ACUSON X150™
Ultrasound System
Release 2.5
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3-Scape™ real-time 3D imaging, productivity enhancing technologies including phase inversion Tissue Harmonic Imaging (THI) and TGO™ tissue grayscale optimization technology and connectivity solutions such as DICOM Print/Store, DICOM Worklist, DICOM MPPS and DICOM OB/GYN SR.

User Interface

- Intuitive PC-based operating principles
- User-centric control panel with home-base layout
- On/Off tasklight and back-lit illumination of control panel
- Variable brightness indicates active state of function keys
- Customizable Soft Key selections are displayed on-screen to provide easy and immediate access to imaging controls and activation of specific functions
- On Screen Menus (OSM) provide easy and immediate access to secondary imaging controls
- Easily accessible, full-size QWERTY keyboard for text entry, function keys and system programming
- Trackball integrated into the control panel
- Wrist support to help reduce operator repetitive stress injuries

System Architecture

All-digital signal processing technology provides best-in-class 2D and Doppler image quality for greater diagnostic confidence.

New generation all-digital beamformer technology enables parallel Quad beam processing of the RF signal data in the time and amplitude domains.

- 2D-mode line density: Up to 256 lines
- Processing channels: Up to 4,480 channels
- Total system dynamic range: > 175 dB

The DIMAQ-IP integrated workstation provides digital acquisition, storage, review and transfer of ultrasound studies. Studies can be reviewed, quantified and stored on the system hard drive and transferred to the built-in CD/DVD R/W or to an external hard drive using USB 2.0 (SN > 330000) for cost-effective archival.

The flexible system architecture enables seamless integration of additional application functionality such as Color Imaging, Cardiac Screening and

GENERAL INFORMATION

The ultra-compact ACUSON X150™ ultrasound system offers unparalleled diagnostic confidence and clinical performance. Maximum upgrade flexibility and exceptional system reliability safeguard your investment for years to come and allow you to grow as clinical applications evolve or patient needs change over time. Intelligent features improve workflow, while our ergonomic system design makes ultrasound exams easier, faster and more comfortable than ever before. The ACUSON X150 system was designed to meet the everyday clinical requirements of private practices as well as dynamic hospital environments. From OB/GYN, early pregnancy and reproductive medicine to abdominal imaging and more, the ACUSON X150 system provides you with clinical application flexibility.
• Up to 32 QuickSet™ user-programmable system presets allow for individual transducer/application settings. QuickSet presets combine all preferred imaging mode parameters, annotation text and measurements into one user preset.

Language Support
• On-screen text, control panel overlay and operating instructions are all available in Chinese, English, French, German, Italian, Russian and Spanish
  - Additional Instructions for Use are available in the following languages — Czech, Danish, Dutch, Finnish, Greek, Hungarian, Korean, Latvian, Lithuanian, Norwegian, Polish, Portuguese, Romanian, Russian, Slovak, Swedish and Turkish
  - Allows Chinese character input in Patient Registration
  - Allows for Russian character input

Monitor
• Flat Panel Display, 15-inch color, high resolution, and progressive scan (non-interlaced) with in plane switching (IPS) technology
  • Resolution: 1024 x 768 pixels
  • Total screen area: 1024 x 768
  • Recordable image area clips 800 x 600
  • Total screen capture is an option.
  • Monitor tilt: 10° up, 75° down and swivel of ±80°
  • Digital on-screen display brightness and contrast controls
  • Energy saving display power management
  • 4 levels of illumination intensity:
    Off, 1, 2, 3
  • Image Display: 256 levels of grayscale and up to 16.7 million colors
  • Liquid Crystal Display (LCD) Monitor

Hard Drive
• Internal 160 GB hard drive
• Allows storage of patient studies that include images, reports and measurements
• Image storage capacity up to 150,000 images with compression (B/W and color)

