COAPT®
GEN2

HANDBOOK (V 3.2)

EVALUATION KIT

Caution: Federal law restricts this device to sale by or on the order of a physician.

CONTENTS

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**

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	
⚠ **WARNING**	Warning regarding possible risk of severe accidents or injury.
⚠ **CAUTION**	Warning regarding possible risks of accident or injury.
NOTICE	Warning regarding possible damage to product or equipment.

⚠ CAUTION   **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.

⚠ WARNING   **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.

⚠ WARNING   **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.

⚠ WARNING   **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.

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.
FC	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	CE Mark	The device is certified with the European Union under the Medical Device Directives (93/42/EEC).
SN	Serial Number	Signifies the identification information for the device.
	Date of Manufacture	Date the device was assembled at Coapt.
EC REP	European Representative	Signifies the European Representative for Coapt.
	Type BF Applied Part	The device has conductive contact with the patient.

OVERVIEW

DESCRIPTION

The Coapt Evaluation Kit is a handheld clinical tool created with technology from the Coapt COMPLETE CONTROL System Gen2. COMPLETE CONTROL employs 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.
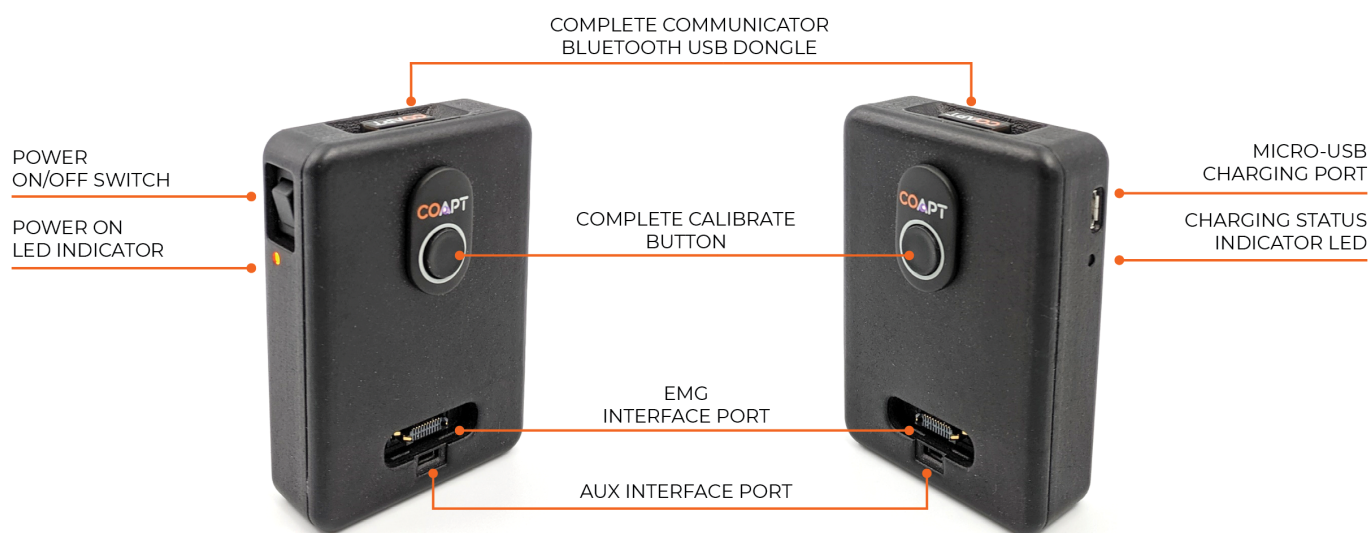
PURPOSE

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.

PATTERN RECOGNITION INTRODUCTION

What Is Coapt Pattern Recognition?

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) like it is its own instrument in that orchestra. Each different arm and hand movement results in a unique but repeatable set of these myoelectric patterns—like different songs in our concert.

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 to cover the whole area of these underlying muscle contractions allows all of 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 their arm or hand action. 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.

The **Complete Control** System Gen2 from Coapt 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.

Benefits of Pattern Recognition Over Standard Myoelectric Prosthesis Control

Muscle signals contain a lot of information. Pattern recognition uses the combined information gathered from all electrodes to control multiple prosthesis movements. In contrast, standard myoelectric control only considers the signal level from one electrode to control each prosthesis movement. In other words, standard myoelectric control is like listening to music and only knowing how loud the sound is, while pattern recognition is like hearing what song is playing.

Key benefits of pattern recognition over standard myoelectric control include the following:

- **Intuitive Control** – Natural movement intents are used to control the prosthesis, generally making it easier to use. For example, the feeling of opening or closing a hand is used to control the prosthetic hand open and close (instead of wrist flexion motions to control the hand common for basic myoelectric devices).

- **No Mode-Switching** – There is no need to use cumbersome actions like co-contractions, pulses, fast-slow gestures, etc. and this makes the control of a prosthesis more seamless.

- **Strong muscle contractions are not required** – Pattern recognition has the advantage of being able to utilize low intensity muscle contractions as needed. This is beneficial for standard myoelectric control users who were required to elicit strong control contractions that tire them out quickly.

- **Superior Proportional Control** – A wider range of control speeds are available because myoelectric inputs do not need to be limited by thresholds and a broader range of input levels can be recognized by the algorithms.

- **_Flexible Electrode Placement_** – There is much less need for isolated signals or precise electrode placements. This opens the door to more functional myotesting, freedom to place electrodes for socket, comfort, or limb constraints and provides helpful forgiveness in prosthesis donning.

- **_Calibration and Setup_** – Control can be refined and personalized at any time using the quick on-board calibration. This makes addressing changes in socket fit, skin condition, fatigue, desired feelings for control much easier to take on without the need to take the prosthesis off or make extra clinic visits.

What Is Key to Making Pattern Recognition Function at Its Best?

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.

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.

Practicing Pattern Recognition Control

- 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 is always helpful to return to those perceptions as needed.

Successful Use of Pattern Recognition Control Relies on Two Priorities:

1. Placing electrodes at locations that make reliable contact with the skin.

2. Good understanding of pattern recognition calibration by the user and the practitioner.

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.

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 medial professional or under supervision of a trained and licensed medical professional.

