Equipment Specifications
Digital Mammography Radiographic System
VISN 23

A. REQUIREMENT OVERVIEW

This document highlights the technical specifications and services being requested by VISN 23 for consideration toward purchase of Mammography Systems. This equipment will be used to provide diagnostic imaging for the following types of procedures: 2D and 3D screening and diagnostic mammography, needle localizations, magnification views, and stereotactic/tomography guided biopsy. Offerors under this proposal shall provide all equipment and accessories, software, installation services, training, and project management support.

Facility	Quantity	Type
Central Iowa VA Healthcare System – Des Moines	1	Replacement
Iowa City VA Healthcare System	2	Replacement and Additional
Minneapolis VA Healthcare System	2	Replacement

B. TECHNICAL REQUIREMENTS

1. Unit physical specifications

a. Minimum generator voltage range [kV]	23-35 kV
b. Generator mAs range [mAs]	3-500
c. Generator ampere range [mA]	50-200
d. Number of generator phases	240 volt/ single phase
e. Minimum spatial resolution [lp/mm]	2D – 7.1 line pairs 3D – 3.5 line pairs
f. Minimum detector size [cm x cm]	24 x 29
g. Minimum focal spot size [mm]	Large focal spot .3mm Small focal spot .1mm
h. Minimum tube head rotation [degrees]	-180 to 180
i. Magnification Device/Stand	1.5x and 1.8x
j. Face Shield	Stationary required, and ability to retract preferred

2. Workstations

a. Number of acquisition workstation monitors	2 (1 for acquisition and 1 for review of priors)

b. Minimum acquisition workstation monitor size [in]	LCD monitors ≥19 inches
c. Minimum acquisition workstation hard disk size [GB]	1 TB
d. Number of review workstation monitors	0 - we do require compatibility with our current Barco Coronis Uniti 12 MP MDMC-12133 Color Diagnostic Displays (4200 x 2800)
e. Minimum review workstation hard disk size [GB]	1 TB

3. Additional specifications

☒	a. Breast tomosynthesis- integrated 3D, should not have to install tomo unit
☒	b. Imaging type both 2D and 3D
☒	c. Tomo guided/stereo biopsy sitting, lateral and vertical approach
☒	d. High-frequency generator
☒	e. AEC detector – both AEC and Manual technique
☒	f. Rotating anode
☒	g. Density reporting software (provide software vendor)
☒	h. Digital detector
☒	i. Rotating arm for acquisition workstation for view across room (must be viewable from the mammo unit while performing an exam).
☒	j. Computer-aided detection (CAD) (must be compatible/FDA approved on CC and MLO full field synthesized images)
☒	k. Ability to do tomo spot views

4. Paddles

☒	a. Biopsy
☒	b. Rectangle spot compression
☒	c. Square spot sliding compression
☒	d. Round spot sliding
☒	e. Needle/wire localization (i.e. Swiss Cheese) sliding compression ***(Qty varies by site see table below)***
☒	f. Sliding standard compression
☒	g. Sliding implant/small breast compression
☒	h. Flex compression in 3D mode
☒	i. Sliding
☒	j. Flexible compression and curved paddles
☒	k. Ability to see through paddles arms (plastic)

5. Security/Connectivity Requirements

☒	a. OEM-supported operating system

☒	b. DICOM 3.0 print, store, commit, radiation dose structured report (RDSR), and modality worklist
☒	c. HL7 integration (HIS/RIS)
☒	d. Encrypted hard drive
☒	e. PACS compatibility – Visage, Medicalis, Acuo

6. Added Value

Specifications listed below are not required, but preferred. Vendors who do not include the below specifications in the submitted offer will not be docked or excluded from consideration. Specifications listed below will be evaluated based on added value.

☒	a. Slave monitor to acquisition workstation, ceiling mounted in exam room
☒	b. Foot pedal for exposure
☒	c. Generator and Mammo unit to be consolidated
☒	d. Ability to change from vertical to lateral approach and vice versa when performing a biopsy without taking patient out of compression
☒	e. Compatibility with Mammography Reporting System (MRS) 7

C. TRAINING REQUIREMENTS

Description	No. of Personnel
1. On-site clinical applications training for **technologists** during go-live	Varies by site. See table below.
2. On-site clinical applications training for **radiologists** during go-live	Varies by site. See table below.
3. On-site clinical applications training for **administrators** during go-live	Varies by site. See table below.
4. On-site follow-up clinical applications training after **technologists** have hands-on experience with the system	Varies by site. See table below.
5. On-site follow-up clinical applications training after **radiologists** have hands-on experience with the system	Varies by site. See table below.
6. Biomedical technician training package (to include tuition)	Varies by site. See table below.

