

Functional Requirements for a **Bi-Plane Interventional Suite**
For **Minneapolis** VA Healthcare System (Station 618)
618-B59001

*The VA Medical Center in Minneapolis is soliciting proposals for a replacement **Biplane** 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 **Biplane** C-arm
2. Flat Panel Image Receptor
 1. 2- 12" x 16" (30cm x 40cm)
3. DSA/DR with road mapping
4. Bolus chase subtracted Stepping
5. Rotational Angiography
6. 3D Rotational Angiography
7. 3DCT
8. In room overlay 3D on Fluoro image
9. High capacity X-ray tube
10. Next generation Dose reduction

Table

1. Standard Pivoting Table
2. Tilting table (cranial, caudal)
3. Separate Upper and Lower lead shields, where lower shield extends past central beam of X-ray for Right and Left side. (X2)
4. Table side control capable of controlling complete Imaging functionality
5. Table pad
6. Table arm boards
7. Table side floor mats (antimicrobial –Hard bottom not spongy)
8. Wireless footswitch
9. Intercom

Monitor suspension

1. Large single panel Display (minimum 56") with multiple input switching and sizing
2. Two additional monitors for the X-ray tech and the Nurses station.
3. Multi input video multiplexer

System Performance, Features

1. Medrad Arterion injector – Table mount with optional trolley
2. Ceiling mounted Radiation shield with cut out to include articulating surgical light
3. Intercom

4. Acquisition rates to include at minimum: 30fps, 15fps, and less than or equal to 10fps??
5. Pulsed Fluoro Frame rates to include 30fps, 15fps, and less <= 4 fps
6. Vascular Virtual collimation and “soft shield” (lung field compensation)
7. Reference and fluoro images can be overlaid.
8. Dose monitoring shall be easily accessible for review throughout the duration of the procedure
9. Ability to Store Fluoro retrospectively to acquisition (Fluoro loop)
10. Ability to see playback from both tableside and control room, independently
11. DICOM formats to include at minimum: Send, Print, Work list, Q/R, MPPS
12. HIS/RIS integration
13. Extended rails will allow placing the C-arm away from the procedure table head end.
14. Vascular Stent optimization
15. Needle optimization
16. CT image can be presented in 3D and overlaid with the live-fluoroscopy
17. Ultrasound Echo integration
18. IVUS integration (Volcano)
19. CO2 software
20. Multimodality fusion
21. CT like imaging with 3D roadmap
22. Vascular Analysis Stenosis Measurements
23. Autocal Measurements
24. Vessel Analysis/Mapping
25. Audio sound system

UPS

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

Training

1. A minimum of 8 days of on-site clinical applications training. VA may request to separate the 8 days.
2. Offsite clinical applications training for 2 technologists
3. One Biomed training episode, to include tuition

Support

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

Manuals/Maintenance Software

- The vendor shall provide, at no charge, two (2) complete and unabridged printed copies and one (1) electronic version (CD) of operator manuals, service manuals, electronic schematics, troubleshooting guides, and parts lists for each piece of equipment purchased. Additionally, any upgrades to these documents shall be provided by the vendor free of charge. These manuals will include all components and subassemblies, including those not manufactured by the vendor. These manuals and documentation shall be identical to the ones supplied to the manufacturer’s service representatives and shall contain the diagnostic codes, commands, and passwords utilized in maintenance, repair and calibration of the equipment.

- Any software not listed on the price quote and required for maintenance of the system, shall be taken as included with the purchase of the system. Any minor upgrades or changes to the maintenance software, hardware, or access keys or codes shall be provided at “no charge” to the medical center during the time the equipment is operational at this facility.

Warranty

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

Other

- FDA Clearance
- CE Mark (MDD)

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. Ongoing applications support
7. VPN connection for Service and applications support.
8. Ongoing Biomedical Technical Support from your Call in center
9. Onsite applications training.
10. Describe your support model for ongoing Biomed technical support (and what is included with purchase). Identify differences between on site vs. phone support, if necessary.
11. Explain how Biomed technicians who have attended full service school are provided factory-level access to the equipment for servicing including how service keys will be provided.
12. Describe your support model for remote support utilizing direct access (and what is included with purchase).
13. Do you have current VA access?

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: 76673

Manufacturer: Siemens

Model: Artis Zee

S/N: 153214

Acq. Year: February 2009