

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA242-18-AP-1215

1. **Contracting Activity:** Department of Veterans Affairs, VISN 02, Syracuse Medical Center
528-18-1-7085-0013

2. **Nature and/or Description of the Action Being Processed** Intra-Aortic Balloon Pumps (firm fixed price – new contract) commonly called IABP, is a cardiac catheterization based procedure that is used as a lifesaving support measure. IABP is equipment that is required to be available at all times for heart catheterization procedures performed in a Cath Lab setting and is used for, but not limited to, the following situations:

- During severe angina episodes
- Before, during, or after open-heart surgery (in certain patients only)
- Before, during, or after balloon angioplasty (in certain patients only)
- During emergency situations, including heart attack and congestive heart failure
- During the waiting period for a donor heart for heart transplantation

Proposed Contractor: TrillaMed (SDVOSB)
Manufacturer: Maquet dba Getinge USA Sales
Address: 30100 Telegraph Rd Suite 366
City, State, Zip: Bingham Farms, MI 48025
Phone: 248 433-0592

3. **FAR13.5 Simplified Procedures for Certain Commercial Items:** Commercial off the shelf products

4. **Description of Supplies/Services Required to Meet the Agency's Needs:**
2 ea Cardiosave Hybrid and 1 year warranty. Cardiosave blood pressure Transducer
Adapter Cable, ECG trunk, 5 lead, ESE llead wires, 50" .5 lead (OP ROOM) AAMI helium
– 3 refillable tanks (available 24 hour remote support w in IABP – 24 hour clinical support)
2 ea MCare Gold Pin – POSEW5Y
2 ea Cardiosave Trainer
[REDACTED]

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

(X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy
Agency Requirements per FAR 6.302-1;

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

FAR13.5 Simplified Procedures for Certain Commercial Items

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

- This manufacturer has the only pump that performs in-vivo zeroing and calibration on startup and every 2 hours.
- The only pump that has batteries that last 3 hours and can be changed while the pump is in use in Battery mode (not plugged in).
- Only pump with one button start up with no warm up period or manual calibration required.
- The only pump with a transport modality which decreases the unit's weight from 114lbs to 53lbs for transporting of the patient.
- the only balloon pumps on the market that are helium pressure based instead of volume based. (improved safety for patient)
- Cardiosave is using newer technology. Competition is still using technology from 2003
- A transport modality which decreases the unit's weight from 114lbs to 53lbs for transporting of the patient. This allows for easier movement of patient between in hospital patient units and onto ambulances or air transport for hospital to hospital movement. Less weight also means lower risk of staff back or other injury. Air transport would be very unlikely but possible. Ambulance transport is the usual mode.
- A one button start with no warm up period or manual zeroing required which decreases time to start therapy and minutes matter in the situations this will be used.
- Automatic condensation removal. Other systems have a liquid collection jar that must be manually emptied.
- 3 hour Lithium ion batteries which are "hot swappable" meaning they can be changed out without shutting the unit down or plugging it in during transport.
- An auto-lock screen feature which automatically locks the screen after 2 minutes, preventing accidental changing of settings which could be devastating.
- Cardiosave performs an in-vivo calibration that is an in depth zeroing process which takes place inside the patient's body. This is done on startup and every 2 hours and on change in patient condition. Other units do not perform any repeat calibration at all.
- Cardiosave uses a scroll compressor which has faster inflate/deflate times. This allows for motor speed to be controlled based on the demand of the patients heart; it ramps its rate up and down based on changes in heart rate. Competition has speed delays because of older bellows technology.
- Cardiosave automatically replaces helium lost from diffusion

- This device is the only one used by local hospitals which we would transfer patients to. If we were to have the other manufacturer's product and sent a patient to another facility, the other facility could possibly use the Arrow catheter but would not have all of the desired features of the Cardiosave available. Ultimately they would have to change the balloon catheter which increases patient risk of adverse event. Compatibility with other local facilities is necessary to provide the continued high standard of care for the Veteran that the VA desires. The frequency of transport to other facilities is low but when it occurs the patients are extremely critical. These pumps are life saving measures and are not used for anything other than critically patients with a high mortality risk.

b. Unusual and Compelling Urgency (FAR 6.302-2, 6.303-2(a)(9)(ii))

7. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Contacted manufacturer for Maquet IABP Pumps for a quote as our current pumps are Getinge/Maquet. Reviewed manufacturer's websites and did a comparison based on Data provided on each manufacturer site. We also obtained comparison information from Getinge/Maquet representative detailing their product vs

Getinge Cardiosave	<p>Scroll Compressor with Pressure/Fill System. The Scroll compressor uses less energy to drive the compressor. Motor is speed controlled based on demand. It ramps up and down based on changes in Heart Rate. The Pressure/Fill system-helium is vented to atmosphere. System measures catheter and tubing volume, and then calculates a targeted fill pressure based on that volume. Helium is added directly into the safety disk until calculated fill pressure is reached.</p> <p>Diffusion Replacement Cycle- Helium loss due to diffusion is replaced at midway between each 2 hour autofill cycle. Process takes under <1 second</p> <p>Autofill cycles every two hours-Helium tank lasts approximately 3 months of continuous pumping.</p> <p>Condensation Removal System with Naflion Technology- as helium passes through a Naflion tube, water vapor is collected on the inside surface. Water vapor then is transferred across the surface to another tube with circulating air which vents the water vapor to atmosphere. Benefits- Continuous water vapor</p>
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VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Sole Source Justification Format >\$150K

	removal with each inflate/deflate cycle and requires no power consumption
	HR 80- 10.0% faster than the CS300
	HR 150- 16.4 % faster than the CS300

Sources Sought Synopsis: posted on FBO 12/19/17 closing 12/22/17 65--CARDIOSAVE - INTRA-AORTIC BALLOON Solicitation Number: 9234

- 1 interested vendors with NAICS code not listed
- 1 SDVOSB Distributor sent an email expressing interest.

8. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** Pricing is fair and reasonable because they are comparable to the prices paid by other on FPDS.

9. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Contacted manufacturer for Maquet IABP Pumps for a quote as our current pumps are Getinge/Maquet. Reviewed manufacturer's websites and did a comparison based on Data provided on each manufacturer site. We also obtained comparison information from Getinge/Maquet representative detailing their product vs [REDACTED]

10. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None

11. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**
Trillamed (SDVOSB) – Getinge's Distributor

12. **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:** None at this time

13. **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.

Oscar

Bartholomew

144642

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Bartholomew 144642
Date: 2018.01.25
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Oscar Bartholomew, RN
Nurse Manager – Cardiology Department
Syracuse VA Medical Center

Approvals in accordance with the VHAPM Part 806.3 OFOC SOP:

Prepared by: Denise Edmonds, Procurement Agent

- 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.

Sam A DeMuzio
375167
NCO2 Contracting Officer

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DeMuzio 375167
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- b. **One Level Above the Contracting Officer (Required over\$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

CHRISTOPHER A.
WARD 174641
Chief, NCO2 Supply Team
NCO2 Contracting Officer

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A. WARD 174641
Date: 2018.02.12 11:39:04 -05'00'