracket Kit, VF12-4
	 EV9F3 Reusable Needle Guide Bracket Kit (Stainless Steel), EV9F3
	 EC9-4w Disposable Needle Guide Bracket Kit, EC9-4w
	 EC9-4w Reusable Needle Guide Bracket Kit (Stainless Steel), EC9-4w
	 Universal, Reusable Needle Guide Kit S (Stainless Steel), C6-2

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ACUSON X700 Transducer Options

Options	Description
Transducers, Curved Array	■ 4C1
	■ 6C2
	■ EC9-4w
	■ MC9-4
Transducers, fourSight 4D	■ C6F2
	■ C8F3
	■ EV9F3
Transducers, Linear Array	■ VF10-5
	■ VF12-4
	■ VF16-5
Transducers, Phased Array	■ 4V1c
	 V5Ms (Requires the Cardio-Vascular Option)
	AcuNav 8F
	AcuNav 10F
	SoundStar 10F
	SoundStar eco 8F
	 SoundStar eco 10F
Transducers, Continuous Wave	(Requires the Cardio-Vascular Option)
	■ CW2
	■ CW5
Transducer Accessories	Transducer Sheaths
	Biopsy Protective Sleeves, sterile, 4C1, 6C2, VF10-5
	 Standoff Gel Pad, disposable, VF10-5
	 SG-3 Needle Guide Bracket Kit, VF10-5
	 SG-5 Needle Guide Bracket Kit, 6C2
	 CH4-1 Needle Guide Bracket Kit, 4C1
	 Infiniti Plus Needle Guide Bracket Kit, VF16-5
	 VF12-4 Reusable Needle Guide Bracket Kit, VF12-4
	 EV9F3 reusable Needle Guide Bracket Kit (Stainless Steel), EV9F3
	 EC9-4w Disposable Needle Guide Bracket Kit, EC9-4w, MC9-4
	 EC9-4w Reusable Needle Guide Bracket Kit (Stainless Steel), EC9-4w, MC9-4
	 Leakage Current Tester (compatible with the V5Ms transducer)

Documentation Devices

Options	Description
Documentation Devices	 B&W Video Printer, P95DW, Mitsubishi
	B&W Video Printer, UP-D897, Sony
	 B&W Video Printer, UP-D898, Sony
	 Color Printer, CP30DW, Mitsubishi
	Color Printer, UP-D25MD, Sony
	For all countries except Korea: DVR, UR-50BD-S, TEAC
	 AC Power Supply, DPS54-M, Astec
	For Korea only: DVR, UR-50BD-SK, TEAC
	 AC Power Supply, DPS53, Astec

Consumables

Options	Description	
Consumables	■ Contact Scan Gel, 0.25 liter	
	 Contact Scan Gel, 5 liter 	
	 Contact Scan Gel, Sterile Packets 	
	 Paper, Black and White Video Printer, Mitsubishi 	
	CD-R 650 MB (10)	
	 Disposable ECG Electrodes 	
	DVD-RW 4X (1)	
	 Stress Echo External/Adapter Cable 	

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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 (8) Ellipse and Trace measurements per image
- Doppler has up to eight (8) points available on the waveform display
- Ratio Calculations
- Customizable summary feature

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
- Continuity Equation

Exam-Specific Measurements and Calculations

The measurement function is arranged by exam type and is available for use with all exam types. All exam types support the following measurement features:

- All general measurements and calculations
- Customizable summary feature
- Exam-specific patient report
- User-defined anatomy assessment selections

Exam	Exam-Specific Measurements and Calculations		
Obstetrics	Amniotic Fluid Index measurement		
Early Obstetrics	 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 		
	Gestational age by single parameter		
	■ Facial angle		

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Exam	Exam-Specific Measurements and Calculations
OB (J) Exams	 User-selectable formula sets for Tokyo, Osaka, and JSUM exams:
(For Japan only)	 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 user-defined 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 ultrasound menstrual age (USMA)
	 Measured Results display lists the values, standard deviation (SD), and resulting estimations of dates for ultrasound menstrual age (AGE) and US EDC ultrasound estimated date of confinement (EDC)
	 Editable patient report
	 Growth Analysis Graphs
Cerebrovascular	Right and left measurements
	CCA, ICA, ECA, and VA measurements
	 User-defined labels
	Cerebrovascular patient report
Peripheral Vascular	Right and left extremity measurements
	 User-defined labels

Exam	Exam-Specific Measurements and Calculations
Gynecology	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	★ WARNING: Do not use the cardiac measurements and calculations unless you are thoroughly trained in echocardiography and thoroughly familiar with the safe operation of the ultrasound system.
	 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
TEE	 All features of the Cardiac exam are available for the TEE exam
Urology	Micturated volume
	Prostate dimensions
	 Prostate and urology patient report
Orthopedic	Right and Left Hip Angle measurement
	 Graf Sonometer
	 Orthopedic (hip angle) patient report
Pediatric Echo	Note: You can use the Cardiac measurements and calculations with the Ped Echo exam.
	 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
Penile	 Measurement labels for anatomy and vessels
	 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

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Exam	Exam-Specific Measurements and Calculations		
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		
Thyroid	 2D-mode volume calculation for lobe and nodule 		
	 Thyroid worksheet and patient report 		
Abdomen	Volume measurements		
Breast	 User-defined labels 		
Pelvic Floor			
Testicle			
Other	User-defined labels are included in the following exam types:		
	Aorta, Musculoskeletal, Neonatal Head, Pediatric Abdomen, Small Parts, Superficial Musculoskeletal, Renal, Transcranial, Venous		

Measurement Accuracy

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

Parameter	Ranges	Accuracy	
Image Depth Scale	20 to 300 mm	< ± 3% of full scale	
Two-dimensional Measurements			
- Distance/Depth	up to 240 mm	3% of the distance or 1.5 mm; whichever is greater assuming 1,540 m/sec speed of sound. Does not apply to trace tool.	
– Area	up to 999 cm ²	$< \pm 6\%$ or $< 66 \text{ mm}^2$, if below 11 cm ²	
- Trace (Ellipse)	up to 999 cm ²	$< \pm 6\%$ or $< 66 \text{ mm}^2$, 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%		$<\pm$ 3% or $<$ 0.5 mm, if below 17 mm	
– Time	ime up to 16 sec. $<\pm$ 2%		
– Heart Rate 15 to 999 bpm $< \pm 5\%$		< ± 5%	
- Velocity	y up to 999 mm/sec. $< \pm 5\%$		
Volume Measurements			
Volume (Area, Length, Diameter)	up to 999 cm ³	$< \pm 9\%$ or $< 3.2 \text{ cm}^3$, if below 36 cm ³	
Distance using SieScape extended field of view	0 - 60 cm Linear transducer: 5% of the distance or 2.5 m whichever is greater assuming 1540 m/sec sp 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 0 - 560 cm ² extended field of view		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 m/sec speed of sound.	

Note: The range of tolerance using the trace tool is user-dependent.

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Image Display

Video Standards:	EIA/NTSC and CCIR/PAL		
Monitor:	Color 50 cm (20"), non-interlaced, MultiSync (HD+)		
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:	3.5 MHz = 30 to 280 mm		
(by frequency)	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 mo 2D/M-mode.	des; 2D image in 2D/D-mode and	
Image Position:	Image can be offset vertically and horizontally.		
Image Screen Display:	 Information for identifying the patient, 	Color bar	
	operator, and hospital or clinic	 Color flow velocity range 	
	 Panel for thumbnails 	Color ROI	
	 Panel for patient information 	Power bar	
	 Panel for measurements 	Power ROI	
	Date and Time	 M-mode cursor 	
	 Active transducer and transmit frequency 	 Doppler cursor 	
	Imaging Parameters	 Doppler scales: Velocity, Frequency 	
	Exam type	 Doppler gate: location, depth 	
	 Active image indicator 	 Doppler flow angle indicator 	
	Focal zone marker: number, position	Doppler angle	
	 DGC curve 	 Doppler invert 	
	 Trackball arbitration 	 Measurement menu 	
	Depth Scale	 Measured Results 	
	 Zoom indicator 	 Active measurement method 	
	Frame rate	 Soft key selections 	
	Error messages	 On-screen menu 	
	 Gray bar 	■ 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~	7.5 amps	50/60 Hz
200V~ to 240V~	180V~ to 264V~	3.5 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 (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.

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	
2 Channel Audio (Right, Left)	RCA-type (2 input, 2 output)	
USB	Series A type (6 ports)	
Ethernet (10BaseT/100BaseT)	RJ45 (1 port)	
Digital Video Interface (DVI)	24-pin DVI-Type (1 input, 2 output)	
Output	Connector	
VGA	15-pin D-sub high density (1 port)	

Video Standard

- Analog VGA
- Digital Video Interface (DVI)

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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	Up to 5,050 meters
	(700 hPa to 1060 hPa)	(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	+10°C to +40°C	-10°C to +50°C
(except MC9-4, C6F2, C8F3, EV9F3)		
MC9-4	+10°C to +40°C	-10°C to +60°C
C6F2, C8F3	+10°C to +40°C	-40°C to +70°C
EV9F3	+10°C to +40°C	-30°C to +70°C
Pencil CW Transducers	+10°C to +40°C	-40°C to +60°C
CW2, CW5		

Protective Measures

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

hazards.

Maximum Physical Dimensions

 Width:
 556 mm

 Height:
 1663 mm

 Depth:
 979 mm

Weight: 98 kg without documentation devices

System Classifications

Type of protection against electrical shock:

- Class I, external powered
- Degree of protection against electrical shock:
 - Type BF applied part for transducers
 - Defibrillation-proof applied part for ECG
- Degree of protection against harmful ingress of water:

Ordinary equipment (transducers and 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 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

Design Standards

- UL 60601-1
- 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)

Note: The system is a Class A device when the barcode reader is in use.

- EN 60601-2-18 and IEC 60601-2-18
- EN 60601-2-37 and IEC 60601-2-37
- EN 60601-1-4 and IEC 60601-1-4
- EN 60601-1-6 and IEC 60601-1-6

Acoustic Output Standards

- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- AIUM/NEMA UD-3, Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 62359 (Test methods for the determination of thermal and mechanical indices, 2010)

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. The CE marking only applies to medical devices that have been put on the market according to the above referenced Council Directive.

Unauthorized changes to this product are not covered by the CE marking and the related Declaration of Conformity.

EU Authorized Representative:

Siemens AG Medical Solutions Henkestrasse 127 91052 Erlangen Germany

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Appendix B Control Panel

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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.

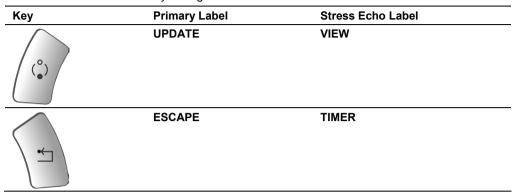


Example of the control panel on the ultrasound imaging system.

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.



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 or 4D imaging.

Primary Label	3D/4D Label	
D	X	
С	Υ	
М	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**
- **E** 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 Elasticity Imaging in Live mode, pressing the **UPDATE** key toggles a split-screen format with a full-screen format.

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 4D 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/4D imaging	3D/4D ROI	Toggles control of the 3D/4D ROI with the 2D FOV.
Steerable continuous wave Doppler	D cursor	Toggles control of the D cursor with the 2D FOV.
Elasticity imaging	EI ROI	Toggles control of the EI ROI 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

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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 dual-function 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.
, ,	Cycles through the available	Selects the highlighted thumbnail(s).
	thumbnails.	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.
3D Imaging or 4D Imaging	Cycles through volumes in the CINE buffer.	Displays full format of the selected volume or MPRs.
Elasticity Imaging	Changes the view scale of the 2D image	Not available.

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



Example of the status icon.

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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

E Customize Keys > Right Pedal

During 3D imaging, pressing the ${\it FREEZE}$ key during volume acquisition completes the acquisition.

During 4D 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 -30 dB to 30 dB. When combined with the DGC control, the gain range is -13 dB to 73 dB. (The DGC control range is -20 dB to +20 dB). The gain value displays in the Imaging Parameters on the upper left of the screen.

During live 4D imaging, rotating **2D** adjusts the overall gain. During other functions in 4D such as 4D Cine, rotating **2D** adjusts the brightness.

Dual



Activates Dual-mode, which displays two separately acquired images, side-by-side.

Pressing the **DUAL** key displays an image on the left side of the screen. Pressing the key again displays an image on the right side of the screen and freezes the image on the left side of the screen.

Only one image is active at a time. Press **DUAL** to toggle the active image. The system indicates the active image by highlighting the on-screen icon.



On-screen icon to indicate image orientation and to identify the active image.

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.

E Exam Configuration > Seamless Dual

During 3D/4D imaging, pressing the **DUAL** key displays two quadrants (2:1 format) on the screen.

M



A dual-function control that activates one function when the control is pressed and another function when the control is rotated.

Pressing the ${\bf M}$ 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 ${\bf M}$ a second time displays 2D/M-mode.

Rotating the \mathbf{M} control changes the overall gain for M-mode. Rotating the \mathbf{M} control clockwise increases the gain, and counterclockwise rotation decreases the gain. The range for gain settings is from -30 dB to 30 dB. The gain value displays in the Imaging Parameters on the upper left of the screen.

During 3D/4D imaging, this control rotates the volume around the "z" axis.

3D



Activates 3-Scape Imaging.

4D



Activates fourSight 4D Imaging.

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 $\bf D$ 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/4D 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 ${\bf C}$ 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/4D 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.

The **STEER** control positions the M-Mode or Doppler cursor or the color region of interest.

Invert



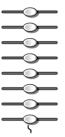
During pulsed wave Doppler, pressing **INVERT** flips the Doppler spectrum vertically on the baseline.

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.

Exam



Displays a list of available system-defined exam types and user-defined settings (QuickSets). You can save, delete, rename, and overwrite the user-defined settings.

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.

Use the system presets to assign the direction of rotation to the ${\bf DEPTH/ZOOM}$ control for increasing the depth.

E 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.

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. When the image is magnified, the system displays a "Z" next to the depth indicator on the image screen. Rotating **DEPTH/ZOOM** changes the magnification level. To exit zoom, press the **2D** control. Or, press **DEPTH/ZOOM**.

Use the system presets to assign the direction of rotation to the **DEPTH/ZOOM** control for increasing the magnification factor.

E 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.

HD Zoom



Displays a high-density zoom image on the screen.

Drag the zoom window over the region of interest (ROI). Rotating **DEPTH/ZOOM** adjusts the size of the window. Pressing **HD ZOOM** or **DEPTH/ZOOM** again magnifies the selection. When the image is magnified, the system displays a "**HD Z**" next to the depth indicator on the image screen. Rotating **DEPTH/ZOOM** changes the magnification level. To exit zoom, press the **HD ZOOM**. **DEPTH/ZOOM** or the **2D** control.

During 3D/4D imaging, pressing the $\mbox{HD ZOOM}$ key displays the single volume image on the screen.

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).

E 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.

Press the toggle key for **Delete Pictogram** to delete a pictogram from the screen.

Press **SET** to confirm the pictogram and return to the previous screen.

Press **ESCAPE** to return to the previous screen without selecting a pictogram.

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.

E Pictogram List

■ General 2 > Common Mode > Pictogram Location

■ General 2 > Common Mode > Delete Pictogram on Unfreeze

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, 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.
- Store a volume, clip, or image.
- **E** Customize Keys > Print/Store 1 Key
- **E** 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.
- Begin fourSight TEE acquisition.
- **E** Customize Keys > Clip Store Key

Review



Accesses the image screen or the study screen 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 of the Doppler signal.

Press the volume control to activate the microphone function during video recording (DVR).

Use the system presets to adjust the volume during video playback (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

You can assign the functionality of DVR recording to the UD 1, TGO / UD 2, or UD 3 key.

Applications



Activates and displays selections for the following optional features:

- Stress Echo
- SieScape
- Axius EF
- Auto Left Heart
- fourSight TEE

UD 1 (User Defined 1), UD 3 (User Defined 3)



Use the system presets to assign functionality to this control. For example, you can configure the control to activate the biopsy function, freeze function, 4B-mode, growth analysis graphs, or the ECG function.

- **E** Customize Keys > User-Defined 1 Key
- **E** Customize Keys > User-Defined 3 Key

During 3D/4D imaging, pressing the ${\bf UD~1}$ key displays the image quadrants in a 4:1 format on the screen.

TGO / UD 2 (User Defined 2)



The update function for the TGO feature is assigned to this control by default.

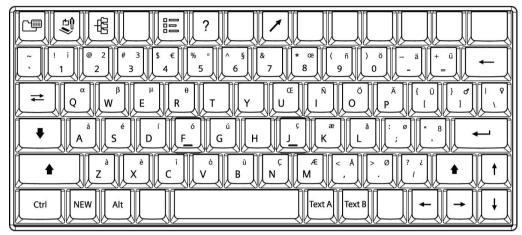
Use the system presets to assign functionality to this control. For example, you can configure the control to activate the biopsy function, 4B-mode, growth analysis graphs, or the ECG function.

E 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.	
Ctrl+←or →	Accesses the thumbnail panel.	

Use the system presets to activate functions without using shortcuts (not available for all functions).

■ General 1 > Display

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
i	ALT 1	à	ALT z
¿	ALT /	è	ALT x
Ñ	ALT I	é	ALT s
ñ	ALT 9	ì	ALT c
á	ALT a	ò	ALT v
é	ALT s	ù	ALT b
ĺ	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 I	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 integrated ultrasound workstation for image and data management, either during a patient examination or from saved studies.	
Exam/QuickSet		Displays a list of available system-defined exam types and user-defined QuickSets. You can save, delete, rename, and overwrite QuickSets (a configuration of imaging settings for a specific transducer and exam type).	
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.	
Video I/O		Displays a video signal that originates from an outside source, for example, a DVR.	
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.	
Insert		Inserts or overwrites text when text cursor is active. Press the key to change from the insert to the overwrite function.	
Home		Places the text cursor in the Home position (as defined with the Home Set key) when the text cursor is active.	
Home Set		Sets the default location of the text cursor. Roll the trackball or press the ARROW key to place the text cursor on the image screen in the required 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 or pressing the ARROW key to position the cursor on the term.	
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 Alphar	numeric Keys	Description
Arrows		Repositions the text cursor in the direction shown on the arrow key.
Alt	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	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	K->I	Moves the cursor to the beginning of the next available entry field.
NEW	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
Text A	Text A	Displays the screen to enter the user-defined annotations that are assigned to Text A .
Text B	Text B	Displays the screen to enter the user-defined annotations that are assigned to Text B .
Blank		No function.

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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.
- **E** Customize Keys > Left Pedal
- **E** Customize Keys > Right Pedal

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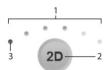
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Soft Key Selections

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 highlighted dots above the "page indicator."
- 2 Mode or function for the soft key selections.
- 3 Highlighted section corresponds to the displayed "page" of soft key selections.



Tab indicators display below 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	М
Anatomical M-mode	АММ
Doppler	PW
Color	С
Power	Р
ECG	Phy
Contrast agent imaging	CAI
Elasticity Imaging	El
3D/4D	3D/4D
	SubPreset
Text	General
	Anatomy
	Position
	User Def (User Defined)
Review	Review
	Apps. (Applications)

Note: The tab for elasticity imaging is unavailable during use of the sector format for a linear transducer.

C - 4 Instructions for Use

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.	Transducer-dependent (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	(Available for linear transducers only when the sector display format is enabled)	
	Resizes the field of view.	
Full Size	(Available for linear transducers only when the sector display format is enabled)	
	Maximizes the field of view.	
Мар	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.	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.	
SieClear	(Not available for phased array transducers)	Off, 2 (SieClear)
Adv. SieClear	Activates SieClear or Advanced SieClear multi-view spatial	3, 5, 7* (Advanced SieClear)
	compounding to reduce speckle and enhance tissue differentiation in 2D images.	*Not available for curved array transducers
Offset	Enables horizontal and vertical scrolling of the image using the trackball.	On, Off

Selection	Description	Settings
ТНІ	Activates Tissue Harmonic Imaging.	On, Off
	Tissue Harmonic Imaging (THI) is a system feature that can enhance contrast resolution with fine tissue differentiation, benefiting difficult-to-image patients.	
Image Presets	Optimizes a configuration of image parameter settings for the active exam and transducer.	GEN, RES, PEN
	 GEN (General) is configured with general settings. 	
	 RES (Resolution) is configured with a higher frequency or R/S (Resolution/Speed) for improved resolution. 	
	 PEN (Penetration) is configured with a lower frequency for improved penetration. 	
TGO Gain	Controls the TGO gain offset for the current 2D-mode imaging feature.	-5 to 5
ClarifyVE	Activates Clarify VE.	On, Off
	(For systems installed with the Clarify VE option)	
ClarifyVE Levels	When Clarify VE is active, selects the level of flow information to add to the image.	1 to 7
	(For systems installed with the Clarify VE option)	
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.	
DTO	Activates Dynamic Tissue Optimization for user-selectable levels of gain compensation.	
LVO Contrast	Adjusts the contrast for left ventricular opacification imaging.	
DTCE	Provides edge diffusion and pyramidal processing to reduce speckle and enhance contrast.	Off, Low, Med, High
Rotate	Rotates the image 90 degrees clockwise or counterclockwise.	
EFW	(Available only for OB(J) exams)	
	Calculates an estimated fetal weight (EFW).	

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Modify Map Screen

Button	Tool Tip	Description	Settings
	Save	Displays the User Map box.	
X	Exit	Closes the Modify Map screen.	
5	Undo	Removes the most recent modification.	
(3	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	Select the destination to save map settings.	User Map 1
	(drop-down list)		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.	Transducer-dependent (in dB units)
Sweep	Adjusts the scrolling speed of the M-mode sweep.	1, 2, 3, 4, 5, 6, 7, 8
Full M	Displays a full-screen M-mode sweep.	On, Off
Мар	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.	
AMM	Activates Anatomical M-mode.	on, off

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
Мар	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

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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
Scale	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, 6, 7, 8
Gate (Gate Size)	Adjusts the size of the Doppler gate.	Transducer-dependent
DTI	Activates the DTI Doppler Tissue Imaging feature.	On, Off
Мар	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, Abv, Both, Off
	Blw displays a trace below the baseline.	
	Abv displays a trace above the baseline.	
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, 1 sec, 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.	
Sensitivity	Adjusts the sensitivity of the trace tool.	1, 2, 3, 4, 5

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
Scale	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.	L, M, H
	 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. 	
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
DTE	Activates the DTE Doppler Tissue Energy feature.	On, Off
Мар	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

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Selection	Description	Settings
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%
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.	
Soft Key Selec	tions for Power Mode	
	Description	Settings
Soft Key Selection Thumbnail		Settings
Selection	Description	Settings
Selection Thumbnail	Description Accesses the thumbnail panel on the right of the screen. Note: This selection displays only when the system is	Settings Transducer-dependent
Selection	Description Accesses the thumbnail panel on the right of the screen. Note: This selection displays only when the system is frozen.	

