

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA250-16-AP-5247

1. **Contracting Activity:** Department of Veterans Affairs, VISN 10, John D. Dingell VA Medical Center (2237: 553-16-3-244-0470).

2. **Nature and/or Description of the Action Being Processed:**

Requesting procurement of Vevo High-Frequency Ultrasound 3100 System (Vevo 3100) equipment for VA Research Service on a sole source basis from FujiFilm Visual Sonic. A new, firm fixed-price contract will result from this action" or something similar. Delete the rest of the information, as it describes the product, and re-insert in paragraph 2.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement will be conducted 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:** The Vevo High-Frequency Ultrasound 3100 System (Vevo 3100) including software, transducers, modular component, on-site training, one year maintenance, and a 5 year warranty (\$497,000). This is a new requirement for Vevo High-Frequency Ultrasound 3100 System (Vevo 3100) equipment for VA Research Service. The Vevo 3100 is the "only commercially available imaging platform that permits the research to obtain *in vivo* anatomical, functional, physiological and molecular data simultaneously, in real-time and with a resolution of 30 μ m." These capabilities provide a single platform to acquire dynamic imaging with repeated imaging potential to follow longitudinal parameters (cardiac function, perfusion, respiratory parameters, and vascular function including shear stress and distensibility and organ perfusion, among others). The Vevo 3100 imaging system includes the workstation, all transducers and Vevo CQ advanced contrast quantification software needed for analysis as well as installation, 2 day on site user training and preventive maintenance with 5 year warranty. The Shared Equipment Enhancement Program (ShEEP) project was research grant funded. The Vevo 3100 is available for multiple users as required by the ShEEP.

4. **Statutory Authority Permitting Other than Full and Open Competition:**

- (x) (1) FAR 13.5 in accordance with 41 USC 1901;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;
- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;

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- () (6) National Security per FAR 6.302-6;
() (7) Public Interest per FAR 6.302-7;

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

FujiFilm Visual Sonics is the only supplier that provides the high frequency ultrasound imaging system that is a major system of a highly specialized imaging and data acquisition platform that permits *in vivo* anatomical, functional and physiological and molecular data acquisition simultaneously, in real time and with high resolution (30 μ m) in small rodents (rats and mice) in both the anesthetized and conscious state. Visual Sonics holds the patents on several of the features for the imaging and arrayed data including the specific small animal transducers, synchronization of Doppler data with breathing signals and integrated multi rail imaging systems as well as ECG triggered receptive color flow imaging such that the interface of these components with an alternative supplier's instrument would result in substantial duplication or enhanced costs that would not be recovered via competition, but would result in an instrument with a limited range of capabilities rather than the state of the art full range of capabilities essential to the requirements of all researchers involved in the ShEEP research team. These include VA funded investigators in respiratory, cardiac, neural and vascular function as well as malignancy. Other instruments do not have the range and depth of acquisition and analytical capabilities as the requested high frequency ultrasound imaging system. Visual Sonics is the only firm capable of providing the state of the art high frequency ultrasound imaging platform and accompanying modular transducers, software and support services described in Section 3 above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition. The requested Vevo 3100 model and accessories provide comprehensive capabilities in a single platform that fulfills the needs of each investigator of the ShEEP. Purchase of individual components for each investigator in open competition would increase cost, lead to duplication, and limit the integrated and simultaneous analysis of more than one of the components (respiratory and cardiac function; or vascular permeability and tumor growth; or brain perfusion and correlation with brain imaging). The Vevo 3100 offers a number of unique capabilities that are not offered by any other system for this research project. This is the sole source ultrasound system that has transducers with center frequencies up to 50 MHz, and upper range frequencies up to 70MHz. There are also a number of additional features of this system that are proprietary such as:

- Small animal heart speckle tracking and strain analysis (VevoStrain)
- Small animal vessel wall speckle tracking and wall strain analysis (VevoVasc)
- Small animal based calculation packages (LV Analysis Tool)
- Integrated physiology data with ultrasound image

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: Several other sources were screened for suitability of the multi-use ultrasound imaging. (a) The Xenogen IVIS 200 uses bioluminescence and fluorescence and utilizes laser energy which can be disruptive to tissues in contrast to high frequency ultrasound. (b) The Maestro 2 imaging system also uses liquid crystal tunable filter approach to imaging. (c) The Pearl Li-Cor optical imaging instrument likewise uses bioluminescence and provides static imaging. The resolution is much less than the high frequency ultrasound system requested. Neither (a), (b) or (c) provides the dynamic respiratory function and evaluation of vascular parameters such as shear stress and dynamic distensibility, nor do they provide the ability to calculate and analyze cardiovascular function (ejection fraction, cardiac output, fractional shortening, speckle tracking, wall strain and

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cardiac output). The Vevo 3100 offers a number of unique capabilities that are not offered by any other system for this research project. This is the sole source ultrasound system that has transducers with center frequencies up to 50 MHz, and upper range frequencies up to 70MHz. There are also a number of additional features of this system that are proprietary such as:

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- Small animal based calculation packages (LV Analysis Tool)
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7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The final contract price of \$497,000 has been determined fair and reasonable based on Independent Government Cost Estimate. Additionally the Share Equipment Enhancement Program (ShEEP) approved this grant funding based on similar projects nationwide.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** All known alternative systems were screened for suitability to the needs of the ShEEP research. The optical and fluorescence system do not offer ultra-high frequency ultrasound to provide functional cardiovascular imaging and vessel wall imaging down to 30 microns. The other systems do not offer the cardiovascular function calculations such as ejection fraction, cardiac output, stroke volume, fractional shortening, speckle tracking, and wall strain that the Vevo3100 does. The other systems also do not have the ability to perform multiple assessments at different longitudinal time points without damage to tissue which is a necessity to provide ECG and respiratory gating to minimize or eliminate the artifacts commonly found in small rodent measurements. The method of synchronization of breathing signal with capture of Doppler data is of particular importance to the ShEEP investigators and is patented by Visual Sonics.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The specific uses for each investigator participating in the ShEEP have been outlined in the funded ShEEP Proposal. This high resolution ultrasound imaging will provide our five major users with capabilities to enhance their funded studies. (1) The Rossi laboratory will obtain serial, dynamic measurements of cardiac output, stroke volume, diastolic function, vascular wall thickness, arterial stiffness, and shear stress and in the two-kidney, one-clip rat model of renovascular hypertension rather than static histologic data at the termination of experiments or *ex vivo* measures of arterial parameters. (2) The Mateika laboratory will obtain a wide range of cardiovascular parameters, including right heart function, myocardial perfusion, tissue hypoxia and angiogenesis in murine models of acute intermittent hypoxia in transgenic mice lacking tryptophan hydroxylase needed for serotonin signaling and in mice with spinal cord injury. (3) The Conti laboratory has identified cardiovascular parameters associated with post-traumatic stress disorder (PTSD) including hypertension and myocardial dysfunction. Her studies will benefit from the ability to detect vascular remodeling of blood vessels and cerebral blood flow, cardiac load and shear stress in PTSD-hypertension. (4) Dr. Ding will evaluate cerebral blood flow and oxygenation in his model of stroke. (5) Dr. Rishi who studies new therapeutic agents for treatment of malignancies will be able to quantify tumor size and volume as well as angiogenesis within the tumors as the tumors grow and/or regress. This cutting edge technology will also permit minor users to study the microanatomy of vascular remodeling and integrity in genetic models of diabetes and tumor angiogenesis and growth/regression, respectively. Ultrasound technology is currently available in clinical practice and the approaches and findings

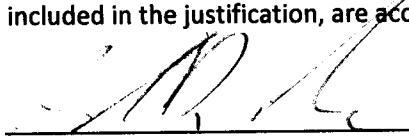
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would be immanently translatable into the clinical armamentarium for improvement of Veterans' health.

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** FujiFilm Visual Sonics

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:** Given that FujiFilm Visual Sonics holds proprietary patents for the necessary components of our research, it is unlikely that delay will change the barrier to competition. However, market research will continue to be conducted should any future requirement exist to ensure competition is maximized.

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.



SAMUEL P. MCVEAN
AO, Research Department
Detroit VA Medical Center

9/27/16

Date

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.

DIANA J. BURTON
NCO 10, Contracting Officer
Battle Creek VA Medical Center

9-27-2016

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.

JAMES J. HALLOCK
NCO 10, Supervisory Contract Specialist
Indianapolis VA Medical Center

Date