

VA SAN DIEGO HEALTHCARE SYSTEM
3350 La Jolla Village Drive
San Diego CA, 92161

**SCOPE OF WORK AND GENERAL SPECIFICATIONS FOR VITAL SIGN MONITORS
AND CPRS INTEGRATION PURCHASE**

1. **Contracting Officer's Representative (COR).**

Section:	Nursing Service
Address:	3350 La Jolla Village Drive. San Diego CA 92161
Phone Number:	(858) 552-8585 ext. 6175

2. **Contract Title.**

Purchase and installation of vital signs monitors to include integration to the current VA nationwide system, Veterans Health Information Systems and Technology Architecture (Vista)/ and Computerized Patient Record System (CPRS).

3. **Introduction**

The following Statement of Work (SOW) details the VA San Diego Healthcare System (VASDHS) requirements for the Contractor to provide a complete vital sign monitor solution. The solution shall include:

vital signs monitors, roll around stands, bar code scanners, software, licenses, installation, training, maintenance, trade-ins, wireless capability, and a full working interface to VISTA and CPRS. These requirements are detailed below.

4. **Background**

The Nursing Service is a vital clinical service within VASDHS to provide care for our veterans. Patient care and treatment often requires periodic measurements of certain vital signs that are recorded into CPRS. Currently, VASDHS must move around vital sign monitors in critical patient cares to accommodate the needs of recording this information, and must then manually input the information into CPRS. Transcribing information from manual system to CPRS is a known source of medical errors. The integration for automatic entry into CPRS with BCMA will remove the errors involved with manual entry. Also, the purchase of additional equipment will allow nurses to have ready access to a vital sign monitor in each room to measure vitals.

5. Project Scope

VASDHS is looking to purchase 370 new vital sign monitoring machines and systems able to be configured and installed in several departments and community based outpatient clinics (CBOCs) within VASDHS in the San Diego, CA area. This will include the mounts and baskets that come with the vital sign monitors. In addition, system software and licenses will be offered to provide the CPRS integration as mentioned above. Overall, the scope of work will also include testing of the HL7 interface inbound and outbound from the centralized system. This system must provide barcode scanners to allow for scanning of patient names and entry into CPRS. Also, the necessary cables for integration with the Work Stations on Wheels (WOWs) must also be provided. The system must have full connectivity and HL7 interface that can be used in the inpatient and outpatient settings. This will require ability to utilize wristbands and most recent version of the Veterans Identification Cards (VICs).

Definitions

Acceptance Signature - COR or VA designee signature; indicates COR accepts work status as stated in SOW

Biomedical Engineer(ing) - Supervisor or designee

BCMA – Bar Code Medication Administration

BMI – Body Mass Index

O - Contracting Officer

COR - Contracting Officer's Representative

COW – Computer on Wheels

CPRS – Computerized Patient Record System

HL7 – Health Level 7 Standards for Information Transfer

SDS – Safety Data Sheet

MAP – Mean Arterial Pressure

NIBP – Non-invasive Blood Pressure

VA – Department of Veterans Affairs

VAMC – Department of Veterans Affairs Medical Center

VistA – Veterans Health Information Systems and Technology Architecture

6. Specifications

VASDHS monitoring equipment and CPRS integration specifications are designed to outline all the VASDHS Nursing and Biomedical Engineering requirements. These specifications also meet the ECRI criteria. These requirements will be provided to the Contracting Officer Representative (COR) before final approval. The specifications are provided below:

- CPRS Integration

- VA-approved Class II Interface to VistA CPRS which is verifiably functioning in a live environment at a minimum of 4 VA facilities.
 - The integration must contain a method for a centralized repository. This means that it takes information from the multiple Vital Sign Monitors and then passes on this information to CPRS for all parameters. This centralized system must support up to 400 simultaneous unit connections.
 - The Integration must contain a method for BCMA use at the point of care. This means that the user must be able to scan a patient wrist band or Veterans Identification Card to associate data collected with the patient's record.
 - The information must meet HL7 message formatting and VistA integration based on existing CPRS standards. This must be true for both inbound ADT and outbound traffic.
 - The integration to CPRS must be seamless. A seamless integration means that any validation of information going into the patient record must be achievable from the point of care.
 - The integration must be wireless capable using existing VASDHS infrastructure and must be proven to comply with Federal Information Processing Standard (FIPS) 140-2.
 - Installation and integration must also be provided.
- Server specifications
 - Server(s), physical or virtual, operating system must be Windows Server 2012 or newer.
 - There must be at least 10 terabytes (TB) of disk space/memory available with ability to be expanded.
 - There must be at least 32GB of RAM available.
 - If a SQL server is required, SQL version must be enterprise Windows SQL Server 2012 and must be able to run on a VA regional consolidated SQL server. Must not use mixed mode authentication.
 - The contractor will provide a physical server, but if VHASDHS so desires the server(s) can be virtualized. VMs will run on VA regionalized vCenter.
 - All relevant software licensing, including third party licensing, will be provided by vendor
 - This system must have an FDA-approved bidirectional HL7 interface.
 - The contractor can have remote access or virtual private network (VPN) ability. Higher amount of consideration will be made for a company who has a nationally-approved memorandum of understanding and/or interconnection security agreement (MOU/ISA).
 - The system must be compatible with the Department of Veterans Affairs personal identification verification (PIV) system.

- The server(s) must have the ability to download and maintain the latest versions of Symantec malware protection and McAfee anti-virus. The server(s) will connect to the Region 1 WSUS server and download Office of Information Technology (OIT) approved software.
- The system must have the ability to have at least 340 concurrent licenses when operating system, either video feed viewing or video and still image recording and processing.
- If service accounts are required, VA must be able to change the passwords every 3 years with no more than an estimated 30 minutes of down-time. Vendor will supply a clearly mapped list/diagram of service account locations within system for easy access.
- Vendor will supply completed IT security documentation for networked devices to include:
 - VA Directive 6550 PPA Appendix A
 - ACL Communication Profile
 - MDS2
 - Common Risk Analysis Tool with the following tabs completed:
 - Security Posture Tab
 - Analysis – Security Posture Tab
 - Analysis – Network Comms Tab
- Vendor shall supply a diagram of vital signs network topology
- Mobile Vital Sign Monitors – requesting 370 monitors
 - NIBP Systolic pressure from 30-260 mmHg
 - NIBP Diastolic pressure from 20-220 mmHg
 - MAP from 20-230 mmHg
 - Pulse from 20-250 bpm
 - Autodeflate pressure of 300+/- 15
 - Provides cuffs of small adult, adult, large adult, and thigh
 - Oral temperature probe
 - Built-in End Tidal CO₂ monitoring
 - Approximately 15 seconds on measurement time
 - Must display Systolic pressure, Diastolic, MPA, Pulse, SpO₂, temperature
 - Can monitor height, weight, BMI, pain level, respiration rate
 - Must provide 2D Barcode Scan capabilities for CPRS interface and recognition.
 - Battery must be able to sustain constant use for at least 5 hours and hold a charge for at least 5 days.
 - Must allow for continuous monitoring for all parameters.

- Automated customizable patient scoring calculator at point of care with color coded scores.
- Option for trended pulse rate and respiration rate and a solution to early detection of patient deterioration using those parameters
- Must have mobile stand with cable management and storage bin
- Internal 802.11 a/b/g Wireless Radio; 100-240 V, 50-60 HZ ac, IEC Plug type B (FIPS 140-2 Compliant)
- Supply centralized service dashboard to facilitate managing all vital signs monitor troubleshooting and device availability from one location.
- Equipment Alarms
 - Alarms shall be audible and visual. Audible alarms can be temporarily silenced, but a visual alarm will remain until the issue is addressed.
 - The following measured parameters shall have the capability to be utilized as alarm parameters. Setting the ranges for the alarm shall be easy and user friendly.
 - Cuff leak
 - Cuff disconnect
 - Hose leak
 - Inflation/deflation errors
 - Failure to take successful reading
 - Low-battery notice
 - Battery
 - The operating time of the vital signs monitor from a fully charged battery shall be at least 1 hour.

7. Delivery Location:

3350 La Jolla Village Drive
 Building 1
 San Diego CA, 91961

8. Warranty and Support

VA Biomedical Engineering will have full access to the hardware and software that constitute the system, including any diagnostic software features and general administration rights. The VA Biomedical Engineering point of contact must be briefed, by the vendor, on all software upgrades and changes and agrees to each prior to installation. The vendor will provide two (2) sets of user manuals and technical manuals to VA Biomedical Engineering.

9. Installation

All work and installation will be coordinated with the COR, Nursing, and Biomedical Engineering groups. Phasing and work schedule will be provided and coordinated with the COR. A detailed installation schedule will be provided during the project implementation kick-off meeting. The installation will occur at the discretion of the COR and be coordinated with the VA. The full deployment shall have a 60 day deployment window. In addition to the COR, an additional representative at the facility will act as a liaison to ensure that the vendor meets government expectations and follows the guidelines as set by the Contracting Officer. Vendor will have no access to VA sensitive information during the installation. Vendor may utilize a remote connection (VPN) to the system server only. The vendor must have a nationally-approved memorandum of understanding and/or interconnection security agreement (MOU/ISA).

The vendor will confine operations (including storage of materials) on Government premises to areas authorized and approved by the Contracting Officer. The Contractor shall hold and save the Government, its officers and agents, free and harmless from liability of any nature occasioned by the Contractor's performance. Working space and space available shall be as determined by the COR.

The vendor shall provide a description of the installation services offered, for the entire Vital Signs Monitor solution, specifically addressing each of the following requirements:

- The vendor shall provide professional project management services to organize the trade-in, training, installation, and go-live activities at each facility coordinated through the Contracting Officers Representative (COR).
- The vendor shall identify a single project manager to oversee the VASDHS vital signs monitor installation, and include an organization chart identifying all installation team members.
- The vendor shall provide a timeline that details each step in the installation process.
- The vendor shall be responsible for testing the system at each facility to ensure that the system is functioning as defined by the SOW.
- The vendor shall be responsible for managing all waste created by the product installation, including clean-up and disposal.
- Ongoing clinical applications and technical support via telephone, for 12 months following the installation.

10. Testing

The contractor shall verify to Biomedical Engineering and Nursing staff that the system meets all requirements stated on this contract through demonstration and validation. Vendor will have no access to VA sensitive information during the testing.

11. Training Requirements

The Contractor will be responsible for providing on-site super user training and general staff user training for the units. VASDHS will have five days of onsite user training included to be used at their discretion. Training shall have a 1 year window to be used. Vendor will have no access to VA sensitive information during the training. Training at a minimum shall include the following characteristics:

Clinical training Requirements:

On-Site User (Clinical-User) Training: Vendors shall provide a detailed training plan on how they will accomplish the training as described above. The vendor providing the system will be responsible for training all clinical users on their application and use. The vendor, at the time of installation, shall provide staff education at the main VASDHS facility and designated CBOCs. This on-site "Go-Live" training shall include training for all shifts. A clinical education professional shall administer the training.

Education curriculum must include but is not limited to the following:

- Operations and set-up
- User maintenance
- Safety
- User troubleshooting.
- Negotiating and understanding machine profiles to better serve the patient and staff

Biomedical Engineering Training Requirements

Biomedical Technical Training: The vendor shall provide a detailed training plan on how they will provide technical training for maintenance and service for Biomedical Engineering personnel. This training is to be completed at some point between time of award and the end of warranty. This shall include factory service training courses, if applicable.

- The vendor will indicate details about each training session offered.
- The vendor shall provide any special service tools and/or test equipment comparable with that provided to the OEM's service personnel.
- Training should, at minimum, address the following topics:
 - Theory of Operation.
 - Use of schematics and circuit diagrams.
 - Use of Technical Service Mode.
 - Commissioning and Preventative Maintenance.
 - Calibration procedures.
 - Troubleshooting.
 - Interpreting and correcting alarm conditions.
 - Spare parts.