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

LIMITATIONS

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

IN THE KIT

The Coapt Evaluation kit is to be used in conjunction with a Coapt EMG Interface Cable (sold separately) and the Coapt **Complete ControlRoom** Gen2 user interface application.

The Coapt Evaluation Kit contains the following components:

1. Evaluation Kit main unit

2. **Complete Communicator** USB Bluetooth Dongle – provided with the Evaluation Kit to enable Bluetooth connection to a personal computer

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)
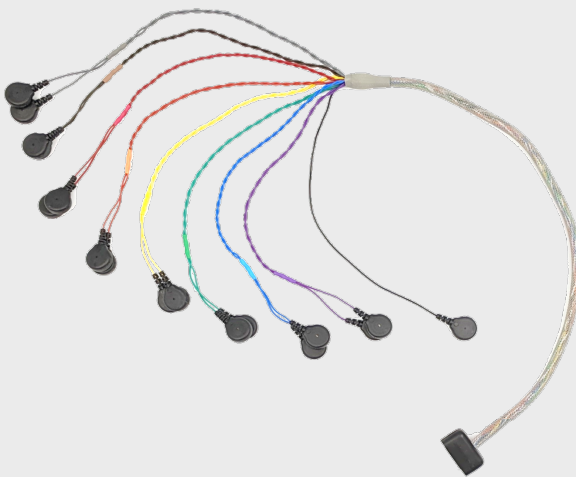
Accessories to the Evaluation Kit not included but may be required:

1. EMG Interface Cable(s) (sold separately)

2. Coapt Dome Electrodes (if necessary, sold separately)

3. Temporary Evaluation Electrode "Stickers" (if necessary, sold separately)

ACCESSORIES

EMG Interface Cable

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
Standard Eyelets EMG Interface Cable	17 ring/eyelet terminations for use with a set ofCoapt Stainless Steel Dome Electrodes

Snap Style EMG Interface Cable	17 snap terminations for use with with disposable, Temporary Evaluation Electrode "Stickers" or set of liner-snap electrode contacts (sold by third party)

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

Electrodes

Coapt recommends the use of FDA cleared electrodes whenever possible.

Where the Evaluation Kit is used with an Eyelets style EMG Interface Cable, Coapt recommends the use of FDA cleared, Coapt Dome Electrodes. Contact a Coapt representative to purchase these separately.

Where the Evaluation Kit is used with a Snap Style EMG Interface Cable, Coapt recommends the use of FDA cleared, Temporary Evaluation Electrode "Stickers". Contact a Coapt representative to purchase these separately.

Please contact a Coapt representative with any questions about use of other potentially compatible electrodes.

PRODUCT INFORMATION	RELATED PRODUCT REGISTRATION	510(K)
Manufacturer: Coapt, LLC **Product Name:** Dome Electrodes **Part Number(s):** D37C13T4L50	**Proprietary Name:** Dome Electrode **Registered Establishment Number:** Coapt, LLC, 3010605876 **Product Code and Regulation Number:** GXY, 882.1320	K190416

⚠ 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.

CLINICIAN GUIDE

PLANNING EMG ELECTRODE SITES FOR COAPT GEN2™ PATTERN RECOGNITION

Pattern recognition loves information. The more information it can be fed, the better it will work. Valuable myoelectric (or, EMG) control information can come from all over a user's residual limb, so, unlike a conventional single- or dual-site myoelectric system, you will be planning for several pattern recognition electrode contacts to capture all their limb has to offer.

You are likely already aware that pattern recognition is quite different than conventional single- or dual-site myoelectric control. Maybe it is no surprise that myotesting and evaluating users for electrode placement is quite different too. Yes, there may be a higher number of electrode contacts with pattern recognition, BUT, as you will experience, it will produce desired patient outcomes.

Here, Coapt will guide you through the two major electrode site-planning tasks:

1. Determining where there is underlying muscle tissue on the residual limb of your user.

2. Planning the Coapt electrode contacts to reliably cover those areas of residual muscle activity.

Step 1: Have a thorough discovery chat with your user

Before you dive into any palpation for muscle activity with a prospective user, plan to have a thorough discussion with them about what they can feel and do with their limb. Forget instructing them to imagine isolating wrist flexion and extension or simple elbow up/down (we know—it can be hard to change old habits) but instead, have them tell you ALL of what their fingers, hand, wrist, elbow, etc. perceptions are.

Why? Well, this is a great way for both clinicians AND users to work together, explore and learn what intuitive motions and feelings users may want to use for their prosthesis control. Let them tell you what they can do. And don't mistakenly limit them by cornering them into the old "flex/extend" box.

> **GOALS**
>
> **GOALS OF THIS DISCUSSION ARE TO DETERMINE WHAT MUSCLE CONTRACTIONS (MOTIONS) THE USER FEELS:**
>
> 1. Are intuitive to use for prosthesis control.
> 2. Can be performed consistently.
> 3. Are unique for each intended prosthesis action.

A HELPFUL APPROACH TO LEADING THIS DISCUSSION:

TIPS

- Ask questions to determine what movements the user can perceive and produce with their phantom limb, such as:
    - "Can you feel your hand? Which fingers do you feel you can move?"
    - "Can you imagine making a fist? What about opening your hand with your fingers spread apart?"
    - "Does it feel like your hand is squeezing down on something?"
    - "Do you feel like you can turn your wrist? Does your hand stay relaxed?"
    - "Does your thumb move? How far? Which direction?"
    - … and so on. Remember, the goal is to learn together what more might be available for control with more multi-site contacts.

- When you have your user perceive these motions, ask that they hold them at a medium intensity and for about 3-4 seconds each. This is good practice for the eventual prosthesis controls' (and users' self-led) calibration procedure.

- Encourage the user to mirror their perceived motions with their sound limb if possible.

- Start the discussion with the most intuitive motions and add variations as needed; i.e. try natural hand close for "hand close" and if they have poor perception of hand close but good perception of one specific finger (for example), try practicing the use of that finger perception for "hand close." In another example, if wrist rotation is difficult to perceive, discuss the feeling of adding thumb or pinky finger ab/adduction to accentuate rotation.

- Focus on motions that are distinct and repeatable.

- Take considerable time with this process.

- Be patient and listen.

- Perform this discussion in a relaxed environment.

- Develop a common vocabulary for specific motions.

