

V.A MEDICAL CENTER
5406 E. EL CAMPO GRANDE AVE
SUITE 150
LAS VEGAS, NV 89115

PO# 593-B30015

Configuration - Included Items

Item - Description	Qty
<p>1 -SonoSite EDGE</p> <p>SonoSite EDGE high-resolution, all-digital, 8.5-pound (3.85 kg) ultrasound system with 12.1in. LED display. This product is designed with SonoSite's proprietary Chip Fusion Technology that integrates digital signal processing and multiple system functions into a custom application-specific integrated circuit (ASIC) microchip. As a result complex system functions that typically require several large circuit boards can be accomplished using a small chip in a compact space. SonoSite EDGE high-resolution, all-digital, 8.5-pound (3.85 kg) ultrasound system with 12.1in. LED display. This product is designed with SonoSite's proprietary Chip Fusion Technology that integrates digital signal processing and multiple system functions into a custom application-specific integrated circuit (ASIC).</p> <p>The purchase of the EDGE visualization tool includes the following software technologies:</p> <ul style="list-style-type: none">- 2D grayscale with SonoMB Multi Beam Technology- Auto Gain with SonoADAPT Tissue Optimization Technology- M-Mode- Clips Storage- Application specific calculation packages <p>The EDGE combines the high performance of cart-based systems with the speed, flexibility and durability of hand-carried ultrasound. 8 GB of on-board Flash memory will retain enough data for over 40 standard exams (or 2,400 seconds of clips, 1,200 still frames and 40 report pages) even after power is turned off. The system supports USB media playback, and connectivity is accomplished through one of two USB slots on the system, which allow for direct sharing of images (JPEG) and Clips (MPEG4) to a PC or Mac. Additional connectivity is achieved via the EDGE Mini-Dock, to meet your specific needs. The system supports a HIPAA compliance tool set for the protection of sensitive information and PC direct connectivity capability (through USB Memory Stick or via SiteLink and USB Cable ordered separately).</p> <p>EDGE's reliability and durability are backed by a five-year standard warranty, which is included in the price of the system. Software upgrades to the main system and transducer databases are accomplished through one of two USB ports on the system. Also includes battery, ultrasound gel, and user guide on a CD (Printed user guides also available as a purchasable option).</p> <p>Additional features available to add to the Edge system include: SonoMBe, PW Doppler, TDI PW, CW Doppler, DICOM, Worksheets, and a full array of multi-frequency, broadband transducers.</p> <p>Included with the purchase of your SonoSite EDGE, you will receive the system battery, ultrasound gel, a user guide CD.</p>	<p>1</p>

Item	Description	Qty
2	<p>-Color Application Software Package Edge</p> <p>This package provides the following capabilities for the transducers that support these features:</p> <ul style="list-style-type: none"> - Tissue Harmonic Imaging (THI), a capability in which the system transmits at one frequency and receives at a higher harmonic frequency to reduce noise and clutter and improve resolution. - SonoHD Imaging Technology, technology which significantly reduces speckle noise while enhancing tissue margins, thereby dramatically improving contrast and structural resolution. - Velocity color flow imaging provides the clinician with the color sensitivity to perform color Doppler examinations with all transducers during a clinical procedure. - PW Doppler is available on all transducers. - CW Doppler is a quantitative assessment of blood flow with Duplex imaging for higher flow velocities. 	1
3	<p>-SonoMBe, EDGE</p> <p>Proprietary software that enhances the systems ability to aid needle visualization.</p>	1
4	<p>-ICTx / 8-5 MHZ Transducer Biopsy Compatible</p> <p>ICTx / 8-5 MHz intracavity curved array broadband 11mm transducer for intracavity gynecologic and obstetrical exams. Supports 2D with SonoMB Multi Beam Technology and Auto Gain capabilities, SonoHD Imaging Technology, M-mode, Color Power Doppler, Velocity Color Flow Doppler and Pulsed Wave Doppler. Biopsy guide available. Maximum depth is 10</p>	1
5	<p>-L25X / 13-6 MHZ Transducer Transverse Biopsy Compatible</p> <p>L25x / 13-6 MHz multi-frequency, broadband, 25 mm linear array transducer for nerve, vascular, venous, ophthalmic, musculoskeletal, and superficial exams. Supports 2D with SonoMB Multi Beam Technology and Auto Gain capabilities, SonoHD Imaging Technology, M-mode, Color Power Doppler, Velocity Color Flow Doppler and Pulsed Wave Doppler. Transverse biopsy guide available. 1-meter drop-test durability.</p>	1
6	<p>-P21X / 5-1 MHZ Transducer Biopsy Compatible</p> <p>P21x / 5-1 MHz phased array transducer for cardiac, abdominal and obstetric, TCD and orbital exams. Supports 2D with SonoMB Multi Beam Technology and Auto Gain capabilities, SonoHD Imaging Technology, Tissue Harmonic Imaging, M-Mode, Velocity Color Flow Doppler, Color Power Doppler, Pulsed Wave, TDI Pulsed Wave, and Continuous Wave Doppler. 1 meter drop-test durability. Maximum depth</p>	1
7	<p>-EDGE Stand</p> <p>Ergonomic stand and mobile work platform for the EDGE system and transducers. Complete with power supply, mini-dock and accessory basket.</p> <p>OEM peripherals include: B/W or color printer. Unable to use together</p>	1
8	<p>-Powerpark System</p>	1

