

Performance Work Statement

Contractor shall provide Total Protection Agreement and Preventive Maintenance on Edwards Lifesciences devices and associated peripheral equipment. Services shall be provided for the Department of Veterans Affairs Northern California Health Care System – Sacramento Medical Center. All services shall be provided in accordance with the specifications, terms and conditions contained herein.

Item(s) List

The following equipment located at the VAMC, 10535 Hospital Way, Mather CA 95655

ICU

2 EV1000 A Monitors and Data Box Assemblies
S.N. : EV054637 and EV054636

SURGERY

4 EV1000 A Monitors and Data Boxe Assemblies
S.N.EV060496, EV060486, EV060505, EV060495

4 EVPMP (Pump)
S.N.60015302886, 600153000494, 600153002858,600153002866

4PC2K (Pressure Controller)
S.N. 600101003362, 600101003395, 60101002399, 600101003294

4VHRS
S.N. 600104024697, 600104024710, 600104024698, 600104024696

- The services covers Physical and Liquid Damage to the Equipment
- Associated Optical Module Cable Failures Replaced at no extra cost to the customer
- Next Day Replacement on Covered Equipment
- Shipping costs, parts and labor are no charge to the customer
- 24 x 7 x 365 Technical Phone support
- 1 (one) Preventive Maintenance included in this 3 year service.

1. SERVICES:

Contractor shall furnish the following (Labor, Travel Expenses & Parts (excluding consumables)):

- Unlimited (8:00 AM – 12:00 AM EST) telephone support for instruments, reagents and applications at no extra charge
- (2) Preventative Maintenance Inspections performed during (12) month period includes (2) PM kits
- Unlimited Service Visits (M-F exclude BD Holidays)
- Guaranteed Priority Service Response w/in 48 hours (On-site) M-F exclude BD Holidays

- Software Revisions released during Agreement Term: any software revisions must have approval from Biomedical Engineering before implementation.

2. 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.
- J. OEM - Original Equipment Manufacturer

3. CONFORMANCE STANDARDS:

Contractor shall provide services and material to ensure that the equipment functions in conformance with the latest requirements of NFPA-99, JCAHO, CAP, NEC, OSHA, HIPAA, Federal and VA security 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.

4. PREVENTIVE MAINTENANCE (PM):

- A. Contractor shall perform Preventive Maintenance inspections 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.

5. EMERGENCY MAINTENANCE:

- A. All required parts shall be furnished, with the exception of expendable, consumable parts. 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.
- C. On-site response within 48 hours. Failure to meet commitment, \$500 Response Time Credit will be issued per BD Terms and Conditions. Credit must be utilized within 90 days following the end of term and may be used to purchase spare parts, consumable parts (excluding reagents and sheath fluid), applied toward the renewal cost of maintenance service agreement or applied toward the tuition fee for training courses offered by BD Biosciences.

6. HOURS OF COVERAGE:

Normal hours of coverage are (Monday through Friday) from 8:00am to 5:00pm, excluding holidays as identified in Section H. Work performed outside the normal hours of coverage at the request of COR will be billed at the government rate. A separate purchase order will be issued to cover the cost(s) associated with any call back service as described herein.

7. PARTS:

The contractor shall furnish and replace parts at no cost with next delivery by 10:30 AM PST. The contractor shall have ready access to unique and/or high mortality 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 or rebuilt parts. Used parts, those removed from another system, shall not be installed without approval by the COR. The contractor is required to install VA supplied parts when said parts are determined to be fully compatible. All defective parts must be returned to BD Biosciences. The determination of compatibility is at the discretion of the COR.

Shipping & Handling: Shipping & Handling charges for replacement parts that are covered under Warranty or Maintenance service agreements will be at no charge. Shipping & handling charges for reagents, consumables and priority parts shipments are specifically excluded and will be billed at government rate with COR approval only.

8. 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.

9. 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. VA Purchase Order Number(s) (if any) covering the call, if outside normal working hours.
- F. Description of Problem Reported by COR/User.
- G. 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.
- H. 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.
- I. Total Cost to be billed.
- J. Signatures from the following:
 - 1. FSE performing services described.
 - 2. VA Employee who witnessed service described.
- K. Equipment downtime, calculated in accordance with Conformance Standards.

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

10. 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 COR 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.

11. 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.

12. 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 described in Section B, 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(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 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. 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.

17. 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, mouthpieces for the employee during performance of the contract.

18. Performance Standards Summary

In Development

19. Gray Market Prevention

(a) Gray market items are Original Equipment Manufacturer's (OEM) goods sold through unauthorized channels in direct competition with authorized distributors. This procurement is for new OEM medical supplies, medical equipment and/or services contracts for maintenance of medical equipment (i.e. replacement parts) for VA Medical Centers. No remanufactures or gray market items will be acceptable.

(b) Vendor shall be an OEM, authorized dealer, authorized distributor or authorized reseller for the proposed medical supplies, medical equipment and/or services contracts for maintenance of medical equipment (i.e. replacement parts), verified by an authorization letter or other documents from the OEM, such that the OEM's warranty and service are provided and maintained by the OEM. All software licensing, warranty and service associated with the medical supplies, medical equipment and/or services contracts for maintenance of medical equipment shall be in accordance with the OEM terms and conditions.

(c) The delivery of gray market items to the VA in the fulfillment of an order/award constitutes a breach of contract. Accordingly, the VA reserves the right enforce any of its contractual remedies. This includes termination of the contract or, solely at the VA's election, allowing the Vendor to replace, at no cost to the Government, any remanufactured or gray market item(s) delivered to a VA medical facility upon discovery of such items.

20. 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:

1. 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.
2. 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.

3. 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.
4. 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.
5. Contractor shall not create or maintain any records containing any Government Agency records that are not specifically tied to or authorized by the contract.
6. The Government Agency owns the rights to all data/records produced as part of this contract.
7. 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.
8. 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.].
9. 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.
10. 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.