EDANUSA

Acclarix AX2/AX3 Series Diagnostic Ultrasound System Datasheet

Product Description

The remarkable Acclarix AX2/AX3 series Compact Ultrasound System delivers a powerhouse combination of features to meet the demands of point of care and general imaging applications.

The Acclarix AX2/AX3 series has been designed from the ground up with a relentless focus on delivering unexpected levels of innovation and performance at a price point that is equally surprising. One active transducer port design enables switching transducer seamlessly at a finger tip Dual batteries extend the imaging scanning. Extremely light body embodied with brand new EIS operating system empowers smooth system operation and fast system response.

Advanced Technique and Features

- TAI Tissue Adaptive Imaging
- eSRI Adaptive Speckle Reduction Imaging
- Frequency Compounding Imaging
- Adaptive Spatial Compounding Imaging
- Harmonic Imaging
- B mode Auto Optimization
- Digital Multi-Beam forming
- Trapezoid Imaging
- Adaptive Doppler imaging
- Spectrum Enhancement
- B Steer
- Digital Zoom
- Auto Doppler trace

System Overview

System Architecture

Physical Channels: 64
Beam Forming: Quad beam
Processor: ARM
Memory: 2 GB
Hard Drive: 120G SSD
Operating System: Android
System Boot-up: About 30s
Boot-up from sleep: 5s
Shutdown: 3s

Dimensions and Weight

Dimension: 375 mm×380 mm×58 mm
Net Weight (No Battery): 4.2kg (1 transducer port)
Net Weight (1 battery): 4.65 kg (1 transducer port)

Monitor

- 15.6'' high resolution LCD monitor
- Resolution: 1920 x 1080
- Image Size: 1040 780
- Open angle: 0° - 180°
- Magnetic latch closure
- Built-in stereo speaker
- Brightness and Contrast adjustable

Transducer Port

- One active transducer port
- Single transducer port configurable

Battery

- Rechargeable
- Max. two batteries configurable
- 5000mAh capacity for each battery
- Removable
- Approximately 1 hour of typical ultrasound exam use for one fully charged battery.
- Approximately 2 hours of typical ultrasound exam use for two fully charged batteries.
- Standby time: > 4 hours (two batteries)
- One battery fully charged in about 2.5 hours
- Two batteries fully charged in about 5 hours
- Battery indicator on the console near the handle
- Battery level icon displayed on the main screen

AC Power Requirements

Voltage: 100-240 V~
Frequency: 50Hz/60 Hz

Environment Requirements

Operating Environment

Ambient temperature: 0° to 40°C
Relative Humidity: 15%~95% (no condensing)
Atmospheric pressure: 86kPa-106kPa

Storage Environment

Ambient temperature: -20° to 55°C
Relative Humidity: 15%~95% (no condensing)
Atmospheric pressure: 70kPa-106kPa

Language Supported

• English
• Chinese

I/O Ports

• S-Video
• USB 3.0
• HDMI
• Ethernet

Options

• Transducers
• Needle Guide Bracket Kits
• Printers
• Battery
• USB Disk
• WiFi
• Footswitch
- Single button/Double buttons
- User-defined Functions (Freeze, Save, Print)
• Simple Cart: MT-808
- Height Variable
- A drawer for glossary storage
- A shelf for Video printer
- 4 transducer holders and 2 gel holders with removable silicon cover
- Cable manager
- Drawer height and position adjustable
• Suitcase

System Ergonomic Design

Handle

Provides wrist support during imaging

Magnesium alloy body

Extremely light weight realizes the true portability.

User Interface

Control Panel

• Interactive back-lighting
• Hard Keys provides tactile feedback
• User-defined keys

Touch Screen

• 10.1” Touch screen
• Gesture-control
• Virtual TGC sliders
• Support QWERTY keyboard for text input
• Brightness adjustable

Main Screen Display

Information Field

- EDAN logo
- Hospital name
- Date
- Time
- Patient ID
- Patient Name
- Patient Gender
- Patient Age
- Transducer model
- Exam Preset

Image Field

- Mechanical Index (MI)
- Thermal Index (TI)
- Imaging parameters
- Gray Scale bar
- Depth Scale
- Center Mark
- Measured result window
- TGC curve

Mini Report

- Measurement and calculation results
- Measurement and calculation results for multiple fetus

Thumbnail Field

- All captured static images and cline clips
- Shortcut keys for selecting, viewing, deleting, exporting images.

