COAPT

GUIDE (V 6.0)

REIMBURSEMENT & AUTHORIZATION

DISCLAIMER; GENERAL NATURE OF THE REIMBURSEMENT GUIDE

The reimbursement guide is intended to provide general information to assist you in invoicing and receiving payment from third-party payers for the Coapt **Complete Control** pattern recognition add-on kit that is purchased from Coapt and installed into upper extremity, myoelectric prosthetics. The enrolled supplier (Certified O&P clinician, O&P Care Facility or DME Provider) is fully responsible for accurately billing for the product and all related services; ensuring payer criteria are met; using appropriate HCPCS codes, modifiers and charges and establishing accurate medical necessity of Coapt **Complete Control** and all related services.

Coapt assumes no responsibility for errors or omissions contained in this guide, which is made available as a courtesy to our customers to assist in gaining approval of Coapt **Complete Control**. The information in the guide is provided on an "as is" basis. Coapt does not provide any representations, warranties or guarantees regarding completeness, accuracy or outcome of approval. Your use of the guide and all the information contained in the guide is voluntary. The information provided in the guide should be utilized as a supplement to your current process. You should not rely on the included information or advice as a substitute, nor is it intended to replace your clinical judgement or responsibility.

The suggested HCPCS coding is provided as a reference. The supplier who is submitting the claim will maintain the responsibility to determine and submit correct coding that considers all the rules and regulations of the applicable third-party payer. We recommend contacting the applicable payer for any coding and coverage guidance prior to delivery of Coapt **Complete Control** to your patient. The information contained in this guide is based on what we believe is reasonable judgement regarding coverage and claim submission but does not replace the Supplier's responsibility.

The product information provided in this guide is for informational purposes only. Your use of this guide and all information contained within, including implementation or the use of any included recommendations does not create a professional-client relationship between Coapt and any of its affiliates and you. The content provided in this guide is not intended as and should not be utilized as legal or professional revenue cycle management advice.

PROCESS AND DOCUMENTATION CHECKLIST

As you work through the authorization process it is imperative to keep in mind that the insurance and reimbursement space is constantly changing. It is the provider's responsibility to ensure all documentation is appropriate for meeting industry and payor-specific standards and regulations.

As you prepare, keep in mind the most important and critical elements of successfully obtaining reimbursement for Coapt's pattern recognition technology:

- Ensure that the medical record and clinician recommendations are concise, patient-specific and written in such a way that a lay person will understand the functional benefit the Coapt system provides to the patient.
- Ensure your documentation and recommendations are individualized to each patient and not copied and pasted from this guide or other patient notes. This is strongly recommended to maximize your case for medical necessity and minimize denials.

TIPS

- Each page/chart note in the authorization packet must clearly identify the patient.
- The amputation side should be clearly and consistently identified, particularly for individuals with bilateral amputations.
- All documentation must be authenticated by the original author by application of signature, credentials and date.

PROCESS AND DOCUMENTATION CHECKLIST

GET READY

INTAKE AND VERIFY ELIGIBILITY

- ☐ Obtain a copy of your patient's summary plan documents (or contract of coverage) and the payer's clinical coverage policy applicable to the service, and verify benefits and eligibility
- ☐ Request relevant, existing record notes and review them to understand what medical problems or co-morbidities may impact your patient's function or ability to utilize a prosthesis
- ☐ Consider OT evaluation prior to prosthetics evaluation to better identify functional deficits that help establish medical necessity for a prosthesis and pattern recognition
- ☐ Overview pattern recognition technology with your patient (APPENDIX A)

EVALUATE CANDIDACY

- ☐ Utilize Coapt Evaluation Kit to verify candidacy (APPENDIX B)
- ☐ Identify prosthesis history and any functional limitations with previous/current control strategy or device
- ☐ If the patient has not previously utilized other control strategies, consider performing an evaluation for dual site or more basic forms of myoelectric control using appropriate equipment for comparison
- ☐ Identify and document how Coapt's **Complete Control** pattern recognition system will provide functional benefit to your patient (APPENDIX C)
- ☐ Consider OT assessment to identify functional deficits—impeded function, limited range of motion, limited strength, restricted activities of daily living, etc.—that persist with the use of a more basic (eg. dual site) system and are resolved or improved with the use of Coapt's **Complete Control** pattern recognition system
- ☐ Perform and Document avaialble Upper Extremity (UE) Outcome Measures