Step 2: Determine where there is underlying muscle tissue on the residual limb

Palpation isn't what it used to be. For single- or dual-site, conventional myoelectric control electrode planning, you may have been used to feeling for strong, isolated contractions using your fingertips. Forget that. For pattern recognition go all in. Use all of your hands to feel as much of their residual limb as possible, at once. Hold on and feel while you repeat and continue the discussion from Step 1.

Why do you want to do this? The continued discussion helps to further discover their intuitive motion plans while, at the same time, lets you feel for the general and global areas of underlying muscle tissue. Remember, pattern recognition doesn't always require strong and isolated sites, it wants to get info from lots of muscle areas—even the areas that may seem weak and hardly perceptible.

GOALS

THIS WHOLE-HANDED PALPATION SHOULD:

1. Feel for all "areas of interest" corresponding to any and all underlying muscle activity related to the control motions.

2. Keep note/remember these "areas of interest" as good locations to place electrode contacts.

A HELPFUL APPROACH TO PERFORMING THIS PALPATION:

- Perform this exercise in a relaxed environment
- Take time with this process.
- Be patient and listen.
- Grasp and cover as much of the user's limb as possible; do not use only your fingertips to feel.
- Have the user perform and hold (3-4 seconds) each of the useful motions discovered during the discussion phase.
- Feel for the overall muscle activity – like what the pattern recognition algorithm does – by sensing the patterns of activity at multiple areas simultaneously.
- Do not ignore areas of slight/subtle/weak underlying muscle contraction (these signals are just as valuable).
- Note any unique and unexpected areas of underlying muscle contraction.
  - o For transhumeral amputees, this may mean unique muscle activity distal on their residual limb.
- If the user tenses muscles quite hard for all motions, ask them to make contractions a little more softly.
- If desired, make temporary markings on the user's residual limb to help remember areas of activity.

GENERAL THINGS TO AVOID:

- Do NOT seek only strong muscle contraction sites (subtle signals are important too)
- Do NOT focus only on precise and isolated muscle sites
- Do NOT limit electrode placement to "hotspot" areas

PLACING AND CONNECTING COAPT ELECTRODE CONTACTS

If you've performed the discussion and palpation steps of the Electrode Site Planning for Coapt pattern recognition, you will have a good idea of the underlying muscle "areas of interest" on your user's residual limb. Perhaps you've even made a series of temporary markings on their limb or taken some pictures for planning.

You may be ready to place Stainless Steel Dome Electrodes in a check socket or definitive socket/liner interface, or you may be continuing an evaluation using the temporary evaluation Electrode "Stickers" directly on the skin. In either case, this section will guide you if this is your first Coapt fitting and provide useful tips if you're already a pro.

A few very important things to know before you get started:

- Definitive Electrode contacts with a Coapt system are solid Stainless-Steel Dome Electrodes. Each one will be connected to a wired lead of a Coapt cable.

- Temporary Evaluation Electrode "Stickers" are single-use contacts for direct-on-skin evaluations. Each one will be connected to a wired Snap-end lead of a Coapt Snap Style EMG Interface Cable harness.

- Two electrode contacts work together to create one "channel" of EMG information.

  o If you picture an imaginary oval encircling the two placed electrode contact points, this is the general region the EMG channel data will be from. The farther apart the pair of electrode contacts, the larger (and deeper) the sensed area will be. Conversely, electrode contacts close to each other will detect a more focused channel of EMG.

- The Coapt system has 8 EMG channels (16 electrode contact points) and one ground/reference contact (17 electrode contact points in total).

- In some space-constrained fittings, the 17 Coapt Dome Electrodes can be reduced to as few as 9, by way of contact-sharing (see below for details). Contact sharing is not possible when using the Temporary Evaluation Electrode "Stickers" and the Snap Style EMG Interface Cable.

The most important thing to remember with electrodes: **Electrodes MUST MAKE CONTACT WITH THE SKIN** to work. Electrodes that do not stay in contact with the user's skin will lead to serious prosthesis control limitations. Take care in planning and be sure to fabricate a well-fitting interface for all fittings.

GOALS

THE POSITIONING OF ELECTRODE CONTACTS SHOULD:

1. Cover the areas of interest discovered during Palpation.

2. Plan accordingly for socket/liner constraints.

TIPS

A HELPFUL APPROACH TO POSITIONING THE ELECTRODE CONTACTS:

- Consider starting with locations that correspond to existing myosites when retrofitting existing myoelectric users.
- Identify locations to AVOID electrode contact, such as
    - Areas that will lose electrode-to-skin contact during use.
    - Areas outside of socket trim-lines or co-located with valves.
    - Areas that have no underlying muscle (i.e. bone only).
    - Sensitive skin areas.
    - Areas with active EMG during positional loading (e.g. deltoids, brachioradialis).

The Evaluation Kit connects to a Coapt EMG Interface Cable to evaluate eight EMG signal channels. To make up a single EMG channel, a pair of passive electrode contacts work together and pick up an oval-shaped area of muscle signal underlying these two contacts. The closer the two contacts are to each other, the smaller the area of detected EMG and vice versa.

When using the Standard Eyelets, Snaps, or Osseointegration-style Cuff EMG Interface Cable, each EMG channel will have its own pair of electrode contact points, plus one contact for system-wide reference/ground, making a total of 17 contact points.

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

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

For best results, clean and dampen underlying skin areas before placing the cuff.

Fit the Evaluation-style cuff snugly around the most muscular section of the limb being evaluated and secure with the Velcro attachment.

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

PLACING THE STANDARD EYELETS OR SNAPS EMG INTERFACE CABLE:

Contact Spacing – Plan to place the two electrode contacts for an EMG channel approximately 30–60 mm apart.

Contact-Pair Orientation – While it is generally a good idea to align a pair of 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 EMG interest, and for geometrically unique and congenital limb presentations.

Contact Sharing – For a limb that is too small to reliably fit all 17 Dome Electrode contacts, it is acceptable to have a few of the EMG channels share an electrode contact. Take care, however, that you do not place the two wires for any EMG channel (same color) on the same Dome Electrode—that will result in zero signal for that channel and not be helpful for pattern recognition. Also very important: All Coapt Conductor wires must be connected to a Dome Electrode contact; do not leave any unconnected. Contact sharing is not possible when using the Temporary Evaluation Electrode "Stickers" and the Snap Style EMG Interface Cable.

