COAPT GEN2

# Reimbursement & Authorization Guide

v2.0



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Dear Intuitive Control Trailblazer,

Thank you for your considering the Coapt COMPLETE CONTROL System Gen2 pattern recognition platform for your patient. We commend you as an innovative clinician who embraces technological advances for the benefit of your clients. As a company dedicated to providing advanced solutions to individuals with upper-extremity limb loss, we are confident the Coapt COMPLETE CONTROL System Gen2 is the best choice to improve control and function for your patient. We are committed to our partnership with you—both supporting you in providing our product to your patients and providing you with information and support as you go through the reimbursement process.

In this package, we have prepared a comprehensive reimbursement guide containing information that may be helpful to you as you submit a comprehensive and compelling reimbursement justification. Our package provides you with information on the necessary steps to facilitate the reimbursement process, along with helpful information to increase your chances of receiving successful authorization. While we strive to provide you with the most up-to-date information and tips to support your reimbursement claim, please remember this package contains sample text only, and use of this guide does not guarantee reimbursement.

Please do not hesitate to contact us if you have any questions, if you would like additional information to support you in providing our system to your patients, or if you need further help funding request.

Founded in 2012, based on research from the Shirley Ryan AbilityLab (formerly known as the Rehabilitation Institute of Chicago), Coapt is focused on developing the best advanced control technologies for myoelectric prostheses. By providing exceptional customer service, we ensure our technologies are made fully available to our customers and provide a support system to assist you with any questions along the way.

Again, we thank you for your interest and look forward to partnering with you to meet your patients' needs.

Kind regards,

Blair Lock, CEO

Coapt LLC

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# OVERVIEW OF COAPT'S COMPLETE CONTROL PATTERN RECOGNITION TECHNOLOGY

## WHAT IS PATTERN RECOGNITION CONTROL?

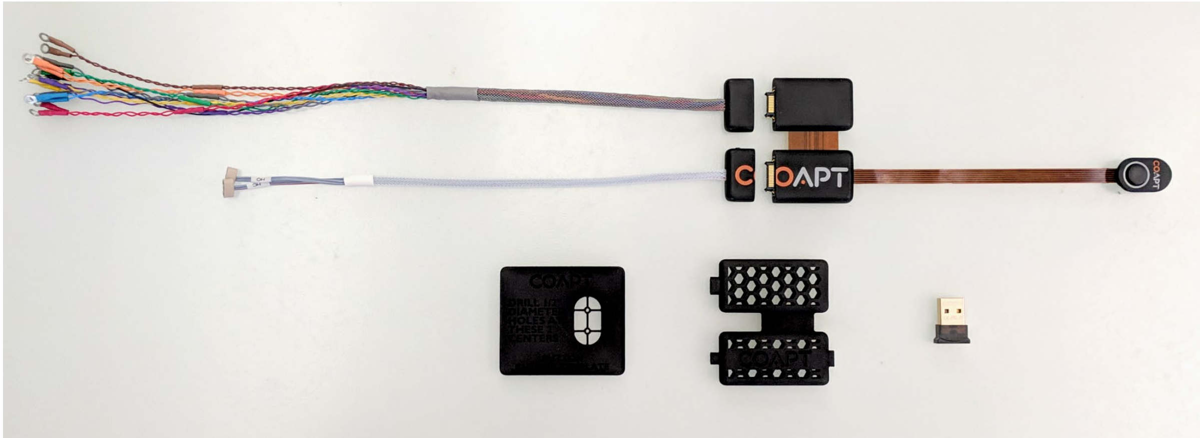
When an individual attempts to move his or her limb (or residual limb), multiple muscles contract to accomplish the intended motion. As these muscles work together, they each generate an electromyographic (*EMG*, or synonymously, *myoelectric*) signal. The combination of these muscle signals creates a pattern of EMG activity that is unique for each movement. For example, the pattern of forearm muscle EMG activity during hand opening is different than the pattern for hand closing.

Electrode contacts placed on the skin over residual muscles can detect these patterns of activity from several muscles. A microcomputer algorithm can learn to recognize which EMG signal patterns correspond to different desired movements. Once trained, the algorithm can decode a patient's EMG patterns and command the appropriate movement of a prosthesis in real time. Thus, a patient controls their powered prosthesis simply by attempting the movement they want to make. Pattern recognition technology for prostheses can be likened to speech recognition technology for our smartphones; sets of input information are processed by the recognition algorithms to produce a desired output. For prosthetists, pattern recognition simplifies electrode placement, since there is no need to locate isolated control sites. Signal artifacts such as cross talk or co-contraction are treated as a natural part of the EMG signal pattern for a particular movement. With pattern recognition, even weaker EMG signals can provide valuable control information.

## THE COAPT COMPLETE CONTROL SYSTEM GEN2 PRODUCT LINE

The Coapt COMPLETE CONTROL System Gen2 is an advanced pattern recognition solution to enhance the functionality of myoelectric prosthetic arms. Together with our intuitive software package, the system non-invasively acquires the rich information in muscle signals to unlock unprecedented prosthesis control for your patient, leading to better rehabilitation outcomes and increased patient satisfaction.

The modular COMPLETE CONTROL System Gen2 is customized to new and existing myoelectric prostheses. The interconnections are simple and secure, and the modular pieces allow better cosmetic fit into a patient's prosthesis. Battery power for the system comes from the connection to the prosthesis; thus, separate batteries are not required. The EMG wire harness is configurable for many different socket types and eliminates the need for the standard EMG electrode "boxes."



*The modular Coapt pattern recognition system can be customized to both new and existing myoelectric prostheses*

**COMPLETE CONTROLLER:** The central brain of the system – where the pattern recognition computation happens. This unit houses a powerful microcontroller – like what is found in smartphones – that decodes the patient’s EMG signals with pattern recognition algorithms to command the prosthesis.

**COMPLETE CALIBRATE:** This simple press button, which is mounted into the exterior wall of the prosthesis, can be pressed at any time by the wearer to recalibrate control. The COMPLETE CALIBRATE button is a module connected to the COMPLETE CONTROLLER.

**COMPLETE COMMUNICATOR:** This USB device plugs into the clinician's computer and allows wireless Bluetooth communication between the COMPLETE CONTROLLER and COMPLETE CONTROLROOM software for robust setup and practice tools.

A custom Device Interface Cable connects the COMPLETE CONTROL system to the prosthesis.

The EMG Interface Cable connects the COMPLETE CONTROL system to electrodes embedded in the user’s socket.

# HOW WILL COAPT’S COMPLETE CONTROL PATTERN RECOGNITION SYSTEM BENEFIT MY PATIENTS?

Pattern recognition has been extensively studied by researchers around the world and experts agree that it provides clear functional benefits for patients.

As you evaluate your patient for pattern recognition, some key questions you should consider are:

1. *Is it difficult or impossible to locate EMG signals from agonist/antagonist muscle pairs that are free from crosstalk (EMG signal interference from surrounding muscles)?* In contrast to traditional EMG control systems, the Coapt system does not need isolated control signals.
2. *Does your patient have difficulty reliably initiating co-contraction to switch modes?* The Coapt system eliminates the need for mode switching and allows patients to control movements using physiologically appropriate movements (i.e., attempting to open the hand causes the prosthetic hand to open).
3. *Does your patient inadvertently co-contract?* Unintended co-contractions can make it difficult or impossible to configure a robust control system. The Coapt system simply learns to recognize EMG signals resulting from co-contractions as part of the EMG signal pattern for that movement.

