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VA NEW ENGLAND HEALTHCARE SYSTEM

STATEMENT OF WORK

Portable Fluoroscopy (C-Arm)



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OBJECTIVE

This document highlights the requirements, technical specifications, and services being requested by the Department of Veterans Affairs (VA) medical centers listed below for consideration towards purchase of a portable fluoroscopy unit; commonly referred to as a C-Arm. The C-Arm will either replace or be an upgrade to current portable fluoroscopy units. Offerors under this proposal shall provide all labor, material, parts, tools, software, project management and equipment necessary to furnish and install a fully functional digital radiography room in the following medical center(s).

- VA White River Junction Vermont

DEFINITIONS

VistA Veterans Health Information Systems and Technology Architecture - is VA's award winning Health Information Technology (IT) system. It provides an integrated inpatient and outpatient electronic health record for VA patients, and administrative tools to help VA deliver the best quality medical care to Veterans. This serves as the VA's HIS/RIS.

PROJECT MANAGEMENT

This procurement will include all interface and networking required to utilize this portable equipment in multiple locations within each facility.

MEDICAL EQUIPMENT TECHNICAL SPECIFICATIONS

The following technical specifications represent a minimum set of requirements for each C-Arm. Offerors must reply outlining specifically how they meet the requirements for a portable fluoroscopy device in a format that is easy to interpret by a common lay person. Each facility may require a different primary function from the portable fluoroscopy device so the final quote(s) should be configured in such a way as to allow selection of additional option package(s) above the base proposal. The intent is to present a quote for a system suitable for general OR and pain management use with options representing increased functionality for orthopedic and vascular surgical use. Offerors should submit a single quote for a base C-arm plus options for orthopedic and vascular surgery.

- Hardware
 - Generator
 - High frequency generator with automatic dose rate control
 - $\geq 15\text{kW}$ generator
 - Up to 120kVp
 - Ability to power from a standard wall outlet
 - Pulse and continuous fluoroscopy modes
 - C-arm
 - Deep "C" configuration to allow imaging of large patients (please specify)
 - 180 degree arc and rotation or greater
 - Remote operator controls for bedside movement
 - Remote controlled motorized movement (option)

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- Bed side protocol parameter adjustment via remote or bedside controls
- Image intensifier
 - 12"x12" or greater field of view (FOV)
 - 1.6 lp/mm or greater central resolution
 - Ability to select smaller FOV with increased resolution.
- Video Display
 - Dual, articulating antiglare LCD high resolution (1280x1024 or greater) monitors
 - Articulating support arm to allow for vertical and horizontal adjustment of the monitors for optimum viewing angle anywhere in the room.
 - Touch screen controls (optional)
 - Video zoom / roam
 - Last image hold / hold and save
- User interface
 - Multifunction foot and hand controls (wireless remote optional)
 - Keyboard and/or touchscreen keyboard
 - Audible/visual x-ray on warning
 - User configurable threshold dose warning
 - Worklist integration for ease of patient entry
 - Image annotation
- Software Solutions
 - Image Processing-
 - Anatomy based image optimization automatic and/or protocol based
 - Image optimization pre and post exposure (rotate, flip, contrast, brightness, etc.).
 - Image hold/display and simultaneous real time image display (dual monitor)
 - On board image storage (800 images or greater) and image retrieve from PACS (Bi-directional DICOM interface)
 - Interface with VistA (Bi-directional worklist/HL-7)
 - Monitoring of Dosage- The system must be able to supply a technology that allows for monitoring and tracking of radiation dose provided to a patient; DICOM structured reporting is preferred.
 - Dose Reduction- The system must have systems in place to facilitate regular protocol optimization and reduced radiation dose to the patient.
- Application specific software options-
 - Vascular (option package to include at minimum)
 - Increased frame rate from base model 30fps or greater
 - Real time digital subtraction
 - Roadmapping
 - Increased image storage (1000 images or greater)
 - Bolus tracking
 - Vessel measurement tools and calculations
 - Catheter / guidewire visualization enhancement
 - Preset vascular profiles
 - Orthopedic (option package to include at minimum)
 - Metallic edge suppression

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- Bone visualization optimization (soft tissue suppression)
- On screen measurement tools (distance, angle, etc.)
- Image comparison tools (side-by-side display, image overlay)
- Preset orthopedic profiles

EDUCATION/TRAINING TO BE PROVIDED

The following is a list of education and training options that each medical center may be interested in purchasing along with their scanner. Offerors are encouraged to list out their education and training options that can be provided.