DVD Multi-Drive (DVD±R/RW & CD/RW)
• Removable 4.7 GB single layer DVD
• Removable 650 MB, 700 MB and 790 MB CD-R and 650 MB or 700 MB CD-RW
• Allows storage and archiving of complete patient studies including images, dynamic clips, reports and measurements
• Storage capacity dependent upon patient study size
• Export of images in TIFF, JPG or DICOM format, clips in AVI or DICOM format and reports in PDF format
• Export of summary reports in PDF and RTF format
• DICOM viewer for export of DICOM format to CD/DVD
• DICOM viewer is Vista compatible

Transducer Ports
• Up to 3 active universal transducer ports that support phased array, curved array and linear array transducers (optional third array port)
• Electronic transducer selection (instantaneous switching between transducers)
• Industrial design provides easy access to the transducer ports

Transducer Storage
• (4) configurable transducer holders support all transducer designs and provide gel bottle storage
• SuppleFlex™ transducer cables and integrated cable management for protection during exams and transport
Transmit frequencies: Up to 7 frequencies
- 2D and M-mode: Up to 3 frequencies
- THI: Up to 2 frequencies
- Color, power, or pulsed wave Doppler: Up to 2 frequencies

Focusing
- Transmit focal zone: Up to 4 zones
- Digital dynamic receive focusing with dynamic apodization

Synthetic Aperture
- Synthetic Aperture technology is available on the CH5-2 and VF10-5 transducers for higher image resolution at depth
- User can turn Synthetic Aperture On and Off

2D Image Processing
- All-digital parallel signal processing with frame rates up to 498 F/sec (transducer dependent)
- MultiHertz imaging: Up to 5 user-selectable transmit frequencies, when optional THI is included
- Res/Speed: 6 selections
- Persistence: 5 levels
- Edge enhancement: 4 levels
- Display dynamic range: 30 – 70 dB in 5 dB increments
- Gain: 0 – 60 dB in 1 dB increments
- Depth Gain Compensation: 8 controls
- Gray maps: 9 maps
- 2D colorization maps: 16 maps

2D Image Display
- Full screen, Split, Quad and Dual Select screen formats
- L/R flip and U/D flip for all formats in real-time and digital cine replay
- Image depth: 3 – 28 cm in 1.0 cm increments (transducer dependent)

System Review
- (4) multi-directional swivel wheels for easy mobility
- (4) swivel locking brakes (one for each wheel)

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

OPERATING/DISPLAY MODES
- 2D imaging in fundamental and harmonic modes
- M-mode
- Color Doppler Velocity mode
- Power Doppler mode
- Pulsed Wave (PW) spectral Doppler mode
- Duplex mode
- Triplex mode
- 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 or 2D/color with M-mode and/or spectral Doppler mode: top-bottom or side-by-side in real-time and digital cine replay
- Virtual Format

MultiHertz Multiple Frequency Imaging
Siemens’ unique MultiHertz™ multiple frequency imaging is designed to combine the resolution and penetration of several transducers in one. At the push of a button, the user can independently change frequencies for 2D, THI (optional), color and spectral Doppler to select the optimal combination for image resolution, penetration and sensitivity.

- Special transducer holder provides secure storage and easy access to endocavity transducer
- Transducer holders can be removed for cleaning
• Virtual Format Imaging
  - Left/Right steer
  - Trapezoid Imaging
• Digital read/write zoom with image pan
  - Available on live and cine replay images
  - Up to 10x zoom (transducer dependent)
• 90° image rotation on orthopedic of the VF10-5 transducer

2D Calipers – Generic Measurements and Calculations
• Multiple cursor sets on frozen, live, dual screen and cine playback images
• Distance measurements: Up to 8 measurements per screen
• Distance, depth from skin line
• Angle measurement
• Area and circumference: ellipse, trace
• Compound Measurements:
  - Volume: user-selectable preset by 1 distance, 2 distance, 3 distance; 1 ellipse and 1 distance
  - Flow volume: 1 velocity and 1 distance, or 1 velocity and 1 ellipse
  - Stenosis: user-selectable preset calculated by 2 ellipse, or 2 distance measurements

