

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID:36C260-18-AP-0604 / 663-18-3-9961-0192

1. **Contracting Activity:** Department of Veterans Affairs, Network Contracting Office (NCO) 20 on behalf of the VA Puget Sound Healthcare System
2. **Nature and/or Description of the Action Being Processed** This requirement is a new, brand-name requirement for the purchase of fourteen (14) Maquet SERVO-U Ventilators to replace and supplement existing equipment for the Seattle Campus Intensive Care Unit.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for commercially available equipment in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** This requirement is for 14 new ICU ventilators capable maintaining ventilation for both Acute and Chronic Respiratory failure. The estimated cost for this requirement is \$436,496.40 and includes the following components:

Item	Qty	Item	Qty
Base unit SERVO-U	14	Hose, Air Yellow, 4.5m M/F- DISS	14
Handle -	14	Hose, O2 Green, 4.5m M/F - DISS	14
SERVO-U6692510			
Expiratory cassette	14	DISS, Air Filter	14
Upgrade via E-delivery	14	SW Automode, SERVO-U	14
SW Basic Options SERVO-U	14	SW CO2 analyzer, SERVO-U	14
Country kit SERVO-U, US, DISS, N	14	SW NIV, SERVO-U	2
AmCSA			
Mobile Cart-flat pack	14	SW Alarm output, SERVO-U	14
Support Arm 178	14	Water Bag Pole	14
Cable holder	14	Gas cylinder retractor kit	14
Humidifier Holder	14		
O2 Sensor	14		

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

- ☒ (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements;
- ☐ (2) Unusual and Compelling Urgency;
- ☐ (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services;
- ☐ (4) International Agreement;
- ☐ (5) Authorized or Required by Statute;
- ☐ (6) National Security;
- ☐ (7) Public Interest;

FAR13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

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 VA Puget Sound Healthcare System currently uses Maquet critical care ventilators. This requirement is to replace and supplement the old system.

The Maquet SERVO-U enables both invasive and non-invasive ventilation independent of pressure and/or flow triggering by the patient interface. Neurally Adjusted Ventilator Assist (NAVA) and Edi (electrical activity of the diaphragm) monitoring technology uses the patient's physiologic signal from the diaphragm to trigger breath delivery. Therefore, the patient interface does not need to be tightly affixed and ventilation is provided in synchrony with the patient's needs, both of which support patient comfort and improved outcomes¹. This feature is essential to the Government. The SERVO-U is the only FDA approved critical care ventilator that has a NAVA mode with Edi. Additionally, the SERVO-U includes built-in medication nebulization and humidification.

The SERVO-U O2 sensor is the only FDA approved ventilator O2 sensor that operates off of Ultrasonic technology. The ultrasonic O2 sensor is designed to last the life of the ventilator reducing the cost of ownership.

The Maquet SERVO-U utilizes a touch screen interface that allows the facility to customize views; this includes the "family view" that provides the clinician with the necessary information for providing care while appearing more calming than the standard waveforms to loved ones. Furthermore, the unit allows the clinicians to display five waveforms simultaneously: pressure, flow, volume, etCO2 and the Edi signal. Lastly, the unit provides for the ability to capture and download up to 40 thirty-second screen recordings for case analysis. This capability is essential in quality clinical case management for the veterans.

¹Yonis H, Crognier L, Conil JM, Serres I, Rouget A, Virtos M, Cougot P, Minville V, Fourcade O, Georges B. Patient-ventilator synchrony in Neurally Adjusted Ventilatory Assist (NAVA) and Pressure Support Ventilation (PSV): a prospective observational study. BMC Anesthesiol. 2015 Aug 8; 15:117. doi: 10.1186/s12871-015-0091-z.

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The SERVO-U displays remaining battery time in minutes on the main screen to allow staff to anticipate when AC power is needed. Furthermore, the ventilator is lightweight which aids in intra-hospital patient transport. Both features are necessary to support patient safety.

Finally, the SERVO-U is designed as modular; this allows the Government to interchange and upgrade specific modules to meet future needs thereby reducing duplication of costs for the Government.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Research was conducted to identify the availability of sources for this requirement. A sources sought synopsis, 36C26018Q9687, was issued on August 11, 2018 requesting information related to the manufacturers of ICU ventilators meeting the essential characteristics or equivalent noted above. Four responses were received: two responders were distributors of the Maquet SERVO-U, one was a distributor of the Draeger Evita Infinity V500, and one was a distributor of Carefusion Vyaire. A technical review of the systems was conducted. Neither the Evita or Vyaire systems had an equivalent to the NAVA/Edi monitoring system or had built-in medication nebulization capabilities. Only the Maquet SERVO-U met every essential characteristic. Market research did identify possible sources for this requirement as a brand-name requirement.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated cost will be considered fair and reasonable based on competition.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** As described in Section 6 above, market research, in accordance with FAR Part 10, was conducted by a search in the Vendor Information Pages, all mandatory source listings, GSA's Advantage and on FPDS. Market research was also conducted by issuing a synopsis of the proposed acquisition, advising industry of the pending acquisition and soliciting inquiries from interested parties. No SDVOSB, VOSB or SB vendors were identified that could meet the Government's requirements and those of the Non-Manufacturer Rule as a set aside. Market research identified sources that can provide the required equipment on an unrestricted basis.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** This requirement is for specialized medical equipment with features that do not have marketplace equivalents currently.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

<u>HMS</u> One Discovery Place Martinsburg, WV 25403	<u>Draeger</u> Evita Infinity V500
<u>Janz Corp</u> 6950F Americana Parkway Reynoldsburg, Ohio, 43068	<u>Vyaire (Carefusion)</u>

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Technical Communities, Inc.
d/b/a TestMart
1111 Bayhill Drive
San Bruno, CA 94066

Maquet
SERVO-U

Fidelis
204 West Spear Street, # 3319
Carson City, NV 89703

Maquet
SERVO-U

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:** No further actions are planned for acquisitions of this nature. The current approval is sought for a single requirement fulfillment. However, if a similar requirement does become necessary, market research will review the technical capabilities of the market at that time. Technical capabilities change in the market frequently.
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, which are included in the justification, are accurate and complete to the best of my knowledge and belief.


Richard B. Goodman
Chief, Pulmonary and Critical Care
VA Puget Sound Healthcare System

9/6/18
Date

13. **Approvals in accordance with the VHAPM Part 806.3 OFOC SOP:**

- 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.

Jacob P. Jackson
Contracting Officer
NCO 20 Supply Branch II

Date

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

Jonathan Jewel
Branch Chief
NCO 20 Supply Branch II

Date