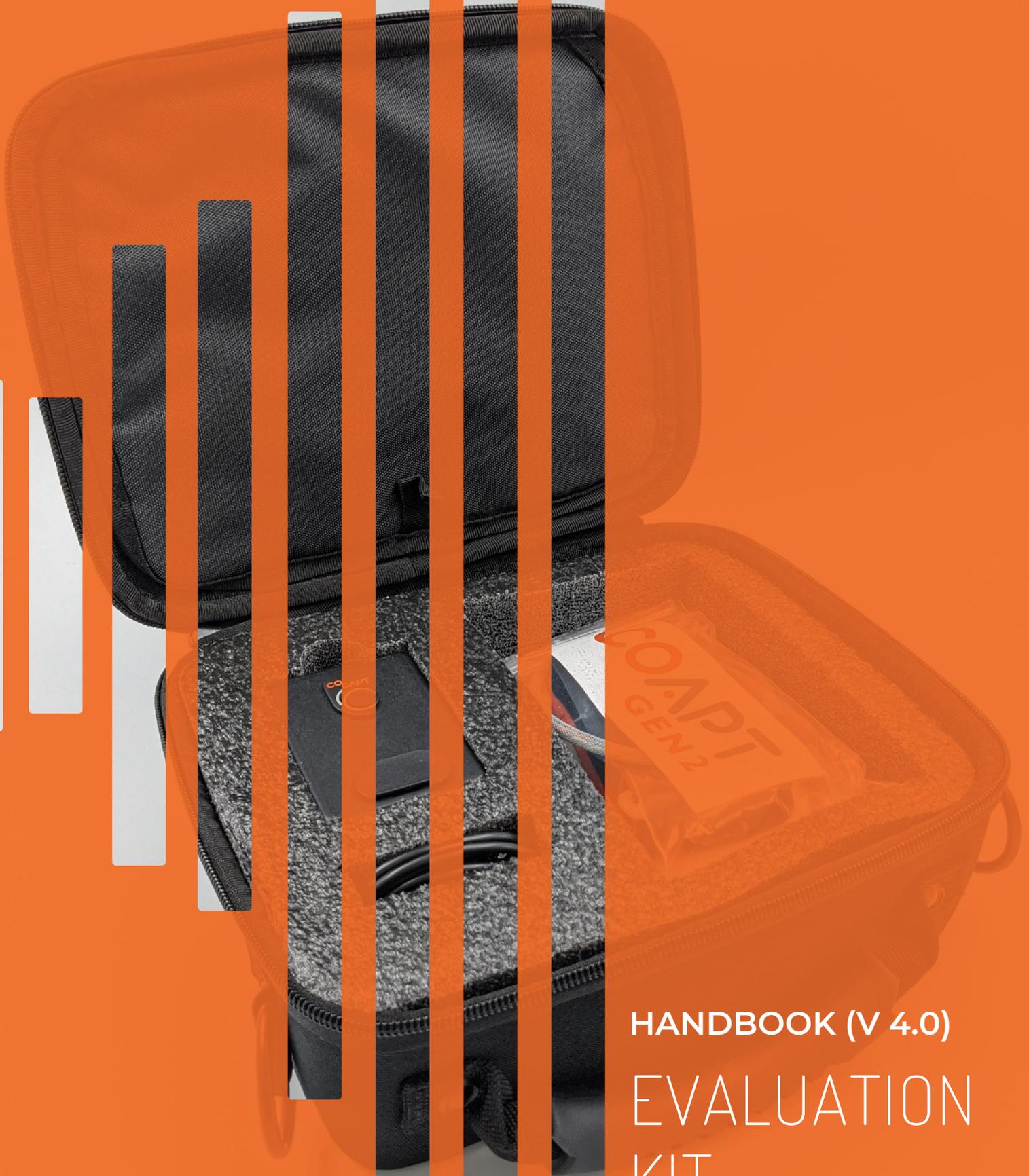


COAPT<sup>®</sup>  
GEN2



HANDBOOK (V 4.0)

EVALUATION  
KIT

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# USER ASSISTANCE & SAFETY

## USER ASSISTANCE

Contact your prosthetist if you have difficulty operating your device. You may also contact Coapt for support (toll free) at 844-262-7800. Additional information about connecting and using the Evaluation Kit may be found online at [www.coaptengineering.com](http://www.coaptengineering.com)

## GENERAL WARNINGS AND PRECAUTIONS

For safety and to prevent damage to the Evaluation Kit, please read and adhere to all safety precautions found in this handbook. In addition, please follow the safety guidelines found in the user manual(s) for any connected electrodes or prosthetic device(s). Failure to heed all warnings and precautions could cause damage to the device and void the warranty. The following symbol definitions pertain to warnings in this handbook and on all device labels.

SYMBOL DEFINITIONS	
 <b>WARNING</b>	Warning regarding possible risk of severe accidents or injury.
 <b>CAUTION</b>	Warning regarding possible risks of accident or injury.
 <b>NOTICE</b>	Warning regarding possible damage to product or equipment.

 **Read and follow safety instructions.** Read this entire manual before operating the Evaluation Kit. Failure to do so could result in suboptimal system performance or injury, or damage to the device.

 **NEVER attempt to remove or modify the battery** in any way. Maintenance, repairs and upgrades may only be performed by Coapt, LLC. Unauthorized device modification or disassembly could cause damage to the device resulting in device malfunction, and injury to the user.

 **NO modifying or disassembling device.** Do not disassemble componentry or modify in any way. Maintenance, repairs and upgrades may only be performed by Coapt, LLC. Unauthorized device modification or disassembly could cause damage to the device resulting in device malfunction, and injury to the user.

 **Use with implanted electronic devices.** Do not bring the Evaluation Kit into the immediate proximity of active implanted devices (e.g., pacemakers, defibrillators) unless assured by a qualified healthcare professional that it is safe to do so. Interference between the Evaluation Kit and the implanted device could cause the implanted device to malfunction.

**⚠ CAUTION**

**Use near open flame.** Use care when operating device near an open flame, and do not allow device to remain directly over an open flame. Direct exposure to an open flame may cause the device to exceed safe temperature limits and may cause device malfunction.

**⚠ CAUTION**

**Exposure to extreme temperatures.** Do not expose to extreme low (<-20°C) or high (>45°C) temperatures. Exposure to extreme temperatures could cause damage to the device and minor injury.

**⚠ CAUTION**

**Use near sources of high radio frequency (RF) energy.** Use caution when operating the device in proximity to sources of high RF energy (e.g., broadcast antennas or radar systems). Interference could cause malfunctioning of the device.

**⚠ CAUTION**

**Use in a corrosive environment.** Do not expose the device to excessive amounts of corrosive substances (e.g., salt water, sweat) or clean with acetone, benzene, or similar solution. Exposure of electronics to corrosive substances can cause damage to the device resulting in device malfunction, and minor injury to the user.

**⚠ CAUTION**

**Exposure to excessive moisture, vibration, dust, or shock.** Do not expose to excessive moisture, liquid, dust, vibration, or shock. Doing so can cause damage to the device resulting in device malfunction, and minor injury to the user.

**⚠ CAUTION**

**Crushing of device.** Take care not to allow the device to become smashed or crushed. Crushing of the device can cause device malfunction, and minor injury to the user.