Single Reference (Ground) Contact – The Coapt system requires a single Dome Electrode contact for purposes of EMG reference/ground. This contact should NOT be shared with any other EMG signal wires. The reference contact should be positioned in a location that maintains excellent electrode-skin contact.
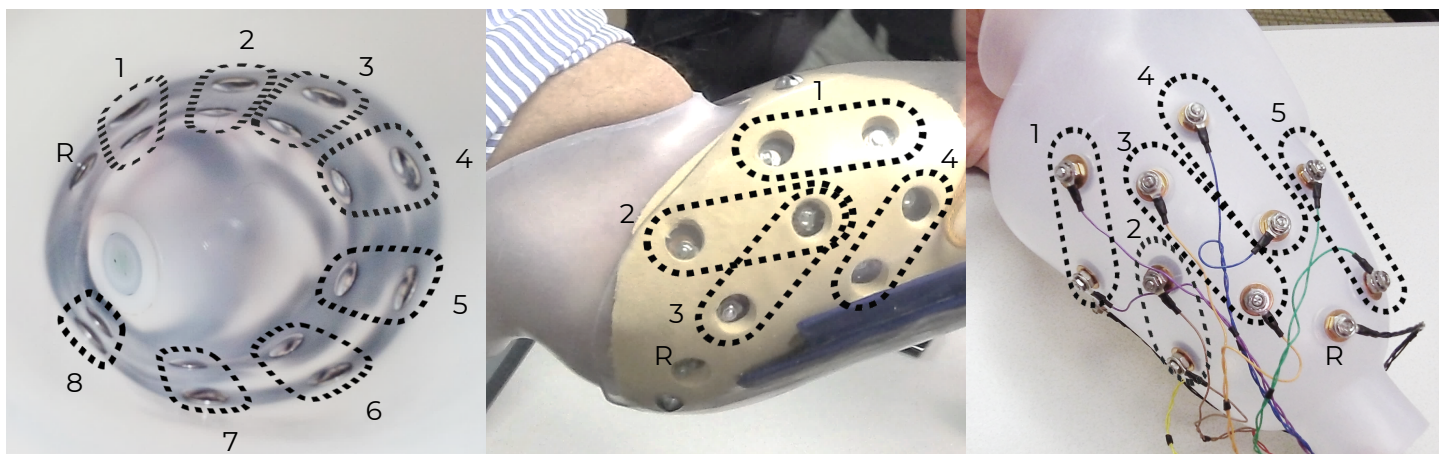
> **NOTE**
>
> Contact your Coapt representative with any questions about myotesting and/or electrode placement. Coapt is willing and able to assist with placement instruction and suggestion—these can often be accomplished by submitting socket and/or limb shape images to Coapt.

EVALUATION KIT INSTRUCTIONS

CHARGING

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
RED	Low battery warning. Charge the Evaluation Kit.
AMBER	Evaluation Kit is charging.
GREEN	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 **Complete ControlRoom** Gen2 user interface application 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.

SOFTWARE/APPLICATION SETUP

The Evaluation Kit is designed to be used in conjunction with the **Complete ControlRoom** Gen2 user interface application. This is an easy-to-use user interface application for Windows PCs and iOS devices. **See the comprehensive instructions in the COMPLETE CONTROLROOM GEN2: USER INTERFACE section before using the Evaluation Kit.**

CALIBRATING PATTERN RECOGNTION CONTROL

Good prosthesis control depends on good calibration from you. This section has everything you will need to know about performing a great calibration for the best prosthesis control.

Calibration is how the Coapt system learns your muscle signals patterns. Specifically, the patterns that you will use to control the virtual arm of the Evaluation Kit. The better you calibrate, the easier it will be to control. Calibration should come easy. You will be prompted (by instructions on a screen) to make and hold muscle contractions exactly the way you want to naturally control the motions of a prosthesis. As you hold these contractions, the Coapt system listens and learns these signals in order to compute a memory of what your patterns look like. After any calibration, the Coapt system uses these memories to understand how you are controlling your virtual prosthesis in real time.
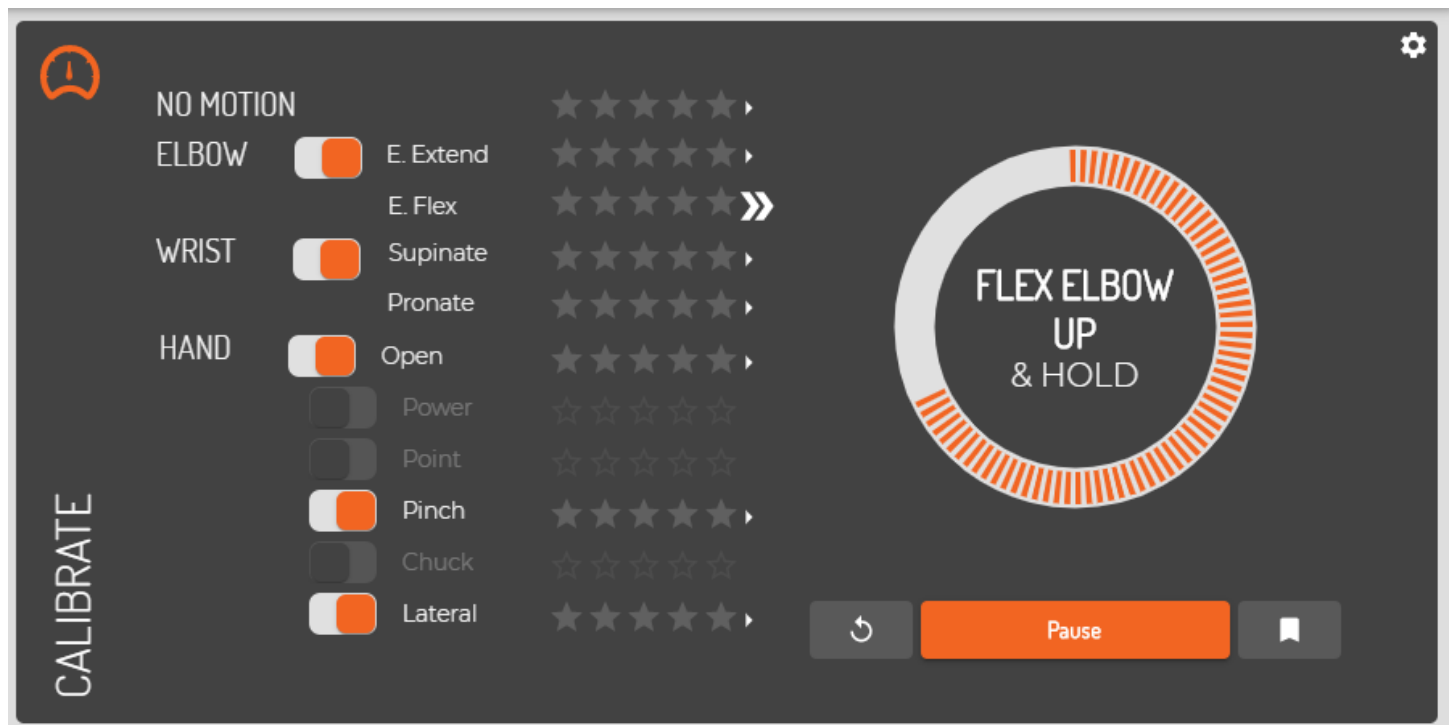
TIPS

