

Justification
for Other than Full and Open Competition

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

2. Description of Action: The proposed action is for a brand name, 3-year Firm-Fixed Price Requirements type contract that includes decentralized orders for General Electric (GE)® Brand Vital Signs Monitors (VSM) to include related software and accessories. The proposed effort is in support of Veterans Health Administration (VHA), Procurement and Logistics Office who provides Life Cycle Management support for GE® VSMs to 12% (21 of 170) of the VA Medical Centers that will be replacing equipment due to expiring service life within the next 36 months.

3. Description of Supplies or Services: The GE® VSMs are used to measure pulse, blood pressure, temperature and venous blood oxygen saturation (i.e. vital signs) electronically and with minimal effort and maximal accuracy. The proposed action is to provide replacement of GE® VSMs with software and related equipment for those centers listed in Table 1 which are currently only using the GE® VSMs with forecasted replacement quantities.

Table 1

| Centers | VISN | *Forecasted Replacements | | |
|--|------|--------------------------|--------|--------|
| | | Year 1 | Year 2 | Year 3 |
| (523) Boston HCS (Boston) | 1 | 37 | 37 | 37 |
| (689) Connecticut HCS (Westhaven) | 1 | 27 | 27 | 27 |
| (526) Bronx, NY | 2 | 25 | 25 | 25 |
| (528A6) Bath, NY | 2 | 31 | 31 | 31 |
| (562) Erie, PA | 4 | 42 | 42 | 42 |
| (646) Pittsburgh HCS (Pittsburgh PA) | 4 | 58 | 58 | 58 |
| (460) Wilmington DE | 4 | 18 | 18 | 18 |
| (688) Washington DC | 5 | 43 | 43 | 43 |
| (546) Miami, FL | 8 | 35 | 35 | 35 |
| (578) Hines, IL | 12 | 22 | 22 | 22 |
| (537) Chicago (Westside), IL | 12 | 51 | 51 | 51 |
| (556) North Chicago, IL | 12 | 27 | 27 | 27 |
| (585) Iron Mountain, MI | 12 | 26 | 26 | 26 |
| (657A4) Poplar Bluff, MO | 15 | 22 | 22 | 22 |
| (586) Jackson, MS | 16 | 28 | 28 | 28 |
| (598) Central Arkansas HCS (AR) | 16 | 26 | 26 | 26 |
| (549) North Texas HCS (Dallas TX) | 17 | 28 | 28 | 28 |
| (671) South Texas HCS (San Antonio TX) | 17 | 23 | 23 | 23 |
| (635) Oklahoma City, OK | 19 | 25 | 25 | 25 |
| (662) San Francisco, CA | 21 | 42 | 42 | 42 |
| (570) Central California HCS (Fresno CA) | 21 | 28 | 28 | 28 |

GE® VSMs

*Forecasted replacements for each center is based on inventory replacement data for various configurations of VSMs.

The brand name items required are listed in Attachment A, GE® Product List. The total estimated cost is \$REDACTED.

4. Statutory Authority: The statutory authority permitting other than full and open competition is 41 U.S.C. 3304(a)(1) as implemented by Federal Acquisition Regulation (FAR) 6.302-1(c), "Only One Responsible Source and no Other Supplies or Services will Satisfy Agency Requirements, Application for Brand-Name Description."

5. Rationale Supporting Use of Authority Cited Above: The products identified in Attachment A, GE® Product List have been determined to be the only VSMs capable of connecting directly to the specified hospitals already installed GE® patient monitoring telemetry (Tele) networks. Tele networks are standalone networks that are built specifically for a patient monitoring system and are designed and implemented solely based on the patient monitor product being used. The GE® VSMs come with a wireless card that connects directly to a facilities' already installed GE® Tele network and transmits patient vital signs information directly to the GE® Carescape Gateway by means of the GE® Mobile Vitals Plus software package. No other brand of vital sign monitor has the ability to be utilized with the currently installed Tele systems which were installed in the identified 21 centers at a total estimated cost of \$16.8M with an installation period of 3-6 months per center. Using an alternate brand of vital sign monitors would require the complete replacement of the current Tele system and would result in extensive delays in facility operations and duplicated costs that would not be recovered through competition.