User Feedback Field

- Illustration of trackball and trackball keys
- Cine bar
- Exit icon for exiting RawData review status

Status Bar

- Utility Icon (access to Utilities function)
- Image Store Icon
- USB Icon
- Printer Icon
- WiFi Icon
- Network Transfer Status Icon
- Hard Drive Icon
- Battery Icon

Exam Presets

- System pre-defined exam presets include (Transducer specific):
- ABD
- Abd Difficult
- Aorta
- Lung
- FAST
- Early OB
- OB
- Fetal Echo
- GYN
- IVF
- Urology
- Prostate
- Thyroid
- Breast
- Testis
- Carotid
- Up Ext A (Upper Extremity Artery)
- Up Ext V (Upper Extremity Vein)
- Low Ext A (Lower Extremity Artery)
- Low Ext V (Lower Extremity Vein)
- Vascular Access
- Spine
- MSK
- Sup MSK (Superficial MSK)
- Nerve
- Sup Nerve (superficial Nerve)
- Shoulder
- Adult Cardiac
- Pediatric Cardiac
- TCD
- User customizable presets: Copy, Delete, Save as and rename
- Exam presets are configurable in Set-up
- Supports a second page, up to 30 presets per transducer
- Each preset can share comment, body mark, and measure presets

Annotations

Comments

- User-programmable home position
- Arrow with user controlled orientation
- QWERTY keyboard
- Block move and delete for separate blocks of text
- Smart text replacement for predefined text (e.g., Log replaces Trans with one keystroke)
- 310 pre-defined comments
- User customizable

Body Mark

- Up to 100 Body Mark graphics in library

Imaging

Imaging Modes

B-mode
M-mode
Color Doppler
PDI/DPDI
PW Doppler
CW Doppler

Display Modes: Dual Imaging

- Available for B and Color (PDI/DPDI) mode.
- Displays two image side-by-side, two frozen or one active/one frozen.
- Allows to switch between two images

Imaging Mode Combinations

- B+M
- B/C (PDI or DPDI), Single
- B/C (PDI or DPDI), Dual
- B+B/C (PDI or DPDI), Dual live
- B+PW (Duplex)
- B+PW (Update)
- B/C (PDI or DPDI)+PW (Triplex)
- B/C (PDI or DPDI)+PW (Update)
- B+CW (Update)
- B/C (PDI or DPDI)+CW (Update)

Imaging Parameters

B-mode (Live imaging)

Image Type	Detail/General/Penetration
Auto	TGC, Gain
Digital Zoom	x0.8-x2.0, x0.5-x16.0 (Tender)
Display Depth	1-45cm
Frequency	1-17MHz, 1-19 MHz (Tender) 3 fundamental +2 harmonic 5 fundamental +5 harmonic (tender)
eSRI	Off, Low, Med, High
FOV	Small, Med, Large, Full
Steer	0°,±10°
Gain	0-100dB 0-260dB (tender)
TCG	8 segments
Dynamic Range	40-96dB 20-320 dB (tender)
Line Density	Low, Med, High
Max. Frame Rate	551f/s, depends on transducer
Map	11 Types 20 Types (tender)
Persistence	Off, Low, Med, High
Focus Position	Max. 16 positions, adjustable
Focus Number	1-3, adjustable 1-4, adjustable
Colorize	On, Off
Tint	5 Types 20 Types (tender)
Up/Down Flip	
Left/Right Flip	
Spatial Compounding	On, Off (max 3 angles)
Trapezoid	On, Off
Acoustic Power	10%-100%

B-mode (Post-processing & retrospective)

- Gain
- TGC
- Zoom
- Dynamic Range
- eSRI
- Colorize
- Map
- Up/Down Flip
- Left/Right Flip

M-mode (Live imaging)

Sweep Speed	Fast/High/Med/Low/Slow Corresponds to sweep time of 1s, 2s, 4s, 8s, and 12s per screen respectively.
Line Persist	Off, Low, Med, High
Map	11 Types
Colorize	On, off
Tint	5 Types 20 Types (tender)
Gain	0-100dB 0-260dB (tender)
Frequency	1-17 MHz 1-19 MHz (tender) 3 fundamental+2 harmonic 5 fundamental+5 harmonic (tender)
Dynamic Range	40-96 dB 20-320 dB (tender)
Strip size	Full, large, Med., small
Side-by-side	On (Left/Right) Off (Up/Down)
Acoustic Power	10%-100%

