Statement of Work (SOW)
DEPARTMENT OF VETERAN AFFAIRS
James J Peters Bronx VA Medical Center

Physiological Monitoring System

I. BACKGROUND

a. GENERAL PROJECT DESCRIPTION

The mission of the Department of Veterans Affairs (VA) is to provide excellent healthcare services to veterans of the United States. James J Peters Bronx VA Medical Center is seeking competitive proposals from prospective vendors to provide and install a patient monitoring and telemetry system for the James J Peter hospital to include, at minimum, bedside monitors, central nursing station monitors, telemetry transmitters and appropriate supporting quantities of portable/transport monitors and telemetry. These systems will be built upon a network provided by the vendor. This purchase will also include a Clinical mobile communication system in order to integrate communication, event notification and patient data. All system components are prohibited from using Microsoft Windows XP, Server 2003 and Windows XP Embedded or any operating systems released prior to these. The purchase must include training for nursing and Biomedical staff.

b. DEFINITIONS

i. ACI-TIPI – Acute Cardiac Ischemia Time-Insensitive Predictive Instrument
ii. CES – Clinical Engineering Service
iii. CO – Contracting Officer
iv. COR – Contracting Officer technical Representative
v. INV BP – Invasive Blood Pressure
vi. PM – Preventive Maintenance Inspection. Services which are periodic in nature and are required to maintain the equipment in such condition that it may be operated in accordance with its intended design and functional capacity with minimal incidence of malfunction or inoperative conditions.
vii. NIBP – Non Invasive Blood Pressure
viii. VistA –Veterans Health Information Systems and Technology Architecture
ix. WMTS – Wireless Medical Telemetry Service
x. CPRS – Computerized Patient Record System

II. TASKS/REQUIREMENTS

All system components must meet the following characteristics:

a. Monitor requirements are listed below:

Patient Care Area	Bedside Physio Monitors	Spare Physio Monitors	Total Physio Monitors	Central Stations	Transport Physio Monitors	Transmitters (includes spares)
Emergency Department	11	2	13	1	2	
Intensive Care Unit	20	2	22	5	4	
Operating Room	10	1	11	0	2	
Post-Anesthesia Care Unit (PACU)	11	0	11	1	2	
PACU Mobile	3	1	4			
IR/CT Biopsy	2	0	2			
Stepdown				1		
Telemetry				1 (with 16 licenses)		16+2(spares)
Total	**57**	**6**	**63**	**9**	**10**	**18**

b. Central Station:
    a. This sub-system shall allow a user to remotely view all networked monitors under the particular care area. The central station shall also include the following components: a large high quality display, software, mounts, Uninterrupted Power Supply (UPS) and all connections/accessories.

    b. The central station shall display physiologic waveforms and patient identifications each for 16 wired and/or telemetry patients concurrently on a single screen.

    c. Users in central stations must be able to adjust, update status of or silence clinical alarms. Alarms shall differ in tone and/or frequency depending on the seriousness of the event occurring.

    d. The system shall be able to respond to remote input for the purpose of diagnosing and troubleshooting any networked equipment in the care area.

    e. The central station shall include patient identification features in addition to patient name.

    f. Central Station Monitor shall provide a minimum of 72 hour full disclosure, or the ability to access a patient's data within a minimum of the last 72 hours, at any time.

    g. Provide graphical interface on the central telemetry and nursing station monitors to display ST elevation (typically defined as 0.1 mV difference between the EKG trace and resting electrical signal measured 40 milliseconds after the S

wave in a limb lead). This display should be separate from an EKG waveform and provide visual or audio alarms when elevation falls out of a range defined by the clinical staff.

b. 3.2.2 Operating Room (OR) Monitors:
    a. OR monitor shall be able to view any monitor within the OR patient monitoring network.

    b. Shall be mounted onto the sides of existing Drager Apollo and Drager Fabius Tiro anesthesia machines.

    c. Monitoring shall be continuous from post-surgery to recovery without losing patient information.

    d. Shall display large flat panel touch-screen.

    e. Anesthesia gas modules, Bispectral Index (BIS) modules, and SpO2 (Masimo) modules shall be included and capable of communicating with the OR central station client.

    f. Shall be able to record invasive/non-invasive blood pressures and temperatures.

c. Pre-Operational Unit (Pre-Op) Monitors:
    a. Shall be able to view any monitor within the Pre-Op patient monitoring network.