- Clinical Education
 - At least one (1) week of onsite training for the technologist from each medical center with options for additional training (i.e. 2 weeks on-site to be used in the next 2-3 years). (*Option*)
 - On-going Clinical education for technologist(s) from each medical center via on-line, webinar, etc. (*Option*)
 - Clinical phone applications support for the technologist(s) from each medical center.
- Clinical or Biomedical Engineering Training- Biomedical Engineering training for one (1) Biomedical Engineering Support Specialists (technicians) from each medical center at Offeror's training location to include travel and accommodations with options for additional training. (*Option*)

NETWORKING CAPABILITIES

The Offeror's product must be able to meet the following network capabilities.

- Must be on the VistA Imaging Approved DICOM Modality Interfaces list. [VA DICOM Website](#)
- Must have the ability to interface with hospital Picture Archiving and Communication System (PACS) and third (3rd) party post-processing workstations, specifically Carestream's PACS product.

The Offeror is required to submit the following documentation along with their proposal.

- A complete Manufacturer Disclosure Statement for Medical Device Security (MDS²) form. See attachment A.
- A complete VA Directive 6550 Pre-Procurement Assessment form. See attachment A.

SERVICE

- VPN/Remote Access – The vendor shall provide, at no additional charge, any and all equipment service programs, such as remote diagnostics, during the warranty period. The vendor shall

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provide post-warranty remote diagnostic service program as an “Add Option” with the offer. The system shall provide Vendor Remote Diagnostics via VPN. Vendor shall utilize the VA national Site-to-Site VPN, or the vendor shall work with the Office of Cyber and Information Security and the Boston VAMC Information Security Officer to establish a Client-Based VPN.

- Service and Operator Manuals – The vendor shall provide the following documentation for the proposed system:
 - Two (2) copies of operator's instruction manuals per unit purchased
 - Two (2) copies of complete technical service manuals including detailed troubleshooting guides, necessary diagnostic software, service keys, schematic diagrams, and parts lists
 - Two (2) copies of a system manager's manual outlining back-up procedures, managing privilege group limits, routine tasks, etc.

EVALUATION CRITERIA

Offerors will be evaluated on the following factors. There is no specific ranking for any factors listed.

- General System Offering (Functional Capabilities and Technical Performance as Outlined Above and Additional Features Listed)
- Radiation Dose Monitoring and Reduction Capability
- Training Plan (both Clinical and Technical)
- Anticipated Reliability and Serviceability
- Past Performances
- Human Factors Design (i.e. Ease of Use, Intuitive Operation, Capabilities, and Workflow Efficiencies)
- Implementation Management and Schedule
- Price

It is understood that every Offeror's product(s) may differ from the specifications outlined in this document. As such, Offerors are encouraged to propose these variances. It is required that each Offeror clearly identify how they meet the specifications listed above. It is also required that, whenever a variance from these specifications occurs, the proposed item meets or exceeds the specified characteristics or level of performance. The Offeror shall also identify each product line item that differs from the specifications and list its associated cost.

FURTHER CONSIDERATION

Offeror's are provided the opportunity to obtain further details from the VA New England Healthcare System in order to better tailor the product quote(s). All requests for information derived from any Offeror will be shared with each Contracted vendor per the National Acquisition centers supplied vendor list for this modality.

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ATTACHMENT A

The following document is required to be completed for all products contained within the proposal.



MDS2FormInstructions.pdf



6550_Pre-Procurement Assessment.pdf