4. *Does your patient fatigue easily?* Studies have shown pattern recognition (the Coapt system) requires less forceful muscle contractions, which reduces patient fatigue and allows them to continue using their device longer.
5. *Does your patient have volume fluctuations in their residual limb?* Volume fluctuation can mean electrode positions change with respect to the residual limb. With traditional myoelectric control, volume fluctuation reduces control reliability and increases the need for socket re-fabrication. With the Coapt system, the computer algorithm can be retrained to recognize new signal patterns as needed. Patients can initiate a brief (approximately one minute) calibration procedure that allows the algorithm to adapt to EMG signal changes wherever and whenever the patient feels that control is poor.
6. *Are your patient's ideal traditional electrode sites located over scarring or sensitive areas, or areas that would be uncomfortable for the patient?* Pattern recognition does not require specific electrode placement, so there are no ideal locations. With the Coapt COMPLETE CONTROL System Gen2, you have the freedom to place electrodes in locations that are comfortable for the patient and that maintain good contact with the residual limb.
7. *Does your patient have difficulty with proportional control?* The Coapt COMPLETE CONTROL System Gen2 uses an enhanced proportional control algorithm that lets patients operate at a broader range of speeds, improving functional outcomes.
8. *Does your patient have weak EMG signals?* Pattern recognition is very suitable for low-amplitude signals and can extract patterns even with very weak EMG signals – signals so weak that traditional control would be impossible.
9. *Does your patient have more than two EMG control sites?* If your patient has had Targeted Muscle Reinnervation (TMR) surgery, then they may have up to 4 or 5 available control sites. Pattern recognition provides reliable, enhanced control using EMG information from all of these sites.
10. *Can your patient control the number of degrees of freedom (DOFs) required to achieve their goals?* Pattern recognition allows patients to control more degrees of freedom than traditional control systems. This may be critical in creating a prosthesis that allows your patient to achieve their specified goals.
11. *Does your patient have difficulty using non-intuitive muscle contractions to control their prosthesis, instead of the intrinsic muscle contraction pattern that comes naturally to them?* The Coapt COMPLETE CONTROL System Gen2 allows the patient to move their phantom limb intuitively on the amputated side, quickly learns the intent of the user, and commands the prosthetic component to react in the intended way. This is novel and superior to the traditional control strategy for various amputation levels (i.e., at the transradial level, wrist flexion and extension contraction patterns are traditionally used to operate the myoelectric hand instead of hand open and hand close muscle contraction patterns).

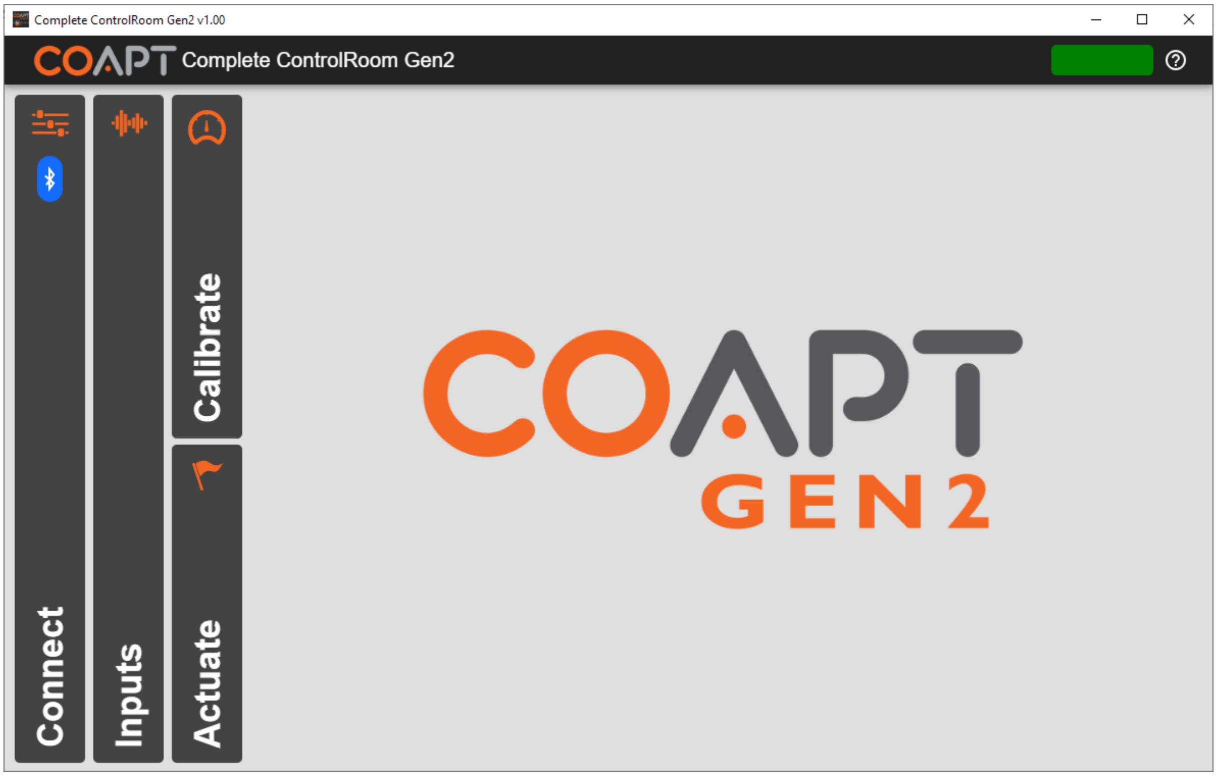
**If you answered yes to even one of the above questions, then pattern recognition can be considered medically necessary for your patient**. The Coapt COMPLETE CONTROL System Gen2 pattern recognition platform will allow your patient to control a prosthesis and achieve functional outcomes that otherwise would not be possible.

We encourage you to discuss these issues with your patient and explain how Coapt's COMPLETE CONTROL System Gen2 can help them achieve better control. ***Asking the refferer to highlight how Coapt's pattern recognition system would resolve one or more such problems when they write a referral for your patient is critical and will strengthen your justification.***

If you find additional clinical issues that Coapt's COMPLETE CONTROL System Gen2 pattern recognition platform seems to resolve, please contact Coapt. We are happy to discuss these observations with you and, if necessary, update our recommendations accordingly.

# WHAT TOOLS ARE AVAILABLE TO HELP ME EVALUATE MY PATIENT?

The Coapt COMPLETE CONTROL System Gen2 has associated clinician PC software called COMPLETE CONTROLROOM Gen2. This on-screen software provides basic environments for access and control to help you in your evaluations.