    b. Monitoring shall be continuous from admitting to Pre-Op until Surgery.

    c. Shall be able to monitor 12-lead EKG signals, Central venous pressure signals, ST wave elevation and data from third party equipment such as Continuous Cardiac Output monitoring.

d. Post-Anesthesia Care Unit (PACU) Monitors:
    a. Shall be able to view any monitor within the PACU patient monitoring network.

    b. Monitoring shall be continuous from discharge of post-op to admitting to floors.

    c. Shall display on large flat panel touch-screen.

e. Intensive Care Unit (ICU) Monitors:
    a. Shall be able to view any monitor within the ICU patient monitoring network.

    b. Monitoring shall be continuous from transfer from one care unit to another.

    c. Shall display on large flat panel touch-screen.

d. Capnography modules, invasive and non-invasive blood pressure monitoring modules and SpO2 (Masimo) modules shall be included and capable of communicating with the ICU central station client.

e. Shall be able to monitor temperature, 12-lead EKG signals, Central venous pressure signals, ST wave elevation and data from third party equipment such as Continuous Cardiac Output monitoring.

f. Shall be able to interface to the Clinical Information System (CIS) and Electronic Medical Record (EMR) system at the James J Peters Bronx VA.

f. Medical/Surgical/ER (Telemetry) Monitors:

a. Shall have the ability to be mounted near the patient bedside while permitting efficient workflow for the patient care staff.

b. Shall be able to associate with specific telemetry transmitters.

c. Monitoring shall be continuous from transfer from one care unit to another.

d. Shall include batteries that are easily replaceable.

e. Non-invasive blood pressure monitoring modules and SpO2 (Masimo) modules shall be included.

f. Shall be able to monitor temperature, 12-lead EKG signals, non-12-lead EKG signals, Central venous pressure signals and ST wave elevation.

g. Shall have ability to display telemetry parameters through connection to telemetry transceiver.

h. Shall have the capability of running 16 Telemetry stations concurrently.

g. Transport Monitors:

a. Shall be easy to carry and compact, while offering multiple mounting options for effective transport.

b. Shall include batteries that are easily replaceable.

c. Non-invasive blood pressure monitoring modules and SpO2 (Masimo) modules shall be included.

d. Shall include electrocardiograms (EKG) and respiratory monitoring

h. Telemetry Packs

a. Shall utilize patient worn wireless device for monitoring physiological data (at minimum: EKG).

b. Shall allow monitored data to be viewed from remote central monitoring stations.

i. Portable monitor requirements are listed below:

LOCATION	CO2	12 Lead	ACI TIPI	Alarm Event Sharing	CARDIAC	INV BP	Roll Stand
8B	X	X	X	X	X	X	X
CATHLAB					X		X
CT Scanner	X				X		X
DENTAL					X		X
DENTAL					X		X
ED	X						X
IR		X	X	X	X	X	X
OR	X				X		X
PACU/Portable	X				X		X
RESP THERAPY	X	X	X	X	X	X	X
SPARE 1	X				X		
SPARE 2	X				X		
SPARE 3	X				X		
WOMEN'S HEALTH 6F					X		X

j. Clinical Mobile Communication system
   a. A total of seven (7) secure cellphones or similar sized devices that will perform all of the following:
      i. Allows for secure voice and texting communication between devices
      ii. Allows access to patient data such as EKG waveforms, physiological monitoring, Lab results, connection to the electronic medical record (VistA), etc.
      iii. Is able to scan barcodes (both 1 and 2-D barcodes)
      iv. Alarm management – including notification and alarm tone customization consistent with IEC standard 60601-1-8. All alert tones and colors will be displayed on the home screen of the software.
      v. WIFI connection available (must be FIPS compliant)

k. Cabling/Network and Installation
   a. Contractor shall provide turn-Key Installation providing all hardware and accessories for a complete networked system, including servers, network drops, running fiber, switches et al, and services shall include removal of current patient monitoring infrastructure.
      i. Uninterruptible Power Supplies (UPS) will be provided by the James J Peters Hospital

b. Contractor shall be responsible for a site survey, design, system infrastructure, installation, commissioning and project management prior to installation.

c. As part of installation, HEPA-grade dust Carts with heap filtration shall be provided by the contractor to prevent dust from entering patient care areas when working above the ceiling.

d. All cabling and accessories to provide a complete and functional system.