If Coapt calibration is new to you, some helpful hints to keep in mind: make sure the muscle contractions you calibrate with feel similar to the contractions you will want to use it with; try to make sure you do each motion differently enough; and try to make the same motion feel consistent each time.

Calibrating control on-screen (via mobile or desktop)

With the Coapt Evaluation Kit, you calibrate your control by watching on-screen prompts. Great calibration tools are provided in the Coapt **Complete ControlRoom** software interface or app.

To use the PC software, make sure you have an available Coapt **Complete Communicator** Bluetooth radio dongle, and then make sure you download and install the Coapt **Complete ControlRoom** application software from the Coapt website. To use a mobile device version of the application, visit the Apple or Google Play store for the Coapt **Complete ControlRoom** app.

Once you've established a Bluetooth connection to your Coapt Evaluation Kit in the **Complete ControlRoom** application, navigate to the "Calibrate" panel. This is a screen area where your available virtual arm motions can be selected/deselected for calibration, and where an orange button labeled "Calibrate Enabled Motions" sits. When you press this button, be ready, because the sequence for calibration will promptly begin. During the calibration sequence, you will see on-screen prompts of what to do. Follow along by holding your muscle patterns for each motion when prompted and relaxing when it instructs. At the end of the calibration sequence, virtual arm control will be returned to you, and your **Control Coach®** quality ratings will be updated.


TIPS	The on-screen calibration prompt sequence can also be started by the **Complete Calibrate** button on the Evaluation Kit. Press and hold the **Complete Calibrate** button for two seconds until you hear it beep once. Release the button after that beep and the on-screen calibration prompting sequence will begin.

CALIBRATING INDIVIDUAL MOTIONS FROM THE SOFTWARE:

While you are in the "Calibrate" panel, you will also see that each available motion has a small arrow icon next to its name and quality rating. Clicking on that arrow brings up your detailed **Control Coach®** information for that specific motion. Here **Control Coach®** will have feedback for you, if applicable. Clicking the "Add Data" button is how you can add calibration muscle signal data for this one motion — once it is pressed, an empty circle appears. As you hold your muscle contraction steady for this motion, the circle will begin filling up with orange segments. Make sure you hold your signals until the whole circle fills.
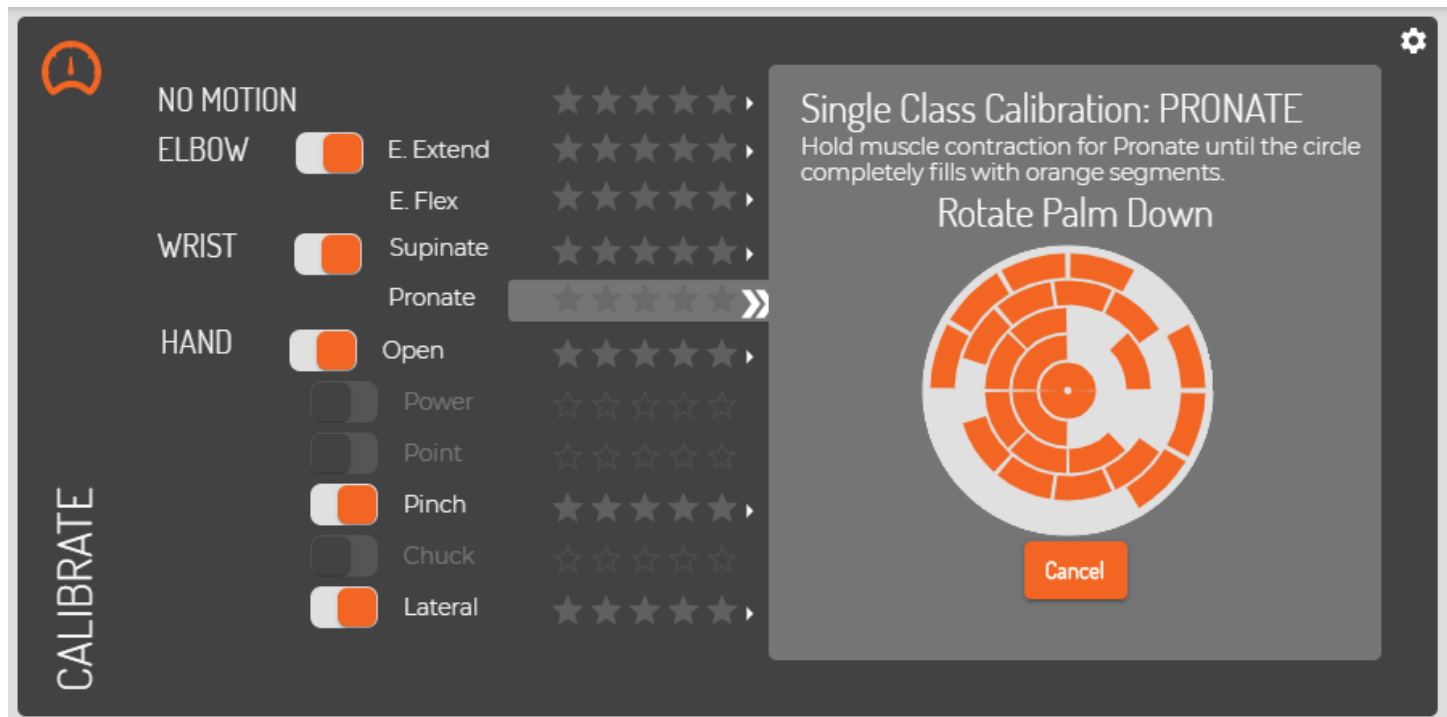
> **NOTE**
>
> After any calibration activity, it's great to see if the **Control Coach®** white LED is blinking. If so, **Control Coach®** has useful calibration performance info waiting in the Coapt **Complete ControlRoom** application.

