

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 10, Louis Stokes VA Medical Center, 6150 Oak Tree Blvd, Suite 300, Independence, Ohio 44131, will enter into a one-time firm fixed price purchase that requires justification for other than full and open competition. The Research Department at the VA Medical Center has requested an upper limb prosthetic device by submitting 2237s# 541-13-3-2321-0333 and 541-13-3-2321-0336.
2. **Nature and/or Description of the Action Being Processed:** Procurement of upper limb prosthetic devices required to copy the configurations of daily-use limbs already in use by the population of Targeted Reinnervation amputees at the Rehabilitation Institute of Chicago (RIC). These limbs will be built as the primary limbs for continuing research into establishing a sense of neurally integrated touch for prosthetic limbs.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**

(2) BE300TMR+ Boston Digital Arm-Plus System-TMR, 6-site input, 5 outputs for TMR patients

System includes the following components: Elbow Drive Unit, Lamination Collar, Forearm Frame, Input Connector Board, Main Circuit Board Prefabricated Forearm, Cross-Elbow cable, two lithium-polymer batteries (11V, 2000 mAh) with internal regulator (BE361) for multi-articulating hands. Color = Caucasian

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|-----------------|---|
| (4) BE370 | Cable, input splitter for one Myo input and one analog input |
| (2) BE366 | Fast Battery Charger, for Lithium (BE360) battery 115/220V, 50/60 Hz |
| (2) BE330 | Remote Myoelectrode Amplifier Set, 2-site (inc REC cables & Electrodes) |
| (4) REC-XX | Remote Electrode cable, one supplied with each BE electrode |
| (4) EL-XX | Metal Electrode Contact, Qty 3 supplied with each BE electrode. |
| (4) DC200L | Remote Electrode, includes cable and metal electrodes |
| (4) REC-XX | Remote Electrode cable, one supplied with each DC200L |
| (4) EL-XX | Metal Electrode Contact, Qty 3 supplied with DC200L. |
| (1) BE340 | Cable, Input, two Touch Pads |
| (1) BE341 | Cable, Input, two Touch Pads |
| (2) BE343 | Cable, Output TD with electronics (on-board controller) |
| (2) BE244 | Cable, Output to wrist rotator - (co-contract select control) |
| (2) TP01 | Touch Pad Kit - 3 Pads, 3/4" dia |
| (2) SJ90 | LTI Locking Shoulder Joint, Exoskeletal, Manual Lock Actuator |
| (1) SJ45L/SJ46R | Lock Release, Sierra Nudge Kit, Left or Right with base plate |
| (2) MC5010054 | MC Wrist Rotator - Tan |
| (2) MC1100295 | MC Lamination Collar for Boston Elbow - Tan |
| (2) 8E38=8 | Otto Bock Sensor Speed Hand, QD wrist |
| (1) 8E33=9 | Otto Bock Greifer, DMC VariPlus, QD wrist |

This requirement is for Liberating Technologies, Inc., a small business, to build an exact copy of the configuration of the daily-use prosthetic limb currently in possession of the Targeted Reinnervation amputee. This device will be used at the Louis Stokes Cleveland VA Medical Center Research/Prosthetics department. The estimated cost is not to exceed \$85,246.10.

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):

Our research requires that we build an exact copy of the configuration of the daily-use prosthetic limb currently in possession of the Targeted Reinnervation amputee. Targeted Reinnervation amputees have been provided with a direct neural-machine interface that allows them to control multifunction advanced prosthetic limbs. The Boston Digital Arm System, which includes the Boston Elbow and Motion Control wrist rotator, is specifically manufactured to provide multiple simultaneously active input/output channels for control of multiple functions by these amputees. Furthermore, these devices have a specially configured wrist and myoelectric hand system that will allow for more than three input/output channels to pass from the hand through the wrist to the controllers in the forearm. HDT Robotics a government-sponsored key-members of the research team, will utilize the additional channels to build in a touch feedback system into the limb. Sensors will be added to the shell or cosmesis of the Otto Bock Sensor Speed prosthetic terminal device. Signals from the tactile sensors will be integrated within and passed through the computer control architecture of the elbow/wrist system. Liberating Technologies Inc. is the only manufacturer that allows access to the onboard system for manipulation. Other systems researched include the Utah Arm 3+, and the Otto Bock Axon-Bus System. While the Utah Arm 3+ is very similar to the Boston Digital Arm System, the Arm 3+ device and control performance are different and will be rejected by the amputees in addition, to not matching the limb configurations prescribed by their physician. The Otto Bock Axon-Bus System with the Otto Bock wrist rotator only allows for 3 electrical channels to pass through the wrist. Furthermore, we are not permitted access to the control architecture of the limbs by these manufacturers.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: Due to proprietary rights, there is no other company who can supply this equipment. Liberating Technologies is the only provider who can provide the capabilities of what we are looking for. Market research was conducted to see if other companies could provide this specific equipment, but there were no others out there.

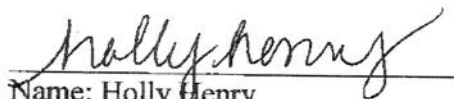
Furthermore, in accordance with FAR 5.202(a)(13) this action will not be synopsisized on the Federal Business Opportunity page.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The Contractor Officer has determined the anticipated cost to the Government will be fair and reasonable based on the price offer to the government for the upper prosthetic device in the amount of \$85,246.10.

The fingertip and palm touch sensors that connect to the robotic engagement to the neural-machine interface must retrofit to commercially available prosthetics. HDT Robotics designed the touch feedback devices to have this characteristic. HDT Robotics and Liberating Technologies Inc. together have already manufactured and configured much of the required computer hardware necessary for this approach for use in earlier government-sponsored research programs. Much of the equipment and computer architecture are not yet widely available in a competitive commercial market and have been in development under preceding government contracts for over five years. Liberating Technologies Inc. is the only firm that can provide the best value for the necessary supplies and services described above without the Louis Stokes VA Medical Center experiencing substantial duplication of cost that could not be expected to be recovered through competition. Awarding to any other vendor other than Liberating Technologies Inc. would result in substantial duplication of cost and unacceptable delays to design and manufacture of these 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 and the Utah Arm 3+ and the Otto Bock Axon-Bus system were compared. While Utah Arm 3+ system may be comparable they do not offer the exact equipment and we do not have access to the onboard system containing the microprocessor. We are also required to duplicate the prosthetic limb currently in use at RIC for accurate data collection during our research.
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:** State "See Section VI above."
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:** In order to remove or overcome barriers to competition in future acquisitions for this requirement, the Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be fully competed.

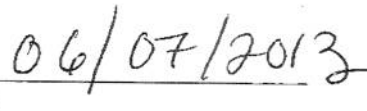
12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.



Name: Holly Henry

Title: Administrative Officer

Facility: Louis Stokes Cleveland VA Medical Center


Date

13. **Approvals in accordance with FAR 6.304** This contract action does not exceed \$650,000, the certification below required by FAR 6.303-2(b)(12) services as approval.

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



Name: Thomas P. Moore

Title: Contracting Officer

Facility: NCO 10


Date

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



Name: Terry Spitzmiller

Title: Network Contract Manager

Facility: NCO 10


Date