e. All above ceiling cabling runs shall be tie-wrapped and placed in telephone/data trough, in a conduit, or properly routed through interstitial area per hospital facilities requirements and local electric codes.

f. Cables shall be bundled neatly and in a professional manner especially when cables converge at network hardware.

g. Cables shall be marked at each end indicating the termination point of the other end.

h. Network cabling, terminations, and any patch panels used shall be CAT6 certified.

i. All cables shall be terminated TIA568A.

j. Any cable run through plenum space shall be plenum rated according to National Electric Codes and applicable fire codes.

k. All cable runs shall be tested and certified in accordance with TSB-67 and TIA/EIA 568-A or latest TIA/EIA Revisions.

l. The system shall be configured to allow users to view patients throughout the hospital or care areas.

m. Drawings that indicate the location of the monitoring devices will be provided for the Medical Center.

n. Interface shall be compliant with VA National interface standard.

o. All networking hardware shall be rack mounted in a room designated by Facility Project Manager or Contracting Officer's Technical Representative (COR).

p. The contractor must provide ceiling mountable antennae or access points to continuously transmit clinical patient information between central nursing station monitors and telemetry devices. Any contractor-provided access points must operate at the 2.4GHz band. Antennae should be installed by the contractor in locations identified by the James J Peters Bronx VA to provide coverage throughout the main building of the James J Peters Bronx VAMC campus. This will equate to approximately 125,000 sqft.

q. Any telemetry transmitters must send data wirelessly in any of the Wireless Medical Telemetry Service (WMTS) ranges: 608-614, 1395-1400 or 1427-1432 MHz, as mentioned in FCC guidance in order to reduce radio interference. These must communicate in duplex with central nursing stations, either directly or indirectly with access points. Transmitters must not require manual restart when devices fall out of or into the network range. Transmitters must be able to store 12-lead EKG data and associative patient information up to seven days after patient discharge.

r. All necessary wireless access points must comply with both manufacturer's functional requirements and VA's security requirements (VA Directive 6550, Pre-Procurement Assessment for Medical Device/Systems), whether they are provided by the contractor or the VA. A site visit may be accommodated for contractor to determine necessary network components to provide.

s. The contractor shall provide a system that interfaces with VistA (VA's hospital information system) via HL7 protocols and send abbreviated reports to VistA Imaging (VA's imaging storage system). For monitors that will connect to Tele-ICU, the system must send admission-discharge-transfer (ADT), case results, order messages and anesthesia workflows. The system must be able to integrate with the VA's Clinical Procedures system, which is a gateway to the VA's Electronic Medical Record (EMR). The contractor should provide a Manufacturer Disclosure Statement for Medical Device Security (MDS2) and VA Form 6550, Pre-Procurement Assessment for Medical Device/Systems network security documentation.

III. TRADE INS

The following equipment is available from the existing physiological monitoring system for trade in:

Model	Serial #	LOCATION
CIC PRO V5.0	SCH08446371GA	8B
DASH 5000	SD008452361GA	8B
DASH 3000	SD007397839GA	OR
DASH 3000	SD007397840GA	Rehab
SOLAR 8000I	SE408436619GA	ICU
DASH 3000	SD007398133GA	CATHLAB
DASH 3000	SD007397841GA	CT-2 2ND FL
DASH 3000	SD007397838GA	DENTAL
DASH 3000	SD007398130GA	DENTAL
CIC PRO V5.0	JA104470587GA	ED
DASH 4000	SBG05380631GA	ED
DASH 4000	SBG05380651GA	ED