*Dashboard screen environment for Coapt COMPLETE CONTROLROOM Gen2 software*

Launch tabs shown in the dashboard area guide you to the four COMPLETE CONTROLROOM Gen2 environments:

**Connect:** The Connect environment is provided to both maintain and verify the wireless Bluetooth connection as well as the COMPLETE CONTROLLER connection to the prosthetic devices. This environment enables you to test the expected operation of the connected prosthetic device(s). Each available prosthesis movement is represented by a button. When pressed and held, these buttons can be used to command the prosthesis and verify that it performs the correct actions.

**Inputs:** The Inputs environment is provided as a means to verify that all electrode-to-skin connections are reliable, and EMG information is healthy. Dynamic signal activity on eight horizontal bars of color represent the eight EMG channel inputs of the COMPLETE CONTROL System Gen2. The on-screen colors correspond to the EMG wire colors of the EMG Interface cable.

A real-time signal quality assistant monitors for EMG electrodes losing contact with user's skin ("lift-off"). When lift-off is detected, a warning message is displayed on the corresponding signal channel. Each EMG channel has an on/off toggle button that will determine its inclusion or exclusion from the set of pattern recognition inputs.

**Calibration:** The Calibration environment is the centralized location of tools to assist the user with calibration of their COMPLETE CONTROL System Gen2. Each of the prosthesis' actions/functions that are available for calibration of the current device configuration are listed by functional group. Various elements are associated with each action/function label:

- Selection: Each action/function (or logical pairing) that is possible for current device configuration has a toggle selector that allows users to set these functions "on" or "off". Actions/functions that are de-selected (turned off) will be removed from active control outputs and will not be included in any calibration. Turning these items back on will re-enable the function (if prior EMG pattern data existed for them, or, will prompt for data collection if not) and will be included in following calibration activity.
- CONTROL COACH Star Rating: CONTROL COACH analyzes calibration data and produces a quality estimate for each action/function. The estimated quality is displayed via a 5-star rating. five bright stars indicate high quality while one bright star indicates low quality.
- CONTROL COACH Info Call-out: Next to each action's Star Rating is a small arrow that invites the user to click. Clicking this call-out arrow expands an area of the screen that contains feedback specific to that action/function's CONTROL COACH evaluation.

*Calibrate* – This single-press button initiates User Interface-Guided Calibration.

*Undo* – This single-press button in the software application allows a user to undo the effect of the last completed calibration activity. Thus, returning the control of the prosthesis to the state that it was just before the most recent calibration activity. This applies to any type of calibration, Prosthesis-Guided Calibration, User Interface-Guided Calibration, or Single Motion Calibration. Undo functionality only applies to one calibration step; that is, more than one calibration step undo is not possible.

*Favorites* – This single-press button opens a small pop-up window where it is possible to store or recover a state of the control system calibration.

**Actuate:** The Actuate environment is intended to provide patients with both virtual and real-world practice of pattern recognition control. This helps develop and enhance a user's proficiency with control of each movement and may be used to demonstrate that your patient is a suitable candidate for pattern recognition.

# IS THE COAPT COMPLETE CONTROL SYSTEM GEN2 SAFE?

Yes, Coapt is committed to ensuring that all our products are engineered and deployed with the highest of standards for patient and clinician safety. Below are the official statements associated with the COMPLETE CONTROL System Gen2.

**FDA:** Coapt, LLC is registered with the Food and Drug Administration of the United States Government (Registration Number: 3010605876; Owner Operator Number: 10045459) for the manufacture and supply of prosthetics and orthotics products.

The Coapt COMPLETE CONTROL System Gen2 has been cleared as substantially equivalent to legally marketed predicate devices as a Class II device via Section 510(k) premarket notification; K191083.

**FCC WARNING STATEMENTS:**

- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
  1. This device may not cause harmful interference, and
  2. This device must accept any interference received, including interference that may cause undesired operation.
- Radiation Exposure Statement for Portable Devices: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment is in

direct contact with the body of the user under normal operating conditions. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

- This equipment was tested and found to meet the radio interference radiated emission requirements of FCC "Rules and Regulations," Part 15, subpart B, Section 15.109a for Unintentional Radiators, Class B digital devices.
- Any changes or modifications not expressly approved by Coapt, LLC could void the user's authority to use this device.
- FCC ID: T9JRN4020

**IEC:** This equipment was tested and found to meet the requirements of International Standard IEC 60601-1-2:2007 Medical Electrical Equipment Part 1: General Requirements for Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility Requirements and Tests using test procedures from: IEC 61000-4-2, IEC 61000-4-3, and IEC 61000-4-8.

This equipment was tested and found to meet the Radio Interference Power Line Conducted and Radiated Emission requirements of CISPR 11 for Measuring RF Emissions from Group 1, Class B ISM Equipment as part of IEC 60601-1-2:2007 Medical Electrical Equipment Part 1: General Requirements for Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility Requirements and Tests using CISPR 11:2009, A1:2010 – Class B, Group 1 Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment Electromagnetic Disturbance Characteristics Limit and Methods of Measurement.

**CE:** This device is fully compliant with the CE Marking Requirements under the European Medical Device Regulation (MDR). Coapt, LLC's European Union Authorized Representative (EC REP) is Fillauer Europe AB.

# PROCESS TO ACHIEVE APPROVAL OR AUTHORISATION

Every clinical practice is different, and each will have its own unique methods of achieving authorization and reimbursement for prosthetic technologies. While there is no exact process, Coapt provides a suggested progression below to highlight the areas we believe are important for successful outcomes.

To help with the consistent collection and organization of the materials that will be part of this effort, we have provided a process and documentation preparation checklist as Appendix A of this guide.

## 1. CONDUCT PATIENT EVALUATION TO DETERMINE IF THEY ARE A CANDIDATE FOR COAPT'S COMPLETE CONTROL SYSTEM GEN2

If your patient is a current myoelectric prosthesis user, they are likely a great candidate for the COMPLETE CONTROL System Gen2 already. If your patient is new to myoelectric control, they should be evaluated to ensure that they satisfy the Medical Necessity Criteria established in the National Coverage Determination Manual for the Centers for Medicare and Medicaid Services (also known as *CMS* or *Medicare*) for coverage of a myoelectric prosthesis (conveniently shown below).

| Medical Necessity Criteria | Sample Questions to Evaluate Criteria |
|---|---|
| The patient has an amputation or missing limb at the wrist or above (i.e. forearm, elbow, etc.); and | Is the patient of suitable amputation level? |
| The patient has sufficient neurological, myocutaneous and cognitive function to operate the prosthesis effectively; and | Can the patient use the Coapt COMPLETE CONTROLROOM software to control a virtual limb and confirm the prosthesis responds appropriately?<br>Does the patient understand how to initiate and follow the calibration? |
| The patient is free of comorbidities that could interfere with maintaining function of the prosthesis (i.e., neuromuscular disease, etc.); and | Is there anything in the patient's medical history that suggests they have neuromuscular disease or other conditions? |
| The patient retains sufficient microvolt threshold in the residual limb to allow proper function of the prosthesis; and | Are EMG signals viewable using the Coapt COMPLETE CONTROLROOM software? |
| Standard body-powered prosthetic devices cannot be used or are insufficient to meet the functional needs of the patient in performing activities of daily living; and | Can the patient achieve **all** activities of daily living using a body-powered prosthesis? Does body powered harnessing interfere with their activities? Do they complain of strain or fatigue associated with operating the body-powered prosthesis? Are they limited in the items they can grasp and the bimanual tasks they can complete because of the limitations of the body-powered terminal device? Could the patient benefit from a multi-function prosthesis? |

| | |
|---|---|
| The patient does not function in an environment that would inhibit function of the prosthesis (i.e., a wet environment or a situation involving electrical discharges that would affect the prosthesis). | Is the patient a Scuba Diver or Lifeguard, etc.? Even if the patient functions in an environment that would inhibit use of a myoelectric prosthesis, a combination of prosthetic interventions may be suitable. |

# 2. OBTAIN MEDICAL RECORDS, PHYSICIAN PRESCRIPTION, AND RELATED DOCUMENTATION

## Medical Records/Patient Notes

Obtaining copies of your patient's medical records (surgery notes, clinic notes, occupational therapy notes) should not require more than a phone call and/or a faxed request to a physician's/ hospital's medical records department. Receiving medical records should only take a few days.

