

**LIMITED SOURCES JUSTIFICATION**

**ORDER >\$150,000**

**FAR PART 8.405-6**

**Acquisition Plan Action ID:** \_642-17-2-315-0081

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:** Nellcor Puritan Bennett Inc., (dba Covidien), is the original manufacturer for material.

Manufacturer/Contractor: Nellcor Puritan Bennett Inc. (dba Covidien)

Manufacturer/Contractor POC & phone number: Fara Cooper, 609-432-1113

Mfg. /Contractor Address: 675 McDonnell Blvd, Hazelwood, MO 63134

Dealer/Rep address/phone number: N/A

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

**(1) AGENCY AND CONTRACTING ACTIVITY:**

Department of Veterans Affairs  
3900 WOODLAND AVENUE  
PHILADELPHIA, PA 19104

**VISN: 4**

**(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:**

PB980 Puritan Bennett ventilators -- This justification provides the rationale for soliciting using a brand name only description for PB980 Puritan Bennett ventilators an item peculiar to one manufacturer in accordance with FAR 8.405-6 (b). Award will be firm fixed priced

**(3) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:**

1. 10086042, Rechargeable Li-Ion Battery 20 ea.
2. 980S3ENDIUUS, PB Adult-DC Compressor base-ships with adult exhalation filter, 2 EVQs, 1 EVQ seals kit. Flex arm,, gold standard circuit, Op Man on CD, power cord and software options PAV+, leak Sync, Bi-Level 2.0,(plus standard software features including VV+, Respiratory Mechanics, Trending, Tube Compensation) and 3 year all-inclusive service coverage. 10 ea.

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|--|--------|
| 3. 10086042 Rechargeable Li-Ion Battery-Each Ventilator one battery to operate | 20 ea. |
| 4. 10086049, PB980 Humidifier Bracket  | 10 ea. |
| 5. 10086050, PB980 Cylinder Holder   | 10 ea. |
| 6. 4-PBTRAD-T, 840 VENTILATOR  | 10 ea. |
| 7. BIO-MED TRAINING  | 1 ea.  |

**ESTIMATED DOLLAR VALUE: \$455,330.00**

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**REQUIRED DELIVERY DATE: 30 DAYS ARO**

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**(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.

- Puritan Bennett 980 ventilator includes unique safety capability called Puritan Bennett Ventilation Assurance: In the event of certain system failures, the ventilator will continue to deliver ventilator support as close to the preset settings as feasible. Ventilation assurance feature is unique to the Puritan Bennett™ 980 ventilator that may help improve safety for ventilated patients in the event of certain system failures.
  - This safety feature is specific to Puritan Bennett 980 Ventilator.
- The Puritan Bennett 980 ventilator incorporates an N100 rated integrated heated expiratory filter. These N100 rated filters are uniquely designed to protect patients, clinicians and family members from microbial contamination.
  - The design and integration of the N100 rated expiratory filter chassis is unique to Puritan Bennett line of ventilator systems, including the Puritan Bennett 980.
- PAV+ software for the Puritan Bennett 980 ventilator is a breath type that better manages the patient's work of breathing and promotes natural breathing compared to conventional mechanical ventilation. The real-time feedback on work of breathing

provided by PAV+ software helps the clinician keep the patient at a sustainable level of work—reducing the risk for respiratory muscle atrophy, but off-loading enough work to avoid fatigue.

- PAV+ software provides this monitoring and support non-invasively without the use of catheters or intra-pleural sensors; a key differentiator for this Closed Loop form of ventilation. This approach can reduce operational cost of the ventilator and reduces overall consumable footprint of the product.
  - No other manufacturer offers a product with this spontaneous breath type
- Puritan Bennett 980 ventilator includes 3 years of Premium Service Coverage standard with purchase. Coverage includes telephone support, remote diagnostics, remote software updates, and time and materials for onsite repairs.
  - An all-inclusive service approach reduces the maintenance burden on biomedical and clinical engineering departments, which can lower operational costs.
- The PB980 ventilator incorporates advances in ventilator technology while maintaining the PAV+ technology and the heated expiratory filter both of which are unique to the Puritan Bennett product line. The PAV+ software for the Puritan Bennett 980 ventilator is a breath type that better manages the patient's work of breathing and promotes natural breathing compared to conventional mechanical ventilation. PAV+ software manages the patient's work of breathing differently than other current modes of mechanical ventilation. The heated expiratory filters trap 99.97% of pathogens to shield patients, clinicians and visitors from exposure to viruses and bacteria from exhaled gases. The filters can be used for 15 days without changing. The PB980 system help protect our caregivers from pathogens like Ebola. The occlusion alarm and automatic patient detection are additional safety features it provides to our patients. These aspects give us the potential of reducing sedation requirements and improving patient comfort Transitioning to the PB980 will allow us to continue with our current clinical practices helping to ensure patient safety. Nellcor Puritan Bennett Inc, (dba Covidien), is the original manufacturer for the requested equipment.

☐ A patent, copyright or proprietary data limits competition. The proprietary data is: (If FAR 8.405-6(a) (2) iii before posting. Do not include specific proprietary data. Only mention the type of equipment, procedure, etc. to show that proprietary supplies or services are being procured.)

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

☐ 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.

☐ 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:**

The ventilators are currently able to be distributed among various SDVOSB distributors. We are able to get competition to help drive the cost lower.

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

PB-980 PAV+™ mode of ventilation is patented proprietary data that limits competition. The market research for our proposal is derived from a similar approved and implemented project request (PB-840 to PB-980 upgrade) dated 10/27/2017 from **Durham VAMC**. An additional source of market research was conducted mid-year 2015 at the Philadelphia VAMC during a trial that was conducted in the medical and surgical intensive care units, that compared the PB-980 to the DRAGER AVITA ventilator, the trial resulted in respiratory therapy, critical care nursing and medical staff ~~favoring~~ the PB-980 over the DRAGER unit, primarily due to the seamless learning / training curve that would be minimized during the "switchover" from the present PB-840 to the 980 unit.

Contacted the manufacturer and they provided a list of their SDVOSB distributors authorized to distribute these ventilators. A competitive RFQ will be issued on FBO.

**(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:**

Transitioning away from the Puritan ventilator would limit clinical practice due to the absence of PAV and patient safety could be at risk without the existence of the heated expiratory filter and other unique safety systems

**(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:**

For future requirements and before making subsequent acquisitions of this type, in order to overcome any barriers to competition, market research will be used as a guide to determine whether or not the market for competition exists. The appropriate procurement strategy will then be determined and followed. The contracting agency will continue to

monitor the market for the inception of other companies capable of meeting the requirement.

**(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.)*

_____	9/13/2017
SIGNATURE	DATE
_____	Director, Respiratory Care Services
NAME	TITLE
_____	SERVICE LINE/SECTION
FACILITY	

**(10) 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.

_____	9/13/17
CONTRACTING OFFICER/DESIGNEE'S SIGNATURE	DATE
AMANDA SAUNDERS	PITTSBURGH VAMC - HEINZ
NAME AND TITLE	FACILITY

**b. Director of Contracting/DESIGNEE:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

_____	09/14/2017
SIGNATURE	DATE
Benjamin A. Grogg	
NAME	
NCO/PCO X Director of Contracting	