Selection	Description	Settings
Flow	Optimizes hemodynamic flow conditions. The system automatically adjusts the parameters for wall filter and pulse repetition frequency (PRF) for the selected Flow state.	L, M, H
	 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. 	
Persist (Persistence)	Adjusts the time over which power data are processed in calculating the power amplitude display.	0, 1, 2, 3, 4
Dir Power (Directional Power)	Select a map to identify direction of flow in relationship to the transducer.	Off, On
	Directional power mode detects and assigns color to the energy and direction generated by the reflections of blood flow.	
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
Мар	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.	

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Soft Key Selections for Clip Capture

Use the system presets to assign default settings to the clip capture options and assign a documentation control to the clip capture function.

E Clip Capture

E Customize Keys > Customize...

Selection	Description	Settings
Trigger Type	Select clip capture over a period of seconds or heart beat cycles.	Time Capture
		Beat Capture
		Rwave Capture
sec	Specify the duration of each clip in seconds or minutes.	1, 2, 3, 4, 8*, 60*, 120* [sec]
	Note: Available when Time Capture is selected for Trigger Type .	5*, 6*, 7*, 8*, 9*, 10*, 15*, 20* [min]
beats	Specify the duration of each clip in heart beat cycles.	1, 2, 3, 4, 5*, 6*, 7*, 8*, 9*,
	Note: Available when Beat Capture is selected for Trigger Type .	10*, 15*, 20
beats	Specify the duration of each clip in heart beat cycles. The system captures only the frames with R-waves into the clip.	1, 2, 3, 4, 5*, 6*, 7*, 8*, 9*, 10*
	Note: Available when Rwave Capture is selected for Trigger Type .	
Chronology	Retrospective selects a clip of previous images.	Retrospective
	Prospective selects a clip of succeeding images.	Prospective
Acquisition Rate	Select the frame rate of the acquisition	normal, high
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).
Мар	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.
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.

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Soft Key Selections for Video Playback

A DVR counter is displayed on the upper left of the playback screen.

	. ,
Selection	Description
REW (Rewind)	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.
FF (Fast Forward)	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.
Shuttle	Plays the media in a forward or backward direction, at low or high speed, using the trackball.
	When you select Shuttle , a shuttle indicator displays on the left of the screen. Before you move the trackball in either direction, the shuttle indicator displays only a vertical line and the media plays at a low speed.
	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 (01 to 99).
	Note: Index markers include bookmarks entered using the Write Index function and the starting point of each chapter.
	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.
Counter Search	Searches the recording media in the selected direction for the specified counter value and displays the corresponding frame.
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 first chapter of the current study.
Next Study	Plays the next study.

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.	
%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.	

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Trans distance recommends have a first	
Trace distance measurement between two points.	
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.	
Calculate ratios A/B, B/A, and (A-B)/A for distance.	
Calculate ratios A/B, B/A, and (A-B)/A for area.	
Calculate ratios A/B, B/A, and (A-B)/A for volume.	

Applies to OB and Early OB exam types.

Selection	Description
Quik EFW	Advances through the required parameters (measurement labels) for calculating an
Auto EFW*	estimated fetal weight (EFW).
7.0.00 =	*Indicates a selection available only for OB(J) exams
Quik Graph	Displays the current study graphs in a quad format.
Quik Trend	Displays all the graphs from current and previous studies in a quad format.
ATD/ASD	Reassigns the ATD (Abdominal Transverse Diameter) and ASD (Abdominal Sagittal Diameter) measurements.
	Note: Displays when AC measurement label is selected from the measurement menu.
Auto OB	Activates syngo Auto OB.

Applies to gynecology exam types.

Selection	Description
Auto Follicle	Activates syngo Auto Follicle.

Soft Key Selections for M-Mode Measurements and Calculations

Description
Distance over time. The measurement is determined by two distance measurement markers.
Vertical distance between two points in the M-mode sweep.
Heart rate determined over one heart cycle in 2D/M-mode.
Interval in seconds between two measurement markers.
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.
Calculate ratios A/B, B/A, and (A-B)/A for distance.
Calculate ratios A/B, B/A, and (A-B)/A for time.

Soft Key Selections for Doppler Measurements and Calculations

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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.
Velocity Ratio	Calculate a ratio of two velocity measurements.
VTI	Automatically selects the default method to determine a Velocity-time Integral.

Soft Key Selections for the Standard Description Tab in the Standard OB Report

Selection	Description
User Setting	Updates all data fields in the report with a predefined set of options.
Clear	Removes all displayed data options from the data fields.
Create Setting Defines a set of options to apply to all data fields.	Defines a set of options to apply to all data fields.
	The system applies the modified options to subsequent exams when you press the toggle key for Create Setting .
Factory Setting	Restores the factory default settings for all data fields.

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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	Displays comments inserted from the Report page.
Recommendations	Insert predefined recommendations or enter recommendations directly in the form.
Signature	Displays a signature line which can be included in the printed Summary.
Graph	Displays graphs for Obstetric exam types.
Огарп	Displays graphs for Obstetile exam types.

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 or pressing the arrow keys to position the cursor on the term.
	(Performs the same function as the Delete Word key on the keyboard.)
Hide Text	Hides or displays all annotations and arrows.
Show Text	
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.

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Soft Key Selections for Arrows

Selection	Description	
New	Anchors the arrow at the current location and displays a new arrow.	
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.
Delete Pictogram	Removes the selected pictogram from the screen.

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.
fourSight TEE	Activates the fourSight TEE feature.

Soft Key Selections for Review

The following selections are available when the image screen or study screen for image and data management is active.

Soft Key Selections for Study Screen

Selection	Description
Show Archive	Displays the archival history for the selected study.
Image Screen	Displays the 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 controls available for use with image and data management.
Show All	Exits simultaneous display and displays all images in the study.
Select All	Selects all images in the Image screen. The system displays a blue border around selected images.
Unselect All	Cancels the selection of all images.
Mark Image	Displays a check mark on the selected image(s).
Show Marked	Displays the images with check marks in a new Image screen.
Unmark Image	Removes the check mark from the selected image(s).
Clear Marked	Removes all check marks on the images.
Teaching File	Displays a dialog box for combining images from multiple patient studies into a single teaching file.
Export Image	Copies the selected images to a connected USB storage device or CD/DVD.
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 — Apps. Tab

Selection	Description
VVI	Activates the VVI function.
Axius EF	Activates the Axius EF function.
Auto Left Heart	Activates the Auto Left Heart function.
AHP	Activates the AHP function.
fourSight TEE	Activates the fourSight TEE feature.
MVA	Activates the MVA (Mitral Valve Analysis) feature.

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Selections during Review of Patient Data

The patient browser displays selections for reviewing patient data on the following screens:

- Study screen lists studies that are saved on the selected disk or storage media.
- Image screen displays images for the currently selected study.

Study Screen

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).
Archive Source	Displays available storage locations for patient studies:
	 Local Disk lists studies on the system's hard disk
	 CD/DVD lists studies on the inserted disk media
	Removable Disk lists studies on the connected USB-compatible storage device
	 Server configured for the query/retrieve function
	Each storage location includes patient information, for example, the hard disk lists patient name and identification number, the study date, time, size, contents (clips and images), and archive status.
Screen	
Image Screen	Displays the Image screen with the images from the selected study.
Worklist Screen	Displays the Worklist screen.
Procedure Screen	Lists the available procedures for the selected study.
Live Screen	Exits the Study screen and the Review function; redisplays the real-time imaging screen.
DICOM Screen	Displays the DICOM screen.
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	Exits the selected study.
Delete	Removes the selected study from the hard disk. Studies on disk media cannot be deleted using the patient browser.
Reopen	Reopens a closed study that was created within the last 24 hours.

Study Screen Selection	Description
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.
Query/Retrieve	
Query	Searches the server configured for the query/retrieve function for studies matching your crtieria.
Retrieve	Imports studies to the system's hard disk from the server configured for the query/retrieve function.
Export/Import	
Export	(Available only for completed studies stored on the system's hard disk)
	Copies the selected study from the system's hard disk to the inserted disk media.
	Note: Select the name of the connected USB device from the drop-down list next to the USB selection.
Import	Copies the selected study from the inserted disk media to the system's hard disk. This selection is available when the Archive Source selection is CD/DVD or Removable Disk 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	(Available only for the system's hard disk)
	Specifies the format(s) of exported images:
	 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.
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.

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Image Screen

Note: In this chapter, the term "Image screen" refers to a screen in the patient browser. 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.
A	When enabled (checked), locks the selected layout format until system shutdown.
U	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	Sends the selected image to the DICOM BW Printer Layout page.
Color Print	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; redisplays 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 selected image one space forward.
<u></u>	Moves the selected image one space backward.
	Moves the slider. Or, click in the slider bar to select a frame.

Image Screen Selection	Description
H	Goes to the first frame in the displayed clip.
4	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.

Description
Disables simultaneous playback of all clips in the currently displayed study.
Enables simultaneous playback of all clips in the currently displayed study.
Begins each playback cycle at the same time.
Note: This selection is available only when Play All Clips is selected.
Configures clips and images for sequential viewing in the currently displayed study.
Specifies the length of display for each image.
Specifies the number of times each clip is played back.

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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 redisplays the Image screen.	
	Moves the slider. Alternatively, click in the slider bar to select a frame.	
K	Goes to the first frame in the displayed clip.	
4	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 Image Screen.

DICOM Screen Selections

The following descriptions for the Study, Image, and DICOM screens are specific to the DICOM Connectivity option. 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 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.		

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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		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.	
· · · · · · · · · · · · · · · · · · ·		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	
1x2 3x5 2x2 4x5		setting (Display Layout) is selected separately in the system presets for each type of printer and cannot be changed from a layout page.	
			2x3
3x2 5x6			
		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		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 imag		Displays the preceding page of print images.	
Next Displays the next page of print images.		Displays the next page of print images.	

Print and Store Queues

Page tabs displayed along the top of the DICOM screen include:

Queue status indicator.

- DICOM Print Queue
- DICOM Store Queue
- Retrieve Queue

Status

The system lists the following items for each queue entry on the **DICOM Print Queue** page:

The system lists the	e 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	e following items for each queue entry on the DICOM Store Queue page:
Item	Description
Туре	Type of operation:
	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:
	None
	 Stored
	Committed
The selections avai	lable 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.
The system lists the	e following items for each queue entry on the Retrieve Queue page:
Item	Description
Patient Name	Patient name.
Patient ID	Patient ID.

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Soft Key Selections

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 , redisplays 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.	

fourSight 4D Imaging and 3-Scape Imaging Controls

The system displays 4D and 3D imaging selections as soft key selections for viewing, displaying, selecting, editing, and animating the 4D or 3D data set(s).

Soft Key Selections for Set Up

Selection	Description	Settings
Scan	Selects the scan method for volume acquisition.	Linear, Rocked, AutoSweep
Angle/Length	Selects the scan length or scan angle for volume acquisition.	Transducer-dependent
Speed	(Available only for 3D)	Slow, Medium, Fast
	Selects the scan speed or quality setting for volume acquisition.	
ROI (Region of Interest)	Activates display of the ROI.	On, Off
3D/4D	Displays the soft key selections for 3D or 4D.	3D, 4D
Quality	Selects the quality setting for volume acquisition.	1, 2, 3, 4, 5, 6
Steering Angle	(Available only for the EV9F3 transducer)	Transducer-dependent
	Changes the steering angle within the transducer's array.	
	Range of settings: -30 to +30 in increments of 5	
	Note: During <i>four</i> Sight imaging or 3-Scape imaging (when using the automatic sweep method), the range of settings depends on the selected angle.	
	depends on the selected angle.	

 $\textbf{Note:} \ \mathsf{For} \ \mathsf{2D} \ \mathsf{FOV} \ \mathsf{settings}, \ \mathsf{adjust} \ \mathsf{the} \ \mathsf{activated} \ \mathsf{soft} \ \mathsf{keys}.$

Soft Key Selections for Acquisition — 3D or 4D tab

The system applies opacity settings to the volume quadrant only.

Selection

Description

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
Format	Selects a display format:	1:1, 4:1, 1:3, 2:1
	 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 	
Render	Selects a display method for the volume quadrant:	Slice
	 Slice — Displays a one-voxel-thick slice in its 	Opacity
	three-dimensional context. The displayed slice (within the	MPR Only
	volume) corresponds to the most recently selected slice (MultiPlanar Reformatting or MPR) quadrant.	MinIP
	 Opacity — Smooths image contours, creating a soft, 	MaxIP
	sculptured appearance for highlighting surface features. Uses the mode-specific selections for opacity percentage and thresholds.	MeanIP
	 MPR Only — Increases the rendering speed by displaying the MPRs (arbitrary slices) only. 	
	 MinIP (Minimum Intensity Projection) — Limits the display to minimum-value pixels by selecting pixels with the lowest value along each projection of the volume. May be helpful in visualizing hypo-echoic lesions and large vascular structures. 	
	 MaxIP (Maximum Intensity Projection) — Limits the display to maximum-value pixels by selecting pixels with the highest value along each projection of the volume. May be helpful in visualizing hyper-echoic structures and fetal skeletons. 	
	 MeanIP (Mean Intensity Projection) — Limits the display to average-value pixels by selecting pixels with the arithmetic mean (average) value along each projection of the volume. 	
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.	Off, A, B
	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.	
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, Curved, Off

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Selection	Description	Settings
Мар	Not available for Quadrant D.	A, B, C, D, E, F, G, H, I
	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.	
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, 75, 80, 85, 90 (in de 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	Available only for Opacity rendering methods.	0 to 255
Threshold)	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.	
Opacity	Available only for Opacity rendering methods.	0% to 100% (in increments
	Adjusts the percentage of opacity in the volume to smooth image contours.	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 only for Opacity and Surf. Shading (Surface Shading) rendering methods.	0% to 100%
	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.	
Contrast	Adjusts the percentage of contrast.	0% to 100%
Editing	Displays the Editing soft key selections.	
Animation	Displays the Animation soft key selections.	
Reset	Displays soft key selections for resetting formats.	
4D Cine	Displays soft key selections for editing the CINE data.	
P	Adjusts the transmit power.	0.20% to 100%
Steering Angle	(Available only for the EV9F3 transducer)	Transducer-dependent
	Changes the steering angle within the transducer's array.	
	Range of settings: -30 to +30 in increments of 5	
	Note: During <i>four</i> Sight imaging or 3-Scape imaging (when using Auto Sweep), the range of settings depends on the selected angle.	
Angle	Selects the scan length or scan angle for volume acquisition.	Transducer-dependent
Quality	Selects the quality setting for volume acquisition.	1, 2, 3, 4, 5, 6

Soft Key Selections for Resetting

Selection	Description	Settings
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.	
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.	
Flip	Reverses the render direction.	
Back	Returns to Imaging mode.	

Soft Key Selections for 4D Cine

Selection	Description
4D Cine	Activates 4D CINE soft key selections.
Play/Stop	Starts or stops playback of data in the CINE buffer.
Edit Start	Defines new beginning point of a loop of CINE data.
Edit End	Defines new ending point of a loop of CINE data.
Edit Reset	Resets the beginning and ending points to their originally acquired positions.
Rate	Changes the speed of CINE review while in motion review.
Back	Returns to Imaging mode.

Soft Key Selections for Editing

•	•	
Selection	Description	
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	temoves all the voxels from the nearest corner of the volume to a selected depth inside the olume. Activated for Quadrant D.	
Large Eraser	Displays the large eraser cursor for editing.	
Small Eraser	Displays the small eraser cursor for editing.	
Undo Last Edit	Removes the most recent edit.	
Undo All Edits	Removes all edits.	
Back	Returns to Imaging mode.	

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Soft Key Selections for Animation

Selection	Description	Settings
Animation	Automatically rotates the volume according to the selected range, speed, and axis.	On, Off
	Note: The system dithers the Editing selections and the general selections from the 3D Parameter menu (except Wireframe) while the volume is automatically rotating.	
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:	Axial
	 Axial — Rotates around the Axial axis. 	Lateral
	 Lateral — Rotates around the Lateral axis. 	
Clip Time	Selects the storing time for clip store.	2, 4, 8, 16 (sec)
Back	Returns to Imaging mode.	

Soft Key Selections for Advanced Imaging

Selection	Description			
MultiSlice	Displays soft key selections for viewing multiple cross-sectional slices at the same time in any plane.			
TSI	Displays soft key selections to adjust the thickness of an individual slice to improve contrast resolution.			
Curved MPR	Displays soft key selections for drawing a curved MPR (multiplanar rendering) to straighten curved anatomy.			

Soft Key Selections for MultiSlice

Selection	Description	Settings
Plane	Selects the MPR quadrant.	A, B, C
Axis	Displays horizontal or vertical slices of the volume relative to the	Horizontal
	selected MPR quadrant.	Vertical
Layout	Displays the arrangement of slices.	2x2
		3x3
		4x4
		6x6
Slice Spacing	Displays the spacing of the volume slices.	0.2mm to 10.0mm
Prev Page	Displays the previous page.	
Next Page	Displays the next page.	
Prev Image	Displays the previous image.	
Next Image	Displays the next image.	
Back	Returns to Imaging mode.	

Soft Key Selections for TSI

Selection	Description	Settings	
View	Displays MPR Plane A (Plane C) on the left with a dotted line indicating the center of the thick slice and volume Plane C (Plane A) on the right with the default slice thickness.	A/C, A/A	
Slice Thickness	Displays the thickness of the volume slice in millimeters.	2, 3, 5, 7, 10, 15, 20, 25, 30 (mm)	
Back	Returns to Imaging mode.		

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Soft Key Selections for Curved MPR

Icon	Selection	Description
	Line	Defines a curved line structure with two marker positions.
-	Spline	Defines a curved line structure with three or more marker positions.
2	Trace	Defines a free-form drawn outline.
	Back	Returns to Imaging mode.

Soft Key Selections for SubPreset

Selection	Description
Define >>	Display the dialog box to create an optimized configuration of imaging parameters for use during 3D or 4D imaging.

Soft Key Selections for Physiologic Function

Use the system presets to enable the ECG function (or the external ECG function), auxiliary function, or the respiratory 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.

Traces or signals can be activated separately.

	Internal ECG		Aux ECG		
	0	N	OFF	ON	OFF
Aux Signal	0	Χ	0	Х	0
Respiration	Х	0	0	0	0

Note: During an open study, activating the Aux ECG disables other functions, but respiration can be activated by pressing the soft key.

Soft Key Selections for ECG

Selection	Description	Settings
ECG	Activates (On) the ECG function.	On, Off
Aux ECG	Activates (On) the auxiliary physiologic input 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 trace on the image screen.	0 to 29 in increments of 1
Gain	Increases or decreases the trace amplitude.	0 to 12 in increments of 1
Invert	Vertically inverts the 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
Trigger Type	Selects Single or Dual trigger within one cardiac cycle.	Single, Dual

Soft Key Selections for Respiratory Traces

Selection	Description	Settings
Resp (Respiratory)	Activates (On) the respiratory trace.	On, Off
Position	Adjusts the vertical position of the trace on the image screen.	0 to 29 in increments of 1
Gain	Increases or decreases the trace amplitude.	0 to 12 in increments of 1

Soft Key Selections for Auxiliary Signals

Selection	Description	Settings
Aux Signal	Activates (On) the auxiliary signal.	On, Off
Position	Adjusts the vertical position of the signal on the image screen.	0 to 29 in increments of 1
Gain	Increases or decreases the trace amplitude.	0 to 12 in increments of 1

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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 redisplays the real-time imaging screen. This button is available only when acquisition of Stress Echo loops is not yet complete.
66	Select Mode	Enables Select Mode.
6	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 .
3	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.
S	Exit	Closes the Stress Echo screen and exits the Stress Echo feature; redisplays 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.

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Toolbar button		Description
▶I	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.
O	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:
		 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 Contrast Agent Imaging

E CAI > CAI Mode

E CAI > Extended Clip Duration

Selection	Description	Settings
CAI	Activates or deactivates the contrast agent imaging function.	On, Off
CAI Capture	Starts or stops image captures during contrast agent imaging.	On, Off
CAI Dur (CAI Duration)	Defines the duration of the contrast agent imaging capture.	1, 2, 3, 5, 10, 15, 20 sec
Balance	Displays the referenced 2D image or the contrast agent image.	CA, 2D
Timer	Activates or deactivates the on-screen timer. The timer displays the time elapsed since the timer was started. When the image is frozen, the system also displays the time when freeze occurred.	Off, On
Extended Clip	Starts and stops clip capture for contrast agent imaging.	On, Off
FR Control	(Not available during Doppler or M-mode)	Off, 0.5, 1, 2, 5, 7,
(Frame Rate Control)	Limits the frame rate to the selected maximum value.	10, 13 fps
Start Burst	Initiates the burst process during imaging.	On, Off
Burst Dur (Burst Duration)	Defines the duration of the burst process in seconds.	1, 2, 3, 5, 10, 15, 20 sec

Soft Key Selections for Elasticity Imaging (EI)

Selection	Description	Settings
El	Elasticity Imaging	On, Off
	Activates or deactivates the eSie Touch elasticity imaging feature.	
Split	Displays the 2D image on the left and an elastogram on the right. When Off is selected, displays a full screen image.	On, Off
Map Index	Cycles through the map index selections for gray scale and color maps.	0, 1, 2
	0 is the standard map	
	 Map index 0 is the natural result of the strain estimation from the echo signal without compensation for pre-compression (stress) or non-uniform stress applied by the user. 	
	• 1 is the normalized map	
	 Map index 1 compensates for the potential that non-uniform stress is applied with the transducer during scanning. 	
	2 is the inverse map	
El Color	Activates or deactivates the color map.	Off, 1, 2
	Off deactivates the color map.	
	• 1 applies a range of color to depict tissue stiffness from soft to hard.	
	• 2 applies blue to depict harder tissue and red to depict softer tissue.	
R/S	Adjusts the balance between the image line density (resolution) and the	0, 1, 2, 3
(Resolution/Speed)	frame rate.	