A physician must evaluate your patient and document both medical necessity and functional capabilities. In order to be compliant with requirements to receive reimbursement, the following information needs to be documented by the referring physician in your patient's medical records and provided to you as part of the referral process.

**A. Physical Exam** – to identify functional deficits in body systems impacting the patient's functional ability

- Weight, height, significant changes
- Cardiopulmonary health
- Arm/shoulder/torso strength and ranges of motion
- Neurological examination

**B. Amputation History**

- Diagnosis/Date/Side of amputation
- Clinical and therapeutic plans, interventions, and results
- Overall prognosis

**C. Deficits limiting functional dexterity**

- Relevant medical history
- Activities of daily living (ADL) and how these are impacted by deficit(s)
- Diagnoses of symptoms
- Other comorbidities (e.g., reduced range of motion/strength in the contralateral side, amputations (even fingers) on the contralateral side, back and shoulder injury)

**D. Level of Function***

- Patient's ADLs on a typical day in terms of functional capabilities prior to amputation
- Patient's current ADLs on a typical day in terms of functional capabilities with current prosthesis
- Patient's expected functional potential with use of the Coapt COMPLETE CONTROL System Gen2 and explanation for any differences

**E. Motivation to use prosthesis**

- Describe patient's desire to use a prosthesis

**F. Residual limb condition**

- Healed limb?
- Skin irritation, breakdown, or infection?
- Limb volume changes?

**G. Current prosthesis control and need for pattern recognition**

- Describe why a pattern recognition control system is needed
- Describe why the traditional control system is no longer appropriate
- Describe why the current prosthesis will not allow the patient to achieve the desired function

**H. Patient's past experience with prostheses (if applicable)**

- Which other traditional control systems have been tried in the past?
- Describe any problems the patient experienced (e.g., inability to perform activities, fatigue, low EMG signals, problems with back or contralateral limb)

**I. Recommendation for pattern recognition control system and rationale for decision**

# 3. OBTAIN LETTER OF JUSTIFICATION/LETTER OF MEDICAL NECESSITY

The Letter of Justification, or commonly, Letter of Medical Necessity, is an important written document summarizing the medical and functional history and the prosthetist's assessment for why the patient specifically needs the Coapt COMPLETE CONTROL pattern recognition system, and why lesser components are vastly inferior, inadequate, or inappropriate for the patient's needs. Many of these points can be found in the Establishing Medical Necessity section of this guide. Furthermore, Appendix B contains a sample Letter of Medical Necessity that can be used as a template for your own cases.

***The key with the Letter of Justification is to humanize the patient by citing specific examples of the patient's goals and daily needs for Coapt's level of control, and to focus less on the details of the system.*** It is also essential to indicate relevant studies endorsing the effectiveness of the myoelectric pattern recognition prescription (see the Establishing Medical Necessity section of this guide for a list of references). Only cite literature that applies to your specific patient's condition. Credibility of your letter and your credibility as an informed prosthetist are important.

For the Letter of Medical Necessity, it is not enough for the prosthetist to rely solely on his/her own expertise. Actual physician/therapist notes for your case and literature interpreted in lay terms (as the reviewers are not always medical/prosthetic experts) help to highlight that it is not just the prosthetist's opinion. That is, ***the letter should be written as a collaborative effort between the physician and prosthetist and should include all relevant detail from the therapists involved in the case.*** The Letter of Medical Necessity must be produced on a physician's letterhead and must be signed and dated before the date of reimbursement claim submission.

# ESTABLISHING MEDICAL NECESSITY

Traditional one- or two-site myoelectric control is an outdated method for amputees to control their upper limb prostheses. Using traditional control, there is a drastic limitation in the amount of communication from an amputee's body to their prosthesis. This is somewhat analogous to using Morse code to communicate in this modern era of smartphones. In contrast to traditional myoelectric control, pattern recognition employs modern-day technology and algorithms allowing amputees to control their prostheses intuitively and functionally. Pattern recognition is becoming a new standard of care for all externally powered upper extremity prosthetic users.

The Coapt COMPLETE CONTROL system is a product that reimbursement parties may not be familiar with it, or perhaps even with the concept of myoelectric pattern recognition control. We recommend writing a strong Letter of Medical Necessity (see Appendix B) that serves to introduce the patient, the recommended prosthesis, and the Coapt COMPLETE CONTROL pattern recognition system. Below we provide details on the many advantages of pattern recognition control and the scientific studies that illustrate and support these benefits.

## ESTABLISHED BENEFITS OF THE COAPT COMPLETE CONTROL PATTERN RECOGNITION SYSTEM GEN2

### Enables intuitive control

With Coapt's COMPLETE CONTROL pattern recognition system, natural, intuitive control of the myoelectric prosthesis is possible, which means a patient's intuitive hand open and close contractions will control the prosthetic hand, while wrist rotation contractions will control the prosthetic wrist, and so on.

Compared to Alternatives: With traditional myoelectric control, patients are required to make non-physiological and non-intuitive contractions to command prosthesis actions. A good example of this is that wrist extension and flexion contractions have to be used to command a prosthetic hand opening and closing and/or wrist rotation with traditional myoelectric control.

Daily Life Implications: A patient using pattern recognition to control their prosthesis is doing so in a more natural and intuitive manner. This type of control decreases a user's concentration thus leading to increased overall usage of their device. An easier-to-use device that reacts more consistently to user intent is more functional and satisfying to wear and can lead to enhanced social and functional use leading to accelerated back-to-work incorporation, ability to complete activities of daily living (ADL's) and an overall positive experience with the prosthesis.

Supporting Studies: Deeny et al. (2014) showed quantitatively that pattern recognition was more intuitive than traditional control by measuring users' brain activity. They found that users had to concentrate less on controlling their prosthesis with pattern recognition – indicating that control felt more natural – which would likely reduce device abandonment.

### Eliminates mode switching

With Coapt's COMPLETE CONTROL pattern recognition system, patients can directly control each function of their prosthesis without the cumbersome and non-intuitive mode switching between powered prosthetic actions. Pattern recognition allows direct, natural command of the prosthesis components.