M-mode (Post-processing & retrospective)

- Gain
- TGC
- Dynamic Range
- Colorize
- Map
- Stripe Size
- Side-by-side

Color/PDI/DPDI Mode (Live imaging)

Image Type	HighFlow/MidFlow/LowFlow
Dual Live	
ROI size/position	
Frequency	2 levels 5 levels (tender)
Gain	0-100dB
Line Density	Low, Med, High
Dynamic Range	10-70 dB Not available for Color mode
Max. Frame Rate	257f/s, depends on transducer
Persistence	Off, Low, Med, High
Smooth	Off, Low, Med, High
Wall Filter	Low, Med, High
Color Map	8 Types 20 Types (tender)
Steer Angle	0°±10°, ±20° (L12-5Q, General) 0°±15°, ±30° (L12-5Q, thyroid) 0°,±5°, ±10° (L17, 7Q) 0°,±10°,±20° (L17-7HQ)
PRF	0.6-11.4kHz
Baseline	25 levels (Not available for PDI mode)
Threshold	0-100
Invert	On, Off (Not available for PDI mode)
Acoustic Power	10%-100%

Color/PDI-DPDI Mode (Post-Processing & Retrospective)

- Zoom
- Color map
- Invert (Not available for PDI mode)
- Baseline

PW-mode (Live imaging)

Image Type	HighFlow/MidFlow/LowFlow
HPRF	Automatic invocation to maintain gate location/scale
Auto Trace	
Trace Side	Up, down, both
Duplex	
Triplex	
Frequency	2 levels 5 levels (tender)
PRF	0.9-14.7kHz
Gain	0-100dB
Dynamic Range	10-70 dB
Wall Filter	Low, Med, High
Sweep Speed	Fast/High/Med/Low/Slow Corresponds to sweep time of 2s, 3s, 4s, 6s and 8s per screen respectively.
Baseline	9 levels
Angle Correction	-80° to 80°
Quick Angle	-60°/0°/60°
Steer	0°,±10°,±20° (L12-5Q) 0°,±5°,±10° (L17-7Q) 0°,±10°,±20° (L17-7HQ)
Invert	
Volume	0-99
Map	11 Types
Colorize	On, Off
Tint	5 Types 20 Types (tender)
Gate Size	0.5-20 mm
Strip size	Full, Large, Med., Small
Acoustic Power	10%-100%

PW Mode (Post Processing & Retrospective)

- Gain
- Dynamic Range
- Colorize
- MAP
- Baseline
- Angle Correct
- Invert
- Strip size
- Auto trace
- Trace side

CW-mode (Live imaging)

Image Type	HighFlow/MidFlow/LowFlow
PRF	1-100 kHz
Gain	0-100dB
Dynamic Range	10-70 dB
Wall Filter	Low, Med, High
Sweep Speed	Fast, High, Med., Low, Slow Corresponds to sweep time of 2s, 3s, 4s, 6s and 8s per screen respectively.
Baseline	9 levels
Angle Correction	-80° to 80°
Quick Angle	-60°/0°/60°
Invert	
Volume	0-99
Map	11 Types
Colorize	On, Off
Tint	5 Types 20 Types (tender)
Strip Size	Full, Large, Med., Small
Acoustic Power	10%-100%

CW Mode (Post Processing & Retrospective)

- Gain
- Dynamic Range
- Colorize
- Map
- Baseline
- Angle Correct
- Invert
- Strip Size

Review and Post Processing functions

Cine Review

- Frame by frame manual review
- Auto playback with 6 level speed adjustable
- Start frame and end frame are selectable for cine loop review
- Independent cine review in Dual mode.
- Maximum cine memory depends on transducers and image parameters:

- 200000 frames for B mode
- 35000 frames for Color mode
- 180s for M mode
- 240s for PW/CW Doppler mode

Post-Processing Features

All the image/cine are stored in Raw Data format in local disk. The following Post Processing features are available when in image/cine review of current exam or the stored exam.

