

**DEPARTMENT OF VETERANS AFFAIRS**

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

**Acquisition Plan Action ID: VA260-17-AP-6158**

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 20, VA Puget Sound Healthcare System (VAPSHCS).
- 2. Nature and/or Description of the Action Being Processed:** Justification for “Brand name and sole source” selection. This action will be awarded as a new contract under a “Firm Fixed Price”.

(1) Purchasing of a Spectralis Tracking OCT System - HRA+OCT w/OCT2, multicolor with options for the Puget Sound VAHCS, (2) This document requests a Brand name and sole source J&A for the purchase of this system, (3) This contract addresses the following items and services:

Item #	Description/Part Number*	Qty	Price
1	Spectralis Tracking OCT System - HRA+OCT w/OCT2, multicolor	1	\$
2	Spectralis Anterior segment module	1	\$
3	Ultra-wide field angiography module	1	\$
4	Spectralis Nsite Axonal Analytics Software	1	\$
5	Glaucoma Module Premium Ed.	1	\$
6	GMPE Software - Installation & On-Site training	1	\$
7	Spectralis - Animal Imaging Lens -Contact- Mouse Only	1	\$
8	Spectralis - Animal Imaging Lens -Non-Contact + 25 Diopter	1	\$
9	Spectralis - Animal Imaging Mount	1	\$

Grand total: \$ as quoted by SDVOSB L1

(4) Contractor identity & related information: L1 Enterprises, Medical Equipment and Supplies, 340 W. Patrick St., Frederick, MD 21701, Phone: 301-698-5798, Email: Info@L1Enterprises.com. DUNS#: 800190782. Federal EIN: 20-8709736. Cage code: 4SEC9. Verified SDVOSB. The estimated value: Grand total estimated at \$ if sourced through SDVOSB contractor “L1” The requested contract covers goods & services to supply the Government with a confocal scanning laser ophthalmoscope with options that enables enhanced research capabilities for use in rodents while maintaining the ability to perform stringent FDA-approved applications for clinical research. This make and model is currently in use in the VA system and is the only way in which to ensure that basic rodent research methodologies are completely consistent with clinical methodologies and interpretations. High translational consistency between clinical and pre-clinical research components is required to establish an essential research capacity that, in part, fulfills the VAPSHCS VISN20 MIRECC’s Congressionally-mandated investigation of posttraumatic stress disorder (PTSD) and its comorbidities which includes, but is not limited to, traumatic brain injury (TBI). Estimated award date: July/August 2017.

- 3. Description of Supplies/Services Required to Meet the Agency's Needs:** The VISN 20 VAPSHCS MIRECC requires the following capabilities from a FDA-approved confocal scanning laser ophthalmoscope (cSLO) / optical coherence tomography (OCT): The system must be a cSLO which combines the selectivity of laser light scanning with optical confocality to provide image detail and clarity not available from standard fundus photography or non-cSLO instruments. The system must have scanning laser angiography capable of conducting fluorescein angiography fluorescence with transgenic GFP (green fluorescent protein)-expression in retinal cell populations, fluorescein or indocyanine green dyes. This is required to provide high-resolution images and video sequences showing movement of dye through the vessel network. The instrument must have active eye tracking that utilizes two beams of light simultaneously to track and image the eye to improve image registration and clarity and improve longitudinal imaging quality. This is essential because actively tracking the eye in real-time throughout imaging reduces artifacts caused by eye motion. Active tracking increases OCT scan data accuracy. The system must have a noise reduction system/toggle to remove the noise inherent in scanning laser imaging. By capturing multiple images in the exact same location, this technology is able to differentiate structural information from noise which is an essential feature to detect and quantify differences between populations and treatment conditions. Noise reduction filters must be able to be turned off as needed. The unit must AutoRescan™. This technology uses fundus images like a map to automatically place follow-up scans in precisely the same position visit after visit to track disease progression longitudinally within subjects. Similarly, the system must have fovea-to-BMO (Bruch's Membrane Opening) Alignment Technology to automatically track and align scans to improve accuracy and reproducibility of retinal nerve fiber layer (RNFL) measurements. The system must have blue laser autofluorescence, which is a non-invasive, scanning laser fundus imaging modality that provides a map of the retina which can reveal metabolic malfunction of diagnostic significance in many conditions such as AMD (Age-Related Macular Degeneration), MS (multiple sclerosis) and potentially TBI. The system must have imaging / viewing in multiple Color modalities which typically use 3 lasers simultaneously to provide diagnostic images showing distinct structures at different depths within the retina. A critical requirement is the ability to analyze the optic nerve head. To do this an analytical software package is required to provides a comprehensive analysis of the optic nerve head, retinal nerve fiber layer, and ganglion cell layer by precisely matching unique scan patterns to the fine anatomic structures relevant in glaucoma diagnostics. Increased scan speed of 85,000 Hz and enhanced image contrast across a larger depth from vitreous through choroid is required for throughput and sampling capacity while reducing the total exposure each subject has while scanned. The system is required to have a widefield imaging module to provide the standard field of view of a mydriatic fundus camera for fundus and OCT imaging modalities. This is designed to simplify diagnostic protocols and facilitate detection of peripheral pathology which is indicated in studies of TBI / PTSD in orb and eye nerve health. The system requires Non-Contact, Ultra-Widefield Module delivers evenly illuminated and undistorted, high-contrast scanning laser images from the macula through the periphery which is instrumental in preforming translationally

