

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: June 12, 2017

Re: Sole Source Certification Number **SS5100 SPECTRALIS® Tracking Optical Coherence Tomography System**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS55100** for **SPECTRALIS® Tracking Optical Coherence Tomography System**, please be advised that UMMC intends to award the purchase to **Heidelberg Engineering** as the sole source provider.

UMMC issues this notice in accordance with Mississippi state law, policy, and procedures for sole source procurements.

Sole Source Criteria

1. Where the compatibility of equipment, accessories, or replacement parts is the paramount consideration (and manufacturer is the sole supplier).
2. Where a sole supplier's item is needed for trial use or testing.
3. Where a sole supplier's item is to be required when no other item will service the needs of UMMC.

Schedule

Task	Date
First Advertisement Date	June 12, 2017
Second Advertisement Date	June 19, 2017
Response Deadline from Objectors	June 26, 2017, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before June 27, 2017

Project Details

1. Describe the commodity that the agency is seeking to procure:

The University of Mississippi Medical Center (UMMC) seeks to purchase the SPECTRALIS® Tracking Optical Coherence Tomography System (SPECTRALIS). The system is an expandable diagnostic imaging that combines the scanning of laser fundus imaging with high resolution Optical Coherence Tomography (OCT).

The confocal Scanning Laser Ophthalmoscope (cSLO) in the SPECTRALIS platform is an innovative technology for examining and imaging the retina and other eye structures. Combining the selectivity of laser light with the pinpoint resolution of confocal scanning, the cSLO provides image detail and clarity. The cSLO technology not only offers documentation of clinical findings but it also often highlights critical diagnostic detail not visible on traditional clinical ophthalmoscopy. Additionally the cSLO imaging minimizes the effects of light scatter, so it can be used effectively even in patients with cataracts.

2. Explain why the commodity is the only one (1) that can meet the needs of the agency:

The Department of Ophthalmology uses these devices to follow changes in a patient's eyes over time. The SPECTRALIS does this by utilizing two scanners simultaneously. One scanner maps and tracks the eye so the other scanner can capture a scan that is in exactly the same location as the scan from the patient's previous visit therefore providing the most accurate information for physicians to best decide how to treat the patient with image storage on a server. The instrument accesses the previous scans from this server while scanning in order to align the scans being captured with scans from the past. The department has used the Heidelberg Engineering system for nine years and switching systems would eliminate comparison views. There are over 11,000 patients in our current database.

Each manufacturer of OCT equipment uses proprietary software to view and access images. Patients who require these examinations performed are generally seen multiple times during a year, many on a monthly basis. Having the same equipment at UMMC Grants Ferry that we have at UMMC Lakeland Medical will allow the providers to compare images on all patients.

3. Explain why the source is the only person or entity that can provide the required commodity:

Heidelberg Engineering is the sole manufacturer and supplier of the SPECTRALIS® Tracking Optical Coherence Tomography System. The system is not available from any other distributor. See supporting letter from Heidelberg Engineering, Attachment A.

4. Explain why the amount to be expended for the commodity is reasonable:

The estimated amount to be expended is for the purchase of the **SPECTRALIS® Tracking Optical Coherence Tomography System** is \$195,798.00. This amount is within the expected price range for these products.

5. Describe the efforts that the agency went through to obtain the best possible price for the commodity:

Through market intelligence, UMMC was able to negotiate best pricing for these products. All applicable discounts were explored and applied.

Submission Instructions and Format of Response from Objecting Parties

Interested parties who have reason to believe that the **SPECTRALIS® Tracking Optical Coherence Tomography System** (hereafter, “Products”) should not be certified as a sole source should provide information in the Vendor Form for the State to use in determining whether or not to proceed with awarding the sole source to **Heidelberg Engineering**. The Vendor Form may be found at <http://www.dfa.state.ms.us/Purchasing/documents/ObjectiontoSoleSourceDetermination.pdf>.

Objections must include the certification in Attachment C.

Comments will be accepted at any time prior to June 26, 2017, at 3:00 p.m. (Central Time) to solesource@umc.edu. Responses may be delivered via email to solesource@umc.edu. UMMC WILL NOT BE RESPONSIBLE FOR DELAYS IN THE DELIVERY OF RESPONSES. It is solely the responsibility of the Interested Parties that responses reach UMMC on time. Responses received after the deadline and responses that lack all required information will be rejected. UMMC reserves the right to inspect Interested Party’s commodity for comparison purposes.

If you have any questions concerning the information above or if we can be of further assistance, please contact solesource@umc.edu.

Attachment A: Vendor Correspondence
Attachment B: Vendor Correspondence
Attachment C: Objection Certification

Attachment A

January 2017



To Whom It May Concern:

The **SPECTRALIS® HRA+OCT** is a unique ophthalmic diagnostic imaging and angiography platform used primarily to examine the structures of the retina, macula, and optic nerve. It combines two technologies, confocal scanning laser ophthalmoscopy (cSLO) and spectral domain optical coherence tomography (SD-OCT). It is the only spectral domain OCT imaging platform to incorporate all the essential features listed below.

- **Confocal Scanning Laser Ophthalmoscope** combines the selectivity of laser light with the pinpoint resolution of confocal scanning to provide image detail and clarity not available from fundus photography.
- **Scanning Laser Angiography (Fluorescein and Optional Indocyanine Green)** provides high-resolution images and video sequences showing the dynamic movement of dye through the vessels and minute details of the parafoveal capillary network.
- **TruTrack™ Active Eye Tracking** is a patented imaging technology that utilizes two beams of light simultaneously to track and image the eye. Actively tracking the eye in real-time throughout image capture mitigates the effects of eye motion, resulting in accurate OCT scan data.
- **Heidelberg Noise Reduction™** is a proprietary technology that removes 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.
- **AutoRescan™** uses the SPECTRALIS fundus image like a map to automatically place follow-up scans in precisely the same position visit after visit.
- **Fovea-to-BMO (FoBMO) Alignment Technology** automatically tracks and anatomically aligns circle scans, improving accuracy and reproducibility of RNFL measurements.
- **Heidelberg Eye Explorer (HEYEX™) Networking Solutions** allow for remote image review and optional EHR/PACS interface.
- **BluePeak™ Blue Laser Autofluorescence** 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.
- **Optional MultiColor™ Scanning Laser Imaging** uses three laser wavelengths simultaneously to provide diagnostic images showing distinct structures at different depths within the retina.
- **Optional Glaucoma Module Premium Edition** 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.
- **Optional OCT2 Module** offers increased scan speed of 85,000 Hz and enhanced image contrast across a larger depth from vitreous through choroid.
- **Optional Widefield Imaging Module** provides the standard field of view of a mydriatic fundus camera for all SPECTRALIS fundus and OCT imaging modalities, simplifying diagnostic protocols and facilitating detection of peripheral pathology.
- **Optional Non-Contact, Ultra-Widefield Module** delivers evenly illuminated and undistorted, high-contrast scanning laser images from the macula through the periphery.
- **Optional Anterior Segment Module** enables high-resolution OCT imaging of cornea, sclera, and anterior chamber angles.

Heidelberg Engineering, Inc.
10 Forge Parkway
Franklin, MA 02038

Customer 1st Direct Connect
(800) 931-2230

www.HeidelbergEngineering.com

Attachment B

- **Up to seven (7) imaging modes:** Spectral domain OCT, infrared (IR), MultiColor scanning laser imaging, BluePeak blue laser autofluorescence, blue reflectance (BR) (*sometimes referred to as “red-free”*), fluorescein angiography (FA), and ICG angiography (ICGA).
- **Up to ten (10) simultaneous imaging options:** OCT+MultiColor, OCT+IR, OCT+BluePeak, OCT+BR, OCT+FA, OCT+ICGA, IR+BluePeak, IR+FA, IR+ICGA, FA+ICGA.
- **Up to five (5) separate light sources at the following wavelengths:** 870 nm SLD, 815 nm diode laser, 786 nm diode laser, 518 nm diode laser, 486 nm diode laser.
- **Fundus image field of view** ranges from 15° up to 102° with exchangeable optical lenses.
- **Panning camera head** allows the camera to move from side to side and tilt up and down.
- **Movie image capture** is available in single frame and high speed modes.
- **Touch panel** enables the user to easily select acquisition modalities and settings.

Heidelberg Engineering, Inc., is a wholly-owned subsidiary of Heidelberg Engineering GmbH, the equipment manufacturer, and is the only U.S. source for this equipment.

For additional information on Heidelberg Engineering, Inc., and the SPECTRALIS imaging platform, please visit www.HeidelbergEngineering.com or call us at 800-931-2230.

Sincerely,

Heidelberg Engineering, Inc.

Attachment C

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5100
Accepted until June 26, 2017, at 3:00 p.m.**

I certify that the information contained in this objection is true and accurate to the best of my knowledge. I understand that UMMC will investigate all statements made in this objection and that any false or misleading information provided may result in adverse action.

Objector Name

Objector's title

Date