

Functional Requirements for a **Single-Plane Cardiac Catheterization Suite**
For **Nebraska-Western Iowa** VA Healthcare System (Station 636)
Obligation Number 618-B59002

*The VA Medical Center in Omaha is soliciting proposals for a new **Single plane Cardiac CATH Lab**. The following language outlines the basic requirements for the desired system. Vendors submitting proposals shall provide a response to each requirement, or requested elaboration, directly – even if those responses are repeated in standard product literature. There will be a Trade –in of our current equipment listed in this request.*

Technical Requirement:

Gantry

1. Interventional Cardiology Single Plane, Single C-arm
2. Ceiling Mounted
3. Flat Panel Image Receptor greater than 10cm x 10cm
4. DSA/DR with road mapping
5. 3DCT like imaging
6. In room overlay of 3D on Fluoro image
7. High capacity X-ray tube
8. Next Generation Dose reduction

Table

1. Tilting Pivoting Table
2. Table side control capable of controlling complete Imaging functionality including 3D tools
3. Table side controls can be run from foot end
4. Table rail at foot
5. Table pad
6. Table arm boards
7. Table side floor mats (antimicrobial - Hard Bottom not spongy)
8. Auto positioning table

Monitor suspension

1. Large single panel Display (minimum 56") with multiple and simultaneous input display
 - a. Allows users to control input switching and sizing for multiple sub-screens
 - b. Include option to display live fluoro case and previous Cath or Echo cardiology cases simultaneously adjacent on the same screen
2. Review workstation in control room to review previous cases and view live fluoro
3. Multi input video multiplexer

Accessories

1. Two Foot control (Digital acquisition and Fluoro)
 - a. Location must be adjustable around and under patient table
2. Lower lead shield, where lower shield extends past central beam of X-ray for Right and Left side. (X2)
3. Intercom and audio sound system
4. Ceiling mounted articulating surgical procedure lamp/light
5. Ceiling mounted Radiation shield with cut out
6. Staff dose monitoring system including a minimum of 10 Dose badges for clinical staff.

7. Required cabinets to store support components, such as UPSs

System Performance, Features

1. Cardiac Acquisition rates to include at minimum: 30fps, 15fps
2. Pulsed Fluoro Frame rates to include 30fps, 15fps, and less \leq 4 fps
3. Single-shot exposure option for Fluoro
4. Virtual collimation and “soft shield” (lung field compensation)
5. Dose monitoring shall be easily accessible for review throughout the duration of the procedure
6. Ability to Store Fluoro retrospectively to acquisition (Fluoro loop)
7. Ability to see playback from both tableside and control room, independently
8. DICOM formats to include at minimum: Send, Print, Work list, Q/R, MPPS, DICOM dose structured report
9. HIS/RIS integration: VistA Imaging (HIS) and Compass (RIS)
10. Table, C-arm, and exposure functions must be controllable from the foot of the bed, while the Physician works on the left or right side of the bed
11. Physician must be able to view C-arm parameters (arm angle, bed position, DAP, dose rate, etc.) while X-ray technician can view the same from the end of the table
12. Extended rails will allow placing the C-arm away from the procedure table head end
13. Quantitative Coronary Analysis (QCA) and Left Ventricular Analysis (LVA)
14. Cardiac measurements and quantification
15. Auto cal for measurements
16. Stent optimization for cardiac and vascular
17. Stent subtraction (removing background from stent image)
18. Integrated Ultrasound (Ultrasound NOT supplied by vendor)
19. Multimodality fusion
20. CT like imaging with 3D roadmap
21. TAVR planning and fusion

Systems Integration

The systems listed immediately below are networked to the existing Cath Lab Interventional X-Ray system. Strong consideration will be given to proposed systems that can be integrated with these to display real-time data across sub-systems and store data on a Cardiology PACS.

1. Philips Xper IM
2. Philips Xcelera
3. Volcano Ultrasound s5/s5i

UPS

- Power conditioner to allow fluoro to remain available during a power outage for a minimum of 5 minutes

Training

1. A minimum of 9 days of on-site clinical applications training separated into 3 segments.
2. Offsite clinical applications training for 2 technologists – to include tuition, travel, and lodging.
3. One Biomedical Engineering Technical Training School for Seasoned Biomed - to include tuition, travel and lodging. Include Biomed school for advanced features.

Support

1. Clinical Applications Phone Support
2. Technical Phone Support
3. Remote Technical Support (VPN)

Warranty

- One year standard parts and installation coverage included with equipment purchase.

REQUIRED PROPOSAL ELABORATIONS

In your proposal, please speak directly to the following points:

- Explain how patient dose is recorded, and where it is available to the clinicians post procedure
- How does your System enhance Stent placement
- What Fusion capabilities are available on the system
- Describe all available dose reduction enhancements/features included in the proposal and how it affects image quality
- Elaborate on your foot pedal design. How are physician and X-ray technician given control during procedure?
- Describe your support model for ongoing clinical applications support (and what is included with purchase). Identify differences between on-site versus phone support, if necessary.
- Ongoing applications support
- Remote Service Connection for Service and applications support. Describe your support model for remote support (and what is included with purchase).
- Ongoing Biomedical Technical Support from your call-in center
- Describe your support model for ongoing Biomedical Engineering technical support (and what is included with purchase). Identify differences between on-site vs. phone support, if necessary.
- Explain how Biomedical Engineering Technicians who have attended full service school are provided factory-level access to the equipment for servicing including how service keys will be provided.
- Describe your support model for remote support utilizing VPN access (and what is included with purchase).

REQUIRED PROPOSAL INCLUSIONS

In addition to providing documentation speaking directly to the above stated requirements, also provide:

- A completed Manufacturer Disclosure Statement for Medical Device Security (MDS2) and Pre-Procurement Assessment (PPA) in accordance with VHA Directive 6550.
- A DICOM conformance statement for proposed solution.
- An IHE conformance statement for proposed solution.

Trade in

Option 1 **ALL Hard Drives will be retained by the VA.**

EE: 2955243

Manufacturer: Philips Healthcare

Model: Allura Xper FD20

S/N: 225

Site ID: 544184

Acq. Year: 2007