**⚠ CAUTION**

**Use in areas of large static buildup.** Take care when operating the device in areas with large amounts of electrostatic buildup (e.g., very low humidity). Exposure to electrostatic discharge can cause damage to the device resulting in device malfunction, and minor injury to the user.

**⚠ CAUTION**

**Opening enclosures.** Never open the Evaluation Kit enclosure. Opening the enclosure could cause permanent damage to the Evaluation Kit resulting in device malfunction and minor injury to the user.

**⚠ CAUTION**

**Use of heat guns.** Do not bring a heat gun or other heating device into proximity to the Evaluation Kit. Overheating can cause damage to the Evaluation Kit, resulting in device malfunction and minor injury to the user.

**⚠ CAUTION**

**Use with incorrect or incompatible electrodes.** Make sure the Evaluation Kit is only connected to an EMG Interface Cable referenced in this instruction manual. Use with an EMG input that is incompatible with the system, may cause damage to and/or malfunction of the device and could result in minor injury to the user.

## ADVERSE REACTIONS

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your healthcare provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is NOT required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

### SUBMITTING ADVERSE EVENT REPORTS TO FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

- Report Online at [www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home](http://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)
- Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at [www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf](http://www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf)
- Call FDA at 1-800-FDA-1088 to report by telephone
- Reporting Form FDA 3500 commonly used by health professionals. The form is available at <https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>

### SUBMITTING ADVERSE EVENT REPORTS IN THE EU

If you or someone in your family has experienced a serious adverse event, you are encouraged to report this event to Coapt and/or the national competent authority of the country in which the event occurred. Serious adverse events are defined as: any incident that led to or may lead to a death, serious deterioration of health, or public health threat. You must report the event as soon as possible. Please contact Coapt if you have any questions or need assistance.

## LABEL SYMBOL DESCRIPTIONS

SYMBOL	INFORMATION	EXPLANATION
	Waste Electrical and Electronic Equipment Directive Symbol	Electrical and electronic items should not be disposed of in your dustbin or wheelie bin, but should be recycled.
	Consult Accompanying Documents Symbol	Please read the entire instruction manual before using the device.
	FCC Symbol	This device is certified with the United States Federal Communications Commission.
	Non-ionizing Radiation Symbol	This device emits non-hazardous levels of non-ionizing radiation.
	CE Mark	The device is certified with the European Union under the Medical Device Directives (93/42/EEC).
	Serial Number	Signifies the identification information for the device.
	Manufacturer	Manufacturer Name and Address
	Date of Manufacture	Date the device was assembled at Coapt.
	European Representative	Signifies the European Representative for Coapt.
	Type BF Applied Part	The device has conductive contact with the patient.

# OVERVIEW

## PURPOSE OF THE DEVICE

The Coapt Evaluation Kit is intended to be used for the planning and/or practice phases of an upper limb myoelectric prosthesis fitting with two main purposes:

1. The Evaluation Kit allows potential upper limb prosthesis users to “test drive” Coapt COMPLETE CONTROL myoelectric pattern recognition technology. It permits visualization of EMG control signals and enables control of a virtual prosthetic arm in real time using the COMPLETE CONTROLROOM Gen2 user interface application. The Evaluation Kit can also be used as a training tool to assist users in enhancing their function with pattern recognition myoelectric control.
2. The Evaluation Kit assists with determining location of electrodes in the socket by allowing the clinician to validate potential for pattern recognition myoelectric control. This enables efficient planning of the prosthesis socket. With less time spent in the clinic searching for the best muscle control sites, more time will be available for in-clinic functional practice.

## INDICATIONS FOR USE

The Coapt Evaluation Kit is an accessory tool intended to be used during the planning and alignment of myoelectric control contact locations for an upper limb prosthetic socket.

## CONTRAINDICATIONS

None known.

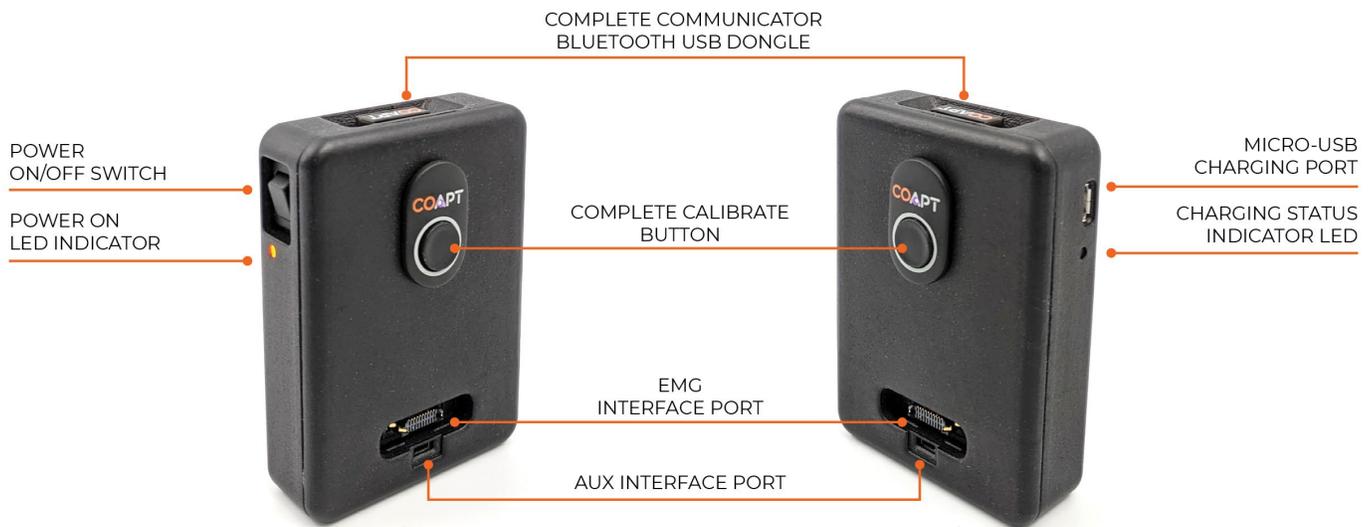
## LIMITATIONS

Careful evaluation is required to determine if individuals with brachial plexopathy or high-level amputations without targeted muscle reinnervation surgery could benefit from the Coapt **Complete Control** System Gen2. The Coapt Evaluation Kit can aid in determining this.

## DESCRIPTION

The Coapt Evaluation Kit is a handheld clinical tool created with technology from the Coapt **Complete Control** System Gen2 using pattern recognition technology to revolutionize the way muscles' bioelectrical activity (electromyogram, EMG) signals are analyzed, recorded, and used for the control of upper limb prostheses.

The Evaluation Kit allows for visualization and evaluation of myoelectric signals generated from muscle contractions. The Evaluation Kit permits virtual practice and training for pattern recognition myoelectric control.



## DESCRIPTION OF THE DEVICE

The Coapt Evaluation kit is to be used in conjunction with a Coapt EMG Interface Cable (sold separately) and either Coapt's **Control Companion** mobile app or **Complete ControlRoom** software app.