Pulsed Wave (PW) Spectral Doppler
• Available on all imaging array transducers
• Transmit frequencies: Up to 2 frequencies per transducer
• Sweep speed: 5 selections
• Post-processing gray maps: 8 maps
• Doppler colorization maps: 12 maps
• Gain: 0 – 90 dB in 1 dB increments
• PRF range: 100 – 19,500 Hz
• Velocity scale range: ±350 cm/sec with 0° angle correction
• Angle correction: 0 - 89° in 1° increments
• Gate size: 1.0 – 20 mm

• Wall filter: 8 selections (transducer dependent)
• Baseline shift: 17 levels
• Spectral invert
• Autotrace function

Spectral Doppler Display
• Full screen Doppler trace, 2D/Doppler mode, triplex or update 2D/C/Doppler
• (4) imaging display formats – top-bottom: 1/3-2/3, 1/2-1/2, 2/3-1/3; 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
• Autotrace measurements and calculations including PS, ED, TAMx, TAMn, PI, RI and S/D
• Resistive Index (RI)
• Pulsatility Index (PI), including Peak-to-Peak method
• Time Average Velocity (TAV) max
• Systolic/Diastolic (S/D) ratio
• 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
• Multi-Beam Formation technology provides parallel signal processing for high color Doppler frame rates (transducer dependent)
• Left/right steer on all linear transducers
• Advanced processing in color mode resulting in excellent spatial resolution and superior flash suppression
• Transmit frequencies: Up to 2 frequencies per transducer
• Color velocity: Up to 8 maps (6 velocity and 2 velocity/variance)
• Velocity scale range: ±0.6 ~ ±150.4 cm/sec
• PRF scale range: 100 – 19,500Hz (transducer dependent)
• Gain: -20 – 20 dB in 1 dB increments
• Color line density: 6 selections
• Wall filter: 4 selections
• Color smoothing: 4 levels
• Tissue/color priority: 5 selections
• Color persistence: 5 levels
• Color invert

Power Doppler Imaging
• Available on all imaging array transducers
• Left/right steer on all linear array transducers
• Up to two user-selectable transmit frequencies per transducer
• Power Doppler: 8 maps
• PRF scale range: 100 Hz – 19,500 Hz (transducer dependent)
• Gain: -20 – 20 dB in 1 dB increments
• Color line density: 6 selections
• Wall filter: 4 selections

Color and Power Doppler Display
• 2D/C mode, Split 2D-2D/C mode
• Dual real-time 2D/C mode
• 2D/C/D mode (simultaneous triplex), 2D/C/D mode (update)

M-mode
• Available on all imaging array transducers
• Transmit frequencies: Up to 3 frequencies, including fundamental and harmonics
• Edge enhancement: 4 selections
• Display dynamic range: 30 – 70 dB in 5 dB increments
• Gain: 0 – 60 dB in 1 dB increments
• Gray maps: 7 maps
• M-mode colorization: 16 maps
• Sweep speed: 5 selections

M-mode Image Display
• Full screen M-mode, 2D/M-mode
• (4) imaging display formats – top-bottom: 1/3-2/3, 1/2-1/2, 2/3-1/3; side-by-side: 40-60

M-mode Calipers – Generic Measurements and Calculations
• Multiple cursor sets on frozen and cine playback images
• Distance
• Time
• Slope
• Heart rate
FREEZE, CINE CLIP FUNCTIONS

Cine Store
- Multiple frame storage with clipboard review allowing post-processing, measurement and annotation functions
- Prospective clip capture during real-time imaging in two compression rates up to 120 sec or 3600 frames

Cine Review
Cine feature is standard and 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 is up to 2729 frames
- Up to 30 seconds Doppler cine, or up to 16 seconds M-mode cine

Post Processing Features in Freeze Frame
- 2D-mode
  - Zoom/pan
  - Gray map
  - 2D-mode colorization map
  - Measurements/reports/annotations/pictograms
- Color Doppler
  - Zoom/pan
  - Color map
  - Color invert
  - Measurements/reports/annotations/pictograms
- Spectral Doppler
  - Gray map
  - Doppler colorization map
- Angle correct
- Measurements/reports/annotations/pictograms
- M-mode
  - Gray map
  - M-mode colorization map
  - 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 user-selection of independent 2D and color frequencies for optimal resolution and penetration
- Reusable, stainless steel and disposable biopsy guides for specified linear and curved array transducers
- Innovative ultra low-loss lens materials and microelectronic technologies for efficient performance and increased signal bandwidth
- Frequency range: 2.0 – 13.0 MHz
- Hanafy lens acoustic technology
- microCase™ transducer miniaturization technology and SuppleFlex cables

Note: See dedicated transducer flyer for more information.

