LIMITED SOURCES JUSTIFICATION
ORDER >$3,000
FAR PART 8.405-6

2237 Transaction # or Vista Equipment Transaction #: 586-14-3-047-0061 (INSERT)

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

Restricted to the following source: Provide *original manufacturer's* name for material or contractor's name for service. (If a sole source manufacturer distributes via dealers, *ALSO* provide dealer information.)

Manufacturer/Contractor: Physio-Control, INC; Contract #V797D-30038
Manufacturer/Contractor POC & phone number: 800-442-1142
Mfgr/Contractor Address: 11811 Willows Road NE/PO Box 97023; Redmond, WA 98073-9723
Dealer/Rep address/phone number: Chris Risner, 800-442-1142 X72415

☐ The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY: Department of Veterans Affairs

VISN: 16 - (G.V) Sonny Montgomery VAMC

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:
The G.V. (Sonny) Montgomery VA Medical Center is currently requesting replacement defibrillators that are have or are nearing the end of their life cycle. The procurement package includes the purchase and delivery of 25 Monitor/Defibrillator with 4 Chest Compression Systems.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:
The LifePak 15, Monitor/Defibrillator from Physio-Contract is a clinically and operationally innovative device that puts early, effective defibrillation into the hands of first responders. The LifePak 15 utilizes a biphasic truncated exponential waveform with voltage and duration compensation for patient impedance and offers a range of defibrillation therapy from 2 joules up to 360 joules.

In either AED or manual mode, the defibrillator offers the widest range of defibrillation therapy available while also offering more advanced monitoring parameters such as ECG, external pacing, synchronized cardioversion, NIBP, SPO2 monitoring and diagnostic 12 lead capabilities.

[redacted]

(c) **REQUIRED DELIVERY DATE:** September 30, 2014

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE. (CHECK ALL THAT APPLY AND COMPLETE)

☒ Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.

The delivery of defibrillation up to 360J is vital, especially in the overweight, obese population. Mississippi is a medically underserved state, and tops the nation in overweight/obese population. When time is of the essence and every second counts, we want to be able to provide appropriate levels of care to all our Veterans. The Lifepak 15 is the only monitor/defibrillator with the capability to escalate energy dose up to 360J for difficult-to-defibrillate patients. Clinical research exists to that shows 200 J biphasic defibrillator being ineffective in providing defibrillation/cardioversion therapy to a patient, whereas a subsequent shock from a different 360 J biphasic defibrillator resulted in immediate defibrillation/cardioversion. Also, rapid defibrillation reduces the risk of delay in defibrillation when every second increases the chance of survival. Without rapid defibrillation, the chance of any Veteran surviving a Code drops dramatically. Market research indicates the LifePak 15, Monitor/Defibrillator from Physio-Control is the only defibrillators that meet the required specifications.

[redacted]

☐ These are "direct replacements" parts/components for existing equipment.

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☐ The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

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☐ The new work is a logical follow-on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures.

☐ An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

Prices have been negotiated on the Federal Supply Schedule Contracts and determined to be fair and reasonable.

(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:

According to *the* American Heart Association's Shock energy guidelines, biphasic engery levels should be at manufacturer recommendation (e.g., initial dose of 120-200 J) If unknown, use maximum available. The second and subsequent doses should be equivalent or higher doses may be considered. At 360 J, a higher dose would be available to provide higher levels of energy/defibrillation.

According to the FDA, there have been at least 14 events since 2006 in which a 200 J biphasic defibrillator was ineffective in providing defibrillation/cardioversion therapy to a patient, whereas a

subsequent shock from a different 360 J biphasic defibrillator resulted in immediate defibrillation/cardioversion.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:
As a teaching facility, we have many Providers (Attendings/Residents and particularly Electrophysiology Staff) that work at the medical center. Standardization within community practice and a consistent standard of care also reduces the risk of delay in defibrillation and reduces the risk of human error. Educating new staff and re-education current staff is one thing, but it does not trump hands on experience when a life is on the line.

(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:
Market research and demonstrations were done by the CPR Committee. This product was recommended because of its innovation in the standard of care we are able to offered to our Veteran population.

(9) 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. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. *(This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)*

[redacted]

(10) APPROVALS IN ACCORDANCE WITH FAR 8.405-6(d):

a. CONTRACTING OFFICER'S CERTIFICATION (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

[redacted]

b. **P&C:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

[redacted]

c. **NCM/PCM/DESIGNEE:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

[redacted]

HIGHER LEVEL APPROVAL (Required *For orders over $650,000*):

e. **SAO:** I certify the justification meets requirements for restricting consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

[redacted]

f. **VHA HCA REVIEW AND APPROVAL (over $650,000 to $12.5 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4

[redacted]