#### **DEPARTMENT OF VETERANS AFFAIRS**

# Justification and Approval (J&A) For Other Than Full and Open Competition (>SAT)

Acquisition Plan Action ID: 36C776-18-AP-0250

1. <u>Contracting Activity</u>: Department of Veterans Affairs, Program Contracting Activity Central, PCAC

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

This is a brand name justification for GE Healthcare items listed in the table below (Section 3). This action will be awarded as a new Firm-Fixed-Price contract in accordance with Federal Acquisition Regulation (FAR) Part 13.5

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### 3. Description of Supplies/Services Required to Meet the Agency's Needs:

	Item#	JSN	Description	Qty	Unit Cost	Ext Cost
0001	Logic E9 w/XDclear (H4911ZR)	X2100	Scanner, Ultrasound, General Purpose (GE Healthcare Imaging Systems)	1		
0002	GE Dinamap Pro Series (2038172-001)	M4116	Monitor, Vital Signs (GE Helathcare Monitoring Systems)	32		
0003	MAC 5500 HD (2053900- 014/Cart)	M7710	Electrocardiograph, 12 Lead, Portable (GE Healthcare Monitoring Systems)	3		
					TOTAL	

#### 1. X2100: Item (Logic E9 w/XDclear) Scanner, Ultrasound, General Purpose

High definition, diagnostic ultrasound system for Radiology, Cardiology, Vascular, ob-gyn, Perinatology, and Surgical imaging applications. The unit employs curved, phased, and linear array imaging technology. The system supports colorflow, pulse, and continuous wave imaging modalities. On board software measurement packages available for all imaging applications. The system is DICOM 3.0 compatible, for easy linkage to filmless image management systems and review stations. In addition, a full line of probes and conventional recording devices are available.

- Mobile general purpose ultrasound unit.
- Unit to include multiple general use probes as well as vaginal probe.
- Depth" 45

- Weight (lbs) 590
- Height" 64
- Width" 27

### 2. M4116: Item (GE Dinamap Pro Series) Monitor, Vital Signs

Electronic sphygmomanometer. LCD displays non-invasive blood pressure, pulse rate, and temperature. Used in hospitals and clinics. Includes a mobile stand.

- Rolling stand
- Accessory basket
- Wired connectivity
- Measures: SpO2, Temperature, blood pressure

### 3. M7710: Item (MAC 5500 HD) Electrocardiograph, 12 Lead, Portable

Used to detect the electrical signals associated with cardiac activity, diagnose cardiac abnormalities, determine a patient's response to drug therapy and reveal trends or changes in heart function. Capable of recording two or more leads simultaneously, recording an entire 12 lead ECG in about 10 seconds. Includes a 3.5-inch, high density, portable drive for test storage. Features included:

- Wired connectivity to electronic medical records
- Printer
- Lead Wires -12
- LCD display
- Depth" 17
- Weight (lbs) 28
- Height" 7
- Width" 16

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

**FAR13.5 Simplified Procedures for Certain Commercial Items:** This acquisition is being conducted under FAR 13 – Simplified Acquisition Procedures. The authority for restricting competition under simplified acquisition procedures is 41 U.S.C. 1901, as implemented by FAR 13.5.

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

The Department of Veterans Affairs (VA) Northern California HealthCare System (VANCHCS) currently has GE Dinamap Carescape V100 Vital Sign Monitors, MAC 5500 HD EKGs, and Logic E9 Ultrasounds. GE Healthcare is the only brand that is capable of connecting to CPRS via hardwiring of the vital sign monitor to the workstation with a USB cable. This is vital to clinical workflow and to reduce human error that occurs when nurses type in vitals information by hand. GE Healthcare is also the only brand that has integrated Exergen with temporal monitors. Temporal monitors are less invasive and provide a level of comfort that our veteran patients have come to expect.