APPLICATIONS

The ACUSON X150 system is designed to support a wide range of general and specialty imaging applications. Factory-supplied exam and transducer dependent imaging presets have been carefully
EXAM-SPECIFIC MEASUREMENTS AND CALCULATIONS

All measurement and report packages are available for use with all exam types.

All exam specific measurement and reports support:

- All general measurements and calculations
- Comprehensive, customizable, patient reports and worksheets
- Customizable Anatomy Descriptions
- Physician summary utility – supports on-system report generation including customizable letterhead, patient data, results, graphs, images, comments, recommendations and a customizable signature line.

The following Measurements and Reports packages are available on the ACUSON X150 system:

**Abdomen**

**Renal**

**Obstetrics**
- Early Obstetrics Menstrual Age (MA) measurements are MSD, CRL and Yolk Sac
- Menstrual Age parameter labels are MSD, CRL, BPD, OFD, HC, AC, ATD, ASD, FL, HL, UL, TL, FT, FTA, and BN
- (10) user-defined labels are available in 2D-mode
- Calculations include: EFW from the selected reference, Williams EFW%, HC/AC, TCD/AC, LVW/HW, CorBPD, FL/AC, FL/BPD, CI, AFI, AXT and Fetal Heart Rate
- Fronto Maxillary Facial Angle
- Customizable anatomy descriptors
- Calculations for both Gestational Age (GA) and ultrasound menstrual age and Estimated Date of Confinement (EDC)
- 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
- Multiple fetus reporting capabilities
- Growth Analysis Graphs with exam file linking
- Obstetric patient report and worksheet including Fetal Heart report page

**Gynecology**
- Micturated and residual volume calculation
- Uterus, right and left ovary measurements, including ovarian volume
- Easily track 15 right follicles and 15 left follicles, including follicular volume
- Gynecology volumes automatically populate to the report
- DICOM SR for Gynecology (GYN)
- Gynecology patient report

**Cardiac**
- Volume formulas for Left Ventricular function assessment in 2D-mode and M-mode
- 2D-mode, M-mode and Doppler calculations
DIGITAL PATIENT STUDY STORAGE AND ARCHIVING

The DIMAQ-IP integrated workstation allows for digital acquisition, storage and review of complete ultrasound studies, including static images as well as measurements, calculations and reports. Reports can be customized by editing content, logo, order, format as well as allows for adding up to four images into the summary reports.

Supports compatibility with Telexy Q-path* Ultrasound Workflow Manager for point-of-care reporting, quality assurance, billing, research, teaching and credentialing.

Patient Study Management

Playback of digitally stored images in a selectable 1-up, 4-up, 9-up, 16-up or 25-up screen format. The patient study screen allows searching, selecting and deleting studies, and exporting studies to CD-R/W, DVD±R/RW, DVR and USB 2.0.

- 100 GB of 160 GB internal hard drive reserved for patient data management
- Compatible with removable 650 MB, 700 MB, and 790 MB CD-R and 650 MB or 700 MB CD-RW

*Mixed text

- M-mode slope, heart rate, time and distance measurements
- Doppler acceleration, trace, heart rate, time and velocity measurements
- Cardiac patient report and worksheet for 2D-mode, M-mode and Doppler
- AO/LA or LA/AO calculation

Cerebrovascular (C-Vas)
- CCA, ICA1, ICA2, ICA3, ECA, and VA measurements
- Area Percent Stenosis and Diameter Percent Stenosis measurements
- Cerebrovascular patient report

Peripheral Vascular (P-Vas)
- Right and left extremity measurements
- Peripheral vascular patient report

