

JUSTIFICATION AND APPROVAL
FOR A LIMITED SOURCE AWARD UNDER A FEDERAL SUPPLY SCHEDULE

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Acquisition Operations
Strategic Acquisition Center
10300 Spotsylvania Avenue, Suite 400
Fredericksburg, VA 22408

2. Description of Action:

The proposed sole source action is for a firm-fixed-price (FFP) contract for procurement of the **Spectralis HRA + OCT diagnostic imaging system upgrade**. The SPECTRALIS® HRA+OCT is a unique ophthalmic diagnostic imaging and angiography device used to generate diagnostic imaging data pertaining to the structures of the anterior and posterior segments of the eye including the conjunctiva and cornea, the anterior chamber angle, the iris, the central and peripheral retina, and the optic nerve via multimodal wide field and high magnification imaging that yields both structural and functional information about the tissues and structures under consideration. The Spectralis HRA+ OCT produces unique imaging data through simultaneous application of multiple scanning laser technologies that combine to produce diagnostic information and demonstrate response to therapy that is unique among similar diagnostic imaging devices.

The procurement will include installation, acceptance testing, training, and a manufacturer's warranty. This effort is proposed to be awarded to the L-1 Enterprises Medical Equipment and Supplies – A Service Disabled Veteran Owned Small Business, with Federal Supply Schedule Contract # V797P-4176B. L-1 Enterprises is the only Federal Supply Schedule holder authorized to distribute Spectralis HRA+ OCT. The Spectralis is a proprietary product sold in the commercial market by its manufacturer Heidelberg Engineering Inc. 1808 Aston Ave Carlsbad, CA 92008.

3. Description of the Supplies or Services:

VA Boston Health Care System provides eye care through a network of Medical Centers, Outpatient facilities and community based outpatient clinics that deliver the full spectrum of eye care from community centered primary care throughout eastern Massachusetts to the Tertiary level medical and surgical eye care for the New England Region. VABHCS seeks to provide our veterans advanced diagnostic data to accurately diagnose their conditions and determine their change in condition over time that we may best determine and apply the most appropriate therapeutic options available for a given patient's condition.

Our network of local facilities employ the diagnostic data generated from our Heidelberg Engineering Spectralis imaging devices to interface with specialty level providers at our central tertiary care facility. The data generated through our Spectralis devices helps our patients achieve timely and accurate diagnoses. We wish to upgrade our current system to bring those diagnostic and network capabilities to their highest potential through the elements in this proposal. We wish to add equipment to our current network

to improve the scope and effectiveness of the patient care we currently provide. We are requesting the equipment in this proposal because the equipment we currently have in place within our network requires equipment solely from this vendor in order to maintain and enhance our current clinical function. We have chosen this vendor to provide the equipment we currently have in place and wish to upgrade for the reasons outlined below. No other vendor's equipment will function in the way that the Heidelberg Engineering equipment functions and no other vendors equipment and software will interface with our equipment and network the way that this vendor's equipment will. We wish to upgrade our Heidelberg engineering Spectralis HRA OCT system platform and we wish to add additional Heidelberg Engineering equipment and software to our current equipment because this platform offers our patients benefits not available through other vendors.

The Heidelberg HRA OCT platform is based on a well established confocal scanning laser ophthalmoscopy (cSLO) platform, the Heidelberg Retina Angiographer (HRA) which has been proven through many years of service as the state of the art platform for fluorescein angiography and more recently, fundus auto fluorescence imaging of structures in both the anterior and posterior segments of the eye. The diagnostic functionality of the system has been augmented by the addition of an integrated high speed Spectral Domain Optical Coherence Tomography (SDOCT) system which is unique among SDOCT platforms in its ability to acquire SDOCT data while actively tracking the eye which is being scanned.

The system has Six (6) imaging modes including: Spectral domain OCT, Infrared (IR) cSLO, blue laser fundus auto fluorescence (FAF), blue reflectance cSLO (BR), fluorescein angiography (FA), and Indocyanine Green angiography (ICGA). The system is able to generate Nine (9) simultaneous imaging options: OCT+IR, OCT+FAF, OCT+BR, OCT+FA, OCT+ICGA, IR+FAF, IR+FA, IR+ICGA, FA+ICGA. The system generates these imaging modes via five (5) separate light sources at the following wavelengths: 870 nm SLD, 815 nm diode laser, 786 nm diode laser, 515 nm diode laser, 488 nm diode laser. The system employs very rapid image processing to allow for movie image capture for high speed video angiography in both fluorescein and indocyanine green angiography as well as movie image generation for IR and BR imaging to assess vascular activity.

The scanning laser technologies that are employed in diagnostic evaluations of the sort performed by this device are inherently "noisy" as the eye being imaged and measured is always moving and the image information being generated through light introduction into the eye is characterized by irregular reflectance and scatter. The Spectralis HRA+OCT system employs proprietary active tracking of the moving eye (TruTrak active eye tracking) as it acquires scan information and processes that registered scan information through proprietary Heidelberg Noise Reduction to filter the image information to subtract the extraneous image data to reveal the high quality image information which it generates.

The system is additionally able to generate forms of autofluorescence information that similar systems are unable to reliably generate because the tracking and image processing capabilities of the system allow the acquisition and representation of very weak fluorescence signals from a variety of sources in the eye as a result of the ability of the system to generate confocal scanning laser ophthalmoscopy image data enhanced with active tracking and proprietary Heidelberg Noise Reduction.

The system can generate image view fields for the posterior segment from 15 degrees out to 150 degrees via auxiliary lenses and auxiliary lens contained in the Anterior Segment Module allow full cornea scanning as well as highly magnified OCT views into the anterior chamber angle. The system presents SDOCT data with very high resolution and has been demonstrated to generate reproducibility of measurements in healthy people within a few microns on serial examination.