Compared to Alternatives: With traditional myoelectric control, the number of electrode control sites is limited because of the need for isolated EMG signals. This, in turn, means fewer control sites are available than the number of possible prosthesis functions. Patients have to use the same control sites to control several functions and cycle the prosthesis between different functions by activating some type of switch. Examples include using co-contraction of two muscle signals to toggle between hand and wrist control or a physical/electrical switch that the patient must activate with another movement of their body. This switching takes time and affects the functional tasks of the patient. In some cases, the number of prosthetic functions may be limited due to the difficulty, awkwardness, or cognitive load of mode switching options. Because of this increased difficulty in controlling the prosthesis and time to switch between functions, the patient may be more likely reject or abandon the prosthesis, because performing a task one handed may be quicker.

Implications: Operating the multiple actions of a powered prosthesis without having to pause to switch modes (e.g., from hand control to wrist control, etc.) means more natural, smooth, and intuitive functional use of the prosthesis that requires less time. Eliminating the mode switching burden allows some patients to control more components. The natural operation this provides can promote increased prosthesis use, increased acceptance, and increased ADL's. In some cases, a prosthetic joint that is traditionally controlled by body motion and burdensome straps/harnesses is eliminated when using pattern recognition.

Supporting Studies: Hargrove et al. (2010) found that users preferred pattern recognition over traditional myoelectric control because they strongly disliked mode switching during real-time performance tasks.

## Does not require strong, isolated muscle contractions

Coapt's COMPLETE CONTROL pattern recognition system has the advantage of being able to utilize low intensity (weak), poorly isolated (crosstalk), or unbalanced muscle contractions while still providing excellent prosthesis control.

Compared to Alternatives: With traditional myoelectric control, operation of a prosthesis is limited to using one or two amplitude-sensing electrodes. To provide enough control information, the underlying EMG signals have to be sufficiently strong and isolated. In many cases, the patient must make contractions that are strong enough, which leads to fatigue throughout the day. Also, if signals of adequate strength cannot be found on the limb, control of any kind may be difficult or impossible. Similarly, if one signal doesn't stay sufficiently "quiet" while the other is active, control can be tiresome and difficult. In stark contrast, Coapt's pattern recognition system uses much more information than just the signal amplitude. Therefore, patients' low-amplitude, non-fatiguing signals can operate their prosthesis. Additionally, the muscle co-activation that is unwanted with traditional control can be beneficial for pattern recognition as it provides useful functional intent information.

Implications: This is beneficial for patients who have used traditional myoelectric control to elicit strong control contractions that quickly fatigued their muscles. It also implies patients with control signals that are generally weak or disturbed by crosstalk can become good myoelectric prosthesis users, including those who have experienced neuropathy or other impairment of antagonistic muscle control. Furthermore, an ideal EMG control site for traditional control can sometimes end up in an area where an electrode is difficult to place (e.g., over scarring, sensitive areas, socket hardware, etc.) but with pattern recognition there is the benefit of moving that contact site while achieving natural prosthesis control. Collectively this makes pattern recognition feasible for new patients; those who have developing EMG signals may no longer need to wait for significant strengthening. The control signals an amputee generates when using pattern recognition require much less effort and this promotes earlier fittings, better overall health, reduces frustration and fatigue, and reduces other long-term health effects such as back and shoulder pain.

Supporting Studies: Studies supporting these conclusions were performed by Deeny et al. (2014), who quantitatively showed that users generated less EMG activity when using pattern recognition to complete performance tasks. Wurth and Hargrove (2014) also found that transradial amputees and transhumeral amputees who had undergone Targeted Muscle Reinnervation surgery used less mental and physical effort using pattern recognition compared to using traditional myoelectric control. Soulis (2015) reported that an individual previously incapable of using a myoelectric prosthesis because of impaired antagonistic muscle control and muscle fatigue due to neuropathy was able to successfully control a myoelectric prosthesis with pattern recognition.

## Enables enhanced proportional control

Coapt's COMPLETE CONTROL pattern recognition system can take full advantage of the patient's ability to vary their muscle contraction intensities and relate *all* of that to modulate motor speeds, and hence prosthetic movements. The full dynamic range of signal can be used by the pattern recognition system.

Compared to Alternatives: Because of the necessity of isolating EMG control sites with traditional myoelectric control, much of a patient's ability to modulate and control the speed of the prosthesis is tuned out because signal thresholds are applied to overcome baseline noise and signal crosstalk. That is, even if a patient can make a light control contraction, it is commonly ignored and unused. Similarly, strong contractions may increase crosstalk and patients have to learn not to use their strongest available muscle signals.

Implications: Enhanced proportional control means better speed control of the prosthetic components. This can increase function in activities of daily living as patients can manipulate softer, fragile objects with greater confidence while maintaining the availability of strong and quick actions when needed. This enhanced control can also give a more natural look and feel to the operation prosthesis as well as conserve battery energy. Use of a prosthesis with pattern recognition becomes much more efficient. In the long term, this means less wear and tear on prosthetic equipment and it gives the patient fluid and practical use of their prosthesis.

Supporting Studies: Scheme et al. (2014) found that using enhanced proportional control resulted in significantly improved task performance in comparison to use of trivial proportional control strategies. Additionally, Simon et al. (2011) found that enhanced proportional control performed better than on/off control during tracking tasks.

## Simplifies electrode placement

With Coapt's COMPLETE CONTROL pattern recognition system, there is much less need to precisely place control-site electrodes over exact muscle locations. EMG information from the limb is collected in a more general and generic sense. Pattern recognition does not require the sustained, isolated "hot-spots" of EMG signals.

Compared to Alternatives: Myotesting to determine ideal EMG control sites for traditional myoelectric control can be time consuming and challenging. This task is further complicated by the tendency for these locations to shift and change over time. If suitable sites are located, it can be a significant challenge to incorporate them into the patient's socket so that the ideal locations are maintained during subsequent donning. Additionally, any rotation or distraction of the prosthetic socket during use can cause the electrodes to no longer detect the myoelectric signal.

Implications: Simplified electrode placement means less time spent myotesting. In fact, electrodes can be placed to promote fit and comfort, rather than being constrained to specific, isolated control sites. Because of this, different donned socket positions are tolerated and yield consistent function. With less time spent in the clinic searching for the muscle control sites, time available for in-clinic functional practice with the prosthesis is increased, thus helping patients accept their prosthesis and increasing functional at-home use.

Supporting Studies: Farrell and Weir (2008) have shown that targeted specific muscle is not important for optimal pattern recognition control for control of wrist and hand movements. Hargrove et al. (2007) have shown that electrodes do not need to be placed in locations to avoid muscle crosstalk, and that muscle crosstalk can actually enhance control patterns. Tkach et al. (2014) have shown that a generic electrode placement over the residual limb is sufficient for optimized control for amputees who have received Targeted Muscle Reinnervation.

## Enables rapid, convenient recalibration, when necessary

With Coapt's COMPLETE CONTROL system, the algorithm that provides functional prosthesis control can adapt to changing conditions (such as those listed below and many more) by means of recalibration that the patient can do quickly and conveniently.

Compared to Alternatives: With traditional myoelectric control, changes in socket fit, patient skin condition, muscle fatigue, mental state, battery health, and many other factors can diminish the patient's control of their prosthesis. For many of these issues a repair visit or call to a prosthetist is necessary, often resulting in time-consuming prosthesis adjustments and software reconfiguring, which in turn can lead to rejection of or dissatisfaction with the prosthesis.

Implications: The advantage of Coapt's pattern recognition system is dramatic. If something changes with the patient's myoelectric control, it can typically be overcome with a simple recalibration. Furthermore, the recalibration is accomplished while the prosthesis is worn and can be conveniently done anywhere the patient is, as it does not require a computer or handheld device. This means that a patient can enhance their own control and overcome fit, fatigue, and other control issues without calling or visiting their prosthetist. In general, having the ability to overcome functional control limitations quickly and conveniently can lead to increased prosthesis use and avoided frustration. Traditional myoelectric control styles are not capable of this adaptation and can commonly end in rejection of or dissatisfaction with the prosthesis.

Supporting Studies: Simon et al. (2011) introduced this calibration style to prosthesis users who all responded favorably in functional questionnaires and unanimously indicated they could use a pattern recognition–controlled prosthesis calibrated by themselves. Simon et al. (2012) then demonstrated the effectiveness of allowing the patient to recalibrate in an accelerated life-cycle test. During in-laboratory experiments, these researchers artificially corrupted the patients' myoelectric signals during functional tasks and recorded when they chose to recalibrate and if the recalibration resulted in reestablishing successful prosthesis control. The tested patients were able to tolerate signal anomalies placed on 5 of 8 electrodes before deciding to discontinue the test.

## Improves Functional Outcomes

A prosthesis using Coapt's COMPLETE CONTROL system is less fatiguing and easier to control, which yields improved functional outcomes for patients.

Compared to Alternatives: The non-intuitive nature of traditional myoelectric control inherently places limitations on achievable functional performance. Patients tend to compensate for the limitations in traditional myoelectric prosthesis control by over-using their sound limb, using their mouth/teeth, and simply not participating in activities. Some of these limitations can also lead to longer-term health complications.

Implications: When patients can control their prosthesis intuitively, they can to use it to complete activities rather than relying on compensatory mechanisms. This important aspect has significant long-term implications in preventing overuse injuries of joints and teeth as well as posture-related health problems. Additionally, more intuitive operation leads to faster and more efficient functional task completion. A prosthesis that is more functional can promote increased incorporation into activities of daily life, return to work, enhanced social interactions, and overall positive attitude.

Supporting Studies: Hargrove et al. (2013) have shown that pattern recognition outperforms traditional control during a clothespin relocation task, a box and blocks task, and a tower stacking task. These tasks were selected in the functional study because they require control over multiple degrees of freedom and evaluate gross and fine motor movements. A functional use study by Beachler (2014) recently found that pattern recognition outperformed traditional control on 43 out of 46 outcomes tests in a preliminary trial. In another Hargrove et al. study (2007), pattern recognition was shown to outperform traditional myoelectric control during a virtual clothespin task. Miller et al. (2013) have shown improvements in pattern recognition over traditional myoelectric control in a transradial amputee case series. Kuiken et al. (2016) found that pattern recognition improved performance in the Clothespin Relocation Task and significantly outperformed traditional myoelectric control in the Southampton Hand Assessment Procedure (SHAP) Index of Function scores for patients with transhumeral amputations who had undergone the targeted reinnervation procedure. In a study of 14 upper limb prosthesis users, including multiple etiologies and amputation levels, pattern recognition was found to offer an improvement over conventional myoelectric control in all cases (Uellendahl, Tyler et al. 2016). In a similar study, tracking 13 other pattern recognition users over the course of two years, highlighted that pattern recognition can be utilized successfully in externally powered prostheses for patients with all levels of upper limb differences (Baschuk, Katzenberger et al. 2017). Finally, another study of real-world users showcases the applicability to the transhumeral amputee without TMR surgery (Jackman and Macedonia 2017).

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# SAMPLE EXCERPTS FOR ESTABLISHING MEDICAL NECESSITY IN A LETTER OF JUSTIFICATION

Coapt recommends incorporating all of the applicable pattern recognition benefits stated above in the Letter of Justification. The letter should be written to summarize the patient's medical and functional history and combine the prosthetist's assessment for why the patient specifically requires the Coapt COMPLETE CONTROL System Gen2, and why lesser components are vastly inferior, inadequate, or inappropriate based on the patient's needs.

***The key with the Letter of Justification is to humanize the patient; cite specific examples of your patient's goals and daily needs for Coapt's level of control and focus less on the details of the system. It is important to use your patient's specific circumstances to create a compelling story to demonstrate medical necessity***.

While we provide a full sample Letter of Medical Necessity in Appendix B, the paragraphs below offer several examples of medical necessity content that you can use as examples as you write your own specific letter of medical necessity:

**Example A**: John Doe acquired a mid-length transradial amputation of his left arm as a result of a motor vehicle accident on July 8th, 2014. We have verified Medical Necessity Criteria listed in this assessment, which were taken directly from the National Coverage Manual for CMS for coverage of myoelectric prostheses. During initial myoelectric signal testing, we found that Mr. Doe could generate vigorous myoelectric activity, but could not independently control agonist/antagonist muscle pairs. The patient was assessed using an electrode sensor array and a demo unit of the Coapt pattern recognition system, which collects myoelectric features over the entire surface of his residual limb. The patient could generate patterns of myoelectric activity that were distinct for four different movements as visualized in the computer interface of the Coapt system. Furthermore, when the sensor array and Coapt COMPLETE CONTROL pattern recognition system was attached to a handheld evaluation kit, John Doe could control both wrist rotation and the multi-articulating prosthetic hand. Mr. Doe demonstrated the ability to independently control the two degrees of freedom using intuitive strategies, including wrist pronation, wrist supination, hand open and hand close. John also demonstrated proportional control of his muscle contractions to control the speed of movement and grip strength of the powered prosthetic components. This indicates he will be a successful pattern recognition user. Using Coapt pattern recognition, John Doe, who is a motivated individual, will be able to control a wrist rotator and terminal device and reach the goals that he has discussed with the rehabilitation team. Some tasks he will be able to perform that he could not with his previous prosthesis include gardening and opening bottles – important activities of daily living that help him achieve a sense of independence. This prosthesis control would not be possible for Mr. Doe with traditional myoelectric control and is only possible with the Coapt COMPLETE CONTROL pattern recognition system.

**Example B**: Jane Doe traumatically acquired a long transradial amputation of her right side on September 15th, 2013 after being injured in a fire. Ms. Doe is best suited for a multi-articulating hand to achieve the goals that she has set to return to employment and complete activities of daily living. She has significant scarring and sensitive skin on the palmar aspect of her residual forearm directly over the flexor muscle group. However, she has healthy skin on her remaining residual limb. Unfortunately, we cannot locate two locations to place electrodes for traditional myoelectric control. We have investigated single-site myoelectric control; however, Ms. Doe fatigues quickly and cannot reliably perform the contractions to switch between prosthesis functions. We have evaluated her for a Coapt pattern recognition system and found that she can make patterns corresponding to her desired prosthesis functions. This is only possible because pattern recognition does not require specific electrode placement over independent muscle groups and eliminates the need for co-contraction switching. Furthermore, pattern recognition reliably interprets smaller muscle contractions in comparison to traditional control. To reach her rehabilitative goals, the pattern recognition system is medically necessary. As a result of using Coapt's pattern recognition system, Ms. Doe will be able to return to her position as manager of a daycare center, helping the children she watches comb their hair, zip up their jackets, and open bottles.