Venous
- Right and left extremity measurements
- Venous patient report

Testes

Thyroid
- Thyroid volume
- Nodules
- Thyroid report

Urology
- Penile Doppler package available on VF13-5 and VF10-5 transducers
- Residual volume calculations
- Prostate and urology patient report

Orthopedic
- Right and left hip angle measurement
- Hip calculation package
- Classification and Graf Sonometer
- Hip angle patient report

*Software sold separately by Telexy Healthcare and requires a wireless or LAN connection.
Cardiac Screening
Software installable license to enable phased array imaging capabilities for adult and pediatric cardiac screening with the P4-2 and P8-4 transducers (Requires Color Imaging Option).

Phase Inversion Tissue Harmonic Imaging (THI)
THI with selectable frequencies increases success with difficult-to-image patients, improving diagnostic confidence. Dramatically improves contrast and spatial resolution by reducing noise and clutter in the image.

- MultiHertz imaging capability in THI
- Available on the CH5-2, P8-4, P4-2, VF10-5 and VF13-5 transducers

DICOM 3.0 Connectivity
Enables digital data transfer via a DICOM network for both printing and storage. The ACUSON X150 system acts as a DICOM Storage Class User and DICOM Print Class User.

Functionality supported:
- Connectivity to PACS system for storage of all digital images and dynamic clips with patient demographic data
- In-Progress Store during the exam
- Image printing to DICOM color and grayscale printers
- DICOM Storage Commitment
- DICOM Exchange Media export to DVD±R/RW and CD-R/W
- DICOM Region Calibration

DICOM Modality Worklist
Enables query and direct download of the patient worklist schedule from the Hospital/Radiology Information System (HIS/RIS) to the ACUSON X150 system, automatically populating the "New Patient" screen with patient demographic information (requires DICOM 3.0 Connectivity option).

OPTIONS

Color Imaging
Software installable license to enable color and power Doppler imaging capabilities.

- Compatible with removable 4.7 GB single layer ± DVD
- Hard drive capacity:
  - Approximately 150,000 B/W and color images
  - Approximately 40,960 two-second clips
  - Storage and retrieval of frozen static images
  - Storage and retrieval of reports
  - Instant dial-in and replay of static images in 1-up screen format
- Supports Measurements and Calculations on current, as well as on saved and retrieved images
- Acoustic clip capture from cine review
- Prospective clip capture during real-time imaging with a selectable duration of 1, 2, 3, 4, 8, 60 or 120 seconds
- Export of patient studies from hard drive to DVD±R/RW, CD-R/W drives or external drive using USB 2.0. Studies can be individually selected.
- Studies can also be exported to an external memory drive using USB 2.0 (S/N > 330000
- The system supports the following data export file formats RTF, PDF, TIFF, AVI, JPG and DICOM. Connectivity to PACS, other off-line storage (such as USB flash drive) or EMR device is achieved via LAN or WLAN connection.
- Clips are exported in AVI format or DICOM format
- Reports are exported in PDF format
- M-mode Still Frame Scroll and Store
- PW spectral Doppler Still Frame Scroll and Store
- Patient database sorting by Name, ID, Study Date and Exam type
DICOM–Modality Performed Procedure Step (MPPS)
Enables automatic exchange of “Modality Performed Procedure Step” information with the Hospital/Radiology Information System (HIS/RIS) (requires DICOM 3.0 Connectivity option and DICOM Modality Worklist option).

DICOM OB Structured Reporting (SR)
DICOM OB provides a standardized report architecture to allow for easy transfer of OB measurements to offline PCs, workstations and archiving systems. DICOM OB will automatically populate OB measurements to their respective fields in an external software package. (To send the DICOM OB SR data over network the DICOM 3.0 connectivity option is required).

TGO Tissue Grayscale Optimization Technology
TGO technology provides one-button image optimization. It automatically adjusts all imaging B-mode parameters to the tissue type being imaged. TGO technology improves the consistency and quality of ultrasound imaging to enhance productivity by removing time-consuming and operator dependent manual adjustments. TGO technology can be used with every transducer, for every exam type and at every imaging frequency, including THI.