Item	Description	Qty
	PowerPark docking station for the Universal stand. This stand module and docking station allows the M-Turbo ultrasound systems to charge without plugging in the power cord. .	
9	-Power Pack The PowerPack is an external battery pack that mounts quickly and easily to the universal stand. The PowerPack extends the system battery life for performing more exams on a single charge.	1
10	-Triple Transducer Connect (TTC) w/ quick disconnect Three-transducer module for mobile docking system that allows connection of	1
11	-User Guide EDGE EDGE Ultrasound System User Guide, English	1
12	-Service Manual, Edge EDGE Ultrasound System Service Manual	1
13	-Service Manual, Edge EDGE Ultrasound System Service Manual	1
14	5-YR-WARRANTY -60 MONTHS - STANDARD COVERAGE WARRANTY 60 MONTHS - STANDARD COVERAGE WARRANTY	1



TAKE A CLOSER LOOK AT SONOSITE'S NEW EDGE ULTRASOUND SYSTEM

The Edge® ultrasound system is SonoSite's fifth generation of point-of-care ultrasound. The screen is noticeably larger so you can see the ultrasound image from across the patient or across the room. Enhanced image quality aids your diagnostic confidence. Rapid boot-up takes you from power-on to scanning in less than 20 seconds. A magnesium shell with a solid aluminum core drop-tested at 3 feet/91.4 cm helps to protect your investment for the long term. And a splash resistant silicone keyboard makes cleaning and disinfecting that much easier. With the Edge ultrasound system, you have access to a new generation of point-of-care visualization.

EDGE TECHNOLOGY FROM SONOSITE

SonoHDr Second Generation Imaging Technology — provides a new series of image enhancement algorithms that reduce speckle noise and image artifacts to give the Edge ultrasound tool a new standard in

point-of-care visualization image quality

SonoADAPV Tissue Optimization — eliminating complicated manipulation of multiple controls.

SonoMB® Multi-beam Imaging — increasing resolution of small structures and enhancing border delineation.

Advanced Needle Visualization — aiding needle visualization while maintaining striking image quality of the target and surrounding anatomy.

ColorHD® Technology — increasing color performance, sensitivity and frame rates for more diagnostic information.

PONTOFCARE APPLCATIONS NCLUDE:

Anesthesia, Critical Care, Cardiology, Cardiovascular Disease Management, Emergency Medicine, Musculoskeletal, OB/Gyn, Radiology, Vascular, Surgery, Women's Health.

To learn more about our products contact us at 1 (877) 6578050 or visit www.sonosite.com/products/edge



EDGE®

DESIGNED FOR THE POINT OF CARE



12.1" 130.7 cm LCD monitor

Large clinical image area

PC- and Mac-friendly for effortless data management with 2 high-speed USB 2.0 ports

8.5 lbs. 13.85 kg with battery

Backlit keyboard

Splash-resistant keyboard for easy cleaning



MADE IN THE USA

Solid aluminum core

TECHNOLOGY DRIVEN
5-YEAR STANDARD WARRANTY

5 YEAR

unregistered intellectual property of SonoSite, Inc. a subsidiary of FUJIFILM.

