AWARD NUMBER: W81XWH-16-1-0767

TITLE: Workflow Optimization for Tuning Prostheses with High Input Channel

PRINCIPAL INVESTIGATOR: Daniel Merrill

CONTRACTING ORGANIZATION:
Ripple LLC

Salt Lake City, UT 84109-2319

REPORT DATE: October 2017

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2017	Annual	30 Sept 2016 - 29 Sept 2017

4. TITLE AND SUBTITLE

Workflow Optimization for Tuning Prostheses with High Input Channel

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-16-1-0767

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Daniel Merrill

E-Mail: dan@rppl.com

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Ripple, LLC
2056 S 1100 E
Salt Lake City, UT 84106-2319

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

This program will develop a control system that provides amputees outfitted with high-channel-count myoelectric signal monitoring systems, simultaneous use of multiple degrees of freedom (DOF) of a prosthetic limb. The program will also develop software and hardware tools prosthetists can use to adjust controller behavior to maximize limb function for each patient. The main strength of this program is that it combines basic research with existing, proven technology to provide novel rehabilitation strategies that meet a critical need in the military and civilian upper-limb amputee population.

15. SUBJECT TERMS

None provided

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	21	19b. TELEPHONE NUMBER *(include area code)*

TABLE OF CONTENTS

1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

This program will develop a control system that provides amputees outfitted with high-channel-count myoelectric signal monitoring systems, simultaneous use of multiple degrees of freedom (DOF) of a prosthetic limb. The program will also develop software and hardware tools prosthetists can use to adjust controller behavior to maximize limb function for each patient. The main strength of this program is that it combines basic research with existing, proven technology to provide novel rehabilitation strategies that meet a critical need in the military and civilian upper-limb amputee population.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

High-channel count myoelectric control of multi-articulating prosthetic limbs
Prosthetist tool development for improved fitting and tuning of limbs

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

The Statement of Work is as follows. Completion dates / percentage of completion is shown in bold and italics.

1. In Specific Aim 1 we will develop strategies for control of a prosthesis comprising a two degree-of-freedom wrist (pronation/supination and flexion/extension) and single degree-of-freedom hand (finger flexion/extension) based on input from multiple surface EMG sites. We will acquire EMG data from subjects using surface electrodes, implement control strategies on a Neural Interface System to control a virtual limb, and evaluate various control strategies with the goal of determining the suitability of each to clinical deployment. These strategies will be evaluated with unilateral transradial amputees.

1.1 Software development of control strategies for a virtual limb will **occur over the first 18 months of the project.** This will be an iterative process, taking account of feedback from initial clinical usage.

66% complete. As detailed below, our software efforts have been two-fold: (1) developing the initial control scheme, comprising direct muscle motor control, and (2) developing tools for embedding algorithms on the data acquisition system ("code on the box"). We have achieved the major technical milestones for portable algorithm deployment in the clinic.

1.2 IRB submissions will be made at two clinical sites **by the end of month 3**. IRB approval for this non-significant risk study is expected by the end of month 6.

The initial IRB package for a clinical study at two sites had been approved, and was submitted for review by the Human Research Protection Office (HRPO). However, a follow-up phone conversation on 10/4/2017 with HRPO Human Use Review Specialist, Sandra Mancha-Wright revealed a problem with the HRPO server, which led to our documentation to not being formally accepting or reviewed. On this phone call, we discussed the opportunity for an expedited review given the situation.

1.3 By the end of month 12, we will provide the first clinical demonstration of control of a three-DoF virtual limb using surface-acquired EMG on a unilateral amputee.

Given that the IRB-approved materials were submitted to HRPO, but not received, we are considering minor revisions with the IRB to expand the inclusion criteria for subject recruitment to maximize the clinical benefit of this study.

1.4 By the end of month 21, we will provide clinical demonstration of control of a three-DoF virtual limb using surface-acquired EMG at two clinical sites.

2. In Specific Aim 2 we will advance the control strategy development of Specific Aim 1 by driving a commercially available two DoF wrist and single DoF hand. The high-level control system will provide analog signals with the appropriate features of EMG for presentation to the individual controllers of a bench-mounted prosthesis.

2.1 Software development supporting a system of emulated EMG signals supplying the controllers of a commercial prosthesis will occur from the beginning of month 19 through the end of month 33. Software development will occur iteratively with feedback from clinical sites.

