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TITLE: A Pilot Trial to Assess Implantable Myoelectric Sensors (IMES) to Improve Prosthetic Function for Transhumeral Amputees with Targeted Muscle Reinnervation

PRINCIPAL INVESTIGATOR: Dr. Paul F. Pasquina, MD

CONTRACTING ORGANIZATION: Henry M. Jackson Foundation for Advancement of Military Medicine

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14. ABSTRACT The overall project goal is to investigate the functional performance of transhumeral amputees who have received targeted muscle reinnervation with EMG signals measured intramuscularly using a fully wireless implant. This year we fabricated the clinical implant and base-station units and performed testing required to submit for an investigational device exemption to the FDA through the early feasibility study mechanism. The FDA responded with a request for additional information with regards to biocompatibility. We have prepared a supplementary test plan and submitted it to the FDA for additional feedback.					
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1. Introduction

The inadequacies of current prosthetic technologies severely limit rehabilitative options for upper limb amputees and contribute to the disability caused by upper limb loss. TMR presents new possibilities for control of upper limb prostheses, and, building on this success, our team has developed innovative technologies to address key remaining challenges in the design and control of advanced prosthetic systems. The overall objective of this grant is to improve functional independence for individuals with transhumeral amputees, who have had TMR using implantable MyoNodes. Our hypothesis is that chronic implants within reinnervated muscle will provide stable EMG recordings that will allow intuitive, simultaneous control of 3 DOF prosthesis system. Furthermore, we hypothesize that this technology will result in significant functional improvements for users as measured through the ACMC, SHAP, clothespin relocation, Jebsen Hand task, and box-and-block tasks.

Aim 1: Obtain a feasibility study investigational device exemption for the MyoNode system.

Extensive preliminary work has already been conducted to develop and test the MyoNode prototype, with demonstration of successful wirelessly powered and telemetered data from a tissue depth of 10 cm in an animal model. All design files have been transferred to Cirtec Medical Systems to create final form factor devices under GMP and are working with Med Institute Inc., to obtain a feasibility Investigational Device Exemption (IDE) from the FDA. The engineering, fabrication, and regulatory team has extensive experience in developing implantable medical devices.

Aim 2: Assess the accuracy with which transhumeral amputees can control isolated and simultaneous movements of a three DOF myoelectric prosthesis utilizing the MyoNode system after successful TMR surgery.

TMR has proven very useful for enhancing prosthesis control. However, to date, subjects have been limited to using surface EMG signals to control a prosthesis. Surface EMG is often corrupted by muscle cross-talk and instability in the skin-electrode interface necessitates frequent recalibration of controllers. We will recruit three individuals with transhumeral amputations and who have had TMR surgery. As our basic control platform, we will use natively innervated biceps and triceps to provide direct proportional control of the elbow, and we will try both direct control and pattern recognition of EMG from reinnervated muscles to control the wrist and hand. Subjects will complete 3-DOF Fitt's Law virtual testing to measure throughput of discrete and simultaneous measurements. We will also measure subjects' control of a physical prosthesis as they complete movements which require discrete and simultaneous movements. A commercially available prosthesis with an elbow, a wrist rotator, and a hand will be used in conjunction with commercially available pattern recognition software (Coapt LLC). The only variable will be the input signals; allowing us to compare performance using IM and/or surface EMG signals, and with data from other transhumeral TMR subjects using the pattern recognition controller with surface EMG (W81XWH 12-02-0072).

Aim 3: Determine the ability of transhumeral amputees to successfully perform functional activities using a three DOF myoelectric prosthesis control by the MyoNode system and TMR.

We hypothesize that the MyoNode implant system will improve control of the prosthesis, and that this will subsequently improve functional activities. We will measure functional performance prior to implantation and during training with the MyoNode system, using the SHAP, ACMC, a clothespin relocation task, the Jebsen task, and the box and blocks task. We will also provide the subjects with a questionnaire for subjective feedback at the end of the study.

In our original project plan, The MyoNode System was planned to be ready for implantation by March 2016, allowing for adequate time for FDA approval and to complete the three aims within the 4 year trial period. However, delays in receiving approval for an Investigational Device Exemption (IDE) from the FDA have delayed our project.

2. Body

In the first 3 years of the project, we completed the necessary development work to create the MyoNode system and put it under design controls. We made a pre--submission inquiry to the FDA to create a plan for an investigational device exemption. During the first half of the project year, we completed the necessary testing required to submit for a FDA Investigational Device Exemption. The IDE (Appendix A) was submitted to the FDA in December. Furthermore, all components to fabricate clinical and testing builds have been secured.

We received feedback from the FDA in January. The most substantial item from the feedback was related to biocompatibility testing of the implant. Our original plan was to use known, and previously biocompatible materials as part of the implant assembly. These materials included zirconia, platinum-iridium with a gold braze. The FDA requested additional biocompatibility tests which included an animal test, specifically to ensure that no residuals as part of the manufacturing process are introduced which may cause an inflammatory response. We have found a test a registered test laboratory, NAMSA, to perform the additional testing, and submitted a revised test-plan with more extensive biocompatibility information to the FDA. We have also reached out to begin planning for appropriate animal testing oversight to ACURO; however, the final protocol will not be submitted until after we receive additional FDA feedback.

3. Key Research Accomplishments

- Submitted Investigational Device Exemption to the FDA.
- Fabricated the base-stations and implants required to perform clinical testing.
- Nordstrom M, Beachler M, Butkus J, et al. Evaluating the feasibility and complications of transhumeral osseointegration rehabilitation specifically using the osseointegrated prostheses for the rehabilitation of amputees (OPRA) system. Poster presented at: Myoelectric Controls Symposium (MEC); August 15, 2017; New Brunswick, Canada.
- Nordstrom MJ, Beachler MD, Butkus JA, et al. Service members and veterans with transhumeral osseointegration: Initial clinical rehabilitation experiences. Poster presented at: Military Health System Research Symposium (MHSRS); August 27-30, 2017; Kissimmee, FL.

4. Reportable Outcomes and Conclusions

The critical technical developments for the MyoNode project are now complete. Long lead-time items have been procured, and the implants and base-stations have been fabricated. The project has been delayed in response to additional testing required by the FDA to receive the IDE. We have asked for and received a NCE to perform this additional testing. Fortunately, our overall project remains on budget, and we expect to be able to perform the additional testing with the original proposed budget.

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November 8, 2019

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Device: MyoNode Wireless Implantable EMG Recording System
Submission Number: Not Yet Assigned
This Submission: Original IDE Application for Early Feasibility Study

Dear Sir or Madam:

Please find enclosed an original Early Feasibility Study IDE application for the MyoNode Wireless Implantable EMG Recording System intended to measure intramuscular EMG signals in the microvolt range and transmit the signals to a base-station for the purpose of controlling a commercially available motorized hand/arm prosthesis. Pattern recognition software supplied with the controller of the prosthesis will analyze these EMG signals and use them to control the movements of the prosthesis. So to be perfectly clear, the device subject of this IDE is the implantable Myonode EMG recording sensors and their associated base station. The prosthesis and its controller will be commercially available, FDA-approved products. The pertinent relationship is the requirement that the output signal(s) from the MyoNode base station meet the specification for input to the commercially available prosthesis' controller.

The Shirley Ryan AbilityLab (formerly, the Rehabilitation Institute of Chicago) in collaboration with the Purdue Center for Implantable Devices requests approval for enrollment of three patients at one investigative site, for the evaluation of the safety and effectiveness of the MyoNode system. The purpose of this feasibility study is to determine changes in functional independence for individuals with transhumeral amputation who have had Targeted Muscle Reinnervation and are using intramuscular EMG signals recorded from the implantable MyoNodes to control their motorized prosthesis. The hypothesis is that long-term implants within reinnervated muscle will provide stable EMG recordings that will allow intuitive, simultaneous control of a 3 degree of freedom (DOF)

Implantable EMG Recording System is intended to measure intramuscular EMG signals and wirelessly transmit the signals to its base-station, which subsequently transfers the signals to the

control unit of a commercially available arm/hand motorized prosthesis for the purpose of directing its motion.

The target patient population for this specific application is transhumeral amputees who have had Targeted Muscle Reinnervation (TMR) Surgery, have a long enough residual limb to adequately fit a prosthesis, and have adequate residual muscle within which to implant the MyoNodes.

This submission is divided into 21 volumes, as follows:

Volume 1 Early Feasibility Study Original IDE
Volume 2 - 21 Appendices A through T

This submission consists of the cover letter and one CD containing an exact electronic copy of the cover letter, the IDE, and the appendices.

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Applicant Information:

Same as Sponsor

Additional Information:

- a. Discussions with FDA reviewing division regarding this device:

<u>Date</u>	<u>Communication</u>
May 23, 2017	Submitted a Pre-Sub for a Feasibility IDE - Request for Meeting
Sept. 25, 2017	Written feedback from FDA (e-mail) regarding pre-Sub
Sept. 28 2017	Pre-IDE meeting at White Oak
October 10, 2017	Draft Minutes from Pre-IDE meeting (e-mail)

- b. Waiver Requests: None

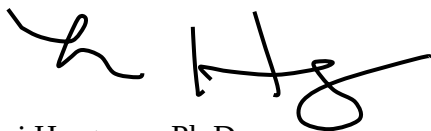
- c. Referenced Files: Q170872 – Pre-sub for a Feasibility IDE - Request for Meeting

In addition to FDA review of this application, the Shirley Ryan AbilityLab requests Category B designation with respect to medical reimbursement coverage for the investigational use of the MyoNode system.

Thank you for your review of this submission. If there are questions, please contact Levi Hargrove, Ph.D. via telephone (312.238.2084) or e-mail (lhargrove@srnlab.org). For administrative questions, please contact William Voorhees, Ph.D. (VP/Chief Science Officer, MED Institute Inc.) via telephone (765.463.1633 ext. 4275) or e-mail (wvoorhees@medinstitute.com).

Respectfully,

Shirley Ryan AbilityLab



Levi Hargrove, Ph.D.
Director, Center for Bionic Medicine

Enclosures: Original IDE Application (1 electronic copy on CD)

INVESTIGATIONAL DEVICE EXEMPTION

Early Feasibility Study

ORIGINAL APPLICATION

MyoNode Wireless Implantable EMG Recording System

1. Cover Page

1.1 IDE Application Statement

This is an original IDE application for an early feasibility study.

1.2 Name and Address of the Sponsor

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1.3 Name and Address of Manufacturer

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1.4 Device Name and Indications for Use

The MyoNode Wireless Implantable EMG Recording System is intended to measure intramuscular EMG signals in the microvolt range and transmit the signals to a base-station for the purpose of controlling motorized arm/hand prostheses. The target patient population of this specific application is transhumeral amputees who have had Targeted Muscle Reinnervation (TMR) Surgery, with a long enough residual limb to adequately fit a prosthesis, and adequate residual muscle within which to implant the MyoNodes.

1.5 Human Subjects Justification.

This first-in-human study is intended to determine changes in functional independence for individuals with transhumeral amputation who have had Targeted Muscle Reinnervation and who have wireless MyoNodes implanted to record intramuscular EMG signals to be used to control the movement of their motorized prosthesis.

While it is possible to evaluate certain specific functional elements of the MyoNode Wireless Implantable EMG Recording System *in vitro* and in animals, proof of concept of the entire integrated system can only be evaluated by testing in humans under real-world clinical conditions.

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2. Report of Prior Investigations

2.1 Background

2.1.1 Clinical Context for the Early Feasibility Study

The loss of an arm is a major disability that profoundly limits the everyday capabilities and interactions of upper-limb amputees. The impairment of bimanual dexterity limits employment opportunities and can impede routine activities such as driving and cleaning. Difficulty in holding objects also impedes leisure activities such as reading or playing sports. Upper-limb amputation interferes with basic activities of daily living including dressing, eating, and personal hygiene. The disability is magnified with bilateral arm amputation and can threaten a person's basic independence. The majority of upper-limb amputations are due to trauma and happen to relatively young and active individuals; therefore, the majority of upper-limb amputees are otherwise active and able individuals who must live with their disability for many years.

Myoelectric prostheses use electromyogram (EMG) signals, the electrical signals generated during a muscle contraction, to control motorized prosthetic arm components. The current standard of care is to measure EMG signals by placing an electrode(s) on the skin surface over muscle on the residual limb that remains after the amputation. Challenges associated with measuring and using EMG signals recorded at the skin surface to control a prosthesis include:

- ensuring robust, continuous skin/electrode contact,
- ensuring reproducible electrode placement each time the prosthesis is donned,
- finding electrode placement locations that are free from excessive nearby muscle EMG signals (i.e., cross-talk),
- recording signals from deep or small muscles, and
- ensuring the prostheses can be attached to the patient comfortably without causing movement artifact of the EMG signals.

Measuring EMG signals intramuscularly has been proposed for decades as an alternative to using surface EMG signals. Intramuscular recording helps alleviate all of the previously mentioned challenges to recording from the skin surface. Up to now, the difficulty to be overcome has been measuring the signals intramuscularly in a safe, reliable, and clinically viable manner. The technology described herein, called the MyoNode Wireless Implantable EMG Recording System, accomplishes these objectives.

2.1.2 Design Concept

2.1.2.1 Device Description

The MyoNode system (Figure 2-1) is comprised of two main components:

- **EMG Recording Implant:** A small, cylindrical, wirelessly powered implantable EMG recording/transmitting unit hermetically sealed in a 5.1 mm diameter x 24.8 mm long ceramic case. Multiple units are implanted to control a single limb. The EMG Recording Implant, also referred to as the MyoNode Implant, does not contain a battery, and does not provide stimulation.
- **Base-Station:** A system that wirelessly delivers energy to power multiple MyoNode implants through a tuned resonator (coil), receives data telemetered from the implants, and outputs the data onto a digital communication bus. The data may be read or interpreted by the controller of a prosthesis to control motions. The base-station, also referred to as the MyoNode Base-Station, does not contain a battery, but receives power from batteries approved for use in the prosthetic and orthotics industry, similar to how existing EMG amplifier systems operate.

The entire functional system is modular with the MyoNode System (EMG recording implants and base-station (Module 1)) comprising the EMG signal recording module, a pattern recognition “controller” (Module 2) capable of interpreting the digitized EMG signals and telling the prosthesis (Module 3) how to move. Different FDA-cleared controllers (e.g., Coapt Complete Control Gen2) and prostheses (e.g., College Park Espire Elbow) can be matched with the MyoNode System. Therefore, the MyoNode System does not include a specific upper-limb prosthesis, but is intended to work with all major designs of such prostheses.

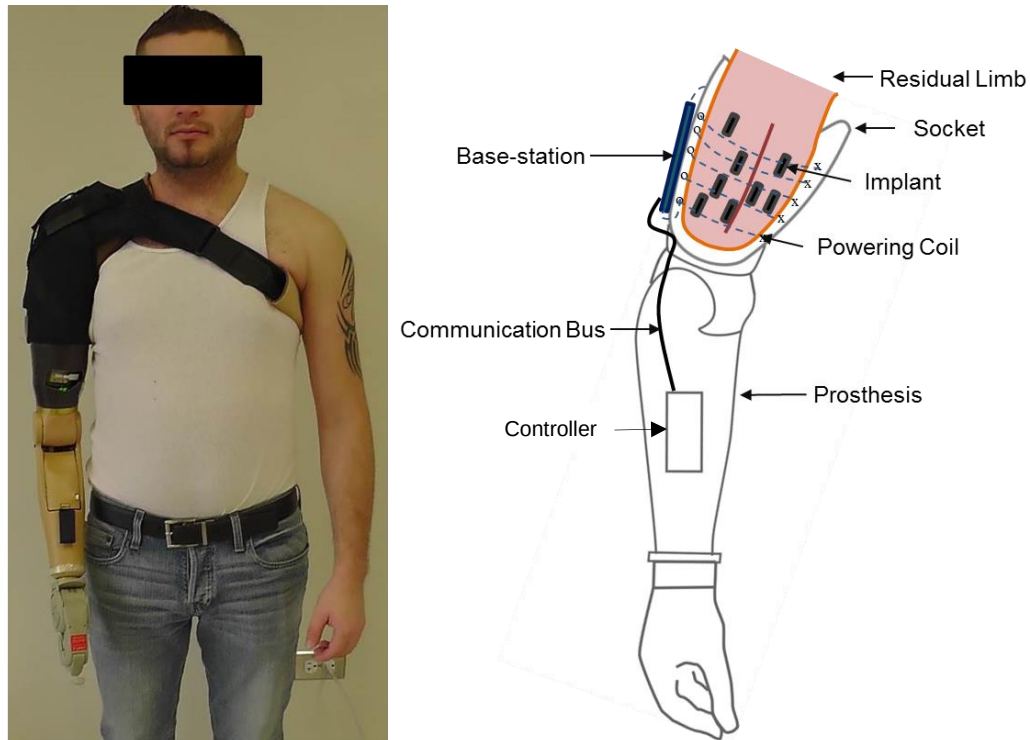


Figure 2-1. Overview of the MyoNode system with a diagram showing the locations of implants, base-station, and controller.

The Implant

The implant is a wireless EMG recording device. It has no stimulating function. It is constructed entirely from off-the-shelf electronic components that are packaged inside a biocompatible, hermetically sealed ceramic capsule. The **implant** is wirelessly powered using a technique called **magnetic resonance coupling** and does not contain a battery. Rather, it relies on receiving energy only when it is excited by a specifically tuned frequency in the ISM band (6.78 MHz) that is supplied by the **base-station** and transmitted through a properly aligned, placed, and tuned coil. The implant does have an onboard microcontroller that is capable of dynamically tuning the coil so that energy is efficiently transmitted. EMG signals are detected by electrodes built into the hermetically sealed ceramic capsule. The EMG signals are digitized and telemetered to the base-station using the ISM band (2.4 GHz) along with a unique identifier indicating from which implant the data were received. In this way, up to eight (8) implants can be used to measure EMG signals from different muscles within the limb. As noted above, the powering and telemetered data both use frequencies in the ISM bands. The implant has a size and shape to contain the necessary off-the-shelf electronic components to detect, amplify, and telemeter EMG data. Given these constraints, the implant has been made as small as possible by using an approximately 5.1 mm x 24.8 mm cylindrically shaped ceramic capsule (Figure 2-2).

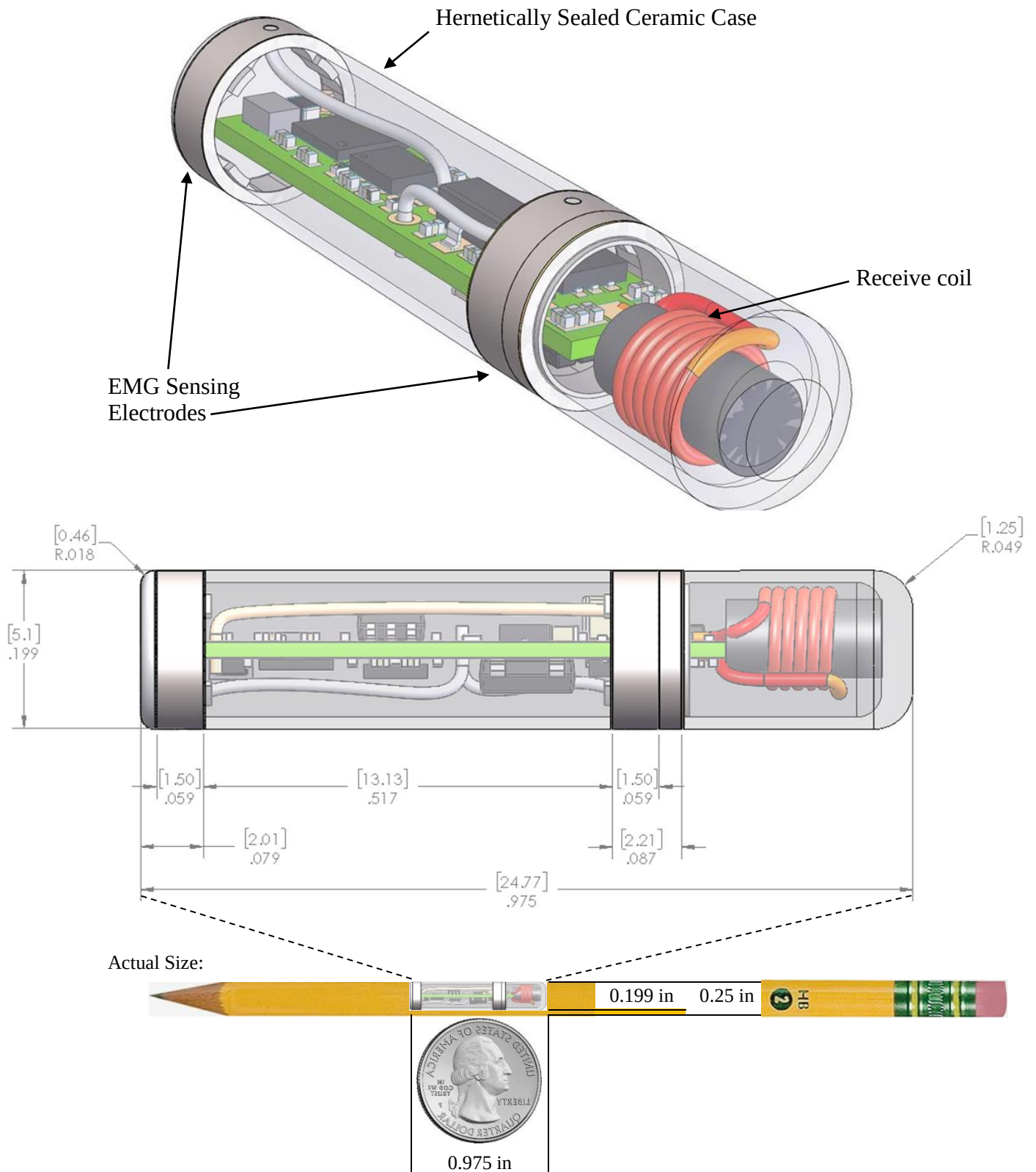


Figure 2-2. Schematic diagram of the implanted component of the MyoNode. The microcircuitry is contained within a hermetically sealed ceramic capsule and contains a power transfer component and a data acquisition and telemetry component.

Base-Station

The base-station (Figure 2-3) supplies energy to the implant(s) and receives data from the implant(s). It is also constructed from off-the-shelf electronics components. The base-station is portable and is designed to be attached to the prosthesis socket and is approximately the size and weight of a modern smartphone. Onboard the base-station, there is a miniaturized power radio frequency signal generator and amplifier. The energy is delivered using a transmitting coil. To power the implant, the powering coil is designed to be wrapped around the circumference of the socket and must be attached to the base-station using a wired connection. The total energy delivered by the coil is less than 1 watt which prevents excessive heating of the entire system. The received data are reconstructed into distinct EMG signals which may be streamed over a digital communication bus. The other end of the communication bus attaches to a controller which deciphers the commands for the prosthesis. The base-station receives power either through a line in the communication bus, or through external batteries commonly used in the prosthetic and orthotics industry.



Figure 2-3. Photograph of the base-station affixed to the prosthetic socket. The entire system (implant and base station) is fabricated from off-the-shelf electronic components.

2.1.2.2 Function / Intended Clinical Use

The role of the MyoNode implants is to amplify electrophysiological signals in the microvolt range using a differential amplifier. This range corresponds to that of EMG signal levels normally produced by muscle contractions. The EMG signals are wirelessly telemetered to the base-station.

To power the implant, a tuned coil on the implant receives power transmitted wirelessly in the ISM frequency band range of 6.78 MHz from an external coil attached to the base-station. The base-station software wirelessly acquires data from the MyoNode, validates the data, time-stamps it, and packages it for transfer over the digital communication bus. The communication bus implements a Controller Area Network (CAN) bus and packages data according to the Prosthesis Device Communication Protocol (PDCP).

Although not a part of the MyoNode system itself, a commercially available pattern recognition controller capable of interpreting digitized EMG signals streamed over a CAN bus will process the EMG signals; for example, The Coapt Complete Control (Coapt, LLC, Chicago, IL). This controller tells the prosthesis how to move based on the pattern of EMG signals presented to it.

2.1.2.3 Minimum Design-life of the Device

Components of prosthetic limbs are routinely adjusted by prosthetists to accommodate changes in body size or to address the comfort of the patient, while limb components are typically replaced after 5 years. Thus the MyoNode base-station is designed to last 5 years. Of note, the base-station may be easily replaced, or transferred to a new socket; however, a new coil will need to be constructed by the prosthetist. The MyoNode implants are intended to be chronically implanted and are designed to be functional at least 10 years; they are solid state devices with no moving parts.

2.1.2.4 Scientific Justification

Surface EMG signals have been used for decades to control powered upper limb prosthetic limbs. Major limitations associated with using surface EMG signals are that they have difficulty in measuring from deep or small muscles and that they can be difficult to reliably incorporate into the assembly of a socket. Individuals with more proximal amputations (e.g., above the elbow or at the shoulder) have a more general limitation in that they lack muscle from which to measure EMG signals entirely, yet require additional degrees of freedom which need to be restored.

Our study addresses these limitations. First, an implant will be used to measure signals from within the body where we expect to reliably measure EMG signals that remain stable over time and will not change each time the patient dons their prosthesis. Second, individuals will receive targeted muscle reinnervation, an established surgical procedure which restores EMG signal information for proximal level amputees. The MyoNode System was developed over several years and is an enabling technology for this purpose.

Purdue's Center for Implantable Devices has been developing small, efficient, wirelessly powered implantable electronics for a wide variety of applications for many years. The MyoNode, created as part of the DARPA RE-NET program, is possible because of a new approach to wireless powering. Our method, termed Resonantly Coupled Filter Energy Transfer (RCFET) shows tremendous promise in addressing the critical issues of system miniaturization and performance tunability. In brief, since its inception, magnetic energy coupling has evolved from inductive powering to magnetic resonance coupling (MRC) using a 4 coil system analyzed via coupled mode theory to RCFET, which uses a 1+n coil system analyzed using a coupled resonator band pass filter approach for n implanted wirelessly powered devices. This evolution has resulted in the current system that is ready for implementation as active, miniaturized implantable or wearable medical devices.

Using this approach, we have already demonstrated full functionality in 8 devices with 5-10 mW average power consumption each, simultaneously powered by a single 500 mW source through up to 10 cm of tissue in prototype devices. Our designs have now been transferred to Cirtec Medical Systems, a company with extensive experience developing FDA approved Class 2 and Class 3 medical devices, to miniaturize the implants and to manufacture both implants and base stations for the Early Feasibility Study using good manufacturing practices (GMP).

2.1.3 Justification of Amount and Type of Information/Data to Support the EFS

Although it is an implant, given that the Myonode is a passive recording device (i.e., it has no stimulating function) comprised of tissue-contacting materials commonly used in chronic implants (zirconia case and Pt90/Ir10 electrodes), we believe that adequate information to justify its use in an early feasibility study can consist of a discussion of the composition of the tissue-contacting components of the implant and bench testing of the electronic functions of the implant in coordination with the external base-station. The proposed testing was presented to the FDA review team in a pre-IDE meeting on September 28, 2017 and is presented again in the Executive Summary herein.

2.2 Executive Summary

2.2.1 Summary Description of Non-Clinical Testing Performed and Relevant Clinical Information

Table 2-1 presents the non-clinical testing proposed and performed for the MyoNode system to support this early feasibility study.

Table 2-1. Non-clinical testing for the MyoNode system supporting the early feasibility study.

Component	Test	Status	Brief Procedure
MyoNode Implant	Baseline Noise Test	Complete	The implant shall be tested to measure the baseline noise level recorded by the MyoNode at expected operating temperatures. The amplifier output will be recorded and confirmed to meet the output specified in the component datasheets. This test will confirm that a low baseline signal will be measured when the subject is not contracting.
MyoNode Implant	Amplifier Gain Test	Complete	A millivolt level differential signal with frequency components chosen to represent frequency components within EMG signals shall be input to the MyoNode electrodes when the implant is at the expected operating temperature. The amplifier output will be recorded and confirmed to meet the signal level expected from the component datasheets. This will ensure that the signal is appropriately amplified and digitized.
MyoNode Implant	Common Mode Rejection Test	Complete	A millivolt level common signal with frequency components of 50 Hz and 60 Hz, rather than differential signal, shall be input to the MyoNode electrodes when the implant is at the expected operating temperature. The amplifier output will be recorded and confirmed to meet common-mode-rejection value from the component datasheets. This will ensure that any coupled noise from the power mains will be attenuated rather than amplified.
MyoNode Implant	Wireless power transfer test	Complete	The depth, location, and implant alignment of the MyoNode implant will be systematically varied within the expected detection volume and the fidelity of the power transfer link will be measured. This will be completed in a free space cavity, and in tissues with electromagnetic properties selected to match body tissues.
MyoNode Implant	Heat Generation Test	Complete	The heat generated by the implant shall be measured when the implant is operating within the detection volume in a medium selected to simulate body tissue to verify it meets performance specifications. ISO 14708-1:2014, Clause 17.1
MyoNode Implant	Hermetic Seal	Performed during manufacturing process	Hermeticity testing is performed during manufacturing. MIL-STD-883K_CHG-3
Implant/Base-Station	Data telemetry test	Complete	The quality of the data telemetry link will be tested to verify that packet throughput/loss meets specifications. This will be tested incrementally as up to 8 MyoNodes are added to the system.
Implant/Base-Station	Power Up Test	Complete	The implant shall be tested to ensure that the implant turns on within a specified time after the base-station power transmission link is established.
Implant/Base-Station	Specific Absorption Rate	Complete	Meets exclusion criteria per 447498 D01 General RF Exposure Guidance v06, 4.2.4, 4.3.1

Base-Station	Heat Generation test	Complete	The heat generated by the base-station and coil shall be tested and be found to meet performance specifications when it is attached to a prosthetic limb socket.
Base-Station	Communication Bus Testing	Complete	The Base-Station shall be tested to ensure that the reconstructed EMG signals conform to the CAN bus protocol specifications.

Component	Test	Brief Procedure
Implant/Base-Station	Electrical Safety	The implant shall undergo electrical testing per the ISO 14708-1:2014 Implants for surgery — Active Implantable Medical Devices — standard, Clause 16 with reference to the IEC 60601-1:2005 - Medical Electrical Equipment, Clause 8.7. Testing requirements will be outlined in an Electrical Safety Testing protocol. Deviations from the protocol will be justified and documented.
Implant/Base-Station	ESD	The implanted device and non-implant device will be tested as a system per the test referenced in the ISO 14708-1:2014 Implants for surgery — Active Implantable Medical Devices — standard, Clause 24.1 with reference to the IEC 60601-1:2005 - Medical Electrical Equipment, Clause 17. Testing requirements will be outlined in an Electrical Safety Testing protocol. Deviations from the protocol will be justified and documented.
Implant/Base-Station	Software	Software of the implant and base station shall be classified using Figure 3 of the IEC 62304:2006 & A1:2016 standard. All requirements associated with the assigned class will comply with this standard and be documented in the Software Development Plan.
Implant	Packaging (Aging & Transit)	IEC 60601-1:9.3, 14708-1:15.2 Finished implant assemblies will be packaged in Cirtec's platform packaging design which has already undergone and passed accelerated aging tests.

2.2.2 Device Evaluation Strategy for an Early Feasibility Study

Preliminary aspects of this device evaluation strategy were discussed with the FDA review team in a pre-sub (Q170872) meeting at White Oaks on September Sept. 28 2017. Table 2-2 describes potential failure modes and strategies to mitigate risks in the clinical study.

Table 2-2. Device Evaluation Strategy Table.

Device Attribute	Potential Failure Modes	Potential Effects of Failure		Knowledge Base			Nonclinical Device Testing	Clinical Study Mitigation Strategies
		Potential Device Effects of Failure	Potential Clinical Effects of Failure	Device Design Information	Supportive Information			
					Leveraged Nonclinical Information	Supportive Clinical Information		
MyoNode Implant								
Implant integrity	Corrosion of components	- Component separation - Device fracture - Loss of EMG recording function	- Loss of control of prosthesis	Use materials for ceramic case and recording electrodes that have been used in other approved implants	Reference literature using these materials in implants.	Reference clinical literature using these materials in implant.	No device-specific testing needed prior to initiation of the early feasibility study. Leveraging fact that these materials have been used in other approved implants.	For all events: - Timely reporting of failure to control prosthesis. Loss of control of prosthesis: - Remove/replace implant if possible. - Only remove implant. Return to standard of care for control. - Do nothing. Return to standard of care for control.
Implant Biocompatibility	Not biocompatible	No device effects	Adverse biological response	Relevant information considered in the design of the device: - Use of materials with histories of clinical use.	Reference literature using these materials in implants.	Reference clinical literature using these materials in implants.	No device-specific testing needed prior to initiation of the early feasibility study. Leveraging fact that these materials have been used in other approved implants.	For all events: - Timely reporting of adverse events. Not biocompatible: - Monitor subjects for inflammatory response during follow-up.
Baseline Noise	EMG signal lost in noise	Loss of EMG recording function	Loss of control of prosthesis	Re-evaluate circuit design.	n/a	n/a	Baseline Noise Test Test#: 1001327 Appendix A	- Remove/replace implant if possible. - Only remove implant. Return to standard of care for control.
Amplifier Gain	Inadequate gain	Loss of EMG recording function	Loss of control of prosthesis	Re-evaluate circuit design.	n/a	n/a	Amplifier Gain Test Test#: 1001328 Appendix B	- Remove/replace implant if possible. - Only remove implant. Return to standard of care for control.
Common Mode Rejection	Noise from the power mains is amplified.	Loss of EMG recording function	Loss of control of prosthesis	Re-evaluate circuit design.	Reference datasheets from amplifier component	n/a	Common Mode Rejection Test#:1001321 Appendix C	- Remove/replace implant if possible. - Only remove implant. Return to standard of care for control.