MAIN FEATURES AT A GLANCE

- A new level of image quality
- Splash-resistant, sealed, silicone keyboard
- Solid aluminum core and magnesium shell provides maximum durability
- Less than 20 second boot-up
- Drop-tested at 3 feet/91.4 cm



o Outw...ry Or **FUJIFILM**

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INTRODUCING THE NEW EDGE® ULTRASOUND SYSTEM FROM SONOSITE

SYSTEM SPECIFICATIONS:

System weight	8.5 lbs./3.85 kg with battery
Dimensions	12.9" x 12.4" x 2.5" / 32.7 cm x 31.5 cm x 6.4 cm (L x W x H)
Display	12.1"/30.7 cm diagonal LCD (NTSC or PAL)
Architecture	All-digital broadband
Dynamic range	Up to 165 dB
Gray scale	256 shades
HIPAA compliance	Comprehensive tool set

- Dedicated AutoGain and exam keys to allow quick activation
- Color controls: size/position, angle, scale, baseline and invert

TRANSDUCERS:

Broadband/Mult if requ en cy:

- Linear Array, Curved Array, Phased Array, Multiplane TEE (U.S. only) and Micro-Convex

Single Frequency:

- Cardiac Static Pencil

IMAGING MODES AND PROCESSING:

Broadband, Multifrequency Imaging:

- 2D / Tissue Harmonic Imaging / M-Mode
- Velocity Color Doppler / Color Power Doppler
- PW, PW Tissue Doppler and CW
- Doppler angle, correct after Freeze

Image processing:

- SonoADAPP Tissue Optimization
- SonoHDr Imaging Technology
- Advanced Needle Visualization
- Dual Imaging, Duplex Imaging, 2x pan/zoom capability, Dynamic range and gain
- ColorHr Technology

USER INTERFACE AND REMAPPABLE CONTROLS:

- Soft keys to drive advanced features
- Programmable A and B keys: each can be assigned by the user for increased ease of use
- Silicone splash resistant sealed QWERTY keyboard
- Track pad with select key for easy operation and navigation
- Doppler controls: angle, steer, scale, baseline, gain and volume
- Image acquisition keys: review, report, Clip Store, save

APPLICATION SPECIFIC CALCULATIONS:

OB/Gyn/Fertility: Diameter/ellipse measurements, volume, ten follicle measurements, estimated fetal weight, established due date, gestational age, last menstrual period, growth charts, user-defined tables, multiple user-selectable authors, ratios, amniotic fluid index, patient report, humerus and tibia measurement and charts

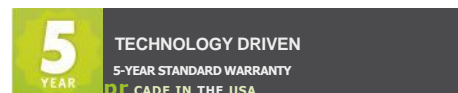
Vascular: Diameter/ellipse/trace measurements, volume, volume flow, percent diameter and area reduction, Lt/Rt CCA, ICA, ECA, ICA/CCA ratio, time average mean (TAM), peak trace, ICA/CCA ratio, angle correction, patient report

CIMT (Carotid Intima Media Thickness):

Embedded SonoCalc® IMT software (optional) - automatic edge detection with mean and maximum thickness reporting

Cardiac: Automated Cardiac Output package and patient report including: ventricular, aortic and atrial measurements; ejection fraction, volume measurements, Simpson's rule, continuity equation, pressure half-time and cardiac output; PA AT, TV E, A, PHT, TVI, MV time, Pulm Veins

Transcranial Doppler (TCD): Complete TCD package including Time Average Peak (TAP)





ONBOARD IMAGE AND CLIP STORAGE/REVIEW:

- 8GB internal Flash memory storage capability
- Potential to store 30,000 images or 960 2-second clips
- Clip Store capability (maximum single clip length: 60 seconds)
- Clip Store capability via either number of heart cycles (using the ECG) or time base. Maximum storage in ECG beats mode is 10 heart cycles. Maximum storage in time base mode is 60 seconds
- Cine review up to 255 frame-by-frame images

MEASUREMENT TOOLS, PICTOGRAMS AND ANNOTATIONS:

2D: Distance calipers, ellipse and manual trace
Doppler: Velocity measurements, pressure half time, auto and manual trace