2.2 Clinical evaluation of multi-DoF control of a commercial prosthesis will begin at one clinical site during month 25. We will provide results of clinical studies from the first site by the end of month 30, and from both clinical sites by the end of month 36.

3. In Specific Aim 3 we will translate the functionality of the bench-top system developed in Specific Aim 2 into a portable system which demonstrates the utility of the control strategy in ambulatory subjects. We will implement recent training hardware-based methodologies such as Prosthesis Guided Training and test their efficacy.

3.1 Software development for the portable system will occur from month 31 through 42. Software development will occur iteratively with feedback from clinical sites.

3.2 Clinical evaluation of multi-DoF control of a commercial prosthesis using a portable controller will begin at one clinical site during month 37. We will provide results of clinical studies from the first site by the end of month 42, and from both clinical sites by the end of month 48.

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Major Accomplishments:

1. ALGORITHM DEVELOPMENT – Direct Control

Prior reports highlighted our accomplishments towards implementation of control strategies for advanced prosthetic movements. First, we utilized a direct control scheme with 4 pairs of surface EMG and a single reference electrode to demonstrate movements 4 degrees-of-freedom (DoF) on a Virtual Reality (VR) limb in the MuJoCo environment. Second, we translated these algorithmic efforts towards the direct control of a commercially available hand and wrist prostheses. Our software innovations required development of a Python API to deploy the Python CAN bus library to read the input movements and output control commands to the robotic limb. Ripple chose this development approach because the interface offers a straightforward, interactive environment, which can be readily expanded or embedded into future analysis suites. This software pipeline solves the major technical challenges for the controlling the limb and ensures a solid foundation for our upcoming efforts with control of other physical limbs.

2. VIRTUAL REALITY (VR) INTERFACE

A specific objective within this program is to development tools to help prosthetists tuning high-channel inputs for simultaneous multi-DoF movements. To this end, we leveraged our early piloting efforts in the MuJoCo VR environment and ported these innovations over to the Gazebo VR environment (http://gazebosim.org/). This offers several key advantages to our overall development goals because: 1.) this is an open source product that can be readily deployed on more platforms; and 2.) this is freely available to the community, compared to the expense for full control of the MuJoCo environment at an estimated $2k. In this effort, notable results include the set-up of Python wrappers for the Gazebo API (since the standard API is written in the C language), and the design of a Python API to more easily facilitate control of the joints. This is a powerful advancement which allows for more intuitive, direct control of the limb, as opposed to control based on lower level motor indices. The back-end development of these software tools to interface with a multi-articulating VR limb with naturalistic movement patterns is a significant accomplishment towards the overall aims of this program.

3. ALGORITHM DEVELOPMENT – Kalman Filter Control

Current efforts are examining the use of Kalman filter decoding in the control of advanced prosthetic limbs. This offers a natural fit for prosthesis-guided training for optimizing prosthetic controller performance. Our work-to-date in the virtual environment allows the subject to train using the visual feedback from the limb to enhance their decoder training. Selection of the Kalman filter is nicely aligned with our objective to provide tools for an improved patient experience because this specific decoder is more stable than direct control strategies, and allows for redundant input sampling, which facilitates the recalibration of the decoder under a wide range of clinical conditions and hence, can account for a variety of electrode placement and input signals.

4. PORTABLE ALGORITHM DEPLOYMENT – "Code on the Box"

We continue to embed decoding algorithms on the wearable Nomad data acquisition system. This is a necessary step to support of all three phases of the project, wherein decoding algorithms will be embedded in our Nomad system, referred to as "code on the box" and well suited for portable at-home use by subjects.

Our prior accomplishments showed an optimized code flow from developing in a MATLAB environment, running a coder to produce the C++ code, and compiling the C++ to run on the Nomad. Decode algorithms were ported to run on board the Nomad. The Nomad controls the virtual reality arms (required in Phase I of the project) on its own and identically reproduces the ported algorithm.

We recently built on this progress and have expanded its functionality to include control of the physical prosthetic hand. While work is ongoing, these efforts have resulted in an online programming interface for improved usability, which will make it easier for a prosthetist to control the program start-up and monitoring.