SOLAR 8000M	RST04430075GA	ED
SOLAR 8000M	RST04430073GA	ED
SOLAR 8000I	SE410175401GA	ED
SOLAR 8000I	SE410175412GA	ED
SOLAR 8000I	SE410175398GA	ED
SOLAR 8000I	SE408436618GA	ED
SOLAR 8000I	SE409099040GA	ED
SOLAR 8000I	SE409099039GA	ED
SOLAR 8000I	SE409099037GA	ED
SOLAR 8000I	SE409099038GA	ED
SOLAR 8000I	SE409038347GA	ED
ATS	SAH08443958GA	ICU
CIC PRO V5.0	SCH08436321GA	ICU
CIC PRO V5.0	SCH08436324GA	ICU
CIC PRO V5.0	SCH08436338GA	ICU
CIC PRO V5.0	SCH08436347GA	ICU
SOLAR 8000I	SE408436609GA	ICU
SOLAR 8000I	SE408436581GA	ICU
SOLAR 8000I	SE408436625GA	ICU
SOLAR 8000I	SE408436610GA	ICU
SOLAR 8000I	SE408436620GA	ICU
SOLAR 8000I	SE408436613GA	ICU
SOLAR 8000I	SE408436617GA	ICU
SOLAR 8000I	SE408436605GA	ICU
SOLAR 8000I	SE408436608GA	ICU
SOLAR 8000I	SE408436621GA	ICU
SOLAR 8000I	SE408436622GA	ICU
SOLAR 8000I	SE408436616GA	ICU
SOLAR 8000I	SE408436615GA	ICU
SOLAR 8000I	SE408436611GA	ICU
SOLAR 8000I	SE408436614GA	ICU
SOLAR 8000I	SE408436631GA	ICU
SOLAR 8000I	SE408436623GA	ICU
SOLAR 8000I	SE408436587GA	ICU
SOLAR 8000I	SE408436612GA	ICU
SOLAR 8000I	SE408436618GA	ICU
DASH 5000	SD008452364GA	IR
SOLAR 8000I	SE409038348GA	IR
SOLAR 8000I	SE409038349GA	IR
DASH 3000	SD007398138GA	OR
DASH 3000	SD007387420GA	OR
SOLAR 8000I	SE409038352GA	OR

SOLAR 8000I	SE409038353GA	OR
SOLAR 8000I	SE409028346GA	OR
SOLAR 8000I	SE409038355GA	OR
SOLAR 8000I	SE409038350GA	OR
SOLAR 8000I	SE409028345GA	OR
CIC PRO V5.0	SDY09090768GA	PACU
DASH 5000	SD008463178GA	PACU
DASH 5000	SD008463181GA	PACU
DASH 5000	SD008462990GA	PACU
DASH 5000	SD008463180GA	PACU
DASH 5000	SD008473962GA	PACU
DASH 5000	SD008473958GA	PACU
DASH 5000	SD008462989GA	PACU
DASH 5000	SD008473528GA	PACU
DASH 5000	SD008462987GA	PACU
DASH 5000	SD008462988GA	PACU
DASH 5000	SD008463179GA	PACU
DASH 3000	SD007398137GA	PACU/Portable
DASH 5000	SD008473959GA	RESP THERAPY
DASH 4000	SBG05380577GA	ICU
DASH 3000	SD007376901GA	Clinical Engineering
DASH 3000	SD007387595GA	OR
SOLAR 8000I	SE408436624GA	ICU
SOLAR 8000I	SE409038354GA	Clinical Engineering
DASH 3000	F2DJ1474G	ICU
DASH 3000	F1DJ1315G	ICU
CIC PRO V5.0	SDY14071620GA	STEPDOWN
DASH 3000	SD007398135GA	WOMEN'S HELATH 6F

IV. **CONTRACT AWARD MEETING**

The contractor shall not commence performance on the tasks for this SOW until the contracting Officer has conducted a kick-off meeting or has advised the contractor that the kick-off meeting has been waived.

V. **DELIVERABLES/DELIVERY SCHEDULE**

The following should be delivered to the location specified in Section X. Place of Performance on the date specified.

a. The Contractor shall provide a detailed work plan and briefing for the COR which presents the contractor's plan for completing all that is required by the SOW. The contractor's plan shall be responsive with this SOW and describe, in further detail, the approach to be used for all installation, training, and re-work if deemed necessary (see Section IX. Acceptance Procedures).

b. (4) Service Manuals (2 physical and 2 electronic copies on CD)– Obtaining the service manual is a VA Mandate per VAAR regulation AS7004 Service Data Manual (SEPT 2007). Therefore, any vendor who is unwilling or unable to provide at a minimum 4 Service Manuals will have their proposal rejected at the time of proposal submission. The VA will not return such proposals and will dispose of them.

c. Any unique necessary items required for PM or general maintenance.

VI. **INSTALLATION**

a. All work and installation will be coordinated with the COR and Clinical Engineering groups. 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.

b. There shall be no interruption in workflow during the installation and switch-over from the current to the new Physiological Monitoring system. The current Physiological Monitoring system should not be shut down until approved by the COR and Clinical Engineering groups.

c. The JJP VA Medical Center 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.

d. The vendor will confine operations (including storage of materials) on Government premises to areas authorized and approved by the Contracting Officer. Working space and space available shall be as determined by the COR.

e. Contractor will have no access to VA sensitive information during installation

f. All Contractor workers are required to sign in and out at the VA Police Dispatch in the ground floor of Building 100 as directed by the COR or designee. A valid state driver's license or state identification card is mandatory for all employees to have access to this facility. All contractor employees are required to wear the assigned VA badge at all times.

g. 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.

