



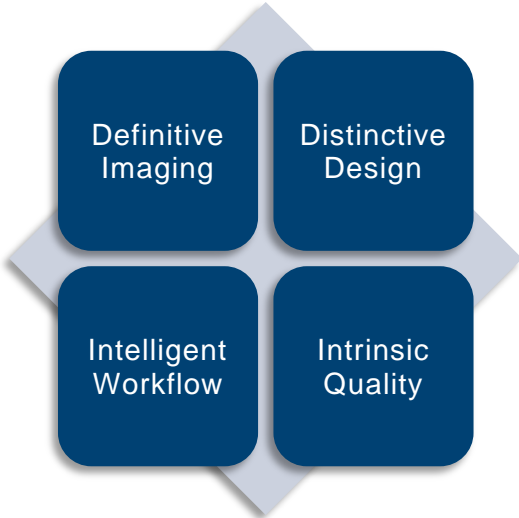
Acclarix™ AX8

Compact Ultrasound System

System Specifications

The Acclarix™ AX8 Compact Ultrasound System redefines innovation through value and performance. Its sleek footprint contains a fully featured, diagnostic ultrasound platform with advanced imaging modes, dual touch screens, a gesture-control user interface and a full suite of next-generation transducers.

The remarkable Acclarix AX8 Compact Ultrasound System delivers a powerhouse combination of features to meet the demands of point-of-care and general imaging applications. The Acclarix AX8 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.





A Clear Vision

Born of a vision to deliver meaningful design innovations that benefit the user, the Acclarix AX8 features a host of design breakthroughs that make day-to-day operation easy, fast and intuitive.



The sleek, compact design of the AX8 System facilitates maneuverability and portability

SYSTEM ARCHITECTURE

- 128 channels, transmit and receive
- Quad beam
- i7 processor with quad virtual cores
- 16Gb memory
- 500Gb hard drive storage

SYSTEM DESIGN

- Dimensions: W 38.8cm, D 40.7cm, H 7.7cm
- Weight: 9.25kg (includes battery)
- 15" main screen with HD resolution (1920 x 1080)
 - 120° tilt
 - 60° left or right swivel
- 10.1" gesture-control user interface touch screen
- 5" touch screen houses electronic virtual trackball
- Magnetic monitor latch for secure transport
- Integrated carrying handle also provides wrist support during imaging
- Removable lithium ion battery provides approximately 60 minutes of typical ultrasound exam use
- Touch sensor battery level indicator in two locations
- Completely sealed control panel aids in maintaining infection control
- Multi-transducer connector (option)
 - Provides simultaneous connection for up to three transducers
 - Integrates onto system cart or use stand-alone

B-MODE IMAGING

- Tissue Adaptive Imaging: continuous and automatic optimization including: dynamic range, speckle reduction, spatial compounding and persistence
- Enhanced border detection algorithms
- One-key auto optimization

- Digital zoom with five levels
- Frequency range: Up to three fundamental and two harmonic frequencies per transducer
- Depth: up to 30cm
- Frequency compounding
- Spatial compounding
- Speckle reduction with four levels
- Imaging formats
 - Curved
 - Linear
 - Phased array
 - Trapezoid
 - FOV for increased frame rate
 - Up/Down, Left/Right invert
 - Linear steered
 - Dual
- Additional optimization parameters
 - Gain, TGC, dynamic range (40-96 dB), frame rate, map, tint, persistence, focus position and number
- Cine loop storage: up to 12,285 frames

COLOR DOPPLER

- Adaptive Doppler Imaging automatically and continuously adapts to the flow state to optimize color fill-in, boundary detection and hemodynamic display
- Supported modes:
 - Velocity
 - Power Doppler Imaging (PDI)
 - Directional PDI (DPDI)
- Side-by-side live format B-mode/color Doppler
- Additional optimization parameters
 - Gain, dynamic range (10-70 dB), frame rate, frequency, persistence, smoothing, wall filter, map, steer angle, scale, invert, baseline, threshold

SPECTRAL DOPPLER

- Adaptive PW and CW spectral Doppler:
automatically and continuously adapts to flow state to optimize spectral display
- One-key access to either PW or CW
- HPRF
 - Automatic invocation as needed to maintain gate location/scale
- Auto Doppler measurements
 - User selectable sensitivity and direction
- Duplex and Triplex displays
- Additional optimization parameters
 - Scale, gain, dynamic range (10-70 dB), wall filter, sweep speed, baseline, angle, steer, invert, volume, map, tint, frequency, gate size
- Display formats: 1/3 image-2/3 spectral, 1/2 image-1/2 spectral, 2/3 image-1/3 spectral, full screen Doppler trace