**Example C**: John Smith acquired a mid-length transhumeral amputation on his left side as the result of an electrical accident while at work on March 5th, 2003. He also suffers from shoulder pain on his non-affected side that is exacerbated by harnessing when he attempts to operate a body-powered prosthesis. Mr. Smith continues to work for the same employer but has taken on more of an administrative role, requiring performance of common clerical duties, along with lifting light objects in the office. He currently uses a body-powered device with a passive elbow component to perform all functional tasks. We assessed Mr. Smith for a traditional myoelectric prosthesis and found he can operate a single degree of freedom but cannot reliably perform a mode-switch to change between operation of his elbow and terminal device. During a physical exam we found that Mr. Smith had strong co-activation patterns that were different when he attempted to move his phantom elbow or his phantom hand and that he had additional myoelectric signals on the distal end of his residual limb. During a pattern recognition evaluation, Mr. Smith demonstrated that his EMG patterns were sufficient to control an elbow, wrist rotator, and terminal device with proficiency and that he can reliably control these movements. Pattern recognition would be medically necessary for Mr. Smith to control a myoelectric prosthesis and allow him to carry out both vocational and activity of daily living tasks.

**Example D**: Jane Smith acquired a short transhumeral amputation on her right, non-dominant arm as a result of a motorcycle accident on August 3, 2012. She is currently unemployed and is a stay-at-home mother of two young children ages 3 and 8. Ms. Smith currently uses a body-powered device for all childcare tasks, household activities, and activities of daily living. She aspired to use a myoelectric prosthesis but realized her residual limb length may be a limitation. Consequently, Ms. Smith had Targeted Muscle Reinnervation (TMR) surgery to restore EMG signals corresponding to wrist and hand movements with the goal of using such signals to operate a myoelectric device. The TMR surgery was successful; however, the resulting control locations are very close together on the limb and control signals are contaminated by muscle cross-talk. As a result, we have been unable to locate four distinct control locations. We have completed a Coapt pattern recognition assessment and determined that Ms. Smith can reliably control a powered elbow, wrist rotator, and terminal device. Ms. Smith has a challenging residual limb to fit and needs to use a silicone-gel liner with Magnesnap electrodes for satisfactory comfort. The convenient calibration feature of the Coapt COMPLETE CONTROL System Gen2 pattern recognition platform will allow Ms. Smith to retain good control each time she dons her prosthesis, even if the electrodes have shifted locations slightly. This pattern recognition technology is medically necessary for Jane Smith's rehabilitation and functional task performance.

**Example E:** Tom Little has a congenital malformation below his elbow on his right side and has used a body-powered terminal device for several years. He has recently been promoted from the shipping department to a management position and requires a multi-articulating hand to complete activities at his desk. We evaluated Mr. Little for a myoelectric prosthesis and found we can measure EMG signals at the microvolt level; but they degrade rapidly as he fatigues, especially when he needs to co-contract to select different grasping patterns. Mr. Little has been evaluated for a Coapt pattern recognition controller and we have found that he can generate the proper commands for this multi-articulating hand. Furthermore, he has demonstrated that he can self-initialize the auto-calibration routine when he feels fatigued and maintain good control of the prosthesis. Coapt's pattern recognition is medically necessary for Mr. Little to achieve his rehabilitation goals and to continue performing to the best of his ability in his current occupation.

# APPENDIX B: SAMPLE LETTER OF MEDICAL NECESSITY/JUSTIFICATION

Use company letterhead:

<<Company Name>>
<<Company Address>>

<<Patient Reference>>
<<Patient SS #>>
<<Case Reference #>>

**Re: Medical Necessity of Pattern Recognition Myoelectric Control**

**<NOTE: THIS SAMPLE LETTER IS AN EXAMPLE ONLY. USE OF ANY TEXT IN THIS SAMPLE LETTER DOES NOT GUARANTEE REIMBURSEMENT.>**

<<Date>>

Dear <<Contact Name>>,

This letter outlines the prosthetic care for <<patient name>> and demonstrates that the Coapt COMPLETE CONTROL pattern recognition system is medically necessary for <<his/her>> functional recovery.

The Coapt COMPLETE CONTROL system employs pattern recognition technology to revolutionize the use of muscle electrical signals to control a prosthesis. With this control system, <<patient name>> can control <<his/her>> prosthesis intuitively and quickly recalibrate their control, as needed, using a unique prosthesis-guided training protocol included in the Coapt system.

<<Be sure to include paragraph(s) to describe the patient's case history: information such as amputation date and level, type/brand of prosthesis they are being recommended for.>>

<<If the manufacturer of the prosthesis has provided you guidance on medical necessity for their device(s), make sure to include that information.>>

Myoelectric prostheses have been traditionally controlled by myoelectric signals from one or two electrodes carefully placed over residual muscles on the amputated limb. The amplitudes of the underlying electromyographic (EMG) signal(s) are then carefully tuned by a clinician to enable the patient to control motors in the prosthesis. However, to be effective, the electrodes need to be placed over muscle that is free from 'crosstalk' (i.e., interfering EMG signals from other muscles) and the inability to locate suitable control sites not affected by crosstalk is a fundamental limitation of traditional myoelectric control. This problem prevents many individuals from using a myoelectric prosthesis and limits the functional ability of many others. Additionally, changes in EMG signals – which can occur during routine prosthesis use because of fatigue, sweating, or socket slippage – cause deterioration of control. Such problems can lead to frustration and abandonment of these costly devices. Finally, most traditional systems control only a single prosthesis movement. The patient must generate non-intuitive, Morse code–like EMG pulses through co-contraction or use a switch to enable control of multiple prosthesis functions. Muscle signals from the residual limb contain rich control information, most of which is not used in traditional control systems.

Pattern recognition makes use of all of this information: EMG signals from the residual limb are decoded by complex algorithms that learn to recognize the distinct patterns of EMG activity resulting from different attempted movements. The algorithms, developed and refined over decades of research, can thus determine which movement the patient intends and commands the prosthesis accordingly. In stark contrast to traditional myoelectric control, pattern recognition systems can utilize many information features from the EMG signals from many electrodes to decipher what the patient wants the prosthesis to do. In other words, traditional myoelectric control is like listening to music but only hearing how loud the sound is; pattern recognition is akin to hearing the melody and lyrics to recognize which song is playing.

The clear advantages of pattern recognition over traditional myoelectric are what makes the Coapt COMPLETE CONTROL pattern recognition system medically necessary for <<patient name>>

The motions required by <<patient name>> to control the prosthesis with pattern recognition are natural. With traditional myoelectric control, <<he/she>> would be required to make non-intuitive contractions to make the prosthesis move (e.g., use wrist extension and flexion motions to make the prosthetic hand open and close). With pattern recognition, natural intuitive control is possible and <<patient name>> opening and closing their missing hand will control the prosthetic hand, and wrist movements will control the prosthetic wrist. This will lead to much better adoption and acceptance of the prosthesis. A study by Deeny et al. showed quantitatively that pattern recognition was more intuitive than traditional control by measuring the brain activity of users (Deeny, Chicoine et al. 2014). They found that users had to concentrate less when using pattern recognition and could control the prosthesis more naturally, likely leading to reduced device abandonment.
<<Patient name>> will not have to use cumbersome and non-intuitive "mode switching" to cycle between functions of <<his/her>> prosthesis with pattern recognition. Conversely, traditional myoelectric control would be limited (because of the need for isolated signals) and <<patient name>> would be forced to utilize co-contractions to toggle between hand and wrist control. In testing, this action was difficult to impossible for <<him/her>> to make consistently. This is exactly what the study by Hargrove et al. found: that patients preferred using pattern recognition because they strongly disliked mode switching during real-time performance tasks (Hargrove, Scheme et al. 2010).
The remaining muscles in <<patient name>>'s residual limb are small because of the amputation. This means that the contractions for traditional myoelectric control would fatigue <<his/her>> muscles quickly, rendering the prosthesis very difficult to control. With the Coapt COMPLETE CONTROL pattern recognition system, strong muscle contractions are *not* required to maintain excellent control. This was studied and proven by Deeny et al. (Deeny, Chicoine et al. 2014), who quantitatively showed that people generated less EMG activity when using pattern recognition to complete performance tasks. Wurth and Hargrove (Wurth and Hargrove 2014) also found that transradial amputees and transhumeral amputees who had undergone targeted muscle reinnervation surgery used less mental and physical effort using pattern recognition compared to using traditional myoelectric control.

Initial myotesting of <<patient name>>'s residual limb determined that isolated and independent myoelectric control sites were difficult to achieve and were inconsistent. This presents a significant barrier to using any traditional control strategies. With pattern recognition, placing electrodes on specific muscles is not important for optimal control of wrist and hand movements – exactly what was found in a study by Farrell and Weir (Farrell and Weir 2008) – and function for <<patient name>> will be possible. In other related studies, Hargrove et al. have shown that electrodes do not need to be placed in locations to avoid muscle crosstalk, and that muscle crosstalk can actually enhance control patterns (Hargrove, Englehart et al. 2007), and Tkach et al. have shown that a generic electrode placement over the residual limb is sufficient for optimized control for amputees who have received Targeted Muscle Reinnervation (Tkach, Young et al. 2014). In addition, Soulis (Soulis, 2015) reported that an individual previously incapable of using a myoelectric prosthesis because of impaired antagonistic muscle control and muscle fatigue due to neuropathy was able to successfully control a myoelectric prosthesis with pattern recognition.

Because of the absence of traditional myoelectric control sites for <<patient name>> as mentioned above, proportional speed control of the prosthesis would be near impossible with traditional control. The Coapt pattern recognition system is capable of restoring a wide range of speed control and this means that <<he/she>> will have vastly improved fidelity with the prosthesis, leading to improved bimanual function and better prosthesis use at home and at work. The ability of pattern recognition to accomplish this has been documented by Scheme et al. who found that using enhanced proportional control resulted in significantly improved task performance in comparison to use of trivial proportional control strategies (Scheme, Lock et al. 2014).

Pattern recognition has been studied for decades, but has only become clinically available recently. Providing patients with a convenient method for recalibrating the control system after doffing and donning their device or when their muscles fatigue, for example, has overcome what used to be a significant barrier to clinical pattern recognition control systems. Simon et al. introduced this calibration style to prosthesis users who all responded favorably in functional questionnaires and unanimously indicated they could use a pattern recognition-controlled prosthesis calibrated by themselves (Simon 2011). Simon et al. also demonstrated the effectiveness of allowing a patient to recalibrate in an accelerated life-cycle test (Simon, Lock et al. 2012). To date, Coapt COMPLETE CONTROL systems have been administered to patients with transradial, transhumeral, and shoulder disarticulation amputations. Pattern recognition control has been used for both unilateral and bilateral amputees. Patients have been very satisfied with their control and none are known to have returned to traditional control of their prosthesis. A study by Beachler measured patients performing better with pattern recognition on 93% of tasks (Beachler and Dennison 2014) while Miller et al. showed the transradial patients improved performance with pattern recognition (Miller, Stubblefield et al. 2013). Kuiken et al. found that pattern recognition improved performance in the Clothespin Relocation Task and significantly outperformed traditional myoelectric control in the Southampton Hand Assessment Procedure (SHAP) Index of Function scores for patients with transhumeral amputations who had undergone the targeted muscle reinnervation (TMR) procedure (Kuiken, Miller et al. 2016). One study by Hargrove et al. (Hargrove, Lock et al. 2013) reported pattern recognition outperforming traditional control in clinical tasks while another (Hargrove, Losier et al. 2007) showed the same pattern recognition benefit in a virtual functional task. Finally, in a study of 14 upper limb prosthesis users, including multiple etiologies and amputation levels, pattern recognition was found to offer an improvement over conventional myoelectric control in all cases (Uellendahl, Tyler et al. 2016).

We have completed a preliminary evaluation to determine that <<patient name>> is a suitable candidate for pattern recognition. We placed the Coapt electrode sensor array on <<his/her>> residual limb and taught <<him/her>> the concept of pattern recognition. <<Patient name>> successfully self-initiated the calibration procedure and we found that the pattern recognition system classified patterns of myoelectric activity that were distinct for 4 different movements as visualized in the computer interface of the Coapt system. <<Patient name>> also demonstrated proportional control which leads to control of the speed of movement and grip strength of the prosthesis. This indicates <<he/she>> will be a successful pattern recognition user. Using Coapt pattern recognition, <<patient name>> will be able to control a wrist rotator and terminal device and reach the goals that <<he/she>> has discussed with the rehabilitative team. This prosthesis control would not be possible for <<patient name>> with traditional myoelectric control.

<<Be sure to note any ADLs that the patient could not perform with his/her prosthesis and that he/she can now perform, as well as limitations that would have prevented the patient from completing these tests with a traditional system. For example, if a co-contraction switch could not be configured, or control sites free of muscle cross-talk could not be found.>>

The Coapt COMPLETE CONTROL pattern recognition system is medically necessary for <<patient name>> to reach <<his/her>> rehabilitation goals. <<He/She>> is very motivated, and we have performed preliminary screening to determine that <<he/she>> will successfully use pattern recognition to control <<his/her>> prosthesis. The intuitive nature of the control and <<his/her>> ability to recalibrate the control system, as necessary, to maintain functional independence are invaluable and will prevent device abandonment.

<<Be sure to include a coding plan>>

Thank you for your attention to this request. We hope to hear from you as soon as possible so that we can continue with <<patient name's>> rehabilitation. Please do not hesitate to contact me should you need additional supporting information.

Sincerely,

<<Name>>
<<Title>>


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