

**ACUSON CV70 Cardiovascular System** 



## **GENERAL INFORMATION**

The ACUSON CV70™ cardiovascular system is a powerful, portable multi-specialty imaging platform that incorporates the latest generation of all-digital ultrasound technologies and proven innovations, providing solutions in flexibility, workflow and performance.

#### SYSTEM ARCHITECTURE

The powerful, all-digital core technology of the CV70 system is built on a combination of: technology migration from other ACUSON™ ultrasound systems. MultiBeam Image Formation, multihertz and the Acuson integrated DIMAQ architecture.

- The all-digital architecture preserves the signal integrity of all ultrasound information throughout the entire signal path from transducer to display.
- MultiBeam Image Formation allows high frame rate imaging, for optimal color flow and motion visualization
- Precision MotionCapture utilizes the full spectrum of signal information which allow the accurate display of cardiac structures for analysis
- DIMAQ integrated workstation acquires, captures and stores digital dynamic clips and static images without interrupting the exam workflow. This technology is the gateway to advanced features

#### **User Interface**

- User-centric control panel with homebase layout
- Windows® based operating principles and on-screen icons to activate most frequently used functions
- Adjustable control panel back-lit illumination
- Intuitive active stage lighting
- Digital Liquid Crystal Display (LCD) provides easy and immediate access to secondary imaging controls
- Wrist support to help reduce operator repetitive stress disorders
- Retractable alphanumeric keyboard with overhead illumination for standard text, function keys and system programming
- Up to 32 user-definable QuickSet™ user programmable system parameters programs for individual transducer/application settings. QuickSets combine all preferred imaging mode parameters, annotation text and measurements into one user preset
- Configurable two-pedal footswitch

#### Language Support

 Image screen, control panel overlay and operating instructions all available in English, German, French, Spanish and Italian

#### Monitor

- MultiSync, 15-inch, high resolution, progressive scan (non-interlaced)
- 800 x 600 pixel display matrix with a recordable image area of up to 800 x 600 pixels (SVGA)
- Monitor tilt of 10 degrees up, 8.5 degrees down and swivel of 180 degrees
- Digital on-screen display brightness and contrast controls with factory default presets
- Energy Savings Compliant per VESA Display Power Management Signaling standard

#### **MO Drive**

- Removable, standard 3.5-inch 640 MB magneto-optical disk
- Allows storage of patient images, reports, and patient ID list, back-up for user and system presets
- Supports system software updates and upgrades

#### **Hard Drive**

- Internal 40 GB Hard Drive for patient database management
- Allows storage of patient studies that include images, dynamic clips, reports and measurements
- Image storage capacity up to 42,000 images; color or black/white, or storage of approximately 6,300 dynamic clips

#### **CD-RW Drive**

- Removable 650 MB read/write CD-R
- Allows storage and archiving of patient studies that include images, dynamic clips, reports and measurements
- Storage capacity dependent upon patient study size
- Export of images in DICOM (Optional), TIF and in AVI file format

#### **Audio Speakers**

High performance audio speakers integrated with the monitor

#### **Transducer Ports**

- Two universal transducer ports that support Phased Array, Curved-Linear Array and Linear Array
- One MP transducer port that supports the V5M Transesophageal transducer
- Single dedicated port for CW pencil-type transducer
- Electronic transducer selection
- Industrial design provides easy access to all transducer ports

#### **Transducer Storage**

- Six configurable transducer holders support all transducer designs and provide gel bottle storage
- Ergonomic cable management and secure cable management during exams and transport

## **Acoustic Output Management**

 On-screen acoustic power indicator (AIUM/NEMA output display standard)

#### **Physiological Interface**

- Standard 3-lead ECG interface
- Continuous display in all real-time modes
- R-Wave Single and Dual Trigger function
- Heart Rate display
- Adjustable gain and trace position on screen
- Selection for one external ECG (DC) input and one Auxillary (DC) input