GET SET

GATHER CARE TEAM DOCUMENTATION (see section below)

- ☐ Obtain relavent medical records
- ☐ Obtain a prescription and/or standard written order for the prosthesis from the patient's Physician
- ☐ Request any additional chart notes and evaluations to aid in the documentation of medical justification and functional limitations to support the claim
- ☐ Obtain relevant prosthetist's records

PREPARE AND SUBMIT THE AUTHORIZATION PACKET (see section below)

- ☐ Verify the payer has added L6700 to their fee schedule and verify the allowable (APPENDIX D)
- ☐ Prepare the cost and service estimate
- ☐ Re-verify benefits & eligibility
- ☐ Make sure the sumbission packet includes:
    - ☐ Patient-specific assessment of functional needs
    - ☐ Benefits of Coapt's **Complete Control** pattern recognition system specific to your patient (APPENDIX A)
    - ☐ Results from UE Outcomes Measures
    - ☐ Description of the Coapt **Complete Control** system
    - ☐ Prosthetic Prescription
    - ☐ Service estimate with L Codes & justification
- ☐ Subimit and follow up to ensure packet was received

GO

RECIEVE AUTHORIZATION AND DELIVER

- ☐ Complete patient fitting
- ☐ Complete post-fitting assessment(s)
- ☐ Final delivery
- ☐ Submit Claim and Proof of Delivery
- ☐ Receive payment
- ☐ Follow up

GATHER CARE TEAM DOCUMENTATION

MEDICAL RECORDS

Obtain copies of your patient's relevant medical records (surgery notes, clinic notes, occupational therapy notes, etc.). HIPAA specifically allows for provider-to-provider information sharing without any prior patient authorization or completion of specific hospital forms.

> ***We strongly recommend diligence in this process. Failure to get relevant medical records accounts for a large percentage of denials from third-party providers. It is recommended you request medical records prior to the patient's first consultation with the prosthetist, to allow ample time to review the medical records and determine what else may be required to proceed with the submission.***

A physician must evaluate your patient and **document both medical necessity and functional capabilities**. 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
- Applicable revision surgeries or nerve procedures

C. Deficits limiting functional dexterity[1]

- Relevant medical history
- Activities of daily living (ADLs) 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[1]

- 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

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. Physician Recommendation for Prosthetic Referral

NOTE

[1] The prosthetist or therapist may assist the physician in evaluating functional capability and provide useful feedback, but it is important that physicians restate the patient's deficits or medical need in their own words and include this in a separate chart note.

PHYSICIAN'S PRESCRIPTION

To accompany the prosthetist's assessment and the medical records, a physician's prescription and/or standard written order* must be acquired. The prescription must be worded carefully and signed by the referring physician. It must contain the following:

- Patient's name
- ICD-9 Diagnosis Code (not required, but recommended)
- Start date of order (for written order use prescription date; for verbal order use date of telephone call)
- Description of item
- Physician's printed name and credentials
- Signature and date (written order needs Physician's signature and date; verbal order needs signature of person taking order, signature, date, and time)

As a practitioner, you may write the standard order, but it must be reviewed and signed by the physician prior to submitting any claim. This standard written order may, in some cases, serve as the prescription and must contain the following:

- Start date of order
- ICD-9 Diagnosis Code (not required, but recommended)
- Side of body for item(s) being provided
- Description of the unique features of item(s) provided, base code and every additional code to bill. Use a narrative description OR brand name and model number
- Physician demographics (printed name, credential, address, phone, NPI)
- Physician's handwritten (or digital for electronic documents) signature and date
- Patient's name on each page.

DOCUMENTATION IN PROSTHETIST'S RECORDS

For most reimbursement cases, it will be important to keep detailed and accurate prosthetist's notes. The documentation should describe the patient's typical daily functional capabilities and should include, but not be limited to:

- Chart notes for each visit with the patient that contain the prosthetist's name, credentials, signature, and date.
- Written description of the patient's desire to use the prosthesis and prosthetic components being ordered
- Recommendation for pattern recognition control system and rationale for decision
    - Current method of prosthesis control (if any) and need for Coapt's **Complete Control** pattern recognition system
        - Describe why a pattern recognition system is needed
        - Describe why the traditional control system is not/no longer appropriate
        - Describe why the current prosthesis will not allow the patient to achieve the desired function
    - Patient's prior experience with a prosthesis (if applicable)
        - Which other traditional control systems have they tried?
        - Describe any problems the patient experienced (APPENDIX A)
- Documention of patient's ADL needs, limitations and goals
- The functional expectations of the prosthesis and prosthetic components
- Short, clearly written **patient-specific** assessment and plan of care

FOR REPLACEMENT PROSTHESIS

- All documentation of the current prosthesis and prosthetic components
- History of the device being replaced
- Description of all prior labor involved
- The reason(s) for replacement

FOR NEW PROSTHESIS

- Recommendation for the new prosthesis and prosthetic components
- Proof from physician's documentation (medical necessity evidence originates from the physician documentation)
- All clinical decision rationale
- All documentation related to medical necessity/billing justification

PREPARE & SUBMIT THE AUTHORIZATION PACKET

SUBMIT ESTIMATE

A comprehensive service estimate covering all cost elements of the prosthesis must be provided to the reimbursement party. This document serves as a full quotation and should be prepared by the practitioner's facility. It is important that each item listed on the service estimate has a description of purpose.

> **NOTE**
>
> Centers for Medicare & Medicaid Services (CMS) has created **L6700**, a Healthcare Common Procedure Coding System (HCPCS) Level II code for adding myoelectric pattern recognition to enhance upper-limb prostheses. This code was added to the Medicare fee schedule April 1, 2025. See Appendix D for correct coding guidance.

In the case of an estimate that contains the Coapt **Complete Control** pattern recognition system, make sure it also includes all other prosthetic components/devices you are recommending. The estimate should also list any training, follow-up, extended warranty, and other services. The basis for cost of each item on the estimate is at the ultimate discretion of the preparer but often reflects established reimbursable costs (for items with HCPCS L-code designation) or the manufacturer's suggested retail price (MSRP) (for components without HCPCS L-code designation).

FOLLOW UP

After all required content is provided to the reimbursement party, it is important to remain patient and diligently follow up.

- It can be helpful to request written confirmation that your content was received in good standing and will be reviewed.
- It is commonplace to ask when you can expect a decision.
- For every instance of inquiry or communication you have with the reimbursement party, document the date, time, and name of the person you spoke with.

APPEAL THE DENIAL(S)

In many cases, additional information will be requested and/or a denial will be given. In either case you should be prepared to offer supplemental materials. You should request a written response covering the detailed reasons for a denial.

It is important to address the exact objection(s) in the denial with valid assertions in your appeal. Be specific, cite examples (eg. from APPENDIX B) and only respond to the reasons for denial provided by the payor. Do NOT attempt to highlight a recreational need as a functional benefit. Confirm your appeal was received when you submit.

Remain patient and persistent with follow-up on the appeal and request information about the appeal process, the review process, and the opportunities for subsequent appeals (if necessary). Always remember to get information from the reimbursement party in writing.

You should communicate with and advise your patient that the authorization request may be denied and require an appeal. It can be important to set the tone that advanced technology is commonly scrutinized by third party payers, and an appeal process with subsequent delay in care may be necessary to secure reimbursement. This information helps to keep the patient engaged in the treatment plan and may prevent the patient from becoming discouraged with this aspect of obtaining their prostheses Note that many payers require the supplier to obtain and submit an Appointment of Representative form that confirms the patient authorizes the provider to represent them in appeals.

RECEIVE AUTHORIZATION AND DELIVER

If you have successfully received reimbursement authorization to incorporate the Coapt **Complete Control** pattern recognition system into your patient's prosthesis you will need to continue to comply with the requirements of reimbursement parties, and you may be required to carefully document the final stages of this process.

PROOF OF DELIVERY

As the supplier of the prosthesis and prosthetic components, you may be required to retain proof of delivery documentation in your patient's records in order to verify the patient received the goods. Your patient may choose a designee to sign and accept delivery of the goods on their behalf, but anyone who has a financial interest in the delivery of the goods cannot be this designee. The nature of the patient's relationship with the designee should be noted on the delivery slip (if applicable) and any designee signature should be legible. It is good practice to note the name of the designee on the delivery slip.

You may deliver directly to the patient or their designee. Proof of delivery is a signed delivery slip and should include:

- Patient's name, quantity delivered, detailed description of the item(s) being delivered, brand name(s), and serial number(s);
- Signature and date that goods were received by the patient or designee;
- Verification of the date the patient goods are received/delivered matches the date of service on the reimbursement claim.

