

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: VA263-17-AP-5759

- 1. Contracting Activity:** Department of Veterans Affairs, NCO 23, St. Cloud VA Health Care System, 4801 Veterans Drive, MN 56303. Organization Activity: Minneapolis VA Health Care System (MVAHCS), One Veterans Drive Minneapolis, MN 55417, 618-17-2-040-0176.
- 2. Nature and/or Description of the Action Being Processed:**
This procurement is for a Brand Name Only, 100% SDVOSB set-aside, firm fixed price purchase order to upgrade the Minneapolis VA Health Care System's Carto 3 system in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.
- 3. Description of Supplies/Services Required to Meet the Agency's Needs:**
This procurement is to upgrade the MVAHCS' Biosense Webster Carto 3 heart mapping system. The upgrade will include software modules and hardware to bring the platform to the latest version and provide additional functionality as well as peripherals to allow for clinical use of the new functionality. The Carto solution develops real time 3D map of the heart by utilizing electromagnetic technology. This technology assists electrophysiologists in navigating the heart and assist with catheter location and orientation. The upgrade shall bring the software version to the latest platform. New features with the upgrade include the ability to take a static fluoroscopy image and combine it with the real time cardiac map generated by the Carto system. In addition, the system will allow for cardiac ablation which corrects tissues that are causing arrhythmias in the heart.

Period of Performance: 60 days ARO

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- 4. Statutory Authority Permitting Other than Full and Open Competition:**
The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).
 - 5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**
The Minneapolis VA's Cardiology department requires an upgrade to their Biosense Webster Carto 3 heart mapping system to include software modules, hardware and peripherals to bring it to the latest software version and provide additional functionality. This upgrade is proprietary to Biosense Webster as they are the manufacture of the Carto3 system. No other vendor's software, hardware or peripherals are compatible with the existing system. Utilizing another vendor's software would require replacing the entire system and all the existing peripherals. Biosense Webster, a large business, was contacted and they verified that there are only 2 other authorized distributors, both of which are SDVSOBs, for the Carto 3 system and upgrade.
 - 6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** This upgrade will be posted as a brand name only solicitation through FBO.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** Price will be determined fair and reasonable through competition, comparing the quotes received with the IGCE, past purchases, Biosense's List Price and any discounts received by the VA.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** VetBiz was searched under NAICS code 339112 which returned 157 results. GSA was searched and the Carto 3 upgrade is not available on contract. Biosense Webster was contacted and they verified that they are the manufacturer and that there are only 2 other authorized distributors for the Carto 3 system and upgrades. Both authorized distributors are SDVOSBs.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** NA

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**
Biosense Webster and Geo-Med.

11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:**
The government will continue to do market research for any future upgrades and if compatible systems are available the procurement will be solicited. The current Carto Mapping System has an expected life cycle of 5-7 years and this upgrade is to add additional functionality.

12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.



13. **Approvals in accordance with the [VHAPM, Volume 6, Chapter VI: OFOC SOP](#).**

a. **Contracting Officer or Designee's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



b. **Director of Contracting /Designee (Required over\$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

