

DEPARTMENT OF VETERANS AFFAIRS

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

1. **Contracting Activity:** Department of Veterans Affairs, VISN 07, Charlie Norwood VA Medical Center, Augusta GA. Ref: 509-17-2-528-0051.

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

The Cardiosave IABP (Intra-Aortic Balloon Pump) Systems are used for direct patient care. They are needed to replace Balloon Pumps that were purchased 10/1/06, and have exceeded their life expectancy of 8 years. The company no longer makes parts for them.

Requesting new, firm-fixed price contract.

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

BRAND NAME ONLY:

Maquet D998-00-0800-53 Cardiosave Hybrid 2 each

Maquet D998-00-0803 Cardiosave Trainer 2 each

Maquet ZSUSTRNG042 Biomed Training 2 each

4. **Statutory Authority Permitting Other than Full and Open Competition:** *41 USC §253(c)(1), as implemented by FAR 6.302-1.*

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

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

The Maquet manufactured equipment is the only device on the market to utilize Intellisense technology. This technology utilizes key landmarks specific to every patient to determine optimal timing of the inflation and deflation of the balloon. This gives the device the capability to make adjustments to meet the patient's specific needs. Maquet makes the only device that utilizes a dual head drive system that enables faster inflation/deflation speed. Faster inflation and deflation of the balloon provides increased hemodynamic support of the patient. This device has true in vivo calibration upon insertion. It does not require a warm-up. It does not require removal of the balloon to recalibrate. It is the only device on the market that recalibrates every 2 hours or sooner, with patient condition changes. This allows for faster time to therapy, ongoing consistency and accuracy of the arterial blood pressure waveform. When a patient codes, it is the only pump on the market that does not require manual changes on the control panel for treatment during CPR. This device automatically goes into pressure

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mode for uninterrupted treatment of the patient. In transport mode, the device is the smallest and lightest intra-aortic balloon pump available at 53 lbs. It is designed to meet the rigorous requirements of transporting patients by ambulance or helicopter. The size and weight reduction make for significantly easier lifting and placement into the vehicle, while the lithium ion batteries offer potentially unlimited run-time with spare batteries. It is the only device on the market to utilize the smallest balloons (50cc and 24cc) to increase efficacy and potentially reduce vascular complications. Maquet pumps are the only balloon pumps on the market that are helium pressure based. If a helium leak occurs, and pressure drops, an alarm will sound protecting the patient. Other pumps are helium volume based; meaning if a leak occurs they will continue pumping helium trying to keep the same volume even though there is a leak.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Market Research was conducted on NAC and GSA Advantage Websites, Google Search, Telephone Inquiries.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** Manufacturer is giving the government a \$5000 trade-in allowance against this procurement.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

Only Brand Name meets the needs of the service. Manufacturer of the requested equipment is Maquet (Getinge), a large business. Maquet's authorized distributor is Technical Communities, a small business. Opsi Technologies, an SDVOSB, is a subcontractor of Technical Communities and is authorized to distribute Maquet Medical Systems products. This equipment is not covered on FSS contract.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:**
The following VISN 7 facilities are utilizing the same Maquet IABP system: Birmingham VA, Charleston, VA, and Columbia VA. They are also being used at Eisenhower Medical, Ft. Gordon, GA, University Hospital, Augusta, GA and Augusta University, Augusta, GA.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

Opsis Technologies
Maquet Medical Systems
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:**

Should there be a requirement in the future, market research will be conducted at that time to determine sources to meet the Government's needs.
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,

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which are included in the justification, are accurate and complete to the best of my knowledge and belief.

Michael Dixon
Name: Michael Dixon
Title: Executive Assistant, ADPCS
Facility: CNVAMC

9/19/2017
Date

13. Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.

- a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

ROUT
NC07 QA
9-20-17

Brigitte Huffin
Name: Brigitte Huffin
Title: Contracting Officer
Facility: Network Contract Office07

9/19/2017
Date

- b. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

Prudence Y. Howard
Name: Prudence Y. Howard
NC07 Director of Contracting

9/20/2017
Date