VANCHCS has server infrastructure, GE Healthcare MUSE, in place to receive, transfer, and store patient records, studies, and pictures captured during electrocardiogram (EKG) tests. The only medical equipment our server infrastructure is compatible with is the specified GE Healthcare

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Equipment. The EKG requested in this package is a networked medical device that will transfer patient data and images for storage using MUSE. The server infrastructure is hosted at the Sacramento DataCenter and is fully managed by VISN 21 contracts currently in place. The total cost of infrastructure for the GE Healthcare MUSE system was over \$300k to cover multiple Healthcare Systems in VISN 21. Purchasing the EKG equipment from any manufacturer other than GE Healthcare would result in the requirement for a new server infrastructure. Not only will the new server infrastructure add a substantial additional cost, it will be a system completely different from the standardized VISN 21 managed system and would isolate the Chico Outpatient Clinic (OPC) from the rest of the VISN. Chico OPC would have to stand up the new server infrastructure and purchase a service contract for the system. Both the EKG and the Logiq E9 ultrasound are networked items that have gone through the review process and meet the DICOM conformance requirements and passed validation. Purchasing a product other than GE Healthcare will not allow for the Chico OPC studies or information to be transferred to the VA's Computerized Patient Record System (CPRS).

Standardization of medical equipment to improve patient safety has been held as a rational basis for contracting brand name equipment as decided in Government Accountability Office (GAO) protest B-411904, November 2015.

"In our view, the VA's rationale for standardizing medical equipment, to reduce medical errors and enhance patient safety, sets forth a reasonable basis for procuring APCs on a brand name basis under the circumstances here. The determination of the government's needs and the best method of accommodating them is primarily the responsibility of the procuring agency, since its contracting officials are most familiar with the conditions under which supplies, equipment, and services have been employed in the past and will be utilized in the future. Columbia Imaging, Inc., supra, at 2. Where, as here, a requirement relates to human safety concerns, the agency has the discretion to set its minimum needs so as to achieve not just reasonable results, but the highest possible reliability and effectiveness. McKesson Automation Sys., Inc., B-290969.2, B-290969.3, Jan. 14, 2003, 2003 CPD ¶ 24 at 8."

Lastly, there are several other facilities in the VANCHCS that currently have the GE Healthcare equipment, equipment specific tools for repair, and spare parts. Should any Equipment be non-operational and need immediate repair, VANCHCS is able to provide rapid assistance service and parts significantly limiting down time to hours verse days, further reducing risk to patients as the result of a downed monitoring system.

# 6. <u>Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable</u>:

See section 8 below for detailed efforts to ensure offers will be solicited from as many potential sources as deemed practicable.

### 7. <u>Determination by the CO that the Anticipated Cost to the Government will be Fair and</u> Reasonable:

The Contracting Officer anticipates multiple offers and, thus, price reasonableness will be based on competitive quotations or offers in accordance with FAR 13.106-3. Should only one (1) response be

received, price reasonableness will be based on comparison to the independent Government estimate (IGE) and/or comparison of the proposed price with prices found reasonable on previous purchases.

# 8. <u>Description of the Market Research Conducted and the Results, or a Statement of the Reasons</u> Market Research Was Not Conducted:

In accordance with FAR Part 10, market research has been conducted for this acquisition. The following *techniques* were used:

Medical Surgical Prime Vendor (MSPV) Contracts: A search was conducted on the National Acquisition Center's MedSurg Catalog search located at <a href="http://www.va.gov/nac/MedSurg/List">http://www.va.gov/nac/MedSurg/List</a> for a list of nationally awarded contractors and/or prime vendor contracts. The MSPV for Chico is Cardinal Health. A search using Cardinal Health as the Contractor demonstrates they do not provide this equipment on their MSPV contract. MSPV is not appropriate source at this time.

GSA eLibrary: <a href="https://www.gsaelibrary.gsa.gov/ElibMain/home.do">https://www.gsaelibrary.gsa.gov/ElibMain/home.do</a>. A search for "cardiology" resulted in services and is not part of this procurement. A search for "ultrasound" led to services and category 66 602 8 that is for Sound and Vibration Standards and Calibration Instruments and not relevant to this procurement. A search for "electrocardiograph" provided no results. A search for "sphygmomanometer" and applying the SDVOSB and VOSB filters provided seven (7) vendors. A search for "GE" led to the category is 65 II A (Medical Equipment and Supplies) and further searching through the sub categories A-14G Other Medical Diagnostic Instruments and A-41 Electrosurgical Apparatus and applying the SDVOSB and VOSB filters provided eighteen (18) vendors. From these results all vendors were contacted via email (Attachment Email – GSA). Zero (0) vendors responded as being able to meet the specifications of the requirement.

**GSAXcess**: <a href="https://gsaxcess.gov/">https://gsaxcess.gov/</a>. A search for electrocardiograph, cardiology, imaging systems, and monitoring systems produced zero (0) results. The conclusion of this search effort is GSAXcess is not a source for acquiring this equipment at this time. (Attachment – GSAXcess).

