

STATEMENT OF WORK

As of March 18, 2016

2237#: 534-16-2-2715-0268

GENERAL INFORMATION

1. Title of Project: **B Braun Dialog Plus Dialysis Machine Preventive Maintenance**
2. Scope of Work: The contractor shall provide all resources necessary to provide full service maintenance on seventeen (17) dialysis units per B Braun Dialog+ Service Manual, at the Ralph H. Johnson Veterans Affairs Medical Center (109 Bee Street, Charleston, South Carolina). Preventive maintenance is defined as such services which involves checking the correct functioning of the dialysis machine and the replacement of expendable parts to ensure the fault-free operation of the dialysis machine.
3. Background: The life-support systems (B Braun hemodialysis units) require regular maintenance. The equipment is used daily in delivering safe patient care and needs maintenance to be completed immediately. Downtime may cause life threatening issues and/or rescheduling. Moreover due to unavailability of equipment services a need to fee-basis patients will occur, which would be cost prohibitive. Also due to the proprietary nature of the equipment and software only a B Braun certified technician should perform the maintenance.
4. Performance Period: The contractor shall complete the work required under this SOW during,

TBD Base Year;
TBD Option Year 1;
TBD Option Year 2;
TBD Option Year 3;
TBD Option Year 4;

unless otherwise directed by the Contracting Officer (CO).
5. Type of Contract: Firm-Fixed-Price

SCOPE

The Contractor shall be fully responsible and accountable for the maintenance of all listed equipment beginning on the date specified in the Notice to Proceed. These specifications are a statement of the minimum level of work and services that are to be provided. They are not intended to be, nor shall they be construed as, limiting specifications or requirements. At a minimum, for each Dialog+ Evolution hemodialysis unit the contractor shall perform Preventive Maintenance every six (6) months and to take all measures which would be taken by a prudent manufacturer to maximize the life expectancy and minimize downtime of related systems and ensure safe and reliable dialysis operation.

All equipment shall be maintained in accordance with the manufacturer's recommendations, the best practices of the industry, and all applicable codes, standards, and regulations. If a conflict arises between these standards, the most stringent will prevail.

The Contractor shall provide a reliable and well-trained certified B Braun service technician on-site to provide non-emergent preventive maintenance and/or repairs, as needed during normal working hours, Monday through Friday, 8:00 am to 4:00 pm with the exception of national holidays. Prior to commencing work, the B Braun service technician will report to Biomedical Engineering (room G200) to sign in every day that he or she is required to be on site.

All scheduled work that requires a dialysis machine to be taken out of service shall be coordinated with the COTR or designee and the contractor shall report to the COTR or designee the status of dialysis equipment or systems not operating by the close of each workday. Any equipment or system not operational by the official start time of the occupants shall be reported to the COTR or designee by 8:00 a.m. that day. The contractor shall be responsible for the installation of signs as related to equipment and/or systems as deemed necessary by the COTR or designee. In the event a dialysis machine is shutdown, a "Do Not Use" sign must be placed on each machine.

The Contractor shall maintain the machinery spaces, shops and storage areas in a clean and orderly manner. When work is performed in these areas, the Contractor's personnel shall clean up all debris and leave the area in a presentable condition. The Contractor must obtain the approval of the COTR or designee before storing anything in equipment spaces. Operating supplies such as lubricants, rags, cleaners, etc., shall be properly secured in containers approved by the COTR or designee. Storage shall not negatively impact the means of egress, fire protection systems, and emergency lighting; nor, shall it significantly increase the amount of combustible material in the equipment space. Safety requirements shall be maintained as required by NFPA, the National Electrical Code and the manufacturer recommendations.

PERFORMANCE REQUIREMENTS

1. MATERIALS TO BE FURNISHED:

The Contractor shall furnish all lubricants, test equipment, cleaning supplies, parts and tools necessary to perform the work described above. Only accessories, disposable items and spare parts that do not pose a technical safety risk and demonstrably comply with Medical Devices Directive 93/42/EEC (MDD) may be used. To ensure the full functionality of the dialysis machine, we recommend using products/parts by B. Braun Medical Inc.

2. SERVICE MANUALS/TOOLS/EQUIPMENT:

The Medical Centers shall not provide tools, (test) equipment, service manuals or service diagnostic software to the contractor. The contractor shall obtain, have on file, and make available to its staff all operational and technical documentation (such as: operational and service manuals, schematics, and parts lists) 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 or COTR upon request.

3. REPORT OF SERVICES/DOCUMENTATION:

Upon completion of any maintenance and/or repair services, the contractor shall report to the COTR or designee and provide an electronic report detailing services performed and obtain an acceptable signature. Contractor shall prepare and submit a written report on or before the third (3rd) day after the service detailing all services performed for each dialysis machine. This report shall be required prior to billing. If this service report is not received, invoices shall not be paid until report is received and verified. Contractor shall maintain a complete orderly and chronological file, including, but not

limited to, parts list, copies of repairs required by contract, etc. This file shall be made available for inspection upon request of the Contracting Officer or COTR.

4. EQUIPMENT TO BE SERVICED:

Unit	EE #	Model	Serial #
1	176798	Dialog+ Evolution	103487
2	176799	Dialog+ Evolution	103488
3	186216	Dialog+ Evolution	211546
4	186217	Dialog+ Evolution	213210
5	186218	Dialog+ Evolution	213175
6	186219	Dialog+ Evolution	213212
7	186220	Dialog+ Evolution	213208
8	186221	Dialog+ Evolution	211545
9	186222	Dialog+ Evolution	213172
10	186223	Dialog+ Evolution	213174
11	186224	Dialog+ Evolution	213173
12	186225	Dialog+ Evolution	213207
13	186226	Dialog+ Evolution	213209
14	186227	Dialog+ Evolution	211535
15	186228	Dialog+ Evolution	213205
16	186229	Dialog+ Evolution	213206
17	186925	Dialog+ Evolution	214276

INFORMATION SECURITY

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

WORK SCHEDULING AND REPORTING ACCOMPLISHMENTS

Hours of Coverage:

Normal hours of coverage are Monday through Friday 8am to 4:30pm. Service will be performed during normal hours of coverage unless requested or approved by COTR.

Federal Holidays observed by the VAMC are:

- | | |
|------------------------|------------------|
| New Years' Day | Labor Day |
| Martin Luther King Day | Columbus Day |
| Presidents' Day | Veterans' Day |
| Memorial Day | Thanksgiving Day |
| Independence Day | Christmas Day |

The Contractor shall instruct his/her personnel that any time they perform work under this contract they shall comply with the following procedures:

- Contact the COTR or his/her designated representative in Biomedical Engineering (room G200) when first arriving at the building. If the work is of a continuing nature, a check-in visit is required each day.

CHANGES TO STATEMENT OF WORK

Any changes to this SOW shall be authorized and approved only through written correspondence from the CO. A copy of each change will be kept in a project folder along with all other products of the project. Costs incurred by the contractor through the actions of parties other than the CO shall be borne by the contractor.

TRAVEL

All work is to be conducted at the Ralph H. Johnson VAMC located at 109 Bee Street, Charleston, South Carolina. The contractor is responsible for any anticipated travel and per diem.

GOVERNMENT RESPONSIBILITIES

The VA shall grant the Contractor and its Subcontractor permission to all areas of the Ralph H. Johnson VA Medical Center that are required access to provide maintenance of the dialysis machines.

REPORTING

All repairs and services that will be performed during normal working hours, should be done in coordination with the Biomedical Engineering Section, as described above, to report/sign-in and to obtain an identification badge which shall be worn at all times while repairman is on station. After all work is completed, the Vendor must again report in person to the Biomedical Engineering Section, to submit in writing, a complete report of services or repairs performed for each item of equipment and must also include a listing of replacement parts, when applicable.

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