relevant studies in mouse subjects. The system must be currently or previously used by the VA Puget Sound Health Care System so that clinical data from VISTA / CPRS could be directly and reasonably comparable with imaging method outcomes from rodents in order to improve translational research interpretations. The system must be able to produce work of the following published nature in mice: [Bosco A, Romero CO, Breen KT, Chagovetz AA, Steele MR, Ambati BK, Vetter ML. Neurodegeneration severity can be predicted from early microglia alterations monitored in vivo in a mouse model of chronic glaucoma. Dis Model Mech. 2015 May;8(5):443-55. doi: 10.1242/dmm.018788. Epub 2015 Mar 9. PMID: 25755083]. Requirement delivery date: 11-1-2017.

4. **Statutory Authority Permitting Other than Full and Open Competition:** This requirement is being solicited from a single source in accordance with FAR 13.106.1(b). The procedures in FAR subpart 13.5 were followed. The statutory authority permitting other than full and open competition for requirements under simplified acquisition procedures is 41 U.S.C. 1901. Further 38 U.S. Code 8127 – small business concerns owned and controlled by veterans: contracting goals and preferences allows the Contracting Officer to award a contract to a small business concern owned and controlled by veterans.

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

**This request satisfies the following Statutory Authorities Permitting Other than Full and Open Competition; and is supported by the below narrative:**

In accordance with 41 U.S.C. 3304(a) an agency may use noncompetitive procedures when the property or services needed by the agency are only available from one source and no other type of property or service will satisfy the needs of the agency.

The VISN20 MIRECC is Congressionally-mandated to investigate military posttraumatic stress disorder (PTSD) and its comorbidities including traumatic brain injury (TBI). PTSD and TBI are complex and both affect and are affected by organ systems outside of the brain. The body systems involved include, but are not limited to, the heart, lungs, and eyes. To fully understand how changes in these organ systems relate to PTSD / TBI over time, it is necessary to compare experimental models with observed clinical outcomes. One of the most common and robustly injured parts of the central nervous system following TBI is optic system injury which results in retinal, optic nerve, visual tracking and processing changes. To establish or maintain an essential capability for theoretical analyses, exploratory studies, and experiments in research of PTSD and or TBI, as mandated by Congress, the VISN 20 MIRECC must develop and establish critical instrumentation that enables detailed and highly-precise longitudinal retinal imaging. In particular, the Government requires the ability to establish and advance research employing clinically-relevant cSLO-HRA-OCT to document relationships between changes in eye health and underlying brain injury patterns in translational PTSD / TBI research studies. To meet these requirements the MIRECC necessitates acquisition of an FDA-approved optical coherence tomography system capable of bedside-to-bench translational research applications in mouse retina that will involve gfp-expressing transgenic mice. This cSLO-HRA-OCT system allows the

MIRECC to non-invasively monitor the changes in retinal tissue, its cells, vasculature and optic nerve head and correlate them with clinical OCT exams and IRB-approved neuroimaging, blood & CSF fluid biomarkers and neuropsychological longitudinal research.

