

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA263-16-AP-3501

1. **Contracting Activity:** Department of Veterans Affairs, SAO Central for Minneapolis VA Health Care System VISN 23 requested assistance from SAOC contracting in procuring an ARMEO Robotic Rehabilitation System. The purchase request (PR) for this acquisition is 618-16-2-040-0160.

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

The government anticipates awarding a new sole source firm fixed-price purchase order to Hocoma Inc. for Armeo System Rehabilitation devices, installation, and training. This purchase order will cover the following requirements: one (1) ArmeoPower; one (1) Module ManovoPower; one (1) day of ArmeoPower Training; one (1) day ArmeoPower Installation; three (3) Mains Cables NEMA5-15HG-C13/SJT; one (1) ArmeoPower User Manual; four (4) Armeo Carts; two (2) ArmeoSprings; one (1) day ArmeoSpring Training; two (2) days ArmeoSpring Installation; two (2) ArmeoSpring User Manuals; two (2) Module ManovoSpring; one (1) ArmeoBoom; one (1) day ArmeoBoom Installation; one (1) Power Cord USA/CAN, C5, 1.8m, Black; one ArmeoBoom User Manual. The anticipated value of this purchase order is \$347,508.00

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for instrumented arm orthosis 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:**

The Minneapolis VA Health Care System (MVAHCS) provides rehabilitation services to support functional therapy for Traumatic Brain Injury (TBI) and Spinal Cord Injury (SCI). The rehabilitation system required is an instrumented arm orthosis with a spring mechanism for upper extremity treatment that is adjustable and has the ability to move three (3) dimensions. The devices are used with software to treat and assess patients with virtual reality integration. The MVAHCS currently utilizes a product line from Hocoma Inc. The new system is required to integrate with current Hocoma technology.

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4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §3304(a)(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;
- () (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: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented 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):** Armeo Spring: (4k) provides a modality the MVAHCS does not have at this time. This is an evidence based tool for neuro rehabilitation that provides multiple options for increasing range of motion and control of position of an arm in space. This provides functional exercises in a 3dimensional workspace that is motivating to veterans, increases concentration and coordination as well. Specifically targets grasp and release, pronation and supination, wrist flexion and extension, and reach and retrieval. Can be used with patients who are beginning to regain active movement of the arm and the hand as it detects trace movements. This device not only provides activities, it provides an arm support exoskeleton to make for a more self-initiated patient control, provides virtual reality training, offers feedback on performance, and has assessment tools. This device allows active treatment for those with trace movement and engages them in a functional, motivating activity, is adjustable for each veteran's needs.

All rehab populations with UE impact resulting in limited motion can benefit from the use of this device. Veterans can utilize this equipment in sessions with therapists 30-60 minutes, 2-3 times a week. Estimated number of patients who could be utilizing at this time: 5-8 inpatients.

Armeo Power: This is also a modality that the MVAHCS does not currently have. The Armeo Power provides a full range of assistance, being able to be graded from full movement guidance to no support. This would allow therapists to treat a wide variety of patients and begin upper extremity intervention earlier on more advanced patients. This ability to grade assistance up to full support allows the therapist to find and exploit muscles that would otherwise be difficult to treat. This device provides immediate feedback on performance through the use of a wide variety of visual tasks and exercises that are able to be tailored to best meet the patient's functional and therapeutic goals. This software is also designed to be rewarding and motivating to the patient to keep them engaged in the therapy process. The assessment tools that are also included with this device will assist in providing a more advanced method of tracking progress over time. Overall outcomes for this device would be increased range of motion and maximized functional use for the affected upper extremities.

All rehab populations with UE impact resulting in limited motion can benefit from the use of this device. Veterans can utilize this equipment in sessions with therapists 30-60 minutes 2-3 times a week. Estimated number of patients who could be utilizing at this time: 5-8 inpatients and 2-3 outpatients, 30-60 min sessions.

Market research could not identify alternatives that are comparable to the Armeo System.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Hocoma was contacted via telephone in August 2016 to inquire about distributors. The contracting office requested distributor information in an effort to find veteran owned, service-disabled veteran owned, and small business concerns that could supply this requirement. Unfortunately, Holcoma does not have ANY authorized distributors.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The government intends to utilize FAR 13.106-3(2)(i), 13.106-3(2)(ii), 13.106-3(2)(iii), and/or 13.106-3(2)(iv) to determine price reasonableness.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research determined that the required instrumented arm orthosis equipment and installation are of a type customarily used by the general public or by non-governmental entities for purposes other than governmental purposes and has been offered for sale, lease, or license to the general public. As a result, this equipment is determined to be a commercial item. A search of SBA's "non-manufacturing" waiver list showed that the selected NAICS code (334510) DOES HAVE a class waiver
(https://www.sba.gov/sites/default/files/articles/NMR%20CLASS%20WAIVER%20LIST-AS%20OF%2001-01-2015_3.pdf).

A search of the SBDS database produced the following results:

Veteran	236;
Currently 8(a) Certified	39;
Service-Disabled Veteran	162;
Currently HUBZone Certified	30;
Currently SDB Certified	28; and
Woman or Woman Owned	251.

Hocoma was contacted via telephone in August 2016 to inquire about distributors. The contracting office requested distributor information in an effort to find veteran owned, service-disabled veteran owned, and small business concerns that could supply this requirement. Unfortunately, Holcoma does not have ANY authorized distributors. On 08/25/16 twenty (20) SDVOSB/VOSB and Small Business concerns were sent a Request for Information to identify if any could provide a product equal to the requirement. As of 8/29/16 two (2) firms responded, both indicated that they did not manufacture this equipment or anything comparable.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Hocoma Inc. has a very unique set of products. As of August 2016 there are no known alternatives that are compatible with the Hocoma Armeo System.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** N/A
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:**
There are no known efforts to overcome any barriers to competition.
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,

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

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

Marnie Roiger
Assistant Chief Occupational Therapy
Minneapolis VAMC

Date

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

Jennifer Johnson
Lead Contracting Officer
SAO Central Contracting

Date

- b. **Director of Contracting /Designee (Required over\$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

Kimberly Hurt
Chief Regional Contracting
SAO Central Contracting

Date