Device Attribute	Potential Failure Modes	Potential Effects of Failure		Knowledge Base			Nonclinical Device Testing	Clinical Study Mitigation Strategies
		Potential Device Effects of Failure	Potential Clinical Effects of Failure	Device Design Information	Leveraged Nonclinical Information	Supportive Clinical Information		
Wireless power transfer	Inadequate power for device function	Loss of EMG recording function	Loss of control of prosthesis	Re-evaluate circuit design.	n/a	n/a	Wireless power transfer test Test#: 1001326 Appendix D	- Remove implant. - Return to standard of care for control.
Heat Generation in Implant	Implant overheats	Loss of EMG recording function	Loss of control of prosthesis Local tissue damage	Re-evaluate circuit design.	Operating datasheets from electronics components used in implant	n/a	Implant Heat Generation Test Test#:1001323 Appendix E	- Remove implant. - Return to standard of care for control.
Hermetic Seal	Implant leaks	Loss of EMG recording function.	Loss of control of prosthesis	Reevaluate sealing materials.	n/a	n/a	Hermetic Seal Tested during manufacture MIL-STD-883K_CHG-3	- Remove/replace implant if possible. - Only remove implant. Return to standard of care for control.
Implant/Base Station								
Data telemetry	Inadequate quality of transferred data	Loss of EMG recording function.	Loss of control of prosthesis	Re-evaluate circuit design.	n/a	n/a	Data telemetry test Test#: 1001326 Appendix D	- Reduce update rate of the output decisions - Reduce sampling rate on implant
Power Up	Insufficient energy available to turn on base-station or implant	Lose of EMG recording function	Loss of prosthesis control	Re-evaluate circuit design.	Reference components from implant and base-station	n/a	Power Up Test Implant/Base Station Test#: 1001329/1001330 Appendix F	- Remove and replace implant - Remove and replace base-station
Specific Absorption Rate	Implant does not conform SAR guidelines	Improper programming	Exposure to higher than expected RF signals	Re-evaluate electronics firmware	Reference component datasheets	n/a	Specific Absorption Test#:1001325/1001326 Appendix D,H	- Remove and reprogram base-station - Return to stand of care control
Base-Station								
Heat Generation in base station	Loss of connection to base-station coil	Loss of implant powering function	Warming of base-station	Re-evaluate base-station/coil connection mechanism	n/a	n/a	Base Station Thermal Test Test#:1001331 Appendix G	- Replace base-station - Replace coil
Communication Bus	Broken connector wire	Loss of EMG communication to prosthesis controller	Loss of prosthesis function	Re-evaluate communication bus connectors	n/a	n/a	Communication Bus Testing Test#:1001325 Appendix H	- Replace communication bus wire

2.3 Detailed Reports

2.3.1 Individual Test Reports

The individual test reports are provided in appendices to this submission as shown in Table 2-3.:

Table 2-3. Location of test reports.

Test/Analysis	Test Report	
	Report #	Appendix #
Baseline Noise	1001327	A
Amplifier Gain	1001328	B
Common Mode Rejection	1001321	C
Wireless power transfer	1001326	D
Heat Generation in Implant	1001323	E
Data telemetry	1001326	D
Power Up	1001329/1001330	F
Specific Absorption Rate	1001325/1001326	G
Heat Generation in base station	1001331	H
Communication Bus	1001325	G

2.3.2 Summary of Leveraged Nonclinical Information

2.3.2.1 Biocompatibility Justification

Biocompatibility testing will not be performed on the MyoNode implant prior to the Early Feasibility Clinical study given that the zirconia (used for case), the platinum/iridium (used for electrodes) and the braze materials for bonding have been used in many current and legacy implant designs. A letter from the vendor is provided in Appendix I to support leveraging the biocompatibility of the brazing material. The following two review articles support the biocompatibility of zirconia and the platinum iridium electrodes, respectively:

H Harianawala, et al. Biocompatibility of Zirconia. Journal of Advanced Medical and Dental Sciences Research, 4(3), May - June 2016.

LA Geddes and R Roeder. Criteria for the Selection of Materials for Implanted Electrodes. Annals of Biomedical Engineering, 31, 879–890, 2003

2.3.2.2 Migration Justification

Migration was not evaluated in a specific study. However, literature describing similar implants suggests that migration will not be a significant issue.

AD Salter, et al. First Clinical Experience with BION Implants for Therapeutic Electrical Stimulation. Neuromodulation 7(1), 38–47, 2004.

MJ Kane, et all. BION microstimulators: A case study in the engineering of an electronic implantable medical device. Medical Engineering & Physics, 33, 7–16, 2011

2.3.3 *In vivo* Animal Studies

Animal studies are not required to mitigate risk for the MyoNode implant. As explained previously (section 2.3.2), the tissue contacting materials that comprise the MyoNode implant have all been used in long-term implants in devices that are currently approved by FDA. We believe this adequately demonstrates safety of the device/tissue interaction for an early feasibility study. Moreover, the device is passive; that is, it only records myoelectric signals, it does not have a stimulating function.

Other relevant testing, for example, determining the distance over which the MyoNode implant can be powered and can transmit signal can be reasonably tested on the bench without implantation in an animal.

2.3.4 Prior Clinical Information

This Early Feasibility IDE is a first-in-human study to establish proof-of-concept that the MyoNode implant can be adequately powered wirelessly to record and transmit an EMG signal through muscle/skin tissue to provide a signal(s) that can be properly interpreted to serve as control for an arm/hand prosthesis. No earlier clinical studies have been performed.

2.4 Compliance of Non-clinical Tests with GLP Regulations

All tests described in Section 2.2.2 were conducted by the Shirley Ryan Ability Lab not strictly in accordance with the GLP regulations, but were performed according to standard measurement practices. Raw data, samples, and photographs have been retained. The fact that these data were not collected under formal GLP protocols does not compromise the integrity of the measurements.

2.5 Clinical Experience

This early feasibility study represents the first use of the Implantable MyoNode EMG Recording System in humans. No clinical studies have been performed previously with this device.

2.6 Bibliography of All Publications (Adverse and Supportive) Relevant to the Safety and Effectiveness of the Device

This is the first use of the MyoNode in humans. Therefore, there are no known publications regarding clinical use of the MyoNode.

2.7 Copies of All Published and Unpublished Adverse Information on the Device

This is the first use of the MyoNode in humans. Therefore, there are no known publications regarding clinical use of the MyoNode.

3. Clinical Investigation Plan Overview

This section provides a summary of the clinical investigational plan. The clinical protocol is presented in section 3.2 and Appendix J (Appendix J will be provided separately to the investigators). Supporting documentation includes: the suggested Informed Consent form (Appendix K), the Case Report Forms content list (Appendix L), and the Investigator Agreement (Appendix M).

3.1 Risk Analysis and mitigation

3.1.1 Risks and Foreseeable Adverse Device Effects

3.1.1.1 Risks of the MyoNode Implantation Procedure

Potential risks associated with the MyoNode implant surgery include:

- Standard surgical risks resulting from the use of antibiotics, local anesthesia, regional anesthesia, conscious sedation, or general anesthesia, including severe allergic reaction, e.g. anaphylaxis
- Bleeding, bruising thromboembolism, or infection from insertion of an intravenous catheter.
- Tissue injury in the area of implantation such as hemorrhage, hematoma, vessel injury, nerve injury.
- Infection
- Chronic pain in the area of implantation
- Inflammation, discomfort or pain, swelling, redness, tenderness, skin irritation, or numbness/tingling in and around the implant site.
- Rejection of the implant
- Excessive scarring or fibrosis around implant. This could potentially pinch a nerve resulting in pain.
- Migration of the implant, which may require an additional surgery to remove or replace.

Device removal may necessitate using fluoroscopy or ultrasound to locate the device, then making a small incision and dissecting the overlying tissues to free the device from encapsulating tissue before lifting it from the body. Risks related to removal are similar to those listed above.

3.1.1.2 Risks Associated with Use of the MyoNode System

Potential risks associated with use of the MyoNodes implants include:

- Residual limb pain due to the presence of MyoNode devices.
- Newly occurring or changes in phantom limb pain.

- Swelling of the residual limb.
- Fatigue, muscle weakness, or muscle soreness in the residual limb.

Potential risks associated with use of the MyoNodes System include:

- Overuse or repetitive stress injuries in the non-amputated side.
- Unexpected opening or movement of the prosthetic wrist and/or hand resulting in injury to self or others (e.g. dropping a hot drink, releasing a handrail or crutch and falling)
- Closing the prosthetic hand with too much force or inability to open the prosthetic hand resulting in injury to self or other (e.g. pinching someone's hand, inability to release a moving object).
- Electric shock or burn

3.1.1.3 Risks Associated with EMG Studies

EMG studies are performed in routine clinical practice. However, they can be considered uncomfortable with some minor pain, tenderness, and/or bruising that may last for up to two weeks. Less likely but possible risks include:

- Infection due to the use of needle electrodes
- Excessive bleeding due to damage to tissue or blood vessels
- Swelling, redness, or other allergic reaction to the needles, wires.
- Injury to the nerves in your arm (which can cause long-lasting tingling, numbness, or pain)

3.1.2 Methods to Minimize Risks

3.1.2.1 Minimizing Risks Associated with Surgical Implant of the MyoNode Device

To minimize risk, surgical implant of the MyoNode will be performed by a board-certified hand, or orthopedic surgeon. The complexity of performing the MyoNode surgery is similar to performing targeted muscle reinnervation. Several members of the study surgical staff have significant experience carrying out TMR surgeries for transhumeral amputees.

3.1.2.2 Minimizing Risks Associated with Use of MyoNodes

Many of the risk associated with using the MyoNode system are also risks of using a prosthesis prescribed as current standard of care, such as unintentional movements of the device, and overuse of the non-amputated side. Biostability and MyoNode functionality risks are minimized by utilizing extensive laboratory bench and chronic pre-clinical testing of the MyoNodes. To

help assure the performance and safety of the prosthetic set-up, regular follow-ups for adverse events, device assessment, and optimization of the system will be specified in the protocol, as well as regular and close monitoring of the subject status.

Risks associated with subject tasks related to daily living with the prosthetic system are minimized by training subjects on the system use, and warning associated with implanted devices, including medical procedure precautions (e.g. diathermy and MRI restrictions). Subjects will receive training detailing these warnings and precautions. In addition, all implanted study subjects are provided with an information card that identifies the subject as having an implanted medical device and includes medical (Investigator) contact information for emergencies. All study subjects are instructed to carry their information card with them at all times

Implantation of MyoNode(s) will not preclude future use of the standard (surface EMG) method of operating a myoelectric prosthesis. Should a study subject's medical condition require implantation of another electrical device or other mode of treatment, the prosthetic can be abandoned; and, if necessary, the implants can be surgically removed. The potential risks in device revision/removal are similar to implant including, but not limited to, additional exposure to anesthesia, infection from a re-operation, and damage to surrounding tissues. These risks are minimized by the use of trained surgeons and proper surgical procedures.

3.2 Clinical Protocol

3.2.1 Purpose

The purpose of this feasibility study is to determine changes in functional independence for individuals with transhumeral amputation who have had Targeted Muscle Reinnervation and are using implantable MyoNodes to record intramuscular EMG signals to control their motorized prosthesis. We intend to use this early feasibility study to collect data to help design a future pivotal clinical study to test our hypothesis that chronic EMG measuring implants located within reinnervated muscle will provide stable EMG recordings that will allow intuitive, simultaneous control of 3 degree of freedom (DOF) prostheses.

3.3 Device Description/Indications for Use

The MyoNode Wireless Implantable EMG Recording System is intended to measure intramuscular EMG signals in the microvolt range and transmit the signals to a base-station for the purpose of controlling motorized arm/hand prostheses. The target patient population of this specific application is transhumeral amputees who have had Targeted Muscle Reinnervation (TMR) Surgery, with a long enough residual limb to adequately fit a prosthesis, and adequate residual muscle within which to implant the MyoNodes.

3.4 Patient Population

Patients will be screened to ensure that all inclusion criteria and no exclusion criteria are met. Prior to study-related baseline assessments and participation in the study, patients will be required to review and sign an informed consent document.

3.4.1 Inclusion/Exclusion Criteria

Inclusion Criteria:

- ☐ Unilateral trans-humeral amputation with residual limb length >50% of the contralateral side
- ☐ Patient has undergone successful TMR surgery
- ☐ Prior successful training and fitting with a myoelectric prosthesis

Exclusion Criteria:

- ☐ Age <18 or >70 years old
- ☐ Metal or shrapnel within the residual limb
- ☐ Evidence of infection or open wounds within residual limb
- ☐ Significant residual limb pain, prohibiting participation from prosthetic fitting/training
- ☐ Bleeding disorder or other potential risk for surgery
- ☐ Patients with active implants (e.g. pacemaker)
- ☐ Pregnant women
- ☐ Cognitive deficits or visual impairment that would impair their ability to give informed consent or to follow simple instructions during the experiments

3.5 Study Design

This is a prospective, single-center, single-arm feasibility study intended to enroll up to three (3) patients.

3.6 Study Endpoints

Primary Endpoint: Assess the accuracy with which transhumeral amputees can control both isolated and simultaneous movements of a three DOF myoelectric prosthesis utilizing the MyoNode system after successful TMR surgery.

Secondary Endpoint: Determine the ability of transhumeral amputees to successfully perform functional activities using a three DOF myoelectric prosthesis controlled by the MyoNode system. Collect data to support the design of a subsequent pivotal study to test the hypothesis that the MyoNode implant system improves control of the prosthesis, subsequently improving performance on functional activities.

Outcome measures that assess this performance directly include:

- 1) a modified box and blocks test, (Appendix O)
- 2) the Jebsen Test of Hand Function, (Appendix P)
- 3) the Assessment of Capacity for Myoelectric Control (Appendix Q), and
- 4) the Southampton Hand Assessment Procedure (Appendix R)

Outcome measures that measure this performance indirectly include:

- 5) electronically logged data from the prosthesis from the prior six months and
- 6) subject questionnaires (the Orthotic Prosthetic User Survey-Upper Extremity Functional [OPUS-UEFS] Status Survey) (Appendix T)

These measures will be assessed during the screening period prior to the MyoNode implant procedure (controls) then on a monthly basis following recovery from the implant procedure. The entire follow-up period will be 6 months.

3.7 MyoNode Implant Procedure

The intervention comprises surgical insertion of electromyographic (EMG) sensors (MyoNodes) into residual muscles to obtain recordings of intramuscular (IM) EMG for improved control of myoelectric prostheses. The muscles chosen for MyoNode insertion will depend on the needs and residual anatomy of each subject; muscles must be under volitional control and generate sufficient EMG signals. Surgery will be performed as an outpatient procedure, typically requiring one session. Although, additional surgeries may be required to remove non-functional devices and/or to insert additional devices if MyoNodes become non-functional after insertion. MyoNodes will be left in place indefinitely, unless the subject desires their removal.

Following surgery, subjects will be trained to control their prosthesis using EMG from MyoNodes. The prosthesis will be a commercially available model.

The prosthesis will be operated as a typical myoelectric device; the only difference will be that EMG signals are recorded intramuscularly, and not from the skin surface. The risks of using this device are the same as for using any myoelectric prosthesis.

3.8 Data Collection and Follow-up Schedule

Upon receiving their custom-fit definitive prosthesis, subjects will undergo monthly assessments to track their progress with the MyoNode system. Subjects will take the prosthesis home and be encouraged to use it in their daily activities, according to the recommendations of their clinicians, during and after training. Assessments will be conducted on a monthly basis to evaluate functional ability. Subjects' opinion of the MyoNode system will be assessed by questionnaire after the 6-month study period. Subjects will be given the choice of returning for additional annual functional assessments during the course of the study. No restriction on medications or activities will be placed on subjects during the study period, providing inclusion/exclusion criteria are met and the activity is safe and appropriate to perform using a myoelectric prosthesis. Table 3-1 presents the data collection and follow-up schedule.

Table 3-1. Data collection and follow-up schedule

Data Collected / Tests Performed	<i>PreImplant</i>	<i>Implant</i>	Post-Implant Follow-Up Visits					
			<i>1-Month</i>	<i>2-Month</i>	<i>3-Month</i>	<i>4-Month</i>	<i>5-Month</i>	<i>6-Month</i>
Demographics	X							
Medical History	X							
Implant Procedure		X						
Box and Blocks Test	X		X	X	X	X	X	X
Jebsen Test of Hand Function	X		X	X	X	X	X	X
Assessment of Capacity for Myoelectric Control	X		X	X	X	X	X	X
Southampton Hand Assessment Procedure	X		X	X	X	X	X	X
Subject Questionnaire								X
Adverse Events		X	X	X	X	X	X	X

4. Manufacturing Information

The manufacturing processes for the implant and the base station are presented as flowcharts in Figure 4-1 and Figure 4-2, respectively. The devices for the clinical trial will be manufactured by Cirtec in accordance with Quality System Regulations.

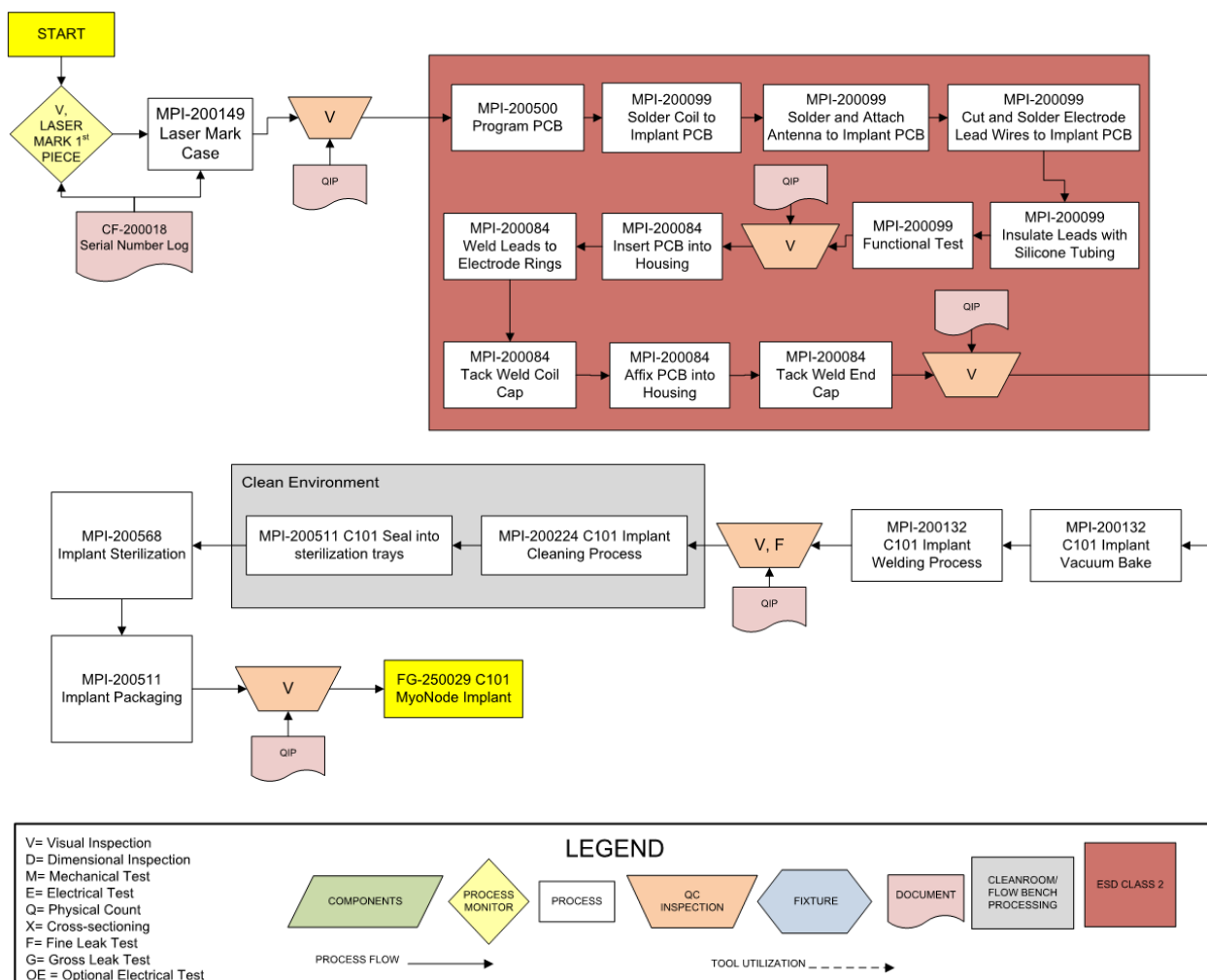


Figure 4-1. Flow diagram describing the MyoNode implant manufacturing plan

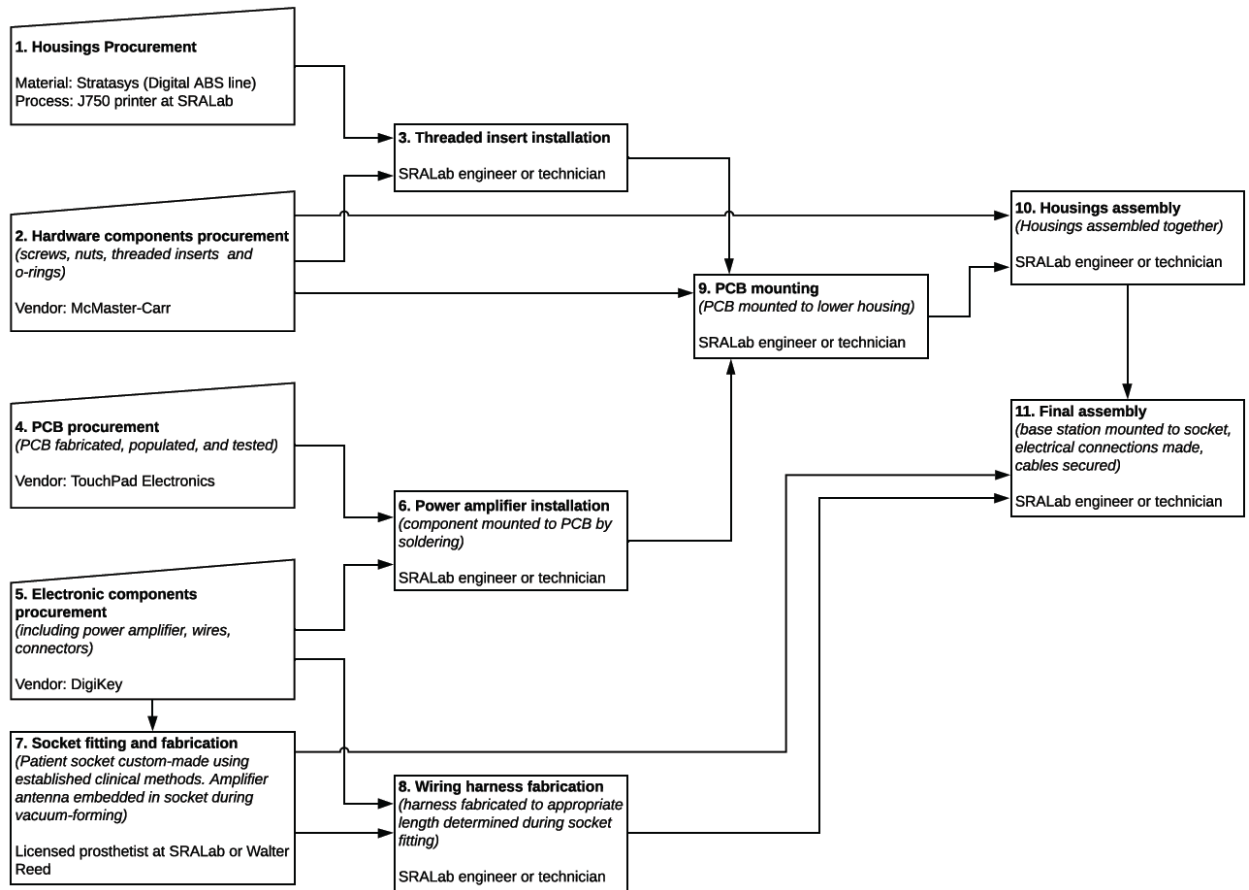


Figure 4-2. Flow diagram describing the base station manufacturing plan.

5. Investigator Information

5.1. Investigator Agreements

An example of the investigator agreement is provided in Appendix M

5.2. Certification that Participating Investigators have Signed Investigator Agreements

Participating investigators will sign the investigator agreements and no investigator will be added until the agreement is signed in accordance with 21 CFR 812.29(b)(5).

5.3. Name and Address of Investigators

Principal Investigator:

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Residency Director, Physical Medicine & Rehabilitation
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6. IRB Information

Walter Reed National Military Medical Center Institutional Review Board
Department of Research Programs, Building 17
Walter Reed National Military Medical Center
Bethesda, MD 20814

IRB CHAIRPERSON: Anmarie Widener

7. Other Institutions

This early feasibility study will be conducted only at Walter Reed National Military Medical Center, Bethesda, MD 20814.

8. Sales Information

The amount charged for the device will not exceed the cost of manufacturing, research, and development in accordance with 21 CFR 812.7(b).

9. Environmental Impact Assessment

Claim for Categorical Exclusion:

The action requested qualifies for a categorical exclusion under 21 CFR 25.34(d). To the best of the applicant's knowledge, no extraordinary circumstances exist.

10. Labeling

A draft of the product label is provided in Appendix N.

11. Informed Consent Materials

A draft Informed Consent form is provided in Appendix K.

12. Other Relevant Information Requested by FDA

Other information relevant to the review of this application will be made available by the sponsor upon request by FDA.

13. References

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APPENDIX A

Baseline Noise Test
Test#: 1001327

Document: 1001327	C101: Baseline Noise Test	ECN: TBD
Revision: 1		Effective: See Master Control

1. Purpose

This document is intended to outline the procedure and methods for determining the baseline noise test of the C101 MyoNode Implant electronics.

2. Scope

This procedure applies to the MyoNode system for the C101 project, at Cirtec Medical (Enfield).

3. Background

The MyoNode Implant is responsible for measuring EMG signals. EMG signals are millivolt level signals amplified using a differential amplifier. Baseline noise of the entire system may be measured when muscles are not contracting (e.g., a person is relaxing). For the MyoNode application, the baseline noise level should be less than a millivolt, which is an order of magnitude less than the expected EMG signals. The equipment and test procedure is the same as for the C101: Signal to Noise Ratio test.

4. Equipment

Description	Equipment Number
MyoNode Implant SN-16	IM_16
MyoNode Powering Socket SN01	PS_01
MyoNode Base Station SN04	BS_04
Aim TTi CPX400D Power Supply	CPX400D
CAPS Computer Software	CAPS_DEV
CANBusUtility Software	CAN_BUS_UTIL

5. Reference Documents

Type	Description	Document Number
JIRA	Raw Test notes, test data	#MYONODE-81

6. Testing Summary

The summary test results are shown in the following table. We found the baseline noise value to be approximately 85 microvolts (uV).

High-Pass Filter Value	Baseline Noise
No HPF	85 uV

7. Testing Procedure

Electrode leads were soldered to inputs of the IM_16 MyoNode input amplifier via two short lead wires that had electrode snaps on the other end. Adhesive Ag/AgCl electrodes were placed on the person's forearm and placed within the powering coil on MyoNode Powering Socket PS_01 to couple power onto IM_16 MyoNode Implant. The person was instructed to rest for a period of time while data were recorded. These data were then digitized onto the communication bus and sent to a computer for viewing and recording using Control Algorithms for Prosthetics (CAPS_DEV) and the data logger (DATA_LOG_GUI). To compute the baseline noise value, the system gain was set to 3.9.

To calculate the baseline noise, the signals digitized by the 14-bit on-board digital to analog converter were examined. The total range of expected measurement is 1.8 V, thus each quantization level corresponds to:

$$Q_L = \frac{1.8V}{2^{14} - 1} \sim 110 \mu V$$

From this quantization level, the raw value of the baseline noise signal can be computed by multiplying the observed quantization level in the raw data (3 bits peak to peak) and dividing by the system gain.

$$N_{BL} = 3 \times \frac{Q_L}{3.9} = 85 \mu V$$

Our recording data show three bits peak-to-peak of quantization levels while the user is resting, which corresponds to a baseline noise level of 85 μV .

8. Conclusions

The MyoNode Implant measures low baseline noise values which are suitable for our myoelectric control approach. When interpreted with the SNR tests (Document 1001324, *C101: Signal to Noise Ratio Test Report*), we expect that the equipment will be able to allow for discrimination between rest and movement periods by identifying muscle contractions.

9. Appendix:

Test description, raw notes, photographs, and raw data are available in JIRA #MYONODE-81.

APPENDIX B

Implant Gain Testing
Test#: 1001328

Document: 1001328	C101: Implant Gain Testing	ECN: TBD
Revision: 1		Effective: See Master Control

1. Purpose

This document is intended to outline the procedure and methods for determining the amplifier gain performance on the MyoNode Implant.

2. Scope

This procedure applies to the MyoNode system for the C101 project, at Cirtec Medical (Enfield).

3. Background

The MyoNode implant has an analog front end with the capability to set the amplifier gain using a digital potentiometer. This is controllable using an I2C bus. The ability to change gains digitally will provide flexibility in detecting EMG signals of various amplitudes. The gain-bandwidth curve will be characterized for a number of gain settings.

4. Equipment

Description	Equipment Number
Agilent MSO-X 3014A Oscilloscope/Signal Generator	MSOX3014A
Mini-Circuits HAT-20+ 20dB Attenuator	AT-20DB
MyoNode Implant Development Board SN-01	IM_DEV_01
Aim TTi CPX400D Power Supply	CPX400D

5. Reference Documents

Type	Description	Document Number
JIRA	Raw Test notes, test data	#MYONODE-64

6. Testing Summary

Testing indicated that the digital pot could be varied using I2C commands. Tested settings included 10 K Ω , 50 K Ω and 100 k Ω , which provided gains of 99, 420, and 720. The 3 dB frequency bandwidths are 90 – 1100 Hz, 70 – 579 Hz, and 60 – 390 Hz respectively. These tests demonstrate the MyoNode implant is capable of providing selectable gain using the I2C bus.

7. Testing Procedure

The MyoNode Implant Development Board IM_DEV_01 was used to complete this test. MSOX3014A was used to generate a 1mVpp sinusoidal wave (MSOX3014A was set to output 100mVpp, then attenuated by 2 of Mini-Circuits HAT-20+ 20dB attenuators). The MyoNode Implant Development Board IM_DEV_01 was programmed to change the value of the onboard digital potentiometer using commands sent on the I2C bus. Three resistance values were selected for this test: 10KOhm, 50KOhm and 100KOhm. After each time the gain was changed, a

frequency sweep was performed to determine the gain and the 3 dB frequency bandwidth at the respective setting.

8. Conclusions

The MyoNode Implants were able to successfully change operating gains digitally which will provide for flexible input ranges of detected EMG signals.

9. Appendix:

Test description, raw notes, photographs, and raw data are available in JIRA #MYONODE-64.

APPENDIX C

Implant Common-Mode Rejection Ratio (CMRR) test Test#: 1001321

Document: 1001321	C101: Implant Common-Mode Rejection Ratio (CMRR) test	ECN: TBD
Revision: 1		Effective: See Master Control

1. Purpose

This document is intended to outline the procedure and methods for determining the common-mode rejection ratio, which informs the amount of common signal that will be attenuated by the C101 MyoNode Implant electronics.

2. Scope

This procedure applies to the MyoNode system for the C101 project, at Cirtec Medical (Enfield).

3. Background

The MyoNode Implant is responsible for measuring EMG signals. EMG signals are millivolt level signals that are amplified using a differential amplifier. The differential amplifier should amplify the differential signal and attenuate any common-mode signal. Inside the body, there are no significant sources of common-mode signals expected, whereas on the surface of the body there are large amounts of common-mode signal caused by the electrical mains (e.g., 50 Hz, or 60 Hz signals coupled capacitively onto the body). Common-mode rejection ratio (CMRR) is a measurement used to quantify the amount of common-mode suppressed by the amplifier. It is defined as the ratio of the differential gain over the common-mode gain, measured in decibels.

$$CMRR = 20\log_{10}\left(\frac{A_d}{A_{cm}}\right)$$

Differential gain is easily accessible and selectable; however, common-mode gain is more difficult to access and must be measured. The acceptance criteria for this test is a CMRR of at least 20dB, which would reduce any residual common mode signals by at least an order of magnitude.

4. Equipment

Description	Equipment Number
MyoNode Implant Development Board SN-02	IM_DEV_02
Aim TTi CPX400D Power Supply	CPX400D
Agilent MSOX3014A Function Generator / Scope	MSOX3014A

5. Reference Documents

Type	Description	Document Number
JIRA	Raw Test notes, test data	#MYONODE-82

6. Testing Summary

The summary test results are shown in the following table. A better CMRR was found for higher gain values. The MyoNode Implant will be programmed with a gain in the midrange of the possible gain values.

Common Mode Frequency	Differential Gain	Measured CMRR (DB)
50 Hz	3.9	36.2
60 Hz	3.9	35.3
50 Hz	498	61.4
60 Hz	498	58.8
50 Hz	1000	64.5
60 Hz	1000	61.2

7. Testing Procedure

IM_DEV_02 was powered using the CPX400D set to 3.3V with a maximum current limit of 100 mA. To test the common-mode rejection, the leads of the amplifier were shorted together, and a common signal was input from a function generator (MSOX3014A) onto the shorted leads. The gain of IM_DEV_02 was set to 3.9, 498, and 1000, which were values that span the range of available input gains. The amplifier output was connected to the same oscilloscope (MSOX3014A) and the value was measured. Small amplitude 50 Hz and 60 Hz sinusoids were generated and the amplitude of the input signal was increased. To ensure a conservative estimate of CMRR, we used the maximum common-mode voltage that could be input to the amplifier while it provided a stable output.

8. Conclusions

The MyoNode Implant provides adequate common-mode rejection. Unlike surface signals, any common signals experienced at the amplifier inputs are expected to be extremely small. When considered in concert with the signal to noise value tests (see Document 1001324, *C101: Signal to Noise Test*), the MyoNode is expected to measure representative EMG signals from inside of the body.

9. Appendix:

Test description, raw notes, photographs, and raw data are available in JIRA #MYONODE-82.

APPENDIX D

Wireless Power Transfer and Data Telemetry Testing Test#: 1001326

Document: 1001326	C101: Wireless Power Transfer and Data Telemetry Testing	ECN: TBD
Revision: 1		Effective: See Master Control

1. Purpose

This document is intended to outline the procedure and methods for determining the wireless power transfer and data telemetry capabilities of the MyoNode system.

2. Scope

This procedure applies to the MyoNode system for the C101 project, at Cirtec Medical (Enfield).

3. Background

The MyoNode system is a wireless system. Magnetic resonance coupling is used to transfer wireless power, and conventional 2.4 GHz communication channels are used to telemeter data between the implants and the Base Station. Depth and orientation of the implant with respect to the powering coil are key parameters that need to be evaluated to determine the quality of the wireless performance. Additionally, the medium through which the power and data are transmitted need to be considered. For all tests, we limited radiated power from the Base Station to be less than 1 Watt (W) and radio telemetry power from the implant to be less than 1 milliwatt (mW) so that the specific absorption test exclusion may be applied according to 447498 D01 General RF Exposure Guidance v06, 4.2.4, 4.3.1. For efficiency, testing wireless power and data telemetry were tested at the same.