VII. VA INFORMATION SECURITY POLICIES:

a. The contractor will not remove any medical system components from the facility without authorization from the Director, Clinical Engineering Service or designee. Any medical system hard drives will remain in the possession of the JJP VAMC.

b. The Contractor will identify if removable media (i.e. USB or DVD/CD Device) is required to perform his/her duties. Personally owned USB thumb drive utilization is prohibited. Non-VA support personnel must furnish their own certified USB thumb drives, and only with the permission of a designated VA supervisor. The Contractor is not permitted to remove any VA sensitive data from the system without approval from the Clinical Engineering Service JJP VAMC director. All USB drives must be scanned with an antivirus program running current virus definitions by the local VA staff, prior to connection to any VA device. The Director, Clinical Engineering Service or designee will ensure the removable media is scanned with anti-virus software running current virus definitions prior to connection to any medical device system. The computer system for scanning removable media is located in the biomedical engineering shop, Building 100, 6th Floor.

VIII. **TRAINING**

a. The Contractor will be responsible for providing on-site user training for the patient monitoring equipment. The James J. Peters VAMC will have onsite user training included to be used at their discretion with enough time allocated (to be approved by the COR) for proper training to take place. Training shall have a 1 year window to be used. Contractor will have no access to VA sensitive information during training.

IX. **ACCEPTANCE PROCEDURES**

a. General

i. Upon completion of installation and after contractor makes available to the using activity any training (e.g. initial applications and operator training) required by the manufacturer to properly use the equipment, the equipment shall be turned over to the facility for clinical use and the contractor shall furnish a written notice of readiness for inspection to the following Government personnel:

TBA

ii. Substantial Clinical use will be presumed to begin on the day after the notice of readiness for inspection is received by the Government. The Using Service must notify the contracting officer, Logistics and Clinical Engineering if clinical use is not initiated at this time.

iii. Submission of the notice of readiness for inspection, and any other notice required by this provision by electronic mail is acceptable, provided that the party giving such notice obtains and preserves electronic evidence of receipt at the email address or addresses of the party or parties who have a right to notice under this clause. The Government shall provide appropriate email addresses on the purchasing documentation.

b. Inspection and Testing

i. The Government, through Clinical Engineering shall have the right to inspect and test the equipment within thirty (30) calendar days after receipt of the notice of readiness for inspection (the 30-day period) or thereafter during the warranty period as noted below. The contractor shall provide the necessary technical and applications personnel to perform the inspection (and any re-inspections).

ii. The Government shall provide notice of acceptance of the equipment, via the **James J Peters Bronx VAMC Acceptance Form**, or of unsatisfactory inspection/test results to the contractor within ten (10) calendar days after the date of inspection. The latter notice shall identify to the contractor any deficiencies found during the inspection and whether the deficiencies were significant or not, and will provide the contractor fourteen (14) calendar days to correct such deficiencies.

iii. It is the contractor's responsibility to correct reported deficiencies and to advise the Contracting Officer when all corrections have been made and the equipment is ready for re-inspection.

iv. Re-inspection(s) will be performed by the Government with all costs incurred chargeable to the contractor's account.

c. Warranty Effective Date

i. Any applicable warranty period will commence on the date the notice of readiness for inspection (via the **Acceptance Form**) was submitted unless the equipment is inspected during the 30-day period and one or more significant deficiencies are found and the system is taken out of Substantial Clinical Use.

ii. For systems so failing the initial acceptance inspection and accepted after a Government re-inspection or re-inspections, the warranty period will commence on the date the notice of readiness (via the **Acceptance Form**) for

the successful re-inspection was submitted. If only minor (i.e., non-significant) deficiencies are found during inspection and Substantial Clinical Use continues, the warranty date will commence on the date the notice of readiness (via the **Acceptance Form**) for inspection was submitted.

d. Substantial Clinical Use

i. Substantial Clinical Use has the following meaning in this clause: the delivered equipment is able to perform the basic intended clinical function of the system in a safe manner for the purpose for which it was designed, with most or all system functionality, allowing the equipment to be used clinically. Substantial Clinical Use does not include initial scanning of patients during applications training.