Elasticity Measurement Tools

Selection	Description
Shadow When the shadow function is active, makes a measurement on either the left image or the image, and then duplicates and displays the measurement on the other image.	
Strain Ratio Calculates the ratio of average strain (stiffness of tissue) within two user-selectable region interest.	

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.
1 2 3 4 : :	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.

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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 syngo Auto Left Heart.	

Soft Key Selections for Auto Left Heart

Selection	Description
Soft menu 1	Activates the first function box.
Soft menu 2	Activates the second function box.
Soft menu 3	Activates the third function box.
Soft menu 4	Activates the fourth function box.

syngo VVI Controls

lcon	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	Displays ejection fraction (EF), Dmin, Dmax, volume, and segmental volume information in the Global Measurement window.
	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).
P	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.

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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:
		 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,	Displays the M-mode, R-Waves, Crop window where you can:
	Crop	 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.
M	Next Frame	Displays the next frame of a clip.
K	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

lcon	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 redisplays 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 redisplays the VVI window.

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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.
H	Next Frame	Displays the next frame of a clip.
K	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 redisplays 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 redisplays the VVI window.

Dyssynchrony Analysis Window

lcon	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:
		 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:
		 Longitudinal (strain longitudinal). Long axis and generic curve views only.
		 Circumferential (strain circumferential). Short axis views only.
		 Radial (radial strain). Requires endo/epi traces.

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Icon	Selection	Description
	Strain Rate	Computes and displays values for the selected parameter:
		• 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:
		 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 redisplays 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.

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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.		

syngo Arterial Health Package (AHP) Controls

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.

lcon	Selection (Tool Tip)	Description
	CIMT Border	Displays the Carotid Intima-Media Thickness (CIMT) screen with the Image Quality Panel and the CIMT Editing Tools Panel.
	Reports	Displays the CIMT report and report selections.
	Setup	Displays the AHP Setup screen.
X	Exit	Exits the AHP program.

Image Quality Panel

The image quality panel displays on the right of the screen.

Icon	Selection (Tool Tip)	Description
H	Prior	Displays the previous frame of the clip.
•	Run	Starts playback of the displayed clip.
Ш	Stop	Stops playback of the displayed clip.
M	Next	Displays the next frame of the clip.
Æ	Zoom +	Magnifies the current clip or frame.
P	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.

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CIMT Editing Tools Panel

Tools for editing the borders of the Carotid Intima-Media Thickness (CIMT) display on the right of the screen and are available after establishing the CIMT region of interest (ROI).

Far Wall Tools

Button	Tool Tip	Description
200	Edit lumen- intima	Activates the edit function for the far lumen-intima boundary.
7	Edit media- adventitia	Activates the edit function for the far media-adventitia boundary.
	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.

Trace Editing Tools

Button	Tool Tip	Description
×	Clear borders	Deletes the current border and the CIMT ROI (region of interest).
	Toggle exclude frame	Exclude or include a specific frame from analysis and quantification.
N	Undo Edit	Discards the most recent edit.
P	Zoom to ROI	Magnifies the selected ROI (region of interest).
	Save CIMT	Saves data into the report.

Soft Key Selections for syngo Arterial Health Package (AHP)

Selection	Description
AHP	Activates the syngo Arterial Health Analysis software program (AHP).
Exit	Exits the <i>syngo</i> Arterial Health Analysis software program (AHP).

Soft Key Selections for Carotid Intima-Media Thickness (CIMT) Reports

Selection	Description	
Exit	Exit Closes the report page and activates 2D-mode.	
Export	Exports the report and worksheet to a connected USB storage device.	
Print Preview	riew Displays the report in a printing format.	
Print Prints the report.		

syngo TEE Controls

Soft Key Selections for syngo TEE

Selection	Description	Settings
Exit	Exits syngo fourSight TEE.	Off, 1, 2, 3
Step Angle	Specifies the step angle rotation increment for acquisition of each heart cycle.	3, 5
R-Gating	Displays soft key selections for heart rate gating setup.	On, Off
Auto Set	Automatically sets the acceptable range for the heart rate based on the patient's current heart rate.	
HR Min	Adjusts the minimum heart rate acceptable for acquisition.	
HR Max	Adjusts the maximum heart rate acceptable for acquisition.	

syngo Screen Controls

Icon	Selection	Description
	Review	Accesses the TEE Review screen and selections.
	Volume Measurement	Accesses the TEE Volume Measurement screen and selections.
×	Exit	Exits syngo fourSight TEE.

Slider Controls

To display the current value representing a "slider" selection:

Position the cursor over the slider.

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Toolbar (Review Screen)

The program displays the following selections on the toolbar at the top of the TEE review screen.

Icon	Selection	Description
7	Undo	Removes the most recent edit.
7	Redo	Cancels the most recent edit removal.
•	Reset	Restores the initial orientation for all quadrants; displays the first phase; retrieves any removed data; deletes measurements, annotations, arrows; and clears the memory buffer.
4	Pivot/Orbit	Orients (pivots or tilts) the cut plane when the cut plane or a plane quadrant is selected.
		Rotates the volume when a portion of the volume quadrant outside the volume is selected.
G	Rotate	Rotates the selected quadrant (plane or volume) in the clockwise or counterclockwise direction. When the volume quadrant is selected, rotates the volume around its center. When a plane quadrant is selected, rotates the plane around the location of the cursor.
\Leftrightarrow	Pan	Shifts the image (plane or volume) in the selected quadrant.
\searrow	Slice	Positions the cut plane by traversing the active plane quadrant through the volume along the orthogonal axis. Traversing the active plane is also called stepping through the volume.
\triangleright	Zoom	Magnifies the plane or volume in the selected quadrant.
Z	D↑Art	Activates the D ↑ Art function to display only the segment of interest in the volume quadrant. The segment of interest is defined by the selected plane (MPR).
•	Synchronize VR view with active MPR view	Aligns the orientation of the volume quadrant (VR view, or Volume Rendered view) to that of the selected plane quadrant (MPR view, or Multi-Planar Rendered view).
		Note: When this selection is active, the following selections are available for the planes only (not for the volume): Pivot/Orbit , Rotate , Pan , Slice , and Zoom .
	Show Tissue	Displays only the 2D data within the volume.
		Note: This selection is available for volumes that contain both 2D data and Color Doppler data.
	Show Color	Displays only the Color Doppler data within the volume.
		Note: This selection is available for volumes that contain both 2D data and Color Doppler data.

lcon	Selection	Description
	Show Color and	Displays both the 2D data and the Color Doppler data within the volume.
	Tissue	Note: This selection is available for volumes that contain both 2D data and Color Doppler data.
X	Clip Tissue	Activates the cut plane for 2D data in the volume.
X	Clip Color	Activates the cut plane for Color Doppler data in the volume.
00		Note: This selection is available for volumes that contain both 2D data and Color Doppler data.
	Tissue ROI	Adjusts the wireframe boundaries of the volume for 2D data.
4	Color ROI	Adjusts the wireframe boundaries of the volume for Color Doppler data.
		Note: This selection is available for volumes that contain both 2D data and Color Doppler data.
	Show Decorations	Displays a gray wireframe around the volume.
	Stop Phase Loop	Stops playback of the phase loop.
•	Play Phase Loop	Starts playback of the phase loop.
4	Previous Phase	Displays the previous phase.
 	Next Phase	Displays the next phase.
	Create Bookmark	Saves the dataset as an AVI-formatted clip on the system if the phase loop is playing. Includes actual settings; does not include rendered settings.
		Saves the displayed quadrant(s) as images to the system if the phase loop is not playing.
	Export AVI/BMP	Stores and exports clips and images to a USB device.

Controls — TEE Selections (Review Screen)

The program displays **Tools**, **Measurements**, or **Render Settings** selections depending on the selected control on the upper right of the TEE review screen.

Icon	Selection	Description
¥	Patient Information	Displays patient information for the current study.
Ti	Tools	Displays the selections in the Tools group.
	Measurements	Displays the selections in the Measurements group.
\triangle	Render Settings	Displays the selections in the Render Settings group.

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Tools

The program displays the following selections when you select the Tools control from the upper right of the TEE review screen.

lcon	Selection	Description
举	Brightness	Slider control. Lightens or darkens shades or colors (plane quadrants only).
	Contrast	Slider control. Adjusts the difference between the light and dark shades or colors (plane quadrants only).
•	Play Phase Loop	Starts or stops playback of the phase loop.
4	Previous Phase	Displays the previous phase.
▶	Next Phase	Displays the next phase.
<u>(L)</u>	Set Phase Animation Speed	Slider control. Adjusts the speed of playback for the phase loop and/or the automatic rotation (animation).
		The triangle below the slider indicates the heart rate at acquisition relative to the speed of playback/rotation.
	Play Animation	Automatically rotates the currently displayed phase in a rocking motion around its center point at the selected angle and speed.
	Slow Motion	Enables or disables slow motion for automatic rotation of the volume.
M	Set Angle	Slider control. Adjusts the vertical axis motion angle for automatic rotation of the volume.
		The total rotation is two times the motion angle setting. For example, the total rotation for a 45 degree motion angle is 90 degrees.
#	Mirror	Inverts the sequence of the acquired slices in the volume dataset.
	Scalpel Standard	Removes the outlined section of data from the volume.
*	Remove Erasings	Retrieves data that was removed using Scalpel .
翔	Toggle Lines of Intersection	Displays or hides the axes on the planes, which indicate the main axes through the volume.

Measurements

The program displays the following selections when you select the **Measurements** control from the upper right of the TEE review screen.

Icon	Selection	Description
	Distance	Makes a distance measurement.
.∠.	Angle	Makes an angle measurement.
\blacksquare	Area	Makes an area measurement.
AI	Annotation	Annotates the selected plane or volume.
	Arrow	Places an arrow on the selected plane or volume.
X	Delete selected annotation or measurement	Deletes the selected annotation, measurement, or arrow. If there is not a selected annotation, measurement, or arrow, then deletes all annotations, measurements, and arrows.

Render Settings

The program displays the following selections when you select the **Render Settings** control from the upper right of the TEE review screen.

lcon	Selection	Description
	Threshold Tissue	Slider control. Eliminates darker gray shades, background noise, and "snow" from the 2D data in the volume by removing voxels with values below the selected threshold.
	Transparency Tissue	Slider control. Adjusts the level of surface transparency for the 2D data in the volume. Higher values "smooth" the data while lower values "solidify" the data.
	Threshold Color	Slider control. Applies a unique color to each velocity direction in the Color Doppler data, then eliminates lower amplitude data and background noise from the Color Doppler data in the volume by removing voxels with values below the selected threshold.
	Transparency Color	Slider control. Adjusts the level of surface transparency for the Color Doppler data in the volume. Higher values "smooth" the data while lower values "solidify" the data and display data of higher velocities.
	Gradient Mode	Applies a mixture of gradient shading and texture shading to the 2D data within the volume.

lcon	Selection	Description
\mathfrak{D}	Gradient/Gradient Mode	Slider control. Applies a mixture of gradient shading and texture shading to the 2D data and color Doppler data within the volume.
	Gradient-Texture Ratio	Slider control. Mixes and adjusts gradient shading and texture shading.
	Texture Intensity	Slider control. Adjusts the concentration of texture shading.
■ M/X	Max IP Mode (Tissue)	Displays only the maximum intensity (highest value) 2D data within the volume.
■ M/X	Max IP Mode (Color)	Displays only the maximum intensity (highest value) Color Doppler data within the volume.
Hills	No 3D Filter	Increases the structural detail of the volume.
-	Smooth 3D (normal)	Applies a mild, low-pass filter to the volume for a display that emphasizes both structural detail and smoothness.
J	Smooth 3D (heavy)	Applies a moderate, low-pass filter to the volume for a display that emphasizes smoothness.
1	Smooth 3D (massive)	Applies a strong, low-pass filter to the volume for a display that strongly emphasizes smoothness.
	Invert Tissue	Inverts bright and dark voxel values of the 2D data within the volume.
	Show Beutel	Toggles display of the volume (surface rendering) with display of the most recently calculated volume measurement.

Controls — TEE Toolbar (Volume Measurement Screen)

The program displays the following selections on the toolbar at the top of the **TEE** volume measurement screen.

lcon	Selection	Description	
9	Undo	Removes the most recent edit.	
[2]	Redo	Cancels the most recent edit removal.	
•	Reset	Restores the initial orientation for all quadrants; displays the first phase; retrieves any removed data; deletes measurements, annotations, arrows; and clears the memory buffer.	
	Stop Phase Loop	Stops playback of the phase loop.	
•	Play Phase Loop	Starts or stops playback of the phase loop.	
4	Previous Phase	Displays the previous phase.	
 	Next Phase	Displays the next phase.	
* 🖹	Create Bookmark	Saves the dataset as an AVI-formatted clip on the system if the phase loop is playing. Includes actual settings; does not include rendered settings.	
		Saves the displayed quadrant(s) as images to the system if the phase loop is not playing.	
	Export AVI/BMP	Stores and exports clips and images to a USB device.	

Volume Measurements

The program displays the following selections (on the TEE volume measurement screen) when you select ${\bf Volume\ Measurement}$.

lcon	Selection	Description	
汝	Brightness	Slider control. Lightens or darkens shades or colors (plane quadrants only).	
	Contrast	Slider control. Adjusts the difference between the light and dark shades or colors (plane quadrants only).	
**	Previous plane pair	Displays the previous plane pair in the upper two quadrants.	
№ _※	Next plane pair	Displays the next plane pair in the upper two quadrants.	
兴	Double number of planes	Displays two times the originally displayed plane pairs.	
×	Halve number of planes	Reduces the displayed plane pairs by one-half.	
Ô	Set Enddiastole	Defines the currently selected phase as the end of diastole.	
ŝ	Set Endsystole	Defines the currently selected phase as the end of systole.	
	Calculate Volume	Calculates the traced volume (measurement).	
X	Delete volume	Deletes the traced volume measurement.	

syngo MVA Controls

Controls consist of on-screen selections and keys on the alphanumeric keyboard.

Toolbar

Review Tools

Button	Selection	Description	
•	Reset	Displays the dataset as it was originally displayed after it was imported.	
	Store Secondary Capture	Creates a bookmark of the Workspace content. Each bookmark is displayed as a thumbnail in the Bookmark Screen.	
	Export AVI/BMP	Exports animation files to a USB-compatible device.	
E	MVA Presettings	Changes settings for the workflow.	
€	MVA Delineation	Activates MV-Assessment Delineation.	
?	About	Displays information about the product version.	
	Stop Phase / Play Phase Loop	Toggles stop and start for the animation of a displayed phase sequence.	
	Play Phase / Stop Phase Loop	Toggles start and stop for the animation of a displayed phase sequence.	
4	Previous Phase	Shows the previous phase. This is unavailable until the analysis stage of the review.	
	Next Phase	Shows the next phase. This is unavailable until the analysis stage of the review.	
The followin	g review tools become	e available on the Toolbar when analysis begins.	
Button	Selection	Description	
H	Go to Frame of Interest	Skips to the defined phase.	
	MVA Analysis	Activates MV-Assessment Analysis.	
	MVA Analysis 2D	Activates MV-Assessment Analysis 2D.	

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Navigation Tools

Button	Selection	Description	
4	Pivot/Orbit	Orients the image target by rotating the selected Cut Plane / 3D/4D Data Cube around its vertical/horizontal axis.	
G	Rotate	Rotates one of the selected default cut planes (Front View, Left Side View or Top View) or the 3D/4D Data Cube around the axis perpendicular to the screen.	
\bigoplus	Pan	Relocates one of the selected default cut planes (Front View, Left Side View or Top View) or the 3D/4D Data Cube within a quadrant.	
P	Zoom	Zooms in and out on the image. All other planes are magnified by the same factor.	

Workspace

The following tools display directly on the Workspace and are used to control the image.

Icon	Selection	Description	
	Single Tiling	Displays the quadrant in maximum size in the Workspace.	
	Quad Tiling	Displays three 2-dimensional cut planes (Front View, Left Side View, and Top View) and the three-dimensional reconstruction (4D Data Cube) in the Workspace.	
	Replay Bar	Displays several locations of important frames (Frame of Interest, actual frame) within a phase sequence.	
		This example of a Replay Bar shows the seventh of twenty frames.	
	Orientation Cube	Shows the scan direction. The scan direction is indicated by two colors. The red side of the Orientation Cube represents the first view and the blue side represents the last view of the acquired dataset.	

Review Tools

The Toolspace provides three tabs, each with a set of review tools. The **Analysis** tab provides tools used to begin the analysis, the **Settings** tab provides tools that enhance and clarify the image for more accurate analysis, and the **Measurements** tab provides the tools to include your own measurements with the automatically acquired measurements.

Analysis

The **Analysis** tab is the start point for your analysis.

Button/	Colootion	Description
Icon	Selection	Description
✓	Landmark Placement Cine Loop	Toggles continuous animation with interrupted animation of a displayed phase sequence.
Н	Go to Frame of Interest	Skips to the defined phase.
\Box	Surgical View	Displays the normal surface of the MV annulus ring (shown in the 4D Data Cube).
		Note: Available in 3D only.
✓	Show Annulus	Displays the model of the annulus ring within the 4D Data Cube.
✓	Show Closure Line	Displays the model of the closure line within the 4D Data Cube.
Pr	New	Places an LM at a location of interest within an MPR and assigns a name to it. The name will also be displayed at the 3D/4D Data Cube, if Text in 3D is enabled.
		Note: Available in 2D only.
□ T	Rename	Edits a selected LM label.
[\ T]		Note: Available in 2D only.
$\overline{\mathbf{V}}$	Delete	Removes a selected LM.
		Note: Available in 2D only.
	Text in 3D	Enables the label display within the 3D reconstruction.
V		Note: Available in 2D only.
\checkmark	Show Automatic Labels	Displays automatically created labels for an overview of the anatomic structure of the MV. The automatic labeling takes place according to the Carpentier classification (A1-A3 anterior leaflets, P1-P3 posterior leaflets).
A	Add Label	Creates an annotation. Annotations created within the MPR are also applied to the 4D Data Cube. Annotations created within the 4D Data Cube are only applied to the 4D Data Cube.
X	Delete	Removes all annotations or only a selected annotation.

Settings

Settings (4D Data Cube representation):

Button/			
lcon	Selection	Description	
	Play Animation	Starts/stops a rocking motion of the 3D/4D Data Cube around its vertical axis.	
	Slow Motion	Toggles fast rocking motion with slow rocking motion.	
M	Set Angle	Adjusts the degree of the rocking motion angle. The displayed angle corresponds with the angle between the central position and final position at one side.	
ettings [•]	Tools		
Button/			
lcon	Selection	Description	
举	Brightness	Lightens or darkens tissue and colors equally.	
	Contrast	Adjusts the difference between light and dark tissue as well as light and dark colors.	
(Set Phase Animation Speed	Adjusts the animation speed. The triangle within the slider range indicates the original acquisition speed.	
•	Play Phase Loop	Starts the animation of a displayed phase sequence.	
H	Previous Phase	Displays the previous phase.	
H	Next Phase	Displays the next phase.	
	Show Tissue	Displays only black and white data.	
	Show Color	Displays only color data.	
	Show Color and Tissue	Displays color and black and white data in the 3D/4D reconstruction.	

Button/ Icon	Selection	Description
	Threshold Tissue	Separates an object of interest from the background and/or unwanted data (noise). Threshold settings help to define which structures are relevant for a 3D/4D reconstruction and which ones are not. Gray values above the adjusted threshold are taken into account for the reconstruction, and gray values below are ignored.
	Transparency Tissue	Determines the appearance of a 3D/4D Data Cube. A value of 0 creates a solid surface. Increasing this value increases the transparency of the object.
	Threshold Color	Defines which colors (velocities) are relevant for a 3D/4D Data Cube.
		Two basic colors represent velocities in contrary directions. Color values above the adjusted threshold are taken into account for the reconstruction, and values below are not. A low threshold setting displays all colors (velocities) of a data set; a high threshold only displays high velocities.
	Transparency Color	Determines the appearance of a 3D/4D Data Cube. A value of 0 creates a solid surface. Increasing this value increases the transparency of the object. A high transparency setting can help display higher velocities in the center of a velocity profile.
	Gradient-Texture Ratio	Mixes and adjusts the gradient shading and texture shading for maximum image quality.
	Texture Intensity	Adjusts the concentration or strength of texture shading.
الإلاك	No 3D Filter	Displays the 3D/4D Data Cube with increased structural details.
الخطيلا	Smooth 3D (normal)	Applies a mild low-pass filter to the 3D/4D Data Cube for a good compromise between structural detail and a smooth image.
	Smooth 3D (heavy)	Applies a moderate low-pass filter to the 3D/4D Data Cube for a smooth image, removing artifacts and some noise.
1	Smooth 3D (massive)	Applies a strong low-pass filter to the 3D/4D Data Cube for a very smooth image.
%	Tissue Color	Applies one of the available color schemes to the 3D/4D Data Cube.

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Measurements

The tools available on the **Measurements** tab enable measurements directly on the image.

Measurement Tools

Button	Selection	Description	
Distance		Measures a distance between two defined points simultaneously within an MPR and within the 4D Data Cube when measured within the MPR.	
		Measurements created within the 4D Data Cube are only applied to the 4D Data Cube.	
	Angle	Calculates an angle between three defined points simultaneously within an MPR and within the 4D Data Cube when calculated within the MPR.	
		Calculations created within the 4D Data Cube are only applied to the 4D Data Cube.	
×	Area	Calculates an area defined by a spline simultaneously within an MPR and within the 4D Data Cube when calculated within the MPR, or only within the 4D Data Cube if done there.	
		Calculations created within the 4D Data Cube are only applied to the 4D Data Cube.	
	Curve	Calculates a curve defined by a spline simultaneously within an MPR and within the 4D Data Cube when calculated within the MPR.	
		Calculations created within the 4D Data Cube are only applied to the 4D Data Cube.	
X	Delete	Removes all measurements or only a selected measurement.	
	Export Measurements	Exports measurement data to the connected USB device.	

The **Presettings** dialog box enables the activation of these selections before you begin delineation or analysis.

Checkbox/ User Entry	Selection	Description	
\checkmark	Fast Workflow Transitions	Increases the workflow speed by reducing the number of selections required to step through the workflow.	
\checkmark	Fast Landmark Placement	Automatically skips to the next cut plane after all landmarks which belong to the current cut plane have been set.	
Numerical value	Number of Closure Line Cut Planes	Increases or decreases the number of closure line cut planes. The new fragmentation will cause the deletion of any set landmarks.	
Numerical value	Number of MV Annulus Delineation Cut Planes	Increases or decreases the required number of annulus delineation line cut planes. The new fragmentation will cause the deletion of any set landmarks.	
Time value	Time Delay for Landmark Placement Cine Loop	Stops the loop for a preset time(s) at each Frame of Interest .	

Automatic Measurement Descriptions

This section provides a description for **Automatic Measurements** calculated by the system. The drawings provide guidance for landmark placement.

Measurement	Description	Drawing
Automatic measurement:	Distance between landmarks	1
AP Diameter (3D)	Anterior LM and Posterior LM.	
		2
		AP diameter.
		 Anterior LM AP diameter (3D) Posterior LM
Automatic measurement:	Two orthogonal planes:	1
AL-PM Diameter (3D)	The first plane is defined by the segment [Anterior LM, Posterior LM] and the Surgical View ray. Both lie in this plane.	
	The second plane is orthogonally placed at the center of the segment [Anterior LM, Posterior LM].	2
	The distance between the two intersection points of the annulus ring with the second plane is defined as AL – PM Diameter (3D).	3
		AL-PM diameter.
		 Anterior LM Posterior LM AP diameter (3D)
Automatic measurement: Sphericity Index (3D)	Ratio AP Diameter (3D) to AL – PM Diameter (3D).	1
		2
		3
		Sphericity index.
		1 Anterior LM
		2 AP diameter (3D)
		3 Posterior LM
		4 AL – PM diameter (3D)

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Measurement	Description	Drawing
Automatic measurement: Commissural	A plane defined by the Surgical View and the end points of the closure line. All characteristics	1
Diameter (3D)	mentioned above lie in this plane.	
	The distance between the two intersection points of the annulus ring with this plane is defined as Commissural Diameter (3D).	2
		Commissural diameter.
		1 Anterior LM
		2 Posterior LM3 Commissural diameter (3D)
Automatic measurement:	Angle formed by the middle point of	3 Commissural diameter (3D) 1 2
Non-Planar Angle (3D)	the Commissural Diameter (3D) (apex), Anterior LM, and Posterior LM.	
		4 3
		Non-planar angle.
		1 Anterior LM
		2 Non-planar angle
		3 Commissural diameter (3D)
Automatic measurement: Anterior Annulus Length (3D)	Curve length between the end points of the Commissural Diameter (3D) through the anterior part of the annulus ring.	4 Posterior LM 1 2
	amaido mig.	
		Anterior annulus length.
		1 Anterior LM 2 Anterior annulus length (3D)
		2 Afficion affidius length (3D)

Measurement	Description	Drawing
Automatic measurement:	Curve length between the end points	1
Posterior Annulus Length (3D)	of the Commissural Diameter (3D) through the posterior part of the annulus ring.	2 Posterior annulus length.
		1 Anterior LM
		2 Posterior LM3 Posterior annulus length (3D)
Automatic measurement: Annulus Circumference (3D)	Sum of Anterior and Posterior Annulus Length.	
Automatic measurement: Annulus Area (2D)	Projection of the 3D Annulus Area to a plane orthogonal to the surgical view. The area of the resulting planar region is defined as Annulus Area (2D) .	
Automatic measurement: CL Length (2D)	Projection of the 3D Closure Line to a plane orthogonal to the surgical view. The length of the resulting planar region is defined as CL Length (2D).	
Automatic measurement: CL Length (3D)	Closure Line length in 3D structure.	

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Appendix E Reserved for Future Use

Appendix E Reserved for Future Use

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Appendix F Acoustic Output Reference

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Display Resolution and Measurement Accuracy

When a transducer is capable of exceeding a mechanical or thermal index of 1.0, the ultrasound imaging system displays indices starting from 0.4 in increments of 0.1 for all displayed values.

A number of factors contribute to the estimation error for the displayed index. Variation among transducers and systems, approximation for real-time index calculations, and measurement errors contribute to the index display error. The measurement uncertainty for acoustic pressure, power, and center frequency is within 12%, 12%, and 7% respectively. The total estimated display accuracy is +/-15% for MI and +/-30% for TI. Definitions for these parameters can be found in the AIUM/NEMA document entitled Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (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)

Refer to Chapter 1 and Appendix A in this manual to identify transducers compatible with your ultrasound system.

	Mode											
	В			М	Р	WD	scw		Co	olor	C	WD
Transducer	MI	TI	MI	TI	MI	TI	MI	TI	MI	TI	MI	TI
4C1	1.22	0.6(S1) 0.6(B2)	1.01	0.4(S1) 0.5(B2)	0.74	0.9(S1) 2.8(B2)	ı	-	0.83	0.4(S1) 0.4(B2)	-	-
6C2	0.91	0.6(S1) 0.6(B2)	1.15	0.4(S1) 0.7(B2)	0.41	1.0(S1) 1.0(B2)	ı	-	0.60	0.9(S1) 0.9(B2)	-	-
EC9-4w MC9-4	1.50	<0.1(S1) <0.1(B2)	1.50	<0.1(S1) 0.1(B2)	0.80	0.2(S1) 0.6(B2)	-	-	1.48	0.5(S1) 0.5(B2)	-	-
4V1c	0.95	0.2(S1) 0.2(B2)	1.21	0.5(S1) 1.0(B2)	0.62	0.6(S1) 2.2(B2)	0.07	0.8(S1) 0.8(B2)	0.85	0.4(S1) 0.4(B2)	-	-
VF10-5	1.29	0.2(S1) 0.2(B2)	1.23	<0.1(S1) 0.1(B2)	1.09	0.4(S1) 1.2(B2)	-	-	1.14	1.0(S1) 1.0(B2)	-	-
VF12-4	0.93	1.1(S1) 1.1(B2)	0.56	0.1(S1) 0.1(B2)	1.23	0.4(S1) 1.3(B2)	-	-	0.93	0.7(S1) 0.7(B2)	-	-
CW2	-	-	-	-	-	-	-	-	-	-	0.04	0.8(S1) 0.8(B2)
CW5	-	-	-	-	-	-	-	-	-	-	0.04	3.6(S1) 3.9(B2)
C8-5	0.57	0.5(S1) 0.5(B2)	0.69	0.1(S1) 0.1(B2)	0.57	0.7(S1) 1.0(B2)	1	-	0.46	0.4(S1) 0.4(B2)	-	-
C8F3	0.75	0.2(S1) 0.2(B2)	1.12	0.2(S1) 0.5(B2)	0.45	0.4(S1) 1.0(B2)	ı	-	0.67	0.4(S1) 0.4(B2)	-	-
C6F2	0.81	0.2(S1) 0.2(B2)	0.97	0.1(S1) 0.5(B2)	0.48	0.6(S1) 1.5(B2)	1	-	0.66	0.3(S1) 0.3(B2)	-	-
EV9F3	0.63	0.6(S1) 0.6(B2)	1.04	0.2(S1) 0.3(B2)	0.31	1.1(S1) 1.1(B2)	1	-	0.41	0.8(S1) 0.8(B2)	-	-
P8-4	0.38	1.3(S1) 1.3(B2)	0.38	0.1(S1) 0.1(B2)	0.46	1.1(S1) 1.2(B2)	0.03	4.1(S1) 4.1(B2)	0.61	1.0(S1) 1.0(B2)	-	-
VF16-5	1.11	0.3(S1) 0.3(B2)	0.74	<0.1(S1) <0.1(B2)	1.17	0.7(S1) 1.8(B2)	ı	-	1.11	0.4(S1) 0.4(B2)	-	-
CH5-2	1.17	0.6(S1) 0.6(B2)	1.22	0.3(S1) 0.7(B2)	0.77	2.0(S1) 3.3(B2)	ı	-	0.89	1.1(S1) 1.1(B2)	-	-
C6-2	1.03	1.0(S1) 1.0(B2)	0.98	0.6(S1) 0.6(B2)	0.61	2.0(S1) 2.8(B2)	-	-	0.86	1.3(S1) 1.3(B2)	-	-
AcuNav 8F, SoundStar eco 8F	0.38	1.1(S1) 1.1(B2)	0.53	0.1(S1) 0.1(B2)	0.23	0.7(S1) 0.9(B2)	0.02	<0.1(S1) <0.1(B2)	0.34	1.0(S1) 1.0(B2)	-	-
V5Ms	0.12	0.3(S1) 0.3(B2)	0.19	0.1(S1) 0.1(B2)	0.38	0.5(S1) 1.0(B2)	0.02	0.2(S1) 0.4(B2)	0.27	0.2(S1) 0.2(B2)	-	-
AcuNav 10F, SoundStar 10F, SoundStar eco 10F	0.38	1.1(S1) 1.1(B2)	0.53	0.1(S1) 0.1(B2)	0.23	0.7(S1) 0.9(B2)	0.02	<0.1(S1) <0.1(B2)	0.34	1.0(S1) 1.0(B2)	-	-

S1: Soft Tissue Thermal Index, B2: Bone Thermal Index

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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.

Note: The acoustic output reporting tables are equivalent for the SoundStar eco 8F transducer and the AcuNav 8F transducer.

Note: The acoustic output reporting tables are equivalent for the SoundStar 10F transducer, the SoundStar eco 10F transducer, and the AcuNav 10F transducer.

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."

		ACUSON X60	00 Ultrasound	System							
		Operating Mode									
Transducer Model	B-mode (2D)	M-mode	Pulsed Doppler	Color Flow or Power	SCW Doppler	CW Doppler					
EC9-4w	Х	Х	Х	Х							
4V1c	Х	Х	Х	Х	Х						
VF10-5	Х	Х	Х	Х							
VF12-4	Х	Х	Х	Х							
CW2						Х					
CW5						Х					
C8F3	Х	Х	Х	Х							
C6F2	Х	Х	Х	Х							
EV9F3	Х	Х	Х	Х							
CH5-2	Х	Х	Х	Х							
C6-2	Х	Х	Х	Х							

		ACUSON X70	00 Ultrasound	System						
	Operating Mode									
Transducer Model	B-mode (2D)	M-mode	Pulsed Doppler	Color Flow or Power	SCW Doppler	CW Doppler				
4C1	Х	Х	х	Х						
6C2	Х	Х	х	Х						
EC9-4w MC9-4	x	x	x	x						
4V1c	Х	Х	Х	Х	Х					
VF10-5	Х	Х	Х	Х						
VF12-4	Х	Х	х	Х						
CW2						Х				
CW5						Х				
C8-5	Х	Х	х	Х						
C8F3	Х	Х	х	Х						
C6F2	Х	Х	х	Х						
EV9F3	Х	Х	х	Х						
P8-4	Х	Х	х	Х	Х					
VF16-5	Х	Х	х	Х						
V5Ms	X	Х	Х	Х						
AcuNav 8F, SoundStar eco 8F	х	х	х	x						
AcuNav 10F, SoundStar 10F, SoundStar eco 10F	х	х	х	х						

The following rules apply to the summary table:

B-mode	No other mode active.
(2D)	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.

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Definitions

Symbol		Definition						
FDA	IEC	FDA	IEC	Units				
MI	MI	Mechanical Index	Same as FDA	n/a				
TIS _{scan}	TIS Scan	Soft Tissue Thermal Index in autoscanning mode	Same as FDA	n/a				
TIS _{non-scan}	TIS Non-scan	Soft Tissue Thermal Index in non-autoscanning mode	Same as FDA	n/a				
TIB	TIB	Bone Thermal Index	Same as FDA	n/a				
TIC	TIC	Cranial Thermal Index	Same as FDA	n/a				
A _{aprt}	A _{aprt}	Area of the active aperture	-12dB output beam area	cm ²				
P _{r.3}	p _{ra}	Derated peak rarefactional pressure	Attenuated peak-rarefactional acoustic pressure	MPa				
Wo	P	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} (z ₁)	$P_{\alpha}(z_{\rm s})$	Derated ultrasonic power at axial distance z ₁	Attenuated output power at z _s	mW				
I _{TA.3} (z ₁)	$I_{\text{ta, }\alpha}(z_{\text{s}})$	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 $(W_{.3}(z), I_{TA.3}(z) \times 1 \text{ cm}^2)$], 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}	z _b	Axial distance at which TIB is a maximum (i.e., $z_{sp} = z_{B.3}$)	Depth for TIB	cm				
z@PII _{.3max}	z at max. I _{pi,α}	The axial distance corresponding to the maximum of the derated spatial-peak pulse intensity integral (megapascals).	Depth at the point where the free-field, attenuated pulse intensity integral is a maximum	cm				
d _{eq} (z)	$d_{ m eq}(z)$	Equivalent beam diameter as a function of axial distance z, and is equal to $ \left[\left(\frac{4}{\pi} \right) \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	f _{awf}	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	t _d	Pulse duration	Same as FDA	μs				
PRF	prr	Pulse repetition frequency	Pulse repetition rate	Hz				
p _r @PII _{max}	$p_{\rm r}$ at max. $I_{\rm pi}$	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}	d _{eq} at max. I _{pi}	Equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum	Same as FDA	cm				
FL	FL	Focal Length, or azimuthal and elevational lengths, if different	Same as FDA	cm				
I _{PA.3} @MI _{max}	I _{pa,α} at max. MI	Derated pulse-average intensity at the point of global maximum reported MI	Same as FDA	W/cm ²				

Note: Pulse-average intensity (I_{pa}) is the ratio of the pulse-intensity integral (I_{pi}) to the pulse duration (I_{d}).

Legend

English	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
At surface	n/a
Below surface	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

F - 8 Instructions for Use

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **4C1** Operating mode: **2D-Mode**

				MI	TIS Scan Non-scan			TIB	TIC
	Inde	x Label						Non-scan	
						At surface	Below surface		
	Maximum Value			1.40	1.41	-	-	-	4.01
	FDA	IEC	Units						
w	P _{r.3}	p_{ra}	(MPa)	2.09					
ters	Wo	P	(mW)		81.35	-		-	303.19
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)						
ic P	Z ₁	Zs	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	5.00					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	2.22	3.64	-	-	-	1.82
4	Dim. of A _{aprt} X		X (cm)		1.62	-	-	-	2.00
			Y (cm)		1.40	-	-	-	1.40
	PD	t _d	(µsec)	0.81					
tion	PRF	prr	(Hz)	23.46					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.06					
nfoi	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	1.89
erl	Focal Length	FLx	(cm)		4.00	-	-		4.00
oth		FLy	(cm)		4.80	-	-		4.80
	I _{pa.3} @ MI _{max}	$I_{pa.3}$ @ MI_{max} $I_{pa,q}$ @ $max. MI$ (W/cm		543.34					
tor ol	TX-Level (dB)			0	0	-	-	-	0
Operator Control	Focus (mm)	•		60.00	40.00	-	-	-	40.00
ర్ధిర	PRF(prr) (Hz)								

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

TIS

TIB

TIC

287.50

122.69

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **4C1** Operating mode: **Color / Power**

Ind	ex Label			Scan	Non-scan		Non-scan	
					At surface	Below surface		
Maximum Value			0.52	1.50	-	-	-	4.17
FDA	IEC	Units						
P _{r.3}	p_{ra}	(MPa)	0.77					
Wo	P	(mW)		102.27	-		-	550.41
min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Z ₁	Zs	(cm)				-		
Z _{bp}	Z _{bp}	(cm)				-		
Z _{sp}	Z _b	(cm)					-	
z@PII.3max	z @ max. $I_{pi,\alpha}$	(cm)	5.10					
$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
f _c	f _{awf}	(MHz)	2.22	3.08	-	-	-	2.22
Dim. of A _{aprt}		X (cm)		4.44	-	-	-	6.11
		Y (cm)		1.40	-	-	-	1.40
PD	t_{d}	(µsec)	1.68					
PRF	prr	(Hz)	1219.51					
Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.15					
d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	3.30
Focal Length	FLx	(cm)		18.27	-	-		28.75
	FLy	(cm)		4.80	-	-		4.80
I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	74.70					
	$\begin{tabular}{ll} \textbf{Maximum Value} \\ FDA \\ P_{r,3} & W_o \\ min of [W_{:3}(z_1), 1/4, 3(z_1)] \\ Z_1 & Z_0 \\ Z_{sp} & Z_0PII_{:3max} \\ d_{eq}(z_{sp}) & f_c \\ Dim. of A_{aprt} & \\ PD \\ PRF \\ P_{r}Q PII_{max} \\ d_{eq}Q PII_{max} \\ d_{eq}Q PII_{max} \\ Focal Length \\ \end{tabular}$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$				

PRF(prr) (Hz)

a This Index is not relevant to this operating mode.

(dB)

(mm)

TX-Level

Focus

0

85.60

1219.51

182.70

122.69

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.

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: 4C1

Operating mode: Pulsed Doppler

				MI	TIS			TIB	TIC	
	Inde	x Label			Scan	Nor	n-scan	Non-scan		
						At surface	Below surface			
	Maximum Value			0.91	-	-	1.49	3.47	4.58	
	FDA	IEC	Units							
	P _{r.3}	p_{ra}	(MPa)	1.36						
ters	Wo	P	(mW)		-	-		512.85	604.53	
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				140.95			
ic P	Z ₁	Zs	(cm)				4.00			
onst	Z _{bp}	$z_{\sf bp}$	(cm)				3.42			
Acc	Z _{sp}	$z_{\rm b}$	(cm)					4.20		
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.00						
cial	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					3.30		
SSC	f _c	f _{awf}	(MHz)	2.22	-	-	2.22	2.22	2.22	
4	Dim. of A _{aprt}		X (cm)		-	-	2.91	6.11	6.11	
			Y (cm)		-	-	1.40	1.40	1.40	
	PD	t _d	(μsec)	1.68						
Other Information	PRF	prr	(Hz)	152.59						
mal	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.84						
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					3.30	3.30	
er	Focal Length	FLx	(cm)		-	-	12.18		30.00	
Oth		FLy	(cm)		-	-	4.80		4.80	
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	103.17						
tor ol	TX-Level (dB)			0	-	-	0	0	0	
Operator Control	Focus (mm)			100.00	-	-	121.80	300.60	300.00	
8 ర	PRF(prr) (Hz)			152.99	-	-	1775.57	1395.09	1775.57	

This Index is not relevant to this operating mode.

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: 4C1

Operating mode: M-mode

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	No	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.35	-	-	0.57	1.10	1.61
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	2.01					
ters	Wo	P	(mW)		-	-		69.50	174.19
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				53.92		
. <u>S</u>	Z ₁	Z _S	(cm)				4.00		
onst	Z _{bp}	Z _{bp}	(cm)				3.53		
Acc	Z _{sp}	Z _b	(cm)					3.80	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.60					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					2.08	
SSC	f _c	f _{awf}	(MHz)	2.22	-	-	2.22	2.22	2.22
4	Dim. of A _{aprt}		X (cm)		-	-	3.10	2.43	4.10
			Y (cm)		-	-	1.40	1.40	1.40
	PD	$t_{\sf d}$	(µsec)	0.85					
ion	PRF	prr	(Hz)	384.00					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.65					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					2.08	2.70
e	Focal Length	FLx	(cm)		-	-	8.00		20.00
O#		FLy	(cm)		-	-	4.80		4.80
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	335.42					
o to	TX-Level (dB)			0	-	-	0	0	0
Operator Control	Focus (mm)		40.00	-	-	80.00	60.00	200.00	
ర్ధి	PRF(prr) (Hz)								
	This leaders is a starter								

This Index is not relevant to this operating mode.

F - 10 Instructions for Use

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

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.

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

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.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 6C2 Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.50	1.67	-	-	-	3.84
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	2.45					
ters	W _o	P	(mW)		83.30	-		-	294.35
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)						
i P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.80					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	2.67	4.21	-	-	-	4.21
•	Dim. of A _{aprt}		X (cm)		2.40	-	-	-	2.40
			Y (cm)		1.20	-	-	-	1.20
	PD	t _d	(µsec)	0.67					
ţio	PRF	prr	(Hz)	32.07					
шa	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.89					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	1.92
er	Focal Length	FLx	(cm)		6.00	-	-		6.00
o ₽		FLy	(cm)		7.00	-	-		7.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	353.68					
tor ol	TX-Level (dB)				0	-	-	-	0
Operator Control	Focus (mm)		20.00	60.00	-	-	-	60.00	
ర్ధి	PRF(prr) (Hz)								

This Index is not relevant to this operating mode.

- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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: 6C2 Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.32	1.21	-	-	-	2.98
	FDA	IEC	Units						
(O	P _{r.3}	p_{ra}	(MPa)	2.16					
eter:	Wo	P	(mW)		69.81	-		-	86.34
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
으	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.00					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\SS(f _c	f _{awf}	(MHz)	2.67	3.64	-	-	-	2.67
٩			X (cm)		0.78	-	-	-	0.34
			Y (cm)		1.20	-	-	-	1.20
	PD	$t_{\rm d}$	(μsec)	0.55					
Other Information	PRF	prr	(Hz)	195.31					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.12					
u Į	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	0.72
er	Focal Length	FLx	(cm)		3.22	-	-		1.46
oth		FLy	(cm)		7.00	-	-		7.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	1597.11					
<u>,</u>	TX-Level (dB)			0	0	-	-	-	0
Operator	Focus (mm)			37.50	32.20	-	-	-	14.60
30	PRF(prr) (Hz)			195.31	5580.36	-	-	-	9764.63

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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: 6C2

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.32	-	-	1.63	3.02	3.65
	FDA	IEC	Units						
w	P _{r.3}	p_{ra}	(MPa)	2.16					
ter	Wo	P	(mW)		-	-		88.58	360.74
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				94.04		
Si	Z ₁	Z _S	(cm)				3.00		
onst	Z _{bp}	Z _{bp}	(cm)				1.70		
Acc	Z _{sp}	z_{b}	(cm)					3.60	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.00					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					1.11	
SSO	f _c	f _{awf}	(MHz)	2.67	-	-	3.64	2.67	2.67
4	Dim. of A _{aprt}		X (cm)		-	-	0.84	0.81	3.99
			Y (cm)		-	-	1.20	1.20	1.20
	PD	t _d	(µsec)	1.40					
ţion	PRF	prr	(Hz)	2741.23					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.37					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					1.11	2.47
er	Focal Length	FLx	(cm)		-	-	3.52		20.46
o₩		FLy	(cm)		-	-	7.00		7.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	133.05					
Operator Control	TX-Level (dB)		0	-	-	0	0	0	
era	Focus (mm)			11.80	-	-	35.20	34.30	204.60
ಕ್ಷಿ	PRF(prr) (Hz)			2741.23	-	-	11160.70	14204.50	3255.21

This Index is not relevant to this operating mode.

- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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: 6C2

Operating mode: M-mode

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	No	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.27	-	-	0.51	0.69	1.22
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	2.01					
ters	Wo	P	(mW)		-	-		93.12	117.23
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				25.44		
S.	Z ₁	Zs	(cm)				4.10		
onst	Z _{bp}	Z _{bp}	(cm)				2.34		
Acc	Z _{sp}	Z b	(cm)					5.60	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.10					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					1.92	
SSO	f _c	f _{awf}	(MHz)	2.50	-	-	4.21	2.50	2.50
4			X (cm)		-	-	1.59	2.40	3.78
			Y (cm)		-	-	1.20	1.20	1.20
	PD	t _d	(µsec)	0.58					
ion	PRF	prr	(Hz)	384.00					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.86					
Je J	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					1.92	2.40
e	Focal Length	FLx	(cm)		-	-	4.00		20.00
Oth		FLy	(cm)		-	-	7.00		7.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	473.98					
Operator Control	TX-Level (dB)			0	-	-	0	0	0
era	Focus (mm)	Focus (mm)			-	-	40.00	60.00	200.00
ဝီပိ	PRF(prr) (Hz)								
2	This Index is not rele	want to this anaron	ting made						

This Index is not relevant to this operating mode.

F - 12 Instructions for Use

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

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.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: EC9-4w and MC9-4 Operating mode: 2D-Mode

				MI		TIS		TIB T	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.50	0.84	-	-	-	0.98
	FDA	IEC	Units						
(n	P _{r.3}	p_{ra}	(MPa)	2.54					
ters	Wo	P	(mW)		24.26	-		-	17.05
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)						
i P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.90					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	2.86	7.27	-	-	-	7.27
4	Dim. of A _{aprt}		X (cm)		0.25	-	-	-	0.25
			Y (cm)		0.60	-	-	-	0.60
	PD	t _d	(µsec)	0.76					
ţion	PRF	prr	(Hz)	46.50					
mai	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.06					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.43
er	Focal Length	FLx	(cm)		0.50	-	-		0.50
e E		FLy	(cm)		2.00	-	-		2.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	411.19					
tor ol	TX-Level (dB)			0	0	-	-	-	0
Operator Control	Focus (mm)			20.00	5.00	-	-	-	5.00
ర్ధి	PRF(prr) (Hz)								

a This Index is not relevant to this operating mode.

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: EC9-4w and MC9-4 Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.55	0.61	-	-	-	1.06
	FDA	IEC	Units						
(n	P _{r.3}	p_{ra}	(MPa)	3.10					
ters	Wo	P	(mW)		24.03	-		-	22.84
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
.S	Z ₁	Zs	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.30					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSO	f _c	f _{awf}	(MHz)	4.00	5.33	-	-	-	5.33
4	Dim. of A _{aprt}		X (cm)		0.35	-	-	-	0.38
			Y (cm)		0.60	-	-	-	0.60
	PD	t_{d}	(µsec)	0.95					
Other Information	PRF	prr	(Hz)	781.25					
шa	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.71					
ufo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.54
er	Focal Length	FLx	(cm)		1.41	-	-		1.51
₽		FLy	(cm)		2.00	-	-		2.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	490.24					
Operator Control	TX-Level (dB)			0	0	-	-	-	0
era	Focus (mm)	Focus (mm)		12.00	14.10	-	-	-	15.10
రిర	PRF(prr) (Hz)			781.25	4863.81	-	-	-	19531.25
1	This Index is not relevant to this operating mode						-		

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.

Wo data is provided for this operation condition since the maximum index value is not reported for the reason listed.

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.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: EC9-4w and MC9-4 Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Noi	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.51	-	-	0.77	1.73	0.76
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	3.49					
ters	W _o	P	(mW)		-	-		27.48	30.34
Associated Acoustic Parameters	min of [W $_3(z_1)$, $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				30.34		
ic P	Z ₁	Zs	(cm)				1.80		
onst	Z _{bp}	Z bp	(cm)				1.50		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					2.20	
ted	z@PII _{.3max}	z @ max. I _{pi,α}	(cm)	0.80					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					1.00	
SSC	f _c	f _{awf}	(MHz)	5.33	-	-	5.33	4.00	5.33
4	Dim. of A _{aprt}		X (cm)		-	-	1.30	1.30	1.30
			Y (cm)		-	-	0.60	0.60	0.60
	PD	t _d	(µsec)	0.48					
tion	PRF	prr	(Hz)	3906.25					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	4.04					
Je	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					1.00	1.00
ë	Focal Length	FLx	(cm)		-	-	13.55		13.95
oth		FLy	(cm)		-	-	2.00		2.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	786.50					
Operator Control	TX-Level (dB)			0	-	-	0	0	0
era	Focus (mm)		10.50	-	-	135.50	134.30	139.50	
ర్ధిర	PRF(prr) (Hz)			3906.25		-	4734.85	13020.80	4734.85

a This Index is not relevant to this operating mode.

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: **EC9-4w and MC9-4** Operating mode: **M-mode**

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Noi	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.50	-	-	0.10	0.18	0.11
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	3.08					
ters	W _o	P	(mW)		-	-		3.46	3.89
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				2.89		
. <u>S</u>	Z ₁	Z _S	(cm)				1.80		
onst	Z _{bp}	Z _{bp}	(cm)				1.30		
Acc	Z _{sp}	Z _b	(cm)					1.80	
eq	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.60					
cial	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.87	
SSC	f _c	f _{awf}	(MHz)	4.21	-	-	7.27	7.27	7.27
4	Dim. of A _{aprt}		X (cm)		-	-	0.99	0.99	1.02
			Y (cm)		-	-	0.60	0.60	0.60
	PD	$t_{\rm d}$	(μsec)	0.53					
ion	PRF	prr	(Hz)	384.00					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.88					
Je J	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.87	0.88
e	Focal Length	FLx	(cm)		-	-	6.00		8.00
₽		FLy	(cm)		-	-	2.00		2.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	921.59					
o to	TX-Level (dB)			0	-	-	0	0	0
Operator Control	Focus (mm)		60.00	-	-	60.00	60.00	80.00	
ర్ధి	PRF(prr) (Hz)								
	This lades is a 4 selected 4 this are retired as								

a This Index is not relevant to this operating mode.

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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.

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.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4V1c Operating mode: 2D-Mode

				МІ		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	ı-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.50	0.97	-	-	-	3.94
	FDA	IEC	Units						
m	P _{r.3}	p_{ra}	(MPa)	2.02					
ter	Wo	P	(mW)		111.92	-		-	268.87
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z bp	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	5.20					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
ASSC	f _c	f _{awf}	(MHz)	1.82	1.82	-	-	-	1.82
1	Dim. of A _{aprt}		X (cm)		1.63	-	-	-	1.63
			Y (cm)		1.40	-	-	-	1.40
	PD	t _d	(µsec)	0.76					
tion	PRF	prr	(Hz)	61.26					
ща	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.81					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	1.71
er	Focal Length	FLx	(cm)		11.00	-	-		11.00
ē ₽		FLy	(cm)		6.90	-	-		6.90
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	1655.35					
Operator Control	TX-Level (dB)			0	0	-	-	-	0
era	Focus (mm)		70.00	110.00	-	-	-	110.00	
80	PRF(prr) (Hz)								

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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: 4V1c Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.89	0.97	-	-	-	3.55
	FDA	IEC	Units						
(O	P _{r.3}	p_{ra}	(MPa)	1.26					
sters	W _o	P	(mW)		81.48	-		-	189.92
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
С	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z b	(cm)					-	
ted	z@PII.3max	z @ max. $I_{pi,\alpha}$	(cm)	5.40					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
ASSC	f _c	f_{awf}	(MHz)	2.00	2.50	-	-	-	2.00
4			X (cm)		1.02	-	-	-	1.00
			Y (cm)		1.40	-	-	-	1.40
	PD	t _d	(μsec)	1.89					
Other Information	PRF	prr	(Hz)	3551.14					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.83					
uţo	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	1.34
er	Focal Length	FLx	(cm)		4.09	-	-		4.01
oth		FLy	(cm)		6.90	-	-		6.90
	I _{pa.3} @ MI _{max}	$I_{pa,\alpha}$ @ max. MI	(W/cm ²)	650.58					
<u> </u>	TX-Level (dB)			0	0	-	-	-	0
Operator	Focus (mm)			70.00	40.90	-	-	-	40.10
3 S	PRF(prr) (Hz)		3551.14	5580.36	-	-	-	5580.36	

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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: 4V1c

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.58	-	-	1.25	3.12	3.53
	FDA	IEC	Units						
	P _{r.3}	p_{ra}	(MPa)	2.50					
ters	Wo	P	(mW)		-	-		121.92	260.19
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				131.25		
iS T	Z ₁	Zs	(cm)				6.50		
onst	Z _{bp}	Z _{bp}	(cm)				2.76		
Acc	Z _{sp}	Z _b	(cm)					6.50	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	5.20					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					1.84	
SSC	f _c	f _{awf}	(MHz)	2.50	-	-	2.00	2.00	2.00
^	Dim. of A _{aprt}		X (cm)		-	-	1.90	1.90	1.90
			Y (cm)		-	-	1.40	1.40	1.40
	PD	t _d	(μsec)	1.51					
.io	PRF	prr	(Hz)	100.16					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.91					
Je.	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					1.84	1.84
ē	Focal Length	FLx	(cm)		-	-	12.91		12.96
₽		FLy	(cm)		-	-	6.90		6.90
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	1505.48					
힏	TX-Level (dB)			0	-	-	0	0	0
Operator Control	Focus (mm)		78.00		-	129.10	129.10	129.60	
ဝီပိ	PRF(prr) (Hz)			100.16		-	19531.30	19531.30	19531.30
_				•		•			

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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: 4V1c

Operating mode: M-mode

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	No	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.50	-	-	0.64	1.65	2.04
	FDA	IEC	Units						
ro.	P _{r.3}	p_{ra}	(MPa)	2.12					
ter	W _o	P	(mW)		-	-		59.73	139.21
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				73.85		
:S	Z ₁	Z _S	(cm)				5.20		
onst	Z _{bp}	Z _{bp}	(cm)				2.56		
Acc	Z _{sp}	Z _b	(cm)					5.20	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	5.20					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					1.71	
SSC	f _c	f _{awf}	(MHz)	2.00	-	-	1.82	1.82	1.82
4	Dim. of A _{aprt}		X (cm)		-	-	1.63	1.63	1.63
			Y (cm)		-	-	1.40	1.40	1.40
	PD	t _d	(µsec)	0.72					
io	PRF	prr	(Hz)	480.00					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.04					
Jo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					1.71	1.71
e	Focal Length	FLx	(cm)		-	-	7.00		18.00
o H		FLy	(cm)		-	-	6.90		6.90
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	2122.23					
Operator Control	TX-Level (dB)			0	-	-	0	0	0
era	Focus (mm)			70.00	-	-	70.00	70.00	180.00
ర్ధి	PRF(prr) (Hz)								
2	This Index is not rele	uant to this anaron	tina mada						

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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.

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(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4V1c Operating mode: SCW Doppler

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.07	-	-	1.92	1.92	6.00
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	0.09					
sters	Wo	P	(mW)		-	-		24.61	442.26
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				221.54		
ic P	Z ₁	Zs	(cm)				2.30		
onst	Z _{bp}	Z bp	(cm)				1.73		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					2.30	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.80					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					1.15	
SSC	f _c	f _{awf}	(MHz)	1.82	-	-	1.82	1.82	1.82
•	Dim. of A _{aprt}		X (cm)		-	-	0.75	0.75	1.90
			Y (cm)		-	-	1.40	1.40	1.40
	PD	t _d	(µsec)	1.00					
tion	PRF	prr	(Hz)	7812.50					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	0.11					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					1.15	1.84
e	Focal Length	FLx	(cm)		-	-	3.02		24.75
₽		FLy	(cm)		-	-	6.90		6.90
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	0.02					
Operator Control	TX-Level (dB)		•	0	-	-	0	0	0
era	Focus (mm)		•	129.70	-	-	30.20	30.20	247.50
80	PRF(prr) (Hz)			7812.50	-	-	15625.00	15625.00	15625.00

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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

TIC	TIB		TIS		МІ		_		
	Non-scan	ı-scan	Non	Scan			x Label	Inde	
		Below surface	At surface						
2.32	-	-	-	1.08	1.37			Maximum Value	
						Units	IEC	FDA	
					2.97	(MPa)	p _{ra}	P _{r.3}	(O
97.70	-		-	36.88		(mW)	P	W _o	ters
		-				(mW)	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Associated Acoustic Parameters
		-				(cm)	Z _S	z ₁	С
		-				(cm)	Z _{bp}	Z _{bp}	onst
	-					(cm)	Z _b	Z _{sp}	Acc
					1.50	(cm)	z @ max. I _{pi,α}	z@PII.3max	ted
	-					(cm)	$d_{\rm eq}(z_{\rm b})$	$d_{eq}(z_{sp})$	ocia
6.15	-	-	-	6.15	4.71	(MHz)	f _{awf}	f _c	\SS(
1.74	-	-	-	1.74		X (cm)		Dim. of A _{aprt}	٩
0.50	-	-	-	0.50		Y (cm)			
					0.24	(µsec)	t _d	PD	
					32.15	(Hz)	prr	PRF	ion
					3.79	(MPa)	P _r @ max. I _{pi}	P _r @ PII _{max}	ma
1.05	-					(cm)	d _{eq} @ max. I _{pi}	d _{eq} @ PII _{max}	uţo
7.00		-	-	7.00		(cm)	FLx	Focal Length	er
2.00		-	-	2.00		(cm)	FLy		oth
					682.52	(W/cm ²)	I _{pa,α} @ max. MI	I _{pa.3} @ MI _{max}	
0	-	-	-	0	0	TX-Level (dB)			<u> </u>
70.00	-	-	-	70.00	20.00	Focus (mm)		ontr	
						PRF(prr) (Hz)			ე ၓ
		-	-	2.00	0	(cm) (cm) (W/cm²)	FLx FLy I _{pa,q} @ max. MI	Focal Length I _{pa.3} @ MI _{max} TX-Level (dB) Focus (mm)	ω Operator Other Information

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	ı-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.07	1.26	-	-	-	1.83
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	2.65					
ters	Wo	P	(mW)		43.02	-		-	69.37
Associated Acoustic Parameters	min of [W $_3(z_1)$, $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Si	z_1	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.50					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	6.15	6.15	-	-	-	6.15
4	Dim. of A _{aprt}		X (cm)		1.59	-	-	-	1.41
			Y (cm)		1.50	-	-	-	0.50
	PD	t _d	(μsec)	0.47					
Other Information	PRF	prr	(Hz)	15625.00					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.65					
Jo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.95
e	Focal Length	FLx	(cm)		4.75	-	-		4.25
O E		FLy	(cm)		2.00	-	-		2.00
_	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	751.83					
힏	TX-Level (dB)			0	0	-	-	-	0
Operator Control	Focus (mm)			18.70	47.50	-	-	-	42.50
ి ర	PRF(prr) (Hz)			15625.00	7812.50	-	-	-	3125.00
	This leaders is a standa								

This Index is not relevant to this operating mode.

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

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	No	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.22	-	3.11	-	3.11	2.47
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	2.82					
eter	Wo	P	(mW)		-	106.20		123.16	121.39
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ю Б	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					1.30	
ted /	z@PII.3max	z @ max. $I_{pi,\alpha}$	(cm)	1.30					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					1.14	
SSOC	f _c	f _{awf}	(MHz)	5.33	-	6.15	-	6.15	6.15
4	Dim. of A _{aprt}		X (cm)		-	2.04	-	2.04	2.37
			Y (cm)		-	0.50	-	0.50	0.50
	PD	$t_{\sf d}$	(μsec)	0.52					
Other Information	PRF	prr	(Hz)	100.16					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.58					
uţo	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					1.14	1.23
er	Focal Length	FLx	(cm)		-	8.51	-		9.94
oth		FLy	(cm)		-	2.00	-		2.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	700.06					
Operator Control	TX-Level (dB)	TX-Level (dB)			-	0	-	0	0
ontr	Focus (mm)			20.00	-	85.10	-	85.10	99.40
50	PRF(prr) (Hz)			100.16	-	10416.70	-	10416.70	8680.56

This Index is not relevant to this operating mode.

F - 18 Instructions for Use

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

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.

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

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.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF10-5** Operating mode: **M-mode**

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Noi	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.27	-	0.20	-	0.20	0.17
	FDA	IEC	Units						
m	P _{r.3}	p_{ra}	(MPa)	3.15					
ter	Wo	P	(mW)		-	6.83		16.85	7.16
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic	z_1	Z _S	(cm)				-		
onst	Z_{bp}	Z bp	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					1.40	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.20					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					1.05	
Asso	f _c	f _{awf}	(MHz)	6.15	-	6.15	-	6.15	6.15
_	Dim. of A _{aprt}		X (cm)		-	1.74	-	1.74	1.74
			Y (cm)		-	0.50	-	0.50	0.50
	PD	t _d	(µsec)	0.22					
tion	PRF	prr	(Hz)	384.00					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	4.06					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					1.05	1.05
e	Focal Length	FLx	(cm)		-	7.00	-		7.00
O#		FLy	(cm)		-	2.00	-		2.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	795.58					
Operator Control	TX-Level (dB)			0	-	0	-	0	0
pera	Focus (mm)			15.00	-	70.00	-	70.00	70.00
ర్ధి	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: VF12-4 Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.98	3.99	-	-	-	6.00
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	2.26					
ters	W _o	P	(mW)		73.31	-		-	405.67
Associated Acoustic Parameters	min of [W $_3(z_1)$, $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
. <u>S</u>	Z ₁	Zs	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z b	(cm)					-	
eq	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.40					
cial	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	5.33	11.43	-	-	-	11.43
4	Dim. of A _{aprt}		X (cm)		3.20	-	-	-	3.20
			Y (cm)		0.70	-	-	-	0.70
	PD	t _d	(µsec)	0.22					
ion	PRF	prr	(Hz)	54.51					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.93					
Je J	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	1.69
e	Focal Length	FLx	(cm)		8.00	-	-		8.00
o∰		FLy	(cm)		2.50	-	-		2.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	321.38					
Operator Control	TX-Level (dB)			0	0	-	-	-	0
era	Focus (mm)			20.00	80.00	-	-	-	80.00
ర్ధి	PRF(prr) (Hz)								
	This had a discount and a								

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: VF12-4 Operating mode: Color / Power

		•	·	MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.38	2.89	-	-	-	5.98
	FDA	IEC	Units						
ø	P _{r.3}	p_{ra}	(MPa)	2.76					
ters	W _o	P	(mW)		90.99	-		-	147.64
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
iсР	Z ₁	Zs	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.10					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ss(f _c	f _{awf}	(MHz)	4.00	6.67	-	-	-	6.67
٩	Dim. of A _{aprt}		X (cm)		0.56	-	-	-	0.43
			Y (cm)		0.70	-	-	-	0.70
	PD	t _d	(µsec)	0.27					
tion	PRF	prr	(Hz)	100.15					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.21					
uţo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.62
er	Focal Length	FLx	(cm)		1.48	-	-		1.24
oth		FLy	(cm)		2.50	-	-		2.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	245.60					
<u> </u>	TX-Level (dB)		0	0	-	-	-	0	
Operator	Focus (mm)		15.20	14.80	-	-	-	12.40	
30	PRF(prr) (Hz)			100.15	3551.15	-	-	-	3551.14

This Index is not relevant to this operating mode.

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: VF12-4

Operating mode: Pulsed Doppler	Operating	mode:	Pulsed	Doppler
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				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Noi	1-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.26	-	-	2.11	2.41	2.49
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	2.52					
ters	Wo	P	(mW)		-	-		60.84	109.75
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				110.78		
S P	Z ₁	Z _S	(cm)				2.60		
nst	Z _{bp}	Z _{bp}	(cm)				1.65		
Acc	Z _{sp}	Z _b	(cm)					2.60	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.20					
cial	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					1.09	
SSC	f _c	f _{awf}	(MHz)	4.00	-	-	4.00	4.00	4.00
۹	Dim. of A _{aprt}	-	X (cm)		-	-	1.36	1.34	1.36
			Y (cm)		-	-	0.70	0.70	0.70
	PD	t_{d}	(µsec)	0.94					
Other Information	PRF	prr	(Hz)	100.16					
mai	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.97					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					1.09	1.10
ē	Focal Length	FLx	(cm)		-	-	5.77		5.77
∯ H		FLy	(cm)		-	-	2.50		2.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	226.39					
Operator Control	TX-Level (dB)			0	-	-	0	0	0
era	Focus (mm)	Focus (mm)			-	-	57.70	56.50	57.70
ర్ధి	PRF(prr) (Hz)			100.16	-	-	1953.13	1953.13	1953.13
2	This Index is not rela		Alan an ann and a	•					

This Index is not relevant to this operating mode.

F - 20 Instructions for Use

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

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.

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

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.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF12-4** Operating mode: **M-mode**

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Noi	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.83	-	1.61	-	1.61	1.14
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	2.06					
ters	Wo	P	(mW)		-	29.58		13.32	77.08
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					0.80	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.50					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					1.69	
SSC	f _c	f _{awf}	(MHz)	6.15	-	11.43	-	11.43	11.43
•	Dim. of A _{aprt}		X (cm)		-	3.20	-	3.20	3.20
			Y (cm)		-	0.70	-	0.70	0.70
	PD	t _d	(µsec)	0.24					
ţio	PRF	prr	(Hz)	384.00					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.83					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					1.69	1.69
er	Focal Length	FLx	(cm)		-	8.00	-		8.00
o ₽		FLy	(cm)		-	2.50	-		2.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	295.57					
to o	TX-Level (dB)			0	-	0	-	0	0
Operator Control	Focus (mm)			25.00	-	80.00	-	80.00	80.00
ర్ధి	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: CW2 Operating mode: CW Doppler

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.04	-	-	0.85	0.85	2.28
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	0.06					
ters	W _o	P	(mW)		-	-		23.73	89.96
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				89.25		
G.	Z ₁	Zs	(cm)				2.30		
nst	Z _{bp}	$Z_{ m bp}$	(cm)				1.48		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					2.30	
ted/	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.80					
<u>G</u> i	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.99	
SSC	f _c	f _{awf}	(MHz)	2.00	-	-	2.00	2.00	2.00
٩	Dim. of A _{aprt}		X (cm)		-	-	0.88	0.88	0.88
			Y (cm)		-	-	0.87	0.87	0.87
	PD	t _d	(μsec)	1.00					
Other Information	PRF	prr	(Hz)	5580.36					
mat	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	0.07					
Je	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.99	0.99
e e	Focal Length	FLx	(cm)		-	-	10.00		10.00
O.		FLy	(cm)		-	-	10.00		10.00
-	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	0.05					
ا ا	TX-Level (dB)			0	-	-	0	0	0
Operator Control	Focus (mm)	` '							
ద్ది	PRF(prr) (Hz)			5580.36	-	-	5580.36	5580.36	5580.36

- a This Index is not relevant to this operating mode.
- 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: CW5 Operating mode: CW Doppler

				MI	TIS			TIB	TIC
Index Label				Scan Non-scan			Non-scan		
					At surface	Below surface			
Maximum Value				0.04	-	-	3.85	3.85	5.06
Associated Acoustic Parameters	FDA	IEC	Units						
	P _{r.3}	p _{ra}	(MPa)	0.09					
	W _o	P	(mW)		-	-		328.85	128.94
	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				161.70		
	Z ₁	Zs	(cm)				2.30		
	Z _{bp}	Z _{bp}	(cm)				0.96		
	Z _{sp}	$z_{\rm b}$	(cm)					2.30	
	z@PII.3max	z @ max. $I_{pi,\alpha}$	(cm)	2.80					
	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.64	
	f _c	f _{awf}	(MHz)	5.00	-	-	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	t _d	(µsec)	1.00					
	PRF	prr	(Hz)	13020.80					
	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	0.15					
	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.64	0.64
	Focal Length	FLx	(cm)		-	-	9.00		9.00
		FLy	(cm)		-	-	9.00		9.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	0.06					
Operator Control	TX-Level (dB)			0	-	-	0	0	0
	Focus (mm)								
	PRF(prr) (Hz)			13020.80	-	-	13020.80	13020.80	13020.8

This Index is not relevant to this operating mode.

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

	·			MI		TIS	TIB	TIC	
Index Label				Scan Non-scan			Non-scan		
					At surface	Below surface			
	Maximum Value			1.37	0.83	-	-	-	1.02
Associated Acoustic Parameters	FDA	IEC	Units						
	P _{r.3}	p_{ra}	(MPa)	2.67					
	W _o	P	(mW)		30.53	-		-	46.05
	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
	Z ₁	Z _S	(cm)				-		
	Z _{bp}	Z _{bp}	(cm)				-		
	Z _{sp}	Z _b	(cm)					-	
	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.20					
	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
	f _c	f _{awf}	(MHz)	3.81	5.71	-	-	-	5.71
	upit .		X (cm)		2.00	-	-	-	2.00
			Y (cm)		0.50	-	-	-	0.50
Other Information	PD	t_{d}	(μsec)	0.46					
	PRF	prr	(Hz)	57.23					
	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.13					
	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	1.13
	Focal Length	FLx	(cm)		9.00	-	-		9.00
		FLy	(cm)		1.90	-	-		1.90
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	453.26					
Operator Control	TX-Level (dB)			0	0	-	-	-	0
	Focus (mm)			20.00	90.00	-	-	-	90.00
	PRF(prr) (Hz)								

This Index is not relevant to this operating mode.

F - 22 Instructions for Use

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

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.

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

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.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: C8-5

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.35	0.77	-	-	-	0.97
	FDA	IEC	Units						
	P _{r.3}	p_{ra}	(MPa)	2.77					
ters	W _o	P	(mW)		32.34	-		-	39.56
Associated Acoustic Parameters	min of [W $_3(z_1)$, $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
is P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
eq	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.20					
cial	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	4.21	5.00	-	-	-	5.00
٩	Dim. of A _{aprt}		X (cm)		1.63	-	-	-	1.63
			Y (cm)		0.50	-	-	-	0.50
	PD	t _d	(µsec)	0.85					
Other Information	PRF	prr	(Hz)	100.15					
mat	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.30					
Je	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	1.02
e	Focal Length	FLx	(cm)		4.02	-	-		4.12
O E		FLy	(cm)		1.90	-	-		1.90
_	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	468.41					
힏	TX-Level (dB)		•	0	0	-	-	-	0
Operator Control	Focus (mm)			20.00	40.20	-	-	-	41.20
[క్రి ర	PRF(prr) (Hz)			100.15	244.14	-	-	-	195.31
	This leaders is a standa								

a This Index is not relevant to this operating mode.

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

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Noi	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.27	-	0.93	-	1.46	0.98
	FDA	IEC	Units						
· "n	P _{r.3}	p_{ra}	(MPa)	2.61					
ters	Wo	P	(mW)		-	39.06		15.55	44.77
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Ö.	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					1.30	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.30					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.79	
SSO	f _c	f _{awf}	(MHz)	4.21	-	5.20	-	4.21	5.00
4	Dim. of A _{aprt}		X (cm)		-	2.05	-	0.98	2.05
			Y (cm)		-	0.50	-	0.50	0.50
	PD	t_{d}	(μsec)	0.86					
Other Information	PRF	prr	(Hz)	1562.50					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.15					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.79	1.14
erl	Focal Length	FLx	(cm)		-	12.11	-		7.32
₽		FLy	(cm)		-	1.90	-		1.90
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	483.94					
Operator Control	TX-Level (dB)			0	-	0	-	0	0
era	Focus (mm)			16.80	-	121.10	-	19.60	73.20
రిర	PRF(prr) (Hz)			1562.50	-	2441.41	-	1953.13	2441.41

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.

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.

Transducer model: C8-5 Operating mode: M-mode

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	No	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.50	-	0.41	-	0.52	0.49
	FDA	IEC	Units						
m	P _{r.3}	p _{ra}	(MPa)	3.08					
ters	Wo	P	(mW)		-	20.45		11.44	22.39
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ïР	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$Z_{\rm b}$	(cm)					1.30	
ted	z@PII.3max	z @ max. $I_{pi,\alpha}$	(cm)	1.10					
ciate	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.90	
\SS(f _c	f _{awf}	(MHz)	4.21	-	4.21	-	4.21	4.21
٩	Dim. of A _{aprt}		X (cm)		-	2.05	-	1.26	2.05
			Y (cm)		-	0.50	-	0.50	0.50
	PD	t _d	(μsec)	0.75					
Other Information	PRF	prr	(Hz)	384.00					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.61					
nfo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.90	1.14
er	Focal Length	FLx	(cm)		-	9.00	-		9.00
ð		FLy	(cm)		-	1.90	-		1.90
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	529.53	·				
Operator	TX-Level (dB)			0	-	0	-	0	0
ontr	Focus (mm)			30.00	-	90.00	-	50.00	90.00
3 8	PRF(prr) (Hz)								

This Index is not relevant to this operating mode.

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: C8F3 Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.39	0.66	-	-	-	1.47
	FDA	IEC	Units						
m	P _{r.3}	p_{ra}	(MPa)	2.07					
ters	Wo	P	(mW)		41.62	-		-	99.42
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.50					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	2.22	3.33	-	-	-	3.33
4	Dim. of A _{aprt}		X (cm)		1.87	-	-	-	1.87
			Y (cm)		1.20	-	-	-	1.20
	PD	t_{d}	(μsec)	1.14					
Other Information	PRF	prr	(Hz)	14.58					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.71					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	1.69
erl	Focal Length	FLx	(cm)		6.00	-	-		8.00
Oth		FLy	(cm)		6.50	-	-		6.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	277.00					
Operator Control	TX-Level (dB)			0	0	-	-	-	0
era	Focus (mm)			40.00	60.00	-	-	-	80.00
ర్ధి	PRF(prr) (Hz)								
2	This Index is not rela	want to this anaron	Alan and and a					•	

This Index is not relevant to this operating mode.

F - 24 Instructions for Use

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

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.

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(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: C8F3 Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.63	0.71	-	-	-	1.42
	FDA	IEC	Units						
m	P _{r.3}	p_{ra}	(MPa)	1.03					
ters	W _o	P	(mW)		44.77	-		-	48.97
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
iS P	Z ₁	Zs	(cm)				-		
onst	Z _{bp}	$z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.10					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ss(f _c	f _{awf}	(MHz)	2.67	3.33	-	-	-	3.33
4	Dim. of A _{aprt}		X (cm)		0.30	-	-	-	0.49
			Y (cm)		1.20	-	-	-	1.20
	PD	t _d	(µsec)	1.41					
ţi	PRF	prr	(Hz)	100.15					
щ	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.14					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.86
e	Focal Length	FLx	(cm)		1.25	-	-		2.01
₽		FLy	(cm)		6.50	-	-		6.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	35.45					
ᅙ	TX-Level (dB)			0	0	-	-	-	0
Operator Control	Focus (mm)			14.20	12.50	-	-	-	20.10
ర్ధిర	PRF(prr) (Hz)			100.15	1562.50	-	-	-	488.09

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- 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: C8F3 Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.74	-	-	0.81	1.28	1.60
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	1.35					
ter	Wo	P	(mW)		-	-		68.90	55.18
Associated Acoustic Parameters	min of [W $_{.3}(z_1)$, $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				51.08		
으	Z ₁	Z _S	(cm)				3.90		
onst	Z _{bp}	Z _{bp}	(cm)				2.00		
Αcc	Z _{sp}	z _b	(cm)					4.10	
ted	z@PII _{.3max}	z @ max. I _{pi,α}	(cm)	3.90					
cial	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.86	
\SS(f _c	f _{awf}	(MHz)	3.33	-	-	3.33	3.33	3.33
4	Dim. of A _{aprt}		X (cm)		-	-	1.16	0.49	0.49
			Y (cm)		-	-	1.20	1.20	1.20
	PD	t _d	(µsec)	1.12					
ion	PRF	prr	(Hz)	152.59					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.11					
of Jo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.86	0.86
e	Focal Length	FLx	(cm)		-	-	4.69		2.01
₽		FLy	(cm)		-	-	6.50		6.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	46.40					
<u> </u>	TX-Level (dB)			0	-	-	0	0	0
Control	Focus (mm)		39.60	-	-	46.90	20.10	20.10
50	PRF(prr) (Hz)			152.59	-	-	976.56	19531.30	19531.30

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- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: C8F3 Operating mode: M-mode

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	No	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.22	-	0.51	-	0.87	0.81
	FDA	IEC	Units						
ro.	P _{r.3}	p_{ra}	(MPa)	2.06					
ter	Wo	P	(mW)		-	37.45		29.38	87.65
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Zs	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					3.50	
ted	z@PII _{.3max}	z @ max. I _{pi,α}	(cm)	3.90					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					1.76	
ASSC	f _c	f _{awf}	(MHz)	2.86	-	2.86	-	2.86	2.86
1	Dim. of A _{aprt}		X (cm)		-	4.79	-	2.02	4.79
			Y (cm)		-	1.20	-	1.20	1.20
	PD	t _d	(µsec)	0.90					
Other Information	PRF	prr	(Hz)	384.00					
ша	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.03					
nfo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					1.76	2.71
ē	Focal Length	FLx	(cm)		-	20.00	-		20.00
₽		FLy	(cm)		-	6.50	-		6.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	142.84					
lo o	TX-Level (dB)			0	-	0	-	0	0
Operator Control	Focus (mm)			20.00	-	200.00	-	40.00	200.00
ರಿರ	PRF(prr) (Hz)								

This Index is not relevant to this operating mode.

- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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: C6F2 Operating mode: 2D-Mode

			MI		TIS		TIB	TIC
Inde	ex Label			Scan	Nor	n-scan	Non-scan	
					At surface	Below surface		
Maximum Value			1.17	0.72	-	-	-	1.73
FDA	IEC	Units						
P _{r.3}	p _{ra}	(MPa)	1.85					
Wo	P	(mW)		41.54	-		-	152.96
min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Z ₁	Z _S	(cm)				-		
Z _{bp}	Z _{bp}	(cm)				-		
Z _{sp}	Z _b	(cm)					-	
z@PII.3max	z @ max. I _{pi,α}	(cm)	4.80					
d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
f _c	f _{awf}	(MHz)	2.50	3.64	-	-	-	2.50
Dim. of A _{aprt}		X (cm)		0.65	-	-	-	2.95
		Y (cm)		1.30	-	-	-	1.30
PD	t _d	(µsec)	0.58					
PRF	prr	(Hz)	12.16					
Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.80					
d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	2.21
Focal Length	FLx	(cm)		2.00	-	-		16.00
	FLy	(cm)		8.00	-	-		8.00
I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	606.88					
TX-Level (dB)			0	0	-	-	-	0
Focus (mm)		60.00	20.00	-	-	-	160.00	
PRF(prr) (Hz)								
	Maximum Value FDA P _{r.3} W _o min of [W _{.3} (Z ₁), I _{TA.3} (Z ₁)] Z ₁ Z ₂ Z ₂ Z ₂ PII _{.3max} d _{eq} (Z _{2p}) f _c Dim. of A _{aprt} PD PRF P _r @ PII _{.max} d _{eq} @ PII _{.max} Focal Length I _{pa.3} @ MI _{.max} TX-Level (dB) Focus (mm)	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{ c c c c c } \hline \textbf{Maximum Value} & & & & & & & \\ \hline \hline \textbf{FDA} & & \text{IEC} & & \text{Units} & & & \\ \hline \textbf{P}_{r.3} & & p_{ra} & & \text{(MPa)} & & 1.85 \\ \hline \textbf{W}_{0} & & P & & \text{(mW)} & & & 41.54 \\ \hline \textbf{min of } [W_{.3}(\textbf{z}_{1}), & $	$ \begin{array}{ c c c c c c } \hline \textbf{Maximum Value} & & & & & & & & & & \\ \hline \textbf{Maximum Value} & & & & & & & & \\ \hline \textbf{FDA} & & & & & & & & & & & $	$ \begin{array}{ c c c c c c c } \hline \textbf{Naximum Value} & Scan & Noto-Incomplete & Scan & Scan$	$ \begin{array}{ c c c c c c c c c } \hline \textbf{Maximum Value} & \textbf{Scan} & \textbf{Non-scan} \\ \hline \textbf{Maximum Value} & \textbf{I.1.17} & \textbf{0.72} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{FDA} & IEC & Units & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{W}_{o} & \textbf{P}_{ra} & (MPa) & \textbf{1.85} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{W}_{o} & \textbf{P}_{ma} & (MPa) & \textbf{1.85} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{min of [W_{3}(z_{1}), I_{1z_{0}}(z_{2})]} & (mW) & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{1z_{0}}(z_{2})] & (mW) & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{1z_{0}}(z_{2})] & (mW) & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{1z_{0}}(z_{2})] & (mW) & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{1z_{0}}(z_{2})] & (mW) & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{1z_{0}}(z_{2})] & (mW) & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{1z_{0}}(z_{2})] & (mW) & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{1z_{0}}(z_{2})] & (mW) & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{1z_{0}}(z_{2})] & (mW) & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \textbf{M}_{1z_{0}}(z_{2})] & (mW) & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{1z_{0}}(z_{2})] & (mW) & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} & \textbf{-} \\ \hline \textbf{M}_{2} & \textbf$

This Index is not relevant to this operating mode.

F - 26 Instructions for Use

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

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.

TIC

8.00

8.30

6510.42

59.20

4734.85

TIB

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: C6F2 Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.73	0.74	-	-	-	1.29
	FDA	IEC	Units						
	P _{r.3}	p_{ra}	(MPa)	1.28					
ters	W _o	P	(mW)		50.45	-		-	143.28
Associated Acoustic Parameters	min of [W $_3(z_1)$, $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Si	z_1	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.80					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	3.08	3.08	-	-	-	2.50
4	Dim. of A _{aprt}		X (cm)		0.51	-	-	-	4.66
			Y (cm)		1.30	-	-	-	1.30
	PD	t _d	(μsec)	1.21					
Other Information	PRF	prr	(Hz)	100.15					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.55					
Je J	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	2.78
e	Focal Length	FLx	(cm)		2.11	-	-		28.75
o∰		FLy	(cm)		8.00	-	-		8.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	58.26					
힏	TX-Level (dB)			0	0	-	-	-	0
Operator Control	Focus (mm)			258.70	21.10	-	-	-	287.50
ဝီပိ	PRF(prr) (Hz)			100.15	1953.13	-	-	-	1219.51
_	This Index is not role		E	•	•				

- a This Index is not relevant to this operating mode.
- 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: C6F2 Operating mode: Pulsed Doppler

	Ind	ex Label			Scan	No	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.79	-	-	1.04	1.77	3.45
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	1.25					
ters	Wo	P	(mW)		-	-		59.28	76.26
Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				70.91		
	Z ₁	Z _S	(cm)				4.30		
Associated Acoustic	Z _{bp}	Z _{bp}	(cm)				1.94		
Acc	Z _{sp}	Z _b	(cm)					4.10	
ted	z@PII _{.3max}	z @ max. I _{pi,α}	(cm)	4.00					
ocial	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					1.56	
SSC	f _c	f _{awf}	(MHz)	2.50	-	-	3.08	2.50	2.50
٩	Dim. of A _{aprt}		X (cm)		-	-	1.01	1.48	0.18
			Y (cm)		-	-	1.30	1.30	1.30
	PD	t _d	(µsec)	1.50					
ion	PRF	prr	(Hz)	152.59					
r Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.76					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					1.56	0.55
Ξ	Focal Length	Fly	(cm)		_		4 11		0.83

TIS

8.00

41.10

12019.20

PRF(prr) (Hz)

a This Index is not relevant to this operating mode

(dB)

(mm)

I_{pa.3}@ MI_{ma}

TX-Level

Focus

FLy

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

 $I_{pa,\alpha}$ @ max. MI (W/cm²)

c This formulation for TIS is less than that for an alternate formulation in this mode.

(cm)

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

123.80

0

97.40

152.59

Transducer model: C6F2 Operating mode: M-mode

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Noi	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.17	-	-	0.23	0.58	0.46
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	1.85					
ters	W _o	P	(mW)		-	-		24.93	40.67
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				19.32		
ic P	Z ₁	Z _S	(cm)				4.00		
onst	Z _{bp}	Z _{bp}	(cm)				3.32		
Acc	Z _{sp}	Z _b	(cm)					3.90	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.90					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					2.01	
SSC	f _c	f _{awf}	(MHz)	2.50	-	-	2.50	2.50	2.50
•	Dim. of A _{aprt}		X (cm)		-	-	2.95	2.44	2.95
			Y (cm)		-	-	1.30	1.30	1.30
	PD	t _d	(µsec)	0.58					
tion	PRF	prr	(Hz)	384.02					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.59					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					2.01	2.21
er	Focal Length	FLx	(cm)		-	-	8.00		16.00
o ₽		FLy	(cm)		-	-	8.00		8.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	606.88					
Operator Control	TX-Level (dB)			0	-	-	0	0	0
era	Focus (mm)			60.00	-	-	80.00	60.00	160.00
ဝီပိ	PRF(prr) (Hz)								

This Index is not relevant to this operating mode.

- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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: EV9F3 Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.43	4.71	-	-	-	4.54
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	2.73					
ters	W _o	P	(mW)		123.64	-		-	149.73
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
으	Z ₁	Zs	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Ä	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.00					
ciate	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SS	f _c	f _{awf}	(MHz)	3.64	8.00	-	-	-	8.00
4	Dim. of A _{aprt}		X (cm)		0.94	-	-	-	0.90
			Y (cm)		0.60	-	-	-	0.60
	PD	t_{d}	(μsec)	0.44					
tion	PRF	prr	(Hz)	34.56					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.09					
<u>u</u>	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.82
e	Focal Length	FLx	(cm)		8.00	-	-		6.00
₽		FLy	(cm)		3.50	-	-		3.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	400.14					
Control	TX-Level (dB)		•	0	0	-	-	-	0
ort.	Focus (mm	Focus (mm)		15.00	80.00	-	-	-	60.00
} ၓ	PRF(prr) (Hz)								

This Index is not relevant to this operating mode.

F - 28 Instructions for Use

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

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.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **EV9F3** Operating mode: **Color / Power**

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Nor	ı-scan	Non-scan	
						At surface	Below surface		
	Maximum Value		0.58	1.30	-	-	-	1.75	
	FDA	IEC	Units						
Associated Acoustic Parameters	P _{r.3}	p_{ra}	(MPa)	1.34					
	Wo	P	(mW)		51.22	-		-	53.73
	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
	Z ₁	Z _S	(cm)				-		
	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ssociated ,	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.50					
	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
	f _c	f _{awf}	(MHz)	5.33	5.33	-	-	-	4.00
٩	Dim. of A _{aprt} X (X (cm)		1.30	-	-	-	0.78
			Y (cm)		0.60	-	-	-	0.60
	PD	t _d	(µsec)	0.71					
Other Information	PRF	prr	(Hz)	781.25					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.76					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.77
e	Focal Length	FLx	(cm)		7.00	-	-		3.00
ОĦ		FLy	(cm)		3.50	-	-		3.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	115.95					
<u> </u>	TX-Level (dB)			0	0	-	-	-	0
Control	Focus (mm))		140.00	70.00	-	-	-	30.00
5 8	PRF(prr) (Hz)			781.25	867.45	-	-	-	1562.50

- 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: EV9F3

Operating mode: Pulsed Doppler	Operating	mode:	Pulsed	Doppler
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2.92
133.90
133.90
133.90
4.00
1.73
0.60
1.15
8.12
3.50
0
81.20
7102.27

- a This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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.

Transducer model: EV9F3 Operating mode: M-mode

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.18	-	-	0.97	0.97	0.94
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	2.56					
ters	Wo	P	(mW)		-	-		8.07	34.58
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				33.12		
i P	Z ₁	Z _S	(cm)				1.50		
onst	Z _{bp}	Z _{bp}	(cm)				1.38		
Acc	Z _{sp}	Z _b	(cm)					1.50	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.10					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.92	
SSC	f _c	f _{awf}	(MHz)	4.71	-	-	6.15	6.15	6.15
•	Dim. of A _{aprt} X (X (cm)		-	-	1.12	1.12	1.12
			Y (cm)		-	-	0.60	0.60	0.60
	PD	t _d	(μsec)	0.41					
ţio	PRF	prr	(Hz)	384.00					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.06					
Jo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.92	0.92
e	Focal Length	FLx	(cm)		-	-	8.00		8.00
oth		FLy	(cm)		-	-	3.50		3.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	359.98					
tor o	TX-Level (dB)			0	-	-	0	0	0
Operator Control	Focus (mm)			25.00	-	-	80.00	80.00	80.00
ర్ధి	PRF(prr) (Hz)								

This Index is not relevant to this operating mode.

- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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

_	_		MI		TIS		TIB	TIC
Inde	x Label			Scan	Nor	n-scan	Non-scan	
					At surface	Below surface		
Maximum Value			0.79	2.41	-	-	-	2.40
FDA	IEC	Units						
P _{r.3}	p_{ra}	(MPa)	1.39					
W _o	P	(mW)		75.88	-		-	94.95
min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Z ₁	Z _S	(cm)				-		
Z _{bp}	$z_{\sf bp}$	(cm)				-		
Z _{sp}	Z b	(cm)					-	
z@PII.3max	z @ max. I _{pi,α}	(cm)	2.90					
d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
f _c	f _{awf}	(MHz)	3.08	6.67	-	-	-	6.67
Dim. of A _{aprt} X (cm)		X (cm)		0.96	-	-	-	0.96
		Y (cm)		0.80	-	-	-	0.80
PD	t _d	(μsec)	0.71					
PRF	prr	(Hz)	55.73					
Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.89					
d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.99
Focal Length	FLx	(cm)		7.00	-	-		7.00
	FLy	(cm)		5.00	-	-		5.00
I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	166.45					
TX-Level (dB)			0	0	-	-	-	0
Focus (mm)			50.00	70.00	-	-	-	70.00
PRF(prr) (Hz)	PRF(prr) (Hz)							
	Maximum Value	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{ c c c c c c } \hline \textbf{Maximum Value} & Scan & Nor-san \\ \hline \textbf{Maximum Value} & 0.79 & 2.41 & - & - \\ \hline \textbf{FDA} & IEC & Units & & & & & \\ \hline \textbf{P}_{r,3} & p_{ra} & (MPa) & 1.39 & & & & \\ \hline \textbf{Min. of } [P_{\sigma}(z_{o}), I_{ta,a}(z_{o})] & I_{ta,a}(z_{o})] & I_{ta,a}(z_{o}) & I_{ta,a}(z_{o}$	$ \begin{array}{ c c c c c c c c } \hline \textbf{Maximum Value} & \textbf{Scan} & \textbf{Non-scan} \\ \hline \textbf{At surface} & \textbf{Below surface} \\ \hline \textbf{FDA} & IEC & Units & & & & & & & & & & & & & & & & & & &$

This Index is not relevant to this operating mode.

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

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.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P8-4** Operating mode: **Color / Power**

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.68	1.31	-	-	-	1.70
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	1.43					
ters	Wo	P	(mW)		61.96	-		-	67.26
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.40					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\SS(f _c	f _{awf}	(MHz)	4.44	4.44	-	-	-	4.44
4	Dim. of A _{aprt} X		X (cm)		0.96	-	-	-	0.96
			Y (cm)		0.80	-	-	-	0.80
	PD	t _d	(µsec)	0.62					
tion	PRF	prr	(Hz)	2441.41					
maj	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.07					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.99
e	Focal Length	FLx	(cm)		12.52	-	-		6.96
₽		FLy	(cm)		5.00	-	-		5.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	146.20					
Operator Control	TX-Level (dB)			0	0	-	-	-	0
era	Focus (mm)	•	•	70.00	125.20	-	-	-	69.60
ಕ್ಷಿ	PRF(prr) (Hz)			2441.41	1099.38	-	-	-	1953.13

- 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: Pu	Ilsed Doppler
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	isaucei illouei.			MI	3	TIS		TIB	TIC
	Indi	ex Label		IVII	Scan		n-scan	Non-scan	110
	inde	ex Labei			Scan		Below surface	Non-scan	
	Mandan Malor		4.40				1.32	4.00	
	Maximum Value	IEC	11-2-	1.10	-	-	1.32	1.32	1.68
ers	FDA		Units	0.40					
	P _{r.3}	p _{ra}	(MPa)	2.10				70.00	00.47
jete	W _o	P	(mW)		-	-		78.32	66.47
Param	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				62.43		
Ö	z_1	Z _S	(cm)				2.40		
Associated Acoustic Parameters	Z _{bp}	$z_{ m bp}$	(cm)				1.48		
	Z _{sp}	Z _b	(cm)					2.40	
	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.40					
	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.99	
SSC	f _c	f _{awf}	(MHz)	3.64	-	-	4.44	4.44	4.44
⋖.			X (cm)		-	-	0.96	0.96	0.96
			Y (cm)		-	-	0.80	0.80	0.80
	PD	t _d	(μsec)	0.75					
tion	PRF	prr	(Hz)	610.35					
mai	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.84					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.99	0.99
ē	Focal Length	FLx	(cm)		-	-	14.07		6.37
O.H		FLy	(cm)			-	5.00		5.00
-	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	310.18					
o c	TX-Level (dB)		0	-	-	0	0	0	
Operator Control	Focus (mm)			60.40	-	-	140.70	140.70	63.70
ಕ್ತಿರ	PRF(prr) (Hz)			610.35	-	-	3004.81	3004.81	2604.17

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- Who data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: P8-4 Operating mode: M-mode

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	No	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.50	-	-	0.79	0.87	1.10
	FDA	IEC	Units						
arameters	P _{r.3}	p _{ra}	(MPa)	2.93					
	Wo	P	(mW)		-	-		47.68	43.52
	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				43.54		
ïР	Z ₁	Z _S	(cm)				2.00		
Acousti	Z _{bp}	$Z_{ m bp}$	(cm)				1.48		
Acc	Z _{sp}	$Z_{\rm b}$	(cm)					1.60	
Associated Acoustic Parameters	z@PII.3max	z @ max. $I_{pi,\alpha}$	(cm)	1.80					
	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.99	
	f _c	f _{awf}	(MHz)	3.81	-	-	3.81	3.81	3.81
٩	Dim. of A _{aprt} X (c		X (cm)		-	-	0.96	0.96	0.96
			Y (cm)		-	-	0.80	0.80	0.80
	PD	t _d	(μsec)	0.57					
Other Information	PRF	prr	(Hz)	384.00					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.71					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.99	0.99
er	Focal Length	FLx	(cm)		-	-	9.00		3.00
oth		FLy	(cm)		-	-	5.00		5.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	439.99					
<u> </u>	TX-Level (dB)			0	-	-	0	0	0
Operator	Focus (mm)			40.00	-	-	90.00	30.00	30.00
5 8	PRF(prr) (Hz)								

This Index is not relevant to this operating mode.

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-mode

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.03	-	-	4.09	4.09	6.00
	FDA	IEC	Units						
arameters	P _{r.3}	p_{ra}	(MPa)	0.06					
	W _o	P	(mW)		-	-		586.86	237.39
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				235.96		
С	Z ₁	Z _S	(cm)				2.30		
nst	Z _{bp}	$Z_{ m bp}$	(cm)				1.48		
Associated Acoustic Parameters	Z _{sp}	Z _b	(cm)					2.30	
	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.30					
	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.99	
	f _c	f _{awf}	(MHz)	3.64	-	-	3.64	3.64	3.64
٩	Dim. of A _{aprt} X (cm)		X (cm)		-	-	0.96	0.96	0.96
			Y (cm)		-	-	0.80	0.80	0.80
	PD	t _d	(µsec)	1					
ion	PRF	prr	(Hz)	12019.20					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	0.08					
Jo Jo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.99	0.99
Other Information	Focal Length	FLx	(cm)		-	-	4.65		4.65
ð		FLy	(cm)		-	-	5.00		5.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	0.77					
Control	TX-Level (dB)			0	-	-	0	0	0
ontr	Focus (mm)	Focus (mm)		46.50	-	-	46.50	46.50	46.50
ჭŏ	PRF(prr) (Hz)								
	This Index is not rele	vant to this opera	ting mode	-					

This Index is not relevant to this operating mode.

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

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.

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

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.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: VF16-5 Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.28	0.63	-	-	-	1.57
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	3.62					
ters	W _o	P	(mW)		16.54	-		-	44.81
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i P	Z ₁	Zs	(cm)				-		
onst	Z _{bp}	Z bp	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.70					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	8.00	8.00	-	-	-	8.00
•	Dim. of A _{aprt} X (c		X (cm)		0.50	-	-	-	1.33
	· · · · · · · · · · · · · · · · · · ·		Y (cm)		0.30	-	-	-	0.30
	PD	t _d	(µsec)	0.25					
ţio	PRF	prr	(Hz)	90.42					
шa	Pr@ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	4.39					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.71
er	Focal Length	FLx	(cm)		1.50	-	-		4.00
o ₽		FLy	(cm)		1.50	-	-		1.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	670.58					
tor ol	TX-Level (dB)			0	0	-	-	-	0
Operator Control	Focus (mm)			15.00	15.00	-	-	-	40.00
ర్ధి	PRF(prr) (Hz)								

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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: VF16-5 Operating mode: Color / Power

	•			MI		TIS	·	TIB	TIC
	Inde	ex Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.99	0.68	-	-	-	1.14
	FDA	IEC	Units						
arameters	P _{r.3}	p_{ra}	(MPa)	2.46					
	W _o	P	(mW)		26.79	-		-	20.01
	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
5 T	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
Associated Acoustic Parameters	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.70					
	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
	f _c	f _{awf}	(MHz)	6.15	5.33	-	-	-	5.33
4	Dim. of A _{aprt} X (cm)		X (cm)		0.50	-	-	-	0.50
			Y (cm)		0.30	-	-	-	0.30
	PD	t_{d}	(µsec)	0.43					
ion I	PRF	prr	(Hz)	100.15					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.85					
亨	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.44
ē	Focal Length	FLx	(cm)		2.15	-	-		2.15
÷ O		FLy	(cm)		1.50	-	-		1.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	282.39					
ō	TX-Level (dB)			0	0	-	-	-	0
Control	Focus (mm)			22.60	21.50	-	-	-	21.50
) ၓ	PRF(prr) (Hz)			100.15	488.09	-	-	-	488.09

- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: VF16-5

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Noi	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.17	-	1.30	-	2.13	2.11
	FDA	IEC	Units						
m	P _{r.3}	p_{ra}	(MPa)	2.70					
ters	W _o	P	(mW)		-	51.22		29.75	35.00
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Zs	(cm)				-		
onst	Z _{bp}	$z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					0.70	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.70					
Cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.41	
\ss(f _c	f _{awf}	(MHz)	5.33	-	5.33	-	5.33	5.33
4	Dim. of A _{aprt}		X (cm)		-	1.42	-	0.45	0.45
			Y (cm)		-	0.30	-	0.30	0.30
	PD	t _d	(µsec)	0.70					
ţi	PRF	prr	(Hz)	1220.70					
шa	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.07					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.41	0.41
ē	Focal Length	FLx	(cm)		-	6.01	-		1.93
₽		FLy	(cm)		-	1.50	-		1.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	415.84					
Operator Control	TX-Level (dB)			0	-	0	-	0	0
ontr	Focus (mm)	Focus (mm)			-	60.10	-	19.30	19.30
උඊ	PRF(prr) (Hz)			1220.70	-	1220.70	-	1953.13	1953.13

a This Index is not relevant to this operating mode.

- 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.
- Wo 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: VF16-5

Operating mode: M-mode

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	No	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.28	-	-	0.22	0.22	0.25
	FDA	IEC	Units						
m	P _{r.3}	p_{ra}	(MPa)	3.62					
ters	Wo	P	(mW)		-	-		1.78	7.13
Associated Acoustic Parameters	min of $[W_3(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				5.78		
ic P	Z ₁	Z _S	(cm)				1.10		
onst	Z _{bp}	Z _{bp}	(cm)				1.07		
Acc	Z _{sp}	Z _b	(cm)					1.10	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.70					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.71	
SSC	f _c	f _{awf}	(MHz)	8.00	-	-	8.00	8.00	8.00
4	Dim. of A _{aprt}		X (cm)		-	-	1.33	1.33	1.33
			Y (cm)		-	-	0.30	0.30	0.30
	PD	t_{d}	(μsec)	0.25					
tion	PRF	prr	(Hz)	384.00					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	4.39					
nfoı	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.71	0.71
e	Focal Length	FLx	(cm)		-	-	4.00		4.00
₽		FLy	(cm)		-	-	1.50		1.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	670.58					
Operator Control	TX-Level (dB)			0	•	-	0	0	0
era	Focus (mm)			15.00	-	-	40.00	40.00	40.00
ಕಿರ	PRF(prr) (Hz)								
2	This Index is not rele	word to this anare	Alan and and a						

a This Index is not relevant to this operating mode.

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

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.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: CH5-2 Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	ı-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.48	1.83	-	-	-	4.96
	FDA	IEC	Units						
ø	P _{r.3}	p_{ra}	(MPa)	2.21					
eter	Wo	P	(mW)		173.11	-		-	504.47
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII _{.3max}	z @ max. I _{pi,α}	(cm)	3.80					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
ASSC	f _c	f _{awf}	(MHz)	2.22	2.22	-	-	-	2.22
_	Dim. of A _{aprt}		X (cm)		2.86	-	-	-	3.63
			Y (cm)		1.40	-	-	-	1.40
	PD	$t_{\sf d}$	(µsec)	0.70					
tion	PRF	prr	(Hz)	13.63					
шa	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.95					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	2.54
ē	Focal Length	FLx	(cm)		8.00	-	-		10.00
₽		FLy	(cm)		5.00	-	-		5.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	382.54					
Operator Control	TX-Level (dB)			0	0	-	-	-	0
pera	Focus (mm)	Focus (mm)			80.00	-	-	-	100.00
ರಿರ	PRF(prr) (Hz)								

a This Index is not relevant to this operating mode.

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

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.03	2.18	-	-	-	5.37
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	1.46					
ters	Wo	P	(mW)		171.46	-		-	207.79
Associated Acoustic Parameters	min of $[W_3(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.40					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	2.00	2.67	-	-	-	2.00
4	Dim. of A _{aprt}		X (cm)		0.72	-	-	-	0.52
			Y (cm)		1.40	-	-	-	1.40
	PD	t _d	(µsec)	1.87					
io	PRF	prr	(Hz)	100.15					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.97					
Je J	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.97
ē	Focal Length	FLx	(cm)		2.92	-	-		2.17
oth		FLy	(cm)		5.00	-	-		5.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	147.21					
Operator Control	TX-Level (dB)			0	0	-	-	-	0
era	Focus (mm)	` '		130.00	29.20	-	-	-	21.70
පි රි	PRF(prr) (Hz)			100.15	1953.13	-	-	-	5580.36
2	This Index is not rele		£				•		

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.

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

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.

Transducer model: CH5-2

Operating mode: Pulsed Doppler

			MI		TIS		TIB	TIC
Inde	x Label			Scan	Nor	n-scan	Non-scan	
					At surface	Below surface		
Maximum Value			1.03	-	-	3.35	6.00	6.00
FDA	IEC	Units						
P _{r.3}	p _{ra}	(MPa)	1.46					
Wo	P	(mW)		-	-		341.77	442.72
min of [W ₃ (z ₁), I _{TA 3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				263.48		
Z ₁	Z _S	(cm)				2.20		
Z _{bp}	Z _{bp}	(cm)				2.05		
Z _{sp}	Z_{b}	(cm)					4.20	
z@PII.3max	z @ max. I _{pi,α}	(cm)	4.20					
d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					1.87	
f _c	f _{awf}	(MHz)	2.00	-	-	2.67	2.00	2.00
Dim. of A _{aprt}		X (cm)		-	-	1.05	1.96	1.91
		Y (cm)		-	-	1.40	1.40	1.40
PD	t _d	(μsec)	1.87					
PRF	prr	(Hz)	152.59					
Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.95					
d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					1.87	1.84
Focal Length	FLx	(cm)		-	-	4.19		7.56
	FLy	(cm)		-	-	5.00		5.00
I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	136.71					
TX-Level (dB)			0	-	-	0	0	0
Focus (mm)			131.20	-	-	41.90	78.00	75.60
PRF(prr) (Hz)			152.59	-	-	3906.25	1953.13	2170.14
	Maximum Value	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{ c c c c c } \hline \textbf{Maximum Value} & Scan & Non-scan \\ \hline & At surface & Below surface \\ \hline \textbf{FDA} & IEC & Units & & & & & \\ \hline P_{\Gamma.3} & p_{ra} & (MPa) & 1.46 & & & & \\ \hline W_o & P & (mW) & & - & - & \\ \hline min of [W_3(z_1), & Min. of [P_a(z_8), I_{1a.a}(z_8)] & (mW) & & & \\ \hline z_1 & z_8 & (cm) & & & & & \\ \hline z_{0p} & z_{0p} & (cm) & & & & \\ \hline z_{0p} & z_{0p} & z_{0p} & (cm) & & & & \\ \hline z_{0p} & z_{0p} & z_{0p} & (cm) & & & & \\ \hline z_{0p} & z_{0p} & z_{0p} & z_{0p} & (cm) & & & \\ \hline z_{0p} & z_{0p} \\ \hline z_{0p} & z_{0p} \\ \hline z_{0p} & z_{0p} \\ \hline z_{0p} & z_{0p} \\ \hline z_{0p} & z_{0p} \\ \hline z_{0p} & z_{0p} \\ \hline z_{0p} & z_{0p}$	$\begin{array}{ c c c c c c c c } \hline \textbf{Maximum Value} & 1.03 & - & - & 3.35 & 6.00 \\ \hline \textbf{FDA} & IEC & Units & & & & & & & & & & & & & & & & & & &$

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Noi	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.48	-	-	0.38	0.98	1.45
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	2.21					
ters	W _o	P	(mW)		-	-		130.16	189.13
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				35.95		
.S	Z ₁	Z _S	(cm)				4.40		
onst	Z _{bp}	Z _{bp}	(cm)				4.38		
Acc	Z _{sp}	Z _b	(cm)					4.40	
eq	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.80					
cial	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					2.92	
SSC	f _c	f _{awf}	(MHz)	2.22	-	-	2.22	2.22	2.22
•	Dim. of A _{aprt}		X (cm)		-	-	4.77	4.77	5.96
			Y (cm)		-	-	1.40	1.40	1.40
	PD	t _d	(μsec)	0.70					
ţio	PRF	prr	(Hz)	384.00					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.95					
Jo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					2.92	3.26
er	Focal Length	FLx	(cm)		-	-	13.00		16.00
o∰		FLy	(cm)		-	-	5.00		5.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	382.54					
to o	TX-Level (dB)			0	-	-	0	0	0
Operator Control	Focus (mm)			60.00	-	-	130.00	130.00	160.00
ర్ధి	PRF(prr) (Hz)								
	This is also is a stanta								

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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.

F - 36 Instructions for Use

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: C6-2 Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.38	2.58	-	-	-	6.00
	FDA	IEC	Units						
w	P _{r.3}	p_{ra}	(MPa)	2.18					
ters	Wo	P	(mW)		175.91	-		-	414.44
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
is P	Z ₁	Zs	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.60					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	2.50	3.08	-	-	-	3.08
•	Dim. of A _{aprt}		X (cm)		2.13	-	-	-	2.13
			Y (cm)		1.10	-	-	-	1.10
	PD	t _d	(µsec)	0.88					
tion	PRF	prr	(Hz)	29.02					
шa	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.25					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	1.73
er	Focal Length	FLx	(cm)		6.00	-	-		6.00
o ₽		FLy	(cm)		6.20	-	-		6.20
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	228.44					
tor ol	TX-Level (dB)			0	0	-	-	-	0
Operator Control	Focus (mm)			60.00	60.00	-	-	-	60.00
ర్ధి	PRF(prr) (Hz)								

This Index is not relevant to this operating mode.

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: C6-2 Operating mode: Color / Power

		_		MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.88	2.58	-	-	-	3.63
	FDA	IEC	Units						
(O	P _{r.3}	p_{ra}	(MPa)	1.39					
er:	W _o	P	(mW)		162.70	-		-	374.61
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
으	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	Z b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.90					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SS	f _c	f _{awf}	(MHz)	2.50	3.33	-	-	-	3.33
4	Dim. of A _{aprt}		X (cm)		1.48	-	-	-	4.75
			Y (cm)		1.10	-	-	-	1.10
	PD	t _d	(μsec)	1.48					
tion	PRF	prr	(Hz)	100.15					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.12					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	2.58
e	Focal Length	FLx	(cm)		5.98	-	-		25.43
ð		FLy	(cm)		6.20	-	-		6.20
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	207.16					
<u> </u>	TX-Level (dB)			0	0	-	-	-	0
Control	Focus (mm)	Focus (mm)			59.80	-	-	-	254.30
3 0	PRF(prr) (Hz)	•		100.15	195.31	-	-	-	100.15

This Index is not relevant to this operating mode.

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

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.

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

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.

Transducer model: C6-2

Operating mode: Pulsed Doppler

MI				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.88	-	-	3.54	3.54	6.00
	FDA	IEC	Units						
	P _{r.3}	p_{ra}	(MPa)	1.39					
ters	Wo	P	(mW)		-	-		350.99	123.84
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				223.24		
ic P	Z ₁	Zs	(cm)				4.00		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				1.99		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					4.00	
ted	z@PII _{.3max}	z @ max. I _{pi,α}	(cm)	3.60					
cial	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					1.33	
SSC	f _c	f _{awf}	(MHz)	2.50	-	-	3.33	3.33	3.33
4	Dim. of A _{aprt}		X (cm)		-	-	1.25	1.25	0.19
			Y (cm)		-	-	1.10	1.10	1.10
	PD	t _d	(μsec)	1.45					
Other Information	PRF	prr	(Hz)	152.59					
mal	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.90					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					1.33	0.52
er	Focal Length	FLx	(cm)		-	-	5.11		0.83
Oth		FLy	(cm)		-	-	6.20		6.20
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	129.45					
tor ol	TX-Level (dB)			0	-	-	0	0	0
Operator Control	Focus (mm)			92.60	-	-	51.10	51.10	8.30
ి ర	PRF(prr) (Hz)			152.59	-	-	3255.21	3255.21	3255.21

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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: C6-2

Operating mode: M-mode

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Noi	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			1.17	-	-	0.62	0.72	1.70
	FDA	IEC	Units						
ro.	P _{r.3}	p_{ra}	(MPa)	1.85					
ter	Wo	P	(mW)		-	-		94.08	171.17
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				52.08		
Ö	Z ₁	Z _S	(cm)				3.40		
onst	Z _{bp}	Z _{bp}	(cm)				2.59		
Acc	Z _{sp}	Z _b	(cm)					3.40	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.20					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					2.24	
SSC	f _c	f _{awf}	(MHz)	2.50	-	-	2.50	2.50	2.00
4	Dim. of A _{aprt}		X (cm)		-	-	2.13	3.57	4.52
			Y (cm)		-	-	1.10	1.10	1.10
	PD	t _d	(µsec)	0.68					
tion	PRF	prr	(Hz)	384.00					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.44					
Jo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					2.24	2.52
e	Focal Length	FLx	(cm)		-	-	6.00		20.00
O#		FLy	(cm)		-	-	6.20		6.20
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	333.08					
tor ol	TX-Level (dB)			0	-	-	0	0	0
Operator Control	Focus (mm)			40.00	-	-	60.00	100.00	200.00
දි ර	PRF(prr) (Hz)								
	This last suit as a stanta								

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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.

F - 38 Instructions for Use

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: AcuNav 8F, SoundStar eco 8F Operating mode: 2D-Mode

			MI		TIS		TIB	TIC
Inde	x Label			Scan	Nor	n-scan	Non-scan	
					At surface	Below surface		
Maximum Value			0.74	1.25	-	-	-	2.69
FDA	IEC	Units						
P _{r.3}	p_{ra}	(MPa)	1.65					
Wo	P	(mW)		52.50	-		-	45.57
min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Z ₁	Z _S	(cm)				-		
Z _{bp}	Z _{bp}	(cm)				-		
Z _{sp}	Z _b	(cm)					-	
z@PII _{.3max}	z @ max. I _{pi,α}	(cm)	1.40					
$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
f _c	f _{awf}	(MHz)	5.00	5.00	-	-	-	5.00
Dim. of A _{aprt}		X (cm)		0.70	-	-	-	0.70
		Y (cm)		0.20	-	-	-	0.20
PD	t _d	(µsec)	0.36					
PRF	prr	(Hz)	40.00					
Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.11					
d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.42
Focal Length	FLx	(cm)		6.00	-	-		6.00
	FLy	(cm)		1.00	-	-		1.00
I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	113.15					
TX-Level (dB)			0	0	-	-	-	0
Focus (mm)			20.00	60.00	-	-	-	60.00
PRF(prr) (Hz)								
	Maximum Value FDA FDA	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{ c c c c c } \hline \textbf{Maximum Value} & 0.74 \\ \hline FDA & IEC & Units \\ \hline P_{r.3} & p_{ra} & (MPa) & 1.65 \\ \hline W_o & P & (mW) & \\ \hline \min of [W_3(z_1), & Min. of [P_a(z_5), I_{la.a}(z_5)] & (cm) \\ \hline Z_1 & Z_5 & (cm) & \\ \hline Z_{bp} & Z_{bp} & (cm) & \\ \hline Z_{sp} & Z_b & (cm) & \\ \hline Z_{gpHI_{3max}} & Z @ max. I_{pl.a} & (cm) & \\ \hline I_{c} & f_{swf} & (MHz) & 5.00 \\ \hline Dim. of A_{aprt} & T & (Hz) & 40.00 \\ \hline PRF & prr & (Hz) & 40.00 \\ \hline Pr@ PII_{max} & P_r@ max. I_{pl} & (cm) & \\ \hline I_{pa.a}@ PII_{max} & d_{eq}@ max. I_{pl} & (cm) & \\ \hline I_{pa.a}@ MI_{max} & I_{pa.a}@ max. MI & (W/cm^2) & 113.15 \\ \hline TX-Level & (dB) & & 0 \\ \hline PRF(prr) & (Hz) & & 0.00 \\ \hline PRF(prr) & (Hz) & & 0 \\ \hline \hline Procus & (mm) & & 0.00 \\ \hline \hline PRF(prr) & (Hz) & & 0.00 \\ \hline \hline PRF(prr) & (Hz) & & 0.00 \\ \hline \hline PRF(prr) & (Hz) & & 0.00 \\ \hline \hline \end{tabular} $	$\begin{array}{ c c c c c } \hline \textbf{Maximum Value} & & & & & & & \\ \hline \hline \textbf{FDA} & & & & & & & \\ \hline \textbf{FDA} & & & & & & & \\ \hline \textbf{FDA} & & & & & & & \\ \hline \textbf{P}_{r.3} & & p_{ra} & & & & & \\ \hline \textbf{Mw}_{o} & & P & & & & & \\ \hline \textbf{Min of } [W_{3}(z_{1}), & & & & & \\ \hline \textbf{I}_{La.o}(z_{2})] & & & & & \\ \hline \textbf{Min of } [P_{o}(z_{5}), & & \\ \hline \textbf{I}_{la.o}(z_{5})] & & & & \\ \hline \textbf{Min of } [P_{o}(z_{5}), & & \\ \hline \textbf{Imanum } & & & & \\ \hline \textbf{Min of } [W_{3}(z_{1}), & & & \\ \hline \textbf{Min of } [P_{o}(z_{5}), & & \\ \hline \textbf{Min of } [W_{3}(z_{1}), & & \\ \hline \textbf{Min of } [P_{o}(z_{5}), & & \\ \hline \textbf{Min of } [W_{3}(z_{1}), & & \\ \hline \textbf{Min of } [P_{o}(z_{5}), & & \\ \hline \textbf{Min of } [W_{3}(z_{1}), & & \\ \hline \textbf{Min of } [W_{3}(z_{1}), & & \\ \hline \textbf{Min of } [P_{o}(z_{5}), & & \\ \hline \textbf{MWV} & & & \\ \hline \textbf{MWV} & $	$ \begin{array}{ c c c c c c } \hline \textbf{Maximum Value} & & & & & & & & & & & \\ \hline \textbf{Maximum Value} & & & & & & & & & \\ \hline \textbf{FDA} & & & & & & & & & & & $	N N N N N N N N N	Name Name

a This Index is not relevant to this operating mode.

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: AcuNav 8F, SoundStar eco 8F Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.60	1.08	-	-	-	2.47
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	1.34					
ters	W _o	P	(mW)		45.36	-		-	41.84
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.20					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSO	f _c	f _{awf}	(MHz)	5.00	5.00	-	-	-	5.00
4	Dim. of A _{aprt}		X (cm)		0.70	-	-	-	0.70
			Y (cm)		0.20	-	-	-	0.20
	PD	t _d	(µsec)	0.73					
tion	PRF	prr	(Hz)	100.15					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.65					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.42
e	Focal Length	FLx	(cm)		9.46	-	-		9.46
₽		FLy	(cm)		1.00	-	-		1.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	32.35					
Operator Control	TX-Level (dB)			0	0	-	-	-	0
era	Focus (mm)			50.00	94.60	-	-	-	94.60
రిర	PRF(prr) (Hz)			100.15	6250.00	-	-	-	6250.00
2	This Index is not rela		E						

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.

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.

Who data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: AcuNav 8F, SoundStar eco 8F Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value	0.59	-	-	1.65	3.15	3.86		
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	1.32					
ters	Wo	P	(mW)		-	-		97.56	58.94
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				69.30		
ic P	Z ₁	Z _S	(cm)				1.20		
onst	Z _{bp}	Z _{bp}	(cm)				0.64		
Acc	Z _{sp}	$Z_{\rm b}$	(cm)					1.10	
ted	z@PII.3max	z @ max. $I_{pi,\alpha}$	(cm)	1.20					
Scia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.41	
SSC	f _c	f _{awf}	(MHz)	5.00	-	-	5.00	4.00	5.00
4	Dim. of A _{aprt}		X (cm)		-	-	0.70	0.65	0.57
			Y (cm)		-	-	0.20	0.20	0.20
	PD	t _d	(µsec)	0.73					
ion	PRF	prr	(Hz)	100.16					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.62					
Je.	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.41	0.38
Other Information	Focal Length	FLx	(cm)		-	-	1.53		1.15
Ö		FLy	(cm)		-	-	1.00		1.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	32.88					
Operator Control	TX-Level (dB)			0	-	-	0	0	0
ontr	Focus (mm)			20.00	-	-	15.30	13.00	11.50
උඊ	PRF(prr) (Hz)			100.16	-	-	17361.10	19531.30	19531.30

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: AcuNav 8F, SoundStar eco 8F Operating mode: M-mode

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Noi	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.74	-	-	0.94	0.94	2.02
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	1.65					
ters	Wo	P	(mW)		-	-		5.84	34.22
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				39.48		
.S	Z ₁	Z _S	(cm)				1.00		
onst	Z _{bp}	Z _{bp}	(cm)				0.64		
Acc	Z _{sp}	Z b	(cm)					1.00	
eq	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.40					
cial	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.42	
SSC	f _c	f _{awf}	(MHz)	5.00	-	-	5.00	5.00	5.00
•	Dim. of A _{aprt}		X (cm)		-	-	0.70	0.70	0.70
			Y (cm)		-	-	0.20	0.20	0.20
	PD	t _d	(µsec)	0.36					
ţio	PRF	prr	(Hz)	384.00					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.11					
Jo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.42	0.42
er	Focal Length	FLx	(cm)		-	-	6.00		6.00
o∰		FLy	(cm)		-	-	1.00		1.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	113.15					
to o	TX-Level (dB)			0	-	-	0	0	0
Operator Control	Focus (mm)			20.00	-	-	60.00	60.00	60.00
ర్ధి	PRF(prr) (Hz)								
	This is also is a stanta								

a This Index is not relevant to this operating mode.

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

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.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **V5Ms** Operating mode: **2D-Mode**

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			<1	<1	-	-	-	<1
	FDA	IEC	Units						
m	P _{r.3}	p_{ra}	(MPa)	#					
eter:	Wo	P	(mW)		#	-		-	#
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
iс	Z ₁	Zs	(cm)				-		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	#					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSO	f _c	f _{awf}	(MHz)	#	#	-	-	-	#
4	Dim. of A _{aprt}		X (cm)		#	-	-	-	#
			Y (cm)		#	-	-	-	#
	PD	t _d	(µsec)	#					
tion	PRF	prr	(Hz)	#					
щ	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	#					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	#
er	Focal Length	FLx	(cm)		#	-	-		#
Ö ₽		FLy	(cm)		#	-	-		#
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	#					
to o	TX-Level (dB)			#	#	-	-	-	#
Operator Control	Focus (mm)	•	•	#	#	-	-	-	#
ర్ధిర	PRF(prr) (Hz)								

a This Index is not relevant to this operating mode.

- 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.
- Wo 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: Color / Power

Index Label				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			<1	<1	-	-	-	<
	FDA	IEC	Units						
ters	P _{r.3}	p _{ra}	(MPa)	#					
	W _o	P	(mW)		#	-		-	#
arame	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
S P	z_1	Zs	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
Associated Acoustic Parameters	z@PII.3max	z @ max. I _{pi,α}	(cm)	#					
	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSO	f _c	f _{awf}	(MHz)	#	#	-	-	-	#
4	Dim. of A _{aprt}		X (cm)		#	-	-	-	#
			Y (cm)		#	-	-	-	#
	PD	t_{d}	(μsec)	#					
tion	PRF	prr	(Hz)	#					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	#					
uţo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	#
Other Information	Focal Length	FLx	(cm)		#	-	-		#
oth		FLy	(cm)		#	-	-		#
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	#					
Operator Control	TX-Level (dB)	•	•	#	#	-	-	-	#
era	Focus (mm)	•	#	#	-	-	-	#
50	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.

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.

Transducer model: V5Ms

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.52	-	-	0.47	1.47	0.82
	FDA	IEC	Units						
ro.	P _{r.3}	p_{ra}	(MPa)	0.99					
ter	Wo	P	(mW)		-	-		36.06	29.24
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				27.12		
is P	Z ₁	Zs	(cm)				3.40		
onst	Z _{bp}	Z _{bp}	(cm)				1.46		
Acc	Z _{sp}	Z _b	(cm)					2.00	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.00					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.97	
SSC	f _c	f _{awf}	(MHz)	3.64	-	-	3.64	3.64	3.64
٩	Dim. of A _{aprt}		X (cm)		-	-	0.96	0.96	0.81
			Y (cm)		-	-	0.77	0.77	0.77
	PD	t _d	(μsec)	1.04					
ion	PRF	prr	(Hz)	8680.56					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.28					
Je l	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.97	0.89
e	Focal Length	FLx	(cm)		-	-	6.06		1.63
O#		FLy	(cm)		-	-	6.00		6.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	42.43					
Operator Control	TX-Level (dB)			0	-	-	0	0	0
era	Focus (mm)			19.00	-	-	60.60	19.60	16.30
ర్ధి	PRF(prr) (Hz)			8680.56	-	-	8680.56	9191.18	10416.70

This Index is not relevant to this operating mode.

- This transducer is not intended for transcranial or neonatal cephalic uses.
- 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: M-mode

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Noi	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value	1.18		-	0.11	0.24	0.16		
	FDA	IEC	Units						
s	P _{r.3}	p _{ra}	(MPa)	2.36					
ters	Wo	P	(mW)		-	-		1.79	6.21
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				5.78		
ic P	Z ₁	Z _S	(cm)				3.00		
onst	Z _{bp}	Z _{bp}	(cm)				1.46		
Acc	Z _{sp}	Z _b	(cm)					1.90	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.90					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.97	
SSC	f _c	f _{awf}	(MHz)	4.00	-	-	4.00	4.00	4.00
4	Dim. of A _{aprt}		X (cm)		-	-	0.96	0.96	0.96
			Y (cm)		-	-	0.77	0.77	0.77
	PD	t_{d}	(μsec)	0.45					
Other Information	PRF	prr	(Hz)	384.00					
mai	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.67					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.97	0.97
e	Focal Length	FLx	(cm)		-	-	5.00		5.00
₽		FLy	(cm)		-	-	6.00		6.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	254.42					
Operator Control	TX-Level (dB)			0	•	-	0	0	0
era	Focus (mm)			10.00	-	-	50.00	20.00	50.00
ಕಿರ	PRF(prr) (Hz)								
2	This Index is not rela	word to this anare	Alan and and a						

This Index is not relevant to this operating mode.

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

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.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: AcuNav 10F, SoundStar 10F & eco 10F Operating mode: 2D-Mode

			MI		TIS		TIB	TIC
Inde	x Label			Scan	Nor	n-scan	Non-scan	
					At surface	Below surface		
Maximum Value			0.74	1.25	-	-	-	2.69
FDA	IEC	Units						
P _{r.3}	p_{ra}	(MPa)	1.65					
Wo	P	(mW)		52.50	-		-	45.57
min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Z ₁	Z _S	(cm)				-		
Z _{bp}	Z _{bp}	(cm)				-		
Z _{sp}	Z _b	(cm)					-	
z@PII _{.3max}	z @ max. I _{pi,α}	(cm)	1.40					
$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
f _c	f _{awf}	(MHz)	5.00	5.00	-	-	-	5.00
Dim. of A _{aprt}		X (cm)		0.70	-	-	-	0.70
		Y (cm)		0.20	-	-	-	0.20
PD	t _d	(µsec)	0.36					
PRF	prr	(Hz)	40.00					
Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.11					
d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.42
Focal Length	FLx	(cm)		6.00	-	-		6.00
	FLy	(cm)		1.00	-	-		1.00
I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	113.15					
TX-Level (dB)			0	0	-	-	-	0
Focus (mm)			20.00	60.00	-	-	-	60.00
PRF(prr) (Hz)								
	Maximum Value FDA FDA	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{ c c c c c } \hline \textbf{Maximum Value} & 0.74 \\ \hline FDA & IEC & Units \\ \hline P_{r.3} & p_{ra} & (MPa) & 1.65 \\ \hline W_o & P & (mW) & \\ \hline \min of [W_3(z_1), & Min. of [P_a(z_5), I_{la.a}(z_5)] & (cm) \\ \hline Z_1 & Z_5 & (cm) & \\ \hline Z_{bp} & Z_{bp} & (cm) & \\ \hline Z_{sp} & Z_b & (cm) & \\ \hline Z_{gpHI_{3max}} & Z @ max. I_{pl.a} & (cm) & \\ \hline I_{c} & f_{swf} & (MHz) & 5.00 \\ \hline Dim. of A_{aprt} & T & (Hz) & 40.00 \\ \hline PRF & prr & (Hz) & 40.00 \\ \hline Pr@ PII_{max} & P_r@ max. I_{pl} & (cm) & \\ \hline I_{pa.a}@ PII_{max} & d_{eq}@ max. I_{pl} & (cm) & \\ \hline I_{pa.a}@ MI_{max} & I_{pa.a}@ max. MI & (W/cm^2) & 113.15 \\ \hline TX-Level & (dB) & & 0 \\ \hline PRF(prr) & (Hz) & & 0.00 \\ \hline PRF(prr) & (Hz) & & 0 \\ \hline \hline Procus & (mm) & & 0.00 \\ \hline \hline PRF(prr) & (Hz) & & 0.00 \\ \hline \hline PRF(prr) & (Hz) & & 0.00 \\ \hline \hline PRF(prr) & (Hz) & & 0.00 \\ \hline \hline \end{tabular} $	$\begin{array}{ c c c c c } \hline \textbf{Maximum Value} & & & & & & & \\ \hline \hline \textbf{FDA} & & & & & & & \\ \hline \textbf{FDA} & & & & & & & \\ \hline \textbf{FDA} & & & & & & & \\ \hline \textbf{P}_{r.3} & & p_{ra} & & & & & \\ \hline \textbf{Mw}_{o} & & P & & & & & \\ \hline \textbf{Min of } [W_{3}(z_{1}), & & & & & \\ \hline \textbf{I}_{La.o}(z_{2})] & & & & & \\ \hline \textbf{Min of } [P_{o}(z_{5}), & & \\ \hline \textbf{I}_{la.o}(z_{5})] & & & & \\ \hline \textbf{Min of } [P_{o}(z_{5}), & & \\ \hline \textbf{Imanum } & & & & \\ \hline \textbf{Min of } [W_{3}(z_{1}), & & & \\ \hline \textbf{Min of } [P_{o}(z_{5}), & & \\ \hline \textbf{Min of } [W_{3}(z_{1}), & & \\ \hline \textbf{Min of } [P_{o}(z_{5}), & & \\ \hline \textbf{Min of } [W_{3}(z_{1}), & & \\ \hline \textbf{Min of } [P_{o}(z_{5}), & & \\ \hline \textbf{Min of } [W_{3}(z_{1}), & & \\ \hline \textbf{Min of } [W_{3}(z_{1}), & & \\ \hline \textbf{Min of } [P_{o}(z_{5}), & & \\ \hline \textbf{MWV} & & & \\ \hline \textbf{MWV} & $	$ \begin{array}{ c c c c c c } \hline \textbf{Maximum Value} & & & & & & & & & & & \\ \hline \textbf{Maximum Value} & & & & & & & & & \\ \hline \textbf{FDA} & & & & & & & & & & & $	N N N N N N N N N	Name Name

a This Index is not relevant to this operating mode.

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: AcuNav 10F, SoundStar 10F & eco 10F Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value		0.60	1.08	-	-	-	2.47	
	FDA	IEC	Units						
eters	P _{r.3}	p_{ra}	(MPa)	1.34					
	W _o	P	(mW)		45.36	-		-	41.84
Associated Acoustic Parameters	min of [W $_3(z_1)$, $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Ö.	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	Z b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.20					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ss(f _c	f _{awf}	(MHz)	5.00	5.00	-	-	-	5.00
٩	Dim. of A _{aprt}		X (cm)		0.70	-	-	-	0.70
			Y (cm)		0.20	-	-	-	0.20
	PD	$t_{\sf d}$	(µsec)	0.73					
ţion	PRF	prr	(Hz)	100.15					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.65					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	0.42
er	Focal Length	FLx	(cm)		9.46	-	-		9.46
oth		FLy	(cm)		1.00	-	-		1.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	32.35					
Operator	TX-Level (dB)			0	0	-	-	-	0
ontr	Focus (mm)			50.00	94.60	-	-	-	94.60
3 8	PRF(prr) (Hz)			100.15	6250.00	-	-	-	6250.00

a This Index is not relevant to this operating mode.

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.

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

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(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: AcuNav 10F, SoundStar 10F & eco 10F Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Nor	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.59	-	-	1.65	3.15	3.86
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	1.32					
ters	Wo	P	(mW)		-	-		97.56	58.94
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				69.30		
ic P	Z ₁	Z _S	(cm)				1.20		
onst	Z _{bp}	Z _{bp}	(cm)				0.64		
Acc	Z _{sp}	Z _b	(cm)					1.10	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.20					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.41	
SSC	f _c	f _{awf}	(MHz)	5.00	-	-	5.00	4.00	5.00
•	Dim. of A _{aprt}		X (cm)		-	-	0.70	0.65	0.57
			Y (cm)		-	-	0.20	0.20	0.20
	PD	t _d	(µsec)	0.73					
tion	PRF	prr	(Hz)	100.16					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.62					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.41	0.38
er	Focal Length	FLx	(cm)		-	-	1.53		1.15
o ₽		FLy	(cm)		-	-	1.00		1.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	32.88					
Operator Control	TX-Level (dB)	•		0	1	-	0	0	0
era	Focus (mm)	•		20.00	1	-	15.30	13.00	11.50
80	PRF(prr) (Hz)			100.16	1	-	17361.10	19531.30	19531.30

a This Index is not relevant to this operating mode.

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: AcuNav 10F, SoundStar 10F & eco 10F Operating mode: M-mode

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	No	n-scan	Non-scan	
						At surface	Below surface		
	Maximum Value			0.74	-	-	0.94	0.94	2.02
	FDA	IEC	Units						
ģ	P _{r.3}	p _{ra}	(MPa)	1.65					
ters	W _o	P	(mW)		-	-		5.84	34.22
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				39.48		
으	Z ₁	Z _S	(cm)				1.00		
onst	Z _{bp}	Z _{bp}	(cm)				0.64		
Acc	Z _{sp}	Z _b	(cm)					1.00	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.40					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.42	
\SS(f _c	f _{awf}	(MHz)	5.00	-	-	5.00	5.00	5.00
4	Dim. of A _{aprt} X		X (cm)		-	-	0.70	0.70	0.70
			Y (cm)		-	-	0.20	0.20	0.20
	PD	t _d	(μsec)	0.36					
tion	PRF	prr	(Hz)	384.00					
ща	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.11					
Jo Jo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.42	0.42
Other Information	Focal Length	FLx	(cm)		-	-	6.00		6.00
oth		FLy	(cm)		-	-	1.00		1.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	113.15					
<u> </u>	TX-Level (dB)	•	•	0	-	-	0	0	0
Control	Focus (mm)		•	20.00	-	-	60.00	60.00	60.00
} ၓ	PRF(prr) (Hz)								
	This Index is not rele	want to this opera	ating mode						

a This Index is not relevant to this operating mode.

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

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

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