4. Equipment

Description	Equipment Number
MyoNode Implants SN-04, SN-05, SN-13, SN-14, SN-15, SN-17, SN-18, SN20	IM_XX
MyoNode Powering Socket SN-01, SN-03	PS_01, PS_03
MyoNode Legacy Base Station SN-02	BS_02_LEGACY
2 Cell Lithium-ion Battery	BATT
Base Station Development Board SN-01, SN-02, SN-03, SN-04, SN-05, SN-06, SN-07, SN-08	BD_XX
Implant Holding Rig	IH
Dynamometer Holding Rig	DYNO
Agilent MSO-X 3014A Function Generator / Scope	MSO
Fluke 87 Digital Multimeter	FLUKE_87
Fluke 289 Digital Multimeter	FLUKE_289
Aim TTi CPX400D Power Supply	CPX400D
CAPS Computer Software	CAPS_DEV

PuTTY Serial Terminal (one per Base Station development board)	PUTTY_XX
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5. Reference Documents

Type	Description	Document Number
JIRA	Raw Test notes, test data	#MYONODE-57, #MYONODE-64

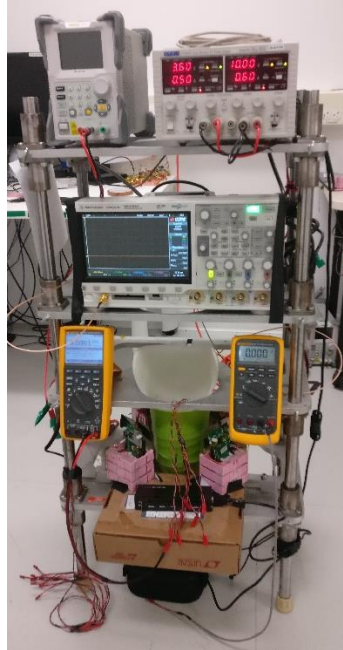
6. Testing Summary

The MyoNode system was able to couple a sufficient amount of energy to simultaneously power up to 8 MyoNode Implants in either an empty cavity (e.g. free space) or in a socket filled with simulated tissue (e.g. beef plus turkey leg bone, or beef plus stainless steel rod) with misalignments of up to 30 degrees from the ideal alignment (perpendicular to the outside of the MyoNode Powering Socket PS_01) regardless of depth as long as the implants were within the regions spanned by the powering coil. Use of simulated tissue did reduce coupling, but a sufficient amount of energy allowed for all implants to remain powered on. Use of stainless steel to simulate a humerus, rather than using bone, also provided an even further reduction, but the implants still remained on. These measurements were confirmed by taking measurements from the Fluke digital multimeters (FLUKE_87 and FLUKE_289) and on the MSO oscilloscope. When an implant was moved longitudinally outside of the region that was spanned by the coil, the coupled energy was insufficient to power on the implant.

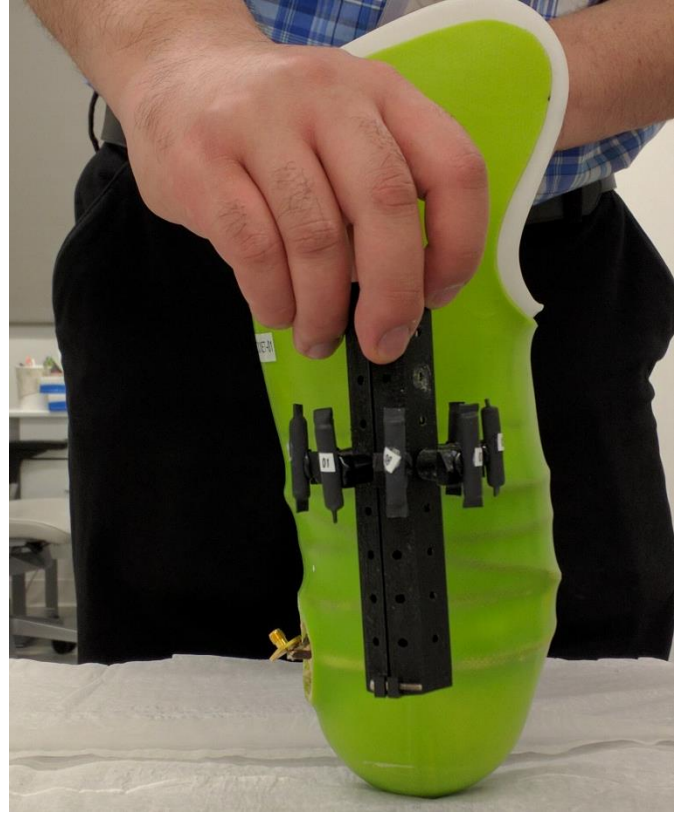
While the individual implants remained consistently powered while residing in the field, the receivers on the Base Station development boards (BD_##) periodically lost connection. Investigation into this issue revealed that this was related to the firmware on the Base Stations and this was resolved satisfactorily prior to performing the full system testing.

7. Testing Procedure

All testing equipment was assembled around a custom-made dynamometer rig (DYNO). Power supplies (CPX400D) and measurement equipment (MSO, FLUKE_87, FLUKE_289) were positioned near and above the MyoNode powering socket (PS_01) to provide power and to facilitate readings and data capture. The MyoNode powering socket (PS_01) itself was positioned in the center of the base of the DYNO with the Base Station Development boards (BD_XX) positioned radially around the powering socket (PS_01). Additionally, each Base Station development board (BD_XX) was connected to serially using PuTTY (PUTTY_XX) to monitor power levels and communication issues. A 2-Cell Lithium-ion battery was used to power a Legacy MyoNode Base Station, BS_02_LEGACY, which energizes the powering socket (PS_01).



The 8 implants were attached to an implant holding IH device. This device was custom fabricated such that implants could be attached to span the depths and orientations (up to ± 30 degrees off-axis) that would be expected for the MyoNode application. Next, the implant holder was inserted into the socket and a measurement of the energy coupled to each implant and the quality of the communication link was recorded from the PUTTY_XX traffic. The implant holder IH was removed, the positioning of the implants systematically changed, and new recordings were taken. Tests were run for 10 minutes and were initiated and halted using the CAPS Computer Software (CAPS_DEV). The entire procedure was completed three times: (1) in open air, (2) when the socket was filled with beef plus a bone, and (2) when the socket was filled with beef surrounding a stainless steel rod.



8. Conclusions

The MyoNode implants were able couple sufficient energy to turn on as long as they were placed within the region that was surrounded by the powering coil (neither BLE communication nor induced power were significantly impacted by orientation in the field). If an implant was placed more than 1-2 centimeters outside of this region, then it would periodically lose power. During all tests, the radiated power by the external coil was limited to 1 watt, and the telemetering power was limited to 1 milliwatt.

9. Appendix:

Test description, raw notes, photographs, and raw data are available in JIRA #MYONODE-57 and #MYONODE-64.

APPENDIX E

Implant Heat Generation Test Test#: 1001323

Document: 1001323	C101: Implant Thermal Testing	ECN: TBD
Revision: 1		Effective: See Master Control

1. Purpose

This document is intended to outline the procedure and methods for determining the heating caused by C101 MyoNode Implant electronics.

2. Scope

This procedure applies to the MyoNode system for the C101 project, at Cirtec Medical (Enfield).

3. Background

The MyoNode Implant is comprised of RF powered electronics system placed inside a ceramic capsule. It is important that the implant not cause significant tissue heating. While the device is not a stimulator, FDA draft guidance suggests that any heating be ≤ 2 degrees Celsius.

4. Equipment

Description	Equipment Number
MyoNode Implant SN-04	IM_04
MyoNode Powering Socket SN-03	PS_03
MyoNode Base Station SN-04	BS_04
Fluke 87 Multimeter with thermocouple	FLUKE_87
Fluke 289 Multimeter with thermocouple	FLUKE_289
Hot Plate Four E's Scientific MI0102003	PLATE

5. Reference Documents

Type	Description	Document Number
JIRA	Raw Test notes, test data	#MYONODE-83
FDA Draft Guidance	Implants for surgery - 780 Active implantable medical devices - Part 3: Implantable neurostimulators	ISO 14708-3
FDA Draft Guidance	Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations	FDA-2014-N-1130

6. Testing Summary

Testing indicated that when the implant case was measured in a liquid medium with a volume reasonably approximating a trans humeral residual limb, a temperature differential of approximately 0.5 degrees Celsius was observed. This is well below the guidance document of 2 degrees Celsius. An additional test was performed in an air chamber with no air circulation.

Test Medium	Temperature Increase (Degrees Celsius)
Distilled water, 150mL	0.5

7. Testing Procedure

Implant IM_04 was sealed to prevent water from entering the capsule. A volume (150mL) of water was heated to approximately 42.5 degrees Celsius and placed inside a heat chamber, consisting of a hotplate, and a chamber covering the hotplate surface. The implant IM_04 was placed within the water, and the volume of water was elevated from the surface of hotplate to position the implant approximately to the center of the socket coil for wireless power. Hotplate temperature was set to 60 degrees Celsius to keep the steady state temperature of the water as close to 37.8 degrees Celsius as possible. FLUKE_289 was placed on the implant case to monitor the temperature. FLUKE_87 was inserted into the water to monitor water temperature. The MyoNode Powering Socket PS_03 was placed around the chamber and the system, and the socket was excited with MyoNode Base Station BS_04, which was allowed to operate for approximately 2 hours. During this time, the temperature was continually monitored. The temperature measured from the implant gradually dropped from 42.5 degrees to 38.3 degrees Celsius indicating that IM_04 was not generating a significant amount of heat.

8. Conclusions

The MyoNode Implant does not cause excessive tissue heating during normal operation.

9. Appendix:

Test description, raw notes, photographs, and raw data are available in JIRA #MYONODE-83.

APPENDIX F

Power On Testing
Test#: 1001329

Document: TBD	C101: Implant Power On Testing	ECN: TBD
Revision: 1		Effective: See Master Control

1. Purpose

This document is intended to outline the procedure and methods for determining the capability of the MyoNode Implant to power on when receiving energy.

2. Scope

This procedure applies to the MyoNode system for the C101 project, at Cirtec Medical (Enfield).

3. Background

The MyoNode Implant is comprised of electronics, including a capacitor to store a limited amount of energy which will smooth momentary disruptions in coupled energy. This powering system needs to be characterized to determine the amount of time required to charge and discharge the capacitor when considering the expected loads required by the electronics system. This will ensure that the implant powers up in a timely manner, and will provide insight into the length of power disruptions that may be tolerated by the circuit.

4. Equipment

Description	Equipment Number
Agilent MSO-X 3014 Oscilloscope	MSOX3014A
MyoNode Implant SN-07	IM_07
Fluke 87 Multimeter	FLUKE_87
MyoNode Legacy Base Station SN-02	BS_02_LEGACY
MyoNode Powering Socket SN-01	PS_01
Aim TTi CPX400D power supply	CPX400D

5. Reference Documents

Type	Description	Document Number
JIRA	Raw Test notes, test data	#MYONODE-54, #MYONODE-56

6. Testing Summary

Testing indicated that a voltage rise-time between 21.5 – 86 ms, depending on the load (and current) requirements. The range of current requirements was varied between 0 and 8.5 mA. The upper end of this range is far larger than would be expected for normal operation of a MyoNode Implant. These range of rise-times will not contribute a significant delay to the system powering on.

7. Testing Procedure

CPX400D was used to supply power(7.4V) to legacy MyoNode Base Station, BS_02_Legacy, whose sole purpose was to energize Powering Socket PS_01. The MyoNode Implant IM_07 was used to complete this test. On the power conditioning circuit there is a 100 microfarad (uF) capacitor which is intended to smooth and store the power delivered to the MyoNode Implant. A test circuit was created such that the 2.3V voltage rail (which drew power from the 100 uF capacitor) would be subjected to various loads. The FLUKE_87 was used to measure the voltage at the 100uF capacitor and an MSOX3014A oscilloscope was used to measure voltage rise time. Measurements were taken with no-load (0 mA), a 270 Ω resistor (8.52 mA), and a 330 Ω resistor (6.97 ma).

8. Conclusions

The MyoNode Implants power on between 21.5 – 86 ms. These values are very responsive and would not contribute to any operational delays.

9. Appendix:

Test description, raw notes, photographs, and raw data are available in JIRA #MYONODE-54, #MYONODE-56.

Document: 1001330	C101: Base Station Power On Testing	ECN: TBD
Revision: 1		Effective: See Master Control

1. Purpose

This document is intended to outline the procedure and methods for determining the ability of the MyoNode Base Station to operate properly when voltages in the range of the prosthetics industry are used to power the device (7.4V – 14.8V).

2. Scope

This procedure applies to the MyoNode system for the C101 project, at Cirtec Medical (Enfield).

3. Background

The MyoNode Base Station should be able to operate using a range of voltages commonly used in the prosthetics and orthotics industry. These range from approximately 7.4 V to 14.8 V. To demonstrate proper operation a test was performed to ensure that the Base Station operates properly in this range.

4. Equipment

Description	Equipment Number
Agilent MSOX3014A Function Generator / Scope	MSOX3014A
MyoNode Base Station SN-01	BS_01
Fluke 289 Multimeter	FLUKE 289
Fluke 87 Multimeter	FLUKE 87
Aim TTi CPX400D Power Supply	CPX400D

5. Reference Documents

Type	Description	Document Number
JIRA	Raw Test notes, test data	#MYONODE-72

6. Testing Summary

Testing indicated that the MyoNode Base Station operated properly as a range of voltages between 6 – 16 V were swept using a power supply. These ranges encompass the ranges expected.

7. Testing Procedure

These tests were conducted upon receiving an order of MyoNode Base Stations. During the bring-up procedure, voltage ranges between 6 – 16 V were swept. During this sweep, all voltage rails (10V, 5V and 3.3V) on the MyoNode Base Station BS_01 were monitored, and all remained at their designed value.

8. Conclusions

The MyoNode Base Station operated properly for voltages within the range of 7.4 – 14.8 Volts, and outside of those ranges, as expected from the design.

9. Appendix:

Test description, raw notes, photographs, and raw data are available in JIRA #MYONODE-72.

APPENDIX G

Base Station Thermal Testing
Test#: 1001331

Document: TBD	C101: Base Station Thermal Testing	ECN: TBD
Revision: 1		Effective: See Master Control

1. Purpose

This document is intended to outline the procedure and methods for determining the heating caused by C101 MyoNode Base Station electronics.

2. Scope

This procedure applies to the MyoNode system for the C101 project, at Cirtec Medical (Enfield).

3. Background

The MyoNode Base Station is comprised of electronics that transmit wireless power to and receive telemetered data from MyoNode Implants. It is intended to be incorporated into the prosthesis assembly by a prosthetist. The maximum allowable temperature for medical equipment parts that are likely to be touched is 48°C (EN60601-1:2006 ME Equipment Parts That Are Likely To Be Touched). Prior testing with non-functional prototypes (TD-200995) suggest revising the original product specification to be in accordance with EN60601-1:2006. Consequently, this test was performed with a functional Base Station and with revised criteria (temperature less than 48°C).

4. Equipment

Description	Equipment Number
RIGOL DP711 Power Supply	RIGOL
MyoNode Base Station SN-02	BS_02
Fluke 289 Multimeter with thermocouple	FLUKE_289

5. Reference Documents

Type	Description	Document Number
JIRA	Raw Test notes, test data	#MYONODE-83
Standard	Medical Electrical Equipment – Part 1 General requirements for basic safety and essential performance	EN60601-1:2006

6. Testing Summary

Testing indicated that the hottest part of the Base Station reached a temperature of 46.2 °C, which is below 48°C. Additionally, this test was performed while the power amplifier was in a ‘disconnected’ state (representing the worst case thermal characteristic for this system). Normal operation generates approximately 90% of the heat (see TD-200995), which thermal models indicate would generate a surface temperature of approximately 41.5 °C, well below the target.

7. Testing Procedure

The Base Station SN-02 was powered using the RIGOL power supply at 8 V. Prior testing had indicated that the worst case thermal performance occurred when the power amplifier on the Base Station was not delivering power through the power coupling coil, but was in a ‘fault’ state corresponding to an open-circuit. While, this is unlikely to happen under normal operating scenerios, and if it did the system would be unresponsive and the users would likely power off the device, we performed the thermal testing under this worst-case scenario. The entire system was placed in a room with an ambient temperature of ~25°C. The system was turned on and allowed to run until the temperature of the Base Station achieved steady-state, 3 hours. Temperature readings were monitored and recorded using the FLUKE_289 with a thermocouple.

8. Conclusions

The MyoNode Base Station surface temperature remains below 48°C, and under normal operation would be projected reach 41.5 °C.

9. Appendix:

Test description, raw notes, photographs, and raw data are available in JIRA #MYONODE-8

APPENDIX H

System Test
Test#: 1001325

Document: 1001325	C101: System Test	ECN: TBD
Revision: 1		Effective: See Master Control

1. Purpose

This document is intended to outline the procedure and methods for testing the complete MyoNode system.

2. Scope

This procedure applies to the MyoNode system for the C101 project, at Cirtec Medical (Enfield).

3. Background

The MyoNode System is designed such that a MyoNode Base Station attached to a Powering Socket for a transhumeral amputee wirelessly powers and communicates with 8 MyoNode Implants. Data received from the Base Station are then digitized to form 8 channels of data which are streamed over a controller area network bus to be processed by a controller for a prosthesis. To function properly, the implants must have a stable power supply and automatically connect/reconnect with the Base Station over Bluetooth Low Energy (BLE). As EMG signals are small and pseudorandom, triangle waveforms are generated by the implants and used to verify that accurate data are communicated and that the implant remains powered on and connected to the Base Station.

4. Equipment

Description	Equipment Number
MyoNode Implants SN-04, SN-05, SN-13, SN-14, SN-15, SN-17, SN-18, SN20	IM_XX
Aim TTi CPX400D Power Supply	CPX400D
MyoNode Powering Socket SN-03	PS_03
MyoNode Base Station SN-02	BS_02
Implant Holding Apparatus	IH
CAPS Computer Software	CAPS_DEV
C# Data Logging GUI v1.5.0	DATA_LOG_GUI

5. Reference Documents

Type	Description	Document Number
JIRA	Raw Test notes, test data	#MYONODE-76

6. Testing Summary

The summary test results are shown in the following table. All 8 MyoNode Implants remained powered on for the duration of the test (approximately 10 minutes) and did not initiate BLE reconnections. Visual triangular waveforms were measured and observed on the data acquisition software.

Implant Number	Number of Lost Power Events	Number of BLE Reconnections
IM_04	0	0
IM_05	0	0
IM_13	0	0
IM_14	0	0
IM_15	0	0
IM_17	0	0
IM_18	0	0
IM_20	0	0

7. Testing Procedure

A decommissioned socket from a large transhumeral amputee (~75th % male) was duplicated by a prosthetist to form a MyoNode Powering Socket (PS_03). A large socket was selected for this test as it represents the most difficult operating conditions for the MyoNode system (deep implant powering conditions and a large geometric mismatch between the tuned coils attached to the Base Station and on the implants). The MyoNode Base Station (BS_02) was incorporated into to the MyoNode Powering Socket (PS_03) using clinical best practices of the prosthetist.



The 8 MyoNode Implants IM_XX were attached to a custom fixture (IH) designed to hold them in place inside of the MyoNode Powering Socket (PS_03).



The Implant Holding Apparatus IH was then placed inside of the MyoNode Powering Socket PS_03. The Base Station was powered on using 7.4 V, and the Base Station (BS_02) was connected to using both the CAPS Computer Software (CAPS_DEV) and Data Logger (DATA_LOG_GUI). The data were analyzed to determine how many times the implant attempted to reconnect its communication channel, how many times the implant lost wireless power, and if there were any issues with the sawtooth transmission sent out over BLE from each implant.

8. Conclusions

The MyoNode Base Station was fabricated into a socket corresponding to a large transhumeral amputee to test the performance under expected operating geometries. The MyoNode Implants remained powered on and connected to the Base Station. Upon power-on, the implants automatically connected to the Base Station. Occasionally the receivers on the base-station failed to receive telemetered data, or to communicate received data of the SPI bus. This is likely resolved with the addition of a wire antenna and with slight modifications to the firmware. However, at this time the performance from the received data appears to be of adequate quality to perform myoelectric control. This test demonstrates full functionality of the core components of the MyoNode Base Station.

9. Appendix:

Test description, raw notes, photographs, and raw data are available in JIRA #MYONODE-76.

APPENDIX I

Letter from Vendor to Justify Leveraging Biocompatibility Testing

Hermetic Solutions Group
PA&E Division
434 Olds Station Road
Tel 509-664-8000
www.hermeticsolutions.com



OCTOBER 31, 2019

Karen Adelman
99 Print Ship Road, Enfield, CT 06082

Dear Karen,

Here are the material details that we discussed on the phone last week.

We are looking to use several material options during the development and optimization of the C101 ceramic braze assemblies.

Preform materials:

- Titanium Active Braze Alloy (Ti ABA)
- NiCuSil-3
- Gold Active Braze Alloy (Au ABA)

All of these braze materials have been leveraged in many current and legacy implantable designs.

PA&E feels that one of these braze materials will be ideal for bonding 90Pt/10Ir to zirconia. We are actively working to evaluate the viability of each of these material combinations.

Please contact me if you or your customer have any further questions.

Best regards,

A handwritten signature in black ink, appearing to read "A. Meade".

Anthony Meade

SENIOR MANAGER – MEDICAL PRODUCTS

APPENDIX J

Draft Protocol for First-In-Man Study of the MyoNode System

This clinical protocol has been formatted in accordance with the requirements of **WALTER REED NATIONAL MILITARY MEDICAL CENTER (WRNMMC)**, therefore, it may differ in some respects from that of a typical IDE.

1. GENERAL INFORMATION

1.1 Protocol Title: Pilot Trial to Assess Implantable MyoNodes to Improve Prosthetic Function for Transfemoral Amputees after Targeted Muscle Reinnervation

1.2 Principal Investigator

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Residency Director, Physical Medicine & Rehabilitation
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Research Course: 10/21/2016

Dr. Paul Pasquina will be responsible for maintenance of the research documents as well as monitoring the Clinical Care-process improvement.

1.3 WRNMMC Lead Investigator

N/A

1.4 Associate Investigator(s)

Brad Isaacson, PhD
Assistant Professor, Department of Orthopedics, University of Utah
Dept of Physical Medicine & Rehabilitation, Uniformed Services University of the Health Services
The Center for Rehabilitation Sciences Research
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Research Course: 6/10/2016

1.5 Collaborators/Consultants

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1.6 Medical / Research Monitor

Keith P. Myers
LTC US Army
Chief, Physical Medicine & Rehabilitation
Walter Reed National Military Medical Center
Phone Number: 301-295-7751
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Research Course Training Date: 1/8/2016

1.7 Study Team Responsibilities

Responsibilities	Principal Investigator	Associate Investigator	Collaborating Investigator	Research Monitor
Study design and general coordination of research	X	X		
Recruit eligible subjects	X	X		
Screen eligible subjects	X	X		
Obtain informed consent/parental permission/child's assent	X	X		
Conduct research procedures involving direct interaction with subjects	X	X	X	
Clinical laboratory tests or support		X	X	
Data entry		X	X	
Data analysis	X	X	X	
Retain/share research data	X	X	X	
Retention of research protocol documents (including consent/information sheets)	X			
Report to appropriate IRB(s), institutional officials, and /or sponsor - unanticipated problems involving risks to subjects or others, adverse events, and serious or continuing non-compliance	X			X
Establish procedures to ensure an adequate plan for the protection of research data containing identifiers (DoD 6025.18R; 45 CFR 160 and 164).	X			
Submission of Continuing Review reports for IRB review	X	X		
Post-approval monitoring of the conduct of the research	X			X
Data monitoring plan – coordination and communication	X	X	X	
Clearance of research-related publications or presentations	X	X	X	

2. ABSTRACT

2.1 Purpose:

The purpose of this feasibility study is to determine changes in functional independence for individuals with transhumeral amputation who have had Targeted Muscle Reinnervation and are using implantable MyoNodes to record intramuscular EMG signals to control their motorized prosthesis. Our hypothesis is that chronic implants within reinnervated muscle will provide stable EMG recordings that will allow intuitive, simultaneous control of 3 DOF prosthesis.

2.2 Research Design:

This is a prospective, non-blinded, single group, interventional, feasibility study.

2.3 Methodology/Technical Approach:

Up to 10 subjects with transhumeral amputation and who have already received targeted muscle reinnervation will be screened with the goal of enrolling 3 subjects to participate in the study. Eligible subjects must meet established inclusion/exclusion criteria (See Section 6.4) and be cleared for initial prosthetic fitting, training and completion of testing activities of daily living.

Subjects will attend a pre-implant screening visit within 90 days preceding the surgical implantation of the MyoNodes devices. During the pre-implant screening visit, an intramuscular EMG exam of the muscles in the residual upper limb will be conducted. The purpose of this exam is to assess the electrical activity elicited by residual upper arm musculature as well as to ensure there has not been significant denervation within the residual muscles of upper arm. If the sponsor and investigators agree that the data shows the subject can elicit EMG of sufficient amplitude from at least six residual upper arm muscles, that subject may continue participation in the study. Otherwise the subject will be exited from the study. The entire screening visit may take up to 4 hours.

Subjects will then have surgical implantation of 6-8 MyoNodes. After surgical healing is complete and any swelling has subsided, residual limb will be cast for fabrication of a custom-fit MyoNode prosthesis. Once the socket is complete the subject will attend a fitting and programming visit with the prosthetist and research team. Subjects will then receive occupational therapy to learn the new prostheses and after adequate in-clinic training has been provided subjects will be allowed to take the device home for 4-5 months to use as their daily-use prosthesis. After completing six months of usage, subjects will be given the option of continuing

to use their MyoNode System (visiting the clinic every six months and undergoing an assessment at Year 1 and Year 2 post-implant) or exiting the study at that time.

A suite of outcome-measures testing will be performed pre-implantation and at 6 month post-implantation intervals until the subjects exit the study. Outcome measures include 1) a modified box and blocks test, 2) Jebsen Test of Hand Function, 3) Assessment of Capacity for Myoelectric Control, 4) Southampton Hand Assessment Procedure, 5) pattern recognition classification error, 6) prosthesis use metrics from the prior 6 months, 7) and subject questionnaires.

3. OBJECTIVES AND SPECIFIC AIMS

Primary Objective:

The overall objective of this study is to determine changes in functional independence for individuals with transhumeral amputation who have had Targeted Muscle Reinnervation and using implantable MyoNodes. This is based on our central hypothesis is that chronic implants within reinnervated muscle will provide stable EMG recordings that will allow intuitive, simultaneous control of 3 DOF prosthesis. Our work will be achieved through 2 specific aims:

Specific Aim 1: Assess the accuracy with which transhumeral amputees can control isolated and simultaneous movements of a three DOF myoelectric prosthesis utilizing the MyoNode system after successful TMR surgery. Surface EMG is often corrupted by muscle cross-talk and instability in the skin-electrode interface necessitates frequent recalibration of controllers whereas implantable EMG is stable over time. Furthermore, implantable EMG signals can be used to measure deep muscles with little cross-talk. For these reasons, we hypothesize that subjects with the MyoNode system will achieve have higher accuracy when completing a pattern recognition accuracy test.

Specific Aim 2: Determine the ability of transhumeral amputees to successfully perform functional activities using a three DOF myoelectric prosthesis control by the MyoNode system and TMR. We hypothesize that the MyoNode implant system will improve control of the prosthesis, and that this will subsequently improve functional activities. Outcome measures that measure this directly include include 1) a modified box and blocks test, 2) Jebsen Test of Hand Function, 3) Assessment of Capacity for Myoelectric Control, 4) Southampton Hand Assessment Procedure. Outcome measures that measure this indirectly include: 5) prosthesis use metrics from the prior 6 months, 6) and subject questionnaires.

4. BACKGROUND AND SIGNIFICANCE

4.1 Literature Review

Most amputations of the upper limb are caused by trauma and more than 85% of service members who undergo amputation due to combat-related injury are under 35 [3]. Hence the majority of upper-limb amputees—particularly military veterans—are young, fit, and engage in active lifestyles. The loss of the hand or arm constitutes a significant disability that can adversely affect life quality [4]. Current prosthetic devices are not adequate to replace the agility and dexterity of the human arm and hand. Myoelectric upper limb prostheses are controlled using surface electromyogram (EMG) signals from residual muscles. While new technologies such as targeted muscle reinnervation (TMR) surgery [5, 6] and advanced pattern recognition-based control algorithms [7, 8] have the potential to provide users with more intuitive control of more degrees of freedom (DOFs), all current myoelectric control systems, are limited by the use of surface EMG signals.

Many of the problems associated with surface EMG may be mitigated by recording EMG from within the muscle. For acute experiments, fine wire intramuscular (IM) electrodes enable recording of the unique output from each muscle. The output of muscles with different functions can be separated out, providing increased control information that can enable simultaneous control of multiple DOFs [9]. Chronic implantation of electrodes would enable stable recording of EMG signals, and also eliminate problems caused by movement of electrodes with respect to the skin or sweating during prosthesis use.

Obtaining robust, permanent IM EMG information is the next most important technological advance needed to improve the control and function of powered prostheses. Dr. Irazoqui at Purdue University has developed an IM EMG system that transmits EMG data wirelessly. It is also powered by a new wireless technology that enables the implant to send and receive information from as deep as 10 cm below the skin—more than adequate to broadcast the EMG from any muscle in the human arm. The system comprises small (1.5-2 cm in length with a 4 mm outer diameter) individual implants, called MyoNodes, which enable recording from 4-8 muscles. We have compelling data indicating that these devices will successfully work in the human arm.

MyoNodes will work synergistically with TMR and pattern recognition technologies to provide the most advanced, robust control system to date, enabling a remarkably stable EMG platform for both conventional and pattern recognition-based control of multiple simultaneous DOFs.

4.2 Preliminary Data and/or Findings.

The premise of EMG-based pattern recognition control is that muscle activation patterns corresponding to different intended arm movements are consistent and distinct—and thus can be

‘learned’ and recognized by computer algorithms. Most research has been conducted at the transradial level of amputation, where the remaining forearm muscles produce rich EMG signals containing information on wrist and hand movements. First the user trains an algorithm by making a series of intended movements with their residual muscles. An array of electrodes records the EMG data and the pattern recognition algorithm then decodes this initial set of signals to identify the unique characteristics of each movement. The algorithm, or classifier, thus ‘learns’ the subject’s natural EMG patterns corresponding to each movement. It can then identify subsequent attempted movements and send the corresponding command to the prosthesis; thus the user controls the device simply by attempting to perform a normal movement and the result is much more intuitive control of the prosthesis. Classification is repeated at 25–300 ms intervals to provide continuous control. For transradial amputees, our lab and others have shown that pattern recognition can enable the user to intuitively operate wrist rotation, wrist flexion/extensions, hand open/close, and even to choose some different hand grasp patterns. Selection of different DOFs is quicker as mode selection is not required. This ability to smoothly transition from one movement class to another is termed *seamless sequential control*. As such, *real-time pattern recognition control offers a significant improvement over direct control because the user can control each DOF by simply eliciting the appropriate physiological contraction*. In addition, pattern recognition control can potentially restore more DOFs than conventional myoelectric control. This technology has now been transferred to a start-up company called Coapt, LLC and is being sold commercially across the United States, including to wounded warriors at **WRNMMC, the Center for the Intrepid (CFI) at SAMMC, and to the Department of Veterans Affairs (VA)**.

With the support of the Congressionally Directed Medical Research Program, we have recently completed an 8 patient home-trial to compare pattern recognition with direct control for transhumeral TMR recipients. All patients used a commercially available 3-DOF prosthesis. We found significant improvements in functional outcomes after an 8 week home trial for the Southampton Hand Assessment Procedure (SHAP) [12], and a clothespin relocation task [11] and no change in box and block scores [13], even though the wrist could rotate unintentionally while moving blocks (Figure 2). Questionnaire data showed that 7 of 8 subjects preferred pattern recognition control.

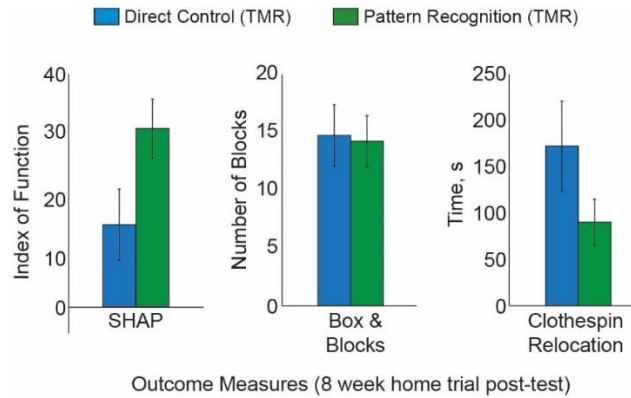


Figure 2: Outcomes metrics from an 8 subject home trial completed with transhumeral TMR recipients.

We have recently completed much research to extend pattern recognition to allow for simultaneous control of multiple DOFs [7, 8]. While the technique works extremely well in the laboratory, changes in surface electrode positioning make it necessary to recalibrate the simultaneous control system frequently, making it non-ideal for clinical deployment using surface EMG signals. However, a pattern-recognition control system would be ideally suited for stable EMG recordings from a chronic intramuscular implant.

4.4 Human Subjects Justification.

This study aims to determine changes in functional independence for individuals with transhumeral amputation who have had Targeted Muscle Reinnervation and using implantable MyoNodes. It would not be possible to replicate these conditions on the bench top or in an animal model

The intramuscular muscle recordings that are made during the pre-implant screening are routine, but may be uncomfortable and cause pain, tenderness and/or bleeding during each needle placement, some minor pain or tenderness during the requested exercises and some minor pain, tenderness, or bruising for up to two weeks after the visit. Less likely, but possible, risks of intramuscular EMG include Infection due to the use of a needle, excessive bleeding due to damage to tissue or blood vessels, swelling, redness, or other allergic reaction to the needles, injury to the nerves in your arm (which can cause long lasting tingling, numbness, or pain). To reduce these risks, only a doctor or assistant trained to perform EMG exams will work on this study. Infection risk will be limited by cleaning the arm with alcohol wipes before inserting needles. Any pain or bleeding that occurs will be addressed immediately by your study doctor or an assistant.

The implantation of the MyoNode devices requires minor surgery. As with any surgery there are risks. To minimize risks, surgical implant of the MyoNodes will be performed by a board certified hand surgeon who has been trained in this procedure. A potential risk associated with the MyoNode implantation is an allergic reaction to antibiotics, local anesthesia, regional anesthesia, conscious sedation, or general anesthesia. This risk is considered small (less than 1%). For example, a reaction could involve symptoms like hives, itching, swelling of the lips, tongue, and roof of mouth and tightness of the throat. Serious but rare reactions include low blood pressure, suppression of breathing, and possibly death.

Even though sterile techniques are used during the surgery, there is the risk of infection. If an infection occurs, it can usually be successfully treated with antibiotics. Chronic pain could result if a nerve is injured during surgical implant. If the MyoNode moves or if excessive scarring develops around the MyoNode such that it is pushing against a nerve, this could also cause chronic pain. Side effects after surgery may include redness, tenderness, swelling, pain, skin irritation, and numbness or tingling in and around the areas where the MyoNodes were implanted or where the IV line was placed. These side effects should be temporary and go away a few days after surgery.