M-Mode: Distance and time measurements, heart rate calculation

User-selectable text and pictograms
User-defined, application-specific annotations
Biopsy guidelines

EXTERNAL DATA MANAGEMENT AND WIRELESS:

- SonoSite Workflow Solutions (SWV): Streamlines exam management for billing, credentialing, archive & EMR Integration
- PC/Mac export configuration
- Export BMP, JPEG or DICOM images to a USB device
- Storage capacity alert if internal storage memory is less than 10%

DURABILITY:

Droptested at 3 feet/914 cm

CONNECTIVITY:

- S-video (in/out) to VCR for record and playback
- DVI output
- Composite video output (NTSC/PAL) to VCR or video printer
- Audio output
- Integrated speakers
- Ethernet or wireless image/data transfer
- USB ports (2)
- RS-232 transfer
- DICOM Image Management: Store, Print, Storage Commit, Modality Worklist, MPPS

POWER SUPPLY:

- System operates via battery or AC power
- Rechargeable lithium-ion battery
- AC: universal power adapter, 100-240 VAC, 50/60 Hz input, 15 VDC output
- Less than 20 sec. from power-on to scanning

EDGE STAND AND PERIPHERALS:

- Transducer and gel holders
- Optional Triple Transducer Connect (TTC) to quickly activate transducers electronically
- Optional foot switch

OPTIONAL PERIPHERALS:

Printers: Medical-grade black and white or color
External data input devices: Bar code reader
ECG module: 3-lead ECG — works with standard ECG leads and electrodes

External analog ECG input also available

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Bluetooth is a registered trademark of Bluetooth SIG, Inc.

Mac is a trademark of Apple Inc., registered in the U.S. and other countries.
DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.



A splash-resistant keyboard for easy cleaning and infection control.



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EDGE™

TRANSDUCERS



**READY FOR
A COMPLETE
RANGE OF
APPLICATIONS**



SonoSite designs, manufactures and tests transducers in-house with real-world customer needs in mind. Our transducers exceed stringent military specifications for drop testing so you can use them with confidence in the most demanding of environments. Maybe that's why SonoSite is the only ultrasound company to offer an industry leading 5-year warranty on the transducers it manufactures.











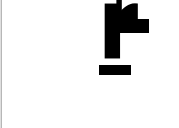
5 YEAR

TECHNOLOGY DRIVEN
5-YEAR STANDARD WARRANTY
MADE IN THE USA

EDGE

TRANSDUCERS

SonoSite

L38xi  10-15MHz Linear Applications: breast IMT musculoskeletal nerve small parts vascular venous Scan depth: 6 cm	HFL38x  13-16MHz Linear Applications: breast IMT musculoskeletal nerve small parts vascular venous Scan depth: 6cm	HFL50x  15-18MHz Linear Applications: breast musculoskeletal nerve small parts Scan depth: 6 cm	L25x  13-6MHz Linear Applications: musculoskeletal nerve superficial vascular venous ophthalmic Scan depth: 6cm	C8x  8-9MHz Curved Applications: prostate (trans) Scan depth: 11,5 cm	
D2x  7MHz Penetrating Applications: cardiology (CM) Scan depth: N/A	10-5MHz Linea  Applications: musculoskeletal ob vascular Scan depth: 15cm	C60x  5-12MHz Curved Applications: abdominal musculoskeletal nerve ob gyn Scan depth: 30 cm	ICTx  8-12MHz Linear Applications: ob gyn Scan depth: 13cm	5-1MHz Hand  Applications: abdominal cardiology ob orbital TCD Scan depth: 35 cm	11-5MHz Hand  Applications: ped. abdominal ped. cardiology neonatal head Scan depth: 14 cm

Needle guides and kits available with the following transducers - L38xi, HFL38x, HFL50x, C60x, ICTx, P21 x, C8x and L25x. A transverse needle guide is available with the L25x transducer.

For detailed information, please visit: www.sonosite.com/products/edge or speak with your SonoSite customer representative.

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Advanced Needle Visualisation Technology

Advanced Needle Visualisation, a proprietary and patented software algorithm from SonoSite, clearly enhances needle visualisation while maintaining striking image quality of the target and surrounding anatomy. Advanced Needle Visualisation (SonoMBe™ Imaging) is easy to use and requires no setup time, additional hardware, or expensive needles.