M-MODE

- Optimization parameters, independent M-mode:
 - Sweep speed, persist, map, tint, dynamic range
- Optimization parameters, shared with B-mode:
 - Gain and frequency
- Display formats: 1/3 image-2/3 trace, 1/2 image-1/2 trace, 2/3 image-1/3 trace, full screen trace, side-by-side

ADVANCED FEATURES

- Panorama
 - Available on all linear array transducers
- Auto IMT*
 - CCA, ICA, Bifurcation
- Needle Visualization
 - Improved needle visualization – even at steep angles
 - Available on linear array transducers

USER INTERFACE

- Touch screen has three levels of access and drag-and-drop functionality for quick customization
 - Core functionality on one page
 - Swipe between pages for second tier controls
 - User created folders store infrequently used controls
- Track pad houses electronic virtual trackball
 - Gesture driven UI
 - Swipe to change gain, scroll cine, etc.
- Hard key access to core controls
 - Provides tactile feedback and landmarks for eyes-up navigation
 - Two programmable hard keys for direct access to most frequently used features
 - Sealed for easy cleaning

- Languages: English, Chinese, German, Italian, French, Turkish, Russian
 - Keyboard support: most European character sets

CONNECTIVITY

- DICOM
 - Verify SCP
 - Static image store SCU
 - Ultrasound multi-image store SCU
 - Four levels of compression
 - Data transfer options
 - Removable media
 - In-progress network storage
 - Auto-store at exam end
 - Manual-store on demand
- 4 USB ports (2 USB 2.0; 2 USB 3.0).
- Export: DICOM studies, AVI and BMP files, PDF report
- Video out: Display port and S-video
- Ethernet (wired RJ45)

CART SPECIFICATIONS (OPTIONAL)

- Snap-in mechanism anchors laptop into the cart
- Height-adjustable cart with 9" of travel
 - Palm rest to floor distance ranges 31" - 40"
- Fixed deck angle of 15°
- Built-in tray houses printer and other incidentals
- Power converter housing under tray

ENVIRONMENTAL OPERATING REQUIREMENTS

- Ambient temperature: 0° to 40°C
- Relative Humidity: 15%~80% (no condensation)
- Atmospheric pressure: 700hPa-1060hPa
- 110V-240V power supply

PRESETS

- Transducer specific presets
- One-key Quick-Set optimization, all imaging modes
- User customizable presets: Update, Copy, Delete
- Each preset can share annotation, body mark, and measure presets

ANNOTATION AND BODY MARKS

- Annotate live or frozen images
- User-programmable home position
- Multiple arrows with user controlled size and orientation
- Soft keyboard with full support for diacritic characters
- Block move and delete for separate blocks of text
- Smart text replacement for pre-defined text (e.g., *Long* replaces *Trans* with one keystroke)

ANNOTATION AND BODY MARKS

(continued)

- User customizable, pre-defined comment presets:
 - Abdomen
 - Breast
 - Cardiac
 - Carotid
 - Gynecology
 - Hand-wrist
 - Knee
 - Upper and Lower Extremity Vascular
 - Nerve
 - Obstetrics
 - Pediatrics
 - Shoulder
 - Testis
 - Thyroid
 - Urology
- User customizable, pre-defined Body Mark presets:
 - Abdomen
 - Breast
 - Cardiac
 - Carotid
 - Gynecology
 - Nerve/MSK
 - OB and OB first trimester
 - Testis
 - Thyroid
 - Vascular
 - Urology

MEASUREMENTS AND REPORTS

- Predefined measurement packages with dedicated report. (Detailed contents in Appendix)
 - OB and OB first trimester
 - Gynecology
 - Breast
 - Abdomen
 - Carotid
 - Fetal Echo
 - Thyroid
 - Cardiac
 - Urology (includes Renal, Testis and Prostate)
 - Lower extremity arteries/veins
 - Upper extremity arteries/veins
- Generic measurements, up to 5 simultaneous tools
- Application specific results from generic tools:
 - B-mode: distance, area or circumference (ellipse or trace), angle, volume, stenosis
 - Doppler: V1, V2, time, accel, HR, PS, ED, MD, RI, PI, S/D, HR, time, TAMx, TAMn, max PG, mean PG, VTI
 - M-mode: distance, time, slope, HR



Unique, user-customizable dual touch screens streamline procedure workflow by letting you decide which functions are most important.

Transducers and Applications

The Acclarix AX8 System boasts a new generation of transducers that span point-of-care and general imaging applications. All transducers feature multiple, selectable fundamental and harmonic frequencies to provide exquisite sensitivity, excellent detail and contrast resolution, and image uniformity throughout the field of view so you can appreciate even the smallest details.