There is a very small chance that you could have an allergic reaction to the metals of the MyoNodes due to an unknown cause. The likelihood of this occurring is rare, as the materials used in the MyoNodes are biocompatible and are commonly used in other implanted devices. A reaction could result in eczema, persistent swelling, the collection of fluid at the site, or delayed healing of the surgical wounds. Skin breakdown over the implant site could occur and the MyoNodes could come out through the skin. If such rejection did occur, the study doctor may advise removing the MyoNodes. Breakage of the MyoNodes is extremely unlikely, but may cause tissue damage, allergic response, or rejection. If a MyoNode device breaks, the study doctor or study surgeon will surgically remove it. An x-ray of the residual limb will be taken following surgical implantation to document the position of the MyoNodes. This x-ray means that the subject will be exposed to radiation. The exposure is estimated to result in a dose of approximately 12 mRem for X-rays, which is below levels expected to result in adverse side effects. It is unlikely, but a MyoNode may move from the location where it was implanted, thus causing it to work less effectively or not at all. If this happens, that MyoNode may become unusable to control the prosthesis. The doctor will discuss with you the benefits and risks of removing the MyoNode, leaving it in place, or inserting a new MyoNode.

Removal of a MyoNode may involve using x-ray or ultrasound to locate the device, then making a small incision and dissecting the overlying tissues. Risks related to removal are similar to those listed above for MyoNode insertion.

All other prosthetic componentry proposed to be used in this study are commercially available and are FDA cleared or approved devices and do not present any additional risks outside of normal standard of care. The normal risks associated with initial prosthetic fitting and training includes, but is not limited to: muscle fatigue, skin breakdown from wearing a socket, and equipment malfunction. To mitigate these risks in the clinical setting as well as in this study, all fitting and training will be performed by certified prosthetists and therapists.

5. MILITARY RELEVANCE

The prevalence of major upper limb amputation in the United States has been estimated at 41,000 individuals and approximately 80% of these cases have been the result of a trauma-related injury, including combat. As of 2010, the number of amputees receiving care within the Veterans Health Administration numbered more than 43,000, with 5,000 amputations performed annually. In a recent survey of Vietnam and Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF) veterans, upper limb loss accounted for 20% and 22%, respectively, of amputated limbs.

Despite modest improvements in upper limb prosthetic devices over the past decade, abandonment rates remain high. According to a study by McFarland et al., who evaluated the satisfaction and prosthetic-device use in service members with combat-related unilateral upper-limb amputation, 30% of Vietnam veterans and 22% of OIF/OEF veterans reported complete prosthetic abandonment, with the primary complaints related to the weight of the device, discomfort, pain, lack of functionality, and poor fit. This rate was significantly higher for those with more proximal amputations, particularly above the elbow, with reported abandonment of 42%. Even the most advanced myoelectric upper limb prosthetics have high rejection rates, and limited dexterity of control is often cited as the primary reason for the abandonment of myoelectric devices. Individuals who rely on only one arm/hand for daily use are also at significantly greater risk of developing overuse injuries and arthritis of their neck, upper back and remaining limbs, further affecting long-term morbidity and quality of life.

The Department of Defense and Veterans Administration have investigated improving the outcomes and quality of life of service members with amputations. The Defense Advanced Research Projects Agency (DARPA) Revolutionizing Prosthetic Program, initiated in 2006, led to the development of two prosthetic arm systems: (1) the Gen-3 Arm System by DEKA Integrated Solutions Corporation and (2) the Modular Prosthetic Limb (MPL) by the Applied Physics Lab at Johns Hopkins. At present neither of these limb systems is commercially available, and the control strategies they currently employ are less than optimal. The Gen-3 Arm System is undergoing clinical trials within the Department of Veterans Affairs and requires foot-switch controls while the MPL is currently being studied using invasive brain/cortical – interface

strategies. While research is also ongoing at the Walter Reed National Military Medical Center (WRNMMC) to control the MPL using surface electrodes and pattern recognition technology, the MPL system is still not robust enough to allow take home use, thereby restricting its clinical feasibility.

A key limitation in use of all myoelectric prosthetic devices, and for development of more advanced devices, is the variability of electromyography (EMG) control signals—which can be compromised by perspiration or movement of the electrodes with respect to the limb during prosthesis use. The objective of this proposal is to evaluate intramuscular EMG sensors, called MyoNodes, as a method of obtaining stable, reliable EMG information for improved prosthesis control. MyoNode technology, funded by the DARPA RE-NET program, allows wireless transmission of EMG data and is wirelessly powered. In order to address these current and emerging needs of our military population, this study will target patients of the WRNMMC with transhumeral amputations.

Over the past decade WRNMMC has been responsible for the care and rehabilitation of more than 1280 service members with major upper limb loss due to injuries sustained in Iraq or Afghanistan. Wounded warriors represent a particularly young and motivated population and are often unwilling to accept a reduction or delay in physical ability. To match this demand, prosthetic devices and control technology must offer a high level of activity, mobility, and reliability. The proposed pilot study is intended to improve the independence and function for service members with major upper limb amputation by enabling simultaneous intuitive control of multiple upper limb degrees of freedom, which should reduce prosthetic abandonment and may mitigate long-term complications related to overuse injuries. Following successful completion, we will be able to rapidly deploy the MyoNode system in patients with TMR surgery. The next progression would be to provide injured service members with TMR surgery and MyoNode implantation simultaneously, in a single surgical intervention.

6. PLAN

6.1 Study Design

The study proposed is a prospective, non-blinded, single group, interventional, feasibility study that will be conducted at a single investigational site under an EFS IDE. We will screen as many as ten subjects with unilateral transhumeral amputation and we will select three individuals for MyoNode Implants. Subjects will be recruited at WRNMMC and, if necessary, at SAMMC by referral from local prosthetists, therapists, and physicians within the Military Healthcare System and Department of Veterans Affairs.

Pre-operative ultrasound and needle EMG testing will be used to identify and evaluate voluntary activation of arm muscles; subjects will be asked to perform intended motions such as elbow flexion/extension, wrist pronation/supination, and hand opening /closing. This examination will establish if sufficient EMG signals can be derived from each muscle. Each of the subjects cleared for MyoNode implantation surgery will then be asked to perform pre-operative outcome measure testing with their current prosthesis.

Three subjects will have between to 6-8 MyoNodes inserted into residual limb muscles. Potential muscle targets are described below (Table 1). MyoNodes will be programmed to control movements of a 3 DOF prosthetic arm (i.e., elbow flexion/extension, wrist pronation/supination, and hand opening/closing). As a baseline control paradigm, subjects will use EMG from natively innervated biceps and triceps muscles for conventional control of the elbow, and pattern recognition technology to decode EMG from reinnervated muscles to control the wrist and hand.

Table 1: Target muscles for MyoNode implants with native innervation or after transferred nerves after TMR surgery. * = native innervation; + = surgically transferred nerves

Target Muscle for MyoNode Implant	Innervation
Biceps Long Head	Musculocutaneous N.*
Biceps Short Head	Median N. +
Biceps Short Head	Ulnar N+ (Secondary choice)
Triceps Lateral Head	Distal Radial N. +
Triceps Long Head	Proximal Radial N. *
Triceps Medial Head	Proximal Radial N. *
Brachialis (if available) or Coracobrachialis	Ulnar N.+

Prior to surgery, subjects will undergo a pre-implantation testing to identify appropriate muscles and a baseline functional assessment. Surgical implantation will be performed at WRNMMC by board certified hand surgeons. Regional anesthesia will be used to minimize surgical risk and to allow the patient to activate muscles during actual implantation. Within 14 days of surgery, subjects will attend a postoperative follow-up visit, in which the surgeon will evaluate the

healing of surgical wounds and confirm that the MyoNodes are functional. No sooner than 14 days following implantation, subjects will begin training with the MyoNode system, programmed to allow simultaneous control of elbow, wrist and hand function. Our goal is to demonstrate enhanced prosthetic control that can be integrated into an amputee's daily life in the near term. Therefore, we have chosen to focus integration of the MyoNode system with prosthetic components that are currently commercially available, as opposed to working with experimental systems that are currently confined to use in the laboratory (e.g. Gen-3 Arm or Modular Prosthetic Limb).

Each subject will undergo 6 weeks of training with the MyoNode System. Subjects will first undergo "preprosthetic training" for approximately 1-3 weeks using a universal prosthetic device that is supported on a stand. This device has an overly large socket and will allow training even if the subject's arm is still swollen or tender from the surgical procedure. During this time, subjects will become orientated to the various functions and features of the MyoNode-controlled prosthesis and the study prosthetist will begin the process of determining the gain, filtering, and threshold levels so that subjects can begin learning to use specific residual limb musculature to activate basic functions of the prosthetic elbow, wrist, and hand. Once swelling has subsided, subjects will be cast for fabrication of a custom-fit MyoNode prosthesis, which will be fitted and programmed as soon as it is available.

Subjects will then begin up to one month of prosthetic training, entailing visits with an occupational therapist up to 3-4 days per week. The subjects will also be instructed to utilize the device outside of the clinic according to the recommendation of the occupational therapist and based on their own comfort level. The pace of training, level of difficulty, and the amount of time allotted to master each skill will be tailored to each individual subject, depending on their motor learning ability.

Prosthetic training will begin by practicing rote tasks that involve approaching, grasping, positioning and releasing objects and control of tension. Subjects will gradually advance toward performing functional, two handed tasks like using a cell phone to make a call, opening a pill bottle, and using a knife and fork to cut. After adequate in-clinic training subjects will take their prostheses home for an additional 4-5 months, during which time subjects will be encouraged to increase the amount and variety of their at-home usage. Their at-home usage will be tracked throughout the study through self-reporting

Subjects will be staggered such that one subject will pass through the screening, implantation and recovery phase and have at least 2-3 months of use and testing before a second subject undergoes surgery. Surgical recovery should take approximately 2 weeks, although measurements and plaster impression for prosthesis fabrication and pre-prosthetic training visits may be delayed if any of the surgical wounds are not fully healed, or if the residual limb is tender

or swollen. Further subjects will not begin the study until the Principal Investigator has verified that the first subject has recovered from the surgery and the implanted electrodes are functioning. This process will allow investigators to assess the safety of the surgical procedure and allow any necessary amendments to the protocol to be submitted to the IRB before another subject undergoes surgery. We expect that the MyoNode System, in conjunction with TMR and pattern recognition technology, will enable better performance, more intuitive control, and increased functionality with their myoelectric prostheses.

6.2 Anticipated Requirements

- a. We expect a minimum duration commitment of 1 year.
- c. There is no cost anticipated for the patients completing this study. All equipment will be paid for using grant funds.

6.3 Subject Population

Study subjects will be male or female military healthcare beneficiaries at the WRNMMC, age 18 years and older, who have a transhumeral amputation with 1/2 or greater residual humeral length as determined by the contra-lateral humeral length and who have also undergone successful TMR surgery to expand user capacity for myoelectric control. Successful TMR will be defined as having the ability to stimulate EMG signaling across a muscle reinnervated muscle. This will be determined by preoperative ultrasound and needle EMG examination of the target muscles. This will determine localization as well as the health and ability of the muscles to be stimulated and produce EMG signaling. In addition, we will record user intent with each muscle

WRNMMC is one of the three major hospitals that treat traumatic upper extremity amputations and has also carried out more than 20 TMR procedures to date. We believe that this particular patient population will provide the necessary patient population for this study; however, we may also recruit from SAMMC if necessary. This study has no gender or ethnic exclusion criteria. The absence of these demographic qualifiers is not expected to have bearing on the overall objective of the study. Investigators will recruit without preference for gender or hand dominance as these should have no effect on the potential efficacy or safety of the MyoNode devices.

6.4 Sample Inclusion and Exclusion Criteria

6.4.1 Inclusion Criteria:

- ☐ Unilateral trans-humeral amputation with residual limb length >50% of the contralateral side
- ☐ Patient has undergone successful TMR surgery and MyoNode implantation into residual limb musculature
- ☐ Prior successful training and fitting with a myoelectric prosthesis

6.4.2 Exclusion Criteria:

- ☐ Age <18 or >70 years old
- ☐ Metal or shrapnel within the residual limb
- ☐ Evidence of infection or open wounds within residual limb
- ☐ Significant residual limb pain, prohibiting participation from prosthetic fitting/training
- ☐ Bleeding disorder or other potential risk for surgery
- ☐ Patients with active implants (e.g. pacemaker)
- ☐ Pregnant women
- ☐ cognitive deficits or visual impairment that would impair their ability to give informed consent or to follow simple instructions during the experiments

6.5 Study Methodology/Procedures

6.5.1 Describe when, where and how the study subjects will be identified and recruited.

Potential subjects will be referred to the investigator by colleagues who are aware of the study's eligibility criteria. Once a potential subject is identified, the Principal Investigator will contact the individual in person to gauge their interest in volunteering. Subjects will likely be recruited from the Military Advanced Training Center or the inpatient clinic when they are at WRNMMC for physical therapy/occupational therapy appointments. The background of the study and the potential benefits and risks of study procedures will be explained. Potential subjects will be shown the investigational device and will be given a demonstration of how it is used. They will be given sufficient time to contemplate the study and will be provided the informed consent form and copy of the protocol to review before meeting with the Principal Investigator to complete the Informed Consent Form.

All information documented on study forms or electronic data will be considered confidential. Only authorized sponsor personnel (the study monitor), center personnel, or government authorities acting in their official capacities will have access to these confidential files. All data used in the analysis and reporting of this evaluation will be without identifiable reference to the subject.

Subjects will not be compensated for their participation. This will be made clear to all potential participants from the beginning of the recruitment process.

Recruitment and advertisement materials may be utilize to disseminate information on the study to potential participants. Any and all advertisement material would undergo review by WRNMMC IRB prior to release or dissemination.

6.5.2 Consent Process

The informed consent process will involve a discussion between the investigator(s) and the potential study subject. The investigator will refer to the subject matter in the informed consent form. The subject will be given adequate time to read the consent carefully and ask questions. If no questions are asked, the investigator will verify the subject's understanding of the material prior to proceeding. Subjects will sign the document as they would any other formal document (i.e. using a non-dominant hand, or grasping a pen using a prosthesis). The form also requires subjects to sign a Health Insurance Portability and Account (HIPAA) agreement. Copies of the signed Informed Consent form and HIPAA form will be given to the patient. Patients will be asked to consent to having pictures and/or video taken of their arm and prosthesis during training and assessment testing.

Pictures and/or video will be edited to blur or block out any identifying features prior to presentation. De-identified picture and/or video may be:

- Sent out to the media with a press release
- Used for publications by the sponsor or investigational site
- Used for data presentation by the sponsor or
- Used for future product development and/or research protocol development by the sponsor

The Investigator will explain the consent form entirely. Adequate time will be provided to the patient for them to review the Informed Consent and fully consider the risks of participation. A draft of the informed consent form follows this section

6.5.3 Compensation for participation

Neither military nor civilians subjects will be compensated for participation in the study.

6.5.4 Research Interventions

This is a longitudinal study of the 3 subjects who receive the MyoNode system. Given the nature of the intervention, it is not possible to randomize the treatment order. The intervention comprises surgical insertion of electromyographic (EMG) sensors (MyoNodes) into residual muscles to obtain recordings of intramuscular (IM) EMG for improved control of myoelectric prostheses. The muscles chosen for MyoNode insertion will depend on the needs and residual anatomy of each subject; muscles must be under volitional control and generate sufficient EMG signals. EMG signals will be transmitted wirelessly to the prosthesis controller via a simple transmitter in the socket. Surgery will be performed as an outpatient procedure, typically requiring one session although additional surgeries may be required if MyoNodes become non-functional after insertion—to remove non-functional devices and/or to insert additional devices. MyoNodes will be left in place indefinitely, unless the subject desires their removal. Following surgery, subjects will be trained to control a prosthesis using EMG from MyoNodes. The prosthesis will consist of commercially available components. Subjects will take the device home and be encouraged to use it in their daily activities, according to the recommendations of their clinicians, during and after training. Assessments will be conducted on a monthly basis to evaluate functional ability and subjects' opinion of the MyoNode system will be assessed by questionnaire after the 6-month study period. Subjects will be given the choice of returning for additional annual functional assessments during the course of the award. No restriction on medications or activities will be placed on subjects during the study period, providing inclusion/exclusion criteria are met and the activity is safe and appropriate to perform using a myoelectric prosthesis.

The prosthesis will be operated as a typical myoelectric device; the only difference will be that EMG signals are recorded intramuscularly, and not from the skin surface. We may investigate combining skin-surface EMG with intramuscular EMG to optimize control. The risks of using this device are the same as for using any myoelectric prosthesis.

6.5.5 Data Collection

Upon receiving their custom-fit definitive prosthesis, subjects will undergo monthly assessments to track their progress with the MyoNode system.

Modified Box and Block Test (BBT): The subject attempts to move as many 1” square blocks from one side of a box, over a low barrier, to the other side of the box in a timed interval, usually 2 minutes. This activity provides a measure of elbow and hand control. [Appendix O]

Jebsen Test of Hand Function: Subjects perform seven subtests, including writing, turning over cards, picking up small objects, etc., and the time taken to complete each subtask is

recorded [18]. This test has been validated for able-bodied subjects, but not for those with an amputation. [Appendix P]

Assessment of Capacity for Myoelectric Control (ACMC): The ACMC is an observational assessment tool that specifically measures the subject's ability to control a myoelectric hand and is the only validated test for subjects with an upper limb amputation. [Appendix Q]

Southampton Hand Assessment Procedure (SHAP): The SHAP is a clinically validated, objective (self-timed) test of unilateral hand function that can be used to evaluate functionality of passive, mechanical, or myoelectric hands without bias to type. [Appendix R]

Pattern Recognition Error: The *pattern recognition error*, is the percentage of the time the classifier does not choose the movement the patient is trying to perform. This continuous variable represents the error of the decoding system and can be measure when the subject is controlling the device during a Fitts law style task. [Appendix S]

Prosthesis Use Metrics: Use of our own microcontroller will give us the opportunity to measure the wear time and functions used on the prosthesis outside of the lab very accurately. We will embed a program into the microcontroller that quantifies the amount of time the prosthesis was used, how often *each* component was operated or used, and how often the patient recalibrates the control system when using pattern recognition.

Subject Questionnaires: We will use customized questionnaires, developed in previous clinical studies that address key issues of prosthetic arm function to evaluate prosthesis control. [Appendix T]

After completing six months of usage, subjects will be given the option of continuing to use their MyoNode System (visiting the clinic every six months and undergoing an assessment at Year 1 and Year 2 post-implant) or exiting the study at that time.

6.5.6 Collection of Human Biological Specimens

N/A

6.5.7 Banking of Human Biological Specimens

N/A

6.5.8 Study Time Line

A timeline of visits, and the procedures that will take place at each visit, are described in Table 6-1.

Table 6-1 Data collection and follow-up schedule

Data Collected / Tests Performed	PreImplant	Implant	Post-Implant Follow-Up Visits					
			1-Month	2-Month	3-Month	4-Month	5-Month	6-Month
Demographics	X							
Medical History	X							
Implant Procedure		X						
Box and Blocks Test	X		X	X	X	X	X	X
Jebsen Test of Hand Function	X		X	X	X	X	X	X
Assessment of Capacity for Myoelectric Control	X		X	X	X	X	X	X
Southampton Hand Assessment Procedure	X		X	X	X	X	X	X
Subject Questionnaire								X
Adverse Events		X	X	X	X	X	X	X

6.6.1 Approval Status of Study Drugs

N/A

6.6.2 Approval Status of Study Devices

The remaining devices proposed to be used in this study will be accompany the FDA IDE submission.

6.7 Statistical Considerations

This is an observational study with only 3 patients. The results are not intended to be analyzed for statistical significance.

6.7.1 Sample Size Estimation

This study is a first-in-man demonstration of proof of concept of the technology and is not intended to be analyzed for statistical significance.

6.7.2 Data Analysis Plan

To evaluate longitudinal data, we will use a repeated measures ANOVA with subject as a random factor and time (evaluation) of evaluation as a fixed factor. We will also use a general correlation analysis and fit a line or exponential to the means of the outcome measure for each subject to determine if the slope is significantly different from zero. Finally, the outcome metrics scores from the 6 month evaluation will be compared to the pre-assessment score obtained using the subject's home prosthesis to determine overall functional changes as a result of the intervention.

7. HUMAN SUBJECT CONSIDERATIONS

7.1 Anticipated Benefits

All Patients will receive a custom fitted prosthetic socket and frame along with a prosthetic hand and wrist. The equipment will be theirs to use for the duration of study participation. All procedures, study equipment, and therapy will be provided at no cost. The MyoNode prosthesis may offer more intuitive prosthesis control, more consistent reliable prosthesis control, and increased independence.

7.2 Risks and Discomforts

Implantation Risks

Potential risks associated with the MyoNode implant surgery include:

- Standard surgical risks resulting from the use of antibiotics, local anesthesia, regional anesthesia, conscious sedation, or general anesthesia, including severe allergic reaction, e.g. anaphylaxis
- Bleeding, bruising thromboembolism, or infection from insertion of an intravenous catheter.
- Tissue injury in the area of implantation such as hemorrhage, hematoma, vessel injury, nerve injury.
- Breakage of implant tools
- Infection
- Chronic pain in the area of implantation
- Inflammation, discomfort or pain, swelling, redness, tenderness, skin irritation, or numbness/tingling in and around the implant site.
- Rejection of the implant
- Excessive scarring or fibrosis around implant. This could potentially pinch a nerve resulting in pain.

- Breakage of the MyoNode causing tissue damage, allergic response, or rejection
- Migration of the implant, which may require an additional surgery to replace.
- Device removal may necessitate using fluoroscopy or ultrasound to locate the device, then making a small incision and dissecting the overlying tissues to free the device from encapsulating tissue before lifting it from the body. Risks related to removal are similar to those listed above.

Risks Associated with Use of MyoNodes

Potential risks associated with use of MyoNodes include:

- Residual limb pain due to the presence of MyoNode devices.
- Newly occurring or changes in phantom limb pain.
- Swelling of the residual limb.
- Fatigue, muscle weakness, or muscle soreness in the residual limb.
- Skin breakdown, rashes, blisters, or chaffing of the residual limb.
- Overuse or repetitive stress injuries in the non-amputated side.
- Unexpected opening or movement of the prosthetic wrist and/or hand resulting in injury to self or others (e.g. dropping a hot drink, releasing a handrail or crutch and falling)
- Closing the prosthetic hand with too much force or inability to open the prosthetic hand resulting in injury to self or other (e.g. pinching someone's hand, inability to release a moving object).
- Electric shock or burn

Risks Associated with EMG Studies

EMG studies are performed in routine clinical practice. However, they can be considered uncomfortable with some minor pain, tenderness, and/or bruising that may last for up to two weeks. Less likely but possible risks include:

- Infection due to the use of needle electrodes
- Excessive bleeding due to damage to tissue or blood vessels
- Swelling, redness, or other allergic reaction to the needles, wires.
- Injury to the nerves in your arm (which can cause long-lasting tingling, numbness, or pain)

Long-Term Restriction on Medical Procedures

Long-term restrictions on medical procedures for subjects with MyoNodes include:

- **Diathermy:** Diathermy is the generation of localized heat in body tissues by high-frequency electromagnetic currents. Due to the unknown interactions between the MyoNode and diathermy, subjects with implanted MyoNodes will be instructed not use any type of diathermy. These treatments, sometimes used for muscle relaxation, may damage the MyoNode. Energy from diathermy can be transferred through the MyoNode and can cause tissue damage at the location of the implanted device. This could result in severe injury.
- **Electrocautery:** To avoid damage to the MyoNode device, the subject should not undergo monopolar cautery. Bipolar cautery forceps can be used, but not within 5 mm of the device. Subjects will be issued an implant card to ensure that they and potential surgeons are aware of this risk.
- **High Intensity Focused Ultrasound (HIFU) and lithotripsy:** Both HIFU and lithotripsy may cause damage to a MyoNode device causing tissue damage at the location of the implant. This kind of ultrasound should not be used.
- **Surface applied electrical stimulation:** This procedure can be applied, but certain precautions must be taken if it is to be applied near an implanted device. This is to prevent potential damage to tissue surrounding the device, as well as damage to the device itself. Do not use surface stimulation below shoulder of the arm that is implanted with MyoNodes. Surface stimulation may be used above the shoulder of the arm implanted with MyoNodes, or anywhere else on the body.
- **Magnetic Resonance Imaging (MRI):** Preliminary data suggest that MRI may be safely performed; however, if the MRI is being performed in the region in which the device is located, image artifact from the device may make the MRI unreadable.
- **CT scan:** CT scans can be safely performed, however, if the scan is of the region where the device is located, the device may distort the image from the CT scan, making the CT scan unreadable.
- **Transcranial Magnetic Stimulation:** Due to the unknown interactions between the MyoNode devices and transcranial magnetic stimulation, individuals with MyoNode devices should not undergo *this procedure*.

Other socks and liners: Some types of stump socks and residual limb liners contain silver or other metallic fibers that could become warm when inside the magnetic field generated by the Coil laminated inside the Frame of the MyoNode prosthesis. In addition, the metal may interfere with communication between the MyoNode implanted inside the limb and the prosthesis. Subjects will be instructed not to use these types of socks or liners when using their MyoNode prosthesis.

7.3 Actions to Minimize Risks

Risks Associated with Surgical Implant of the MyoNode Device

To minimize risk, surgical implant of the MyoNode will be performed by a board-certified hand surgeon. Study surgeons involved have already had the opportunity to train on muscle selection and the MyoNode implantation technique and are also involved in the implantation of all patients in the current MyoNode feasibility study ongoing at WRNMMC. Additionally, several members of the study surgical staff have significant experience carrying out TMR surgery.

Risks Associated with Use of MyoNodes

Biostability and MyoNode functionality risks are minimized by utilizing extensive laboratory bench and chronic pre-clinical testing of the MyoNodes. MyoNode functionality will also be verified by testing the system immediately following implant, just prior to exiting the surgical suite. To help assure the performance and safety of the prosthetic set-up, regular follow-ups for adverse events, device assessment, and optimization of the system will be specified in the protocol, as well as regular and close monitoring of the subject status.

Risks associated with subject tasks related to daily living with the prosthetic system are minimized by training subject on the system use, and warning associated with implanted devices, including medical procedure precautions (e.g. diathermy and MRI restrictions). Subjects will receive a Participant Manual detailing these warnings and precautions. In addition, all implanted study subjects are provided with an Implant Identification Card that identifies the subject as having an implanted medical device and includes medical (Investigator) contact information for emergencies. All study subjects are instructed to carry their Implant Identification Card with them at all times.

The MyoNode will not preclude future use of the standard (surface EMG) method of operating a myoelectric prosthesis. Should a study subject's medical condition require implantation of another electrical device or other mode of treatment, the prosthetic can be abandoned; and, if necessary, the devices removed. The potential risks in device revision/removal are similar to implant including, but not limited to, additional exposure to anesthesia, infection from a re-operation, and damage to surrounding tissues. These risks are minimized by the use of trained surgeons and proper surgical procedures.

Adverse Events

Adverse Events shall be classified according to the following definitions:

Classifications of Seriousness

Serious Adverse Events

An Adverse Event is classified as serious if it meets one or more of the following criteria:

- Is life-threatening
- Results in death
- Requires/prolongs hospitalization
- Causes congenital anomaly
- Causes persistent or significant disability/incapacity

Unanticipated Adverse Device Effect

An unanticipated Adverse Device Effect is any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including supplementary plan or application), or any other unanticipated serious problems associated with a device that relates to the rights, safety, or welfare of subjects.

Classifications of Expectedness

Anticipated Adverse Event

An anticipated Adverse Event (AE) is any adverse event identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or is consistent with the subject's medical history.

Unanticipated Adverse Event

An unanticipated AE is any adverse event not previously identified in nature, severity, or degree of incidence in the current investigational plan or application and is inconsistent with the subject's medical history.

Classification of Relatedness

Device-Related Adverse Events

An AE that is attributable to implantation, presence, and/or use of the investigational device.

Adverse Event Reporting Requirements

All AEs must be documented on the appropriate DRF and source documents, including (at a minimum) a description of the event, date of onset, seriousness, relationship to the device and/or procedure, required interventions, duration, and outcome. All AEs must be monitored until they are adequately resolved or explained. Each Unanticipated Adverse Device Effect shall be reported to the FDA. The site shall follow their local IRB policies on reporting.

Events exempt from recording on Adverse Event forms include minor discomforts required to participate in the study, as long as they are within the severity expected by the investigators. These include:

- Minor pain and bleeding during needle EMG
- Minor pain and swelling following needle EMG, managed by oral medication and lasting less than 1 week.
- Minor pain and swelling following implant, managed by oral medications, lasting 1 week or less.
- Minor muscle fatigue during Preprosthetic Training, Prosthetic Training, or Training Assessment that resolves immediately after the training or assessment is completed.
- Documentation may be requested by the Sponsor, including, but not limited to, a written subject narrative detailing the clinical course of the AE, a copy of any correspondence with the local IRB, hospital records, and an autopsy report, if available.

Outcome

Adverse Events are assigned an “open” or “closed” outcome status by centers depending on the nature of the event of the corrective action involved. When clinically appropriate, centers should work to close events that may not be resolvable during the term of the investigation. At follow-up visits, centers may move outcome status to “closed” or alternatively add text to the adverse event description to update continued efforts to resolve. The outcome of each AE must be assessed according to the following classifications:

Closed: Subject fully recovered, partially recovered with no further recovery expected, or in the event of Death

Open: Subject’s condition improved, unchanged, or worsened, or further recovery is expected.

Death

A subject death during the study must be reported to Sponsor as soon as possible. The WRNMMC IRB must be notified of any deaths in accordance with the WRNMMC IRB policies and procedures.

Notification of death must include a detailed narrative (death letter) that provides detailed information describing the circumstances surrounding the death and is signed by the Principal Investigator or authorized Co-Investigator. The death letter must include the following:

- a) Date and time of death
- b) Place death occurred
- c) Immediate cause of death
- d) The relatedness of the death to the prosthetic system, surgical procedure, or subject condition.
- e) Whether or not the death was witnessed
- f) Device status and/or activity at the time of death
- g) Any other circumstances surrounding the death
- h) Approximate time interval from the initiating event to death (temporal course)
- i) Principal Investigator signature and date
- j) Any information listed above that is unavailable or unknown must be specified. Also submit the following documentation:
 - If the subject expired in the hospital, a copy of the medical records for that admission (e.g., history and physical exams, consults, test results, operative reports, and/or progress notes from the hospital chart) and a discharge summary.
 - Death certificate (if available)
 - Autopsy report (if applicable)
 - A copy of the most recent clinic visit (if not already submitted to Sponsor)

Data collected from the subject up to the point of death will remain documented on CRFs and/or worksheets. Whenever possible, study devices and related system components should be removed intact and returned promptly to Sponsor for analysis.

Causality

The causality of each AE must be assessed according to the following classifications:

Device-Related: The device directly caused or contributed to the AE.

Possibly Device-Related: The device may have caused or contributed to the AE.

Procedure-Related: The AE is directly associated by timing and/or pathophysiology with the procedures described in this protocol.

Possibly Procedure-Related: The AE may be associated by timing and/or pathophysiology with the procedures described in this protocol.

Not Related: The AE is not associated with either the device or the procedures described in this protocol.

Device Failure or Malfunction

A device malfunction is the failure of the device to perform according to the Instructions for Use, protocol, or if it fails to meet specifications. A device malfunction may constitute an AE if an undesirable experience occurs. If a device failure is detected or suspected, it should be documented on the appropriate CRF and, if applicable, the device should be returned according to the Sponsor's standard operating procedure. If the device failure results in an AE, both the device failure and AE must be reported to the Sponsor in a timely manner.

7.4 Reporting Adverse Events

Expected adverse events, which are not serious, are reported on the Continuing Review Progress Report (CRPR). Continuing Review is generally performed on a 12-month cycle, falling on the anniversary month of the protocol's initial approval. More frequent Progress Reports may be required at the discretion of the IRB.

Serious Adverse Events: The PI, within two working days, must report all serious adverse events (SAE) occurring in subjects enrolled at WRNMMC IRB. This is accomplished by submitting an adverse event report to the IRB via IRBNet. For protocols involving investigational drugs or devices, the investigator must also report a serious adverse event to the sponsor of the IND or IDE immediately (within 24 hours). Serious adverse events must be reported even if the PI believes that the adverse events are unrelated to the protocol.

Unexpected (but not serious) adverse events occurring in subjects enrolled at WRNMMC which, in the opinion of the PI, are possibly related to participation in the protocol must be reported by the PI within 10 (ten) working days to the IRB using the same procedure.

For all serious and/or unexpected adverse events, the PI must forward a copy of the adverse event report to the Medical / Research Monitor for the protocol.

8. HIPAA AUTHORIZATION

i. Are you intending to collect subject's Protected Health Information (PHI) and any of the following 18 personal identifiers?

☐ No – HIPAA does not apply – go to question #iv

☒ Yes – please check which ones:

☒ 1. Names

☐ 2. Street address, city, county, 5-digit zip code

☐ 3. Months and dates of major life events (years are OK) and ages >89 (unless all persons over 89 years are aggregated into a single category)

☒ 4. Telephone numbers

☐ 5. Fax numbers

☒ 6. E-mail addresses

☒ 7. Social security number

☒ 8. Medical record number

☒ 9. Health plan beneficiary number

☐ 10. Account number

☐ 11. Certificate/license number

☐ 12. Vehicle identification number (VIN) and/or license plate number

☐ 13. Device identifiers and serial numbers

☐ 14. URLs (Uniform Resource Locators)

☐ 15. Internet protocol address number

☐ 16. Biometric identifiers, such as finger and voice prints

☐ 17. Full face photographic images or any comparable images

☒ 18. Any other unique identifying number, characteristic, or code such as patient initials

ii. Can you limit your collection of personal identifiers to just dates, city/state/zip, and/or “other unique identifier” (#18 of the above)?

☒ Yes – then your dataset may qualify as a Limited Data Set – please complete a Data Use Agreement and submit with your protocol. Then go to question #iv.

☐ No – Go to question #iii.

iii. Is obtaining patient Authorization “impracticable”?

☐ Yes – Authorization may qualify to be waived by the IRB. Submit a Request for Waiver of Consent/HIPAA to the IRB.

☐ No – Research subjects will need to sign a HIPAA Authorization. Complete the HIPAA Authorization template portion of the Consent Template.

iv. What precautions will you take to protect the confidentiality of research source documents (Case Report Forms, questionnaires, etc.), the research data file, and the master code (if any)?

The subject will be identified throughout this study by a coded identifier (i.e. PM1, PM2, MP1, MP2 etc.) assigned by the research team. These codes will be used to label the subjects' study records. The link between the subject's code and personal identity will be kept in a concealed binder/folder in a locked filing cabinet housed at WRNMC for three years after all data collection is completed and the accumulated final analyses published.

v. When will you destroy the research source documents, data file, and the master code?