Because the system employs computerized tracking to align the scan activity the system can remember and recognize the regions which have been previously scanned via the proprietary AutoRescan software that places follow up scans precisely where the baseline scan was performed. This allows precise and reliable interval comparisons to determine if any changes have taken place between clinical encounters. Much of clinical diagnostic assessment and evaluation of response to therapy is dependent upon the identification of clinical change over time.

The Heidelberg HRA+OCT is a Network Ready platform that will interface with DICOM and will integrate seamlessly with our current data network and central system. The Spectralis HRA+OCT upgrades, new equipment and software in this proposal is the only type of equipment which will function with our existing equipment and network in the appropriate manner to allow us to enhance our mission. No other device can integrate with our central data system and interface with our existing systems in this way and we need the components in this justification to bring our networked capabilities up to their potential levels that we may continue to best serve our veteran patients.

This proposal also includes a request for the Heidelberg Edge perimeter and Nsite axonal analytics software that will augment our diagnostic capabilities in glaucoma, multiple sclerosis, and traumatic brain injured patients. These conditions are highly prevalent in our patient population and are conditions that require assessment of both structure and function for proper management.

The Heidelberg Edge Perimeter is a visual field assessment device that will interface with our Heidelberg Engineering structural assessment devices to combine structure and function data to improve our ability to generate accurate diagnoses for neuropathic and vasculopathic disorders that are highly prevalent in our patient population. No other brand of visual field assessment device will interface with our existing equipment in this way. The estimated value of this acquisition is **\$527,500.00**

4. Authority: FAR 8.405-6(a)(1)(i).

Per Federal Acquisition Regulation (FAR) Part 8.405-6(a)(1)(i), L-1 Enterprises is the only one source capable of providing the supplies or services required at the level of quality required because the supplies or services are unique or highly specialized.

5. Rationale Supporting Use of Authority Cited Above:

This is a sole source justification in support of FAR 11.105, Items Peculiar to One Manufacturer. Our clinical circumstances involving well establish utilization of the equipment produced by Heidelberg Engineering require us to employ equipment produced by that company to interface with our existing equipment and existing network.

The equipment and software in this proposal must interface with existing proprietary equipment to function as desired. No other equipment produced by another vendor can interface with existing equipment and network to provide the enhanced function of our existing equipment and network that we seek to achieve with this acquisition. The equipment from this manufacturer is the only diagnostic equipment and software that will meet the requirements of our needs and circumstances. No other vendor's equipment and software is compatible. With regard to installation, warranty and training, only Heidelberg Engineering can provide these services for this equipment due to the proprietary nature of this equipment and software.

6. Efforts to Obtain Competition:

The nature of our existing patient care data set and existing diagnostic equipment require interface with proprietary equipment and software from this manufacturer. There is no known competitor who makes software and equipment which can interface with our existing data and equipment.

Market research was conducted as set forth in paragraph 8 of this document and did not yield any additional sources that can meet the Government's requirements. There is no known competition for this acquisition.

7. Actions to Increase Competition:

The Heidelberg Spectralis HRA+OCT and Heidelberg Edge perimeter and associated hardware and software system is the only FDA approved diagnostic imaging system currently on the market that can successfully interface with our existing network as required by VHA. The Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed.

8. Market Research:

Extensive market research was conducted during the past 12 months through online evaluation of system capabilities and review of available literature to arrive at the conclusion that the proprietary Spectralis systems we currently possess only work with the Heidelberg Engineering-produced equipment that is necessary to make this upgrade work.

The overall North American Industry Classification System (NAICS) code was determined to be 339112 (Surgical and Medical Instrument Manufacturing); with the small business size standard of 500 employees.

A search of Service Disabled Veteran-Owned Small Businesses (SDVOSB) and Veteran-Owned Small Businesses (VOSB) under NAICS Code 339112 was conducted on March 7, 2013, at www.vetbiz.gov and GSA Advantage. Sixty-two (62) SDVOSB and VOSB were identified on Vetbiz. Only L-1 Enterprises was listed on Vetbiz and GSA as an authorized distributor of Spectralis.

SPECTRALIS Anterior Segment Module

Control Number SAC-13-07341

A search of the General Services Administration (GSA) Federal Supply Schedule (FSS) was conducted on March 7, 2013. While Heidelberg Engineering is the only other listed vendor on GSA as the manufacturer as an other than small business; L-1 Enterprises is the only SDVOSS authorized vendor under FSS Special Item Number (SIN) 65 II A (Medical Equipment and Supplies), a review of that section indicated that there were no contractors listed that could supply Spectralis systems.

9. Other Facts:

No other facts are applicable to this J&A.

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: Dr. Robert Dunphy

Date: 3-21-13

Title: OPHTHALMIST

Signature: [Signature]

11. Determination of Best Value: I hereby determine that the proposed contract action will represent the best value to the Government. GSA has already determined that the prices on the FSS contract are fair and reasonable. Additionally, price discounts will be sought.

Name: Zachary Wilcox

Date: 3-22-13

Procuring Contracting Officer

Signature: [Signature]

12. Procuring Contracting Officer Certification: I certify that this justification is accurate and complete to the best of my knowledge and belief. As this contract action does not exceed \$650,000, the certification below required by FAR 8.405-6(d) (1) serves as approval.

Name: Zachary Wilcox

Date: 3-22-13

Procuring Contracting Officer

Signature: [Signature]

Revision History

Page	Paragraph	Changes	Release Date
		Initial	March 20, 2013
4	8	Revised market research information	March 21, 2013