A recent study determined that error rates for vital sign monitoring captured and manually entered into an electronic medical record (EMR) were 4.4 percent.¹ Maintaining a standard GE® system in the 21 facilities already currently using the GE® system will allow for the seamless connectivity between patient monitors, biomedical devices and hospital information systems, where patient data can flow directly into EMRs, which is intended to reduce documentation errors and enhance patient safety.

The 21 hospitals currently only utilize GE® VSMs for patient needs. This system allows the data to be fully integrated in the hospital information system. Any other system would not provide VA system reliability because the procured items must match remaining in-use inventory for reasons of patient safety and to integrate with existing information systems. For another system to be fully integrated there would be a 3 to 6 month turn around to integrate with existing hospital information systems. The introduction of a new brand of VSM with the existing GE® VSM would degrade the clinician's ability to accurately monitor patient vital signs through a centralized monitoring system. This delay causes concern that VA patient safety would be at risk by replacing GE VSMs with some other brand. All VA patients in these hospitals deserve the same standard of treatment which is maintained by merely replacing broken or unusable VSMs with the same monitor which would seamlessly integrate with VA's existing systems.

Medical device user errors are a common source of patient injury and death. Research indicates that there is a clear link between usability problems and user error when different systems were installed due to lack of training and being unfamiliar with the new equipment.

¹ Connected Care: Reducing Errors through Automated Vital Signs Data Upload. LB. Smith, et al. *Computers Informatics Nursing*, Vol. 27, No. 5, 2009

Specifically the impact of new device features and user interfaces (such as auditory cues and warnings, display messages, key information, physical controls, specific wording and labels, and sequence of tasks) were shown as indicators of human error. Patient safety and positive clinical outcomes are critical in a hospital setting and limiting the number of systems/equipment clinicians are required to operate reduces user errors, which in turn, lessen the likelihood of adverse patient outcome.

The goal with this acquisition is to provide medical device users with a means to procure specified makes and models of technical equipment and parts that will satisfy the agency's need for replacement items during life cycle management of GE® VSMs.

- a. The VA National Center for Patient Safety developed a Patient Safety Assessment Tool. This tool was designed to be used before the purchase of any new patient care equipment. The figure below explains the rationale of assessment methods and the tool clearly delineates the following 3 key areas regarding equipment standardization:

Figure 1: Equipment PSAT:

| PROCUREMENT AND EQUIPMENT MANAGEMENT - Element 4 | | | | | | |
|--|---|--|---------|-------------------|-------------|---|
| | Question: | Rationale/Assessment/Methods: | Met (1) | Partially Met (2) | Not Met (3) | If score other than 'met' what are possible root causes |
| 4.1.1 | Procurement and Equipment Are Human Factors Engineering principals considered when purchasing medical devices? Mandatory; Priority A | <i>The medical devices are evaluated for ease of use; feedback to the user (verbal and visual); level of knowledge transfer from existing equipment; and the impact of slips or mistakes on providing patient care. The use of informal usability groups to test the devices is recommended.</i> Copyrighted Refs.doc JC- CAMH EC-02-04-01.pdf | | | | |
| 4.1.5 | Procurement and Equipment When feasible, is equipment standardized by manufacturer and model? Recommended; Priority A | <i>Limiting the number of systems/equipment clinicians and maintenance staff are required to operate/maintain will reduce latent errors in the system. Interview personnel, review examples.</i> | | | | |
| 4.1.7 | Procurement and Equipment Is there a procurement process or plan to acquire an adequate amount of back up equipment? Mandatory; Priority A | <i>Essential Medical back up equipment should be available in all areas, or accessible as needed when primary equipment fails.</i> JC- CAMH EC-02-04-01.pdf | | | | |

GE® VSMs

<https://www.patientsafety.va.gov/professionals/onthejob/assessment.asp>.

b. Emergency Care Research Institute (ECRI) Patient Safety Organization (PSO) is a non-profit organization that has been dedicated to bring the discipline of applied scientific research to discover which medical procedures, devices, drugs, and processes that are the best and will enable VHA to improve patient care. Each year, ECRI PSO publishes a Top 10 Patient Safety Concerns for Healthcare Organizations (See Figure 2):

Figure 2:



<https://www.ecri.org/Pages/Top-10-Patient-Safety-Concerns.aspx>

As seen in Figure 2 above, patient safety risks are critical when purchasing medical equipment. By utilizing GE® VSMs, VHA will greatly improve patient safety by eliminating equipment variations on VSM medical equipment that could lead to “usage error” within a singular medical center.