The new high density, high channel count transducers of the Acclarix AX8 system.

Transducer Name	Imaging Format	Footprint or Radius	Fundamental Frequency Range	Harmonic Frequency Range	Applications Supported
C5-2XQ	Curved linear array	60 mm	2-5 MHz	H2-5 MHz	Abdomen, OB, Gynecology, Spine, Nerve, MSK
C5-2Q*	Curved linear array	60 mm	2-5 MHz	H2-5 MHz	Abdomen, OB, Gynecology, Spine, Nerve, MSK
MC8-4Q*	Micro-convex array	15 mm	4-8 MHz	H4-8 MHz	Neonatal head and Abdomen, Pediatric Abdomen, Nerve, Vascular
L12-5Q*	Linear array	38 mm	5-11 MHz	H6-12 MHz	Small parts, MSK, Nerve, Vascular
L10-4Q	Linear array	38 mm	4-9 MHz	H5-10 MHz	Small parts, MSK, Nerve, Vascular
L17-7HQ	High frequency linear	38 mm	7-15 MHz	H9-17 MHz	Small Parts, MSK, Nerve, Vascular
E8-4Q	Endocavity tightly curved array	10 mm	4-8 MHz	H5-8 MHz	OB, Gynecology, Prostate, Endovaginal, Endorectal
P5-1XQ	Phased array	16 mm	1-5 MHz	H2-5 MHz	Adult and Pediatric Cardiac screening, Abdomen
L17-7SQ	High-frequency compact linear array	26 mm	7-15 MHz	H9 -17 MHz	MSK, Nerve, Vascular, Intraoperative

* Requires regulatory clearance

APPENDIX: Measurement and Report Detail

Package	B-mode	M-mode	Doppler
OB PACKAGE <ul style="list-style-type: none"> Multiple fetuses (up to four) Growth Curves 	<ul style="list-style-type: none"> BPD OFD HC AC FL TAD APAD CER HUM RAD TIB FIB APTD TTD FTA THD NF ULNA Foot AF AFI (Q1, Q2, Q3, Q4) EFW 	<ul style="list-style-type: none"> Fetal heart rate 	<ul style="list-style-type: none"> Middle cerebral artery* Umbilical artery* Placenta artery* Ductus venosus Fetal heart rate
OB FIRST TRIMESTER PACKAGE	<ul style="list-style-type: none"> GS YS CRL NT BPD FL HUM AF 	<ul style="list-style-type: none"> Fetal heart rate 	<ul style="list-style-type: none"> Ovarian artery* Uterine artery* Ductus venosus Fetal heart rate
GYNECOLOGY PACKAGE <ul style="list-style-type: none"> Multiple follicles (up to four) 	<ul style="list-style-type: none"> Uterus length Uterus width Uterus height Uterus volume Endometrium thickness Cervix Uterus length/cervix Ovary length Ovary width Ovary height Ovary volume Follicle length Follicle width Follicle height Follicle volume 		<ul style="list-style-type: none"> Ovarian artery* Uterine artery* HR
BREAST PACKAGE <ul style="list-style-type: none"> Left and right breast (up to five each) 	<ul style="list-style-type: none"> Breast lesion 1 Breast lesion 2 Breast lesion 3 Breast lesion 4 Breast lesion 5 		

APPENDIX: Measurement and Report Detail *(continued)*

Package	B-mode	M-mode	Doppler
ABDOMEN PACKAGE	<ul style="list-style-type: none"> • Liver length • Liver width • Liver height • Portal vein • Common hepatic duct • Gallbladder length • Gallbladder height • Gallbladder wall thickness • Common bile duct • Pancreatic body • Pancreatic duct • Pancreatic head • Pancreatic tail • Spleen length • Spleen height • Renal length • Renal width • Renal height • Renal volume • Renal cortex thickness • Aorta diameter 		<ul style="list-style-type: none"> • Abdominal aorta* • Inferior mesenteric artery* • Superior mesenteric artery* • Hepatic artery* • Splenic artery* • Renal artery* • Portal vein • Inferior vena cava • Main portal vein • Hepatic vein • Middle hepatic vein • Splenic vein • Inferior mesenteric vein • Superior mesenteric vein • HR
FETAL ECHO PACKAGE	<ul style="list-style-type: none"> • RV diameter • RA diameter • RVOT diameter • LV diameter • LA diameter • LVOT diameter • Ascending aorta diameter • Aorta arch diameter • Aorta isthmus diameter • Descending aorta diameter • Main PA diameter • Ductus arteriosus diameter • Cardiothoracic area ratio 		<ul style="list-style-type: none"> • Main PA diameter • Ductus arteriosus diameter • Cardiothoracic area ratio • Fetal aorta* • Descending aorta* • Mitral valve • Tricuspid valve • Main pulmonary vein • Uterine artery* • Ovarian artery* • Fetal heart rate • Ductus venosus • Middle Cerebral Artery • Umbilical artery • Placental artery
CAROTID DOPPLER PACKAGE	<ul style="list-style-type: none"> • Auto IMT • -CCA, ICA, Bifurcation • -Left, Right • -Far, Near • -Proximal, Mid, Distal 		<ul style="list-style-type: none"> • Common carotid artery* • External carotid artery* • Internal carotid artery* • Vertebral artery* • Subclavian artery* • HR
THYROID PACKAGE	<ul style="list-style-type: none"> • Thyroid length • Thyroid width • Thyroid height • Thyroid volume • Isthmus 		<ul style="list-style-type: none"> • Superior thyroid artery* • Inferior thyroid artery* • HR

