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

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Fort Detrick, Maryland 21702-5012

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5b. GRANT NUMBER
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5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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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

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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

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		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.

100% complete. We have completed the software development for controlling the virtual limb.

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

100% complete. The study protocol has been approved by both the IRB and the Human Research Protection Office (HRPO).

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.

100% complete. The first clinical subject has used surface EMG to control three DoFs of the virtual limb.

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.

100% complete. All three subjects for this task have been enrolled and completed the phase I protocol for controlling the virtual limb with surface EMG.

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 testing.

100% complete. We can fully integrate with the controls of a commercial prosthesis using emulated EMG output.

2.2 Clinical evaluation of multi-DoF control of a commercial prosthesis will begin at the clinical site during month 25. We will provide results of clinical study by the end of month 36.

50% complete. We have worked on developing the platform for real-time control.

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.

85% complete. We are continuing work on system integration tasks to implement the Kalman filter into the portable system.

3.2 Clinical evaluation of multi-DoF control of a commercial prosthesis using a portable controller will begin at the clinical site during month 37. We will provide results of clinical study by the end of month 48.

35% complete. We have the protocol approved to begin recruitment for this final validation of the system.

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:

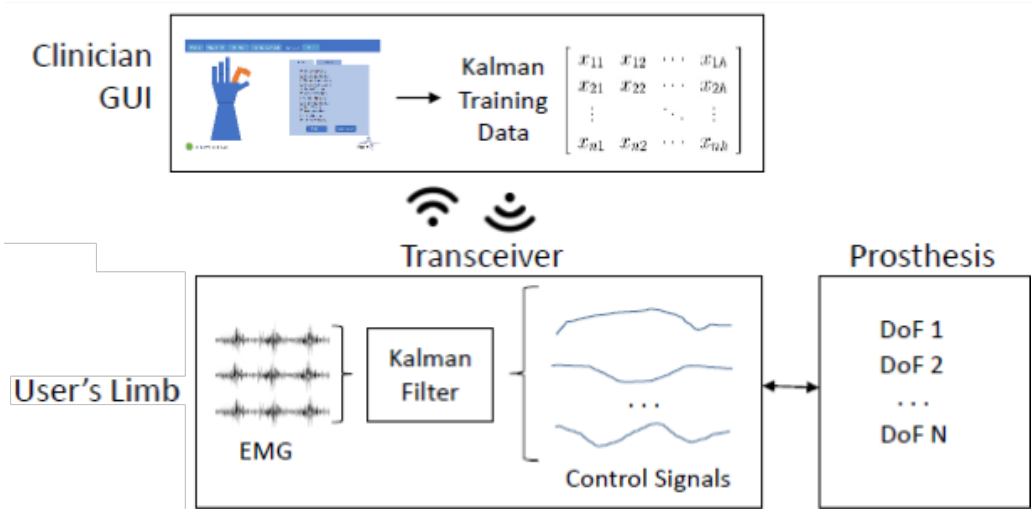
Graphic User Interface

During the initial calibration stage subjects will need to visualize the intended motion they need to perform to clarify subject motion intent matches the particular motion the investigator intends the subject to make. We have worked on concept approaches to develop a graphical user interface (GUI) to present this information for this next stage of the study and for eventual commercial distribution to clinicians. It is important to consider human factors to develop GUIs that can be translated out of our research lab into a tool used by clinicians in real-world settings.

Software Development

Several research groups have demonstrated the use of continuous regression-based approaches to achieve multi-DoF upper-limb control. These algorithms are different than the single-channel proportional control and pattern-recognition algorithms used in currently available commercial systems because they provide a user the ability to continuously adjust each aspect of hand shape and orientation during the movement. Continuous multi-DoF control allows prosthesis users to control their prosthetic limbs in the same manner they are used to controlling their biological limbs (intuitive control). One algorithm that has shown particular suitability to continuous control of complex, multi-in/multi-out systems is the Kalman filter.

For this project we are using a Kalman filter as the primary method for prosthesis control with our myoelectric system. In the context of prosthetic limb control, the EMG signals serve as the inputs to the Kalman filter and commands to control the prosthetic limb are computed as outputs by the filter every update cycle. Before a Kalman filter can be used to control a prosthetic limb, it must be trained to interpret the specific characteristics of EMG activity generated by the muscles in an individual user's residual limb. Continuous multi-DoF regression approaches to upper-limb control work best when there are many independent EMG signals available and the signals remain stable after the regression algorithm is trained. We have developed the system architecture for this approach to meet the goals of Specific Aims 3 with our programmable portable processor system.



System Integration

We believe the proposed system will usher in a new era of myoelectric control for prosthetic limbs, enabling intuitive and reliable control over the wrist and finger motions of the prosthesis. However, we recognize the need to integrate the myoelectric signals from our device with current standards for EMG signal processing and control followed by prosthesis manufacturers. To enhance the functionality of existing and emerging myoelectric devices, the myoelectric implant will support a range of prosthesis control systems.

An ideal system could provide low-latency, simultaneous, and independent control of up to 7 DoF, including flex/extend of four fingers and the thumb in addition to wrist rotation and flex/extend. Major prosthesis manufacturers have built this functionality into existing advanced myoprostheses, but they are not used clinically due to poor signals from sEMG. As part of previous projects, Ripple has already integrated the myoelectric implant system to control simultaneous motion of joints with several advanced prostheses, below a Ripple system is controlling BeBionic hand and prototype 2 DOF wrist.

Update processor to operate with Python

We have previously demonstrated a prototype system was capable of real-time decode of EMG signals using a Kalman filter on the portable processor using code developed in MATLAB. This approach was selected due to the ease of optimizing the Kalman filter using a MATLAB software platform. However, as the goal is to create and validate a tool that can be used beyond the laboratory setting, we have worked this quarter to revise the system to replace the same functionality with a system running on Python, instead of MATLAB. Despite its ease of use, MATLAB is a proprietary software package that is essentially inaccessible beyond academic research labs. Python is a commonly used software platform used by engineers in many settings.

To this end we have re-implemented our portable processor to work on Python. In addition to communicating with the prosthesis, the processor firmware is responsible for multiple different functions that relate to its role in the larger system. First it must be able to identify and control the specific prosthesis worn by the user. The processor must also be capable of communicating with the clinician and user software. The processor hardware already contains a Bluetooth chipset to enable communication with mobile devices. For this project we have worked this quarter to implement firmware to send information (including EMG signals, and logs containing implant and prosthesis status as well as usage data) from the prosthesis to the clinician and user software. We have also implemented firmware to allow the processor to read in and report out coefficients from the Kalman algorithm training.

To support the main operational mode, i.e. where the user is controlling the prosthesis, we will implement an algorithm execution engine that continuously processes the selected EMG signals and sends control signals to the prosthesis. The algorithm will monitor for fault conditions in the prosthesis and stop should it detect an error.

The system also now as a programmable interface that uses Python to support the decode algorithm. Outputs from the decode algorithm are routed through the CAN bus communication protocol on the processor to control the prosthesis. The new Python-based version of the system should be accessible to a larger field of users as we deploy this technology at the end of the project.

Draft Design Input Requirements

We have worked this quarter to complete documentation of the system, specifically working on completing the Design Input Requirements (DIR). The DIR for user interface software development is being drafted following the quality management system put forth by the International Organization for Standardization (ISO).

The DIR has been reviewed for incomplete, ambiguous, or conflicting requirements and will be finalized with objective outputs to ensure that each design input is met. The comprehensive DIR will be used to direct software development decisions.

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.

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

If this is the final report, state "Nothing to Report."

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

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.

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?
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?

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:

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

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.

Nothing to Report.

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.

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

Nothing to Report.

Significant changes in use or care of vertebrate animals

N/A

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.*

- **Website(s) or other Internet site(s)**
  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: Ginger Neil
Project Role: Quality Specialist
Nearest person-months worked: 4.1
Contribution to the Project: Documentation for test platform

Name: Andrew Wilder
Project Role: Senior Computer Scientist
Nearest person-months worked: 7.0
Contribution to Project: Software design for the portable system

Name: Carina Woodruff
Project Role: Design Specialist
Nearest person-months worked: 3.2
Contribution to the Project: Documentation for test platform

Name: Robert Roundy
Project Role: Senior Software Engineer
Nearest person-months worked: 8.3
Contribution to Project: Development of the programmable portable processor

Name: Scott Hiatt
Project Role: Senior Electrical Engineer
Nearest person-months worked: 1.8
Contribution to Project: Bench testing of the portable system

Name: Jonathan Landes
Project Role: Application Engineer
Nearest person-months worked: 3.6
Contribution to Project: Support for algorithm development

Name: Brian Crofts
Project Role: Electrical Engineer
Nearest person-months worked: 1.0
Contribution to Project: System integration

Name: Daniel McDonnall
Project Role: Principal Investigator
Nearest person-months worked: 0.5
Contribution to Project: Project management

Name: Cigy Cyriac
Project Role: Computer Programmer
Nearest person-months worked: 3.9
Contribution to Project: Software testing design

Name: William Talmadge
Project Role: Systems Engineer
Nearest person-months worked: 2.8
Contribution to Project: Systems integration

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.

No change to anticipated effort on this project.

New grants for PI:
U44NS115632 – NIH SBIR Fast-Track – 2.0 anticipated calendar months/year effort
R44NS112072 – NIH SBIR Fast-Track – 0.5 anticipated calendar months/year effort
W912CG-19-C-0004 – DARPA SBIR Phase II – 1.0 anticipated calendar months/year effort

Closed grant:
W81XWH-15-1-0601 – CDMRP Technology Grant

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*
- *Other.*

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

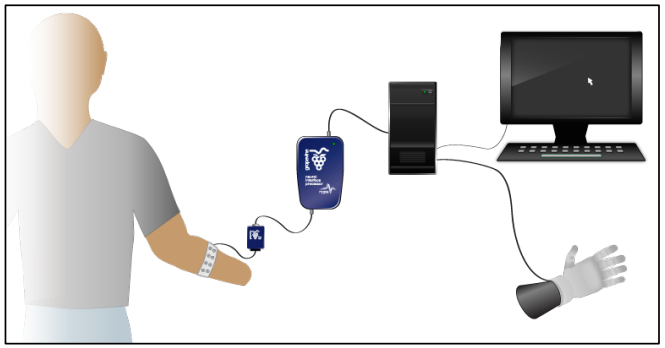
PI: Daniel McDonnall **Org:** Ripple LLC **Award Amount:** $1,288,666

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