The WRNMMC research team will keep the research data for up to three years after the end of the study. At this point, all information will be destroyed. The link between the subject's name and the study will be destroyed three years after all data collection is completed and the accumulated final analyses are published.

vi. Will research data including Identifiable Protected Health Information be sent outside of WRNMMC?

☐ Yes – Please explain assurances you have received from the outside party that they will appropriately follow confidentiality protections, follow the HIPAA requirements, and abide by the provisions of your Authorization.

☒ No

APPENDIX K

DRAFT INFORMED CONSENT FORM

DRAFT INFORMED CONSENT FORM

WALTER REED NATIONAL MILITARY MEDICAL CENTER (WRNMMC), BETHESDA MD

CONSENT TO PARTICIPATE IN RESEARCH

Title: Pilot Trial to Assess Implantable MyoNodes to Improve Prosthetic Function for Transhumeral Amputees after Targeted Muscle Reinnervation

Principal Investigator: PAUL F. PASQUINA

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. What is the purpose and duration of this research and who will take part?

Your decision will not affect your future care at Walter Reed National Military Medical Center (WRNMMC) or another military treatment facility (MTF). If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

You are being asked to take part in this research study because you have a unilateral trans-humeral amputation, have undergone successful Targeted Muscle Reinnervation (TMR) surgery, and are eligible for implantable MyoNodes. The purpose of this research study is to determine if using MyoNodes results in increased functional independence. This study will be conducted in collaboration with the Rehabilitation Institute of Chicago and Northwestern, Center for Neuroscience and Regenerative Medicine (CNRM), and the Uniformed Services University of the Health Sciences (USUHS).

The duration of participation per visit is around 4 hours. Total study participation will last approximately 12 months. There will be about 3 people taking part in this study overall.

If you opt to participate in this study, you will first attend a pre-implantation screening visit within 90 days preceding the surgical implantation of the MyoNodes devices to identify appropriate muscles and a baseline functional assessment. During the pre-implant screening visit, ultrasound and needle EMG testing in the residual upper limb will be used to identify and evaluate voluntary activation of arm muscles. If you are cleared for MyoNode implantation

surgery will then be asked to perform pre-operative outcome measure testing with their current prosthesis. Next, you will have surgical insertion of six to eight electromyographic (EMG) sensors (MyoNodes) into residual limb muscles to obtain recordings of intramuscular (IM) EMG for improved control of myoelectric prostheses. After healing is complete, you will be cast for fabrication of a custom-fit MyoNode-enabled socket (for socket users) or custom-fit MyoNode-enabled band (for osseointegration (OI) interface users). Next, you will be trained to control a prosthesis using EMG from MyoNodes to then be able to be allowed to take the device home for five months to use as your daily-use prosthesis, during which time you will be encouraged to increase the amount and variety of at-home usage.

A suite of outcome-measures will be assessed monthly from pre-implantation to six months post-implantation, at which time the intervals will be extended to one year and two years post-implantation.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you have a unilateral trans-humeral amputation, have undergone successful Targeted Muscle Reinnervation (TMR) surgery, and are eligible for implantable MyoNodes. The purpose of this research study is to determine if using MyoNodes results in increased functional independence. This study will be conducted in collaboration with the Rehabilitation Institute of Chicago and Northwestern, Center for Neuroscience and Regenerative Medicine (CNRN), and the Uniformed Services University of the Health Sciences (USUHS).

The duration of participation per visit is around 4 hours. Total study participation will last approximately 12 months. There will be about 3 people taking part in this study overall.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to have some tests and provide some information so that the Investigator can confirm that you qualify for the study. This is called the “Screening Process”. These tests may have been done or this information collected as a part of your regular medical care.

If you opt to participate in this study, you will first attend a pre-implantation screening visit within 90 days preceding the surgical implantation of the MyoNodes devices to identify appropriate muscles and a baseline functional assessment. During the pre-implant screening visit, ultrasound and needle EMG testing in the residual upper limb will be used to identify and evaluate voluntary activation of arm muscles. The purpose of this exam is to assess the electrical activity elicited by residual upper arm musculature, as well as to ensure there has not been significant denervation within the residual muscles of the upper arm. If the sponsor and investigators agree that the data shows you can elicit EMG of sufficient amplitude from at least six residual upper arm muscles, you may continue participation in the study.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

If you opt to participate in this study, you will first attend a pre-implantation screening visit within 90 days preceding the surgical implantation of the MyoNodes devices to identify appropriate muscles and a baseline functional assessment. During the pre-implant screening visit, ultrasound and needle EMG testing in the residual upper limb will be used to identify and evaluate voluntary activation of arm muscles.

If you are cleared for MyoNode implantation surgery will then be asked to perform pre-operative outcome measure testing with your current prosthesis. Next, you will have surgical insertion of six to eight electromyographic (EMG) sensors (MyoNodes) into residual limb muscles to obtain recordings of intramuscular (IM) EMG for improved control of myoelectric prostheses. Within 14 days of surgery, subjects will attend a postoperative follow-up visit, in which the surgeon will evaluate the healing of surgical wounds and confirm that the MyoNodes are functional. MyoNodes will be left in place indefinitely, unless the subject desires their removal.

After healing is complete, you will be cast for fabrication of a custom-fit MyoNode-enabled socket (for socket users) or custom-fit MyoNode-enabled band (for osseointegration (OI) interface users). The MyoNode system is expected to be compatible with pattern recognition technology, which will allow for incorporation of all implanted MyoNodes to form control decisions. EMG signals will be transmitted wirelessly to the prosthesis controller via a simple transmitter in the socket. The prosthesis will be operated as a typical myoelectric device; the only difference will be that EMG signals are recorded intramuscularly, and not from the skin surface. We may investigate combining skin-surface EMG with intramuscular EMG to optimize control.

Next, you will be trained to control a prosthesis using EMG from MyoNodes. No sooner than 14 days following implantation, you will begin training with the MyoNode system, programmed to allow simultaneous control of elbow, wrist, and hand function. As a baseline control paradigm, subjects will use EMG from natively innervated biceps and triceps muscles for conventional control of the elbow, and pattern recognition technology to decode EMG signals from reinnervated muscles to control the wrist and hand. You will undergo 6 weeks of training with the MyoNode System.

After adequate in-clinic training has been provided, you will be allowed to take the device home for five months to use as your daily-use prosthesis, during which time you will be encouraged to increase the amount and variety of your at-home usage. You will take the device home and be encouraged to use it in your daily activities, according to the recommendations of their clinicians, during and after training. Your at-home usage will be documented and monitored throughout the study through your completion of a Daily Use Log, as well as communication between you and the research team via phone and electronic mail. No restriction on medications or activities will be placed on you during the study period, providing inclusion/exclusion criteria are met and the activity is safe and appropriate to perform using a myoelectric prosthesis. After completion of this phase, you will be given the option of continuing to use your MyoNode System (which entails visiting the clinic every six months and undergoing an assessment at Year one and Year two post-implant) or exiting the study at that time.

A suite of outcome-measures will be assessed monthly from pre-implantation to six months post-implantation, at which time the intervals will be extended to one year and two years post-implantation. Outcome measures include 1) a modified Box and Block Test (BBT), 2) the Jebsen

Taylor Hand Function Test (JTHFT), 3) the Assessment of Capacity for Myoelectric Control (ACMC), 4) the Southampton Hand Assessment Procedure (SHAP), 5) pattern recognition classification error, 5) prosthesis use metrics, 6) and the Orthotics Prosthetics Users Survey - Upper Extremity Functional Status (OPUS - UEFS). Outcome measures and assessments will be conducted on a monthly basis to evaluate functional ability, and your opinion of the MyoNode system will be assessed by questionnaire after the study period. You will be given the choice of returning for additional annual functional assessments during the course of the award.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there is a risk of:

Implantation Risks

- Standard surgical risks resulting from the use of antibiotics, local anesthesia, regional anesthesia, conscious sedation, or general anesthesia, including severe allergic reaction, e.g. anaphylaxis
- Bleeding, bruising thromboembolism, or infection from insertion of an intravenous catheter
- Tissue injury in the area of implantation such as hemorrhage, hematoma, vessel injury, nerve injury
- Breakage of implant tools
- Infection
- Chronic pain in the area of implantation
- Inflammation, discomfort or pain, swelling, redness, tenderness, skin irritation, or numbness/tingling in and around the implant site.
- Rejection of the implant
- Excessive scarring or fibrosis around implant. This could potentially pinch a nerve resulting in pain.
- Breakage of the MyoNode causing tissue damage, allergic response, or rejection
- Migration of the implant, which may require an additional surgery to replace.
- Device removal may necessitate using fluoroscopy or ultrasound to locate the device, then making a small incision and dissecting the overlying tissues to free the device from encapsulating tissue before lifting it from the body. Risks related to removal are similar to those listed above

Risks Associated with Use of MyoNodes

- Residual limb pain due to the presence of MyoNode devices.
- Newly occurring or changes in phantom limb pain.
- Swelling of the residual limb.
- Fatigue, muscle weakness, or muscle soreness in the residual limb.
- Skin breakdown, rashes, blisters, or chaffing of the residual limb.
- Overuse or repetitive stress injuries in the non-amputated side.
- Unexpected opening or movement of the prosthetic wrist and/or hand resulting in injury to self or others (e.g. dropping a hot drink, releasing a handrail or crutch and falling)
- Closing the prosthetic hand with too much force or inability to open the prosthetic hand resulting in injury to self or other (e.g. pinching someone's hand, inability to release a moving object).

- Electric shock or burn

Risks Associated with EMG Studies

- EMG studies are performed in routine clinical practice. However, they can be considered uncomfortable with some minor pain, tenderness, and/or bruising that may last for up to two weeks.

Less likely but possible risks include:

- Infection due to the use of needle electrodes
- Excessive bleeding due to damage to tissue or blood vessels
- Swelling, redness, or other allergic reaction to the needles or wires
- Injury to the nerves in your arm (which can cause long-lasting tingling, numbness, or pain)

Long-Term Restriction on Medical Procedures

- *Diathermy*: Diathermy is the generation of localized heat in body tissues by high-frequency electromagnetic currents. *Due to the unknown interactions between the MyoNode and diathermy, subjects with implanted MyoNodes will be instructed not use any type of diathermy. These treatments, sometimes used for muscle relaxation, may damage the MyoNode. Energy from diathermy can be transferred through the MyoNode and can cause tissue damage at the location of the implanted device. This could result in severe injury.*
- *Electrocautery*: To avoid damage to the MyoNode device, the subject should not undergo monopolar cautery. Bipolar cautery forceps can be used, but not within 5 mm of the device.
- *High Intensity Focused Ultrasound (HIFU) and lithotripsy*: Both HIFU and lithotripsy may cause damage to a MyoNode device causing tissue damage at the location of the implant. This kind of ultrasound should not be used.
- *Surface applied electrical stimulation*: This procedure can be applied, but certain precautions must be taken if it is to be applied near an implanted device. This is to prevent potential damage to tissue surrounding the device, as well as damage to the device itself. Do not use surface stimulation below shoulder of the arm that is implanted with MyoNodes. Surface stimulation may be used above the shoulder of the arm implanted with MyoNodes, or anywhere else on the body.
- *Magnetic Resonance Imaging (MRI)*: Preliminary data suggest that MRI may be safely performed; however, if the MRI is being performed in the region in which the device is located, image artifact from the device may make the MRI unreadable.
- *CT scan*: CT scans can be safely performed, however, if the scan is of the region where the device is located, the device may distort the image from the CT scan, making the CT scan unreadable.
- *Transcranial Magnetic Stimulation*: Due to the unknown interactions between the MyoNode devices and transcranial magnetic stimulation, *individuals with MyoNode devices should not undergo this procedure.*

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?:

There are no direct benefits to you for taking part in the study. However, others may benefit in the future from the information learned during this study. The information we learn from this study may help with the improvement of upper-limb prosthesis control systems and making them better suited for patient use.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Your alternative is not to participate in this research.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, you will not receive any compensation for participating in this study.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Paul Pasquina, MD
Colonel, U.S. Army (Ret.)
Chief, Department of Rehabilitation
Walter Reed National Military Medical Center
Professor and Chair, Department of Physical Medicine and Rehabilitation
Uniformed Services University (USU)
Phone Number – 301-295-6885
paul.pasquina@usuhs.edu

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF)
6720-A Rockledge Drive
Rockville, MD 20817

Uniformed Services University of the Health Sciences (USU) Acquisitions Directorate
4301 Jones Bridge Road, A1040C
Bethesda, MD 20814-4712

12. SOURCE OF FUNDING:

This study is supported by funds that Congress has provided for this type of research.

13. LOCATION OF THE RESEARCH:

The study will take place at WRNMMC.

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

Nothing to disclose.

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at:

<http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf>.

The research team will keep your research records. These records may be looked at by staff from the CRSR and Northwestern, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: coded data, removal of personal information, computer password protection, creation of firewalls around the data, locking of drawers and offices. A lay definition of firewall is: A firewall is a protection or barrier within a computer to protect the information from being viewed by unauthorized people.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. Law. This web site will not include information that can identify you. At most, the Web site will include a summary of results. You can search this Web site at any time.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

Data collected during this study may be shared with Northwestern, CNRM and organizations associated with CNRM including the Uniformed Services University, US Department of Defense (DoD) and the Henry M Jackson Foundation (HJF). Data collected during this study may be shared with CNRM and organizations associated with CNRM including the Uniformed Services University, US Department of Defense (DoD) and the Henry M Jackson Foundation (HJF).

Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will be de-identified.

16. LONG TERM USE OF DATA

The investigator has requested to save selected data collected from your participation in this research study for possible use in future research. Identifiers will be removed, and de-identified information may or may not be used or shared for future research. You have a number of options with regard to this request. If the stored data has an identifying link you can request to be contacted and sign a separate consent form to allow the use or availability of this data in another study. You may also choose either to not allow any further use of your data, allow use of only de-identified data, or give consent now for the use of your identifiable data to be used in future studies. This future research may be in the same area as the original study or it may be for a different kind of study. You will be provided choices at the end of this consent form to allow or deny use in future research studies.

Any future research using your retained data will require a research protocol for the proposed study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

17. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

We will also give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

18. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

19. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, you must let a study investigator know.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if he determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

20. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify your Principal Investigator immediately using the contact information in the section below.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military, dependent of active duty military, retiree), you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are authorized space-available medical care for your injury at a DoD hospital or an DoD clinic; medical care charges for care at a DoD hospital or a DoD clinic will be waived for your research-related injury. If you obtain care for research-related injuries outside of a DoD or DoD hospital or clinic, you will not be reimbursed for those medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

21. CONTACT INFORMATION:

Principal Investigator (PI)

The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Paul Pasquina, MD

Phone: 301-295-6885

Mailing Address: America Building (bldg. 19) Room 2007, Walter Reed National Military Medical Center, Bethesda, MD 20889

Department of Research Programs (DRP) Office

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the DRP Office at:

Department of Research Programs

Walter Reed National Military Medical Center

4650 Taylor Road, Bldg. 17B, 3rd Floor, Room #3054, Bethesda, Maryland 20889-5638

Phone: 301-295-8239

For questions about your rights as a research subject, you may also contact the WRNMMC Staff Judge Advocate Office at 301-295-2215.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

Please initial the sentences that reflect your choices and then sign below:

_____ I authorize the storage of data collected as a part of this study for future use in research studies.

_____ I **do not authorize** the storage of data collected as a part of this study for future use in research studies.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

Printed Name of Participant

Signature of Participant

Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT

(Can only be signed by an investigator or staff approved to administer consent)

Printed Name of Administering Individual

Signature of Administering Individual

Date

APPENDIX L

CASE REPORT FORMS

Upper Limb Prosthetics Subject Case Form

☐ **TH**

Date: _____

☐ **Inclusion and Exclusion criteria reviewed**

Name:	Home Phone:
Date of Birth:	Cell Phone:
E-mail:	Home Address:
Preferred contact method: ☐ E-mail ☐ Cell ☐ Home ☐ Mail	

Specify Ethnicity: Are you?	☐ Hispanic or Latino origin ☐ Not of Hispanic or Latino origin ☐ Unknown or not reported
Specify Race: Which category best describes your race?	☐ American Indian/Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian/Other Pacific Islander ☐ White ☐ More than one race ☐ Unknown or not reported

Date of Amputation:		Amputation Side: ☐ R ☐ L		
TMR : ☐ Y ☐ N Date of TMR:				Handed-ness (pre-amputation): ☐ R ☐ L
Height:	Weight:	Cause of Amputation: ☐ Trauma ☐ Sarcoma ☐ Vascular ☐ Other		
Details/Revisions/History, including TMR surgeon/location:				
Comorbidities/contralateral involvement:				
How frequently do you wear your prosthesis:				
☐ full time, 8+ hrs/day, 7 days per week	☐ part time, 4-8 hrs/day, 5-7 days per week	☐ occasional, <4 hrs/day, 1-7 days per week	☐ sporadic, at least once a month	☐ non-user, new user, or stopped wearing for a period
Hours and tasks used with prosthesis:				

Current Prosthetic Socket:	Is your residual limb $\frac{1}{2}$ the length of your sound limb? ☐ Y ☐ N
Current Prosthetic Components:	Current Prosthetic Control
Therapy Hx:	
Prosthetic components and socket style Hx	
Other comments: pain, limitations, etc.	

Measurements (In mm)

Intact Limb: LatE to ThumbTip _____
Cubital fold to radial styloid: _____
Hand circumference @MCP: _____
Hand width @MCP: _____

Residual Limb Length **TH** (ACR to de) _____
Circumference 2" from de: _____

With prosthesis on: LatE to ThumbTip _____ ACR to Elbow center: _____

Color swatch preference: Otto Bock color _____ Others _____

- ☐ Pictures of residual limb
- ☐ Pictures of prosthesis
- ☐ Pictures with prosthesis on

ROM/Strength	Left			Right		
	Active Without Prosthesis	Active With Prosthesis	Strength	Active Without Prosthesis	Active With Prosthesis	Strength
Shoulder Flexion (0-165)						
Shoulder Extension (0-57)						
Shoulder Abduction (0-183)						
Shoulder Adduction (0)						
Shoulder External Rotation (0-100)						
Shoulder Internal Rotation (0-67)						
Elbow Extension/ Flexion (0-141)						
Forearm Pronation (0-75)						
Forearm Supination (0-81)						
Wrist Flexion (0-75)						
Wrist Extension (0-74)						

Visit Notes

Subject ID: _____ **Date:** _____

Project/Study: _____

Start Time:	End Time:	Total Time:	Updated Consent: ☐ Y ☐ N	
Visit Type:	☐ Socket fitting	☐ Training	☐ Outcomes	☐ Other (see notes)

Hardware Notes: ☐ Same as previous

EMG electronics	☐ MyoNode	☐ Conventional	☐ Other: _____		
Device:	☐ LTI elbow	☐ MC wrist	☐ Bock 1DOF	☐ VOVC	☐ Other: _____
☐ none	☐ Dynamic Arm	☐ OB wrist	☐ Bebionic	☐ RIC VO	_____
	☐ RIC/CBM Arm	☐ RIC WR/WF	☐ ilimb	☐ RIC VC	_____
	☐ M.A. H/W	☐ RIC WR	☐ Taska		_____

Socket/Device Notes ☐ Same as previous

☐ Experimental Socket	☐ Home socket, Clinician initial: _____	☐ No socket
Torque/Loctite complete? ☐ Y ☐ N ☐ N/A		

Data Notes (File locations, etc):

☐ Pain/socket fit issues (see notes)	☐ Also see Data collection form	

Goals for next visit:		
Next visit scheduled? ☐ N ☐ Y: Date/time:		
Financial payment Completed	☐ Y	☐ N
Staff signature:	Date:	

APPENDIX M

INVESTIGATOR AGREEMENT

INVESTIGATOR AGREEMENT

By submitting this protocol and providing an electronic signature in IRBNet, or an ink signature below, I agree to the following statements:

General Assurance: I agree to conduct the study as outlined herein. I certify that all procedures involving human subjects have been described in full.

Starting the Study: I understand that I cannot begin the study until I have received an approval letter documenting approval by the WRNMMC IRB.

Consent: I am responsible for assuring the quality of each subject's consent in accordance with current federal regulations. This includes ensuring that any "designee" that obtains consent on my behalf is completely familiar with the protocol and is qualified to perform this responsibility.

Adverse Events: I understand that I must report serious adverse events within two days to the IRB and provide this information to the Medical / Research Monitor. I will report unexpected (but not serious) adverse events that may possibly be related to participation in the protocol within 10 working days to the IRB using the same procedure.

Training: I verify that the personnel performing these procedures described in this protocol are technically competent, have been properly trained, and are appropriately qualified.

Compensation: I am aware that members of the research team are not authorized to accept any form of personal compensation for our efforts in conducting this research.

Modifications: I am aware that all changes to the protocol must be approved by the IRB before implementation. Examples of changes to protocols that require IRB approval include change of on-site PI, addition of personnel on study, increased sample size, addition of other data points, sources of outside funding, and addition of data collection sites.

Deviations to the Protocol: I am aware that any protocol deviations discovered by either the PI or auditing official will be immediately reported to the IRB. All corrective actions will be documented and become a part of the master study file, along with the report.

Duplication of Effort: I have made a reasonable good faith effort to ensure that this protocol is not an unnecessary duplication of previous experiments.

Reports: I agree to provide a Continuing Review Progress Report 30 days prior to the anniversary of the protocol's initial approval or as stipulated by the IRB. I agree to submit a final report within 30 days following completion or termination of the study.

Maintain Study Files: I agree to maintain a Study File that must be kept for three years from the date the study is closed (32 CFR 219.115(b)). If IND medication or IDE appliances are used, the file must be kept for 2 years after Food and Drug Administration (FDA) approval and can then be destroyed; or if no application is filed or approved, until 2 years after the study is discontinued and FDA notified (21CFR 312.62(c)). I acknowledge that research data is the property of the Command and will not be removed without prior approval. When I am scheduled to PCS or ETS,

study records will be given to a new PI or the Department Chief, or turned over to the Department of Research Programs.

This file may be inspected at any time by Department of Research Programs, the Clinical Investigation Regulatory Office (CIRO), the FDA, and/or other applicable regulatory agencies responsible for the oversight of research. This file will include:

- A. The approved protocol and applicable amendments.
- B. The IRB minutes granting approval to initiate the study.
- C. IRB approval letter.
- D. Each Consent Form/HIPAA Authorization signed by the subject or surrogate.
- E. Continuing Review Progress Reports.
- F. Reports of adverse effects.
- G. Reports of any significant new findings found during the course of the study.
- H. All study documents generated from study date.
- I. Publications, abstracts, reprints resulting from study data.
- J. All information pertaining to an investigational drug or device.

Publications: I am aware that advertisements, abstracts, presentations or publications resulting from research protocols must have their products cleared by the Public Affairs Office, undergo Operation Security (OPSEC) review, undergo review for release of actionable medical information, and Publication Clearance.

Applicable Regulations: I am familiar with applicable regulations governing research, and will adhere to all of the requirements outlined in the DoD Multiple Project Assurance for the North Atlantic Regional Medical Command.

I understand that if I fail to comply with any of these responsibilities, all projects for which I am an investigator may be suspended. (Electronic signature provided on IRBNet)

Authorized Signature:

X _____

PRINCIPAL INVESTIGATOR

Paul F. Pasquina, M.D.

COL U.S. Army (retired)

Chair, Department of Physical Medicine and Rehabilitation

Uniformed Services University of the Health Sciences

Building A, Room A1036

4301 Jones Bridge Rd.

Bethesda, MD 20814

(301) 295-6885

paul.f.pasquina.civ@mail.mil

APPENDIX N

LABELING

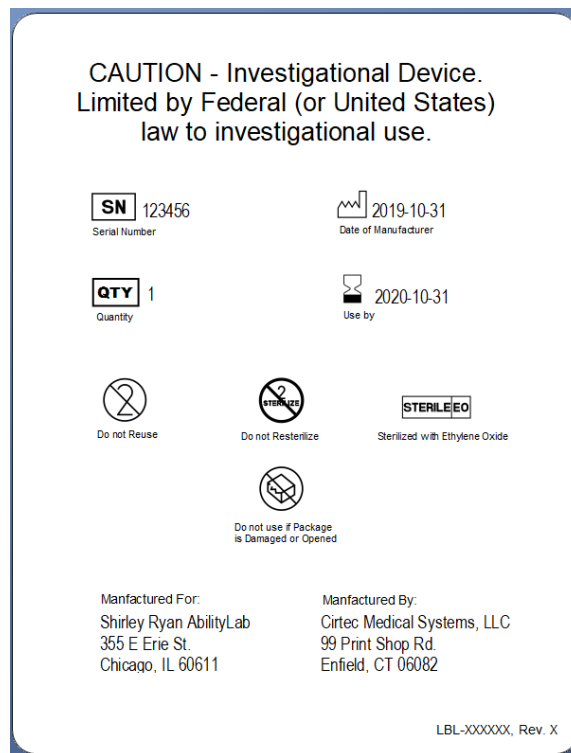


Figure N-1. Package label

APPENDIX O

MODIFIED BOX AND BLOCK TEST

Box and Blocks Test Instructions¹

General Information (derived from Mathiowetz et al, 1985):

- The patient is allowed a 15-second trial period prior to testing
- Immediately before testing begins, the patient should place his/her hands on the sides of the box
- When testing begins, the patient should grasp one block at a time with the dominant hand, transport the block over the partition, and release it into the opposite compartment
- The patient should continue doing this for one minute
- The procedure should then be repeated with the non-dominant hand
- After testing, the examiner should count the blocks
- If a patient transports two or more blocks at the same time, this should be noted and the number subtracted from the total
- No penalty should be made if the subjects transported any blocks across the partition and the blocks bounced from the box to the floor or table

Set-up:

- A test box with 150 blocks and a partition in the middle is placed lengthwise along the edge of a standard-height table
- The patient should be seated on a standard height chair facing the box
- 150 blocks should be in the compartment of the test box on the side of the patient's dominant hand
- The examiner should face the patient so she or he could view the blocks being transported

¹ Downloaded from www.rehabmeasures.org

Test Instructions provided courtesy of Virgil Mathiowetz, PhD, OTRIL

Reference:

Mathiowetz, V., G. Volland, et al. (1985). "Adult norms for the Box and Block Test of manual dexterity." *Am J Occup Ther* 39(3160243): 386-391 .

Patient Instructions (derived from Mathiowetz et al, 1985):

"I want to see how quickly you can pick up one block at a time with your right (or left) hand {point to the hand}. Carry it to the other side of the box and drop it. Make sure your fingertips cross the partition. Watch me while I show you how."

Transport three cubes over the partition in the same direction you want the patient to move them. After a demonstration say the following:

"If you pick up two blocks at a time, they will count as one. If you drop one on the floor or table after you have carried it across, it will still be counted, so do not waste time picking it up. If you toss the blocks without your fingertips crossing the partition, they will not be counted. Before you start, you will have a chance to practice for 15 seconds. Do you have any questions?"

"Place your hands on the sides of the box. When it is time to start, I will say ready and then go."

Trial period: Start the stop watch at the word go. When 15 seconds has passed, say "stop." If mistakes are made during the practice period, correct them before the actual testing begins.

On completion of the practice period, transport the cubes to the original compartment.

Continued with the following directions:

"This will be the actual test. The instructions are the same. Work as quickly as you can. Ready." [Wait 3 seconds]

"Go."

"Stop." [After 1 minute, count the blocks and record as described above]

"Now you are to do the same thing with your left (or right) hand. First you can practice. Put your hands on the sides of the box as before. Pick up one block at a time with your hand, and drop it on the other side of the box."

"Ready." [Wait 3 seconds]

"Go."

"Stop." [After 15 seconds]

Return the transported blocks to the compartment as described above.

"This will be the actual test. The instructions are the same. Work as quickly as you can."

"Ready." [Wait 3 seconds]

"Go."

"Stop." [After 1 minute, count the blocks and record as described above]

Scoring

The score is the number of blocks carried from one compartment to the other in one minute. Score each hand separately.

Box and Blocks Testing Form

Name: _____

Dominant Hand (circle one): Right / Left

Number of blocks transported in one minute:

Date: ____/____/____ Dominant Hand: _____ Non-Dominant Hand: _____

Date: ____/____/____ Dominant Hand: _____ Non-Dominant Hand: _____

Date: ____/____/____ Dominant Hand: _____ Non-Dominant Hand: _____

Date: ____/____/____ Dominant Hand: _____ Non-Dominant Hand: _____

APPENDIX P

JEBSEN TEST OF HAND FUNCTION

Jebsen-Taylor Hand Function Test

With clarification and details for implementation in the RIC CBM

Original Protocol instructions** from the product manual are in boxes and are identified as "Original Instructions"

**Modification to Original Instructions in this document:

Rephrased to "prosthetic" and "non-prosthetic" side, since only to be administered on prosthetic side

Subjects are requested to "write" but they may "print" during the writing task.

The Jebsen-Taylor Hand Function Test is a seven-part, timed diagnostic test to determine the level of hand function. The seven subtests include:

- writing
- stacking
- simulated page turning
- lifting large, lightweight objects
- lifting small objects
- lifting large, heavy objects
- simulated feeding

The "procedure" and 'Verbal Instruction" portions of each subtest can be photocopied and cut to fit 3" x 5" note cards or a spiral notebook.

Directions

The key to proper administration of the Jebsen-Taylor Hand Function test is consistency. In order to ensure accurate results, each subtest must be reproduced exactly as described in these directions. Before each test is performed, make certain the subject understands the instructions completely. Each test must be timed. Included with the test is our electronic Digital Readout Stopwatch (7528) and all materials needed to perform each test. All images show test procedure if the prosthesis is on the left side.

Original Instructions

CBM Specific Clarifications of the testing procedure:

Photos of each test shown as if LEFT hand is prosthesis (under evaluation).

This file is intended to supplement the official Jebsen-Taylor Instructions. All text is from the Jebsen-Taylor Instruction. Images are identified as "Original Image" or "CBM".

Clarifications for use in the CBM:

- The test should be performed seated:
 - Height of seat and table should be set such that, when observing the non-prosthetic arm, the forearm should rest on the top of the table when the elbow is at 90 degrees and the humerus is vertical.
 - Chair can either have or not have arms. However, if the chair has arms, it should be ensured that they do not interfere with the elbow and arm movement
- Only the prosthetic side is to be tested
 - Unless otherwise noted (e.g. feeding and writing), for each test the prosthesis to begin in palm down position, wrist flexion at neutral, and hand closed with the elbow at 90 degrees. For direct control, the subject should begin in hand mode (and the grip that he/she states is most used)
- Subjects should be allowed to rest in between measures
- Subjects should be told, that for all tests:
 - If an item is dropped, they should continue the test. The item will be replaced by the administrator, and they can then repeat the item.
 - They should not stop and restart a test because "they think they can do it better"
- Users should be encouraged to practice the tests so that they know how best to preposition the arm and how to place utensils in the hand. For both the writing and simulated feeding tasks, the utensil should be placed in the terminal device prior to starting the timer.
- Subjects can be allowed to print if this is their preferred handwriting style
- If a task cannot be completed, a score of "CC" (cannot complete) should be recorded
- Board is only used in tests 4-7 and should be set up with longest side towards the subject

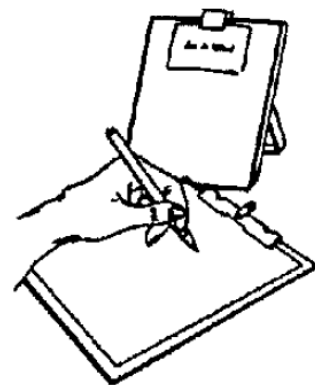
Subtest # 1 Procedure - Writing

Give the client a ball-point pen and four 8.5," x 11" sheets of unruled white paper fastened, one on top of the other, to a clipboard. The sentence to be copied has 24 letters and is of third grade reading difficulty. The sentence is typed in all capital letters and centered on a 5" x 8" index card. Present the card with the typed side face down on a bookstand. After the articles are arranged to the comfort of the subject (see verbal instructions), turn the card and give an immediate command to begin. Time from the word "go" until the pen is lifted from the page at the end of the sentence.

Subtest # 1 Verbal Instructions - Writing

"Do you require glasses for reading? If so, put them on. Take this pen in your prosthesis and arrange everything so that it is comfortable for you to write with your prosthesis. On the other side of this card (indicate) is a sentence. When I turn this card over and say "go", write the sentence as quickly and clearly as you can using your prosthesis. It is preferred that you write, and not print. Do you understand? Ready? Go."

Original Image:



CBM:



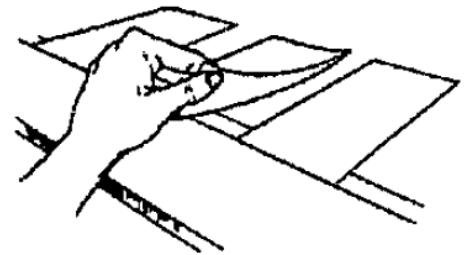
Subtest #2 Procedure - Simulated Page Turning

Place five 3" x 5" index cards, ruled on one side only, in a horizontal row two inches apart on the table in front of the subject. Each card is oriented vertically, 5" from the front edge of the table. The distance is indicated on the side edge of the table with a piece of tape. Time from the word "go" until the last card IS turned over. No accuracy of placement after turning is necessary.

Subtest #2 Verbal Instructions - Simulated Page Turning

"Place your prosthesis on the table please. When I say "go", use your prosthesis to turn these cards over one at a time as quickly as you can, beginning with this card (indicate card to extreme non-prosthetic side). You may turn them over in any way you wish and they need not be in a neat pattern when you finish. Do you understand? Ready? Go."

Original Image:



CBM:



Notes: Begin on extreme **non-prosthetic side**

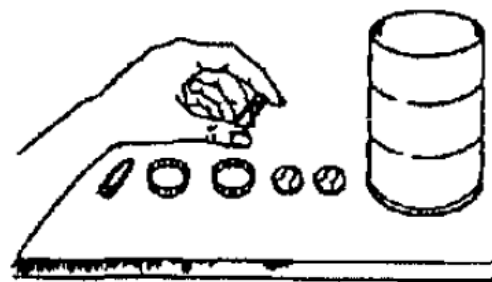
Subtest #3 Procedure - Lifting Small Common Objects

Place an empty 1-lb. coffee can directly in front of the subject, 5" from the front edge of the table. Place two 1" paper clips (oriented vertically), two regular-sized bottle caps (each 1" in diameter, placed with the inside of the cap facing up), and two U.S. pennies in a horizontal row to the prosthetic side of the can. The paper clips are the farthest and the pennies nearest the can. The objects are 2" apart. Time from the word "go" until the sound of the last object striking the inside of the can is heard.

Subtest #3 Verbal Instructions - Lifting Small Common Objects

"Place your prosthesis on the table please. When I say" go"; use your prosthesis to pick up these objects one at a time and place them in the can as fast as you can beginning with tills one (indicate paper clip on the extreme prosthetic side). Do you understand? Ready? Go."

