

## DEPARTMENT OF VETERANS AFFAIRS

### Justification and Approval

For

### Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, Southern Nevada Healthcare System (VASNHS), NCO 22, 6900 North Pecos Rd. North Las Vegas, NV 89086 intends to award a sole source contract for requisition number [REDACTED] for the purchase of two (2) Arctic Sun 5000 Temperature Management Systems.
2. **Nature and/or Description of the Action Being Processed:** The VASNHS has a requirement to purchase two (2) Arctic Sun 5000 Temperature Management Systems. C.R. Bard is the sole manufacturer and provider of the Arctic Sun 5000.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The VASNHS has a requirement to purchase two (2) Arctic Sun 5000 Temperature Management Systems. Arctic Sun has a screen interface that quickly guides clinicians to successfully initiate treatment with fewer steps than traditional methods. It allows for faster initiation of treatment, it provides a comprehensive built-in training module, and easy access to treatment data. The training and data access reduces the need for training costs, while automated therapy enhances the doctor to patient ratio. Previous technologies were cooling blankets, ice packs, and fans to cool the body.
4. **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;
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 Arctic Sun 5000 is the only system that utilizes a non-invasive approach to rapidly reduce and control patient temperature to properly administer Therapeutic Hypothermia; which is the medical recommendation for the care of resuscitation in sudden cardiac arrest patients. The patented adhesive hydrogel pads allow for a rapid heat exchange and protect the skin from damage during the therapy. It is designed to monitor and control a patient's temperature, and consists of an electronic module and disposable Arctic-gel Pads. The system includes a stand-alone electronic module with an interactive touch screen. There are no authorized third party retailers for this product according to C.R. Bard. Any use of

unauthorized or "gray market" resellers could void the warranty of products or result in the purchase of counterfeit, stolen, salvaged or damaged products.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A search of the internet, GSA Advantage, National Acquisition Center, and discussions with C.R. Bard resulted in no results other than C.R. Bard. The technology appears to have been approved by the FDA in 2010 and is a relatively new technology. Federal Business Opportunities was reviewed and no relevant purchases were found other than those with C.R. Bard.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** IAW FAR 13.106-3(a)(2)(ii) the Contracting Officer shall determine pricing fair and reasonable utilizing a comparison of the proposed price with prices found reasonable on previous purchases for the same items.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was conducted by reviewing Vetbiz, Unicor, Ability One, the National Acquisition Center (NAC), GSA Advantage, Federal Business Opportunities (FBO), and other internet sources. During the market research the Arctic Sun 5000 was found to be the only FDA approved product that is a non-invasive Hypothermic Therapy Device that both heats and cools the patient to control body temperature without constant supervision. Prior technologies included cooling blankets, fans, and ice packs to control body temperature. A search of the internet revealed no other sources that were non-invasive and had the capability of the Arctic Sun 5000. A search of FBO revealed prior relevant acquisitions for the purchase of Hypothermic Therapy Devices throughout the federal government. At least two of the purchases were sole source procurements to C.R. Bard for the purchase of Arctic Sun 5000 devices. Prior acquisitions reviewed include VA240C-13-P-0106 and VA257-14-P-2008.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** C.R. Bard provided product literature and an estimated price.
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:** Future requirements will be evaluated and researched on an individual basis. Future advancements in technology may overcome the uniqueness of the Arctic Sun 5000 Temperature Management System.
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.



8/19/14  
Date

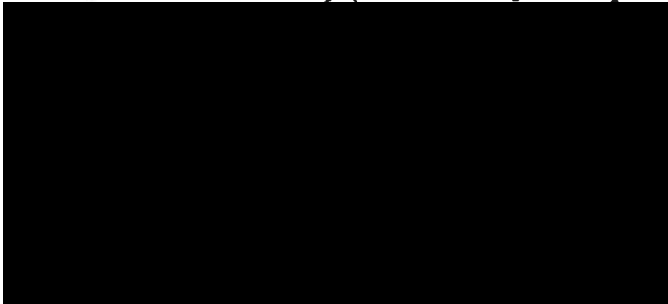
**13. Approvals in accordance with FAR 6.304**

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



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Date

- b. **NCM/PCM (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition.



8/20/2014  
Date