ii. If the equipment is put into Substantial Clinical Use by the Government for thirty (30) calendar days after the inspection request, acceptance will occur thereafter as described below. However, if significant deficiencies in the equipment are identified during the 30-day period while it is in Substantial Clinical Use and clinical use ceases, the requirement for 30 calendar days of Substantial Clinical Use will not be considered met and procedures under "No Substantial Clinical Use" will be followed. It is understood that Substantial Clinical Use is incompatible with and cannot continue in the event significant deficiencies are identified.

iii. For systems in Substantial Clinical Use for thirty (30) calendar days without significant deficiencies being identified during inspection (if inspection occurs), the contractor will notify the Government that the system has been in Substantial Clinical Use for this time period, and request acceptance and payment. The Government will confirm with the customer whether or not Substantial Clinical Use has occurred for thirty (30) calendar days and, upon positive confirmation, the Government will issue a notice of acceptance (via the **Acceptance Form**) and authorize an appropriate payment document, VA receiving report within ten (10) calendar days after receiving the request. In the event that the Government is notified by the customer that Substantial Clinical Use has not occurred for thirty (30) calendar days, the Government shall so notify the contractor within ten (10) calendar days after receiving the request for acceptance and payment. Within this notice, the government will provide rationale for why the equipment was not used.

iv. The failure of the Government to notify the contractor of its intent to dispute Substantial Clinical Use within ten (10) calendar days after receiving the request for acceptance and payment shall constitute acceptance on the part of the Government. Acceptance under this paragraph shall not negate the right on the

part of the Government to later exercise its rights under any remedy available to the Government by federal law or regulation.

v. In the event the Government has not conducted an acceptance inspection of the equipment within thirty (30) calendar days of the date of the notice of readiness for inspection, during the period of Substantial Clinical Use, the Government shall have the right to inspect the equipment during the warranty period. Deficiencies discovered during the inspection shall be presented to the contractor for correction as appropriate under the terms of the warranty.

e. No Substantial Clinical Use

i. No Substantial Clinical Use means that delivered equipment is not able to perform the basic intended clinical function in a safe manner for the purpose for which it was designed and that most or all system functionality is not present, preventing the equipment from being used properly clinically during the 30-day period. If the equipment does not meet the criteria for Substantial Clinical Use, as defined in Section IV.d of this clause, the system will not be accepted without formal testing under Section IV.b, and final payment will not be issued until after the equipment satisfactorily completes formal testing.

f. Final Acceptance/Rejection Procedures

i. In the event the equipment is not placed in Substantial Clinical Use for thirty (30) days, or is so placed and inspected and significant deficiencies are found, within seventy-five (75) calendar days after receipt of the notice of readiness for inspection, the Government shall:

1. accept the equipment; or
2. accept the equipment and request that identified defects be remedied under the contract's warranty provisions; or
3. request the vendor propose an equitable offset in lieu of correcting defects or rejection; or
4. reject and request removal of the equipment.

ii. This section IV.f of the Acceptance Procedures clause is not intended to affect the parties' rights and responsibilities provided in sections IV.a through IV.d and section IV.g of the Acceptance Procedures clause.

iii. When requested, the contractor shall propose offsets within five (5) calendar days. If agreement is not reached with the Government on such offsets within five (5) calendar days thereafter, additional discussion on offsets may continue at the mutual agreement of the contractor and Government, or, at the request of either party, the Government will cease any clinical use, reject and request

removal of the equipment. In cases of an offset, where the equipment is accepted by the Government, the commencement of the warranty period will be established by the contracting officer.

iv. If the equipment is rejected, the Government reserves the right to a complete refund.

v. If equipment is rejected and the contractor is requested to remove such equipment, the contractor shall completely de-install all equipment items and remove them within 10 calendar days from the Government premises at the contractor's expense.

g. Final Payment

i. Final payment is due in 30 calendar days after formal acceptance. In cases where the Government accepts an offset proposal, final payment (if any is owed) is due within 30 calendar days of the Government's formal acceptance of the proposal.