You may also use a shipping service to deliver to the patient. In these cases, proof of delivery should include:

- Patient's name, quantity delivered, detailed description of the item(s) being delivered, brand name(s), and serial number(s).
- The delivery service's package identification number, tracking slip, and your shipping invoice for the package(s) sent to the beneficiary – make sure to document the delivery address, package(s) identification number given by the shipping service, and if possible, the date delivered.
- Documentation showing the shipping date as the date of service on the reimbursement claim.

For more Proof of Delivery information, visit www.cms.gov.

BENEFICIARY AUTHORIZATION

A beneficiary authorization should permit you to bill and receive payment on behalf of your patient (the beneficiary) and exchange medical records in the process. A new beneficiary authorization is required any time a new prosthesis and prosthetic components are provided. In many cases, the beneficiary authorization can be combined with the proof of delivery. A properly completed beneficiary authorization should:

- Name the patient
- Include the patient's written permission to pay you directly
- Authorize you to submit claims on behalf of the patient
- Contain a release authorizing you to obtain confidential medical information about the patient
- Be signed and dated by the patient

APPENDIX A

MYOELECTRIC PATTERN RECOGNITION: TECHNOLOGY & BENEFITS

Pattern Recognition Technology

Muscles in arms and hands rarely work alone. Whenever we move our arms and hands, multiple muscles make coordinated contractions in concert and each muscle emits its own small electrical signature (called myoelectricity or electromyogram, EMG) like it is its own instrument in an orchestra. Each different arm and hand movement results in a unique but repeatable set of these myoelectric patterns—like different songs from the orchestra.

Myoelectric signals are very tiny, but they can be detected by electrodes on the surface of our skin. Using a full array of electrode contacts on the skin—covering the whole area of these underlying muscle contractions—lets all the rich muscle pattern information be captured (akin to an array of microphones over our orchestra).

This is where pattern recognition goes to work. The complex sets of myoelectric patterns need to be "decoded" in real time and matched to the corresponding motion of a prosthetic limb. Coapt's pattern recognition is a system of finely tuned machine learning algorithms that does just that. Specifically, for the residual muscle signals of those with upper limb loss or difference. For example, the pattern of myoelectric activity recorded on the residual forearm during hand opening is different from the pattern recorded while the hand is being closed, or making a point gesutre, or turning a wrist, and so on.

Coapt's **Complete Control** pattern recognition-based intent decoder system listens to the myoelectric activity and uses mathematical algorithms to determine when a pattern matches the user's intention to make an arm or hand movement. It then tells the prosthesis to move accordingly, providing intuitive control of multiple prosthetic movements. Or said another way, the user can personalize the prosthesis to move based on the pattern they want.

The Coapt **Complete Control** System

Coapt's **Complete Control** system is designed to enhance the functionality of a powered upper limb prosthesis. It is designed to work seamlessly with most major manufacturers' devices as an easy plug-and-play add-on (for a list of compatible devices visit the Coapt website).

The main processing unit of the Coapt system is the **Complete Controller** and has two main lobes connected by a semi-flexible bridge. This allows the unit to conform to the curvature of a prosthetic socket.

The **Complete Calibrate** button is permanently connected to the **Complete Controller**. It has one central button, an indicator LED, and the Coapt logo on its top face. It is designed to be secured into the outer socket wall of the prosthesis with its button side exposed to the user. The button is primarily used to initiate the prosthesis calibration process and is not a prosthesis power on/off button. The multicolor LED indicator is positioned in the middle of the Coapt logo.

The **Complete Controller** main unit arrives with two detachable cables. A gray jacketed cable is the EMG Interface Cable. One end of this cable has a wide connector that mates with the **Complete Controller** while the other end will be your EMG interface of choice, e.g. a set of ring-terminal eyelets, snap connectors, or an EMG cuff. A white jacketed cable is the Device Interface Cable. This cable connects the **Complete Controller** to the prosthetic device(s) being controlled. One end of this cable has a wide connector that mates with the **Complete Controller** while the other end has variable terminations for connection to the prosthetic device(s) being controlled.

The **Complete Controller** communicates wirelessly to the **Control Companion** mobile app (available for free download on both iOS and Android devices) for setup, configuration, calibration assistance, and other pattern recognition controls practice.