6. Efforts to Obtain Competition: Market research was conducted, details of which are in the market research section (Section 8) of this document. This effort revealed four authorized distributors that can meet the Government’s requirements and competition is available for this acquisition. Additionally, the proposed action will be synopsized on the Federal Business Opportunities Page in accordance with FAR 5.201 and made available with the published solicitation in accordance with FAR 6.302-1(c).

7. Actions to Increase Competition: The Government will continue to conduct market research to ascertain if there are advance technology changes in the market place that would enable future actions to be competed. However, in order to remove or overcome barriers to competition in future acquisitions, the agency will work with the program office to perform

GE® VSMs

additional market research to consider if alternate solutions can be considered.

8. Market Research: Market research was conducted and concluded that competitors for this product include Welch Allyn, Phillips, and Spacelab. While these companies' manufacturer similar products it has been concluded that due to compatibility and patient safety concerns, GE® VSMs are the only VSMs that meet the needs of those facilities identified in Table 1. As stated, GE® VSMs are the only VSMs capable of connecting directly to the specified hospitals already installed GE® patient monitoring tele network. As such, the original equipment manufacturer was contacted to provide a listing of its authorized distributors. Each of the four identified distributors was contacted to confirm that they currently carry the required products with each responding positively. The next step was to determine whether any of the distributors are Vet Biz certified for the required NAICS code 334510; authorized distributors and Vet Biz search results are listed in Table 2.

| Table 2. Authorized Distributors | | | |
|----------------------------------|-------------------|----------------|--------------|
| Vendor | Vet Biz Certified | Socio-Economic | SAM |
| Jaken Medical Inc. | NA | SB/8A SDB | Yes - 334510 |
| DXE Medical Inc. | NA | SB | Yes - 334510 |
| ALKO Enterprises | Yes - 334510 | VOSB | Yes - 334510 |
| TrillaMed LLC | Yes - 334510 | SDVOSB | Yes - 334510 |

9. Any Other Facts Supporting this Justification: The requested equipment monitors the status of patient's life-sustaining functions and should a clinician be required to rotate from one brand with different components to another because they are dispersed differently throughout the hospital, errors are likely to occur. Both the National Center for Patient Safety and the ECRI PSO recognize the negative impact of having multiple brands of VSMs within a facility and recommend the use of a singular brand instead. In this case the hospitals included are currently utilizing only GE® VSMs and will continue to do so.

Three companies expressed an interest in this procurement. Of the three, two are distributors for the GE Brand VSMs, with the third distributing an alternate brand which isn't capable of connecting directly to the specified hospitals already installed GE® patient monitoring tele network.

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.

420704

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REDACTED, Project Manager

11. Fair and Reasonable Cost Determination: I hereby determine that the anticipated price to the Government for this contract action will be fair and reasonable based on:

- a. Comparison of the proposed prices to the historical prices paid, whether by the Government or other than the Government for the same or similar items.
- b. Comparison with competitive published price lists published market prices of commodities, similar indexes, and discount or rebate arrangements.
- c. Comparison of proposed prices with an Independent Government Cost Estimate.


12. Determination of Best Value: I certify that this justification is accurate and complete to the best of my knowledge and belief.

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REDACTED, Contracting Officer

Approval

In my role as Contracting Activity Competition Advocate, based on the foregoing justification, I hereby approve the acquisition of brand name GE® VSMs with software and related equipment in the estimated total amount of \$REDACTED, on an other than full and open basis, pursuant to the authority cited in FAR 6.302-1(c), Only One Responsible Source and no Other Supplies or Services Will Satisfy Agency Requirements, subject to availability of funds, and provided that the services and commodities herein described have otherwise been authorized for acquisition.

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REDACTED
Activity Competition Advocate