APPENDIX: Measurement and Report Detail *(continued)*

Package	B-mode	M-mode	Doppler
CARDIAC PACKAGE	<ul style="list-style-type: none"> • IVSTd • LVIDd • LVPWd • IVSTs • LVIDs • LVPWs • PV diameter • RVDd • RVDs • RA length • RA width • LA length • LA width • Ascending aorta diameter • Aortic root diameter • LVOT diameter • RVOT diameter • RVW 	<ul style="list-style-type: none"> • IVSTd • LVIDd • LVPWd • IVSTs • LVIDs • LVPWs • EDV • ESV • SV • CO • EF • SI • CI • MVCF • FS • LVET • MV E-F slope • MV EPSS • LAD • AoD • RVOT diameter • LAD/AoD • HR 	<ul style="list-style-type: none"> • MV E/A • MV PHT • MV trace • IVRT • MV A Dur • MV DecT • Vel • TV trace • TR Vmax • LVOT trace • LVOT Vmax • AoV trace • AoV Vmax • PV trace • PV Vmax • PVein S Vel • PVein D Vel • PVein S/D • PV A Vel • HR
	<p>UROLOGY</p> <p>Includes:</p> <ul style="list-style-type: none"> • Renal • Prostate • Testis <ul style="list-style-type: none"> - right and left labels 	<ul style="list-style-type: none"> • Renal cortex thickness • Pre-void and post-void bladder: <ul style="list-style-type: none"> - Length - Width - Height - Volume • Micturated volume • Renal, prostate and testis: <ul style="list-style-type: none"> - Length - Width - Height - Volume • Seminal length • Seminal width • Seminal height 	<ul style="list-style-type: none"> • Renal artery* • Segmental artery* • Interlobar artery* • Arcuate artery* • HR
UPPER EXTREMITY ARTERY PACKAGE			<ul style="list-style-type: none"> • Subclavian artery* • Axillary artery* • Brachial artery* • Ulnar artery* • Radial artery* • HR

APPENDIX: Measurement and Report Detail *(continued)*

Package	B-mode	M-mode	Doppler
UPPER EXTREMITY VEIN PACKAGE			<ul style="list-style-type: none"> • Axillary vein • Basilic vein • Brachial vein • Cephalic vein • Subclavian vein • Ulnar vein • Radial vein • Median cubital vein
LOWER EXTREMITY ARTERY PACKAGE			<ul style="list-style-type: none"> • Common femoral artery* • Deep femoral artery* • Superficial femoral artery* • Common iliac artery* • External iliac artery* • Internal iliac artery* • Popliteal artery* • Peroneal artery* • Posterior tibial artery* • Anterior tibial artery* • Dorsalis pedis artery* • HR
LOWER EXTREMITY VEIN PACKAGE			<ul style="list-style-type: none"> • Common femoral vein • Deep femoral vein • Superficial femoral vein • Common iliac vein • External iliac vein • Internal iliac vein • Great saphenous vein • Popliteal vein • Peroneal vein • Posterior tibial vein • Anterior tibial vein • Small saphenous vein

**These measurements can be done with calipers, trace or Auto trace; depending on the tool, the following may be provided: PS, ED, MD, RI, S/D, TAMax, TAMean, PI, HR.*

REGULATORY APPROVALS

FDA Class II Device

CE/MDD Class IIa

IEC 60601-1: Medical Equipment Safety

IEC 60601-1-2: Medical Device Electromagnetic Safety

IEC 60601-2-37: Ultrasonic Medical Equipment Safety

IEC 60601-1-6: Medical Equipment Usability 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 UD 2: Output Measurement for Diagnostic Ultrasound Equipment

NEMA UD 3: Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment