BRAND NAME JUSTIFICATION

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Acquisition Operations
Strategic Acquisition Center - Frederick
Ballenger Center Drive, 125
Frederick, MD 21703

2. Description of Action: The proposed brand name action is for a firm fixed price purchase order for the delivery and installation of Zeiss FORUM Software and four (4) Zeiss HFA3 Model 840 Visual Field Analyzer with printer/table. This equipment will enable The Department of Veterans Affairs (VA), VISN 07, Atlanta Medical Center Ophthalmology to provide timely patient care and evaluations to prevent blindness.

3. Description of Supplies or Services: The proposed action is for Zeiss HFA 3 Model 840 Visual Field Analyzer Machines and Software. These machines enable the Technology-based Eye Care Services (TECS) Program to improve patient access for specialty eye care, both for detailed screening and long term management of eye diseases. The Contractor will deliver, install, and provide training on the equipment, ensuring that all equipment is fully operable upon completion of installation. The Contractor will provide a connectivity service plan for the Zeiss FORUM Software.

4. Statutory Authority: The statutory authority permitting this action is FAR 13.501(a): Sole source (including brand name) acquisitions.

5. Rationale Supporting Use of Authority Cited Above: The proposed requirement is for Zeiss FORUM Software and the Zeiss HFA 3 Model 840 Visual Field Analyzer Machine. Both manufactured by Carl Zeiss, Meditec Inc. Only the Zeiss visual field machine, the HFA, is approved to connect to the VA Vista Imaging System.

It is critical to have this highly specialized equipment connect to the VA Vista Imaging System because the test results must be entered into the patient medical record as it is necessary to refer to the test results again for continued patient care.

TECS is a remote program, therefore the data obtained at the Community-Based Outpatient Clinic (CBOC) has to be securely transferred to the remote reader for interpretation and that is done through Vista Imaging. If a piece of equipment cannot connect and transfer to Vista Imaging, then remote readers won't be able to interpret the test results and physicians will therefore be unable to care for patients.

Per the VistA Imaging Approved Digital Imaging and Communications in Medicine (DICOM) Modality Interface memo dated May 2017, the Zeiss HFA is the only Visual Field Analyzer that has passed the VA's internet based validation. Refer to the memo (see link below) that provides a list of approved DICOM modalities.

Zeiss commodities are DICOM compliant as per the DICOM Conformance Statement. Therefore, testing results should be able to transfer to VA Vista Imaging using DICOM format. Any system of use must be on the approved VA list (page 29 - ophthalmic photography) http://www.va.gov/HEALTH/imaging/docs/VistA_Imaging_DICOM_Modality_Interfaces.pdf

The Zeiss Humphrey Visual Field testing protocols are proprietary, and not comparable between different devices.

- Glaucoma is a chronic eye disease that needs life-long follow up, and to determine progression, one must be able to compare a visual field test from 2010 to one obtained in 2017.
- These recommendations are standard clinical practice; refer to American Academy of Ophthalmology, Preferred Practice Patterns for Glaucoma (see link): https://www.aao.org/preferred-practice-pattern/primary-open-angle-glaucoma-ppp-2015
- Testing protocols for glaucoma are proprietary to the company that makes the visual field machine. These testing protocols include an algorithm for testing (how targets are presented to patients' and with what order and intensity of light), and a normative database (normal people who take the test and serve as the basis for comparison for disease).
- The Atlanta VA main Eye Clinic uses the Sita-Standard protocol, which is proprietary to Zeiss. Other visual field machine manufacturers e.g. Haag-Streit Octopus, can perform a visual field test. However, Haag-Streit utilizes the "G-pattern" protocol. The G pattern derived visual field result is not comparable to the Sita Standard derived visual field result.
- Testing a patient with two different machines using two different protocols results in an apples-to-oranges comparison and renders the ability to detect disease progression unreliable, which would result in significant patient harm.

6. Efforts to Obtain Competition and Market Research: Market research was conducted to verify that the circumstances surrounding the brand name procurement are factual. In this market research, there have been sources identified that offer visual field machines and middleware. However, none of the items meet the needs of the TECS Program or the Eye Clinic at the Atlanta VA Medical Center. The Government has identified at least eight resale vendors of the specified Zeiss commodities. Therefore, competition is anticipated for this action.

7. Other Facts: Zeiss's visual field machine is on the VA approved DICOM modality interface list which allows the machine to transfer data to the VA Vista Imaging System. This is critical to the functioning of the TECS program (sending images to remote readers) as well as securely storing an important part of the patient's medical record. Other visual field machines do not use the testing algorithm/normative database Site-Standard protocol, (proprietary to Zeiss). This specific protocol is necessary for patient safety and care, as physicians need to make an apples-to-apples comparison of a patient's visual field. To do this, patients need to be tested with the same protocol and the main clinic only uses Zeiss HFA machines. New tests must be directly comparable to previous tests, which is not possible if the algorithms are different. Market research has also indicated that there are no equal product offerings due to the medical landscape of the existing eye equipment and the necessity to integrate all equipment onto one common communicable and image transferable platform.

8. Sources: No other sources have expressed, in writing, an interest in the acquisition.

9. Actions to Increase Competition: All future requirements will be handled on a case-by-case basis to determine any future acquisition strategy.

10. Technical and Requirements Certification: I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.

Name: Vera Banks Date: 9/13/2017

Title: Program Analyst/COR Signature: Vera M Banks 1430549

Digitally signed by Vera M Banks 1430549
DN: dc=gov, dc=va, o=internal, ou=people, 0.9.2342.19200300.100.1.1=vera.banks@va.gov, cn=Vera M Banks 1430549
Reason: I have reviewed this document.
Date: 2017.09.13 13:59:14 -04'00'

11. Fair and Reasonable Cost Determination: I hereby determine that the anticipated price to the Government for this contract action will be fair and reasonable based on FAR 13.106-3.

Carey M Kauzlarich Date: 09/13/2017

Procuring Contracting Officer Signature: Carey Kauzlarich 1058862

Digitally signed by Carey Kauzlarich 1058862
DN: dc=gov, dc=va, o=internal, ou=people, 0.9.2342.19200300.100.1.1=carey.kauzlarich@va.gov, cn=Carey Kauzlarich 1058862
Date: 2017.09.13 15:18:57 -04'00'

12. Procuring Contracting Officer Certification: I certify that this justification is accurate and complete to the best of my knowledge and belief.

Carey M Kauzlarich Date: 09/13/2017

Procuring Contracting Officer Signature: Carey Kauzlarich 1058862

Digitally signed by Carey Kauzlarich 1058862
DN: dc=gov, dc=va, o=internal, ou=people, 0.9.2342.19200300.100.1.1=carey.kauzlarich@va.gov, cn=Carey Kauzlarich 1058862
Date: 2017.09.13 15:19:14 -04'00'