To accomplish this, the Government requires the capabilities, as listed in Section (3) above, from a *“highly specialized”* confocal scanning laser ophthalmoscope. Critical to this are four features: 1) The unit uses FDA-approved angiography modules to detect and quantify fluorescein and GFP fluorescence to supply critical application in analysis of translational neuroscience. This feature, called FAF, must have been demonstrated in published peer-reviewed scientific journals using mouse models of GFP-expressing microglia to monitor and inform trends and outcomes in retinal and optic nerve neurodegeneration.

2) The unit must feature the key ability to differentially detect and resolve wide portions of the naturally occurring blue spectra to identify and analyze retinal structures.

3) The system must be able to produce work of the following published nature: [Bosco A, Romero CO, Breen KT, Chagovetz AA, Steele MR, Ambati BK, Vetter ML. Neurodegeneration severity can be predicted from early microglia alterations monitored in vivo in a mouse model of chronic glaucoma. *Dis Model Mech*. 2015 May;8(5):443-55. doi: 10.1242/dmm.018788. Epub 2015 Mar 9. PMID: 25755083].

4) The system must be currently or previously used by the VA Puget Sound Health Care System so that clinical data from VISTA / CPRS could be directly and reasonably comparable with imaging method outcomes from rodents in order to improve translational research interpretations. This is because published reports conclude that the different OCT systems cannot be used interchangeably for the measurement of macular thickness among other measures since measurement algorithms are specific to each instrument and yield distinct values as a result.

To accomplish the Government's goals, only one responsible source meets the required criteria and no other supplies or services will satisfy the requirement. Therefore the Government elects brand name justification of a Heidelberg Engineering Spectralis HRA-OCT system. This *highly specialized equipment* is the only commercially available instrument which meets the Government's methodological and capability requirements while being an instrument that is also used clinically within the VHA system. The instrument will acquire high-resolution neuroanatomical and vascular detail/resolution, apply advanced analysis and obtain data supporting longitudinal studies in both mouse and man. This unit uses FDA-approved angiography modules to detect and quantify fluorescein and GFP fluorescence to supply critical application in analysis of translational neuroscience. The unit features the key ability to differentially detect and resolve wide portions of the naturally occurring blue spectra to identify and analyze retinal structures.

Following a market survey using internet-based research, in-person interviews and in-person product examinations and demonstrations, no other commercially-available cSLO HRA-OCT systems were identified as potential contenders to satisfy these requirements.

The Spectralis HRA-OCT accomplishes the Government's needs, has the required peer-reviewed scientific acceptability, and its components do not have to be custom manufactured or “rederived” by internal resources or external contractors. By extension, other methodologies are as yet unproven, would require substantial duplication of cost to vet feasibility and adaptability and would contribute unacceptable delays in fulfilling the agency's immediate requirements. Accordingly, Heidelberg Engineering Spectralis HRA-OCT is the only brand name capable of

meeting the supplies and services described in Section III above without the Veteran's Health Administration experiencing unacceptable delays in fulfilling its requirements.

Further according 38 U.S. Code 8127 – small business concerns owned and controlled by veterans: (c) Sole Source Contracts for Contracts Above the Simplified Acquisition Threshold. For purposes of meeting the goals under subsection (a), and in accordance with this section, a contracting officer of the Department may award a contract to a small business concern owned and controlled by veterans using procedures other than competitive procedures if—

- (1) such concern is determined to be a responsible source with respect to performance of such contract opportunity;
- (2) the anticipated award price of the contract (including options) will exceed the simplified acquisition threshold (as defined in section 134 of title 41) but will not exceed \$5,000,000; and
- (3) in the estimation of the contracting officer, the contract award can be made at a fair and reasonable price that offers best value to the United States.