This guide provides practical tips on using this technology to fully optimise visualisation of the needle at various angles and depths.

To Get Started:

- In 2D imaging, select page 2 using the soft key menu.
- Select SonoMBe.
- Change LT/RT lip to align for the needle approach.
- Choose a Shallow, Medium, or Steep angle depending upon the depth of the target structure.
- place the target on the needle side of the angle guide (dotted green line).
- For best visualisation of the needle shaft and tip, insert the needle so that it is perpendicular to the angle guide.
- Use the area defined by the green line for maximum visibility of the needle, keeping the needle on the needle side of the angle guide.
- To return to 2D imaging only, select Off.

Advanced Needle Visualisation Technology



Note that the needle path is **perpendicular** to the angle guide and the target structure is inside the angle guide area.



Note **incorrect** placement of target structure outside the needle guide area. In this case the target structure should be positioned to the left of the dotted green.

Dr. David Auyong
Staff Anesthesiologist, Seattle, Washington

www.sonosite.com/needlevisualization

Universal Stand

The universal stand offers physicians a more ergonomic design with a lighter, more robust, and modular architecture. Ideal for point-of-care ultrasound applications, the universal stand can be easily maneuvered through crowded hospital corridors and optimally positioned at the patient's bedside or in other space-constrained areas. The H-Universal Stand and the V-Universal Stand's are compatible with our third and fourth generation products.

The universal stand can be upgraded to incorporate SonoSite Power Solutions (see reverse side) to offer the most flexible options to meet the challenges of point-of-care environments.

Features:

- Four transducer holders
- Cable hooks
- Locking wheels
- Storage basket
- Power supply
- Keyboard tray*

Peripherals (optional):**

- Sony B&W printer
- Sony color printer
- Sony DVD recorder
- 15 in. auxiliary monitor***
- Triple transducer connect***

Accessories:

- PowerPark—Dedicated charging station
- PowerPack—Extended battery pack

The H-Universal Stand can be configured with the M-Turbo® and MicroMaxx® ultrasound systems.

The V-Universal Stand can be configured with the S Series™ and NanoMaxx™ ultrasound systems.

*V-Universal Stand only

V-Universal Stand only accommodates one peripheral*H-Universal Stand only



Specifications		VUniversal Stand
Width:	20 in./50.8 cm	20 in./50.8 cm
Depth:	23 in./58.4 cm	23 in./58.4 cm
Height:	Min: 33 in./83.8cm. Max: 45 in./114.3 cm.	Min: 42.5 in./108 cm Max: 54.5 in./138.4 cm
Pneumatic height range:	12 in./30.5 cm	12 in./30.5 cm
Weight:	40.0 lbs./18.1 g	45.0 lbs./20.5 g

PowerPark Dedicated Charging Station

For true mobility to any point-of-care location around the hospital or office, the PowerPark is a cordless and convenient charging solution for SonoSite ultrasound systems. The PowerPark provides a dedicated charging station while the ultrasound system is mounted on the stand. Just park and charge.

- Increase workflow and efficiency—System remains fully-charged
- Provide storage—Dedicated storage location for stand and ultrasound system
- Facilitate cord management—No need for ultrasound system electrical cords

Width	8.6 in./21.8 cm
Length	15 in./38.1 cm
Height	4.8 in./12.2 cm
Weight	20 lbs./9 kg

Specifications:



t The PowerPark and PowerPack are compatible with SonoSite's H Universal Stand and V Universal Stand. The PowerPark can be used with the MicroMaxx, NanoMaxx, M Turbo and S Series ultrasound systems and the PowerPack is compatible with the M Turbo, S Series and NanoMaxx ultrasound systems.

tt Product release is expected Q4 2010.

PowerPack Extended Battery Pack

The ultimate power solution for hospital and office settings, SonoSite's PowerPack-F1 is an innovative and streamlined external battery pack. With the ability to double a system's battery life, the PowerPack provides improved flexibility and efficiency, enabling physicians to see more patients on a single battery charge. The PowerPack can be easily installed on the SonoSite universal stand for a ready-to-go charging solution.