Pattern Recognition Benefits

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.

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. Pattern recognition can help to prevent unintentional opening/closing with traditional systems that might lead to object dropping or injury. A device that reacts more consistently to user intent is more functional to wear and can lead to enhanced functional use leading to accelerated return-to-work incorporation, and ability to complete activities of daily living (ADL's).

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 or cognitive load of mode switching options.

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 of 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, the 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 may sometimes correspond with an area where an electrode is difficult to place (e.g., over scarring, sensitive areas, socket hardware, etc.) but with pattern recognition that contact site may be moved, while still achieving natural prosthesis control. Collectively this makes pattern recognition indicated 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 which 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 conventional proportional control strategies. Additionally, Simon et al. (2011) found that enhanced proportional control provided better function than on/off control during tracking tasks.

ELECTRODE PLACEMENT IS FLEXIBLE

*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 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 reduced discomfort, 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 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 targeting 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 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 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 function. Traditional myoelectric control styles are not capable of this adaptation and can 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 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).

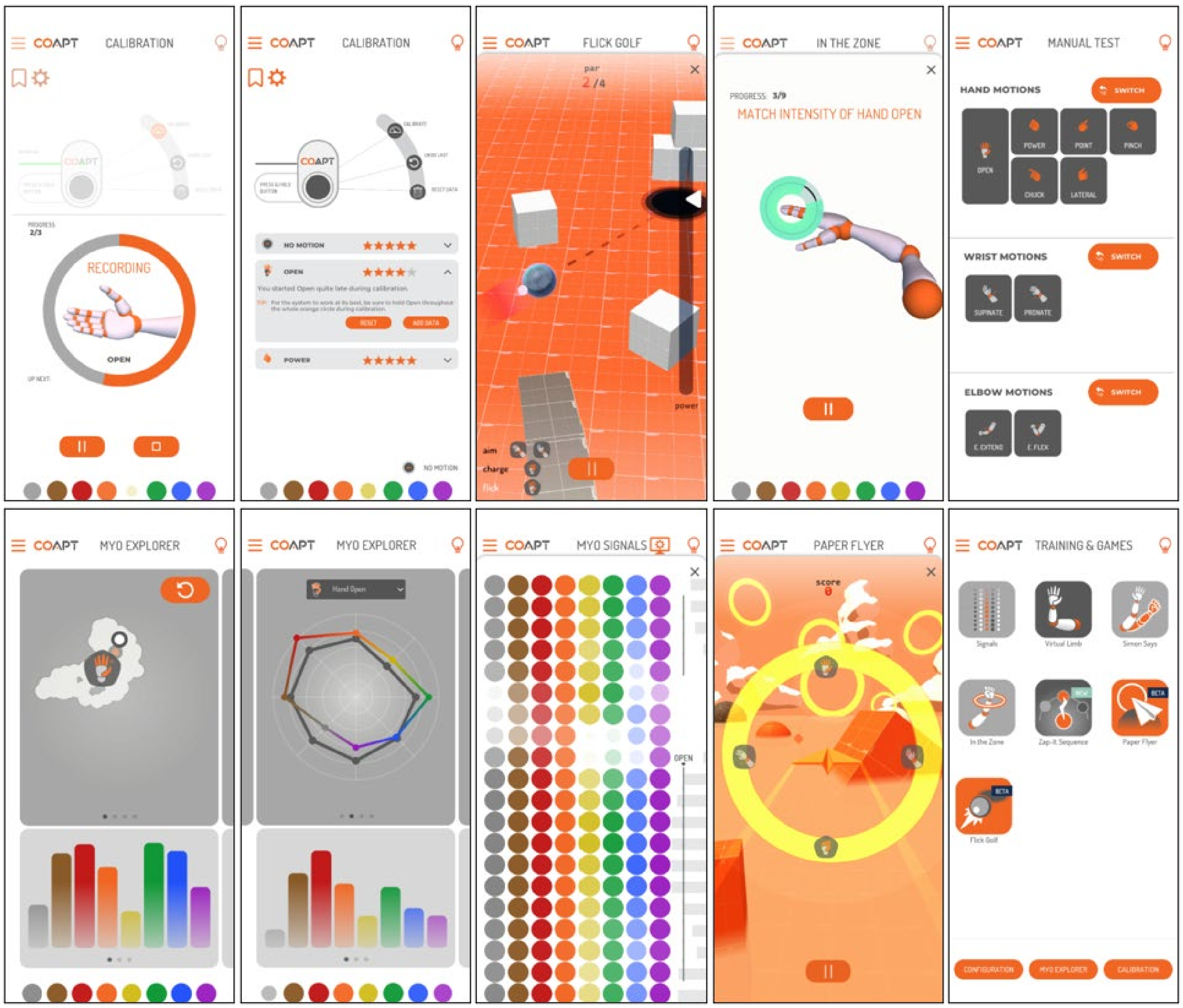
APPENDIX B

TOOLS AVAILABLE TO HELP WITH PATIENT EVALUATION

Control Companion

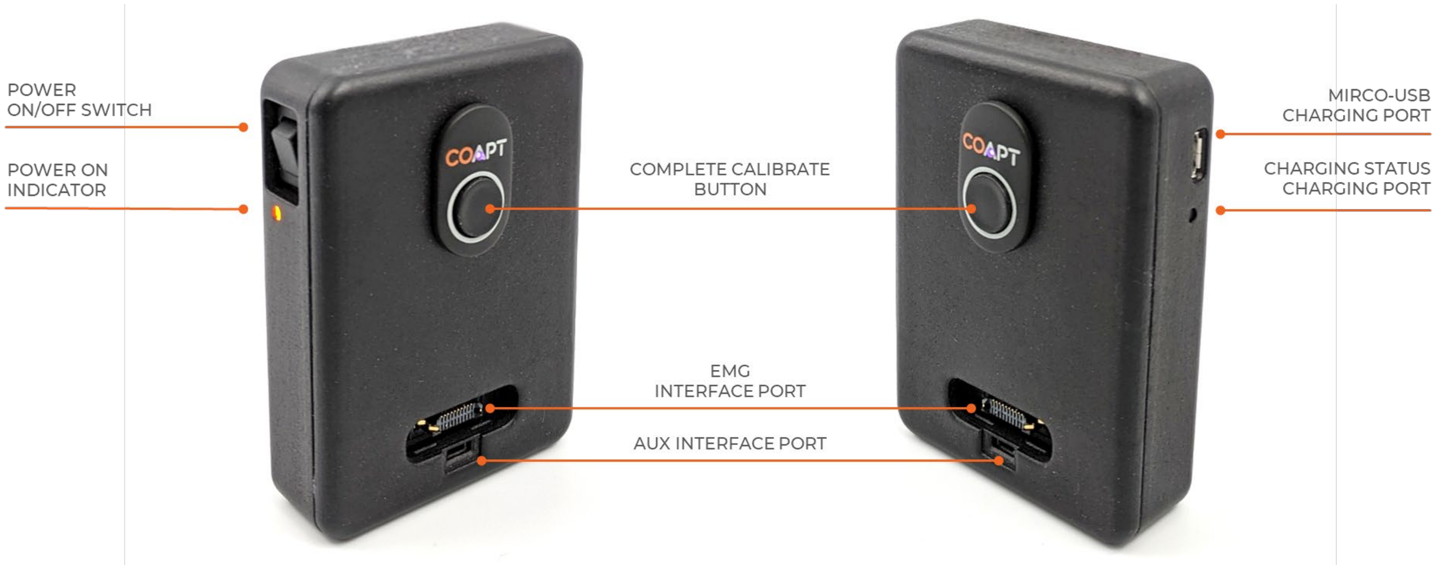
The Coapt **Complete Control** system has a mobile device application for users and clinicians called **Control Companion**. It is available for free download on both iOS and Android devices.

Control Companion can be used for setup, configuration, manual testing, signals exploration, calibration assistance, and other pattern recognition controls practice. The screenshots below illustrate some of the user interface, calibration, and training features.



Evaluation Kit

Coapt also makes available a handheld Evaluation Kit to assist clinicians in evaluating patients with all levels of limb loss and difference without the need for a test socket or prosthesis. Coapt Evaluation Kits are both for sale and available on short-term loan at no cost – please contact a Coapt representative in advance to reserve one.



Using a Coapt Evaluation Kit with the appropriate EMG Interface (noted in the Evaluation Kit Handbook in the Clinician Resources section of Coapt's website) allows your patient to benefit from all the trial, diagnosis, and practice features of the **Control Companion** mobile app.

Using a Coapt Evaluation Kit in clinic will allow you to document several key capabilities which demonstrate a patient's candidacy for the Coapt **Complete Control** system. These include:

- Producing sufficient EMG signals to meet the threshold for myoelectric control
- Ability to produce unique patterns to allow the operation of the proposed prosthetic components
- The ease of how Coapt's **Complete Control** pattern recognition system works, and how it will work for your patient in their definitive prosthesis

From your session with a Coapt Evaluation Kit, it may be valuable to capture a clinical recap with supporting screen shots to reference as you develop your plan of care. These may also be useful to include with your pre-authorization package for certain insurance providers.

TIPS

For an in-depth guide to the setup and use of the Coapt Evaluation Kit refer to the Coapt Evaluation Kit Handbook available on the Coapt website or book a 1:1 with your Coapt representative.

APPENDIX C

LIMITATIONS WITH TRADITIONAL CONTROL STRATEGIES THAT MAY INDICATE WEARER IS AN APPROPRIATE CANDIDATE FOR COAPT

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:

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 depend on a pair of strong, isolated muscle site signals.*
Does your patient have difficulty reliably initiating co-contraction or other emg triggers 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).*
Does your patient inadvertently co-contract?	*Unintended co-contractions can make it difficult or impossible to configure a robust direct 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.*
Does your patient fatigue easily?	*Studies have shown pattern recognition (the Coapt system) requires less forceful muscle contractions, which reduces patient fatigue and allows longer device use durations.*
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 control is poor.*
Are your patient's ideal traditional electrode sites located over scarring, over sensitive areas, or areas that would be uncomfortable for the patient?	*Pattern recognition does not require specific electrode placement, so you can work around sensitive locations on your patient's limb. With the Coapt Complete Control system, you have the freedom to place electrodes in comfortable locations and maintain good contact with the residual limb.*
Does your patient have difficulty with proportional control?	*The Coapt Complete Control system uses an enhanced proportional control algorithm that lets patients operate at a broader range of speeds, improving functional outcomes.*
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.*

Does your patient have more than two emg control sites?	*If your patient has had Targeted Muscle Reinnervation (TMR) surgery or other similar surgical interventions, then they may have up to 4 or 5 available control sites. Pattern recognition provides reliable, enhanced control using EMG information from all available sites.*
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.*
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 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 one or more of the above questions, then pattern recognition may be considered medically necessary for your patient. The Coapt **Complete Control** pattern recognition system will allow your patient to intuitively control a prosthesis and achieve functional outcomes not otherwise possible.

We encourage you to discuss these issues with your patient and explain how Coapt's **Complete Control** system can help them achieve better control. Encourage your patient to discuss their challenges with their referring physician and describe how pattern recognition would help them. ***The physician creates medical necessity by documenting the existence of one or more of these control issues and may also specifically note they are prescribing Coapt's Complete Control system to address these issues. The physician should also include what functional benefit they expect the wearer to experience by providing this addition.***

NOTE

If you find additional clinical issues that Coapt's **Complete Control** pattern recognition system seems to resolve, please contact Coapt. We are happy to discuss these observations with you and, if necessary, update our recommendations accordingly.

APPENDIX D

COAPT CORRECT CODING GUIDANCE

Coapt's **Complete Control** system is an add-on electronics module that personalizes the way a powered, upper extremity prosthesis is controlled by its user. The Coapt system uses a form of machine learning called **myoelectric pattern recognition** to **decode neurological movement intent** of the user. The result is a modern, seamless, myoelectric control interface between the human and prosthesis.

CORRECT CODING

L6700	Upper extremity addition, external powered feature, myoelectronic control module, additional emg inputs, pattern-recognition decoding intent movement.

Coapt's **Complete Control** product is suitable for most levels of upper extremity limb loss and limb difference, and is compatible with virtually every upper extremity powered prosthetic device.

Coapt's **Complete Control** is an FDA Class II, 510K cleared medical device (K191083).

INTERACTIVE COMPATIBILITY TOOL

ADDITIONAL CODING OPTION

L7499	*Coapt Extended Warranty* Coapt's *Complete Control* product includes a standard 2-year Limited Warranty. Purchase of a *Coapt Extended Warranty* is an addition to the upper extremity external powered prosthesis and covers all defects incurred in the normal use of the Coapt system up to years 3, 4 or 5.

APPENDIX E

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