Biomedical technician training shall include any prerequisites required prior to the training and shall be equivalent to the training received by OEM field service representatives. Technicians shall be given all service manuals, schematics, diagrams, diagnostic software, other special tools, and keys equivalent to what OEM field service representatives have available to diagnose, troubleshoot, repair, and maintain the equipment.

Technologists who complete the clinical applications training shall receive continuing education credits (CMEs).

Vendors shall be responsible for accommodating different personnel shifts for clinical applications training during go-live.

D. SERVICE REQUIREMENTS

1. VPN/Remote Access – The vendor shall provide, at no additional cost, 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. The vendor shall either utilize the VA national site-to-site VPN or work with the Office of Cyber and Information Security and the VAMC Information Systems Security Officer to establish a client-based VPN.
2. Service and Operator Manuals – The vendor shall provide the following documentation for the proposed systems:
    a. Two (2) copies of operator instruction manuals (one (1) electronic and one (1) physical copy)
    b. Two (2) copies of a system manager (super user) 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 representatives shall perform installation and maintenance during the warranty period.

Vendors are encouraged to include any offerings for service, warranty, and training that may exceed the requirements with their proposals. Vendors who do not include any added value offerings for service, warranty, and training will not be docked or excluded from consideration. However, any such offerings will be evaluated based on added value.

E. OTHER INFORMATION/DOCUMENTATION REQUESTED

1. Product brochures
2. Technical specification sheets, to include dimensions and weight of the system
3. DICOM Conformance Statement
4. IHE integration statement
5. Completed pre-procurement assessment form (6550)
6. Completed MDS2 form
7. Version/platform long-term plan
8. Detailed information about the curriculum and length of the biomedical technical training
9. Details on any off-site training offered for technologists
10. Information about your company's support structure during the warranty period
    a. Describe on-line or telephonic applications support and availability (include third party coverage)
    b. Provide a listing of field service engineer locations and availability
    c. Provide a listing of part depots
11. Information about your company's support options following the warranty period, including a description of on-line or telephonic applications support and availability
12. Two (2) copies of the product service manual (1 hard copy and 1 digital copy)
13. Information on any FDA safety recalls associated with the proposed equipment

F. TRADE-IN

☒	a. In instances where sanitization of ePHI compromises the OS and/or application software, or requires the removal of internal storage media, the vendor accepts the equipment “as is” and can elect at their own discretion to contract with the original equipment manufacturer (OEM) to restore the system.

The following equipment is available for trade-in. Please reflect any credits provided for trade-in equipment in the proposal.

Station	Minneapolis (618)
Manufacturer	GE
Model	Senograhe Essential
EE/Asset Number	258600
Serial Number	013147

Station	Minneapolis (618)
Manufacturer	GE
Model	Senograhe Essential
EE/Asset Number	258605
Serial Number	013149

Station	Iowa City (636A8)
Manufacturer	GE
Model	Senograhe Essential
EE/Asset Number	162778
Serial Number	665904BUI

Station	Des Moines (636A6)
Manufacturer	GE
Model	Senograhe Essential
EE/Asset Number	368301
Serial Number	51494565

G. SUMMARY OF REQUIREMENTS

Facility	PO Number	B.5.e. Needle/wire localization sliding compression	C.1-2 Technologists for Clinical Apps (go-live/follow-up)	C.3 Biomedical Technical Training	F. Trade In
Des Moines (636A6)	618-B89049	1	2, 2, 1	1	Yes
Iowa City (636A8)	618-B89050	1	2, 1, 2	1	Yes
Iowa City (636A8)	618-B89051	0	0, 0, 2	1	No
Minneapolis (618)	618-B89052	1	2, 2, 2	1	Yes
Minneapolis (618)	618-B89053	1	2, 1, 1	1	Yes