Heidelberg Engineering is a large business and has identified their sole authorized SDVOSB distributor as L1 Enterprises. The Contracting Officer has determined it is in the best interest of the Government to purchase the equipment directly from L1 Enterprises (SDVOSB) an authorized distributor of the OEM based on the above authority from 38 U.S. Code 8127.

**6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**

Sources Sought Synopsis: No formal synopsis was issued.

Other Actions: Seven companies manufacture and sell Spectral Domain Optical Coherence Tomography (SD-OCT) devices: Bioptigen, Inc, Research Triangle Park, North Carolina; Carl Zeiss Meditec, Inc, Dublin, California (Cirrus HD-OCT); Heidelberg Engineering GmbH, Heidelberg, Germany (Spectralis OCT); Optopol Technology, SA, Zawiercie, Poland (SOCT Copernicus HR); Optovue, Inc, Fremont, California (RTVue); Ophthalmic Technologies Inc, OTI, Toronto, Ontario (OCT/SLO); and Topcon Medical Systems, Inc, Paramus, New Jersey (3D-OCT 1000). Market research was conducted to determine the number and types of comparable systems that may reasonably meet the Government's requirements. During the period of March 2015 to May 2017, extensive internet-based commercial product research was conducted. During this same period, in-person and phone-based interviews/consultations were conducted with representatives from Zeiss, Heidelberg Engineering, Optovue and Bioptigen to determine if existing or "in-development" products were available within the market to meet the Government's needs. All attempts to identify multiple options to meet the Government's needs concluded with a single source being identified—Heidelberg Engineering Spectralis HRA-OCT. This was primarily driven by the clinical use of this instrument at VAPSHCS, the instrument's published use in transgenic mice in similar research domains, and its comprehensive capabilities. In brief, the Spectralis met or exceeded the requirements of the Government as described in Sections 3 and 5 of this document.

Below is a chart detailing the characteristics of the market available SD-OCT instruments. This chart comes from <https://www.reviewofophthalmology.com/article/oct-units-which-one-is-right-for-me>. Since publication of this graph, the Spectralis has been equipped with a FDA-approved glaucoma analytic software package and is quoted with the present request.

Therefore, the performance of the Spectralis meets or exceeds all of the market available instruments in addition to being the only instrument to meet the needs of the Government. Critical shortcomings of the other sources are seen in by examining the chart below.

**Figure 1: Comparison of Commercial Optical Coherence Tomography Devices.**

Device	Manufacturer	Axial Resolution	Scanning Speed	Ancillary Devices	Notable Features
Stratus OCT	Carl Zeiss Meditec	10 µm	400 A-scans/sec.	NA	Time domain detection Current gold standard Least costly option
3D-OCT 1000	Topcon	6 µm	20,000 A-scans/sec.	Color non-mydratric fundus camera	Automatic pinpoint registration Software smoothly integrates with IMAGENet
3D SD OCT	Bioprogen	5 µm, upgradeable	20,000 A-scans/sec.	Doppler processing system Small animal probe Pediatric probe Corneal probe	Dual-engine light source: 1,310 nm and 820 nm Suitable for clinical and biomedical research
Cirrus HD-OCT	Carl Zeiss Meditec	5 µm	27,000 A-scans/sec.	NA	Space-saving, single-unit design Mouse-operated set up Dedicated live iris CCD camera Dedicated SLD fundus camera Retinal vessel tracing registration
Copernicus HR	Optopol Technology	3 µm	52,000 A-scans/sec.	Anterior chamber module (5 µm) Doppler analysis module	Fastest scan speed and highest resolution in a commercial OCT
RTVue-100	Optovue	5 µm	26,000 A-scans/sec.	Anterior chamber attachment lens	Real-time scan acquisition Only device to image retina, glaucoma and anterior segment Wide number of scan protocols and analysis functions Retinal vessel tracing registration Oversampling of specific points to decrease speckle
Spectral OCT/SLO	Ophthalmic Technologies	8 µm	27,000 A-scans/sec.	Confocal SLO Microperimetry to assess structure versus function	Real-time point-to-point registration Fast registration via confocal SLO
Spectralis HRA+OCT	Heidelberg Engineering	7 µm	40,000 A-scans/sec.	HRA (FA+ICG) Confocal SLO	Six imaging modalities: SD OCT, FA, <sup>†</sup> ICG, <sup>†</sup> fundus auto-fluorescence, <sup>†</sup> red free <sup>†</sup> and IR Confocal dual beam scanning system for retinal tracking and registration Automatic rescan Oversampling of specific points to decrease speckle

<sup>†</sup> Indicates upgradeable option.