X. **PLACE OF PERFORMANCE**

All units quoted shall be delivered to the following address for initial inspection and acceptance:

James J Peters (Bronx) VAMC
130 West Kingsbridge Road
Bronx, NY 10468

XI. **WARRANTY**

a. All equipment shall have a full warranty of a minimum of 1 year for all failure modes. Equipment may have additional time for a warranty, however, if the additional time corresponds to an increase in the quote price, the extended warranty should be quoted as an option only.

b. During the warranty period, the contractor shall maintain the equipment by furnishing all necessary labor, management, equipment, preventive maintenance, tools, materials, repair service, instruments, software and hardware updates and parts for service to bring the units to their original intended functionality. The contractor will provide repair service such as adjusting, replacing parts, and maintaining the equipment, including all intervening calls necessary between regular services and calibrations.

c. Warranty Effective Date: The warranty period will commence on the date the receipt of delivery is submitted, unless the equipment is inspected during the 21-day period and one or more significant deficiencies are found and the system is not able to be used.

Systems that fail the initial acceptance inspection and accepted after a re-inspection(s) will have the warranty period commence on the date the notice of readiness (via the CO) for the successful re-inspection was submitted.

XII. **CLINICAL SUPPORT**

a. Clinical 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 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 shall provide and install manufacturer recommended software upgrades and changes at no additional charge during warranty/contract period.

b. For any repairs or services that will be performed during normal working hours, the vendor's service representative will report upon arrival to the VA Engineering Point of Contact or his/her designee. Upon completion of the work, the vendor's service representative must report in person to the Point of Contact and must present a copy of his/her field service report signed by the service using the equipment. This report must reflect date and time of service, name of company, and the name of the vendor's service representative. At a minimum, this report must contain a detailed description of any services or repairs performed and identification of the units serviced. It must include a listing of replacement parts, when applicable. The report will also include the vendor's recommendations necessary to maintain the equipment in best operating condition. Preventive maintenance procedures followed should be thoroughly documented (step-by-step) on the service report.

XIII. **SECURITY CLAUSES**

a. **A prohibition on unauthorized disclosure:** "Information made available to the contractor or subcontractor by VA for the performance or administration of this contract or information developed by the contractor in performance or administration of the contract shall be used only for those purposes and shall not be used in any other way without the prior written agreement of the VA." See VA handbook 6500.6, Appendix C, paragraph 3.a

b. **A requirement for data breach notification:** Upon discovery of any known or suspected security/privacy incidents, or any unauthorized disclosure of sensitive information, including that contained in system(s) to which the contractor/subcontractor has access, the contractor/subcontractor shall immediately and simultaneously notify the COR, the designated ISO, and Privacy Officer for the contract. The term "security incident" means an event that has, or could have, resulted in unauthorized access to, loss or damage to VA assets, or sensitive information, or an action that breaches VA security procedures. See VA Handbook 6500.6, Appendix C, paragraph 6.a

c. **A requirement to pay liquidated damages in the event of a data breach:** "In the event of a data breach or privacy incident involving SPI the contractor processes or maintains under this contract, the contractor shall be liable to VA for liquidated damages for a specified amount per affected individual to cover the cost or providing credit protection services to those individuals." See VA handbook 6500.6, Appendix C, paragraph 7.a., 7d.

d. **A requirement for annual security/privacy awareness training:** "Before being granted access to VA information or information systems, all contractor employees and subcontractor employees requiring such access shall complete on an annual basis wither: (i) the VA security/privacy awareness training (contains VA security/privacy requirements) within 1 week of the initiation of the contract, or (ii) security awareness training provided or arranged by the contractor that conforms to VA's security/privacy requirements as delineated in the hard copy of the VA security awareness training provided to the contractor. If the contractor provides their own training that conforms to VA's requirements, they will provide the COR or CO, a yearly report (due annually on the date of the contract initiation) stating that all applicable employees involved in the VA's contract have received their annual security/privacy training that meets VA's requirements and the total number of employees trained, See VA Handbook 6500.6, Appendix C, paragraph 9.

e. **A Requirement to sign VA's Rules of Behavior:** "Before being granted access to VA information or information systems, all contractor employees and subcontractor employees requiring such access shall sign on annual basis an acknowledgement that they have read understand, and agree to abide by VA's Contractor Rules of Behavior which is attached to this contract." See VA Handbook 6500.6, Appendix C, paragraph 9, Appendix D. Note: If medical device vendor anticipates that the services under this contract will be performed by 10 or more individuals, the Contractor Rules of Behavior may be signed by the vendor's designated representative. The contract must reflect by signing the Rules of Behavior on behalf of the vendor that the designated representative agrees to ensure that all such individuals review and understand the Contractor Rules of Behavior when accessing VA's information and information systems.