

Scope of Work
Preventative Maintenance Services for Terumo Heart Perfusion Systems

1. SCOPE:

The Contractor shall furnish all labor, materials, parts, equipment, tools, supervision, and transportation required to service and perform preventative maintenance and emergency repairs on Terumo Perfusion Systems (S/Ns, 1491, 1508, 1509, and 1515) used in the Cardiovascular Surgery Department at the Michael E. DeBakey VA Medical Center (MEDVAMC). The Contractor shall provide calibration and preventive maintenance services by authorized Service providers of the equipment identified in Attachment 1, Equipment Inventory Listing.

2. SPECIFICATION:

2.1. The Contractor shall provide annual calibration and preventive maintenance inspections on all CDI 500 Monitor Art/HS units and all CDI 540 Calibrator equipment listed in Attachment 1.

2.2. The Contractor shall provide semi-annual calibration and preventive maintenance inspections on the remaining equipment listed in Attachment 1.

2.3. The Contractor shall ensure calibration procedures consists of calibrating the entire instrument to raceable calibration standards.

2.4. The Contractor shall ensure all instruments/equipment is properly cleaned.

2.5. The Contractor shall replace any worn or defective parts when necessary, with Original Equipment Manufacturers (OEM) parts, as per manufacturer's specifications.

2.6. The Contractor shall schedule preventive maintenance inspections at least three (3) days in advance with the Contracting Officer Representative (COR). Service also includes all necessary intervening service calls required to replace any worn or defective part needed due to instrument failure.

3. CONFORMANCE STANDARDS: The Contractor shall ensure all equipment functions in conformance with the latest published edition of NFPA-99, UL, OSHA, VA, and CDRH; in addition to the specifications identified in the manufacturer's latest published manuals and guidelines as identified below:

3.1. Manufacturer's specifications, Association for the Advancement of Medical Instrumentation (AAMI), Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), National Fire Protection Agency 99 (NFPA-99), Center for Device and Radiological Health (CDRH), Original Equipment Manufacturer (OEM), American Hospital Association (AHA), Institute of Electrical And Electronic Engineers (IEEE), Underwriters Laboratories (UL), Occupational Safety and Health Administration (OSHA), College of American Pathologists (CAP), VAMC standard operating procedures, and any other Federal, State, and Local regulations pertaining to the equipment listed for this contract.

3.2. The Contractor shall supply certification of tuberculosis testing completion prior to commencing any work located on the MEDVAMC campus.

3.3 The Contractor shall perform all work to the satisfaction of the COR. The COR shall inspect the repairman's work and indicate approval on a signed statement prior to departure.

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4. OPERATIONAL COVERAGE:

4.1. Normal work hours: Monday through Friday, 8:00 a.m. to 9:00 p.m., excluding Federal holidays. All service/repairs shall be performed during normal hours of coverage unless requested or approved by the COR or the Contracting Officer (CO).

4.2. Federal Holidays observed by the VAMC are:

New Year's Day	Martin Luther King Day	President's Day	Memorial Day
Independence Day	Labor Day	Columbus Day	Veteran's Day
Thanksgiving Day	Christmas Day		

4.3. Preventive Maintenance shall be performed in accordance with the terms outlined in the General Requirement section.

4.4. All hardware/software updates/upgrade installations shall be scheduled and performed outside normal work hours of operation (at no additional charge to the Government – unless considered detrimental to equipment up-time {to be determined by the COR}). The Contractor shall provide all software/hardware upgrade/updates.

4.5. Work performed outside the normal hours of coverage at the request of COR or Contracting Officer (CO) shall be billed at the price listed in the resultant contract. Work performed outside the normal hours of coverage at the request of the Field Service Engineer (FSE) shall be considered service during normal hours of coverage.

5. UNSCHEDULED MAINTENANCE (Emergency Repair Service):

5.1. The Contractor shall maintain the equipment in accordance with the manufacturer's specifications. The Contractor shall provide repair service which may consist of calibration, cleaning, oiling, adjusting, replacing parts, and maintaining the equipment, including all intervening calls necessary between regular services and calibrations.

5.2. Only the CO or COR has the authority to approve/request a service call from the Contractor.

5.3. Response Time: - Contractor's Field Service Engineer (FSE) shall respond with a phone call to the COR within two (2) hours after receipt of telephoned notification, twenty-four (24) hours per day. If the problem cannot be corrected by phone (with exception of the CDI 500 Monitor Art/HS and all of the CDI 540 Calibrators), the FSE shall commence work (on-site physical response) within forty-eight (48) hours after receipt of this second notification; and shall proceed progressively to completion without undue delay. This requirement for response time shall be the same for both services calls during the VA normal business hours and after-hour service calls. Corrective work shall be completed within 48 hours from telephone contact time, unless the time is extended by the COR or CO. The CDI 500 Monitor Art/HS and all of the CDI 540 Calibrators shall be sent by the MEDVAMC to the Contractor's depot for repair and a loaner replacement shall be issued upon request with all shipping costs included in the contract's firm-fixed price.

5.4. The Contractor shall provide mandatory safety and performance-related updates to covered equipment and software. Additionally, the contractor must have the ability to concurrently address multiple emergency calls and unscheduled maintenance on different equipment.

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6. SCHEDULED MAINTENANCE:

6.1. The Contractor shall perform Preventive Maintenance (PM) service to ensure that equipment listed in the schedule performs in accordance with Section 3, Conformance Standards. (An outline of the PM procedures and schedule shall be provided to the COR). The Contractor shall provide an utilize procedures and checklists with worksheet originals indicating work performed and actual values obtained (as applicable). This documentation shall be provided to the COR at the completion of the PM. The contractor shall provide written description of Preventive Maintenance Inspections (PMI). This description shall include an itemized list of the procedures performed, including electrical safety. PM services shall include, but need not be limited to, the following:

- Cleaning of equipment.
- Reviewing operating system software diagnostics to ensure that the system is operating in accordance with Section 3, Conformance Standards or the manufacturer's specifications.
- Calibrating and lubricating the equipment.
- Performing remedial maintenance of non-emergent nature.
- Testing and replacing faulty and worn parts and/or parts likely to become faulty, fail or become worn.
- Inspecting and replacing where indicated, electrical wiring and cables for wear and fraying.
- Inspecting, and replacing where indicated, all mechanical components which may include, but is not limited to: X-ray tube mounting hardware, patient restraints and support devices, cables and mounting hardware, chains, belts, bearings and tracks, interlocks, clutches, motors, keyboards, and patient couches for mechanical integrity, safety, and performance.
- Returning the equipment to the operating condition defined in Section 3, Conformance Standards.
- Providing documentation of services performed.
- Inspecting and calibrating the hard copy image device.

6.2. PM services shall be performed in accordance with, and during the hours defined in, Section 4, Operational Coverage. All exceptions to the PM schedule shall be arranged and approved in advance with the COR.

7. PARTS: The Contractor shall furnish and replace parts to meet SOW requirements. The Contractor shall provide new or factory reconditioned OEM parts and components when providing maintenance and repair services as described herein. The Contractor shall have ready access to all parts, including unique and/or high mortality replacement parts. All replacement units, parts, components, and materials to be used in the maintenance, repair, and alteration of equipment shall be compatible with that of existing equipment on which it is to be used; shall be of equal or better quality than original equipment specifications; shall conform to the technical specifications and used in accordance with original design and manufacturer intent. The contract shall include all parts [except - if applicable - those parts specifically listed as being EXCLUDED]. Rebuilt parts, used parts or those removed from other equipment, shall not be installed without specific approval by the CO or the COR. (The Contractor shall also list any excluded parts under the service contract).

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Gray Market Prevention:

(1) Gray market items are Original Equipment Manufacturers (OEM) goods sold through unauthorized channels in direct competition with authorized distributors. This procurement is for a services contract for maintenance of medical equipment (i.e. replacement parts) for the MEDVAMC. No remanufactures or gray market items will be acceptable.

(2) Vendor shall be an OEM, authorized dealer, authorized distributor or authorized reseller for the proposed service contract 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.

(3) 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 to 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 discover of such items.

8. SERVICE MANUALS/TOOLS/EQUIPMENT/TRAVEL: The MEDVAMC shall not provide travel, tools, (test) equipment, service manuals or service diagnostic software to the contractor. The contractor shall obtain, have on file, and make available to its FSE's all travel, 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 shall include detailed descriptions of the scheduled and unscheduled maintenance (i.e., Emergency repairs) procedures performed, including replaced parts and prices (for outside normal working hour services) required to maintain the equipment in accordance with Section 3, Conformance Standards or the manufacturer's specifications. Such documentation shall meet the guidelines as set forth in the Conformance Standards section. The Vendor Engineering Service Report (ESR) shall consist of a separate PM report for the item(s) covered under the "specific" contract. Grouping different equipment from different contracts on "one" ESR is prohibited. In addition, each ESR shall, at a minimum, document the following data legibly and in complete detail:

- Name of contractor and contract number.
- Name of FSE who performed services.
- Contractor service ESR number/log number.
- Date, time (starting and ending), equipment downtime and hours on-site for service call.
- VA purchase order numbers covering the call if outside normal working hours.
- Description of problem reported by COR.

Identification of equipment to be serviced:

- Inventory ID number
- Manufacturer's name
- Device name

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- Model number
- Serial number
- Any other manufacturer's identification numbers.

Itemized Description of Service Performed (including, if applicable, Costs associated with after normal working hour services) including:

- Labor and Travel
- Parts (with part numbers)
- Materials and Circuit Location of problem/corrective action.

Total Cost to be billed (if applicable - i.e., part(s) not covered, or service rendered after normal hours of coverage).

Signatures:

- FSE performing services described.
- Authorized VA Employee who witnessed service described.

NOTE: - Any additional charges claimed must be approved by the COR before service is completed!

10. REPORTING REQUIREMENTS:

10.1. The Contractor shall report to Biomedical Engineering to log in. This check in is mandatory. When the service is completed, the FSE shall document services rendered on a legible ESR(s). The FSE shall be required to log out with Biomedical Engineering 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, authorized copy of the ESR will be sent to the Contractor after the work can be reviewed (if requested or noted on the ESR).

10.2. Points of Contact: Devang Patel, Riksha George and Charles Morris

- Location (Building/Room Number): BA-200
- Telephone Number & Extension(s): 713-794-7271/7270
- Contractor - Provide telephone number(s) to call for your Service Department:
- Provide name(s) of authorized contact person(s):

10.3. Service Report: The Contractor's repairman shall complete a full-service report, in writing, after each service call (emergency or scheduled) and submit either a hardcopy or an electronic version of said report to the COR within 5 (five) days after the service is performed.

11. CONTRACTOR RESPONSIBILITIES: The Contractor shall:

- Be liable to the Government for any damage done to Government property caused by themselves or their employees.
- Upon contract award, provide valid and reliable contact information for service, preventative maintenance, emergency and technical assistance requests.

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- 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.
- Report to the COR, any changes, updates or retrofits made on any component or system for annotation on station equipment manuals and records.
- Ensure all equipment covered in this contract be in optimum working condition at the contract expiration date provided that the Contractor is notified of any deficiencies at least one (1) day before the contract expiration date.
- At no extra charge, provide any engineering and software updates necessary for continued optimum operation of the equipment listed in this contract.

12. CONTRACTOR QUALIFICATIONS/REQUIREMENTS:

- 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.
- "Fully Qualified" is based upon training and on experience in the field. For training, the FSE(s) has successfully completed a formalized training program, for the equipment and is OEM Certified. For field experience, the FSE(s) has a minimum of two (2) years of experience (except for equipment newly on the market) with respect to scheduled and unscheduled preventive and remedial maintenance, on Terumo equipment.
- The FSEs shall be authorized by the OEM to perform the maintenance services. All work shall be performed by "Fully Qualified", OEM Certified 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 MEDVAMC prior to award. The COR or CO may authenticate the training requirements, request training certificates or credentials from the Contractor at any time for any personnel who are servicing or installing any MEDVAMC equipment. The CO and/or COR specifically reserve the right to reject any of the Contractor's personnel and refuse them permission to work on the equipment if evidence is not provided when requested.
- Subcontractor(s), if utilized, must be approved by the CO. The Contractor shall submit any proposed change in subcontractor(s) to the CO for approval/disapproval.

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. REMOVAL OF EQUIPMENT: Should a piece of equipment require repair at the Contractor's facility, the Contractor shall coordinate with the COR prior to removal of the of equipment. The Contractor shall obtain a signed Property Pass from the Acquisition & Material Management Service, Personal Property Section, 4A-320; only after removal is authorized by the COR. The Contractor may not remove equipment from Government site for minor repairs only. The Contractor shall be responsible for damage or loss of equipment while in the Contractor 's charge.

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15. TEST EQUIPMENT: Prior to commencement of work on this contract, the Contractor shall provide the COR with a copy of the current calibration certification of all test equipment which is to be used by the Contractor on MEDVAMC equipment. This certification shall also be provided on a periodic basis when requested by the COR. Test equipment calibration shall be traceable to a national standard.

16. SAFETY REQUIREMENTS:

16.1. In the performance of this contract, the Contractor shall take such safety precautions as the CO or COR may determine to be reasonably necessary to protect the lives and health of occupants of the building. The Contractor shall have one supervisory employee, who will disseminate requirements to those who work at our facility, report to the Safety Manager's office for a one-time training class before working on-site. The CO or COR will notify the Contractor of any noncompliance with the foregoing provisions and the action to be taken. The Contractor shall, after receipt of such notice, immediately correct the conditions to which attention has been directed. Such notice, when served on the Contractor or his representative at the site of work, shall be deemed sufficient for the purpose aforesaid. If the Contractor fails or refuses to comply promptly with such notice, the CO may issue an order stopping all or any part of the work and hold the Contractor in default.

16.2. The VAMC, CO, COR or any of its and/or their associates, employees or descendants under any conditions or circumstances shall not be held responsible for any safety incident or any injury or any inconvenience experienced by the Contractor, their associates, or subcontractors while performing the services, labor, travel, software upgrades or maintenance included within this contract to the extent applicable by federal, local and state law with federal law taking precedence.

17. INSURANCE: The Contractor shall be responsible for:

- Worker compensation and employer's liability: The Contractor shall comply with applicable Federal and State Worker Compensation and occupational disease statutes.
- General Liability: The Contractor shall have Bodily Injury Liability Insurance coverage written on the comprehensive form of policy of at least \$500,000 per occurrence.
- Property Damage Liability: The Contractor shall have Property Damage Liability insurance coverage of at least \$500,000.

18. PRIVACY/SECURITY:

- The Contractor will not have electronic connectivity to the devices. The contractor will only have access to patient databases and PHI when physically troubleshooting image quality and other specific imaging related maintenance. need to access VA systems to perform software upgrades, preventative maintenance and maintenance repairs.
- Any electronic or magnetic data storage devices such as hard drives, etc. shall be turned into the ISO. Electronic or magnetic data storage devices are not to be removed from VA property.

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19. ADDITIONAL REQUIREMENTS:

- The contractor shall obtain all necessary licenses and/or permits required to perform this work. Contractor shall take all precautions necessary to protect persons and property from damage during performance of this contract. Contractor shall be responsible for any injury to himself or his employees, or others, as well as for any damage to personal property that occurs during the performance of this contract that is caused by him/her or his/her employee's fault or negligence
- All employees and subcontractors shall wear a visible name and company identification when onsite. When more than one person is onsite performing work under this contract, one must be designated as a supervisor and must be fully responsible for the work to be performed.
- Employees and subcontractors working onsite must wear the VA Contractor badge. The COR will be responsible for securing contractor badges for each contracted employee.
- The Contractor shall provide all supplies, materials, equipment, qualified personnel, supervision, management, and transportation to perform all tasks as identified herein. All work is to be performed in accordance with the guidelines established by Federal, State, and local ordinances and The Joint Commission. The Contractor's procedures and quality control procedures shall conform to these guidelines.
- Contractor personnel shall conduct their work so as not to interfere with the normal functioning of the facility and will stop work if asked by medical center personnel. Hours of work may need to be limited to daytime on units where patients sleep and night time in areas where patients would be exposed to risk by daytime work.
- The Contractor shall take all precautions necessary to protect the lives and health of occupants of the building.
- The Contractor shall follow procedures required by Infection Control personnel and the construction safety committee, to include any required dust control.
- The Contractor shall immediately correct any fire and safety deficiencies caused by his personnel. If the contractor fails or refuses to correct deficiencies promptly, the CO may issue an order stopping all or any part of the work and may hold the contractor in default of the contract.
- The Contractor shall comply with applicable Federal, State, and local safety and fire regulations and codes which are in effect at the beginning of the contract period. The contractor shall keep abreast of any changes in these regulations and codes applicable to the contract.

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- All material and equipment shall be removed from the facility or stored properly at the end of each work day and secured during the work day in the areas specified by the COR.
- No hot electrical work shall be performed. Any electrical work that is necessary shall be coordinated with the COR, and lockout/tagout provisions must be presented if electrical work is required.
- The Contractor shall require his employees to comply with all VA rules and regulations pertaining to the conduct of his employees while on station. Particular attention is drawn to the fact that the VAMC is a NO SMOKING Facility. Smoking is not permitted in any building and is only permitted in designated smoking shelters on the VA campus.
- Contractor shall have use of station telephones to make business calls related to Medical Center's equipment. Misuse of this privilege will necessitate the need to require the contractor to use public telephones.
- The Contractor shall not allow his/her employees, including Subcontractors' employees, to open desk drawers, cabinets, or to use office equipment, including the use of non-pay telephones for any purpose other than a local emergency call.
- The Contractor shall be responsible to provide all necessary equipment, tools, parts, and materials to perform the work. The Government shall not be obligated to provide any equipment, tools, parts, and materials to assist the Contractor in performing the work.

20. CONTRACT ADMINISTRATION:

20.1. Place of Performance: Michael E. DeBakey VA Medical Center (MEDVAMC)
2002 Holcombe Boulevard
Houston, TX 77030

20.2. Period of Performance: Estimated November 15, 2019 to November 14, 2020 (Base Year plus four (4) one (1) year option periods to be exercised at the discretion of the government).

20.3. Changes to Contract or SOW: The CO is the only individual authorized to approve changes or modify any of the requirements under this SOW or impending contract. The Contractor shall communicate with the COR on all matters pertaining to contract administration. The COR is designated to represent the CO in furnishing technical guidance and advice regarding the work being performed under this contract. Only the CO is authorized to make commitments or issue changes affecting price, quantity or performance of this contract. Costs incurred by the Contractor through the actions of parties other than the CO shall be borne by the Contractor.

20.4. Payments: Invoices shall be submitted in arrears on a quarterly basis. Invoices, SHALL INCLUDE, at a minimum, the following information:

- Contract Number & Purchase Order Number
- Item(s) covered (to include serial #'s) by the PMI and covered period of service.
- Invoice Number and Date

(End of Scope of Work)