**ECAT**: <a href="https://www.medical.dla.mil/WAM/Home/consent/">https://www.medical.dla.mil/WAM/Home/consent/</a>. This requirement includes installation and purchases using ECAT cannot fulfill the installation need. ECAT is not an appropriate source for this requirement at this time.

**SDVOSB/VOSB Sources via VetBiz (VIP)**: In accordance with VAAR Subpart 819.7004, 819.7005, 819.7006 - <a href="https://www.vip.vetbiz.va.gov/">https://www.vip.vetbiz.va.gov/</a>, a search was conducted on Vetbiz.gov in an attempt to locate Service-Disabled-Veteran-Owned-Small-Business (SDVOSB) and Veteran-Owned-Small Business (VOSB) concerns utilizing NAICS code 334510 (this search provided 144 SDVOSB and 23 VOSB results). From these results, all vendors were contacted via email (Attachments Email - SDVOSB and Email - VOSB). Two (2) vendors responded as being able to meet the specifications of the requirement and are verified authorized distributors (see GE Healthcare section below). These vendors have been identified in the market research findings table below.

Small Business Administration (SBA) – Dynamic Small Business Search (DSBS): <a href="http://dsbs.sba.gov/dsbs/search/dsp">http://dsbs.sba.gov/dsbs/search/dsp</a> dsbs.cfm. SBA DSBS market research was conducted utilizing NAICS code 334510 and the keyword "ultrasound" and produced fifty-two (52) results. Another

search using NAICS code 334510 and the keyword "electrocardiograph" produced one (1) result. A search using NAICS code 334510 and the keywords "sphygmomanometer" produced zero (0) results. A search using NAICS code 334510 and the keywords "cardiology" and produced three (3) results. All vendors were contacted via email (Attachment Email - SBA) and zero (0) vendors responded as being able to meet the specifications of the requirement.

**FBO RFI/Sources Sought Notice**: An RFI/Sources Sought Notice was published to Federal Business Opportunities (FBO) on July 20, 2018 (Attachment – S03 - FBO – 36A77618Q9107). Zero (0) vendors responded as being able to meet the specifications of the requirement.

**GE Healthcare**: GE Healthcare was contacted via email asking if they had authorized distributors. GE Healthcare stated they have authorized distributors. These vendors have been identified in the table below (2 duplicate from VIP) (Attachment – GE – Authorized Distributors).

#### MARKET RESEARCH FINDINGS

Vendor	DUNS	Socioeconomic Category	Authorized
TrillaMed, LLC	828126321	SDVOSB	Yes
Alko Enterprises, LLC	181118738	VOSB	Yes
Jaken Medical	068665699	8a	Yes
Jaken Wedical	008003099	Od	163
DXE Medical	Unknown	SB	Yes

#### 9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

GE Healthcare is the only brand that is capable of connecting to CPRS via hardwiring of the vital sign monitor to the workstation with a USB cable and is also the only brand that has integrated Exergen with temporal monitors. There is no other existing product on the market that can operate with the existing GE Dinamap Carescape V100 Vital Sign Monitors, MAC 5500 HD EKGs, and Logic E9 Ultrasounds.

### 10. <u>Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:</u>

- Aldevra cannot meet GE Healthcare Brand Name
- Four Points Technology, LLC cannot meet GE Healthcare Brand Name
- Masimo cannot meet GE Healthcare Brand Name
- ALKO Enterprises
- TrillaMed

# 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:

To remove or overcome any barriers to competition before future acquisitions for the same equipment are conducted, at the system's end of life, the VA will ensure extensive market research

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is performed in a timely manner to evaluate vendor capabilities with the intent of opening competiton to all brands of monitoring and imaging systems that can potentially meet the Government's requirements. The estimated lifecycle of monitoring and imaging systems is approximately seven (7) years.

	Donald Black	Date
	Site Manager	
	VANCHCS	
App	provals in accordance with the VHAPM Par	t 806.3 OFOC SOP:
a.	Contracting Officer or Designee's Certifica	tion (required): I certify that the foregoing
a.	justification is accurate and complete to th	
	Michelle Rhodes	 Date
	Contracting Officer	
	Program Contracting Activity Central	
	One Level Above the Contracting Officer (	Required over SAT but not exceeding \$700
b.		
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