Functional Requirements for a **Single-Plane Interventional Suite**
For **Minneapolis** VA Healthcare System (Station 618)
Obligation Number **618-B49022**

*The VA Medical Center in Minneapolis is soliciting proposals for a replacement **Single plane** Interventional 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 Requirements:

### Gantry

1. Interventional **Single Plane**, Single C-arm
2. Ceiling Mounted
3. Flat Panel Image Receptor 12cm x 16cm
4. DSA/DR with road mapping
5. Rotational Angiography
6. 3D Rotational Angiography
7. Bolus chase subtracted Stepping
8. 3DCT like imaging
9. In room overlay of 3D on Fluoro image
10. High capacity X-ray tube
11. Next Generation Dose reduction

### Table

1. Standard Pivoting Table
2. Tilting table (but not cradle)
3. Table side control capable of controlling complete Imaging functionality
4. Table pad
5. Table arm boards
6. Table side floor mats (antimicrobial - Hard Bottom not spongy)
7. Table width (supply the max. available)
8. Patient table weight (supply the max. available)

### Monitor suspension

1. Large single panel Display (minimum 56”) with multiple input switching and sizing
    - Ceiling mounted – supplied by vendor
2. Two additional monitors (minimum 18”) for the X-ray technologist and in room viewing.
    - 1 mounted to roll around stand – supplied by vendor
    - 1 mounted to wall – wall mount to be supplied by vendor
3. Multi input video multiplexer

**Accessories**

1. Foot control (Digital acquisition and Fluoro) - *Wireless is preferred but not a requirement*
2. Separate Upper and Lower lead shields, where lower shield extends past central beam of X-ray for Right and Left side. (X2)
3. Intercom
4. Table mounted - Bayer/Medrad Arterion Contrast Injector
5. Ceiling mounted articulating surgical procedure lamp/light
6. Ceiling mounted radiation shield with cut out
7. Staff dose monitoring system including a minimum of 10 Dose badges for clinical staff.
8. Audio sound system
9. Pedestal to mount the table controls to as needed (ability to move the table side controls to a pedestal)

**items 5-9 are preferred but not requirements. Therefore, if they are on your NAC contract please include them – if they are not included on your NAC contract it will not be counted against your bid during evaluation*

**System Performance, Features**

1. Acquisition rates to include at minimum: 30fps, 15fps, and less <= 10 fps
2. Pulsed Fluoro Frame rates to include 30fps, 15fps, and less <= 4 fps
3. Vascular virtual collimation and "soft shield" (lung field compensation)
4. Reference and Fluoro images can be overlaid
5. CT image can be presented in 3D and overlaid with the live-fluoroscopy
6. Dose monitoring shall be easily accessible for review throughout the duration of the procedure
7. Ability to Store Fluoro retrospectively to acquisition (Fluoro loop)
8. Ability to have last image hold feature
9. Ability to see playback from both tableside and control room, independently
10. DICOM formats to include at minimum: Send, Print, Work list, Q/R, MPPS, Radiation Dose SR
11. HIS/RIS integration
12. Vascular stent optimization
13. Needle optimization
14. Ultrasound integration (Ultrasound NOT supplied by vendor)
15. IVUS (Volcano) integration (Ultrasound to be included if on contract by vendor)
16. $CO^2$ software
17. Multimodality fusion
18. CT like imaging with 3D roadmap
19. Vascular analysis stenosis measurement
20. Auto-calibration measurement tool
21. Vessel Analysis/Mapping

**UPS**

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

**Training**

1. A minimum of 4 days of on-site clinical applications training during Go-Live.
2. A minimum of 4 days of on-site clinical applications training 3-6 months following Go-Live.

3. A minimum of 2 days of on-site clinical applications training 9-11 months following Go-Live.
4. Offsite clinical applications training for 2 technologists – to include tuition, travel, and lodging.
5. One Biomedical Engineering Technical Training - to include tuition, travel and lodging.

**Support**

1. Clinical Applications Phone Support
2. Technical Phone Support
3. Remote Technical Support (VPN)
4. Renewable in-house Biomed service access

**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:*

1. Explain how patient dose is recorded, and where its available to the clinicians, post procedure
2. How does your System enhance Stent placement
3. What Fusion capabilities are available on the system
4. Describe all available dose reduction enhancements/features included in the proposal
5. Describe your support model for ongoing clinical applications support (and what is included with purchase). Identify differences between on-site vs. Phone support, if necessary.
6. Remote Service Connection for Service and applications support. Describe your support model for remote support (and what is included with purchase).
7. Ongoing Biomedical Technical Support from your Call in center
8. 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.
9. 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.

## REQUIRED PROPOSAL INCLUSIONS

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

1. A completed Manufacturer Disclosure Statement for Medical Device Security (MDS2) and Pre-Procurement Assessment (PPA) in accordance with VHA Directive 6550 (attached at the end of this document).
2. A DICOM conformance statement for proposed solution.
3. An IHE conformance statement for proposed solution.

## Trade in

Option 1 **ALL Hard Drives will be retained by the VA.**
EE: 72482
Manufacturer: Philips
Model: Allura Xper FD20
S/N: 1379
Acq. Year: June 2008