5. SYSTEM INTEGRATION WITH THE STEEPER PROSTHESES

As we broaden the interoperability of our technology platform, we have worked with the engineering team at Steeper to customize two Steeper SP-99 BeBionic multi-articulating hand and wrist systems, both right, medium. These were custom builds, providing active wrist flexion/extension, wrist pronation/supination, and finger flexion/extension (three active degrees-of-freedom). The first of the two hand and wrist systems was received on 17 May 2017.

There were a series of meetings between Ripple and Steeper. There was a challenge in accessing the motor controls for full functionality of the Steeper limb. The meetings highlighted the points of information flow (i.e., communication protocols) required to power up the limb and achieve simultaneous control of more than one degree of freedom. The Steeper engineering staff recognized the source of the problem and developed a firmware upgrade for us to directly control the previously locked motors. As a result, we have since made minor adjustments to our transceiver to execute full simultaneous multi-DoF control of the Steeper hand and wrist. This involved implementing the I^2C communication protocol and hardware modifications for direct motor control of the wrist. Moving forward, we currently have on-going communications with Steeper regarding a fully functional limb (having integrated its wrist control into its hand bus). On completion of this task, Steeper will send the second prosthesis to Ripple.

6. CLINICAL APPROVALS

Pending minor revisions to our IRB-approved protocol, we will submit for an expedited review through the HRPO office. These considerations will offer an improved study without affecting the major aims.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to Report.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

We will be presenting a research poster at the upcoming Society for Neuroscience conference in Washington DC on November 11-15. These results highlight our portable, low-latency data acquisition system (The Nomad) and its straightforward user interface to enable the neuroscience community to execute new experimental paradigms, which were previously either very burdensome to the subject or impossible to achieve.

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Our efforts over the next quarter will be directed primarily along two lines: continued development of decoding algorithms, and initiation of clinical trials.

Algorithm development:
The problem of controlling a multi-DOF prosthesis with multiple myoelectric signals generalizes as the task of finding a transformation, from a high-dimensional myoelectric signal space to a (potentially) lower dimensional movement space, that correctly captures the user's motor intent. Ideally this transformation would be sophisticated enough to interpret the myoelectric signals produced when the user is activating the muscles of the residual limb in a natural manner (as though controlling an actual biological limb). On the input side, multiple "features" are extracted from each myoelectric signal expanding the dimensionality to a multiple of the number of electrodes (for example, 4 features extracted from 8 signals yields a 32-dimensional input vector). On the output side, dimensions can be mapped to actual degrees of freedom of the prosthetic limb or various synergistic movement patterns of the limb components (for example hand grips.

We have started our investigation of control strategies by implementing a control interface for the direct muscle motor decode approach (where each degree of freedom of the prosthesis is proportionally controlled in a one-to-one manner by a fixed pair of myoelectric inputs), and for Kalman filter decoding of muscle inputs. Over the next quarter we will assess the performance of these decoding strategies for clinical VR limb control.

Regulatory Approvals:
Minor revisions to the IRB-approved protocol are underway and will be submitted to for approval by HRPO. Upon HRPO approval, we will be able to initiate subject recruitment at our clinical site.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Patients with transradial amputations using the currently available hand prostheses have limited options for intuitive, smooth movements. Although over the last decade, substantial improvements have been made to prosthetic arm technologies, their full utility has yet to be realized by patients in their daily lives because of poor control systems. Here, we offer a step forward in moving to more intuitive, simultaneous multi-DoF movements using higher input channel count prosthetic limbs. We are offering tools to reduce the burden on prosthetists who must adjust settings for mode switching, and tune controller parameters, including gain and threshold, for many more myoelectric channels. Further exacerbating the challenges prosthetists face, are issues associated with electrode placement, and a general lack of familiarity with multi-electrode control strategies and proprietary controllers. Although many academic research groups have demonstrated innovative multi-electrode limb control strategies, most are not easily adapted to existing clinical practice. In the context of the increased complexity associated with novel control technologies and higher channel counts, and given that prosthetists are reimbursed for only a limited number of hours (typically 4) spent tuning a patient's controller, software and hardware tools are needed to facilitate the prosthetist's tasks. For emerging control technologies to be clinically successful, strong immediate development efforts are needed to generate a set of enabling tools and methodologies that are practical and cost-effective in a clinical setting.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

In the development of clinically relevant neuroprostheses, there is a profound need for the ability to run complex decodes and provide real-time control of stimulation systems and external peripherals. These experiments often require rack mounted data acquisition systems, external stimulators, and extra computers to develop and run the analyses. The need for this equipment and the difficulty of development limits these experiments to laboratory environment where movement and behavior of the subjects are greatly constrained.