CALIBRATION ADAPTATION: **ADAPTIVE ADVANCE**®

Adaptive Advance® is an important feature that is part of calibration. It is an automatic, continuous-learning algorithm that knows exactly how to meld new calibration data into the existing state of your control. Since **Adaptive Advance®** adapts and learns each time you calibrate any or all motions, it acts as a control companion that tracks natural changes over time. Each time calibration is performed, the **Adaptive Advance®** algorithms know exactly what to do with your new data to improve control.

To turn **Adaptive Advance®** on or off (it is on by default), use the Coapt software application. Connect to your device with Bluetooth, navigate to the Calibrate panel, then click on the settings icon (looks like a cogwheel). In the menu that appears, use the On/Off toggle by the **Adaptive Advance®** label.

TIPS

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: ADDITIONAL TOOLS

Calibration Clearing/Resetting

Sometimes you may want or need to erase/reset the calibration control memory of your Coapt system. This can be helpful if there has been an electrode location change or simply if reliable control has become unstable. To help with this, there are a few convenient ways to reset all calibrated motions or to reset one motion at a time.

CLEARING/RESETTING ALL CALIBRATED MOTIONS

To reset ALL calibrated motions to a blank starting state, you can use either the Coapt **Complete Calibrate** button the software application.

To reset ALL calibrated motions using the Coapt **Complete Calibrate** button, press and hold for 10 seconds (until you hear it play a short melody) then let go. This will reset the system back to a starting state and turn the button's LED magenta. Don't expect control of the virtual arm when the LED is magenta—the control memory is empty and it will need at least one new calibration to operate a virtual arm again.

To reset ALL calibrated motions using the Coapt **Complete ControlRoom** software application, connect to your device with Bluetooth, navigate to the Calibrate panel, then click on the settings icon (looks like a cogwheel). In the menu that appears, click the "Reset ALL" button. This will reset the system back to a starting state and turn the Calibrate button's LED magenta. Don't expect control of the virtual arm when the LED is magenta—the control memory is empty and it will need at least one new calibration to operate a virtual arm again.

CLEARING/RESETTING ONE CALIBRATED MOTION

Any single motion can be independently reset. This will not reset your other motions. This can be useful if you have one or more motions that you'd like a fresh start with while keeping the rest as they are. To do this, connect to your device with Bluetooth in the **Complete ControlRoom** application and navigate to the Calibrate panel. Clicking on the small arrow icon next to a motion will bring up your **Control Coach®** information about that specific motion. Here, clicking the "Reset" button will set this motion only to a blank starting state while leaving the other calibrated motions as-is. The control memory for the chosen motion is now empty and it will have to get at least one calibration to regain control.
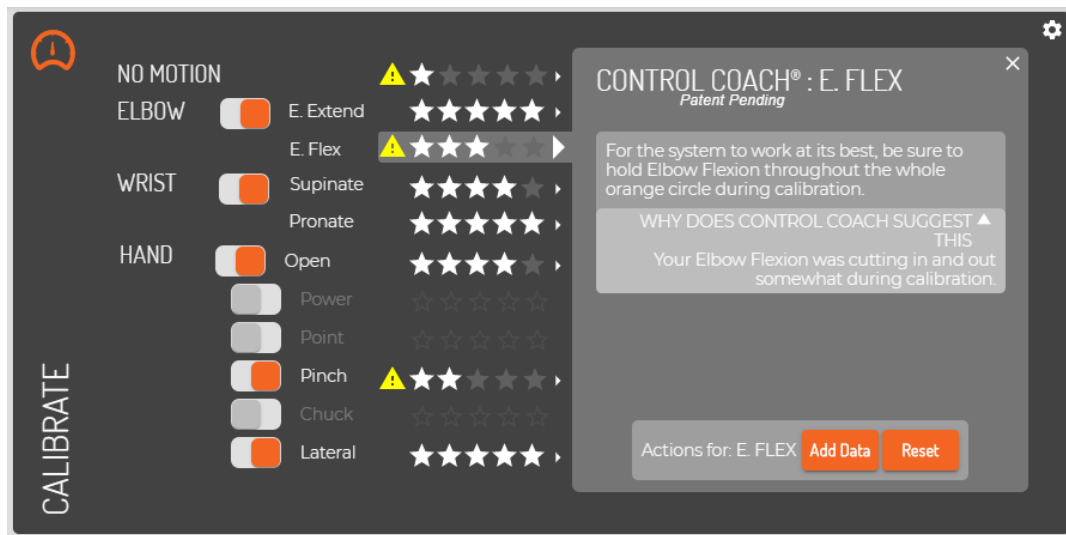
Calibration Undo's

It's absolutely ok if you mess up a muscle contraction or two during calibration—maybe you missed following a prompt, maybe you performed a different motion by mistake, maybe you even held a motion in a way that was too different from how you did it in the past, and so on. This is not a big deal—and no reason to let that affect your control in a bad way. At any time, the Coapt system lets you "Undo" your last (most recent) calibration activity, whether that was a single motion 'Add Data' or a full-sequence calibration. Undoing a calibration jumps your control back to the state it was in just before that last calibration activity. There are two ways to undo the most recent calibration activity:

CALIBRATION UNDO FROM THE BUTTON

To Undo the most recent calibration activity using the Coapt **Complete Calibrate** button, hold it pressed for 6 seconds (until you hear it double beep and see the LED flashing blue) then let it go. It will take a moment to recompute and then return virtual arm control back to you.
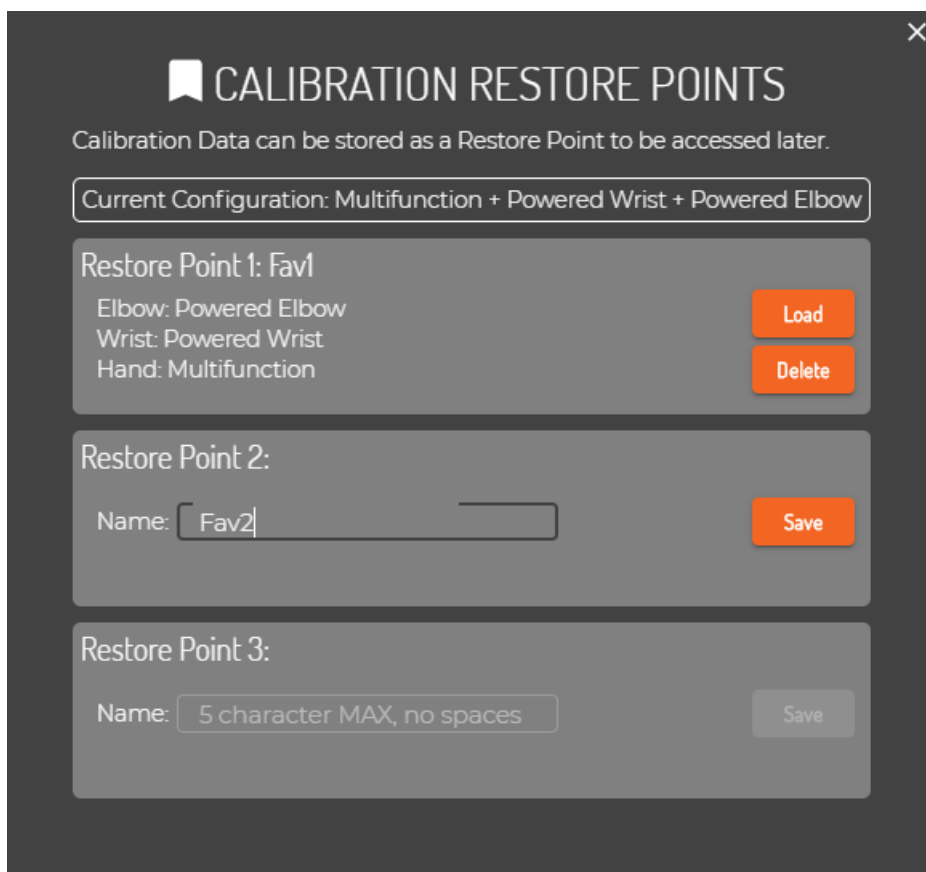
CALIBRATION UNDO USING THE SOFTWARE APPLICATION

To Undo the most recent calibration activity using the Coapt **Complete ControlRoom** software application, connect to your device with Bluetooth, navigate to the Calibrate panel, then click the Undo button (it is an orange button with a circular arrow icon). It will take a moment to recompute and then return virtual arm control back to you.

Calibration Restore Points

Another convenient feature of Coapt calibration is the ability to store up to 3 calibration Restore Points. Restore points act as saved 'snapshots in time' of your control. Whenever you would like to save your current calibration—perhaps at a point when your control performance is noticeably dialed in—simply access the Coapt **Complete ControlRoom** software application and store the current calibration state in an available Restore Point slot. To do this, connect to your device with Bluetooth in the **Complete ControlRoom** application, navigate to the Calibrate panel, then click the Restore Points button (it is an orange button with a bookmark icon).

Whenever you have any Restore Points saved to memory, you can revisit this menu at any time to reload the desired Restore Point matching the current configuration—taking control back to a date or specific control.

CONTROL COACH®

Your Coapt system is smart. Not only can it be calibrated to learn and know your muscle signals patterns for prosthesis control, it also has a built-in coach to help you get the best out of calibrating. Coapt's artificial intelligence (A.I.) **Control Coach®** analyzes your calibration data for nuances and scenarios that it knows can limit your potential. **Control Coach®** was programmed with years' worth of Coapt clinical experience. It knows the tips and tricks that can really help you tweak calibration and get the most out of your control.

Think of **Control Coach®** as an expert in your pocket—giving you the coaching support that can really make a difference. This section describes how you can put **Control Coach®** to work and achieve great performance.