### COMPONENTS

1. Evaluation Kit main unit
2. **Complete Communicator** USB Bluetooth Dongle
3. USB Charging Cable – micro-USB cable for main unit charging via a USB port or USB IEC 62133 certified external wall plug (wall plug not provided by Coapt)



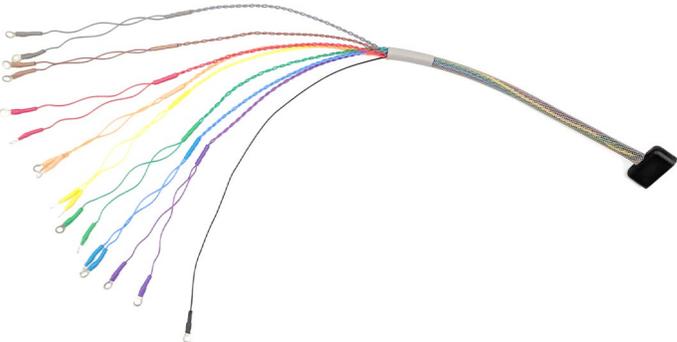
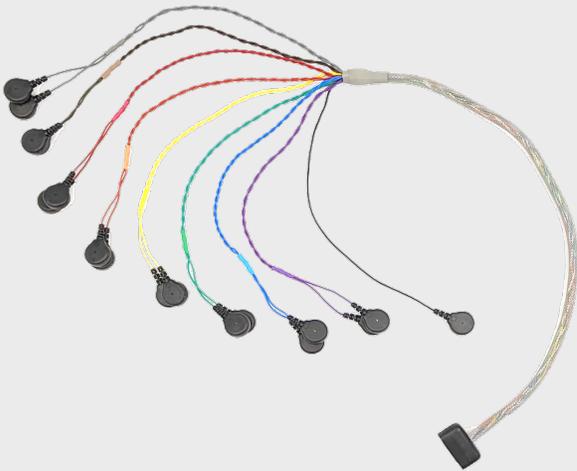
### ACCESSORIES

4. EMG Interface Cable(s) (sold separately)
5. Electrodes Contacts (if necessary, sold separately)

## COMPATIBLE DEVICES

### EMG Interface Cable Types

When purchasing an Evaluation Kit, the EMG Interface Cable(s) are not included and must be ordered separately. The Evaluation Kit is only compatible with Coapt EMG Interface Cable types shown in the table below. Please contact a Coapt representative with any questions about EMG Interface Cable types and uses.

EMG INTERFACE	DESCRIPTION
<p>Standard Eyelets EMG Interface Cable</p>	<p>17 ring/eyelet terminations for use with a set of non-filtering, passive electrode contacts (see below)</p> 
<p>Snap Style EMG Interface Cable</p>	<p>17 snap terminations for use with with disposable, Temporary Evaluation Electrode “Stickers” (see below)</p> 

Evaluation-Style Cuff EMG Interface Cable

Wrap-around, Velcro cuff for evaluation use with transradial and small circumference transhumeral limbs



Osseointegration-Style Cuff EMG Interface Cable

Elastic cuff for definitive Osseointegration use only



## Electrode Contacts

The Evaluation Kit is designed to work with non-filtering, passive electrode contacts. Coapt recommends using these compatible electrode contacts:

COMPATIBLE ELECTRODE CONTACTS	PART NUMBER(S)	FDA 510(K)
Coapt <b>ControlSeal™ Electrodes</b>	ELSB, ELSC, ELSD	K223605
Coapt <b>Dome Electrodes</b>	ELSA	K190416
Coapt Evaluation Electrode “Stickers”	ELEV	K864690

Contact a Coapt representative when using electrode contacts from other manufacturers.

**⚠ CAUTION**

**Skin irritation.** Use of non-biocompatible materials (or materials to which the user is allergic) for electrode contacts may cause skin rash or skin irritation. Ensure electrode contacts are made of biocompatible material and do not cause an allergic reaction.

## CONDITIONS FOR USE

The Evaluation Kit was developed for clinical use and must not be used for unusual activities.

The Coapt Evaluation Kit should only be used by a trained and licensed medical professional or under supervision of a trained and licensed medical professional.

See General Warnings and Precautions for more information regarding acceptable use conditions.

# INSTRUCTIONS FOR USE

## PATTERN RECOGNITION FUNDAMENTALS

Muscle electrical (myoelectric) signals contain a lot of information. Pattern recognition uses the combined information gathered from an array of electrode contacts to control multiple prosthesis movements intuitively.

**Electrode Contact:** All electrode contacts must maintain good contact with the user's skin for ideal pattern recognition function.

**Good Calibration:** Pattern recognition performance depends on good calibration. Users must understand the methods to provide good calibration.

**Pattern Repeatability:** Pattern recognition works best if the user can replicate the patterns of muscle signals for each motion the same way each time. Each motion should "feel" the same each time the user performs it.

**Pattern Differentiation:** Pattern recognition requires the pattern of muscle signals to be different for each distinct motion. Each motion should "feel" different from all other motions.

### **Guidance for Learning and Practice:**

- No need for extra-hard muscle contractions. Contraction levels should be moderate – like the feeling in the strength of a comfortable handshake.
- Start slow and practice patience. This new pattern recognition method of control can take a little time and practice to get used to.
- Control is not position-based. Example: if a hand is commanded to close (and it does) and the user then wishes to turn the wrist, there's no need to "hold" the hand closed while rotating the wrist, as each motion is a separate activity.
- If control becomes erratic, reflect on the "feeling" of the motions when calibrated. The system does not forget the patterns it was calibrated with, so it can always be helpful to return to those perceptions when needed.

For more on myoelectric pattern recognition, please visit: <https://coaptengineering.com/pattern-recognition>

## PLANNING PATTERN RECOGNITION ELECTRODE LOCATIONS

Successful pattern recognition use depends on good muscle signal (myoelectric) information. The more myoelectric information the pattern recognition algorithms get, the better the functional control potential.

**The goal of planning and placing electrode contacts for pattern recognition is to spread electrode contacts out as much as possible to capture all underlying muscle tissue that is providing information.** An analogy to this is planning the camera locations at a professional sports event – strategic locations are needed to capture all angles and information from the area of interest.



Contact a Coapt representative with any questions about myotesting and/or electrode placement. Coapt is willing and able to assist with placement instruction and suggestion—these can often be accomplished by submitting socket and/or limb shape images to Coapt.

### Step 1: Discussing User Contractions

Having a user explore all of the possible muscle contractions they can imagine, feel, and produce – even if some contractions are faint and even contractions that might not be used for prosthesis control – is the important first step in determining where their underlying muscle information “areas of interest” are.

A thorough discussion will have them think about and try all possible residual limb contractions. Ask the user to first try contractions they would want to use for controlling their specific prosthesis functions. Focus on contractions that are distinct and repeatable.



- Allow or encourage the user to mirror their perceived motions with their sound limb as needed.
- When users have difficulty making contractions exactly matching a function (such as not feeling all fingers well enough to mimic a certain grip, or not feeling their wrist turning), explore supplemental contraction variations (for example: adding a feeling of thumb extension to help with wrist supination, a feeling of pinky extension for wrist pronation, or a feeling of fingers spreading for hand open).
- Be patient, listen, and take considerable time with this process.
- Perform this discussion in a relaxed environment.
- Develop a common vocabulary for specific motions.

### Step 2: Palpating to find Underlying Muscle on the Residual Limb

To clinically determine where a user’s muscle information “areas of interest” are, have the user repeat all the contractions from Step 1 while holding and feeling as much of their residual limb as possible. Ask the user to sustain each muscle contraction for 3-4 seconds at a medium strength. Take time with this process. Be sure to explore various contractions and repeat as necessary to feel all of the limb.

While feeling the limb, take note of all areas where underlying muscle activity is felt, even if it is subtle. This will guide where electrode contacts should be placed. Consider taking notes, capturing images, or making temporary markings on the user's skin.



- Feel for the overall muscle activity – like what the pattern recognition algorithm does – by sensing the patterns of activity at multiple areas simultaneously.
- **Remember:** Pattern recognition myoelectric control does not rely on isolated muscle signals, and it does not always need strong muscle signals. Avoid tendencies to only feel with fingertips and to only feel for isolated “hotspots.”
- Do not ignore areas of slight/subtle/weak underlying muscle contraction.
- Note any unique or unexpected areas of underlying muscle contraction – for transhumeral amputees, this may mean unique muscle activity distal on the residual limb.
- If the user contracts muscles quite hard for all motions, ask them to make contractions a little more softly.

### Step 3: Planning Electrode Locations

#### **PLACING THE STANDARD EYELETS OR SNAPS EMG INTERFACE CABLE:**

Use the areas of underlying muscle information discovered in Steps 1 and 2 to plan electrode contact locations.

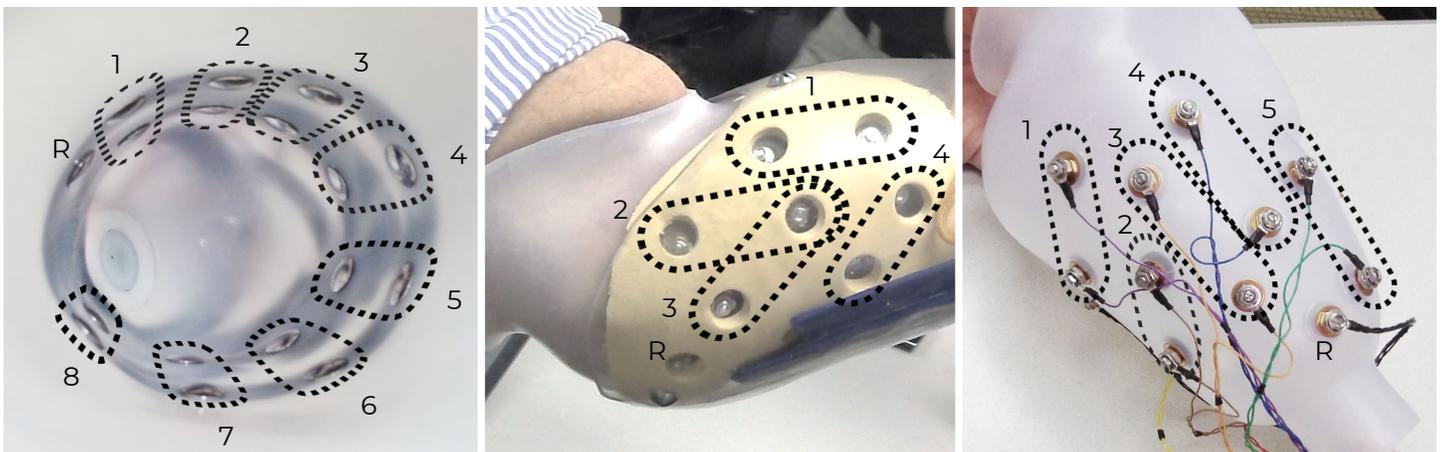
The Standard Eyelets or Snaps EMG Interface cable has 17 electrode contacts to place, where 1 is an independent reference “ground” contact and the remaining 16 are paired to make 8 “signal channels”. Each pair of signal electrode contacts work together to capture the bi-polar, differential measurement of the muscle contraction underlying their location. The two **contacts for a given channel are ideally placed 30-60mm apart** and detect a myoelectric signal from an oval area encompassing their general location. The farther apart the pair of electrode contacts, the larger (and deeper) the sensed area will be, and vice versa.

**General Placement** - Plan to place the 8 sets of 2 signal electrode contacts so their 8 myoelectric detection “oval areas” fully capture all underlying muscle information. The independent reference contact (the 17<sup>th</sup>) should

be positioned in a location that maintains excellent electrode-skin contact and should NOT be shared or paired with any of the signal contacts.

**Contact-Pair Orientation** – While it is generally a good idea to align a pair of signal contacts in the direction of underlying muscle fiber direction, it is ok with pattern recognition to place some of the electrode pairs “off-axis”. This is helpful when fitting a residual limb with unique areas of muscle tissue, and for geometrically unique and congenital limb presentations.

**Contact Sharing** – For a limb that is too small to reliably fit all 17 electrode contacts, it is ok to have a few of the signal channels share an electrode contact. See the Coapt **ControlSeal™** product handbook for assembly detail when sharing. When connecting the Standard Eyelets EMG Interface cable to shared electrode contacts, do NOT place the two wires for the same channel (same color) on the same electrode contact – this will result in zero signal for that channel and not be helpful for pattern recognition performance. Also, do not leave any conductor wires unconnected. That is, always place electrode contacts for all 8 myoelectric signal channels.



- Consider starting with sites that correspond to previous electrode locations when retrofitting existing myoelectric users.
- Do NOT limit electrode placement to “hotspot” areas.
- Identify locations to AVOID placing electrode contacts, such as
  - Areas that will lose electrode-to-skin contact during use.
  - Areas outside of socket boundaries or near valves.
  - Areas that have no underlying muscle (i.e., bone only).
  - Sensitive skin areas.
  - Areas over muscles that contract with arm loading positioning (example: deltoid or brachioradialis muscles).

**PLACING THE EVALUATION-STYLE CUFF OR OSSEOINTEGRATION-STYLE CUFF EMG INTERFACE CABLE:**

For best results, clean and dampen underlying skin areas and secure the Evaluation-style cuff snugly around the most muscular section of the limb being evaluated.

Specific rotational position is not crucial but consider aligning the connection cable with the Ulna (below elbow) or laterally (above elbow) for repeatability.

When using the Evaluation-style cuff, EMG channels will share some electrode contact points, plus one contact for system-wide reference/ground, making a total of 9 contact points.



**CHARGING THE BATTERY**

A micro-USB cable is provided with the Evaluation Kit for charging the internal battery of the main unit. To charge the battery at any time, connect the USB 3.0 side of the cable to a USB computer port or suitable USB wall-charging “brick” then connect the micro-USB side of the cable to the micro-USB port on the side of the Evaluation Kit.

The Evaluation Kit requires 2.5-3 hours to fully charge from a fully depleted battery.



The Charging Status Indicator LED Light is next to the Evaluation Kit’s micro-USB port has three different colors:

CHARGING STATUS INDICATOR LED	STATUS
<b>RED</b>	Low battery warning. Charge the Evaluation Kit.
<b>AMBER</b>	Evaluation Kit is charging.
<b>GREEN</b>	Evaluation Kit is fully charged.

## POWERING ON

To power on the Evaluation Kit, use the power switch located on the side of the main unit. The Power ON LED light next to the power switch will illuminate orange and remain on when the Evaluation Kit is powered on.



When powered on, the LED light of the **Complete Calibrate** button on the top of the main unit may also be illuminated. See below for information on **Complete Calibrate** button LED colors.

The Evaluation Kit will operate for approximately 6 hours from a full charge.

## CONNECTING AN EMG INTERFACE CABLE

The Coapt Evaluation Kit will need to be connected to a compatible EMG Interface Cable (see Accessories section) for proper operation. All EMG Interface Cable types have the same mating connector for attaching to the Evaluation Kit. This connector mates firmly to the EMG Interface Port on the top of the Evaluation Kit.

1. Remove the black plastic EMG Interface Port cap.
2. Plug the connector end of the EMG Interface Cable to the EMG Interface Port with the label side of the EMG Interface Cable connector facing away from the **Complete Calibrate** Button.



**CAUTION**

**Do Not force improper connection.** If the EMG Interface Cable connector is forced in the wrong orientation, damage to the EMG Interface Cable and/or the Evaluation Kit could result.

## BLUETOOTH CONNECTION

The Coapt Evaluation Kit communicates to the **Control Companion** mobile app or **Complete ControlRoom** software app via Bluetooth. To prepare this connection for a personal computer:

1. Remove the **Complete Communicator** USB Bluetooth Dongle from its holder pocket in the top edge of the Evaluation Kit's main unit.
2. Plug the **Complete Communicator** USB Bluetooth Dongle into a USB port on your personal computer.



## TROUBLESHOOTING

Contact a Coapt representative for assistance as required if encountering situations out of the ordinary, not covered in this product handbook, or not found via the online resources at [www.coaptengineering.com](http://www.coaptengineering.com)

Contact Coapt toll free at 844-262-7800

Technical support is available at [support@coaptengineering.com](mailto:support@coaptengineering.com)

Clinical support is available at [clinical@coaptengineering.com](mailto:clinical@coaptengineering.com)

Engineering support is available at [engineering@coaptengineering.com](mailto:engineering@coaptengineering.com)

# GUIDANCE FOR USERS

## PATTERN RECOGNITION CALIBRATION

Calibration is how the Coapt system learns your muscle signals patterns – specifically, the patterns you will use to personalize the control of your prosthesis. The better you calibrate, the easier it will be to control.

Calibration can be done at any time and typically requires less than two minutes. During calibration, you are guided (either by auto-movements of your prosthesis or instructions on a screen) to hold muscle contractions corresponding to the motions of your prosthesis. As you hold these contractions, the Coapt system listens and learns the signals, computing a “pattern recognition” memory of what your muscle contractions look like. After calibration, the Coapt system uses these memories to determine how you are controlling your prosthesis.



TIPS

- Make sure the muscle contractions you control the prosthesis with feel like the contractions you calibrated with.
- Make sure contractions for different actions feel different from each other.
- Make sure contractions for the same action are consistent.



NOTE

If the LED on the **Complete Calibrate** button is blinking white after any calibration, there are helpful calibration improvement messages available in the **Control Coach**® tool of the **Complete ControlRoom** software app or **Control Companion** mobile app.

### Calibrating All Motions in a Sequence

This is a method to provide muscle signals patterns (to compute the pattern recognition memory) for all of the enabled motions of your virtual prosthesis in an organized sequence.

#### USING THE PHYSICAL BUTTON

Hold the Coapt **Complete Calibrate** button for 2 seconds and release it once you hear the beep to start the calibration sequence.

The virtual prosthesis moves itself through a sequence of motions and you follow along with your corresponding muscle contractions. For example, if the virtual wrist is rotating palm up, hold your intended muscle contraction for wrist supination. If the virtual hand is opening, hold your muscle contraction for hand open. If the virtual prosthesis pauses for a moment, be sure to relax your muscle contractions. As you hold and relax muscle contractions corresponding to the prosthesis motions, the system is learning and adapting its pattern recognition memory.

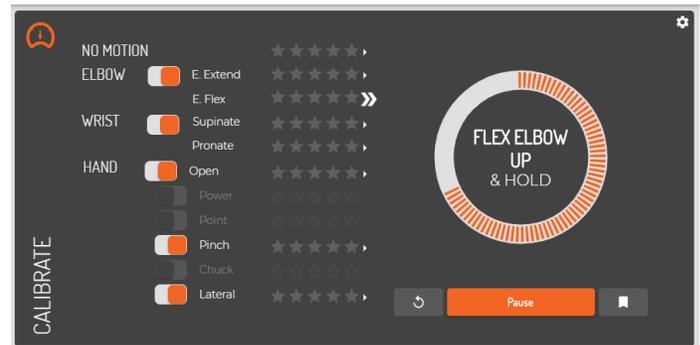


## USING THE SOFTWARE APP

Connect via Bluetooth and navigate to the Calibrate screen of the **Complete ControlRoom** software app.

Once the desired prosthesis' motions are selected, get ready to provide muscle contraction data and press the “Calibrate Enabled Motions” button to initiate full-sequence calibration.

Once calibration starts, follow the on-screen prompts to hold your muscle contractions for each motion when prompted and relax in between. When the calibration sequence finishes, it will take a moment to compute before enabling prosthesis control. **Control Coach**® quality ratings and messages will be updated after calibration.

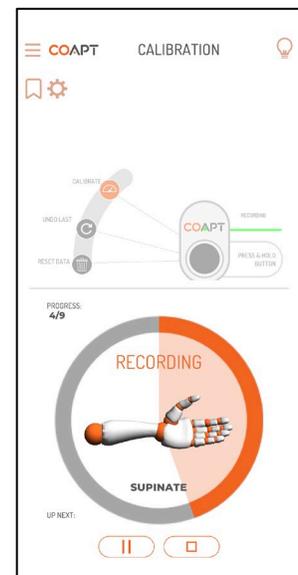


## USING THE MOBILE APP

Connect via Bluetooth and navigate to the Calibration screen of the **Control Companion** mobile app.

Once the desired prosthesis' motions are selected, get ready to provide muscle contraction data and press and hold the image of the calibration button for 2 seconds OR press the “Calibrate” icon to initiate full-sequence calibration.

Once calibration starts, follow the on-screen prompts to hold your muscle contractions for each motion when prompted and relax in between. When the calibration sequence finishes, it will take a moment to compute before enabling prosthesis control. **Control Coach**® quality ratings and messages will be updated after calibration.



## Calibrating Individual Motions

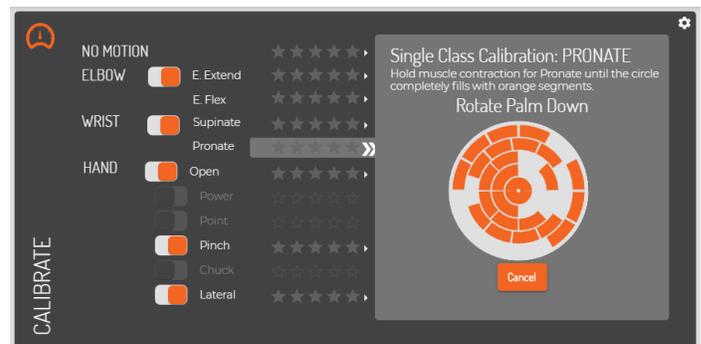
This is a method to provide a muscle signals pattern (to compute the pattern recognition memory) for one of the enabled motions of your prosthesis at a time.

### USING THE SOFTWARE APP

Connect via Bluetooth and navigate to the Calibrate screen of the **Complete ControlRoom** software app.

Press on the name or star rating of any one of the enabled motions to access a menu specific to that motion. To calibrate that specific function, get ready to provide muscle contraction data and press the “Add Data” button to start.

An empty circle will begin to fill with orange segments as you hold your muscle contraction for that motion. Hold your contraction until the whole circle fills. Once filled, it will take a moment to compute before enabling prosthesis control. **Control Coach**® quality ratings and messages will be updated after calibration.

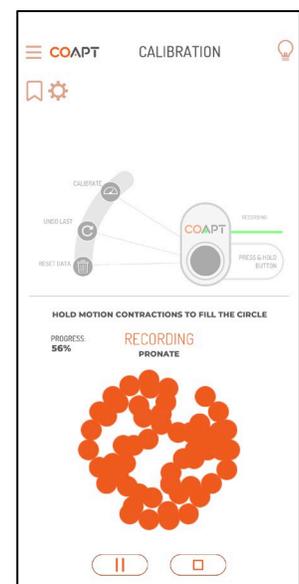


### USING THE MOBILE APP

Connect via Bluetooth and navigate to the Calibration screen of the **Control Companion** mobile app.

Press on the name or star rating of any one of the enabled motions to access a menu specific to that motion. To calibrate that specific function, get ready to provide muscle contraction data and press the “Add Data” button to start.

An empty circle will begin to fill with orange segments as you hold your muscle contraction for that motion. Hold your contraction until the whole circle fills. Once filled, it will take a moment to compute before enabling prosthesis control. **Control Coach**® quality ratings and messages will be updated after calibration.



## ADDITIONAL CALIBRATION TOOLS

### Undoing Last Calibration

When something about a calibration was unexpected or undesired (missed prompt, performed the wrong motion, contraction was different than intended, etc.), you can “Undo” the last calibration.

Undoing a calibration jumps prosthesis control back to the state it was in just before that last calibration activity. There are various ways to undo the most recent calibration activity:



#### USING THE PHYSICAL BUTTON

Hold the Coapt **Complete Calibrate** button for 6 seconds and release it once you hear the double beep and see the LED flashing. After a few moments to recompute, prosthesis control will be returned.



#### USING THE SOFTWARE APP

From the Calibrate screen of the **Complete ControlRoom** software app, press the Undo button (orange with a circular arrow icon). After a few moments to recompute, prosthesis control will be returned.



#### USING THE MOBILE APP

From the Calibration screen of the **Control Companion** mobile app, press and hold the image of the calibration button for 6 seconds OR press the “Undo Last” icon. After a few moments to recompute, prosthesis control will be returned.



If the most recent calibration was a single motion ‘Add Data’, only that single motion calibration will be undone. If the most recent calibration was a full-sequence calibration the full calibration sequence will be undone.

## Clearing/Resetting All Calibrated Motions

Certain scenarios (electrode relocation, major socket change, prosthetic device changes, overall control desire changes, surgical intervention, control has become unreliable/unstable etc.) may require full reset of the calibration memory to a blank, starting state.

There are various ways to fully reset all calibrated motions to a blank, starting state:



### USING THE PHYSICAL BUTTON

Hold the Coapt **Complete Calibrate** button for 10 seconds and release it once you hear the jingle. The button's LED will turn magenta, indicating the blank pattern recognition memory starting state.



### USING THE SOFTWARE APP

From the Calibrate screen of the **Complete ControlRoom** software app, click on the settings  icon: In the menu that appears, click the “Reset ALL” button.



### USING THE MOBILE APP

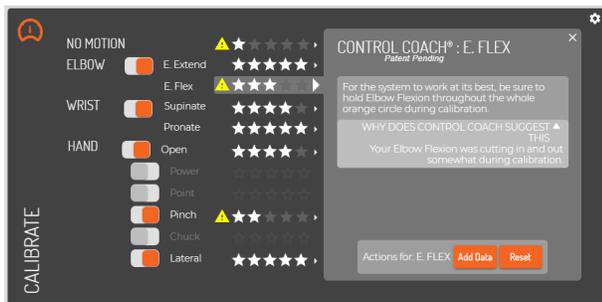
From the Calibration screen of the **Control Companion** mobile app, press and hold the image of the calibration button for 10 seconds OR press the “Reset Data” icon.



Control of the prosthesis is not available when the LED is magenta – the pattern recognition memory is empty and it will need at least one new calibration before controlling the prosthesis.

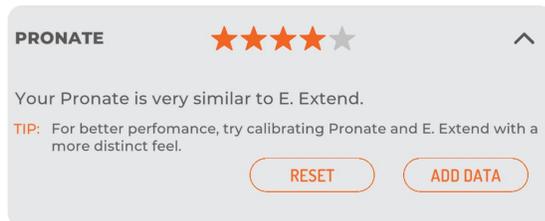
## Clearing/Resetting Individual Motions

When the need arises to reset the pattern recognition memory of one motion while leaving others as-is, calibrated motions can be individually reset to a blank, starting state.



### USING THE SOFTWARE APP

From the Calibrate screen of the **Complete ControlRoom** software app, press on the name or star rating of any one of the enabled motions to access a menu specific to that motion. In the menu, press the “Reset” button to set this specific motion to a blank starting state.



### USING THE MOBILE APP

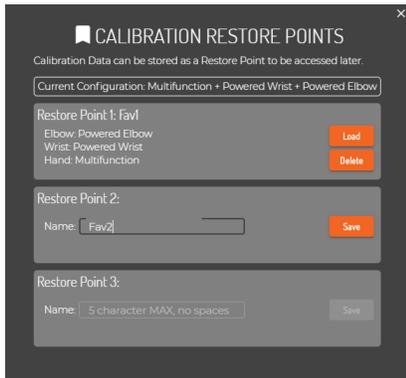
From the Calibration screen of the **Control Companion** mobile app, press on the name or star rating of any one of the enabled motions to access a menu specific to that motion. Press the “Reset” button to set this specific motion to a blank starting state.



The prosthesis' action for an individual motion that has been reset will not be available until at least one calibration for that motion is performed. Other actions that were not reset may remain available.

## Calibration Restore Points

It is possible to store up to 3 Restore Points that are saved 'snapshots in time' of your pattern recognition control memory. This feature can be used to store and recall a control setup that is particularly functional, is tailored to a specific need (work, home, leisure, etc.), and more.

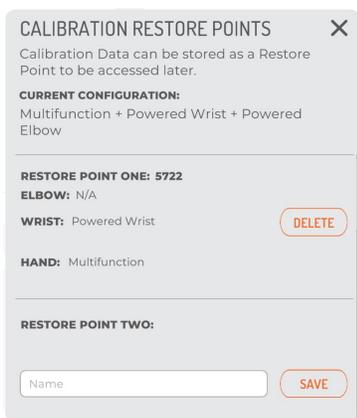


### USING THE SOFTWARE APP

From the Calibrate screen of the **Complete ControlRoom** software app, press the Restore Points button (bookmark icon).



In the menu that appears, follow the guidance to save or load a pattern recognition Restore Point.



### USING THE MOBILE APP

From the Calibration screen of the **Control Companion** mobile app, press the Restore Points button (bookmark icon).

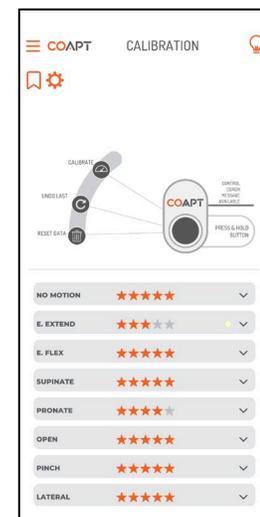
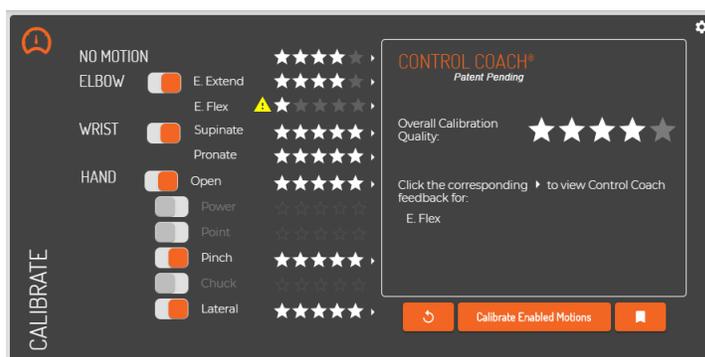


In the menu that appears, follow the guidance to save or load a pattern recognition Restore Point.

## CONTROL COACH®

Each time calibration data is provided, the artificial intelligence (A.I.) **Control Coach**® system analyzes data nuances and conditions that it knows could limit functional potential. **Control Coach**® was programmed with clinical experience to provide tips and tricks to help you tweak further calibrations and get the most out of your control.

**Control Coach**® has a 5-star rating system to give feedback on the quality for each calibrated motion. As the A.I. engine in **Control Coach**® detects things it believes are limiting full potential, it will lower the ratings for affected motions.



**Control Coach**® also provides written guidance for addressing improvements for each calibrated motion. From the Calibrate screen of the **Complete ControlRoom** software app or the Calibration screen of the **Control Companion** mobile app, press on the name or star rating of any one of the calibrated motions to bring up **Control Coach**® information about that motion. After you read the helpful information, consider either adding additional calibration data (see Calibrating Individual Motions above) or first resetting that motion to start from scratch (see Clearing/Resetting Individual Motions above).

## ADAPTIVE ADVANCE®

**Adaptive Advance**® is a continuous-learning algorithm that intelligently blends new calibration data into the existing pattern recognition memory of the system each time calibration happens.

**Adaptive Advance**® is enabled by default but can be turned off in the **Complete ControlRoom** software app or **Control Companion** mobile app.



It can be especially helpful for new pattern recognition users to perform the calibration routine multiple times from a starting state. This allows **Adaptive Advance**® to effectively “layer” extra information into a robust and functional control scheme.

## CALIBRATION BUTTON UNIT: SOUNDS & LED COLOR MEANINGS



### One short beep and a corresponding **GREEN** flash

Power Up

Indicates the system has powered on and “booted” properly.



### Double **RED** blink

Low Power Source

Indicates the power supplying the Coapt system is very low.



### Solid **MAGENTA**

Reset State

Indicates the system is in a blank/empty starting state. Calibration will have to be performed before controlling the prosthesis.



### One beep after the button has been held for 2 seconds (LED is solid **CYAN** while the button is being pressed).

Calibration Start

Letting the button go after this beep will start Prosthesis Guided Calibration.



### Solid **GREEN** periods

Recording EMG Data

Indicates when the system is recording myoelectric signal information during calibration.

**WHITE with short blip off every two seconds**



### Control Coach® Messages Available

Indicates that informational and assistive **Control Coach®** “messages are available in the Coapt **Complete ControlRoom** software app or **Control Companion** mobile app. This indicator is present whenever the overall **Control Coach®** star rating drops below a set value.



**Double beep after the button has been held for 6 seconds (LED is solid CYAN for the first 2 seconds and flashing CYAN from 2 to 6 seconds.**

### Calibration Undo

Letting the button go after this double beep will “undo” the most recent calibration activity and return control to the state it was just before that.



**A 6-note jingle after the button has been held for 10 seconds.**

### Calibration Reset

Letting the button go after this jingle will reset the system to a blank starting state. The LED will turn solid magenta (see Reset State).



**Flashing GREEN**

### System Updating

Indicates the internal code (firmware) of the system is updating. This process may take several minutes. Do not turn off the prosthesis during updates.



**Solid RED**

### Critical Error

Indicates the system has put itself in a protective state. Follow prompts in the app or contact a Coapt representative for assistance.

# CONTROL COMAPNION AND COMPLETE CONTROLROOM USER APPS

**Control Companion** is the mobile app version, available for both iOS and Android devices.

**Complete ControlRoom** Gen2 is the software app version for desktop computers (PCs).

**Complete ControlRoom** and **Control Companion** have similar functions and features and are available to both clinicians and users free of charge. Either app can be used for setup, configuration, calibration assistance, and other pattern recognition controls practice. Both apps use Bluetooth to wirelessly communicate with the Evaluation Kit.

## INSTALLATION

- For iOS **Control Companion**, search for “Complete ControlRoom” in the App Store.
- For Android **Control Companion**, search for “Coapt” in the Google Play Store.
- For PC **Complete ControlRoom** Gen2 download, visit [www.coaptengineering.com](http://www.coaptengineering.com)

## CORE APP USES

### Configuration

Configuration screens facilitate scanning, connection, and disconnection of nearby, powered-on Evaluation Kit units. Once Bluetooth communication is established to one, the app will display the connected Evaluation Kit.

Configuration screens of the app manage setup of the intended virtual prosthetic device control, including:

- Selection of the prosthetic elbow, wrist, and hand (as applicable).
- Selection for left or right prosthesis control.
- Choice of specific prosthesis' functions to be calibrated for controlled by pattern recognition.



#### NOTE

An Evaluation Kit is Bluetooth discoverable for about 3 minutes after any power on. To make it discoverable after that, press the **Complete Calibrate** button once.

When multiple Evaluation Kit units are discoverable, the app will display a selection list by serial number.

## Input Validation

Similar to validating the correct output connectivity, it is important to validate EMG signals from all 8 myoelectric input channels before proceeding with calibration. Electrode contacts not touching the skin, loose electrode hardware, disconnected EMG connection wires, and more can all contribute to a bad EMG channel. Bad channels need to be corrected for optimal functional performance.

The app displays all 8 EMG input signals in a live viewer. The on-screen color of each signal channel corresponds to the wire colors of the EMG Interface Cable for signal locating and troubleshooting. When the system senses loss of skin contact on any channel it will display a warning message for that channel.

## EMG Pattern Exploration

The app contains live visualizer tools to assist new and experienced users develop distinct and repeatable signal patterns for their prosthesis control motions. Visualization tools incorporate signal intensities, signal transitions, and detected motion intention (where applicable).

## Calibration

The app contains a set of calibration tools to conduct, analyze, store, reset, and update pattern recognition control. See Guidance for Users above for detailed descriptions of key Calibration screen features.

## Practice and Games

Whether practicing control before a physical prosthesis is available or needing the benefit of on-screen controls development, the app provides a suite of real-time games and activities specific to pattern recognition outputs. One primary activity is the virtual arm avatar that is actuated with the same pattern recognition commands intended for the physical prosthesis. Other on-screen activities target specific areas of control development, such as mastering proportional speeds, differentiating motions, sequencing motions, and task targeting.

# ADDITIONAL INFORMATION

## LIMITED US WARRANTY

For purposes of warranty, the “Customer” is defined as the entity that Coapt, LLC (“Coapt”) has invoiced for the Coapt component(s) (“Items”). The 2 Year Limited Warranty only applies to Items sold to the Customer by Coapt or an authorized distributor. For an integrated prosthetic system consisting of products or components purchased from both Coapt and other suppliers/manufacturers, in the event that such a system is sent into Coapt for warranty review, if it is found during evaluation the reported problem(s) is associated with a product or component not supplied by Coapt, a non-warranty evaluation charge may be invoiced to the Customer.

Coapt warrants its Items will be free from defects in material and/or workmanship for a period up to two (2) years. In the absence of a prompt notice from the clinician regarding a delay in fitting the patient, Coapt will set the Limited Warranty start date at 30 days after the shipping date. The Limited Warranty becomes null and void if complete payment is not made within the terms specified under Items’ Payment Terms.

This Limited Warranty covers all defects incurred in the clinically-prescribed use of the Items and does not cover: a) loss or damage due to theft, exposure of Items to fire, water, perspiration, corrosive materials such as salt water and extremely basic or acidic solutions, acts of nature or damage otherwise deemed intentional or abusive; b) damage due to failure to follow operating and installation instructions; c) damage incurred by malfunction or improper use of 3rd party components including leaking, damaged or malfunctioning batteries and cabling; d) use in a way not recommended by the manufacturer/distributor; e) Items serviced or modified by an entity other than Coapt (if the service or modifications are in any way related to the problem or defect); f) substitution of parts not approved by Coapt; g) any alteration or repair that, in Coapt's judgment, materially or adversely affects the Items. Damage as the result of normal wear and tear which does not materially affect the function of the system is not covered.

Any warranty claim shall be reported to Coapt, in writing, immediately upon discovering the defect. The defective Items must be returned to Coapt or any other Coapt authorized representative. In returning the Items for repair, the Items must be delivered in packaging offering a sufficient degree of protection. Coapt will not be responsible for any loss or damage in connection with the return of the Items.

The warranty on repaired or replaced Items will be ninety (90) days or until the end of the original warranty, whichever is longer. Coapt will, at its option, repair, replace, or upgrade defective Items returned within this Limited Warranty Period. It is the Customer’s responsibility to adhere to all origin and destination shipping regulations, especially regarding shipments including Lithium-Ion Batteries. Items covered by this Limited Warranty will be repaired, replaced, or upgraded in the United States by Coapt representatives, without charge. Coapt will return the Items to the Customer via UPS ground service or using any comparable carrier. Requests for expedited returns of warranty repairs will be at the expense of the Customer.

THE FOREGOING LIMITED WARRANTY IS COAPT’S ONLY WARRANTY WITH RESPECT TO THE ITEMS AND COAPT MAKES NO OTHER WARRANTY WHATSOEVER, WRITTEN OR ORAL, EXPRESS OR IMPLIED, REGARDING THE ITEMS, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON- INFRINGEMENT.

This Limited Warranty gives the consumer specific legal rights. The consumer may also have other legal rights which vary by country, state, province, territory, or other. If so, some of the above limitations may not apply. If it is determined by a court of competent jurisdiction that a certain provision of this Limited Warranty does not apply, such determination shall not affect any other provision of this Limited Warranty and all other provisions shall remain in effect. This Limited Warranty is given by Coapt, with respect to Items purchased from Coapt in the United States.

## EXTENDED WARRANTY

Additional year(s) warranty extensions are available for purchase at the time of original system purchase.

## RETURNS

Users should return all malfunctioning, damaged, or undesired product components directly to their clinician.

Clinicians should return all unserviceable product components directly to their regional distributor or Coapt.

If sending the Evaluation Kit for repair or return, it is the shipper's responsibility to follow all applicable regulations for shipping lithium-ion batteries.

## PRODUCT RETURN POLICY

- Item(s) returned in resaleable condition within 30 days of receipt are refunded or credited at full value without a restocking fee.
- Item(s) returned in resaleable condition between 30-120 days of receipt will be subject to a 15% restocking fee.
- Item(s) returned after 120 days of receipt are not accepted and no refund or credit is available.
- Applicable refunds will be processed within 30 days of receipt of return.
- Service/refurbishment costs for returning Item(s) to resaleable condition will be deducted from any refund and/or charged separately.

## INTELLECTUAL PROPERTY DISCLAIMER

The Coapt name, Coapt logo, products, and other Coapt trademarks and graphics are all property of Coapt, LLC. The aforementioned intellectual properties are protected by United States and international copyright, trademark, patent, trade secret, and other intellectual property laws where appropriate.

## TECHNICAL INFORMATION

CATEGORY	SPECIFICATION
POWER	<p>The Evaluation Kit has a self-contained, IEC 62133 certified, 3.7 V<sub>DC</sub>, 900 mAh rechargeable Lithium-Ion battery that is charged via micro-USB connection.</p> <p>The Evaluation Kit is intended to provide approximately 6 hours of use on a full charge and will require 2.5 – 3 hours to fully charge from a dead battery state.</p>
OPERATING TEMPERATURE	0°C – 35°C (32°F – 95°F)
HUMIDITY	5 – 95% RH (Non-Condensing)
TRANSPORT TEMPERATURE	-20°C – 45°C (-4°F – 113°F)
ALTITUDE	10,000 feet Maximum
SYSTEM REQUIREMENTS FOR SOFTWARE APP	<ul style="list-style-type: none"> <li>• Operating System: Windows 10 (64-bit or 32-bit) or newer</li> <li>• RAM: At least 1GB of system memory</li> <li>• Storage: At least 1GB of available space</li> <li>• Screen Resolution: Minimum 1280 x 960</li> </ul>
PHYSICAL DIMENSIONS	<ul style="list-style-type: none"> <li>• Length: 83.1 mm (3.27 in)</li> <li>• Width: 59.5 mm (2.34 in)</li> <li>• Height: 22.1 mm (0.87 in)</li> </ul>

**⚠ CAUTION**

**Opening enclosures.** Never open the Evaluation Kit enclosure. Opening the enclosure could cause permanent damage to the Evaluation Kit resulting in device malfunction and minor injury to the user.

**⚠ CAUTION**

**Battery Servicing.** Never open the Evaluation Kit to evaluate or replace the internal battery. Battery servicing must only be done by an authorized Coapt technician.

## REGULATORY INFORMATION



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 Evaluation Kit has been listed with the FDA under device number D362224.



### 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



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.



This device is fully compliant with the CE Marking Requirements under the European Medical Device Directive (MDD) and 2017/745 Medical Device Regulation (MDR). Coapt, LLC’s European Union Authorized Representative (EC REP) is Fillauer Europe AB.

**EC REP** Fillauer Europe AB, Kung Hans väg 2, 19268, Sollentuna, Sweden

**COAPT**

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