- Improves flexibility and workflow
- Extends the operating time of the ultrasound system
- Reduces the need to seek a power supply outlet in the patient exam room

Specifications:

Width	4 in./10.2 cm
Length	10 in./25.4 cm
Height	2 in./5.1 cm
Weight	1.4 lbs./0.6 kg



SonoSite's ndustryleading Warranty

SonoSite's technology-driven, 5-year standard warranty covers damage to the system and SonoSite manufactured transducers due to defective materials, workmanship, and/or failure to operate in accordance with specifications in the User Guide. We will provide customers with loaner equipment of systems and transducers the next day where delivery is available. Additional coverage is available for purchase.



5-year warranty inclusions:

M-Turbo® and S Series— ultrasound systems. Transducers: C60x, HFL38x, L38xi, L25x, C11x, ICTx, P10x, P21x, HFL50xMicroMaxx® ultrasound system. Transducers: C60e, HFL38, L38e, P10, L25e, C11e, ICTe, P17
NanoMaxx— ultrasound system. Transducers: C60n, L38n, L25n, C11n, P21n

Cost savings from SonoSite's 5Year Standard Warranty

Year	SonoSite's 5Year Standard Warranty	ndustry 1Year Standard Warranty*
1	\$0	\$0
2	\$0	\$4,000
3	\$0	\$4,000
4	\$0	\$4,000
5	\$0	\$4,000
Additional cost to customer	\$0	\$16,000

* Based on \$50,0 purchase price and annual service contract of 10% of purchase price.

Warranty for Accessories and OEM Transducers

SonoSite accessories, as well as products and accessories made by our manufacturing partners that carry the SonoSite label, are covered under a 1-year warranty that covers damage due to defective materials and workmanship, and/or failure of the accessoriesand transducers named below to operate in accordance with specifications in the User Guide.

1-year warranty inclusions:

Transducers: C8e, TOE/TEE, SLA, SLT, D2 (Cardiac static pencil)

Accessories: H-Universal™ Stand, V-Universal™ Stand, SonoRemote™ Control

Please see SonoSite's Terms and Conditions for detailed coverage information on SonoSite's warranty offerings. Terms may vary for veterinary products.

Call (877) 657-8050 to speak to a SonoSite representative to find out more about these options or to ask about the status of your warranty.



World leader and specialist in hand-carried ultrasound.

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www.sonosite.com/support/warranty.and.service





How can we offer the best warranty in the industry?



When you build very durable products, you can eliminate annual service contracts and offer a 5-year warranty to deliver the lowest cost of ownership in point-of-care medicine

SonoSite's hand-carried and mounted ultrasound systems are the toughest in the industry. Built to exceed military specifications, our systems and proprietary transducers withstand a 3-foot drop onto a hard surface and resist fluid contamination. In the unlikely event your system or transducer needs repair, we have an overnight loaner program to minimize downtime.

SonoSite's third and fourth generation ultrasound systems comes with the same industry-leading, 5-year warranty that you have come to expect from us. With an installed base of more than 50,000 systems worldwide, our technology-driven warranty is based on a proven record of reliability and durability—just one of the reasons customers give us a 99% satisfaction rating.

Visit www.sonosite.com/support/warranty-and-service or call (877) 657-8050 to speak with a customer service representative.



World leader and specialist in hand-carried ultrasound.

Medical Equipment Pre-Procurement Assessment
(to be completed by potential vendors)

Equipment Description: Hand Carried Ultrasound System

Vendor/Model: SonoSite, Inc - EDGE

Vendor Contact:

Requesting Clinical Service: Medical Equipment Configuration

(to be converted to a VA form)
Medical Equipment Configuration

- ☐ What OS does the system utilize? VxWorks, WinCE 6.0
- ☐ Can critical security patches be installed without prior vendor approval? ☐ YES ☒ NO
- ☐ Does the device incorporate a switch or hub into its design? ☐ YES ☐ NO
- ☐ Is the switch or hub required as part of the system configuration? ☐ YES [33
- ☐ Which Anti-virus software is approved by the device manufacturer? N/A
- ☐ If server based, does the system require a specific version of Java for proper client operation? N/A ☐ YES ☒ NO
- ☐ If server based, does the system utilize an ActiveX control for client interaction? N/A ☐ YES ☐ NO