- 7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The Contracting Officer will compare the proposed price submitted by the offeror to the IGE. In addition, the Contracting Officer will contact the vendor for additional pricing information such as historical prices paid by other customers for similar products to make a fair and reasonable determination.

**Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

As described in Section VI above, market research, in accordance with FAR Part 10, was conducted by synopsis of the proposed acquisition, advising industry of the pending acquisition and soliciting inquiries from interested parties.

(This section is copied from Section VI (above) of this document.) Seven companies manufacture and sell Spectral Domain Optical Coherence Tomography (SD-OCT) devices: Bioptigen, Inc, Research Triangle Park, North Carolina; Carl Zeiss Meditec, Inc, Dublin, California (Cirrus HD-OCT); Heidelberg Engineering GmbH, Heidelberg, Germany (Spectralis OCT); Optopol Technology, SA, Zawiercie, Poland (SOCT Copernicus HR); Optovue, Inc, Fremont, California (RTVue); Ophthalmic Technologies Inc, OTI, Toronto, Ontario (OCT/SLO); and Topcon Medical Systems, Inc, Paramus, New Jersey (3D-OCT 1000). Market research was conducted to determine the number and types of comparable systems that may reasonably meet the Government's requirements. During the period of March 2015 to May 2017, extensive internet-based commercial product research was conducted. During this same period, in-person and phone-based interviews / consultations were conducted with representatives from Zeiss, Heidelberg Engineering, Optovue and Bioptigen to determine if existing or "in-development" products were available within the market to meet the Government's needs. All attempts to identify multiple options to meet the Government's needs concluded with a single source being identified—Heidelberg Engineering Spectralis HRA-OCT. This was primarily driven by the clinical use of this instrument at VAPSHCS, the instrument's published use in transgenic mice in similar research domains, and its comprehensive capabilities. In brief, the Spectralis met or exceeded the requirements of the Government as described in Sections 3 and 5 of this document.

Above in Section VI is a chart detailing the characteristics of the market available SD-OCT instruments. This chart comes from <https://www.reviewofophthalmology.com/article/oct-units-which-one-is-right-for-me>. Since publication of this graph, the Spectralis has been equipped with a FDA-approved Glaucoma analytic software package and is quoted with the present request. Therefore, the performance of the Spectralis meets or exceeds all of the market available instruments in addition to being the only instrument to meet the needs of the Government. Critical shortcomings of the other sources are seen in by examining the chart below.

Heidelberg Engineering identified their authorized SDVOSB retailers and they were contacted to request a quote towards this procurement requirement.

8. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** This requirement is for highly specialized equipment that does not have reasonable marketplace equivalents that either currently exist or can be produced with minimal modification to existing marketplace options.
9. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Elaine Peskind, MD; Murray Raskind, MD; James Meabon, PhD; Aric Logsdon, PhD; Brian Kraemer, PhD; David Cook, PhD

**10. 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:**

No further actions are planned for future acquisitions of this nature. The current approval is sought for a single requirement / fulfillment. This is due in part to the unpredictable nature of scientific and technical advances, the Government cannot forecast relevant technical specifications, agency needs or timeframes for the replacement or upgrading of this equipment.

**11. 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.

James Meabon, PhD  
R&D  
663 VA Puget Sound Health Care System

\_\_\_\_7-25-2017\_\_\_\_  
Date

**12. 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.

Heidi Gallaher  
Contracting Officer  
Program Contracting Activity - Central

\_\_\_\_\_  
Date

- 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.

Richard Dahmen  
Director of Contracting  
Program Contracting Activity - Central

\_\_\_\_\_  
Date



Chapter VI: Other Than Full and Open Competition (OFOC) SOP  
Attachment 3: Request for Sole Source Justification Format >\$150K