The vendor shall provide 16 hours of training to the Biomedical Engineering staff. This shall include but not limited to server, vital sign unit, and VistA interface maintenance and troubleshooting

12. Trade-In Consideration

Any component of the trade-in equipment that contains electronic protected health information (ePHI) will be retained by the VA. The vendor shall provide the trade-in value of each vital signs monitor to be replaced and detail how it will be given to the Government.

13. Maintenance Requirement

Maintenance at a minimum shall include the following characteristics:

Manuals:

The vendor shall provide the following documentation for the proposed equipment:

- Two (2) copies of the Operator Manuals.
- Two (2) copies of complete technical Service Manuals including troubleshooting guides, necessary diagnostic software and equipment, schematic diagrams, and parts lists.

Service:

The vendor shall address how they will meet the following service requirements.

- Prior to and during the guarantee period, all services shall be performed at no charge to the Government.
- Describe remote system support where applicable, including remote diagnostics via VPN/remote access. Contractor shall utilize the VA national Site-to-Site VPN, or the Contractor shall work with the Office of Cyber and Information Security and Health Information Security Division (HISD) to establish a client-based VPN.

The Contractor shall confine all operations (including storage of materials) on Government premises to areas authorized and approved by the Contracting Officer. The Contractor shall hold and save the Government, its officers and agents, free and harmless from liability of any nature occasioned by the Contractor's performance.

Working space and space available shall be as determined by the COR.

Debris will be removed daily by the contractor unless otherwise directed.

Workmen are subject to rules of the Medical Center applicable to their conduct.

Execute work so as to interfere as little as possible with normal functioning of the Medical Center as a whole, including operations of utility services, fire protection systems and any existing equipment, with work being done by others. Do not store materials and equipment in other than the designated contractor storage areas.

14. Phasing:

The contractor shall submit a phasing schedule in writing to the COR for approval two weeks prior to the start of any work.

VASDHS is a fully operational hospital. The Contractor must schedule his work around VA operations and specifically for the convenience of the hospital. Contractor must note work at times other than normal operating hours.

15. Protection of Existing Structures, Equipment, Utilities, and Improvements:

The Contractor shall preserve and protect all structures and equipment on or adjacent to the work site. The contractor shall replace at his own expense damage to such items to the satisfaction of the Contracting Officer.

Contractor shall take all measures and provide all materials necessary for protecting and preserving existing equipment and property in affected areas of installation against dust, debris and physical damage, so that equipment and affected areas to be used in Medical Center operations will not be hindered. Contractor shall permit access to VA personnel through installation areas as required for maintenance and normal Medical Center operations.

When the installation area is turned over to Contractor, Contractor shall accept entire responsibility therefore. Contractor shall maintain in operating condition, existing fire protection, alarm equipment and other operating equipment in the installation area. IT IS VERY IMPORTANT THAT ESSENTIAL AND LIFE SAFETY SYSTEMS BE CONTINUOUSLY MAINTAINED AND NOT INTERRUPTED WITHOUT TWO WEEKS PRIOR WRITTEN NOTICE AND APPROVAL FROM THE VA MEDICAL CENTER.

16. Safety Data Sheet (SDS):

Contractor shall provide three (3) copies of each Safety Data Sheet for every product, chemical, etc. used on this project. SDS sheets shall be provided for any material on the same day those materials arrive on VA property. At no time shall the contractor have, or permit subcontractors to have, materials on station without SDS sheets. All instructions for use shall be followed. Products will not be used until SDS's are submitted to the COR.

The contractor shall maintain a current, loose-leaf notebook on the job site at all times, which is readily available for viewing by the COR or VA Safety Officer.

17. Work Hours:

Normal business hours are 7:30AM to 4:30PM Monday thru Friday excluding Federal Holidays. Work completed outside this time must be requested through the COR.

Requests for after hours work must be submitted in writing to the COR two (2) weeks prior to work. The VA requires that information submitted must contain: extent of work, workers involved, the affected areas, and the estimated times of operation.