The Ripple Nomad being developed as part of this project offers a portable, programmable platform for neural interface researchers. This is a wireless, battery powered data acquisition and stimulator that supports up to 512 channels plus analog and digital inputs. Additionally, the Nomad can control digital outputs and has CAN bus support, common for control of modern upper limb prosthesis. A Nomad can easily be worn by human or animal subjects undergoing freely moving behaviors. The Ripple Nomad system will enable experimenters to easily transition from a laboratory development environment to one where decode, stimulation, and control routines can be run directly on the Nomad hardware. This will allow for animal subjects behave interact under more naturalistic conditions, and for advanced clinical investigators to test their systems in an ambulatory environment.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

There are approximately 18,500 annualized upper limb amputations in the United States within the military and civilian communities. Acquired amputation of the upper limb is more often due to trauma, rather than dyvascular disease, are typically relatively young, active and productive in their careers and communities.

The personal goals of our wounded warriors in many ways follow that of wounded civilians: community reintegration, social acceptance, and the ability to be productive and excel at vocational goals. In addition to these aspects of reintegration into civilian life, many service personnel choose to return to duty after amputation. In 1995, 2.3% of amputee service personnel chose Return to Duty. By 2009, this number increased to an astounding 20%. About 21% of amputees from OIF/OEF are upper limb, and 80% of these use a prosthesis. The number of persons living with UL amputation continues to increase each year. With appropriate medical and rehabilitation intervention, this relatively young, patient population has the potential to return to long and productive lives after amputation.

Upon completion of this project, our wounded warriors can be provided the systems they so deserve to enable a full life, community reintegration, social acceptance, and the ability to be productive, and to partially mitigate a horrendous emotional experience. We expect that the natural and intuitive limb function facilitated by this effort will be an aid to mental and emotional wellbeing. These goals apply equally to both reintegration into civilian life and return to duty.

5. **CHANGES/PROBLEMS:** The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Nothing to Report.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

There is a delay associated with HRPO approval, as a result of a submission problem with their server. We are currently revisiting our IRB-approved protocol for minor revision, and this will be submitted to for approval by HRPO. Upon HRPO approval, we will be able to initiate subject recruitment at our clinical site.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

The purchase of the second limb from Steeper was moved from Y2 to Y1 ($50,000). Authorization was communicated to us from Amber Stillrich at CIV USARMY MEDCOM USAMRAA (US) in an email on November 18, 2016.
The primary reason for this request is that the first arm will be shipped to our clinical site restricting our development efforts until a second limb is acquired. Secondly the vendor for the prosthetic limbs told us that it will be much more efficient for him to make these limb modifications at the same time rather than a year apart. In effect, this change in expenditure timeline did not increase the overall budget or change our scope at all; it just allows us to avoid inefficiencies in the software development after the clinical site begins its portion of the project.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Nothing to Report.

Significant changes in use or care of human subjects

We are revising our protocol to broaden the inclusion criteria and update the time required for data acquisition to enhance subject recruitment and maximize the benefit of this clinical study

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS: List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report.

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report.

  Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing Additional to Report.

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report.

- **Technologies or techniques**
Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Two major technologies were developed as part of the research activities: 1.) The Ripple Nomad, and 2.) an EMG-controlled VR interface.

1. The Ripple Nomad ("Code on the Box")

Our Nomad data acquisition system supports real time execution of the control strategies in a wireless, ambulatory environment. Signals from the passive electrodes can be acquired and processed on Ripple *digital* front ends, for input into control algorithms to be executed in the Nomad's real-time Linux environment; output control signals are able be sent to the prosthesis via *analog i/o* front ends. This system can, at any time, be connected to a computer to visualize signal quality and adjust algorithm parameters. A significant advantage of this technologies is its near-real time control capability, with a round-trip latency as low as 1 ms.