Original Image:



CBM:



Notes: Begin with paper clip

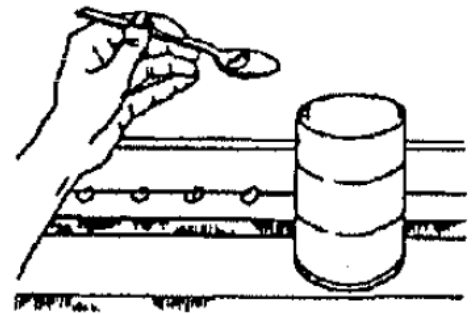
Subtest #4 Procedure - Simulated Feeding

Clamp board 5" from the front edge of the table. Place 5 kidney beans of approximately 0.5" length on a board. The beans are oriented to the prosthetic side of center, parallel to and touching the upright of the board 2" apart. Place an empty 1-lb. coffee can centrally in front of the board. A regular teaspoon is provided. Time from the word "go" until the last bean is heard hitting the bottom of the can.

Subtest #4 Verbal Instructions – Simulated Feeding

"Take the teaspoon in your prosthesis please. When I say "go", use your prosthesis to pick up these beans one at a time with the teaspoon and place them in the can as fast as you can beginning with this one (indicate bean on the extreme prosthetic Side). Do you understand? Ready? Go."

Original Image:



CBM:



Notes:

Set up with LONG side of board toward subject.
Begin on extreme **prosthetic side**

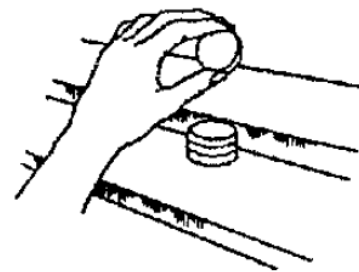
Subtest #5 Procedure- Stacking Checkers

Place four standard sized (1.4" diameter) red wooden checkers in front of the subject, touching a board clamped 5" from the front edge of the table. The checkers are oriented two on each side of the center in 0000 configuration. Time from the word "go" until the fourth checker makes contact with the third checker. The fourth checker need not stay in place.

Subtest #5 Verbal Instructions - Stacking Checkers

"Please place your prosthesis on the table. When I say" go," use your prosthesis to stack these checkers on the board in front of you as fast as you can like this, one on top of the other (demonstrate). You may begin with any checker. Do you understand? Ready? Go."

Original Image:



CBM:



Notes:

Checkers are set up 2" apart.
They may be moved in any order

Subtest #6 Procedure - Lifting Large, Light Objects

Clamp a board 5" from the front edge of the table.
Place five empty #303 cans in front of the board.
These cans are spaced 2" apart with the open end of the can facing down, with the center can centered in front of the user. Time from the word "go" until the fifth can has been released.

Subtest #6 Verbal Instructions - Lifting Large, light Objects

"Place your prosthesis on the table please. When I say "go," use your prosthesis to stand these cans on the board in front of you, like this (demonstrate). Begin with this one (indicate can on extreme prosthetic side). Do you understand? Ready? Go."

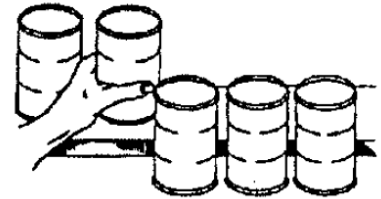
Subtest #7 Procedure - Lifting Large, Heavy Objects

Clamp a board 5" from the front edge of the table.
Place five full, one-pound #303 cans in front of the board. The cans are spaced 2" apart, with the center can centered in front of the user. Time from the word "go" until the fifth can has been released.

Subtest #7 Verbal Instructions - Lifting Large, Heavy Objects

"Now do the same thing with these heavier cans. Place your prosthesis on the table. When I say "go", use your prosthesis to stand these cans on the board as fast as you can. Begin here (indicating can on extreme prosthetic side). Do you understand? Ready? Go"

Original Image:



CBM:



APPENDIX Q

ASSESSMENT OF CAPACITY FOR MYOELECTRIC CONTROL (ACMC)



Assessment of Capacity for Myoelectric Control

Manual

Liselotte Norling Hermansson
Helen Lindner
Wendy Hill

Preface

Several persons contributed to the original development of *ACMC*: my doctoral supervisors professor Ann-Christin Eliasson, Karolinska Instiutet, and professor Lennart Bodin, Örebro University; former colleagues at the Limb Deficiency and Arm Prostheses centre at Örebro University Hospital; and last but not least, all clients who willingly participated in the data-collection for the development and psychometric testing of *ACMC*! I am deeply grateful for their contributions!

We would, further, like to give a special thank you to those who have helped to improve this manual: Kathy Stubblefield, Occupational Therapist at Rehabilitation Institute, Chicago, USA, for her valuable advices on the item definitions and the *ACMC* activities; and all course participants who, by their insightful questions have helped to clarify the item definitions further.

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Introduction

Assessment of Capacity for Myoelectric Control (ACMC) is a standardized clinical assessment designed to measure a person's ability to operate a myoelectric prosthetic hand. This test has been recognized by several reviews on outcome measures for upper limb prosthetic users^{1,2,3} and has also been used in clinical outcome studies⁴. The assessment is based on the observation of a person's performance in a self-chosen bimanual task.

The validity of ACMC was demonstrated earlier on ACMC assessments collected from upper limb prosthesis users; age ranging from 2 to 72 years old^{5,6}. The responsiveness of ACMC to detect ability change was evaluated with prosthetic users over an 18-month period and a change in ability was detected among these users⁷. Regular use of ACMC in daily clinical routine can, for example, be helpful in studying the factors that contribute to the change in ability to control a myoelectric prosthetic hand^{7,8}.

Since ACMC is an assessment that is based on clinical observations, it is important that the ACMC raters have the right assessment skills. During the development of ACMC throughout the years, it has been shown that proper assessment skill is necessary to assure consistent ratings, both within the same rater and among different raters⁹.

The aim of this training manual is to present the theoretical background of ACMC, the structure of the rating scale, and the definitions of the ACMC items. A guide to the administration of ACMC and suggestions for ACMC tasks is also included in this manual.

Theoretical background of ACMC

The hand

The human hand is unique. It can be used to feel the temperature and the shape of objects. It can be used to express our feelings. It can be a useful tool in the performance of our daily activities.

Even though a prosthetic hand can never replace all the functions of a human hand, the device can still be very useful in daily activities given that the prosthesis user knows how to use it.

Most of myoelectric prosthetic hands can be opened and closed voluntarily. In most prosthetic hands, when the hand is closing, the thumb is opposing against the tips of the index and middle fingers. This function enables the person to perform a precision grip, that is, the object is gripped between the fingertips ¹⁰. To perform a power grip, the object is gripped using the whole prosthetic hand. With this grip the object is held against the palm of the hand ¹¹.

One limitation with many of the myoelectric prosthetic hands available in the market is that they do not provide sensory feedback to the brain/body. The prosthesis user does not get any feedback from the prosthesis about, for example, that the prosthesis is resting on or holding something. Thus, in order to use the hand in daily activities, a new prosthesis user will have to practice and be familiar with, for example, that the prosthetic hand is holding, how it can be used to hold different objects and how much strength is needed in order to hold an object firmly etc. In order to review the person's progress in prosthetic use and to facilitate further goal settings, it is therefore important to assess the persons' prosthetic function with reliable and valid methods.

Outcome measures for upper limb prosthetics

There are two general categories of tools that are used to assess prosthetic function ¹². The first category consists of clinical observational assessments such as ACMC. These assessments are designed to assess how the person uses the prosthetic hand. The second category consists of self-rating questionnaires, by which the prosthesis user and/or the parent rate the usefulness of the prosthesis in everyday life. It is important for clinicians to have the knowledge to select the appropriate outcome measures that fit their aim of evaluation. Several authors stress the importance of the fact that clinicians and researchers to a higher degree should use tests that are proven to be valid for this specific population ¹³, and there has been a lot of work done to achieve this ¹⁴.

The *International Classification of Functioning, Disability and Health* (ICF) describes health conditions using different components that are related to human functioning ¹⁵ (Figure 1). Each

component is defined specifically and hence provides a useful framework to connect between treatment and outcome measures, facilitating the selection of the most appropriate outcome measure for the aim of the treatment.

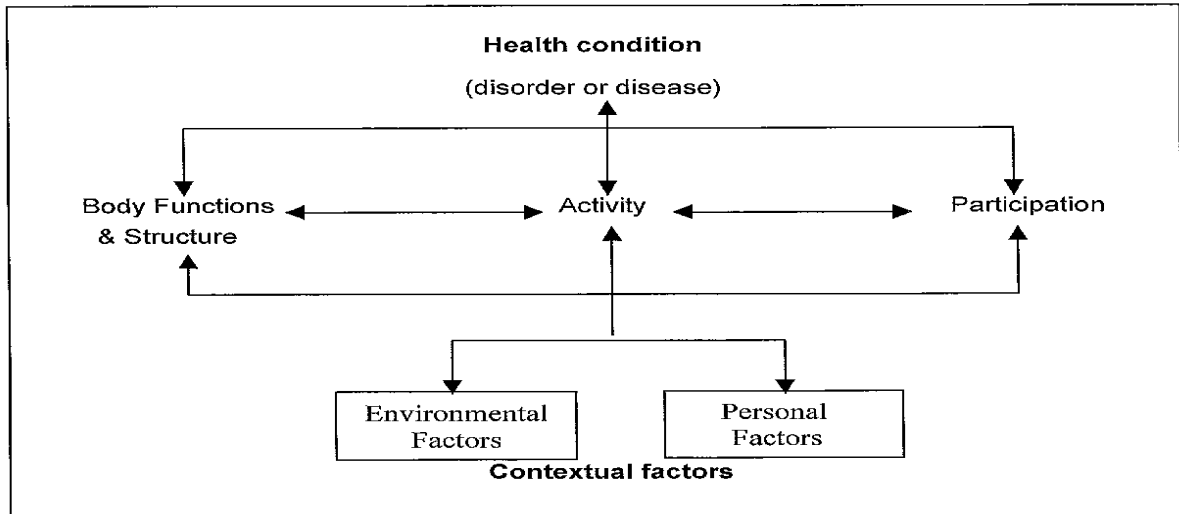


Figure 1. Framework of different components constituting health.

From: World Health Organisation. International Classification of Functioning, Disability and Health (ICF); Geneva, Switzerland: World Health Organisation; 2001 ¹⁵

Note: **Body functions** are the physiological functions of body systems (including psychological functions).

Body structures are anatomical parts of the body such as organs, limbs and their components.

Activity is the execution of a task or action by an individual.

Participation is involvement in a life situation.

According to the ICF component definitions, assessments from the first category, clinical observational assessment, focus on either the ‘*activity*’ component or both the ‘*body function*’ and ‘*activity*’ components. Questionnaires, which belong to the second category, focus on the ‘*activity*’ and ‘*participation*’ components. It is recommended that using both categories of outcome measures in our clinical routine will give us a better picture of the person’s prosthetic skill and the integration of prosthetic use in daily life ¹.

The prosthesis itself, as an assistive device, is categorized under the Contextual Factors as an ‘*environmental factor*’ according to the ICF.

What is the ‘Capacity for Myoelectric Control’?

Components such as a well-fitted socket, good voluntary muscle signals, proper calibration of electrodes, are all essential for the operation of a myoelectric prosthetic hand. The hand can best be operated when all these three components function optimally. The next question is then ‘how to use the hand’? The ability to control a myoelectric prosthetic hand is very individualized and can be trained. It can range from ‘*the need for arm support during holding*’ to ‘*able to adjust the grip of small objects without even having to look at the handgrip*’.

As mentioned earlier, most prosthetic hands can perform two different grips; power grip and precision grip. The three prosthetic hand movements are opening, closing and holding. Opening and closing are controlled voluntarily by the muscles. Holding, on the other hand, is a passive movement in which the muscle signals should maintain at a low level. The signal has to be low enough so that it does not reach the threshold and hence initiates the opening of the handgrip and dropping the object or the opposite – the closing of the handgrip and damaging the object.

From clinical experience we know that when a prosthesis user for the first time is fitted with a myoelectric prosthetic hand, his/her performance may be impacted by the weight of the prosthesis. This is shown by difficulty in activating the controlling muscle without supporting the weight of the arm. Regular prosthetic wearing and daily prosthetic use enables the person to overcome this and develop a ‘high capacity’ in controlling the prosthetic device. By practicing the use of the prosthetic hand in daily life activities the person may develop a capacity to control the hand that makes the prosthetic use smooth and natural. This can be shown by, e.g., the ability of re-adjusting the grip, i.e. to re-adjust the position of objects in the prosthesis with very small and quick repetitive movements. It may even be shown as a capacity to control the hand without use of visual support. Dr Rolf Sörbye (personal communication) explained this as being an “indirect” sensory feedback provided by the prosthetic hand. During the operation of the handgrip, the vibration from the motor in a below-elbow prosthesis is transmitted along the socket to the skin of the residual limb. Gradually, the prosthesis user may be able to associate the change in vibration during the operation of the hand to the grasping/releasing of an object.

Table 1. Rasch generated item difficulty measures for all 22 ACMC items. The items are listed in the order of item difficulty (from the most difficult to the easiest item).

Item name	Item difficulty measure
Repetitive grasp & release, without visual feedback	8.40
Appropriate gripforce, without visual feedback	6.99
Grasping without visual feedback	6.12
Releasing without visual feedback	2.89
Timing during grasping	1.94
Timing during releasing	1.21
Appropriate gripforce during grasping	1.16
Repetitive grasp & release	0.51
Holding in motion, without visual feedback	0.30
Grasping in different positions	0.22
Releasing in different positions	0.20
Coordinating during grasping	-0.01
Coordinating during releasing	-0.55
Holding without visual feedback	-0.62
Precision-grip	-1.99
Holding in motion	-2.52
Power-grip	-3.13
Releasing without support	-3.30
Holding without support	-3.52
Grasping with support	-4.33
Releasing with support	-4.57
Holding with support	-5.39

The ACMC is designed therefore to assess the person's ability to control these prosthetic hand movements. It consists of 22 items that are grouped into four hand use areas: gripping, holding, releasing and re-adjusting the grip (see Appendix 1 and 3). The items are varying in difficulty, ranging from very easy (Holding with support, -5.39 ACMC units) to very hard (Repetitive grasp and release, without visual feedback, 8.40 ACMC units), see Table 1.

The 22 items in the ACMC are rated on a 4-point rating scale.

The use of a 4-point rating scale

The structure of a rating scale, i.e. the number and definitions of the rating scale categories, has considerable influence on the quality of the data collected. All 22 ACMC items are rated on a rating scale consisting of four categories ranging from 0 - *not capable* to 3 - *extremely capable* (see Appendix 2). The scale is designed to represent increasing levels of capacity for prosthetic control. The use of the four-point rating scale has been evaluated⁶ and the category definitions have been changed accordingly. In Fig.2 it shows that the probability of selecting category-2 is now the same as selecting category 1, indicating that the new category-2 definition has improved the functioning of the rating scale (Figure 2).

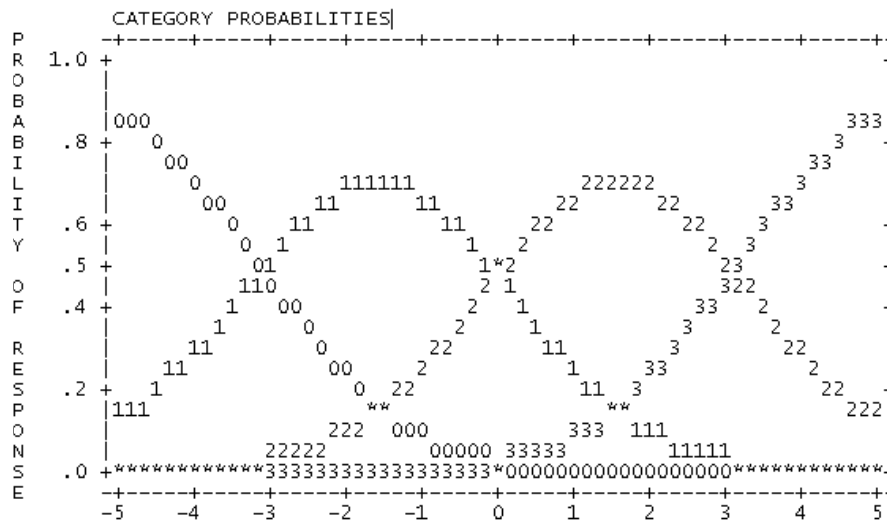


Figure 2. ACMC four-point rating scale category probabilities.

By studying the rating scale category on each item, the therapist can estimate the probability for a person with a specific ability measure to achieve a specific score on an item (Figure 3). For example, a person with an ability measure 0.25 is expected to score a '1' on item 18, Timing during releasing.

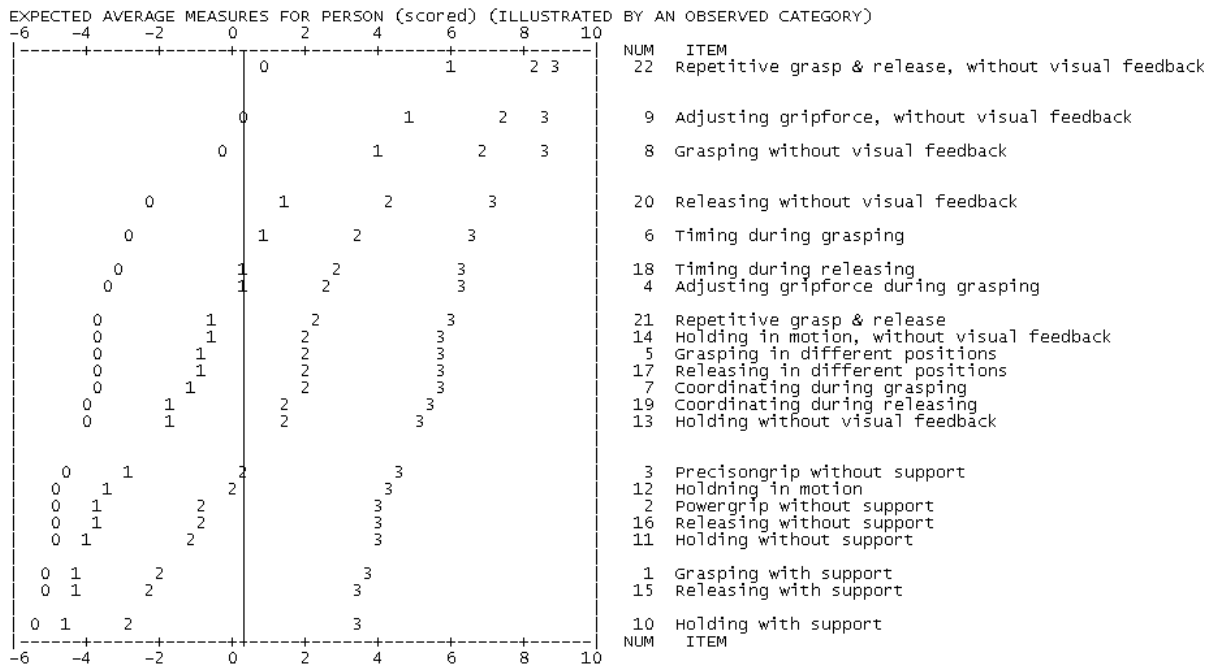


Figure 3. Expected average measures for persons.

In the rating scale, category 0 – *not capable* is assigned to an item when the person has attempted to perform the item but failed to perform it, or refused to try despite request to do so. Category 1 – *somewhat capable* is assigned when the item is performed with difficulty or sometimes fails. It is also assigned to the item when the item is performed with a significant delay, i.e. the item performance is a lot behind or slow. Further prosthetic training is recommended in those items that received category 0 or 1.

Category 2 – *generally capable* is assigned to an item when the quality of movement is questionable even though the person is able to perform the item. It is also given when a slight delay is observed, i.e. the item performance is not immediate and spontaneous. The person may need a reminder or a request before he/she performs this particular item. The reminder or request is embedded in the “slight delay”, which indicates that it is not immediate or spontaneous for some reason.

Category 3 – *extremely capable* is given when the item is performed smoothly and skilfully. The person is immediate and spontaneous in performing the item.

Psychometric properties of ACMC

The ACMC is developed with the help of Rasch analysis, a mathematical technique that constructs linear measures from raw scores that are derived from a ordinal rating scale (e.g. 3-*extremely capable to 0 – not capable*)¹⁶. The relationship between ordinal raw scores and linear measures is shown in Figure 4.

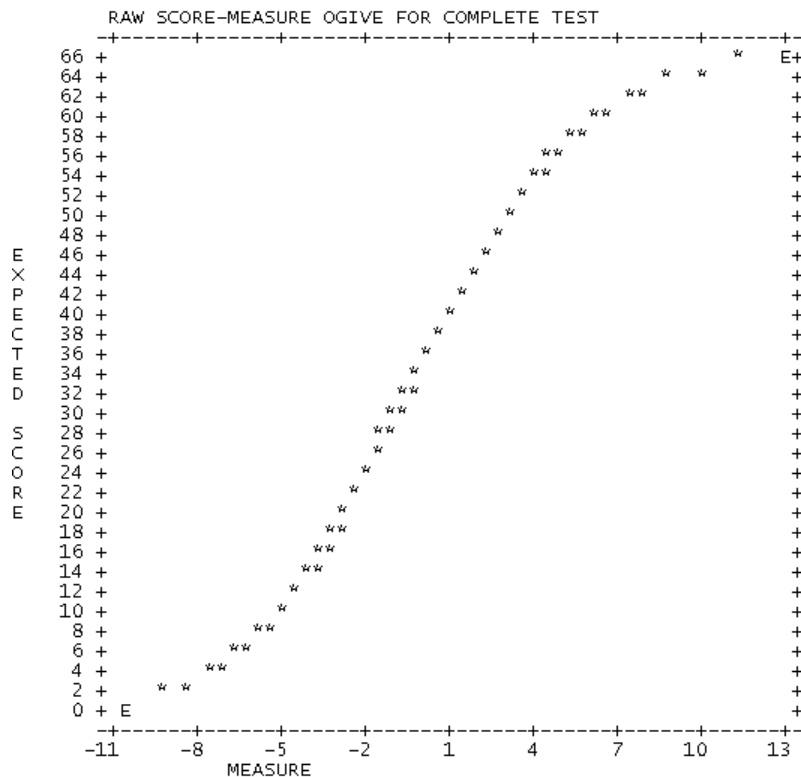


Figure 4. The non-linear relationship between sum raw scores and Rasch measure values in ACMC units.

Linear measures are commonly reported statistically in *logits* (log-odds probability units) in Rasch analysis and you will find logits in all ACMC publications. Many people find the concept of logits difficult to understand. Therefore, we have chosen to replace logits with ACMC unit in this manual. A prosthesis user would thus have an ACMC measure expressed in ACMC units.

The item difficulty and person ability measures represent different positions on the same common linear metric, thus resulting in hierarchies for items and persons. Good validity was shown in the first validity study of ACMC, the 30 item version⁵. All items measure the same single ‘prosthetic control’ dimension. The difficulty of all prosthetic control items was well targeted at the average sample ability. In the second validity study of ACMC⁶, the validity of ACMC was confirmed again. The person-item map in Figure 5 clearly shows the distribution of subjects in relation to the ACMC items. The mean person ability is 2.34 ACMC units (mean item difficulty is set at 0 by default), indicating that this sample has a high ability in operating a myoelectric prosthetic hand (Figure 5). Since 35 out of 58 subjects have more than 5 years of prosthetic experience, a high mean ability is expected.

PERSONS - ITEMS		
9	.#####	+
8	.###	+ Repetitive grasp & release, without visual feedback
7	##	+T Adjusting gripforce, without visual feedback
6	.##	S+ Grasping without visual feedback
5	.#####	+
4	#####	+
3	.##	+
2	#####	S
1	#####	+ Releasing without visual feedback
0	#####	M+ Timing during grasping
-1	#####	+
-2	.###	Holding in motion, without visual feedback
-3	#####	+M Coordinating during grasping
-4	#####	Grasping in different positions
-5	###	Releasing in different positions
-6	#####	Coordinating during releasing
-7	#####	Holding without visual feedback
-8	.#	+
-9	.#	S
-10	.#	+ Precision grip
-11	.##	Holding in motion
-12	###	+ Power grip
-13	.##	S Holding without support
-14	.#	+
-15	.	Grasping with support
-16	.#	+
-17	.#	+
-18	.#	+
-19	.#	+
-20	.#	+
-21	.#	+
-22	.#	+
-23	.#	+
-24	.#	+
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-94	.#	+
-95	.#	+
-96	.#	+
-97	.#	+
-98	.#	+
-99	.#	+
-100	.#	+

Each "#" is 2 persons. Each "." is 1 person.

Figure 5. Person-item map: persons' ability measures in relation to item difficulty measures.

M = mean for person ability and item difficulty. S = standard deviation.

Inter- and intra-rater reliability has also been evaluated in ACMC previously⁹ and the findings indicated that raters with experience in prosthetic rehabilitation made more consistent ratings than those with less experience in this field. Experienced occupational therapists showed excellent intra-rater reliability with repeated measures (*kappa* 0.81) and good inter-rater reliability with other raters (*kappa* 0.60). On the other hand, occupational therapists who had no experience in upper limb prosthetics only showed a good intra-rater reliability with repeated measures (*kappa* 0.65), and a fair inter-rater reliability when compared with other raters that have some experience in upper limb prosthetics (*kappa* 0.47).

The results from the rater reliability study also demonstrated that different raters had different severity in assigning ratings, i.e. some raters could be more severe in assigning ratings than other raters (-0.37 till 0.28 ACMC units). Therefore, ACMC raters must be first trained and then calibrated as to their severity. In the future, rater severity may be added as a factor when calculating person ability measure to prevent from raters influence on the measure. However, before the rater's severity can be calibrated, re-assessments with ACMC on the same prosthesis user should be made by the same rater ¹⁷.

The ACMC rating scale was also analysed in the second validity study of ACMC ⁶. The results showed that the raters have used the 4 rating scale categories in an expected manner. The 4-point rating scale differentiated the subjects on the basis of their abilities but the use of category 2 was somewhat redundant. Hence, a revision of the category 2 definition was suggested. This may improve the overall functioning of the rating scale.

Further development of ACMC, version 2.1 and 2.2

Based on the findings from the previous studies of ACMC's validity and rating scale structure ^{5,6}, a revision of ACMC was warranted. By omitting one item that was a misfit to the model of unidimensionality, and by "collapsing" five pairs of items to five individual items, the number of items was reduced from 30 to 24 in the new version of ACMC, version 2.1. The definition of the four categories in the rating scale have been revised and, as a result of the rating scale analysis, the rating for category 2 definition has been clarified (Appendix 2).

Reducing the length of a test can reduce administration time, which is good for a busy clinic environment. In version 2.2 we have further reduced the number of items to improve the clinical usefulness of ACMC. The items *Holding delicate objects* and *Adjusting opening width* were deleted. The ACMC 2.2 is now based on 22 items only (Appendix 1 and 3). The psychometric testing of this version showed that the items are functioning as expected and that the reduction of items improved the function of ACMC to separate persons on the basis of their ability ¹⁸.

The development of ACMC version 3

The ACMC unit measure has always been calculated using Rasch analysis, which by default sets 'zero' in the middle of the scale. Therefore new prosthesis users often got negative ACMC units.

It is difficult to report a negative value to clients when they want to know how they are doing in terms of prosthetic control. Therefore, we have now decided to report the ACMC units in a range of 0-100 (Table 2).

Table 2. Raw score to ACMC unit conversion (2015-10-14)

Raw Score	ACMC unit	Raw Score	ACMC unit	Raw Score	ACMC unit
0	0.0	23	38.1	46	57.2
1	6.0	24	38.9	47	58.2
2	10.5	25	39.7	48	59.1
3	13.6	26	40.5	49	60.1
4	16.0	27	41.3	50	61.0
5	18.1	28	42.1	51	62.0
6	19.9	29	42.9	52	63.1
7	21.6	30	43.8	53	64.1
8	23.1	31	44.6	54	65.2
9	24.6	32	45.4	55	66.4
10	25.9	33	46.2	56	67.6
11	27.1	34	47.0	57	69.0
12	28.2	35	47.8	58	70.5
13	29.3	36	48.7	59	72.3
14	30.3	37	49.5	60	74.3
15	31.3	38	50.3	61	76.7
16	32.2	39	51.1	62	79.7
17	33.1	40	52.0	63	83.4
18	33.9	41	52.8	64	87.8
19	34.8	42	53.7	65	93.2
20	35.6	43	54.5	66	100
21	36.4	44	55.4		
22	37.2	45	56.3		

Instead of using a scale centered in zero, ACMC units are now linearly transformed into a range of **0 -100**. This conversion is provided automatically by the Winsteps software that is built into the ACMC website. *One important point, if there are missing score, i.e. one or more items are not scored, you cannot use the table.* This is because the conversion is based on raw scores from 22 items and missing score would lead to a different result.

The difference between ACMC version 2.2 and 3 is the conversion 0-100. The ACMC website from now on will only report ACMC units in a range of 0-100. ACMC raters who would like to compare scores from earlier assessments are suggested to re-run the previous data in the ACMC website and get a 0-100 ACMC unit score. Go to the previous assessment and press Update/calculate to receive the results in 0-100 units. *Remember when you refer to ACMC results, always mention what version you refer to, i.e. version 2.2 or 3, to avoid misunderstandings.*

The **minimal detectable change** (MDC) was evaluated in the 2014 study of ACMC ¹⁹. The MDC indicates whether a change between ACMC assessments is due to measurement error or is a real change. Using the new converted scoring, the MDC is 2.5 ACMC units for the same rater (the same rater assesses the same patient) and 3.1 ACMC units for different raters (different raters assess a patient at different occasions, e.g. different clinical visits).

Development of ACMC tasks

ACMC was originally designed to be used with any familiar bi-manual task. Many raters found this difficult to plan and requested more structured task instructions. In order to facilitate the assessment for the raters, a process for selection of tasks and potential items to score was designed (see page 19-35) and was included in version 2.1. The procedure consisted of three stages. The first stage was to ask ACMC course participants (n=52, males=5, females=47) to suggest three activities that they would normally use in their training sessions or assessment. This resulted in 23 suggestions that could be separated into three ADL-areas (Table 3).

The second stage was to select six tasks from these suggestions. The selection was based on the following criteria:

- i) tasks that can be performed with a prosthetic hand
- ii) tasks of functional relevance that challenge the use of a prosthetic hand,
- iii) tasks that can be adjusted to different ages
- iv) tasks that can be performed in a clinical setting,
- v) tasks that can be accomplished within 10 minutes
- vi) all ACMC items can be seen in the different steps of the tasks

Table 3. ACMC task suggestions

PADL	IADL	
Self-caring	Household	Construction/hobby
• Dressing	• Changing car tires/car oil • Installing smoke alarm • Grocery shopping/using wallet • Stocking groceries in shelves • Making simple meals • Changing bed • Dishwashing • Ironing • Hanging laundry • Washing small laundry items • Packing suitcase • Setting up curtains	• Making clipboard, birdhouse, coat rack. • Painting • Hanging up pictures • Sewing • Fishing • Repotting plants • Pitching a tent • Wrapping gift • Making handcraft • Playing doll dress-up

This resulted in the development and standardization of six tasks:

1. Packing a suitcase
2. A ready-to-assemble project
3. Re-potting a plant
4. Setting table
5. Sorting bills or pictures
6. Mixing a store-bought mix

The third stage was to evaluate of the ACMC tasks to establish the difficulty and validity of the tasks¹⁹. The results show that *packing suitcase* (-0.26 units) is the easiest task (Table 4). The most difficult task is *setting table* (0.11 units). The total difficulty range between the tasks is -0.26 to 0.11 units, i.e. 0.37 ACMC units difference. Statistically we know that 0.5 units is

equivalent to 2 ACMC raw scores. Hence, a change in 0.37units is less than 2 ACMC raw scores, suggesting that the impact of the task difficulty difference on the ACMC score is minimal. The fit-statistics showed that all tasks are within the acceptable range, implying that these tasks are appropriate to be used in ACMC assessments, and are therefore valid ¹⁹.

Table 4. ACMC task difficulty

Task	Task difficulty
Packing a suitcase	-0.26
Sorting mail	-0.15
Mixing a ready-to-eat product	0.02
Re-potting plant	0.07
Assemble a ready-made project	0.21
Setting table	0.11

Detailed steps for tasks performance and materials needed for each task are described later in the manual.

Who can be assessed with ACMC?

ACMC is suitable for upper limb prosthesis users of all ages. It can be applied to assess users of different prosthetic levels, i.e. from the shoulder to the hand. Both persons with bilateral upper limb amputation and unilateral upper limb amputation can be assessed with ACMC. When assessing a bilateral upper limb amputee, the rater should only focus on one hand at a time. If a bilateral upper limb amputee wears only one prosthetic hand during the assessment, then the items - *coordinating when gripping*, and *coordinating when releasing* should be marked as ‘-’ in the scoring sheet since it is not possible to coordinate with only one hand.

As long as the person has the ability to operate a myoelectric hand, the person can be assessed with ACMC. As mentioned earlier, ACMC has been validated with persons ranging from 2 – 72 years of age. This means that it is valid for this age range. It is also possible to use ACMC to

assess persons with older age although the validity of ACMC has not been evaluated with persons older than 72 years.

In the second validity study of ACMC ⁶, assessments from 22 new prosthesis users were included. The results showed that ACMC was sensitive enough even to detect the difference in ability among new prosthesis users (see lower end of Figure 5). This sensitivity for differentiation in ability difference is extremely useful for therapists providing prosthetic training. The therapist can use ACMC to assess the initial ability of a new prosthesis user, set relevant training goals at an appropriate ability level, do the training, and use ACMC to evaluate the results from the training by comparing the results from the first and second assessment.

Administration of ACMC

Preparation

It is important to establish a good rapport with the person being assessed. The occupational therapist's assessment shall be based upon the performance of tasks that are meaningful and important to the person ^{20,21}. Every assessment is built upon the contact between the therapist and the person ²². The therapist has to find out, for example, how the person is doing, how the person is doing socially; e.g. with family and friends, what is the person's interest? Is it important to pursue this interest? Are there things that are difficult for the person to perform? etc.

Procedure

Begin with informing the person that you are going to observe how he/she uses the prosthetic hand in a self-chosen task. Ask the person what task he/she would like to choose. Bear in mind that the tasks for children have to be adjusted to their developmental level.

The choice of task is important for the completion of the assessment! Basically, any bimanual task can be used for the assessment with ACMC. In this manual you will find suggestions for six tasks. However, your client may decide to choose another, more appropriate, task. This is not a problem. If you decide to do so, please enter the chosen task on the website to allow for future testing of that.