- Adjusting imaging parameters
- Storing static image/ cine loop

Transducers and Biopsy Guide

Transducer Applications

Transducer		Applications
C5-2Q		Abdomen Fetal / Obstetrics Urology Gynecology Musculoskeletal
L12-5Q		Small parts Peripheral Vascular Musculoskeletal
L17-7Q		Small Parts Peripheral Vascular Musculoskeletal

Transducer		Applications
E8-4Q		Fetal / Obstetrics Gynecology Transvaginal Transrectal Urology
P5-1Q		Adult Cardiac Abdomen Pediatric Cardiac Adult Cephalic
L17-7HQ		Small Parts Peripheral Vascular Musculoskeletal

Transducer	C5-2Q	P5-1Q	L12-5Q	E8-4Q	L17-7Q	L17-7HQ*
Transducer Type	Convex	Phased	Linear	Endocavity	Linear	Linear
Bandwidth @-20dB	1-7MHz	1-5MHz	3-13MHz	3-12MHz	4-19MHz	4-19MHz
Bandwidth @-6dB	2-5MHz	1-5MHz	5-12MHz	4-8MHz	7-17MHz	7-17MHz
Elements	128	64	128	128	128	192
Footprint	NA	16mm	38mm	NA	38mm	38mm
Convex Radius	60mm	NA	NA	10mm	NA	NA
FOV	60°	90°	NA	150°	NA	NA
Display Depth	45cm	30cm	11cm	14cm	11cm	11cm
Max. PW Velocity(±60°)	9m/s	10m/s	4.7m/s	5m/s	3.2m/s	3.2m/s
Max. CW Velocity(±60°)	NA	75m/s	NA	NA	NA	NA
Biopsy Guide	Yes	No	Yes	Yes	Yes	No
Cable Length	2m	2m	2m	2m	2m	2m

Biopsy Guide

Needle Guide

- Supports guide lines of multiple angles.
- Support guide line calibration.

Center Line

- Center Line is a vertical dotted line displayed at the middle of the image field, representing the middle of ultrasound beam It helps to locate the position and depth of a target disease focus for out of plane biopsy, lithotripsy and etc.

Supported Needle Guided Brackets

Model	Angle/Depth	Description
BGK-C5-2	20°, 28°, 40°	For use with the C5-2Q, Supports: 14G-23G
BGK-L40UB	34°, 43°, 53°, 66°	For use with the L17-7Q , Supports: 14G-23G
BGK-001	1.0cm, 1.5cm, 2.0cm	For use with the L17-7Q , Supports: 21G
BGK-002	38°, 46°, 58°	For use with the L12-5Q, Supports: 14G-23G
BGK-003	1.0cm, 1.5cm, 2.0cm	For use with the L12-5Q, Supports: 21G
BGK-CR10UA	2°	For use with the E8-4Q, Supports: 16G, 18G
BGK-008	12°, 22°	For use with the P5-1Q, Supports: 14G-23G

Measurements

• Default measurement unit options
- Distance: mm, or cm
- Area: mm2, or cm2
- Volume: mm3, or cm3
• Caliper Size: switch automatically according to the distance (3 sizes)
• Dynamic display of measurement results
• Reposition caliper

General Measurements

B-mode

• Distance
• Circumference/Area (Ellipse, Trace)
• Angle
• Volume
• Stenosis
- %Dist Stenosis (Distance)
- %Area Stenosis (Ellipse, Trace)

M-mode

• Caliper
- Distance
- Time
- Slope
• HR

Doppler mode

• Caliper: V1, V2, Acceleration, Time, RI, S/D, ΔV, PG1, PG2, PHT
• Trace: PS, ED, MD, RI, PI, S/D, Time, TAMax, VTI, AT, DT, PGmax, PGmean
• Auto Trace: PS, ED, MD, RI, PI, S/D, HR, Time, TAMax, TAMean, VTI, AT, DT, PGmax, PGmean
• HR: HR
• RI: PS, ED, RI, S/D
• TEI: (only available for Cardiac preset)
• dp/dt: (only available for Cardiac preset)

Application Measurements/calculations Abdomen

B-mode:

• Liver
- Length, Width, Height
- Volume (calculation)
- Portal Vein Diameter
- Common Hepatic Duct

• Gallbladder
- Length, Height
- Gallbladder Wall Thickness
- Common Bile Duct

• Pancreas
- Head, Body, Tail, Duct

• Spleen
- Length, Height

• Renal
- Length, Width, Height
- Volume (calculation)
- Renal Cortex Thickness

• Aorta Diameter

PW mode:

• Abdominal Aorta
• Superior Mesenteric Artery
• Inferior Mesenteric Artery
• Hepatic Artery
• Splenic Artery
• Renal Artery
• Portal Vein
• Inferior Vena Cava
• Main Portal Vein
• Hepatic Vein
• Middle Hepatic Vein
• Splenic Vein
• Superior Mesenteric Vein
• Inferior Mesenteric Vein

Gynecology

B-mode:

• Uterus
- Length, Width, Height
- Endometrium Thickness
- UT Cavity
- UT-L/CX-L(calculation)

• Cervix
- Length, Width, Height
- UT-L/CX-L(calculation)

• Ovary
- Length, Width, Height

• Follicle
- D1, D2, D3
- Follicle-Mean

• Cyst
- D1, D2, D3

• Fluid POD

PW mode:

• Uterine Artery
• Ovary Artery

Obstetrics

• Early OB
B-mode: GS, YS, CRL, NT, BPD, FL, HUM, AF.
M-mode: FHR
PW mode: Ductus Venosus, Ovary Artery, Uterine Artery

• OB
B-mode: NF, BPD, OFD, HC, AC, FL, TAD, APAD, CER, HUM, ULNA, RAD, TIB, FIB, APTD, TTD, FTA, THD, Foot, AF, AFI.
M-mode: FHR
PW mode: MCA, Umbilical Artery, Placenta Artery, Ductus Venosus, FHR

• Fetal Echo
B-mode: RV Diam, RA Diam, RVOT Diam, LV Diam, LA Diam, LVOT Diam, Ao Asc, Ao Arch Diam, Ao Isthmus, Desc Aorta, MPA Diam, Ductus A, CTAR
PW mode: FHR, MCA, Umb. Artery, Planenta Artery, Ductus Venosus, MV, TV, MPV, Ovary Artery, Uterine Artery, Fetal Aorta, Desc Aorta, Ductus A

• Gestational Age
• Fetal Growth
• Estimated Fetal Weight (EFW)
• Multi-gestational Measurement

Cardiac

B-mode
• LV Simpson: A4C Dias., A4C Sys., A2C Dias., A2C Sys., SV, EF, CO, SI, CI
• Vent. Dim: RVAWd, RVIDd, IVSTd, LVIDd, LVPWd, IVSTs, LVIDs, LVPWs
(Calculations: SV, EF, FS, CO, SI, CI)
• Ao Asc
• RVOT Diam
• LVOT Diam
• HR
• PV Diam
• RVDs
• RA: Length, Width
• LA: Length, Width
• AoD

M-mode
• Vent. Dim
• LVET
• MV: E-F Slope, EPSS
• LA/AO: LA, AoD, PVOT Diam

PW mode
• MV: E/A, MV PHT, MV Trace, IVRT, MV, A Dur, MV DecT
• TV: TV trace, TV Max
• AoV: LVOT Trace, LVOT Vmax, AoV Trace, AoVVmax
• PV: PV trace, PV Max
• Pulmonic Vein: PVein S Vel, PVein D Vel, PV A Vel

Urology

B-mode:

· Renal
- Length, Width, Height
- Renal Cortex Thickness

· Bladder
- Pre-void Bladder
  (Length, Width, Height, Volume)
- Post-void Bladder
  (Length, Width, Height, Volume)

· Prostate
- Length, Width, Height

· Seminal
- Length, Width, Height

· Testis
- Length, Width, Height

PW mode:

· Renal Artery
· Arcuate Artery
· Segmental Artery
· Interlobar Artery

Small Parts

B-mode:

· Thyroid
- Length, Width, Height
- Thyroid Isthmus

· Breast
- Lesion1, Lesion2, Lesion3, Lesion4, Lesion5

· Testis
- Length, Width, Height

PW mode:

· Superior Thyroid Artery
· Inferior Thyroid Artery

Vascular

B-mode:

· Carotid
- Common Carotid Artery Intima-Media Thickness, Internal Carotid Artery Intima-Media Thickness, Carotid Artery Bifurcation Intima-Media Thickness

PW-mode:

- Common Carotid Artery, External Carotid Artery, Internal Carotid Artery, Vert Artery, Subclavian Artery, HR

PW-mode:

· Upper Extremity Artery
- Subclavian Artery, Axillary Artery, Brachial Artery, Ulnar Artery, Radial Artery, HR

PW-mode:

· Upper Extremity Vein
- Subclavian Vein, Axillary Vein, Brachial Vein, Cephalic Vein, Basilic Vein, Ulnar Vein, Radial Vein, Median Cubital Vein

PW-mode:

· Lower Extremity Artery
- Common Femoral Artery, Deep Femoral Artery, Superficial Femoral Artery, Common Lliac Artery, External Llic Artery, Internal Lliac Artery, Popliteal Artery, Peroneal Artery, Posterior Tibial Artery, Anterior Tibial Artery, Dorsalis Pedis Artery, HR

PW-mode:

· Lower Extremity Vein
- Common Femoral Vein, Deep Femoral Vein, Superficial Femoral Vein, Common Lliac Vein, External Lliac Vein, Internal Lliac Vein, Great Saphenous Vein, Popliteal Vein, Peroneal Vein, Posterior Tibial Vein, Anterior Tibial Vein, Small Saphenous Vein

PW-mode:

• Cephalic
- Anterior Cerebral Artery, Middle Cerebral Artery, Posterior Cerebral Artery, Anterior Communicating Artery, Posterior Communicating Artery, Basilar Artery, Vertebral Artery, Internal Carotid Artery

B-mode:

• Volume Flow
- Volume Flow Area

PW mode:

- TAMean, Volume Flow (Calcu.)

Image Storage & Exam Archiving

Image Storage:

• Static image/Cine clip is stored in local disk in RawData format.
• Two dedicated hard keys on the console for capturing static image and cine clips respectively.
• Cine clips supports prospective and retrospective storing.
• The length of cine clip is configurable.
• Prospective storing: max. 2 min length of clip can be stored in real-time scanning.
• Retrospective storing: all the clip data in the cine buffer can be stored in cine review mode, max. 6 min (tender).
• Supports up to 30,000 lossless single frames
• Supports cine clips of:
- Up to 200,000 frames for B mode
- Up to 35,000 frames for Color mode
- Up to 180s for M
- Up to 240s for PW/CW mode

Exam Database

• Support exam storage without patient info.
• Support exam query
• Support review current exam or prior exam
• Support review images of an exam
• Support export images as BMP, Raw Data or DICOM format
• Support export cine clip as Raw Data format
• Support export exams (including patient info. and images)

Exam Archiving

All clips and Static images stored on the system are stored internally in Raw Data format. They can be archived to other storage device for long-term storage as described below.

- Archived to DICOM server in DICOM format. (Archiving Clip to DICOM server is not available currently)
- Archived to USB device in either DICOM, Raw Data or .bmp format.

Connectivity

Network:

• Wired network connection
• Wi-Fi connection

DICOM 3.0 Service

• DICOM Storage
- Connectivity to DICOM server for storage of all static image with patient information.
- Manual-Transfer in background on demand.
- Transfer management UI for viewing transfer task status.

• DICOM Modality Worklist
- Enables query of the patient worklist schedule from hospital information system to the ultrasound system via DICOM network connection
- Query of worklist on demand or on start of exam.
- Populates with Patient Information screen with patient demographic information automatically when one patient is selected.

Supported Peripherals

Printers:

• Video printers
- SONY UP-X898MD
- SONY UP-D25MD
- SONY UP-25MD

• Graph/text printer
- HP OfficeJet Pro 251dw
- HP LaserJet Pro 200 M251n
- HP LaserJet CP1525n Color
- HP DeskJet Ink Advantage 2010
- HP DeskJet 1010 Color
- HP DeskJet 1510 Color
- HP DeskJet Pro 400
- HP DeskJet Pro M401d
- Canon PIXMA E518
- Canon iP2780
- HP DeskJet 2029
- HP DeskJet 1112
- EPSON L310
- HP DeskJet 1050
- HP DeskJet 2050
- HP DeskJet M252n
- EPSON L130

Safety and Regulatory

The Acclarix AX2/AX3 series Diagnostic Ultrasound System have been designed, manufactured and tested to comply with the following internationally recognized standards:

- IEC 60601-1: Medical Equipment Safety
- IEC 60601-1-2: Medical Device Electromagnetic Safety
- IEC 60601-2-37: Ultrasonic Medical Equipment Safety
- IEC 62133: Battery Safety
- IEC 62304: Medical Device Software Life-cycle Process
- IEC 62366: Medical Device Usability Engineering
- EN ISO 14971: Medical Device Risk Management
- ISO 10993: Medical Device Biocompatibility
- NEMA UD2: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment