

Statement of Work

Contractor shall provide an extended warranty plan, Platinum Level, and a preventative maintenance program to the Northern California HealthCare System. This will include parts, labor and a yearly preventative maintenance check to provide NCHCS with a 97% Uptime Guarantee for the government-owned Triton 36 and peripherals to include a base year and up to 4 option years. Services shall be provided for the Department of Veterans Affairs Northern California Health Care System. All services shall be provided in accordance with the specifications, terms and conditions contained herein.

1. SUPPLIES OR SERVICES AND PRICE/COSTS

Parts, Labor, and Preventative Maintenance Program with a 97% Uptime Guarantee will be provided under a Platinum Level Extended Warranty, which is the most robust extended warranty option that offers the cost of replacement parts, labor cost associated with repairs and expedited shipping for replacement parts and the Preventative Maintenance Program Agreement for the Model Triton 36 with Serial Number 1512XL362371 and VA 612 EE90810 located at the Sacramento Veterans Affairs Medical Clinic, 10535 Hospital Way Mather, CA 95655 for contract year starting November 1, 2016 through October 31, 2017.

2. SERVICES:

Contractor shall furnish labor, travel, technical support and parts covered under the Platinum Level Warranty and the Preventative Maintenance Program, for the contract year starting November 1st, 2016 through October 31st, 2017.

Contractor shall provide the following services:

- A. Labor and preventative maintenance will be provided between 7:00 am to 4:00 pm, M-F, providing 97% uptime of the system.
- B. Phone Response
- C. On-Site Response
- D. Parts Order Requirement will include overnight and expedited shipping
- E. Yearly Planned Maintenance (Preventative Maintenance)

3. PARTS:

The Following Parts are covered under the Platinum Level Extended Warranty Plan.

The following parts are covered under the Platinum Level

Ultrasonic Transducer	Power Cord	Operator Interface Touch Panel ¹
Ultrasonic Generator	Power Entry Module	Operator Interface Cable
Electrical Relays	Pneumatic Lifts	Enzyme Tank Components ²
Electrical Resistor	Temperature Probe	Enzyme Pump (Transfer) ²
Electrical Contacts	Air Regulator(s)	Peristaltic Pump ²
Transformer	Solenoid Valves	Optical Water Level Sensors
Electrical Breakers	Plumbing Connections	Capacitive Water Level Sensors
Power Supply	Plumbing Check Valves	Ultrasonic Basin
Power Control Switch	Lift Sensors	Programmable Logic Controller
UV Light Housing Unit		

The following parts are covered under the Preventative Maintenance Program.

Covered Parts

Optical Level Sensor	Timer Kit
Thermistor	Cabinet Feet
Irrigation Nozzles	Tray Connections
Rinse Nozzle	Overflow Sensor
Detergent Connections*	Power Switch
Peristaltic Pump Tubing	Drain Screen
Liquid Flow Sensor	Plumbing Connection
Heater Pad	LED Light Kit(XL & Triton Series)
Fuses	Enzyme Level Sensor
Ice Cube Relay	Level Sensor Housing

The contractor shall furnish and replace standard parts at no cost. The contractor shall have ready access to all replacement parts. All parts supplied shall be OEM or equivalent and fully compatible with existing equipment. The contract shall include all parts with the exception of consumable or expendable items. The contractor shall use new parts.

4. DEFINITIONS/ACRONYMS:

- A. Biomedical Engineering - Supervisor or designee, Phone Number (916) 366-5481
- B. CO - Contracting Officer.
- C. 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 operative conditions. Service shall consist of calibration and testing in accordance with the manufacturer's latest established service procedures to ensure operation of equipment within manufacturer's or VA's performance specifications, whichever is the most rigorous. PM includes cleaning, inspecting lubricating and testing all equipment. All equipment shall be operated at least one complete operating cycle at the end of each PM.
- D. FSE - Field Service Engineer. A person who is authorized by the contractor to perform maintenance (corrective and/or preventive) services on the VA Outpatient Clinic premises.
- E. ESR - Vendor Engineering Service Report. A documentation of the services rendered for each incidence of work performance under the terms and conditions of the contract.
- F. Acceptance Signature - VAOPC employee who indicates FSE demonstrated service conclusion/status and user has accepted work as complete/pending as stated in ESR.
- G. Authorization Signature - COR's signature; indicates COR accepts work status as stated in ESR.
- H. NFPA - National Fire Protection Association.
- I. CDRH - Center for Devices and Radiological Health.
- J. VAOPC - Department of Veterans Affairs Outpatient Clinic.
- K. OEM - Original Equipment Manufacturer

5. CONFORMANCE STANDARDS:

Contractor shall provide services and material to ensure that the equipment functions in conformance with the latest requirements of NFPA-99, JCAHO, NEC, OSHA, CAP, Federal and VA specifications and requirements as applicable. The equipment shall be maintained such that it meets or exceeds the performance specifications as established in the OEM's technical specifications. Additional performance specifications that exceed the OEM specifications shall be specified in writing by the VA.

6. PREVENTIVE MAINTENANCE (PM):

- A. Contractor shall perform Preventive Maintenance inspections yearly as requested.
- B. The contractor shall furnish documentation, including all measurement and calibration data to certify that the system is performing in accordance with the performance specifications.

7. EMERGENCY MAINTENANCE:

- A. All required parts shall be furnished, with the exception of expendable, consumable. Pricing shall be at exchange price from Ultra Care or one of their subsidiaries. Consumable and expendable parts are defined as items that require replacement on a greater than one month frequency. Any exceptions shall be noted by the contractor in writing prior to the initiation of the contract. All subsequent decisions on classification of parts are at the discretion of the Biomedical Engineer.
- B. The CO, COR or designated alternate has the authority to approve/request a service call from the contractor.

8. HOURS OF COVERAGE:

Normal hours of coverage are (Monday through Friday) from 7:00am to 4:00pm, excluding government holidays.

9. SERVICE MANUALS:

The VAOPC shall not provide service manuals or service diagnostic software to the contractor for use in providing services under this contract. The contractor shall obtain, have on file, and make available to its FSE's all operational and technical documentation, (such as: operational and service manuals, schematics, and parts list), which are necessary to meet the performance requirements of this contract. The location and listing of the service data manuals, by name, and/or the manuals themselves shall be provided to the CO upon request.

10. DOCUMENTATION/REPORTS:

The documentation will include equipment down time and detailed descriptions of the scheduled and unscheduled maintenance procedures performed, including replaced parts and prices (for outside normal working hour services) required to maintain the equipment in accordance with conformance standards. Such documentation shall meet the guidelines as set forth in the Conformance Standards. In addition, each ESR must at a minimum document the following data legibly and in complete detail:

- A. Name of Contractor
- B. Name of FSE who performed services.
- C. Contractor Service ESR Number/Log Number.
- D. Date, Time (starting and ending), Hours-On-Site for service call.
- E. Description of Problem Reported by COR/User.
- F. Identification of Equipment to be serviced to include the following: Equipment ID # or EE# from the bar-code, Manufacturer's Name, Device Name, Model#, Serial #, and any other Manufacturer's identification numbers.

G. Itemized Description of Service(s) Performed (including Costs associated with after normal working hour services), including: Labor and Travel, Parts (with part numbers) and Materials and Circuit Location of problem/corrective action.

H. Total Cost to be billed.

I. Signatures from the following:

1. FSE performing services described.
2. VA Employee who witnessed service described.

J. Equipment downtime, calculated in accordance with Conformance Standards.

NOTE: ANY ADDITIONAL CHARGES CLAIMED MUST BE APPROVED BY THE COR BEFORE SERVICE IS COMPLETED!

11. REPORTING REQUIREMENTS:

The contractor shall report to Biomedical Engineering to "check-in" upon arrival and prior to performance of work under this contract. This check-in is mandatory and can be accomplished in person or by phone contact. When the service(s) is/are completed, the FSE shall document the services rendered on a legible ESR(s). The FSE shall be required to check out with the Biomedical Engineering Department (location to be specified at time of contract award) and submit the ESR(s) to the COR. All ESRs shall be submitted to the equipment user for an "acceptance signature" and to the COR for an "authorization signature." If the COR is unavailable, a signed accepted copy of the ESR will be sent to the COTR within 5 business days of work completion.

FAILURE TO COMPLY, EITHER IN WHOLE OR IN PART, WITH EITHER THE NOTIFICATION OR ESR REQUIREMENTS WILL BE DEEMED SIGNIFICANT NON-COMPLIANCE WITH THE CONTRACT AND MAY BE JUSTIFICATION FOR TERMINATION OF THE CONTRACT.

12. ADDITIONAL CHARGES:

There will be no additional charge for time spent at the site during, or after the normal hours of coverage awaiting the arrival of additional FSE and/or delivery of parts.

13. REPORTING REQUIRED SERVICES BEYOND THE CONTRACT SCOPE:

The Contractor shall immediately, but no later than 24 consecutive hours after discovery, notify the CO and COR, (in writing), of the existence or the development of any defects in, or repairs required to the scheduled equipment which the Contractor considers he/she is not responsible for under the terms of the contract. The contractor shall furnish the CO and COR with a written estimate of the cost to make necessary repairs.

13. CONDITION OF EQUIPMENT:

The contractor accepts responsibility for the equipment in "as is" condition. Failure to inspect the equipment prior to contract award will not relieve the contractor from performance of the requirements of this contract.

14. COMPETENCY OF PERSONNEL SERVICING EQUIPMENT:

A. Each respondent must have an established business, with an office and full-time staff. The staff includes a "fully qualified" FSE and a "fully qualified" FSE who will serve as the backup.

B. "Fully Qualified" is based upon training and on experience in the field. For training, the FSE(s) shall have successfully completed a formalized training program, for the equipment identified in Section B. For field experience, the FSE(s) shall have a minimum of two years of experience, with respect to scheduled and unscheduled preventive and remedial maintenance on equipment identified in Section B.

C. the FSE shall be authorized by the contractor to perform the maintenance services as required. All work shall be performed by "Fully Qualified" competent FSEs. The contractor shall provide written assurance of the competency of their personnel and a list of credentials of approved FSEs for each make and model the contractor services at the VAOPC. The CO may authenticate the training requirements, request copies of training certificates or credentials from the contractor at any time for any personnel who are servicing or installing any VAOPC equipment. The CO and/or the COR specifically reserve the right to reject any of the contractor's personnel and refuse them permission to work on the VAOPC equipment.

15. TEST EQUIPMENT:

Prior to commencement of work on this contract, the contractor shall make available if requested a copy of the current calibration certification of all test equipment that is to be used by the contractor in performing work under the contract. This certification shall also be provided on a periodic basis when requested by the VAOPC. Test equipment calibration shall be traceable to a national standard.

16. COMPETENCY OF PERSONAL SERVICING EQUIPMENT

"Fully Qualified" is based upon training and on experience in the field. For training, the FSE(s) shall have successfully completed a formalized training program, for the equipment identified items in this document. For field experience, the FSE(s) shall have a minimum of two years of experience, with respect to scheduled and unscheduled preventive and remedial maintenance on equipment identified in this document.

The FSE(s) shall be authorized by the contractor to perform the maintenance services as required. All work shall be performed by "Fully Qualified" competent FSEs. The contractor shall provide written assurance of the competency of their personnel and a list of credentials of approved FSEs for each make and model the contractor services at the VAOPC. The CO may authenticate the

training requirements, request copies of training certificates or credentials from the contractor at any time for any personnel who are servicing or installing any VAOPC equipment. The CO and/or the COTR specifically reserve the right to reject any of the contractor's personnel and refuse them permission to work on the VAOPC equipment.

17. IDENTIFICATION, PARKING, SMOKING, CELLULAR PHONE USE AND VA REGULATIONS:

The contractor's FSE shall wear visible identification at all times while on the premises of the VAOPC. It is the responsibility of the contractor to park in the appropriate designated parking areas. Information on parking is available from the VA Police-Security Service. The VAOPC will not invalidate or make reimbursement for parking violations of the contractor under any conditions. Smoking is prohibited inside any buildings at the VAOPC. Cellular phones and two-way radios are not to be used within six feet of any medical equipment. Possession of weapons is prohibited. Enclosed containers, including tool kits, shall be subject to search. Violations of VA regulations may result in a citation answerable in the United States (Federal) District Court, not a local district state, or municipal court.

18. COMPLIANCE WITH OSHA BLOODBORNE PATHOGENS STANDARD:

The contractor shall comply with the Federal/California OSHA Bloodborne Pathogens Standard. The contractor shall:

- A. Have methods by which all employees are educated as to risks associated with bloodborne pathogens.
- B. Have policies and procedures that reduce the risk of employee exposure to bloodborne pathogens.
- C. Have mechanisms for employee counseling and treatment following exposure to bloodborne pathogens.
- D. Provide appropriate personal protective equipment/clothing such as gloves, gowns, masks, protective eyewear, and mouthpieces for the employee during performance of the contract.

19. SECURITY LANGUAGE CLAUSES

A. GENERAL

Contractors, contractor personnel, subcontractors, and subcontractor personnel shall be subject to the same Federal laws, regulations, standards, and VA Directives and Handbooks as VA and VA personnel regarding information and information system security.

B. ACCESS TO VA INFORMATION AND VA INFORMATION SYSTEMS

A contractor/subcontractor shall request logical (technical) or physical access to VA information and VA information systems for their employees, subcontractors, and affiliates only to the extent necessary to perform the services specified in the contract, agreement, or task order.

All contractors, subcontractors, and third-party servicers and associates working with VA information are subject to the same investigative requirements as those of VA appointees or employees who have access to the same types of information. The level and process of background security investigations for contractors must be in accordance with VA Directive and Handbook 0710, Personnel Suitability and Security Program. The Office for Operations, Security, and Preparedness is responsible for these policies and procedures.

The contractor or subcontractor must notify the Contracting Officer immediately when an employee working on a VA system or with access to VA information is reassigned or leaves the contractor or subcontractor's employ. The Contracting Officer must also be notified immediately by the contractor or subcontractor prior to an unfriendly termination.

20. VA INFORMATION CUSTODIAL LANGUAGE

A. Information made available to the contractor or subcontractor by VA for the performance or administration of this contract or information developed by the contractor/subcontractor 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. This clause expressly limits the contractor/subcontractor's rights to use data as described in Rights in Data - General, FAR 52.227-14(d) (1).

B. If VA determines that the contractor has violated any of the information confidentiality, privacy, and security provisions of the contract, it shall be sufficient grounds for VA to withhold payment to the contractor or third party or terminate the contract for default or terminate for cause under Federal Acquisition Regulation (FAR) part 12.

C. The contractor/subcontractor must store, transport, or transmit VA sensitive information in an encrypted form, using VA-approved encryption tools that are, at a minimum, FIPS 140-2 validated.

D. If a VHA contract is terminated for cause, the associated BAA must also be terminated and appropriate actions taken in accordance with VHA Handbook 1600.01, *Business Associate Agreements*. Absent an agreement to use or disclose protected health information, there is no business associate relationship.

4. INFORMATION SYSTEM DESIGN AND DEVELOPMENT

A. Information systems that are designed or developed for or on behalf of VA at non-VA facilities shall comply with all VA directives developed in accordance with FISMA, HIPAA, NIST, and related VA security and privacy control requirements for Federal information systems. This includes standards for the protection of electronic PHI, outlined in 45 C.F.R. Part 164, Subpart C, information and system security categorization level designations in accordance with FIPS 199 and FIPS 200 with implementation of all baseline security controls commensurate with the FIPS 199 system security categorization (reference Appendix D of VA Handbook 6500, VA

Information Security Program). During the development cycle a Privacy Impact Assessment (PIA) must be completed, provided to the COTR, and approved by the VA Privacy Service in accordance with Directive 6507, *VA Privacy Impact Assessment*.

B. The contractor/subcontractor shall certify to the COTR that applications are fully functional and operate correctly as intended on systems using the VA Federal Desktop Core Configuration (FDCC), and the common security configuration guidelines provided by NIST or the VA. This includes Internet Explorer 7 configured to operate on Windows XP and Vista (in Protected Mode on Vista) and future versions, as required.

5. INFORMATION SYSTEM HOSTING, OPERATION, MAINTENANCE, OR USE

A. For information systems that are hosted, operated, maintained, or used on behalf of VA at non-VA facilities, contractors/subcontractors are fully responsible and accountable for ensuring compliance with all HIPAA, Privacy Act, FISMA, NIST, FIPS, and VA security and privacy directives and handbooks. This includes conducting compliant risk assessments, routine vulnerability scanning, system patching and change management procedures, and the completion of an acceptable contingency plan for each system. The contractor's security control procedures must be equivalent, to those procedures used to secure VA systems. A Privacy Impact Assessment (PIA) must also be provided to the COTR and approved by VA Privacy Service prior to operational approval. All external Internet connections to VA's network involving VA information must be reviewed and approved by VA prior to implementation.

B. VA prohibits the installation and use of personally-owned or contractor/subcontractor owned equipment or software on VA's network. If non-VA owned equipment must be used to fulfill the requirements of a contract, it must be stated in the service agreement, SOW or contract. All of the security controls required for government furnished equipment (GFE) must be utilized in approved other equipment (OE) and must be funded by the owner of the equipment. All remote systems must be equipped with, and use, a VA-approved antivirus (AV) software and a personal (host-based or enclave based) firewall that is configured with a VA approved configuration. Software must be kept current, including all critical updates and patches. Owners of approved OE are responsible for providing and maintaining the anti-viral software and the firewall on the non-VA owned OE.

C. (Bio-Medical devices and other equipment or systems containing media (hard drives, optical disks, etc, with VA sensitive information must not be returned to the vendor at the end of the lease, for trade-in, or other purposes. For the specific options:

1. Vendor must accept the system without the drive
2. VA's initial medical device purchase includes a spare drive which must be installed in place of the original drive at time of turn-in; or
3. VA must reimburse the company for media at a reasonable open market replacement cost at the time of purchase.
4. Due to the highly specialized and sometimes proprietary hardware and software associated with medical equipment/ systems, if it is not possible for the VA to retain the hard drive then:
 - a. The equipment vendor must have an existing BAA if the device being traded in has sensitive information stored on it and hard drive(s) from the system are being returned physically intact; and
 - b. Any fixed hard drive on the device must be non-destructively sanitized to the greatest extent possible without negatively impacting system operation. Selective clearing down to patient data folder level is recommended using VA approved and validated

overwriting technologies/ methods/ tools. Applicable media sanitization specifications need to be preapproved and described in the purchase order contract.

6. SECURITY INCIDENT INVESTIGATION

A. 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. The contractor/subcontractor shall immediately notify the COTR and simultaneously, the designated ISO and Privacy Officer for the contract 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.

B. To the extent known by the contractor/subcontractor, the contractor/subcontractor’s notice to VA shall identify the information involved, the circumstances surrounding the incident (including to whom, how, when, and where the VA information or assets were placed at risk or compromised), and any other information that the contractor/subcontractor considers relevant.

C. With respect to unsecured protected health information, the business associate is deemed to have discovered a data breach when the business associate knew or should have known of a breach of such information. Upon discovery, the business associate must notify the covered entity of the breach. Notifications need to be made in accordance with the executed business associate agreement.

7. LIQUIDATED DAMAGES FOR DATA BREACH

A. Consistent with the requirements of 38 U.S.C. §5725, a contract may require access to sensitive personal information. If so, the contractor is liable to VA for liquidated damages in the event of a data breach or privacy incident involving any SPI the contractor/subcontractor processes or maintains under this contract.

B. Based on the determinations of the independent risk analysis, the contractor shall be responsible for paying to the VA liquidated damages in the amount of \$37.50 per affected individual to cover the cost of providing credit protection services to affected individuals consisting of the following:

1. Notification; One year of credit monitoring services consisting of automatic daily monitoring of at least 3 relevant credit bureau reports;
2. Data breach analysis;
3. Fraud resolution services, including writing dispute letters, initiating fraud alerts and credit freezes, to assist affected individuals to bring matters to resolution;
4. One year of identity theft insurance with \$20,000.00 coverage at \$0 deductible; and
5. Necessary legal expenses the subjects may incur to repair falsified or damaged credit records, histories, or financial affairs.

8. SECURITY REQUIREMENTS FOR UNCLASSIFIED INFORMATION TECHNOLOGY RESOURCES

The contractor, their personnel, and their subcontractors shall be subject to the Federal laws, regulations, standards, and VA Directives and Handbooks regarding information and information system security as delineated in this contract.

9. SECURITY ACCREDITATION PACKAGE

The C&A requirements do not apply and a Security Accreditation Package is not required.

Records Management Language for Contracts Required

The following standard items relate to records generated in executing the contract and should be included in a typical Electronic Information Systems (EIS) procurement contract:

- A. Citations to pertinent laws, codes and regulations such as 44 U.S.C chapters 21, 29, 31 and 33; Freedom of Information Act (5 U.S.C. 552); Privacy Act (5 U.S.C. 552a); 36 CFR Part 1222 and Part 1228.
- B. Contractor shall treat all deliverables under the contract as the property of the U.S. Government for which the Government Agency shall have unlimited rights to use, dispose of, or disclose such data contained therein as it determines to be in the public interest.
- C. Contractor shall not create or maintain any records that are not specifically tied to or authorized by the contract using Government IT equipment and/or Government records.
- D. Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected by the Freedom of Information Act.
- E. Contractor shall not create or maintain any records containing any Government Agency records that are not specifically tied to or authorized by the contract.
- F. The Government Agency owns the rights to all data/records produced as part of this contract.
- G. The Government Agency owns the rights to all electronic information (electronic data, electronic information systems, electronic databases, etc.) and all supporting documentation created as part of this contract. Contractor must deliver sufficient technical documentation with all data deliverables to permit the agency to use the data.
- H. Contractor agrees to comply with Federal and Agency records management policies, including those policies associated with the safeguarding of records covered by the Privacy Act of 1974. These policies include the preservation of all records created or received regardless of format [paper, electronic, etc.] or mode of transmission [e-mail, fax, etc.] or state of completion [draft, final, etc.].

- I. No disposition of documents will be allowed without the prior written consent of the Contracting Officer. The Agency and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. Records may not be removed from the legal custody of the Agency or destroyed without regard to the provisions of the agency records schedules.
- J. Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-contractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under, or relating to, this contract. The Contractor (and any sub-contractor) is required to abide by Government and Agency guidance for protecting sensitive and proprietary information.

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