Functional Requirements for Radiology Ultrasound
For Nebraska Western Iowa - Omaha VA Healthcare System (Station 636)
Obligation Number 618-B59049

This radiology ultrasound will be used for the following clinical applications: General purpose, abdominal, small parts, guidance for interventional procedures, breast, pelvic, and vascular.

Technical Requirements:

1. Capable of processing multiple data streams simultaneously built for 2D, 3D and MPR
2. All imaging modes available on a single transducer
    a. 2D
    b. 3D (freehand)
    c. Navigation Software
    d. Image Fusion Software
    e. Harmonic Imaging
3. Doppler displays
    a. Frequency
    b. Velocity
    c. Power - Microvascular/directorial
    d. Duplex
    e. Triplex
    f. Steering for color Doppler is required to be 3 degree increments or less
4. Panoramic mode – less stitching is preferred
5. Ability to query/retrieve previously acquired images that have been archived on our Acuo Vendor Neutral Archive (VNA) and/or our Visage PACS system. This is intended to be used to compare prior studies (not associated with fusion and navigation). This is preferred but not required.
6. Ability to query/retrieve previous CT and MR images from our Acuo Vendor Neutral Archive (VNA) and/or our Visage PACS system to be used with fusion and navigation.
7. Monitor
    a. Size – minimum 20 inches
    b. Active screen size – minimum 14 inches – larger size is preferred
    c. Split screen – minimum of 2
    d. Rotation of the monitor – minimum 345 degrees
    e. Tilting - minimum 25 degrees
8. Control Panel
    a. Physical keyboard - it is preferred that the keyboard can be moved/hidden out of the way
    b. Touchscreen
        - Keyboard ability on touchscreen is preferred
        - Image display on touchscreen is preferred
    c. Rotation of the control panel - minimum 345 degrees
9. One button image optimization
10. One button optimization of Doppler
11. Programmable protocols
12. 4 active transducer ports
13. Elastography – both strain and shear wave
14. Ease of maneuverability (Ergonomics)
    a. Monitor rotation – minimum 345 degrees

b. Control panel rotation – minimum 345 degrees
c. Tilting - minimum 25 degrees
d. Monitor moves up and down
    - Preferred range of height 42 to 70 inches from the floor
e. Control panel moves up and down
    - Preferred range of height from 30 to 40 inches from the floor
f. Size of equipment
    - Width – maximum of 25 inches
    - Depth – maximum of 45 inches
g. Weight of unit – maximum preferred 250 lbs

15. Ability to enter a standby mode or sleep mode is preferred
    a. State boot up time in seconds/minutes
    b. State if the system has the ability to enter standby mode or sleep mode
16. Image storage – minimum 1 TB
17. Supported operating system (e.g. Windows 7, Windows 10, Linux, etc.)
18. License for DICOM SR
19. State battery life in minutes – in both standby mode and in active mode
20. Wireless
    a. Compatible with 802.11b/g/n
    b. FIPS 140-2 compliant

<u>Transducers/ Probe Types</u>

1. Linear array high frequency range
2. Linear array lower frequency range
3. Convex/curved for abdominal & interventional
4. Phased array
5. Multi-frequency
6. Endo cavity (vaginal)
7. Endo cavity (rectal)
8. Transducers - Navigation/Fusion biopsy guide
9. Intraoperative (i.e. hockey stick)
10. Transducers - Mechanical 3D
11. Single crystal technology

- Weight of each transducer – maximum of 4 lbs – lightest transducers are preferred

Each vendor is to respond with transducers that meet the criteria listed above. Please include all other transducers offered by your company in the optional section on the quotes.

<u>Analysis Packages</u>:

1. Procedural
2. Abdominal
3. Pelvic
4. Small Parts
5. Urology
6. Vascular – measurement and analysis of vessels

7. OB
8. Breast

Each vendor is to respond with analysis packages that meet the criteria listed above. Please include all other analysis packages offered by your company in the optional section on the quotes.