2. EMG-controlled VR interface

We have also implemented a software interface to aid prosthetists in assessing whether a patient's remaining neuromuscular function is sufficient for driving simultaneous multi-DOF controllers. The interface has a basic view that displays filtered myoelectric signals as well as various features commonly extracted from myoelectric signals for control. The interface provides a means for prosthetists to select from among the available control strategies and the means to adjust parameters that affect how those features are computed. To enable preliminary assessments of clinical controller performance, this interface will be able to guide the subject through a simple controller training and testing procedure and display the results from the control of a VR limb.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report.

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source

of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Name: Elliott Barcikowski
Project Role: Senior Software Engineer
Nearest person-months worked: 9
Contribution to Project: Validation of the virtual limb environment

Name: Andrew Wilder
Project Role: Principal Software Engineer
Nearest person-months worked: 6.65
Contribution to Project: Development of tools for embedded algorithms on the data acquisition system

Name: Robert Roundy
Project Role: Senior Software Engineer
Nearest person-months worked: 4.54
Contribution to Project: Development of tools for embedded algorithms on the data acquisition system

Name: Dan Merrill
Project Role: Principal Investigator
Nearest person-months worked: 5.2
Contribution to Project: Project management, compilation of regulatory submissions

Name: Ginger Neil
Project Role: Quality Assurance
Nearest person-months worked: 2.12
Contribution to Project: Implementation of quality system and documentation under Good Documentation Practice for the Nomad

Name: Steve Barrus
Project Role: Senior Electrical Engineer
Nearest person-months worked: 4.86
Contribution to Project: Development and integration of prosthesis control

Name: Will Talmadge
Project Role: Senior Software Engineer
Nearest person-months worked: 5.73
Contribution to Project: Development and integration of prosthesis control

Name: Chris Smith
Project Role:
Nearest person-months worked: 0.65
Contribution to Project: Development and integration of prosthesis control

Name: Daniel McDonnall
Project Role:
Nearest person-months worked: 1.61
Contribution to Project: Development and integration of prosthesis control

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to Report.

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*

Nothing to report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to **https://ers.amedd.army.mil** for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

9. APPENDICES:

Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

Workflow Optimization for Tuning Prostheses with High Input Channel Count

W81XWH-16-0767

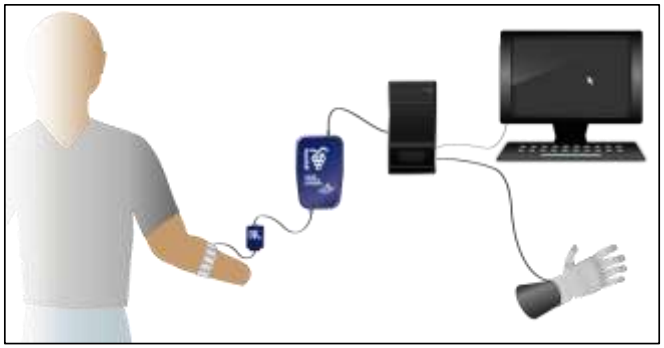
PI: Daniel McDonnall **Org:** Ripple LLC **Award Amount:** $1,288,666

Study/Product Aim(s)

- Aim #1: Develop multichannel myoprosthetic control algorithm
- Aim #2: Test system with transradial subjects using benchtop system
- Aim #3: Validate approach with portable control system

Approach

Ripple is developing an improved myoelectric system for more dexterous upper limb prosthesis control. The approach will utilize a multichannel EMG recording system and a portable data processing unit. In this project, we will develop the control software and validate in a clinical study with transradial amputee subjects.



Accomplishment: Development of control algorithms and processor integration; regulatory submission

Timeline and Cost

Activities CY	17	18	19	20
Control virtual limb				
Control benchtop system				
Control portable system				
Estimated Budget ($K)	**$510**	**$300**	**$300**	**$179**

Updated: October 2017

Goals/Milestones

CY17 Goal

☑ Regulatory submission

❑ Start clinical demo of control of virtual limb

CY18 Goals

☐ Validate software for virtual limb control

☐ Complete clinical testing of virtual limb

CY19 Goal – Production readiness

☐ Software for benchtop control system complete

☐ Clinical testing of benchtop system

CY20 Goal – Navy suitability testing

☐ Software for portable control system

☐ Clinical testing of portable system

Budget Expenditure to Date

Projected Expenditure: $510k

Actual Expenditure: $508k