Functional Requirements for a **Bi-Plane Cardiac EP Suite**
For **Minneapolis** VA Healthcare System (Station 618)
Obligation Number **618-B49017**

*The VA Medical Center in Minneapolis is soliciting proposals for a new **Biplane Cardiac EP** 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 Biplane C-arm
2. 2 Flat Panel Image Receptors less than 12 x 12cm
3. EP 3D Rotational Angiography
4. 3DCT like imaging
5. CT/MR import and fusion
6. EP In room overlay 3D on Fluoro image
7. Auto positioning C-arm
8. High capacity X-ray tube
9. Next generation Dose reduction

Table

1. Tilting Pivoting Table with Maximum weight possible
2. Separate Upper and Lower lead shields, where lower shield extends past central beam of X-ray for Right and Left side. (X2)
3. Table side control capable of controlling complete Imaging functionality and 3D tools
4. Table pad
5. Table arm boards
6. Table side floor mats (antimicrobial –Hard bottom not spongy)
7. Auto positioning Table

Monitor suspension

1. Large single panel Display (minimum 56”) with multiple input switching and sizing
2. Two additional slave monitors for the X-ray tech and the Nurses station to display live fluoro.
    a. 1 mounted to roll around stand – supplied by vendor
    b. 1 sitting on a desk in the procedure room – desk NOT supplied by vendor
3. Multi input video multiplexer

Accessories

1. Two Foot control (Digital acquisition and Fluoro) - *Wireless is preferred but not a requirement*
    a. One for the Physician
    b. One for the X-ray Technologist.
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 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. EP Equipment Boom
9. Audio sound system

**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. Cardiac Acquisition rates to include at minimum: 30fps, 15fps, and less than or equal to 10fps
2. Pulsed Fluoro Frame rates to include 30fps, 15fps, and less <= 4 fps
3. Virtual collimation and "soft shield" (lung field compensation)
4. Dose monitoring shall be easily accessible for review throughout the duration of the procedure
5. Ability to Store Fluoro retrospectively to acquisition (Fluoro loop)
6. Ability to see playback from both tableside and control room, independently
7. DICOM formats to include at minimum: Send, Print, Work list, Q/R, MPPS, DICOM dose structured report
8. HIS/RIS integration
9. 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 with a separate radiation foot switch.
10. 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
11. Extended rails will allow placing the C-arm away from the procedure table head end
12. Integrated Ultrasound (Ultrasound NOT supplied by vendor)
13. EP Navigation
14. EP Rotational Angiography
15. External MR/CT image can be presented in 3D and overlaid with the live-fluoroscopy for EP
16. Ice/Echo integration
17. EP Control room, Equipment consolidation and integration.
18. Include any noise reduction available to minimize EP interference.
19. TAVR planning and fusion

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)
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:

- Explain how patient dose is recorded, and where its 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
- 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 vs. 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 (attached at the end of this document).
- 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: 58094
Manufacturer: GE
Model: Innova 2000
S/N: 421046BU4
Acq. Year: 2003