It is the person who chooses the task but the occupational therapist must make certain that the task performance includes all the 22 ACMC items. The result from an earlier report that analyzed bimanual tasks and ACMC version 1.0 items showed that tasks that included all 30 ACMC items were the tasks that required the person to move around, take out and put different objects back into different places, etcetera ²³. Therefore, when setting up the task for a client, remember the six aspects of prosthetic control:

- arm support
- appropriate grip force
- different positions
- re-adjusting the grip
- coordination
- visual feedback

If necessary, the occupational therapist can show the person where the tools or other materials are, e.g. that knives and forks are in a particular drawer. Young children may need extra support and it is acceptable for the occupational therapist to interact with the child without interfering with the use of the prosthetic hand. If the child does not want to use the prosthetic hand, then the therapist should try to motivate the child to use the hand through play activities.

If possible, the rater should take a passive role and observe how the person performs the task. The assessment should not be based on the result of the task, for example, if the muffins are tasty or not. The assessment should only focus on how the person uses the prosthetic hand during the performance. Is it natural, that is, is the person spontaneous in opening, holding and closing the handgrip?

To help with the scoring that will be completed later, after the observation, the occupational therapist can take notes during the assessment. Short and simple words related to the above mentioned questions can remind you of the person's performance, for example, "looks at the hand", "arm support", "drops the pen", "delay when opening", etc.

Remember: We want to measure the ability to control the prosthetic hand. Some people lack spontaneity in prosthesis use, either because of, e.g. personality or habit. If spontaneity is missing, the capacity for control cannot be observed! That is the reason why we have to actively encourage the person to use the hand. If the hand is not used during the assessment, then it is not possible to assess the person's ability.

If, for example, a person does not use the hand for co-ordination or some other ACMC items, rating "0 – not capable" will be assigned to the items. The occupational therapist should encourage and even demonstrate the most natural way of doing the task by performing this item and ask if the person can perform the same movement. If doing so, the items may be assessed and the person may receive a "2 –generally capable" instead.

Scoring

Use the ACMC scoring sheet to fill in your assessment (Appendix 3). All 22 items are assessed on a 4-point rating scale (Appendix 2). Even if you know that the person is a skillful prosthesis user, you should always rate what you observe, not what you think the person can do or cannot do! Always choose a lower rating if you are in doubt about an item. The aim of the assessment is to help you to find out if the person needs more training in certain areas or movements, not to get as high a score as possible!

Remember: There is an important difference between *missing data* and a score of “0”!

Everything that you put in the scoring sheet will affect the result, and *missing data* and a “0” can make a great difference in the individual person ability measure!

Scoring of persons with a transhumeral amputation level or higher!

One important and useful aspect of myoelectric control is that it gives the person the ability to operate the hand in any position around the body. This is obtained when the muscles that generate control signals to the hand are isolated from the stabilizing muscles. “Support” refers to something external to the residual limb/prosthesis that is used to achieve this. The prostheses in persons’ with transhumeral amputation level or higher is considered un-supported when it is not being supported by another surface or the contralateral arm. A skilled transhumeral prostheses user is capable of prepositioning the elbow and hand, and targeting an object to grasp when the arm is away from the body, hence scored a ‘3’. Someone who is generally capable may take longer to do this or are only occasionally able to do it when the arm is away from the body and will, thus, be scored a ‘2’. A person who is somewhat capable may only be able to grasp when the arm is close to the body (but not supported against the side of the body) or with the elbow in only one position (i.e. 90 degree elbow flexion). This person would be scored a ‘1’. Someone not capable obviously requires external support and should be scored “0”.

The use of the prosthetic hand can depend on the person’s habit!

A person can use the hand differently in different tasks. If a person is quite capable in certain items at a particular task but not capable at another task, the difference in the capability can be due to the familiarity with the tasks or the habit of the person. If the prosthetic use is not spontaneous in the other task, it may be due the fact that the person is not familiar with the other

task and hence there is certain delay in the use of the hand. In order to eliminate the familiarity with the task, the rater should always assess the person's performance based on the entire assessment, which may include several tasks. It is important not to assign a lower rating because the person is spontaneous in a familiar task but not spontaneous in an unfamiliar task.

Choice of tasks

Let the prosthesis user choose what he or she would like to do on the basis of your setting and situation at work. Adjust the activity to your culture – clothing, baking mix, toys, etc.

For small children, the activity chosen should be in the form of playing – adjust the setting so that the child can perform the whole activity in a playing mode. The therapist is encouraged to engage the child in the activity through playing with different objects.

Use the materials that are suitable for the person's age and gender. Adjust the instructions and expectations according to the person's age. For example, choose the clothes that are suitable for the person's age and gender, the weights and sizes of objects are adjusted to the person's prosthetic hand, and even colours and other attributes that you think the person would like or would choose himself/herself!

The materials should be located inside different cupboards and drawers of different heights. If the assessment room does not have a double-door cupboard, pick a single-door cupboard where the cupboard door is opened in the direction towards the prosthetic side. Let the person go around the room to gather the materials. Suggest the person use a table to e.g. fold the clothes or assemble the parts. The person can choose if he or she would like to stand or sit during the activity. Instruct the person to return the materials back to their initial location.

Before the activity, give clear instructions about every activity step. Demonstrate the activity once to the patient. Tell them to use the hand grip as much as possible. Show the person where the materials are in different cupboards.

Remember: Assessment of Capacity for Myoelectric Control is an assessment designed to measure the maximum ability to operate the prosthetic hand. Therefore, it is important for us to

encourage the user to use the hand as much as possible during the assessment, e.g. use both hands to open the cupboard doors, fold the clothes with both hands etc.

During the activity, we may need to give both verbal and/or physical guidance to small children or new prosthesis users.

Trust your own experience and judgement in the choice of materials and verbal instructions to the users!

In the ‘Description of tasks’ section you can find ACMC items that are likely to be observed in each activity step. This is only a suggestion and it depends on how the person uses the hand. It is possible to see more ACMC items in each activity step.

Description of tasks

1. Packing a suitcase for overnight stay/gym bag

Before the activity – give instructions about the different parts of the activity, show where the materials are (use picture sets to show the locations of the materials if necessary). Instructions about the performance of the activity can be given after the client has taken out all the materials. Let the child choose the toys/book.

Material: A small travelling suitcase/gym bag/children cardboard suitcase
Clothes – e.g. trousers, T-shirts, socks, shoes, a string-pulled bag for the shoes
A small toiletry bag, toothpaste that can take the cap off, tooth brush
A bottle of vitamins or medicine with twisted lid and a smaller empty bottle or box to put some pills in (the bottle has to be able to fit nicely inside the prosthetic hand so that a power grip can be observed)
A big bath towel
Toys or a book

The materials should be located inside different cupboards and drawers of different heights. If the assessment room does not have a double-door cupboard, then use a cupboard where the door is opened towards the prosthetic hand.

Instruction: Fold the clothes and the towel neatly
Put the shoes into the shoe bag and use the strings to tighten the bag.
Put the toothpaste, toothbrush and medicine in the toiletry bag.
Put all the items into the suitcase/ bag and zip/clasp it.

Encourage the prosthetic user to use both hands when it is appropriate, e.g. open the cupboard doors, hold the t-shirt with both hands when folding, etc.

Activity step	Detailed steps	Example of ACMC items that can be observed
1. Gather items from the cupboards. Place them on a table.	• Open and close the cupboard doors. Take items out from the cupboards. (Probably the prosthetic hand is passively used when taking out the items i.e. the hand is not opened)	<i>Gripping</i> (with support, appropriate force, position, timing, co-ordinating, without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (with/without support, position, timing, co-ordinating, without visual feedback)

2. Get the clothes/toys/books and place in the suitcase/bag	• Fold the clothes and towel neatly • Fold the socks • Put them in the suitcase/bag	<i>Gripping</i> (precision grip without support, appropriate force, position, timing, co-ordinating, without visual feedback, appropriate force without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback) <i>Re-adjusting the grip</i> (repetitive grip and release with/without visual feedback)
3. Pack the medicine/ vitamins	• Open the bottle and take out some tablets • Put the tablets into the small bottle/box • Put the box into the toiletry bag	<i>Gripping</i> (power grip without support, precision grip without support, appropriate force, position, timing, co-ordinating, without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback)
4. Pack the toiletries	• Put the cap back on the toothpaste • Dry the toothbrush with a paper • Put them into the toiletry bag and zip the bag • Put the toiletry bag into the suitcase/gym bag	<i>Gripping</i> (precision grip without support, appropriate force, position, timing, co-ordinating, without visual feedback, appropriate force without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback)
5. Pack the shoes	• Put the shoes into the string-pulled bag • Pull the strings and tighten the bag • Put the bag into the suitcase/gym bag	<i>Gripping</i> (precision grip without support, appropriate force, timing, co-ordinating, without visual feedback, appropriate force without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback) <i>Re-adjusting the grip</i> (repetitive grip and release with/without visual feedback)
6. Fasten the suitcase /backpack (clasps or zippers)		Depending on the type of suitcase/gym bag, the prosthetic hand may be passively or actively used.

2. A ready-to-assemble project

Before the activity – Get input from the client about a project that he/she would like to assemble, show the finished product (that you have assembled in advance) if possible.

Material: Any craft project that assembles different parts together, e.g. a bird house, bird feeder kit, coat rack, magazine rack, Christmas decoration, Lego, play mobile or any wooden craft project that takes less than 10 minutes. No glue or paint is needed. Some parts should be able to fit nicely inside the prosthetic hand so that a power grip can be observed.

The materials should be located inside different cupboards and drawers of different heights. If the assessment room does not have a double-door cupboard, then use a cupboard where the door is opened towards the prosthetic hand.

Preparation: The parts are wrapped inside different plastic bags and placed inside two different boxes. Put the boxes in two different cupboards of different heights. If the assessment room does not have a double-door cupboard, then try to use a cupboard that the door is opened towards the prosthetic hand. Use picture sets to show the locations of the parts/boxes if necessary.

Instruction: Take the different parts out from the boxes.
Assemble the product according to instruction or to the client's inspiration
Tidy up and put away the boxes

Encourage the prosthetic user to use both hands when it is appropriate, e.g. open the cupboard doors, hold the boxes with both hands, etc.

Activity steps	Suggested detailed steps	Example of APMC items that can be observed
1 Take the boxes out from the cupboards.	• Open and close the cupboard doors • Take out the boxes and put them on a big table. (Probably the prosthetic hand is passively used when taking out the boxes)	<i>Gripping</i> (with support, appropriate force, position, timing, co-ordinating, without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (with/without support, position, timing, co-ordinating, without visual feedback)

2. Open the boxes and take the parts out.	• Stabilizes the box with one hand and open the box with the other hand • Take the parts out from the box. • Take the parts out from the plastic bags.	<i>Gripping</i> (precision grip without support, appropriate force, position, timing, co-ordinating, without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback)
3. Put the different parts together	• Grasp the Lego/wooden/metal pieces etc. and push them together	<i>Gripping</i> (with support, power grip without support, precision grip without support, appropriate force, position, timing, co-ordinating, without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback) Repetitive grasp and release (with/without visual feedback)
4. Tidy up	• Put the empty plastic bags into the boxes. Close the boxes. • Open the cupboards and put the boxes back into the cupboards. Close the cupboards.	<i>Gripping</i> (with support, precision grip without support, appropriate force, position, timing, co-ordinating, without visual feedback, appropriate force without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (with support, position, timing, co-ordinating, without visual feedback)

3. Re-potting a plant

Before the activity – give instructions about the different parts of the activity, show where the materials are (use picture sets to show the locations of the materials if necessary). Instructions about the performance of the activity can be given after the client has taken out all the materials.

Material: A plant pot

A sealed bag of soil

Scissors, spade or a small cup to shovel the soil, water jug

A plastic tablecloth or newspaper to cover the table

A pot plant

Decorative grains or stones in a transparent jar with twist lid (the jar is able to fit nicely inside the client's prosthetic hand so that a power grip can be observed)

A rubber band or a big clip to close the soil-bag

A broom set

The materials should be located inside different cupboards and drawers of different heights. If the assessment room does not have a double-door cupboard, then use a cupboard where the door is opened towards the prosthetic hand.

Instruction: Put the new soil into the new pot.

Take the plant out carefully from its original pot.

Carefully, hold the plant in the middle of the new pot and fill up the pot with new soil.

Decorate the soil surface with the decorative grains and water the plant.

Encourage the prosthetic user to use both hands when it is appropriate, e.g. open the cupboard doors, hold the jar and twist the lid, etc.

Activity step	Detailed steps	Example of ACMC items that can be observed
1. Place the table cloth or newspaper on a table	- Grasp the tablecloth/newspaper corners and open it - Place the cloth/newspaper on the table	<i>Gripping</i> (precision grip without support, appropriate force, position, timing, coordinating, without visual feedback, appropriate force without visual feedback) <i>Holding</i> (without support, in motion, without visual feedback, in motion without visual feedback)

		<i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback) <i>Repetitive grasp and release</i> (with/without visual feedback)
2. Gather the items from the cupboards at different heights around the room and place on a table	• Open and close the cupboard doors • Take out all the items from different shelves	<i>Gripping</i> (with support, appropriate force, position, timing, co-ordinating, without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (with support, position, timing, co-ordinating, without visual feedback)
3. Open the bag of soil and fill the pot with the new soil	• Hold the corner of the soil bag and cut an opening/take the rubber-band off to open it • Hold the opening with one hand and use the other hand to shovel the soil into the new pot	<i>Gripping</i> (precision grip without support, appropriate force, position, timing, coordinating, without visual feedback, appropriate force without visual feedback) <i>Holding</i> (with/without support, without visual feedback) <i>Releasing</i> (with/without support, position, timing, co-ordinating, without visual feedback)
4. Repot the plant	• Hold the new pot with one hand and use the other hand to make a small hole in the middle of the soil • Take the plant out from the old pot and place it in the new pot • Use one hand to hold the plant whilst using the other hand to put more soil to surround the plant	<i>Gripping</i> (with support, precision grip without support, appropriate force, timing, without visual feedback, appropriate force without visual feedback) <i>Holding</i> (with/without support, without visual feedback) <i>Releasing</i> (with/without support, timing, without visual feedback) <i>Repetitive grasp and release</i> (with/without visual feedback)

5. Decorate with the decorative grains and water the plant	• Open the jar and pour out the stones into the other hand • Spread the grains on the soil • Put the lid back to the jar • Fill the water jug with water and water the plant	<i>Gripping</i> (power grip without support, precision grip without support, appropriate force, position, timing, co-ordinating, without visual feedback, appropriate force without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (timing, without visual feedback)
6. Cleaning up	• Close the bag with the clip or rubber band • Put all the materials back to the cupboards or drawers • Fold the newspaper and throw it away, (or) Wipe the cloth and fold it together nicely • Wipe the table • Sweep the floor	<i>Gripping</i> (with support, precision grip without support, appropriate force, position, timing, co-ordinating, without visual feedback, appropriate force without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (with/without support, position, timing, co-ordinating, without visual feedback) Repetitive grasp and release (with/without visual feedback)

4. Setting table for 4 persons (table or picnic)

Before the activity – give instructions about the different parts of the activity, show where the materials are (use picture sets to show the locations of the materials if necessary). Instructions about the performance of the activity can be given after the client has taken out all the materials.

Material: A plastic tablecloth/cloth tablecloth
A serving plate
Four plates, glasses/mugs, napkins
Two muffins/donuts
A knife to cut the muffins/donuts
A bottle of ready-to-drink juice/squash (the bottle has to be able to fit nicely inside the prosthetic hand so that a power grip can be observed)

The materials should be located inside different cupboards and drawers of different heights. If the assessment room does not have a double-door cupboard, then use a cupboard where the door is opened towards the prosthetic hand.

Instruction: The table shall be set for four
Serve drinks
Divide and serve the bread on a plate
After the meal – clear the table

Encourage the prosthetic user to use both hands when it is appropriate, e.g. open the cupboard doors, hold the tablecloth corners and spread it on the table, etc.

Activity step	Detailed steps	Example of ACMC items that can be observed
1Gather the items from the cupboards at different heights around the room and place on a table	• Open and close the cupboard doors • Take out all the items from different shelves	<i>Gripping</i> (with support, appropriate force, position, timing, co-ordinating, without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (with/without support, position, timing, co-ordinating, without visual feedback)

2. Place the table cloth on a surface and 'set the table'	• Grasp the tablecloth corners and open it • Place the cloth on the surface • Place the plates and mugs on the top of the tablecloth • Fold the napkins and place them next to the plates	<i>Gripping</i> (precision grip without support, appropriate force, position, timing, co-ordinating, without visual feedback, appropriate force without visual feedback) <i>Holding</i> (without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback) Repetitive grasp and release (with/without visual feedback)
3. Serving drinks	• Open the bottle and pour out the drinks into the glass/mugs • Put the lid back to the bottle and put the bottle down	<i>Gripping</i> (power grip without support, appropriate force, timing, co-ordinating, without visual feedback) <i>Holding</i> (without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (with/without support, timing, without visual feedback)
4. Dividing and serving the muffins	• Hold the muffin with one hand and cut it into half with the knife • Put the muffins on a serving plate	<i>Gripping</i> (with support, precision grip without support, appropriate force, position, timing, co-ordinating, without visual feedback, appropriate force without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (with/without support, position, timing, co-ordinating, without visual feedback)
5. Clean off the table	• Take away the bottle, plates, glasses/mugs, rubbish etc. from the table • Wipe the plastic tablecloth and fold it; OR: fold the tablecloth and wipe the table	<i>Gripping</i> (precision grip without support, appropriate force, position, timing, co-ordinating, without visual feedback, appropriate force without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback)

		<i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback) Repetitive grasp and release (with/without visual feedback)
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5. Sorting bills or pictures

Before the activity – ask the client how he/she used to do this activity. If possible, let the client chooses his/her own way to open and sort out the bills.

Give instructions about the different parts of the activity, show where the materials are (use picture sets to show the locations of the materials if necessary). Instructions about the performance of the activity can be given after the client has taken out all the materials.

Material: A "post box"

Bills in at least three sealed envelopes of different sizes

A letter knife/a pair of scissors and a felt pen in a pen holder

Two boxes with lid for putting the bills or pictures (the size of the boxes should be able to fit nicely into the client's prosthetic hand so that a power grip can be observed)

White label stickers or colourful stickers

A rubbish bin

The materials should be located inside different cupboards and drawers of different heights. If the cupboard does not have double doors, then it is better to encourage the client to open the door with the prosthetic hand.

Instruction: Pick up the post (bills or pictures)

Open the envelopes and sort out the bills/pictures into different boxes

Close the boxes, put on stickers and put away the boxes

Throw away the rubbish and put away the materials

Encourage the prosthetic user to use both hands when it is appropriate, e.g. open the cupboard doors, hold the box when putting the bills or pictures into the box, etc.

Activity steps	Detailed steps	Example of APMC items that can be observed
1. Empty the post box. Take out the materials	• Open the lid of the postbox and take out the letters	<i>Gripping</i> (with support, appropriate force, position, timing, co-ordinating, without visual feedback)

from the cupboards and drawers. Put them on the table	• Take the boxes out from the cupboard • Open the cupboard and take out the pen holder, letter knife/scissors and stickers	<i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (with/without support, position, timing, co-ordinating, without visual feedback)
2. Use the letter knife/scissors to open the letters and take the bills/pictures out from the envelopes	• Take out the letter knife or scissors • Hold the envelope with one hand and open it with the other hand • Take out the bills or pictures and unfold them • Put the bills/pictures on the table	<i>Gripping</i> (precision grip without support, appropriate force, position, timing, co-ordinating, without visual feedback, appropriate force without visual feedback) <i>Holding</i> (without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback) Repetitive grasp and release (with/without visual feedback)
3. Label the boxes using the stickers	• Take the cap off the felt pen. • Write down the client's name or draw a small cartoon figure on the white label and stick them onto the boxes	<i>Gripping</i> (precision grip without support, appropriate force, position, timing, co-ordinating, without visual feedback, appropriate force without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (with/without support, position, timing, co-ordinating, without visual feedback) Repetitive grasp and release (with/without visual feedback)
4. Sort the bills/pictures and put them into the two boxes.	• Take the lids off from the boxes • Put the bills/pictures into the boxes. • Put the lids back to cover the boxes.	<i>Gripping</i> (with support, appropriate force, position, timing, co-ordinating, without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback)

5. Put away the boxes, penholder into the cupboards. Throw the rubbish	• Open the cupboard and put the materials and boxes back into the shelves. • Put the knife/scissors and pen back in the pen holder. Put the holder back into the cupboard. • Throw the empty envelopes into the bin.	<i>Gripping</i> (with support, power grip with support, precision grip without support, appropriate force, position, timing, co-ordinating, without visual feedback, appropriate force without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback)
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6. *Mixing a store-bought cake/pudding mix*

Before the activity begins, ask what the client would like to bake. The options include anything baked or not baked that can be made starting with a mix from a box. Examples are cakes, muffins, cookies or non-baked items such as pudding or gelatin dessert. Give instructions about the different parts of the activity, show the client where the materials are (use picture sets to show the locations of the materials if necessary). Detailed instructions about how to proceed can be given after the client has taken out the baking utensils and ingredients.

Material: Liquid soap and hand towel, or kitchen paper towel
A box of cake/pudding mix (the box should be able to fit nicely in the prosthetic hand so a power grip can be observed)
A mixing bowl, a whip/beater, stirring trowel or baking spatula
Measurement cups, tablespoon or teaspoon
A pair of scissors to open the bag of mix (if needed)
Depending on the choice of mix: margarine, milk, egg, etc
A saucepan to melt the margarine (if necessary)
Additional ingredients such as cream, fruit, ice-cream or jam (if needed)

The therapist must ensure that all ingredients required for the item are readily available in the assessment setting and placed in appropriate locations in the assessment setting. At least one item should be located in a cupboard with double doors, and other items should be placed at varying heights in the room. . If the assessment room does not have a double-door cupboard, use a cupboard where the door can be opened in the direction towards the prosthetic side.

Instruction: Wash hands!

Take out the ingredients and baking utensils
Open the box and empty it into the mixing bowl
Follow the mixing instructions
Put away the utensils and ingredients

The therapist should discuss the steps involved in the activity and encourage the client to use the prosthetic hand as much as possible throughout the assessment.

Activity steps	Detailed steps	Example of ACMC items that can be observed
1. Wash hands	• Turn on water • Use soap dispenser • Dry hands with towel/paper towel	<i>May be only passive use of the prosthetic hand</i>
2. Retrieve necessary items from around the room and place on work surface	• Open and close the cupboard doors • Take out all the items e.g. whip, mixing bowl, cake mix etc. from different shelves	<i>Gripping</i> (with support, appropriate force, position, timing, co-ordinating, without visual feedback) <i>Holding</i> (with/without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (with support, position, timing, co-ordinating, without visual feedback)
3. Open box and other sealed containers	• Use one hand to hold box and the other hand to open items. Scissors may be used if necessary.	<i>Gripping</i> (power grip, precision grip, appropriate force, position, timing, co-ordinating, without visual feedback) <i>Holding</i> (without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback)
4. Measure and pour ingredients into bowl	• Use one hand to hold box/bag and the other to hold measuring cup	<i>Gripping</i> (precision grip, appropriate force, position, timing, co-ordinating, without visual feedback) <i>Holding</i> (without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback)

5. Mix ingredients and pour into baking vessel or serving dishes	• Hold bowl with prosthesis while stirring or using electric hand mixer • Encourage use of two hands while pouring (one to hold the bowl upright and the other to scrape the sides). This may be eliminated for small children who are not strong enough to hold the bowl upright. • Put in oven or refrigerator	<i>Gripping</i> (precision grip, appropriate force, position, timing, co-ordinating, without visual feedback) <i>Holding</i> (without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback)
6. Put away all items	• Wrap or reseal packages and ingredients used. • Return items to their initial location, using two hands when appropriate.	<i>Gripping</i> (precision grip, appropriate force, position, timing, co-ordinating, without visual feedback) <i>Holding</i> (without support, in motion, without visual feedback, in motion without visual feedback) <i>Releasing</i> (without support, position, timing, co-ordinating, without visual feedback)

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Appendix 1: APMC item definitions

Area: Gripping

Grasping with support

Use the prosthetic hand to grasp objects of different sizes. The 'grasping' action is performed when the prosthetic hand/arm is being supported from underneath (e.g. *by the sound hand, against the body, resting on a table or on the object*).

Examples of ratings:

3

Extremely capable

Grasps an object skilfully, immediately and spontaneously.

2

Generally capable

The person is able to grasp objects but a slight delay is observed in a few occasions.

OR, the person needs to be reminded to grasp an object.

1

Somewhat capable

Significant delay is observed due to difficulty in grasping objects.

OR, sometimes fails to grasp.

0

Not capable

The prosthetic hand is laid on top of the object but the hand is not closed, even after being asked to grasp the object.

Area: Gripping

Power grip without support

Use the whole prosthetic hand to grasp a big object (the object is able to fit into the hand). Prepositioning of the hand and arm in space is demonstrated. No external support to the arm or hand is needed (such as support from a surface or the body or contralateral hand). The 'grasping' action is not affected by the prosthetic weight. The person is able to grasp when the weight of the prosthesis shifts (as with arm position or body position) for example in reaching away from the body.

Examples of ratings:

3

Extremely capable

Grasps the object skilfully, immediately and spontaneously. Good prepositioning of the arm and hand is observed. Is able to grasp away from the body.

2

Generally capable

Able to grasp without support but slight delays are observed occasionally when prepositioning the hand.

Or, when reminded to use the prosthesis, the person can do it skilfully.

1

Somewhat capable

Difficulty or significant delays are observed when grasping large objects without support to the hand.

0

Not capable

Not able to initiate the grip due to the prosthetic weight.

Area: Gripping

Precision grip without support

Use the prosthetic fingers to grasp small or part of large objects. Prepositioning of the hand is demonstrated. No external support to the arm or hand is needed (such as support from a surface or the body or contralateral hand). The grasping action is not affected by the prosthetic weight (e.g. take cap off a pen, tie shoelaces, grasp an envelope, fold a towel). The person is able to grasp when the weight of the prosthesis shifts (as with arm position or body position) for example in reaching away from the body.

Examples of ratings:

3

Extremely capable

Uses the prosthetic fingers to grasp any object skilfully, immediately and spontaneously away from the body.

2

Generally capable

Able to use the prosthetic fingers to grasp without support but occasional slight delays are observed.

1

Somewhat capable

Significant delay is observed or sometimes fails due to difficulty in grasping objects without support to the hand.

0

Not capable

Not able to use the prosthetic fingers in the right position to grasp without support to the hand.

Area: Gripping

Appropriate grip force

Grasp an object with appropriate force so that the object does not slip or crush (e.g. tie shoe strings or grasp a tomato).

Examples of ratings:

- | | |
|----------|--|
| 3 | <i>Extremely capable</i>
Grasp different objects with appropriate force. |
| 2 | <i>Generally capable</i>
Able to grasp the objects but questionable if object is grasped too hard or loose. |
| 1 | <i>Somewhat capable</i>
The object sometimes slips out of the hand.
Able to grasp it firmly to complete the task. |
| 0 | <i>Not capable</i>
The object slips out of the hand all the time, or the object is crushed right away when the person is trying to grasp it. |

Area: Gripping

Grasping in different positions

Grasp objects that are located in different positions relative to the body, e.g. on the floor or far away from the trunk of the body (e.g. grasp a tennis ball on the ground, stretch out the prosthetic hand to grasp a glass). The hand is not supported.

Examples of ratings:

- 3** ***Extremely capable***
The 'grasping' action is skilful, immediate and spontaneous independent of position.
- 2** ***Generally capable***
Able to grasp objects in two positions.
OR, slight delays are observed in certain positions.
- 1** ***Somewhat capable***
A significant delay is observed when grasping objects in certain positions.
OR: fails to grasp in more than one position.
- 0** ***Not capable***
Does not change position of the arm, instead changes body-position to be able to grasp objects at certain positions (e.g. turn towards the object to grasp it).
OR, grasps every object with the other hand and puts it in the prosthetic hand.

Area: Gripping

Timing during grasping

Grasp objects when the arm or the object is in motion. The grasping is performed in “flow”, i.e. without stopping the motion in order to grasp. The objects can be hanging free, moving away from or moving towards the person (e.g. tying apron string, pass the towel from the hand to the prosthetic hand when folding it).

Examples of ratings:

- 3** ***Extremely capable***
Grasp objects with good timing. The grasping action is skilful, immediate and spontaneous.
- 2** ***Generally capable***
Able to catch a moving object. Questionable if the movement is slightly interrupted.
- 1** ***Somewhat capable***
Sometimes able to grasp an object that is moving or hanging free.
- 0** ***Not capable***
Not able to grasp any object that is hanging free/moving towards or away from the person. The object must be stopped by the sound hand before it can be grasped by the prosthetic hand.

Area: Gripping

Coordinating both hands during grasping

Coordinate the grip of both the prosthetic hand and the sound hand when grasping different objects that would normally be performed with two hands together (e.g. opening cupboard doors, or grasping a large bag of soil).

Similar item: repetitive grip and release. Coordinating both hands during grasping can be done without repetitive grip and release.

Examples of ratings:

3

Extremely capable

The coordination of both handgrips is skilful, immediate and spontaneous.

2

Generally capable

Able to use both hands together but a slight delay is observed. OR, when reminded to grip with two hands, can do so skilfully.

1

Somewhat capable

Able to grasp with both hands but a significant delay is observed when coordinating both handgrips.

0

Not capable

Not able to coordinate the handgrips when grasping an object with both hands.

Area: Gripping

Grasping without visual feedback

Grasp an object without looking at the handgrip.

Using the eyes to locate an object is NOT the same as looking at the prosthetic hand when grasping the object.

Examples of ratings:

3

Extremely capable

Grasp different objects without looking at the prosthetic hand.

2

Generally capable

It is questionable if the person needs to look at the handgrip when grasping different objects.

1

Somewhat capable

Sometimes looks at the prosthetic hand when grasping.

0

Not capable

Look at the prosthetic hand all the time when grasping objects.

Area: Gripping

Appropriate grip force without visual feedback

Grasp an object firmly or loosely enough so that the object does not slip out of the hand nor is it crushed by the prosthetic hand. The 'grasping' action is performed without looking at the hand.

Examples of ratings:

3

Extremely capable

Grasps different objects with appropriate force without looking at the prosthetic hand.

2

Generally capable

It is questionable if the person looks at the hand when grasping different objects with appropriate force.

1

Somewhat capable

Sometimes looks at the prosthetic hand when applying appropriate grip force during grasping.

0

Not capable

Looks at the prosthetic hand all the time when grasping objects.

Area: Holding

Holding with support

Able to maintain holding an object with the hand/arm resting on some form of surface (on the sound hand/against the side of the body/on the table/on top of the object). The handgrip is not opened uncontrollably due to unintended activation of muscles.

Examples of ratings:

3

Extremely capable

Maintains holding an object securely, e.g. the bicycle handlebar, when the hand is resting on the object.

2

Generally capable

Attention is required to not activate the hand when holding an object.

1

Somewhat capable

When holding the object, the hand is opened uncontrollably in a few occasions. Able to maintain the 'holding grip' at the end.

0

Not capable

Cannot maintain the 'holding' grip at all. Open the handgrip unintentionally.

Area: Holding

Holding without support

Maintain holding an object without arm being supported from underneath. The handgrip is not opened uncontrollably due to unintended activation of muscles. Example of task: take money out from a wallet

Examples of ratings:

- 3** ***Extremely capable***
Hold, e.g., the wallet firmly when opening the zipper to pay.
- 2** ***Generally capable***
Able to release the support with some delay.
OR, questionable if grip is secure.
- 1** ***Somewhat capable***
Drops the object once or twice during accidental opening of the handgrip.
- 0** ***Not capable***
Drops the object every time when holding it.
Unable to hold without support.

Area: Holding

Holding in motion

Able to maintain holding an object when the body or the arm is in motion, e.g. when moving an object from one place to another. The hand is not supported. The handgrip is not opened uncontrollably due to unintended activation of muscles.

Examples of ratings:

- | | |
|----------|--|
| 3 | <i>Extremely capable</i>
Holds an object securely and spontaneously when the arm is moving. |
| 2 | <i>Generally capable</i>
Questionable if grip is secure. |
| 1 | <i>Somewhat capable</i>
Drops the object in a few occasions. |
| 0 | <i>Not capable</i>
Not able to maintain the grip when holding the object. Drops the object all the time. |

Area: Holding

Holding without visual feedback

Able to maintain the grip when holding objects without looking at the prosthetic hand.

Examples of ratings:

- 3** ***Extremely capable***
Holds objects securely and spontaneously without looking.
- 2** ***Generally capable***
Able to hold without looking at the hand after receiving verbal support from the therapist.
- 1** ***Somewhat capable***
Drops the object in a few occasions if the person is not looking.
OR: Able to hold the objects some of the time without looking at the prosthetic hand
- 0** ***Not capable***
Looks at the prosthetic hand all the time when holding. Drops the objects if the person is not looking.

Area: Holding

Holding in motion, without visual feedback

Holds an object when the body or the arm is in motion. The hand is not supported. No visual feedback is needed when holding. The hand is not opened uncontrollably due to unintended activation of muscles (e.g. holding the skipping rope spontaneously and securely when skipping, or take out food from the fridge spontaneously and securely to the workplace without looking at the handgrip).

Examples of ratings:

3

Extremely capable

Holding different objects in motion without looking at the prosthetic hand

2

Generally capable

Succeeds in holding in motion without looking at the hand after receiving verbal support from the therapist.

1

Somewhat capable

Drops the object once or twice due to not looking at the hand.

OR, needs to secure the grasp by looking at the hand.

Able to maintain the grip at the end without looking at the prosthetic hand.

0

Not capable

Always looks at the hand when holding an object. Drops the object all the time if not looking at the prosthetic hand.

Area: Releasing

Releasing with support

Releases an object when the prosthetic hand/arm is being supported from underneath, e.g., by the sound hand, against the body, resting on a table, or on the object (e.g. release the door handle or put a mug on the table).

Examples of ratings:

- | | |
|----------|--|
| 3 | <i>Extremely capable</i>
Releases objects skilfully, immediately and spontaneously. |
| 2 | <i>Generally capable</i>
Able to release objects with support but a slight delay is observed in a few occasions. |
| 1 | <i>Somewhat capable</i>
Significant delay is observed due to difficulty in releasing the object. |
| 0 | <i>Not capable</i>
Not able to release the object at all despite the arm being supported. |

Area: Releasing

Releasing without support

Releases the object without the hand/arm being supported. Prepositioning of the hand is demonstrated. The action is not affected by the prosthetic weight (e.g. release an envelope or put the tablecloth directly on to the table).