3-Scape Real-Time 3D Imaging
3-Scape 3D imaging provides real-time reconstruction of 3D images during freehand acquisition.

Additional Array Port
The additional array port option adds a third active array port to the ACUSON X150 system and allows the user to connect up to three linear, curved and phased array transducers simultaneously. All linear, curved and phased array transducers offered on the ACUSON X150 system are compatible with the additional array port.

Barcode Reader
- Allows fast and accurate patient information data input
- Easy attachment to USB port
- Supports 2D and 1D patient barcode
- Inputs
  - Patient Name
  - Patient ID
  - Physician ID
- MOTOROLA Symbol DS6707-HD Barcode Reader

Wireless Data Transfer
Utilizes USB dongle to enable wireless connectivity between the ultrasound system and the facility’s LAN to provide functionality equivalent to a wired network.

The Wireless Option supports connectivity with:
- DICOM services - Modality worklist, print, storage commitment and store
- Telexy Q-view*

Technical Specifications
- Standards : IEEE 802.11n, 802.11g, 802.11b, 802.11a
- Security features: WEP, WPA, WPA2 personal, WPA and WPA2 Enterprise

Ultrasound System Security – Virus Protection
Embedded virus protection solution that protects the system against advanced persistent threats, viruses, malware and other executing software by detecting and preventing any unwanted change to improve IT compliance and security.

*Sold separately by Telexy Healthcare and requires a wireless or LAN connection.
**DOCUMENTATION DEVICES**

**Optional On-Board Video Devices**
- Up to two (B/W printer & color printer/VCR) documentation devices can be integrated into the system cart and controlled from the system control panel
  - Supported devices:
    - Mitsubishi P95 USB B/W Printer
    - SONY UP-D897 USB B/W Printer
    - Mitsubishi CP900UM Color Printer (NTSC)
    - Mitsubishi CP900E Color Printer (PAL)
    - USB Inkjet Printer
    - Mitsubishi MD3000UM S-VHS VCR (NTSC)
    - Mitsubishi MD3000E S-VHS VCR (PAL)
    - JVC BD-X201MS DVR

**SYSTEM DIMENSIONS**
- System height: 135 cm (53.15 in) – 156 cm (61.42 in) - upright FPD
- Width: 89 cm (35 in) – when the monitor is fully extended to the left or right
- Depth: 85 cm (33.5 in)
- Weight: 90 kg (198.4 lbs)
- User-select monitor height adjustment
  - Monitor lowest position: 135 cm (53.1 in) - measured to top of monitor
  - Monitor highest position: 156 cm (61.4 in) - measured to top of monitor

**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), RCA jack type

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

**Other Input/Output**
- (1) Foot switch connector, phone jack-type
- (1) Remote control connector, mini jack (stereo)
ELECTRICAL/ENVIRONMENTAL SPECIFICATIONS

The ACUSON X150 system is available in one mainframe configuration, suitable for use in 100/115V and 230V environments.

- Power connections:
  - 100-120/200-240 VAC, 50/60Hz
- Built-in AC isolation transformer
- Power consumption: maximum 600VA with OEM's
- Atmospheric pressure range: 700 – 1060 hPa (525 – 795 mm Hg) or up to 3050 m (10,000 ft)
- Ambient temperature range (without OEM's): +10° – +40° C (50° – 104° F)
- Humidity: 30 – 80%, non-condensing, during operation
- Maximum heat output: 2150 BTU/hr

STANDARDS COMPLIANCE

The ACUSON X150 system meets the requirements of the Medical Device Directive and carries the CE Mark.

Quality Standards
FDA QSR 21 CFR Part 820
ISO 9001
ISO 13485

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)
EN 60601-2-18 and IEC 6061-2-18
EN 60601-2-25 and IEC 6061-2-25
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
- IEC 61157 (Declaration of Acoustic Power

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 put on the market according to the above reference Council Directive. Unauthorized changes to this product are not covered by the CE marking and the related Declaration of Conformity.

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