### **OPERATING / DISPLAY MODES**

- 2D imaging in fundamental and harmonic modes
- Tissue and color M-mode
- SieScape™ panoramic imaging
- Axius<sup>™</sup> edge-assisted Ejection Fraction (option)\*
- Color Doppler Velocity mode
- Power Doppler mode (Vascular only)
- Directional Power Doppler mode (Vascular only)
- Spectral Doppler Tissue Imaging
- PW Pulsed Wave spectral Doppler mode
- CW Continuous Wave spectral Doppler mode (Aux Pencil style and phased array steerable)
- Duplex mode
- Triplex mode (Vascular only)
- ECG trace in all modes
- Flexible combination of imaging modes in side-by-side Dual and Dual Select in real-time, and digital cine replay
- Selectable split screen display formats in 2D/color with M mode and/or spectral Doppler mode: top-bottom or side by-side in real-time and digital cine replay

## **Beamforming in 2D Imaging**

- New generation digital beam former technology enables parallel and quad processing of the RF signal data in the time and amplitude domains
- Patented ASIC technology preserves signal integrity through precision up-sampling for better beam definition
- Configurable signal processing hardware provides a pathway for future performance expansion and technology innovations
- 2D-mode line density up to 322 lines
- Up to 768 Processing Channels
- Total system dynamic range of > 160 dB

#### **Focusing**

- Up to four transmit focal zones
- Digital dynamic receive focusing with dynamic apodization
- SynAps™ aperture control for improved resolution at depth

#### 2D Image Processing

 Precision MotionCapture Technology results in superb contrast and spatial resolution, higher frame rates, and improved signal-to-noise ratio in the real-time image

- Parallel and quad Signal Processing with frame rate > 350 F/sec. transducer dependent
- MultiHertz™ multiple frequency imaging with up to 5 user selectable transmit frequencies
- Res/Speed selection for Std (Standard), Dtl (High line density), and Far (SynAps)
- 5 Persistence levels: off, 1 4
- 4 Edge enhancement levels: off, 1 3
- Display dynamic range: 35 to 70 dB in one-decibel increments
- Adjustable gain from 0 to 40 dB in one-decibel increments, and total of 60 dB including DGC
- 8 DGC controls for Depth Gain Compensation
- 6 user-selectable gray maps
- 4 user-selectable 2D colorization maps (Sepia, Mag, Temp, Bow and Tan)

#### **2D Image Display**

- Full screen, Split and Dual Select screen formats
- L/R for all formats in real-time and digital cine replay
- 90 degree rotation of image for all sector transducers
- Image Depth from 2 to 24 cm in 0.5 or 1.0 cm increments transducer dependent
- Sector: selectable field of view from 10 to 90 degrees
- Left/right steer for all linear array transducers
- Digital read/write zoom with image pan
- Available on live and cine replay images
- Up to 20 X zoom transducer dependent

## 2D Calipers – Generic Measurements and Calculations

- Multiple cursor sets on frozen and cine playback images
- Up to eight distance measurements per screen
- Distance, depth from skin line
- Trace Length measurement
- Angle measurement
- Area and circumference: ellipse, trace, cross, spline
- Compound Measurements:
  - Volume: user-selectable calculated by 2-Plane 3 distances, 2-Plane trace, 1 Plane 2 distances, 1-Plane ellipse or 1-Plane disk measurements
  - Flow volume: Combined velocity and distance, or velocity and ellipse measurements
  - Stenosis: user-selectable, calculated by area, or diameter measurements

## **Tissue Harmonic Imaging**

Tissue Harmonic Imaging with selectable frequencies increases success with difficult-to-image patients, improving diagnostic confidence and reducing noise and clutter in the image.

- MultiHertz multiple frequency imaging capability in Tissue Harmonic Imaging (THI) up to 6.8 MHz
- Available for the P4-2 and 5.0P10 phased array transducers and the C6-2 curved-linear array transducer

#### **PW Pulsed Wave Spectral Doppler**

- Available on all imaging array transducers
- Up to two user-selectable transmit frequencies per transducer, frequency range is 2.1 to 7.0 MHz
- 4 sweep speed selections: 2, 4, 8, 16 sec.
- 4 selectable pre-processing curves
- 8 selectable post processing gray maps
- 4 user-selectable Doppler colorization maps (Sepia, Mag, Temp, Bow and Tan)
- Adjustable gain from 30 to 60 dB in one-decibel increments
- PRF range: 1,400 to 15,300 Hz
- Velocity scale range: ±14.7 cm/sec to ±277.4 cm/sec (with High PRF), up to 554.8 cm/sec in one direction at 0° angle correction
- Angle correction 0 90° in one-degree increments
- Auto angle correction 60/0/60° for vascular applications
- Gate size: from 0.4 up to 15.1 mm
- 7 wall filter selections, range 22 to 2,028 Hz proportional to PRF – transducer dependent
- 9 levels of baseline shift
- Spectral invert
- Auto-Doppler trace function with auto calculation and display of PS, MD, TAVmax, PI, RI and S/D
- Spectral Doppler Tissue Imaging (DTI)
  - Provides one button optimization for analysis of cardiac tissue motion