Warranty and Service:

1. VPN/Remote Access – The vendor shall provide, at no additional charge, any and all equipment service programs, such as remote diagnostics, during the warranty period. The vendor shall provide post-warranty remote diagnostic service program as an "Add Option" with the offer. The system shall provide Vendor Remote Diagnostics via VPN. Vendor shall utilize the VA national Site-to-Site VPN, or the vendor shall work with the Office of Cyber and Information Security and the VAMC Information Security Officer to establish a Client-Based VPN.
2. Service and Operator Manuals – The vendor shall provide the following documentation for the proposed system:
    a. Two (2) copies of operator's instruction manuals (one electronic and one paper copy)
    b. Two (2) copies of complete technical service manuals including detailed troubleshooting guides, necessary diagnostic software, service keys, schematic diagrams, and parts lists (one electronic and one paper copy)
    c. Two (2) copies of a system manager's (super users) manual outlining back-up procedures, managing privilege group limits, routine tasks, etc.
3. Minimum Warranty – The system and accessories shall be covered under the manufacturer's warranty, and shall include all parts and labor for one year following acceptance by the VAMC. This warranty must include PMs as required by the manufacturer. The manufacturer's factory-trained field service personnel shall perform installation and maintenance during the warranty period.

Training

1. On-site
    a. Clinical applications **during go-live** - minimum of 4 days (8 hours each day)
    b. Training should be for both technologists and physicians
    c. 1 day of the training should be dedicated to training on fusion and navigation
2. Same clinical applications trainer for each site, who must be cleared through VISN 23 workgroup. It is expected that the same clinical applications trainer be available for all VISN 23 sites. If a vendor has a specialist for example with Navigation/Fusion that same specialist should be available for all sites.
3. Follow-up
    a. Applications training to be provided after technologists have hands-on experience with the system - between **3-4 months** following go-live for a minimum of 2 days (8 hours each day) for each site.
    b. Applications training to be provided after technologists have hands-on experience with the system – between **6-9 months** after go-live for a minimum of 2 days (8 hours each day) for each site.
4. Off-site
    a. Sonographer Clinical Training for 1 sonographer
        - Tuition and travel (lodging and airfare) is preferred
        - This training should be scheduled and completed after the system has been installed
    b. Biomedical Technical Training for 1 technician
        - Tuition and travel (lodging and airfare) is preferred.
        - Include training for all courses including any prerequisites.
        - Equivalent to what your OEM field service representatives receives.

- All service manuals, schematics, diagrams, diagnostic software, other special tools and hardware keys equivalent to what their OEM field service reps have available to diagnose, troubleshoot, repair and maintain the equipment.

Information and other documentation vendors are to provide:

1. Provide brochures
2. Provide technical specification sheets
3. Provide the weight of the unit (in lbs)
4. Provide weight of each transducer (in ounces and/or lbs)
5. Provide the height (in inches) from the floor to the handle at the lowest setting
6. Provide the height (in inches) from the floor to the handle at highest setting
7. Provide describe in detail the standby mode or sleep mode.
8. Provide version/platform long-range plan.
9. Provide DICOM conformance statement.
10. Provide FIPS 140-2 certification
11. Provide completed pre-procurement assessment form (6550).
12. Provide detail information about the curriculum and length of the Biomedical Technical Training.
13. Provide details on any off-site training offered for sonographers
14. Provide information about your companies support structure during the warranty period
    a. Describe on-line or telephonic applications support and availability
    b. Provide a listing of Field Service Engineer locations and availability
    c. Listing of part depots
15. Provide information about your company's support options following the warranty period
    a. Describe on-line or telephonic applications support and availability
16. Provide 2 copies of the products service manual (1 hard copy and 1 digital copy).
17. Provide references for the clinical applications trainer that will be assigned to VISN 23.
18. Provide any information on FDA safety recalls associated with the equipment and/or transducers.

Trade-in:

Please see trade in summary table below.

Option 1 – VA will retain all hard drives that contain personal health information.

EE Number: 3010804

Manufacturer: PHILIPS

Model: IU22

SN: B06BK7

Acquisition Date: 2/14/2012