Authentication and User Accounts

- ☐ Is an administrator or power user account required to operate the device? ☐ YES ☒ NO
- ☒ Is an administrator account required for service? ☐ YES ☒ NO
- ☐ Can the device be made to require user authentication? YES ☐
- ☐ Does user authentication support Strong Passwords? NO ☒ YES
- ☒ Does user authentication support password aging? ☐ NO
- ☐ Can the device be part of the facility's Windows domain? ☐ YES ☒ NO

Data Handling

- ☐ Will the medical device require data backups? ☐ YES ☒ NO
- ☐ Is ePHI stored only on a drive partition to assist with end of service media sanitization? N/A ☐ YES ☐ NO
- ☐ What ePHI data elements are stored on the device? N/A
- ☐ Can ePHI be stored directly to a network drive, rather than local (machine) storage? N/A ☐ YES ☐ NO

Networking

- ☐ What are the LAN/WAN bandwidth requirements for full connectivity/performance? 100
- ☐ What ports in the TCP/IP stack are utilized for network communication? 50100, 50200
- ☐ Can unutilized ports be closed without negatively impacting device operation? YES ☐
- ☐ Can the device support DHCP for network address configuration? NO
- ☐ How many IP addresses does the device require? 1 YES ☐
- ☐ Can the device operate properly without connection to the Internet? NO
- ☐ Can the target system be addressed via a fully qualified domain name (FQDN)?

Wireless

- ☒ Does the device utilize wireless communication? ☐ YES ☒ NO
- ☐ if so, what protocols are used?
- ☐ Is any ePHI transmitted via the wireless link? N/A ☐ YES ☐ NO
- ☐ Does the device support installation of FIPS 140-2 certified wireless security clients? N/A ☐ YES ☐ NO
- ☒ If so, which ones?

Integration with VA Health Care Information Systems

- ☐ Has the device been validated with VA's Clinical Procedures package? 0 YES 0 NO
- ☐ Has the device been validated with VA's Vista Imaging? IN PROCESS ☐ YES ☐ NO
- ☐ Does the device have a bi-directional HL7 interface? ☐ YES ☒ NO
- ☐ Provide a DICOM conformance statement. NO ☒ YES

Appendix A

Medical Equipment Pre-Implementation Worksheet

Equipment Description: Hand Carried Ultrasound System

Vendor/ Model: SonoSite, Inc - EDGE

Vendor Contact:

Requesting Clinical Service:

Medical Equipment Documentation Review

☐ Manufacturer Disclosure Statement for Medical Device Security (MDS²)

☐ Existing Site-to-Site or One-VA VPN Agreement

☐

have documents and associated equipment quotations

<http://www.sonosite.com/products/edgetsuppodl>

☐ Business Associate Agreement

☐ Equipment description, information flow, and network connectivity requirements

☐ Documentation of network configuration and installation requirements

☐ Clinical Procedures integration documentation provided with VA contacts, if applicable

☐

Purc

DIC

OM conformance statement provide, if applicable

<http://www.sonosite.com/content/dicoml>

Security Precautions

☐ Does the equipment support Anti-virus mtection with updates via McAfee ePolicy Orchestrator? ☐ YES IE

NO

☐

Do

es the equipment support automated OS critical patch installation?

☐ YES NO

☐

Will the medical

equipment be configured for Device Authentication using Active Directory?

☐ YES NO

☐

Will the medical

equipment be configured for User Authentication using Active Directory?

☐ YES NO

☐ Who will provide and manage: Disaster Recovery?

☐

Will vendor require

Remote Access via VPN?

☐ YES NO

☐

Will vendor provide

a network device (switch, router)? Needs risk assessment.

☐ YES NO

☐

Wil

l vendor provide any wireless devices? Needs risk assessment.

☐ YES NO

Network Design and Constraints

- ☐ Notification to network administrator to configure medical VLAN
- ☐ Medical equipment installation location(s)
- ☐ Network administrator reviews risk assessment for any network or wireless devices.
- ☐ List all target systems that the device will communicate with
- ☐ Network administrator configures the ACL with input from Biomedical Engineering, verifies connectivity, and documents configuration.

Medical VLAN:

Post Installation Support Strategy

- ☐ Post implementation support strategy developed.
- ☐ Post implementation secure use strategy developed.(i.e. frequency of removal of 0111 from device, physical security of device, etc.)