#### **CW Continuous Wave Spectral Doppler**

- Steerable CW available on phased array transducers
- Pencil style CW transducers at 2 and 5 MHz for cardiac and vascular applications
- Up to two user-selectable transmit frequencies per transducer
- 4 sweep speed selections: 2, 4, 8, 16 sec.
- 4 selectable pre-processing curves
- 8 selectable post processing gray maps
- 4 user-selectable Doppler colorization maps (Sepia, Mag, Temp, Bow and Tan)
- Adjustable gain from 30 to 60 dB in one-decibel increments
- Adjustable gain from 30 to 60 dB in one-decibel increments
- PRF scale range: 4.0 to 47.6 kHz
- Velocity range: ±0.7 m/sec to ±8.5 m/sec, up to 17.0 m/sec in one direction
- 7 wall filter selections, range 68 to 6,333 Hz proportional to PRF – transducer dependent
- Nine levels of baseline shift
- Spectral invert

#### Spectral Doppler Display

- Full screen D trace, 2D/Doppler mode, triplex or update 2D/C/Doppler, 2D/C/Doppler/M-mode
- Three imaging display formats top-bottom: 1/3 2/3, 1/2 1/2; side-by-side: 40-60

## Doppler Calipers – Generic Measurements and Calculations

- Multiple cursor sets on frozen and cine playback images
- Velocity/Frequency/Pressure Gradient
- Heart rate/Heart cycle/Time
- Auto-Trace measurements and calculations including PS, MD, TAVmax, PI, RI and S/D or VTI (cardiac)
- Resistive Index (RI)
- Pulsatility Index (PI), including Peak-to-Peak method
- Time Average Velocity max (TAV)
- Systolic/diastolic ratio (S/D)
- Velocity Time Integral (VTI)
- Acceleration/Deceleration
- Flow volume using combined velocity and distance, or velocity and ellipse measurements
- Doppler angle correction after measurement

#### **Color Doppler Velocity Imaging**

- Available on all imaging array transducers
- MultiBeam Formation technology provides Parallel and Quad Signal Processing for high color Doppler frame rates – transducer dependent
- Advanced processing in Color mode resulting in excellent spatial resolution and superior flash suppression
- Up to two user-selectable transmit frequencies per transducer, frequency range is 2.1 to 7.0 MHz
- Up to 8 user-selectable color velocity maps (4 velocity; 4 velocity/variance)
- Velocity scale range: 1.2 cm/sec to 229 cm/sec
   – transducer dependent
- Adjustable gain from 0 to 30 dB in one-decibel increments
- 5 Color line density selections
- 4 Motion Cut selections proportional to velocity scale
- 10 Noise Cut filter selections (spatial smoothing)
- 12 Tissue/color priority selections
- 8 Color persistence levels
- 5 Flow state selections per exam type for quick adjustment of color flow depending on pathology
- Color invert

## Power Doppler Imaging Directional Power Doppler Imaging

- Available on all vascular transducers
- Parallel Processing transducer dependent
- Up to two user-selectable transmit frequencies per transducer, frequency range is 2.1 to 7.0 MHz
- Selection of 6 Power Doppler maps
- Selection of 4 Directional Power Doppler maps
- PRF scale range: 330 Hz to 12,550 Hz transducer dependent
- Gain: 0 to 30 dB in one-decibel increments
- 5 Color line density selections
- 4 Motion Cut selections proportional to PRF scale
- 10 Noise Cut filter selections
- 12 Tissue/color priority selections
- 8 Color persistence levels
- 5 Flash suppression levels

 5 Flow state selections per exam type for quick adjustment of color flow depending on pathology

## **Color and Power Doppler Display**

- 2D/C mode, Split 2D-2D/C mode, Dual Select 2D/C mode
- 2D/C/D mode (simultaneous triplex), 2D/C/D mode (update)
- 2D/C/M mode simultaneous

#### M-Mode

- Available on all imaging array transducers
- Up to five user-selectable transmit frequencies, including fundamental and harmonics
- 4 Edge Enhancement selections
- Display dynamic range: 35 to 70 dB in one decibel increments
- Adjustable gain from 0 to 40 dB in one-decibel increments
- 6 user-selectable gray maps
- 4 user-selectable M-mode colorization maps (Sepia, Mag, Temp, Bow and Tan)
- 4 sweep speed selections: 2, 4, 8, 16 sec.

#### M-Mode Image Display

- Full screen M-mode, 2D/M-mode, 2D/C/M-mode, 2D/Doppler/M-mode, 2D/C/Doppler/M-mode
- Three imaging display formats top-bottom: 1/3 2/3, 1/2 – 1/2; side-by-side: 40 – 60

## M-Mode Calipers – Generic Measurements and Calculations

- Multiple cursor sets on frozen and cine playback images
- Distance
- Time
- Ratio
- Heart rate/heart cycle
- Slope
- Compound Measurements:
- Flow volume: Combined velocity and distance, or velocity and ellipse measurements

# FREEZE, CINE AND CINE POST-PROCESSING FUNCTIONS

#### **Cine Review**

## Cine feature offers post-acquisition optimization of all real-time post-processing functions.

- Frame-by-frame cine loop review and continuous cine motion review, including control of playback rate
- Independent cine review in mixed modes (2D/M, 2D/Doppler, 2D/C/Doppler)
- Independent cine review in 2D Dual Select mode with image align playback feature
- Standard Cine Memory: providing up to 511 2D mode images or up to 511 2D/C images
- Up to 60 seconds Doppler Cine, or up to 60 seconds M mode Cine

• Cine Store: Multiple single frame storage with clipboard review allowing post processing, measurement and annotation functions

#### Post Processing Features in Freeze Frame or Cine

- 2D-mode
  - Zoom/pan
  - Gray map
  - 2D-mode B-color maps
  - Measurements/reports/annotations/pictograms
- Color
  - Zoom/pan
- Color map
- Color invert
- Measurements/reports/annotations/pictograms
- Doppler
  - Gray map
  - Doppler B-color maps
  - Angle correct
  - Measurements/reports/annotations/pictograms
- M-mode
  - Gray map
  - M-mode B-color maps
  - Measurements/reports/annotations/pictograms

### TRANSDUCER TECHNOLOGY

Ultra-sensitive, wideband transducers, matched with user-selectable MultiHertz imaging, improve resolution and penetration. Depending on the transducer, the user can select up to five 2D and THI frequencies and two color and spectral Doppler frequencies, expanding the clinical versatility of a single transducer, and thereby maximizing transducer investment.

- Wideband MultiHertz imaging allows two separate Harmonic frequencies user selection of 2D and color frequency for optimal resolution and penetration
- microCase<sup>™</sup> transducer miniaturization technology combined with SuppleFlex<sup>™</sup> transducer cables provide small, lightweight, comfortable transducers, designed to help reduce operator fatigue during prolonged scanning sessions
- Innovative ultra low-loss lens materials and microelectronic technologies for efficient performance and increased signal bandwidth
- Frequency range: 2.0 13.0 MHz

Note: See dedicated transducer cards for more information.

### **APPLICATIONS**

The CV70 system is designed to support cardiac and vascular imaging applications. Factory supplied exam and transducer dependent imaging presets have been carefully optimized for each application to provide consistency, reliability, and increased productivity. Selected applications, text annotation labels, worksheets and reports.

- Cardiac
- Adult, Pediatric and Fetal echocardiograms
- Vascular (Carotid, Brachial artery Imaging, Peripheral and Venous exams)
- Surgery: TEE Monitoring, special access imaging
- TCD vascular
- Surgery
- Abdominal Vascular

# **EXAM-SPECIFIC MEASUREMENTS AND CALCULATIONS**

The measurement function is arranged by exam type and is available for use with all exams types. The ultrasound system has measurement and report packages for the following exam types:

#### Cardiac

All general measurements and calculations

#### Vascular

• All general measurements and calculations

## Peripheral Vascular Option Carotid Artery Imaging Brachial Artery Imaging

Imaging capabilities for the physician to display and measure Intimal medial thickness and brachial reactivity to assess endothelial function.

- All general measurements and calculations
- Right and left extremity measurements
- Peripheral vascular patient report

## Transcranial 2D/Color/Power/PWD Doppler for vascular studies

• All general measurements and calculations

#### **Intraoperative Option**

• Special System configuration for the OR

- OR Monitor output for display of images
- Speciality access Intraoperative transducer for epiaortic Imaging

#### Cardiac

- Adult and pediatric standard measurements and calculations including LA volume, diastolic function and Qp/Qs shunt
- Volume formulas for left atrial volume and Left Ventricular function assessment in 2D-mode and M-mode
- 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 patient report and worksheet for 2D mode, M-mode, and Doppler

# DIGITAL PATIENT STUDY STORAGE AND ARCHIVING

The DIMAQ integrated workstation allows for digital acquisition, storage and review of complete ultrasound studies, including static images and dynamic clips as well as measurements, calculations and reports. Embedded DICOM (option) allows for easy integration of the system into departmental or hospital-wide PACS.

#### **Patient Study Management**

Replay of digitally stored images and clips in a selectable 1-up, 4-up, 9-up or 16-up screen format. The patient study screen allows for study selection, search, and deletion or for export to CD-R.

- Internal 40 GB hard drive for patient data management
- CD-RW drive for 650 MB CD-R provides patient study archiving
- Hard drive capacity:
  - approximately 42,000 b/w or color images or approximately 6,300 dynamic clips (2 sec. Color clip)
- Digital storage of static images and dynamic clips:
- JPEG lossy compression of dynamic clips with user selectable compression level
- Retrospective clip capture during real-time imaging with a selectable duration of 1, 2, 3, or 4 seconds or a selectable duration 1, 2, 3 or 4 beat capture; ECG triggerable
- Prospective clip capture during real-time imaging with a selectable duration of 1 to 120 seconds a selectable duration 1 to 120 beat capture; ECG triggerable
- Editable clip capture from Cine replay
- Storage and retrieval of real-time dynamic clips
- Storage and retrieval of frozen static images

- Storage and retrieval of reports
- Instant dial-in replay of dynamic clips or static images in 1 up screen format
- Perform Measurements and Calculations on current, as well as on saved and retrieved images and clips
- Export of patient studies from Hard Drive to CD RW Drive
- Exported images and clips in standard DICOM (option), TIF and AVI file formats
- M-mode Still Frame Scroll and Store
- CW and PW Spectral Doppler Still Frame Scroll and Store
- Patient database sorting by Name, ID, Study Date and Exam type

#### **Network Export**

- Provides a gateway to selected workstations for patient file reviews
- Can send images, clips, reports, and stress-echo exams to an appropriate workstation for review and diagnosis
- Transfer is password protected to help support the user's compliance with HIPAA regulations
- Can provide access to advanced workstation features such as structured reporting

### **OPTIONS**

## **Stress Echo Imaging (Option)**

The stress echo package provides tools for ECG-triggered acquisition, display, selection comparison, evaluation and archiving of multiple cardiac loops during various stages of a stress echo examination. The software module is based on Microsoft Windows® 2000 standards.

- Standard acquisition protocols for treadmill, ergometric, and pharmacological stress with
- 2-Stage Exercise Stress Echo Protocol (Retrospective)
- 2-Stage Exercise Stress Echo Protocol (Prospective)
- 3-Stage Exercise Stress Echo Protocol (Retrospective)
- 3-Stage Exercise Stress Echo Protocol (Prospective)
- 6-Stage Pharmacological Stress Echo Protocol (Retrospective)
- Full screen or ROI (region of interest) acquisition
- Easy workflow throughout the exam protocol
- Stage Timer
- Prospective Continuous Capture or Retrospective labeled capture
- LVO with contrast capture within Stress echo protocol
- Reference image display during acquisition
- Immediate review of acquired loops
- Flexibility to skip views or stages
- Flexibility to re-acquire and overwrite already acquired images
- Indication of current view, acquired views and skipped views in the workflow diagram
- Wall Motion Scoring, 17-segment model with graphical display and report printing
- LV Volume Measurements with report printing
- Ability for customized studies through Protocol Editor, with up to 12 stages, 6 views per stage, 20 loops per view

### **DICOM 3.0 Connectivity (Option)**

Provides digital image transfer via a DICOM network for both printing and storage. The CV70 system acts as a DICOM Storage Class User and DICOM Print and store Class User and can be connected to a DICOM color or grayscale Printer and/or to DICOM workstation and archive devices.

#### **DICOM Storage Class**

- Allows connectivity to PACS
- Allows storage of all digital images and dynamic clips with patient demographic data

#### **DICOM Print Class**

• Allows printing to DICOM print device

### **DICOM Storage Commitment Class**

- Allows the system to recognize "storage commitment" messages from suitably-equipped PACS systems
- Helps prevent accidental loss of image data in case of PACS system errors

## **DICOM Modality Worklist (Option)**

 Allows automatic import of patient scheduling and demographics from a DICOM server

## DICOM Modality Performed Procedure Step-MPPS (Option)

 Allows the ultrasound systems to automatically exchange 'Performed Procedure Step' information with the Hospital Information System (HIS) or Radiology Information System (RIS)

## **DOCUMENTATION DEVICES**

Optional On-Board Video Devices

- Up to three documentation devices can be integrated and controlled through the control panel
- Supported devices:
- Mitsubishi P93W-S B&W Printer (standard equipped)
- Mitsubishi HS-MD 3000 E/U VCR
- Mitsubishi CP-900 Color Printer

#### SYSTEM INPUT/OUTPUT

#### **Video Standard**

- PAL/CCIR: 625 lines, 50 Hz
- NTSC/EIA: 525 lines, 60 Hz

#### Video/Audio Input

- 1 Composite color Video in, BNC-type
- 1 Y/C Video in, S-terminal (SVHS)
- 1 2-Channel Audio in (Right/Left), phone jack type

#### Video/Audio Output

- 1 Composite B/W Video out, BNC-type
- 1 Composite color Video out, BNC-type
- 2 RGB & Composite Sync out, mini D-SUB (15 pin)
- 2 Y/C Video out, S-terminal (SVHS)
- 1 2-Channel Audio (Right/Left), phone jack-type

#### Other Input/Output

- 1 ECG lead connector, AIUM/NEMA standard
- 1 ECG DC In connector, phone jack-type
- 1 Foot switch connector, phone jack-type
- 2 Remote control connector, mini jack (stereo)

## **System Connections**

- Network
- 1 Ethernet connector, type RJ45 (10/100BaseT)
- Peripherals
  - 2 Serial port RS232-C connector, D-SUB (9-pin) 1 USB port, Series A-type

### **SYSTEM DIMENSIONS**

- System Height: 142.2 cm (56.0 inch)
- Width: 51.0 cm (20.1 inch)
- Depth: 79.8 cm (31.4 inch)Weight: 130 kg (286 pounds) without OEM's

## ELECTRICAL/ENVIRONMENTAL

• Power connections:

**SPECIFICATIONS** 

- 100V version: 90 110 VAC, 50/60 Hz (Japan)
- 115V version: 98 132 VAC, 50/60 Hz
- 230V version: 196 264 VAC, 50/60 Hz
- Built-in AC isolation transformer
- Power consumption: maximum 1050 VA with OEM's
- Atmospheric pressure range: 700 hPa to 1060 hPa (525 to 795 mm Hg) or up to 3050 m (10,000 ft)
- Ambient temperature range (without OEM's): +10°C to +40°C (50° to 104°F)
- Humidity: 30 85%, non-condensing, during operation
- Maximum heat output: 3600 BTU/hr

#### STANDARDS COMPLIANCE

The CV70 platform meets the requirements of the Medical Device Directive and carries the CE Mark.

#### **Quality Standards**

FDA QSR 21 CFR Part 820 ISO 9001:94 ISO 13485 EN 46001:96

#### **Design Standards**

UL 2601-1 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 EN 60601-2-25 and IEC 60601-2-25 EN 60601-2-37 and IEC 60601-2-37

#### **Acoustic Output Standards**

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

#### **CE Declaration**

This product is provided with a CE marking in accordance with the regulations stated in Council Directive 93/42/EEC of June 14, 1993 concerning Medical Devices. Siemens Medical Solutions USA, Inc., is certified by notified body 0123 to Annex 11.3 – Full Quality System.

#### **Authorized EC Representative:**

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\*The Axius edge-assisted Ejection Fraction and advanced quantification and cardiac calculation features require 510(k) review and are not yet commercially available.

## Siemens Medical Solutions that help

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