Examples of ratings:

- | | |
|----------|---|
| 3 | <i>Extremely capable</i>
Releases objects skilfully, immediately and spontaneously without the arm being supported. |
| 2 | <i>Generally capable</i>
Able to release objects without support but a slight delay is observed in a few occasions. |
| 1 | <i>Somewhat capable</i>
Significant delay is observed due to difficulty in opening the hand or releasing objects without support to the hand. |
| 0 | <i>Not capable</i>
Not able to release the objects without having the arm supported. |

Area: Releasing

Releasing in different positions

Release objects in any arm position e.g. on the floor or far away from the trunk of the body. The hand is not supported. Assess if the person changes his/her body position when releasing (e.g. release a bag on the table).

Examples of ratings:

3

Extremely capable

The 'releasing' action is skilful, immediate and spontaneous independent of the body position in relation to the object.

2

Generally capable

Able to release in two positions.
OR, slight delays are observed in certain positions.

1

Somewhat capable

Significant delays are observed when releasing objects in certain positions.
OR, sometimes fails to release in certain positions.

0

Not capable

Does not change position of the arm, instead changes body position.
OR, avoids releasing at certain positions; instead releases to the other hand in order to put the object in the right place, i.e. release in only one position.

Area: Releasing

Timing during releasing

Release of an object, high or low, when the arm or the object is moving (e.g. throw a tennis ball to the ground).
OR: The arm or the object continues the movement after release of the object (e.g. puts down an object to the table without stopping the arm movement, closes a cupboard).

Examples of ratings:

- | | |
|----------|---|
| 3 | <i>Extremely capable</i>
Releases objects with good timing. |
| 2 | <i>Generally capable</i>
Able to release objects with good timing.
Questionable if the movement is slightly interrupted. |
| 1 | <i>Somewhat capable</i>
Sometimes able to release objects with good timing. |
| 0 | <i>Not capable</i>
Releases objects too early or late. |

Area: Releasing

Coordinating the hands during releasing

Coordinate both the sound hand and the prosthetic hand when releasing different objects (e.g. let go of baby carriage, climbing monkey bar, laying table cloth on table top).

Similar item: repetitive grip and release. Coordinating both hands during releasing can be done without repetitive grip and release.

Examples of ratings:

3

Extremely capable

The coordination of both hands to release is skilful, immediate and spontaneous.

2

Generally capable

Able to release with both hands together but a slight delay is observed.

OR, when reminded to release with two hands, can do so skilfully.

1

Somewhat capable

Able to release with both hands but a significant delay is observed when coordinating both handgrips.

0

Not capable

Not able to coordinate the release from both hands.

Area: Releasing

Releasing without visual feedback

Prepositions the prosthetic hand and releases the object without looking at the hand.

Examples of ratings:

- 3** ***Extremely capable***
Releases objects skilfully and spontaneously without looking at the prosthetic hand.
- 2** ***Generally capable***
Releases objects without looking at the prosthetic hand but the quality of the prepositioning is questionable.
OR, questionable if the person needs to look at the hand in a few occasions when releasing.
- 1** ***Somewhat capable***
Sometimes looks at the prosthetic hand when releasing.
- 0** ***Not capable***
Looks at the prosthetic hand all the time when releasing objects.

Area: Re-adjusting the grip

Repetitive grip and release

Changes the position of the object, the position of the hand or the grip force, with repetitive grip and release using the prosthetic hand. Re-adjusting the grip does not necessarily involve the use of both hands, but when using two hands the object is either in the prosthetic hand or in the sound hand, e.g. for task of cutting with scissors. If so, re-adjusting the grip involves coordination of both hands. A high score in this area is, thus, indicating a high score on *Coordinating both hands*.

Examples of ratings:

3

Extremely capable

Grips and releases an object repetitively. The action is skilful, immediate and spontaneous.

2

Generally capable

Able to grasp and release repetitively but a slight delay is observed when changing the grip in a few occasions.

1

Somewhat capable

A significant delay is observed when grasping or releasing the object repetitively.

0

Not capable

Not able to grasp and release the object repetitively.

Area: Re-adjusting the grip

Repetitive grip and release, without visual feedback

Alters the position of the object with repetitive grip and release. No visual feedback is needed when altering the object's position (e.g. for task of tying apron string behind the back). Re-adjusting the grip does not necessarily involve the use of both hands, but when using two hands the object is either in the prosthetic hand or in the sound hand. If so, re-adjusting the grip involves coordination of both hands. A high score in this area is, thus, indicating a high score on *Coordinating both hands*.

Examples of ratings:

3

Extremely capable

Grips and releases an object repetitively without looking at the prosthetic hand. The action is skilful, immediate and spontaneous.

2

Generally capable

Able to grasp and release an object repetitively but questionable if the person needs to look at the hand in a few occasions.

1

Somewhat capable

Tries to re-adjust the grip without looking but fails several times.

0

Not capable

Not able to re-adjust the grip without looking.

Appendix 2: ACMC 4-point rating scale

3 Extremely capable

The item is performed smoothly and skillfully. The use of the prosthetic hand is immediate and spontaneous.

2 Generally Capable

Able to perform the item but the quality of movement is questionable. The use of the prosthetic hand can be slightly delayed, for example, when verbal support is required to perform the item.

1 Somewhat capable

The item is performed with difficulty or sometimes fails. The use of the prosthetic hand can be significantly delayed.

0 Not capable

Cannot perform the item even after several attempts.

OR

Does not attempt to perform the item at all.

– The item cannot be observed due to:

The person is a bilateral amputee and hence hand coordination is not possible.

Appendix 3: APMC Scoring Sheet

Client (name, DOB): _____ Male ☐ Female ☐

Congenital ☐ Acquired ☐ Side, level: _____ Use time: _____

Task: _____ Assessment date: _____

Gripping		Holding	
With support		In motion	
Power grip, without support		Without visual feedback	
Precision grip, without support		In motion, without visual feedback	
Appropriate grip force		Releasing	
In different positions		With support	
Timing		Without support	
Coordinating both hands		In different positions	
Without visual feedback		Timing	
Appropriate grip force, without visual feedback		Coordinating both hands	
		Without visual feedback	
Holding			
With support		Re-adjusting the grip	
Without support		Repetitive grip & release	
		Repetitive grip & release, without visual feedback	

APPENDIX R

SOUTHAMPTON HAND ASSESSMENT PROCEDURE (SHAP)



Assessor's SHAP Protocol

With clarification and details for implementation in the
RIC CBM

Original Protocol instructions from the University of
Southampton are in boxes and are identified as
"Official Instructions"

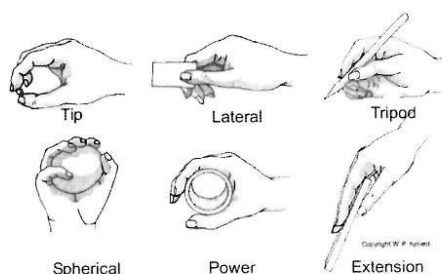
General Information

The Southampton Hand Assessment Procedure (SHAP) has been formed based on the analysis of grip patterns, and their frequency of use in Activities of Daily Living (ADL) tasks. Therefore it is considered to cover the wide range of prehensile tasks the hand usually undertakes (with the omission of specific occupational or recreational requirements).

The test consists of the manipulation of a series of both lightweight and heavyweight abstract objects. These are intended to directly reflect specific grip patterns, whilst also assessing the strength and compliance of the grip. This is followed by 14 ADL tasks. To ensure standardisation, the assessor's test procedure must be followed, whilst objectivity is maintained by participant self-timing. A complete assessment is expected to take around 20 minutes to complete (including all of the relevant explanations to the subject).

The procedure is designed to provide a score of functionality, which can be equated with a percentage; hence on completion of the test a score of optimum hand function is obtained. This score provides a tangible result describing the level of hand impairment, e.g. the participant has 75% of optimum hand function. As the procedure has been designed to be standardised and objective, this score cannot only be used for comparative assessments of a participant's performance throughout a course of treatment, but also provides information on their level of function (this is with respect to the benchmark of an unimpaired participant).

The protocol outlined in the following pages provides details for the assessor concerning the setup and execution of the test. The assessor is required to demonstrate each task to the descriptions given. The following diagram may help identify the appropriate grip patterns.



Official Instructions

Contents of SHAP Test

Quantity	Item
1	Test case containing all SHAP equipment
1	Backboard mounted in case with lock & key, door handle and zip
1	SHAP form-board
1	Foam insert containing all objects
1	Timer unit
6	Lightweight abstract objects (see figure below)
6	Heavyweight abstract objects (see figure below)
1	Lock and key mounted on backboard
1	Zip mounted on backboard
4	Coins (2 x 1p and 2 x 2p)
1	Button board with 4 buttons attached
1	Plasticine block
1	Knife
1	Note card
1	Glass jar with lid
1	Glass jug
1	Cardboard juice carton
1	Empty tin with plastic lid
1	Door handle mounted on backboard
1	Metal arrow unit
1	Screwdriver

SHAP Abstract Object Tasks

Lateral
Extension
Tip
Cylinder
Sphere
Tripod

Official Instructions

Assessor's SHAP Protocol

Setting up the SHAP

The participant should be seated at a table with arms resting on the table. The participant's elbows should be at a 90° angle.

Place the SHAP form-board in front of the participant blue side facing upward, approximately 8cm from the front edge of the table. Fit the timer unit into the space provided in the front of the board. For each of the SHAP abstract object tasks, the board should be moved from left to right so that each task is directly in front of the participant, thereby ensuring no bias toward either hand dominance. The SHAP case and all ADL objects can be removed from the table during this first phase of the assessment.

Procedural Notes

Each task should be demonstrated to the participant using slow, clear movements, ensuring that the participant is aware of the appropriate grip for completion of the abstract object tasks.

It is important to note that the demonstration should be carried out using the corresponding hand under assessment, to avoid any confusion for the participant.

Prosthesis users should be encouraged to practice each task, prior to timing it, in order to determine the most appropriate technique as many users usually carry out tasks with the natural hand alone. Due to the difficulties associated with myoelectric prostheses, if it is apparent that the device has failed to respond to user demand, then a note should be made, and a retest allowed. If the device is similarly unresponsive during the second task, a note should be made of the difficulties encountered.

In other circumstances, the participant should be given only one chance to carry out the timed task. The time taken to complete each task, the appropriate grip pattern if identifiable should be recorded, as well as any relevant notes.

When establishing any form of normative data, it is imperative that the task is carried out fully. Due to the need to complete a task in the minimum amount of time there is often a temptation to 'rush' the task without actually fulfilling the exact requirements. Under these circumstances the task should be repeated.

Completing the SHAP Test

In the forthcoming document, normal text denotes instructions for assessors. Text in italic text denotes instructions to be read to participants. The SHAP website contains video demonstrations to help with accurate placement of the ADL tasks on the form board (please refer to <http://www.shap.ecs.soton.ac.uk/about-usage.php> for further guidance on completing the SHAP tasks).

Official Instructions

CBM Specific Clarifications of the testing procedure:

- ❖ Test is performed seated
 - Height of seat and table should be set such that, when observing the non-prosthetic arm, the forearm should rest on the top of the table when the elbow is at 90 degrees and the humerus is vertical.
 - Chair can either have or not have arms. However, if the chair has arms, it should be ensured that they do not interfere with the elbow and arm movement
 - Unless otherwise noted, for each test the prosthesis to begin in palm down position, wrist flexion at neutral, and hand closed with the elbow at 90 degrees. For direct control, the subject should begin in hand mode (and the grip that he/she states is most used)
- ❖ Only the prosthetic side is to be tested
- ❖ Subjects should be allowed to rest in between measures
- ❖ Subjects should be told, that for all tests:
 - If an item is dropped, they should continue the test. The item will be replaced by the administrator, and they can then repeat the item. Timer should NOT be stopped.
 - They should not stop and restart a test because "they think they can do it better"
 - Timer must be started with prosthetic hand (or restart trial)
- ❖ Practice/instruction is especially important for subject to know how to grasp knife and screwdriver to complete test appropriately. For any test the subject has not done before, let them figure out the best way to do it before beginning the trial.
- ❖ Preposition is allowed but should occur after the timer is started
- ❖ Specific items:
 - Orientation of abstract items should be shifted so that they are centered in front of the subject for each one
 - Square "mug": must be picked up by handle
 - Knife: can be placed into the prosthesis by non-prosthetic hand
 - Cutting putty: It can be held in place by other hand and does not need to be cut into equal size pieces
 - Screwdriver: can be placed into the prosthesis by non-prosthetic hand

CBM

SHAP Abstract Object Tasks

The 6 lightweight objects are to be completed first. If a participant cannot complete a task, this could be recorded as C/C (Cannot Complete) on the supplied SHAP test data sheet. All lightweight abstract objects are completed, followed by all heavyweight abstract objects.

"A series of objects will be placed on the board. The task involves moving the object from the rear slot on the board to the front slot. Only the hand under assessment (dominant hand) should be used for any of these tasks, including the starting and stopping of the timer."

Official Instructions

Set up shown as if LEFT hand is prosthesis (under evaluation)

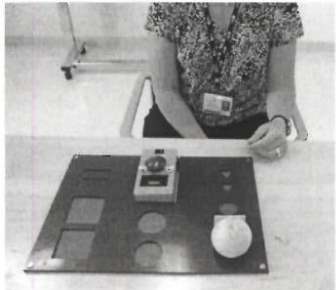
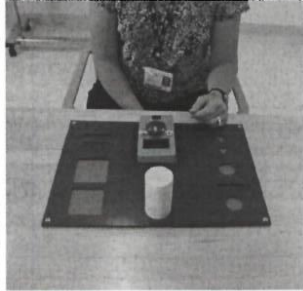
Photos of each test set up are shown in the following pages. This file is intended to supplement the official SHAP manual. The SHAP manual should be reviewed for further detail and for the instructions to read to the subject.

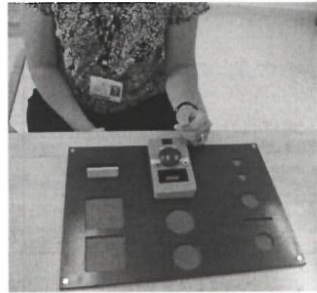
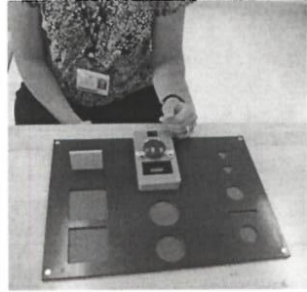
Setup board 8cm (approximately 3") from edge from the edge of the table.
Shift the board such that the object being evaluated is directly in front of the subject.

Start with lightweight objects, repeat with heavy objects



CBM

Official Instructions	CBM clarification of start position
Spherical Place the 'spherical object' in the appropriate rear slot. Place the 'tip object' in the slot between the rear and front 'spherical object' slots to create a small barrier. Move the board so that these slots are directly in front of the participant whilst maintaining the approximate 8cm distance from the front of the table. Using the spherical grip move the object over the barrier and place it in the front slot. <i>"Start the timer, pick up and move the object as demonstrated with as few mistakes as possible, and <u>as quickly as possible</u>, to the front slot. Complete the task by depressing the blue button on the timer again."</i>	
Tripod Place the 'tripod object' in the appropriate rear slot. Using a tripod grip, move the object to the front slot. <i>"Start the timer, move the object as demonstrated and as quickly as possible to the front slot and then stop the timer."</i>	
Power Place the 'power object' in the appropriate rear slot. Move the board so that these slots are directly in front of the participant whilst maintaining the approximate 8cm distance of the board from the front of the table. Using the power grip, pick up the object and move it to the front slot. <i>"Start the timer, move the object as demonstrated and as quickly as possible to the front slot and then stop the timer."</i>	

Lateral Place the 'lateral object' in the appropriate rear slot with the handle facing toward the participant. Move the board so that these slots are directly in front of the participant whilst maintaining the approximate 8cm distance from the front of the table. Using the lateral grip, pick up the object by the handle and move it to the front slot. <i>"Start the timer, move the object as demonstrated and as quickly as possible to the front slot and then stop the timer."</i>	Note: Must pick up with handle 
Tip Place the 'tip object' in the appropriate rear slot. Using a tip grip, move the object to the front slot. <i>"Start the timer, move the object as demonstrated and as quickly as possible to the front slot and then stop the timer."</i>	Note: Shorter rectangle 
Extension Place the 'extension object' in the appropriate rear slot. Using an extension grip, move the object to the front slot. <i>"Start the timer, move the object as demonstrated and as quickly as possible to the front slot and then stop the timer."</i>	Note: Taller rectangle 
The procedure above should now be repeated, in the same order using the heavyweight abstract objects.	

Activities of Daily Living (ADLs)

Once completed, remove all the abstract objects from the table and turn over the form-board. Place the board directly in front of the participant for all ADL tasks at approximately 8cm from the front of the table.

Activities of Daily Living

As before, each task should be demonstrated to the participant using slow, clear movements, ensuring that the participant is aware of the appropriate procedure.

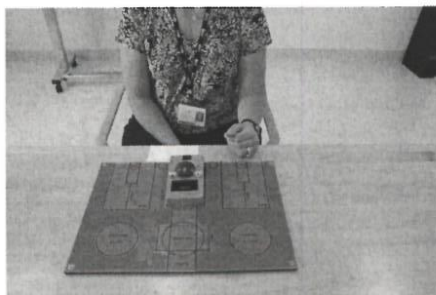
The 'Optional' instructions should be used when the assessor feels that the participant would be unable, is uncomfortable, or unnatural in using the demonstrated grip.

To avoid repetitive filling/emptying of objects with water for the pouring tasks (jug, carton and full jar tasks), it is advisable to fill a separate container with approximately 1 litre of water. It may also be advisable to have a towel nearby to clear any spillage.

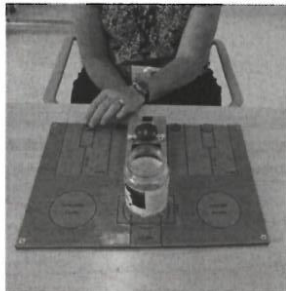
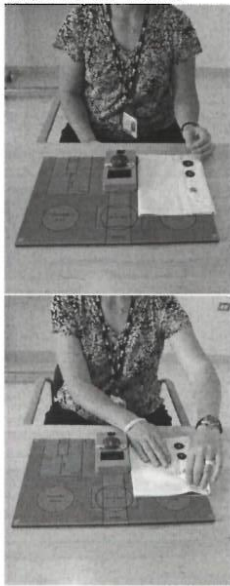
"The second stage of this assessment consists of 14 everyday activities, which should be timed in the same manner by pressing the blue button to start and stop the timer. Again tasks should be completed as quickly as possible, with as few mistakes as possible, using only the appropriate hand unless otherwise stated."

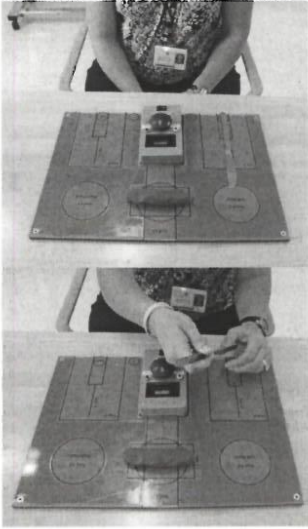
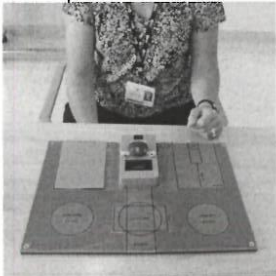
Official Instructions

Setup board 8cm (approximately 3") from edge from the edge of the table.
The timer should remain centered in front of the user, unless noted



CBM

Official Instructions	CBM clarification of start/stop position(s)
Pick Up Coins Arrange the two 2p and two 1p coins in the designated areas on the board. Place the glass jar in the designated spot for this task with the lid removed. Pick up each coin in turn by sliding the coin to the edge of the board using a tip or tripod grip and drop each coin into the glass jar. Move from right to left. Reset the task for the participant. <i>"Start the timer, lift each coin in turn as quickly as possible, and drop it in the jar as demonstrated. Repeat that for all the coins and then stop the timer."</i> <i>[OPTIONAL: If you feel unable to pick up the coins as demonstrated, you may use any method you wish, whilst only using one hand.]</i>	Note: Start on opposite side to prosthetic hand 
Button Board Place the button board to the right of the timer unit if assessing the right hand, and to the left if assessing the left hand. The buttons should be farthest from the timer unit. Undo each button in turn, using only the assessed hand in a tripod grip. The other hand may be used to steady the board, but may not assist in the task. The button board should remain on the form-board at all times. Reset the task for the participant. <i>"Start the timer and using only the appropriate hand, undo all four buttons in any order as demonstrated and as quickly as possible. You may steady the button board with your other hand so that it remains on the form-board throughout the task. Then stop the timer using only the appropriate hand."</i>	Note: Can begin with any button and can stabilize board with other hand 

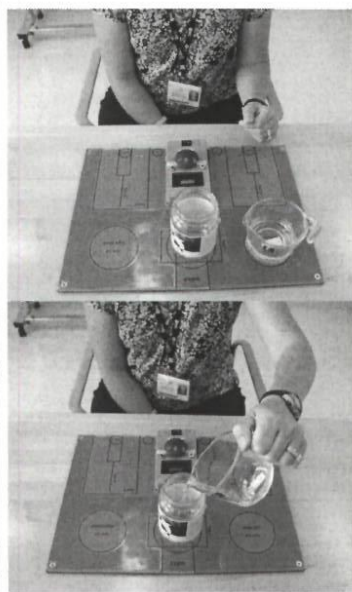
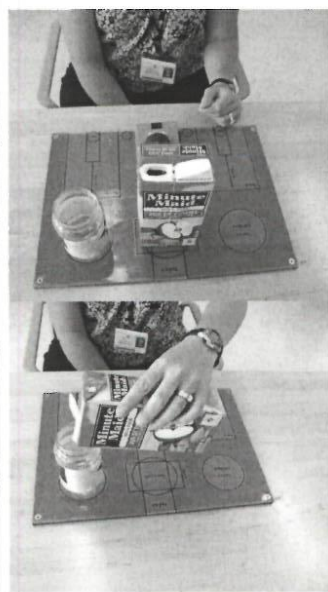
Simulated Food Cutting Place the knife to the side of the timer unit (right side for right-handed assessments, left side for left-handed assessments). Place the plasticine 'food item' in the designated area on the form board (mould to look like a sausage and fit approximately the area on the form board). Pick up the knife, using the other hand to steady the plasticine. Cut it clearly into two sections. Then replace the knife on the form board. Reset the task by remoulding the plasticine for the participant. <i>"Start the timer, use the knife provided to cut the plasticine clearly into two pieces, as demonstrated and as quickly as possible. You may use the other hand to steady the plasticine. Return the knife to its starting position on the board and the stop the timer."</i>	Note: Can use other non-prosthetic hand to place knife, AFTER starting timer. "Food" can be held by non-prosthetic side and it does not need to be cut into equal size pieces. 
Page Turning Place the piece of card in the designated area on the opposite side of the platform to the hand under assessment. Using an extension or tripod grip, pick up the card, turn it over as if turning the pages of a book and place it on the opposite side of the form board (on the side under assessment). Reset the task for the participant. <i>"Start the timer lift and turn over the card as if you were turning the pages of a book and place the card on the opposite side of the board as demonstrated and as quickly as possible. Then stop the timer."</i>	Start position:  End position: 

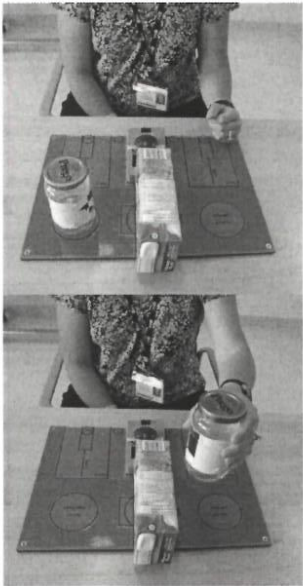
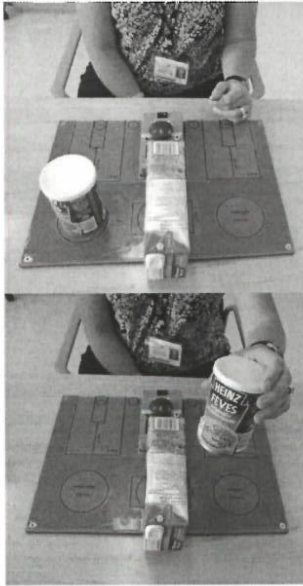
Jar Lid The lid should be placed on the empty glass jar and tightened only with sufficient force as would be expected for everyday use/self storage. The jar should be placed in the designated area on the form board. Both hands should be used for this task. Pick up the jar using a power grip with the non-dominant hand, undo the lid and return both the jar and the lid to the designated areas on the platform. Reset the task for the participant.

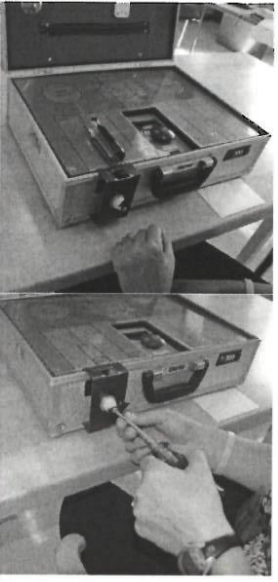
"Start the timer, pick up the jar and undo the lid with the hand under assessment as demonstrated and as quickly as possible. Return the jar and lid to the platform as demonstrated and stop the timer."

Note: Jar empty



Glass Jug Pouring Fill the glass jug with 100ml of water (100ml is marked on the jug). Place the jug in the designated area of the form board with the handle of the glass jug pointing the right for right-handed participants, and to the left for left-handed participants. Place the glass jar (without the lid) on the designated left area for right-handed participants and the right for left-handed participants. Lift the glass jug by the handle using a lateral grip and show how to pour the water into the glass jar. Reset the task for the participant. <i>"Start the timer and whilst ensuring as little spillage as possible, pour the water from the jug into the jar as demonstrated and as quickly as possible. Replace the jug on the board and then stop the timer."</i>	Note: 100ml in "jug" 
Carton Pouring Empty the glass jar from the previous task and replace the jar in the same position on the form board. Fill the carton with 200ml of water (measured out in the glass jug). Place the carton in the designated area on the form board with the spout of the carton pointing toward to glass jar (according to the handedness defined for the previous task). Pick up the carton using a power grip and show how to pour the water into the glass jar. Reset the task for the participant. <i>"Start the timer and whilst ensuring as little spillage as possible, pour the water from the carton into the jar as demonstrated and as quickly as possible. Replace the carton on the board and then stop the timer."</i>	Note: 200ml in carton 

Lifting a Heavy Object Fill the glass jar with water to the top of the label and tighten the lid. Place the jar in the designated area on the form board, on the left side of the board for right-handed participants and the right side of the board for left-handed participants. Place the empty carton lengthways along the middle of the form board (without obstructing the timer unit) to create a barrier. Lift the jar over the carton using a power grip and place on the opposite side of the form board in the designated area. Reset the task for the participant. <i>"Start the timer, move the jar over the carton to the other side of the board as demonstrated and as quickly as possible. Then stop the timer."</i> [THE WATER CAN NOW BE DISPOSED OF AND WILL FORM NO FURTHER PART IN THE ASSESSMENT.]	Note: Jar filled to top of label. 
Lifting a Light Object Place the empty tin (with the plastic lid on) in the same position on the board as defined for the jar in the previous task and keep the carton in the same position on the form board creating a barrier. Lift the tin over the carton using the power grip and place on the opposite side of the form board in the designated area. Reset the task for the participant. <i>"Start the timer, move the tin over the carton to the other side of the board as demonstrated and as quickly as possible. Then stop the timer."</i>	

Rotate a Screw Place the screwdriver in the designated area on the form board on the right side for right-handed participants and the left for left-handed participants. The arrow unit is mounted on a clip, which should be attached to the front of the case (again, the right side for right-handed participants and the left for left-handed participants). Use the area directly in front of the screwdriver between the lock and the handle on the case. Ensure the arrow is pointing upward. Use two hands to guide the screwdriver to the screw and rotate it 90° clockwise to the mark on the clip using one hand only. Hold the screwdriver in a power grip. You may hold the clip on the top of the case to keep it stable with your other hand. Reset the task for the participant. <i>"Start the timer and use the screwdriver to rotate the screw a quarter turn clockwise to, or beyond the white mark as demonstrated and as quickly as possible. Once completed, the screwdriver should be replaced on the platform and the timer stopped. Two hands may be used to guide the screwdriver to the screw, but only the appropriate hand should be used for turning the screw. Your other hand can be used to steady the top of the arrow unit."</i>	Note: Screwdriver can be placed into the prosthesis by non-prosthetic hand. Turn ¼ turn from vertical clock-wise. There is no stop. Do not return to "start" 
Door Handle Rotate the door handle using a power grip until it is fully open, then release the handle. <i>"Start the timer, rotate the door handle until it is fully open and then release it as demonstrated and as quickly as possible. Then stop the timer."</i>	Note: Instruct subject to grasp handle and turn; however, TD does not need to be fully closed around handle. 

APPENDIX S

PATTERN RECOGNITION ERROR

Pattern Recognition Error Form

Subject: _____ Date: _____

Calibration Speed: ☐Slow ☐Medium ☐Fast

Movements:

Notes:

Elbow Flexion	
Elbow Extension	
Wrist Pronation	
Wrist Supination	
Hand Close	
Hand Open	
Rest	

Recorded Data Location: _____

Pattern Recognition Matrix:

	Predicted Movement								
Desired Movement		EF	EE	WP	WS	HC	HO	REST	Error Percent
	EF								
	EE								
	WP								
	WS								
	HC								
	HO								
	Rest								

Error Percent: is defined as the percentage of predicted movements that do not match the number of desired movements.

APPENDIX T

SUBJECT QUESTIONNAIRES



3086

Patient ID#

Date / /

UPPER EXTREMITY FUNCTIONAL STATUS

I. Please indicate your affected limb(s). ☐ Left arm ☐ Right arm ☐ Both arms

II. How many hours per day do you currently wear your prosthesis or orthosis?

III. Using the scale to the right, please indicate how easily you perform the following activities.	Very easy	Easy	Slightly difficult	Very difficult	Cannot perform activity	Not applicable	IV. Do you usually perform this activity using or not using your prosthesis or orthosis?	
							Using	Not using
1. Wash face	☐	☐	☐	☐	☐	☐	☐	☐
2. Put toothpaste on brush and brush teeth	☐	☐	☐	☐	☐	☐	☐	☐
3. Brush/comb hair	☐	☐	☐	☐	☐	☐	☐	☐
4. Put on and remove t-shirt	☐	☐	☐	☐	☐	☐	☐	☐
5. Button shirt with front buttons	☐	☐	☐	☐	☐	☐	☐	☐
6. Attach end of zipper and zip jacket	☐	☐	☐	☐	☐	☐	☐	☐
7. Put on socks	☐	☐	☐	☐	☐	☐	☐	☐
8. Tie shoe laces	☐	☐	☐	☐	☐	☐	☐	☐
9. Drink from a paper cup	☐	☐	☐	☐	☐	☐	☐	☐
10. Use fork or spoon	☐	☐	☐	☐	☐	☐	☐	☐
11. Cut meat with knife and fork	☐	☐	☐	☐	☐	☐	☐	☐
12. Pour from a 12 oz can	☐	☐	☐	☐	☐	☐	☐	☐
13. Write name legibly	☐	☐	☐	☐	☐	☐	☐	☐
14. Use scissors	☐	☐	☐	☐	☐	☐	☐	☐

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3086		Patient ID#							
III. Using the scale to the right, please indicate how easily you perform the following activities.									
	Very easy	Easy	Slightly difficult	Very difficult	Cannot perform activity	Not applicable	IV. Do you usually perform this activity using or not using your prosthesis or orthosis?		
							Using	Not using	
15. Open door with knob									
16. Use a key in a lock	☐	☐	☐	☐	☐	☐	☐	☐	
17. Carry laundry basket									
18. Dial a touch tone phone	☐	☐	☐	☐	☐	☐	☐	☐	
19. Use a hammer and nail									
20. Fold bath towel	☐	☐	☐	☐	☐	☐	☐	☐	
21. Open an envelope									
22. Stir in a bowl	☐	☐	☐	☐	☐	☐	☐	☐	
23. Put on and take of prosthesis or orthosis									
24. Open a bag of chips using both hands	☐	☐	☐	☐	☐	☐	☐	☐	
25. Twist a lid off a small bottle									
26. Sharpen a pencil	☐	☐	☐	☐	☐	☐	☐	☐	
27. Peel potatoes (or fruit) with a knife/peeler									
28. Take bank note out of the wallet	☐	☐	☐	☐	☐	☐	☐	☐	

PROJECT BUDGET SUMMARY

Current as of: APR2020

Organization: HJF-Henry M. Jackson Foundation
Award #/Name: 64991 - MYONODES IMES TRANSHUMERAL
Award Manager: PASQUINA, PAUL
Award Period: 05/01/2016 to 05/30/2020
Award Sponsor: US ARMY MED RES ACQUISITION ACTIVITY
Ref Award#: W81XWH-16-2-0009

Project #/Name: 308586 - IMES MYOELECTRIC SENSORS
Project Manager: TAYLOR, JERIKA ALLISON
Project Period: 05/01/2016 to 05/30/2020
Billing Analyst: LI, MING YIN
Primary Analyst: BAUGH, DAKSHINA U.

Current As of	Award/Project Number	Category Group	Expenditure Category	Current Month Expenses	Budget	Open Commitment	Project-To-date Expenses	Total Funds Used	Balance Available	Percentage Available
04/30/2020	64991 - 308586	DIRECT	PERSONNEL	3,284.39	477,817.00	0.00	14,369.47	14,369.47	463,447.53	96.99
			SUPPLIES	0.00	6,523.00	0.00	0.00	0.00	6,523.00	100.00
			DOMESTIC TRAVEL	0.00	4,000.00	0.00	0.00	0.00	4,000.00	100.00
			PARTICIPANTS	0.00	10,000.00	0.00	0.00	0.00	10,000.00	100.00
			SUBAWARDS	111,648.30	2,008,901.00	691,022.31	1,317,878.69	2,008,901.00	0.00	0.00
			TOTAL DIRECT :	114,932.69	2,507,241.00	691,022.31	1,332,248.16	2,023,270.47	483,970.53	19.30
		INDIRECT	USU OFF-SITE OVERHEAD	127.45	20,487.00	0.00	562.91	562.91	19,924.09	97.25
			COMPANY-WIDE G & A	576.62	74,211.00	0.00	2,377.16	2,377.16	71,833.84	96.80
			SUBAWARD RATE	3,293.62	20,221.00	20,385.16	20,378.81	40,763.97	-20,542.97	-101.59
			TOTAL INDIRECT :	3,997.69	114,919.00	20,385.16	23,318.88	43,704.04	71,214.96	61.97
			TOTAL PROJECT :	118,930.38	2,622,160.00	711,407.47	1,355,567.04	2,066,974.51	555,185.49	21.17

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