Control Coach® Quality Rating System

If you are familiar with restaurant or hotel reviews, you have probably seen a 5-star rating system before. Generally, we know that getting 5 stars is best, and fewer stars is, well, not as good. **Control Coach®** has its own 5-star rating system to give feedback on the quality for each of your calibrated motions. A 5-star rating for a motion means that you are likely getting great, reliable control for that particular action. As the A.I. engine in **Control Coach®** detects things it believes are limiting your full potential, it will lower the ratings for affected motions. A motion with a 3-star or 4-star rating may be functioning just fine, but **Control Coach®** still has feedback you may be interested in. Ratings of 2 stars or lower typically mean **Control Coach®** has some helpful insights you should probably attend to.
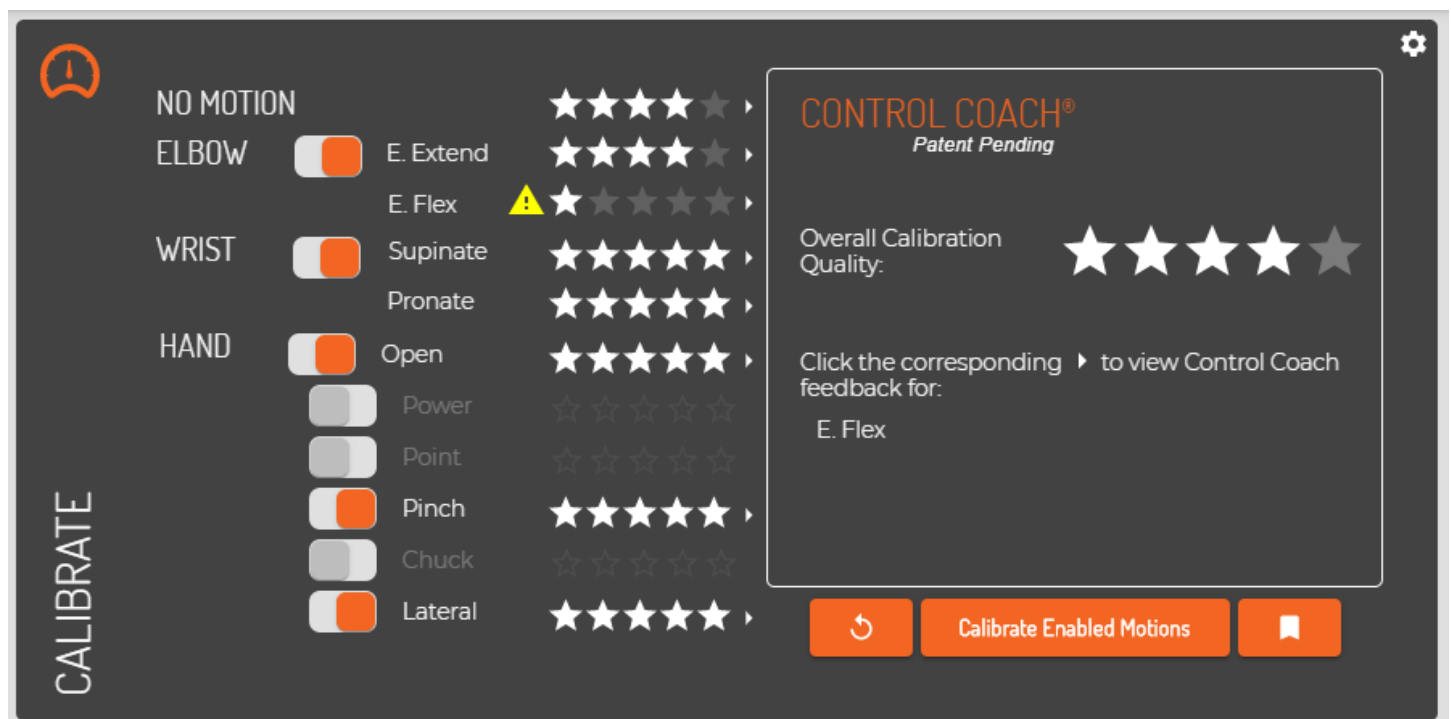
Using **Control Coach**® Information

In Coapt's **Complete ControlRoom** software application, connect to your device with Bluetooth, navigate to the Calibrate panel, and you will see **Control Coach**® quality star ratings for each control motion (on the PC software you will also see an overall quality score). Clicking on the small arrow icon next to any motion brings up your **Control Coach**® information about that motion. After you read the helpful information from your Coach, consider taking appropriate action using the buttons at the bottom.
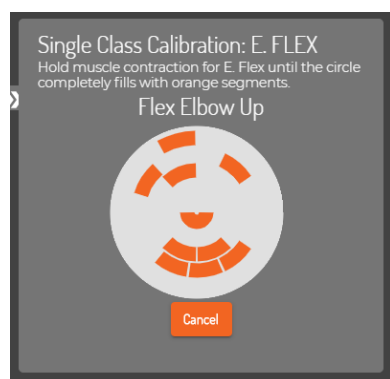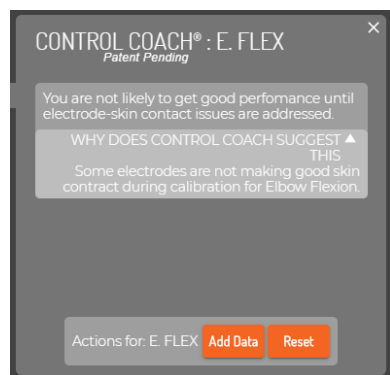
ADD DATA

Clicking the "Add Data" button is how you can add calibration muscle signal data for the selected motion. New data will be combined with already-existing data for this motion in a way that should adapt the control for better robustness. Once the button is pressed, an empty circle appears. As you hold your muscle contraction steady for this motion, the circle will begin filling up with orange segments. Hold your signals until the whole circle fills.

RESET

Clicking the "Reset" button will set this motion to a blank starting state while leaving the other calibrated motions as-is. The control memory for the chosen motion is now empty and it will have to get at least one calibration to be controlled again.

REPLACE DATA
(ONLY SHOWN WHEN ADAPTIVE ADVANCE® IS "OFF")

Clicking the "Replace Data" button is how you can replace calibration muscle signal data for the selected motion. The existing data for this motion will be discarded and the new data you provide will be used to recalibrate your control. Once the button is pressed, an empty circle appears. As you hold your muscle contraction steady for this motion, the circle will begin filling up with orange segments. Hold your signals until the whole circle fills.

The **Control Coach**® "Check Engine" Light

Similar to your car's 'check engine' light indicating the need to improve the performance and reliability of your ride, **Control Coach**® of the Coapt system has its own light to let you know there is helpful performance information available—the LED on the **Complete Calibrate** button (on your socket) will beckon with a slowly blinking white light to indicate the helpful **Control Coach**® messages are waiting for you in the Coapt **Complete ControlRoom** software application. Your Coapt 'Check Engine' light comes on whenever the overall **Control Coach**® rating drops below a set value (the threshold for this is adjustable in the Coapt **Complete ControlRoom**).

BUTTON SOUNDS & LED COLORS

On the Evaluation Kit, you will have access to the Coapt **Complete Calibrate** button. This oval unit has one pressable button, a Coapt logo, a multi-colored LED, and it can make a series of tones for you to hear. This reference section helps you with what all those colors and sounds mean.

Power Up

One short beep and a corresponding GREEN flash

The Coapt system has just powered on and "booted". You should see and hear this about 1 second after each time your system is turned on.

Low Power Source

Double RED blink

Low power source. The double red blink will let you know the source power is dangerously low for Coapt to keep operating for much longer.

Reset State

Solid MAGENTA

Reset state. The Coapt system is in a blank/empty starting state. Calibration will have to be performed to gain control of the virtual arm.

Calibration Start

One high-pitched beep after the button has been depressed for 2 seconds (LED is solid CYAN while the button is being pressed).

This indicates Guided Calibration is beginning. Letting the button go after this single beep will start the calibration routine.

Calibration Recording

Solid GREEN periods

Recording. You will notice the LED green at times during Calibration. When it is lit as green, your signals are being recorded. Periods of no light between the green phases are when you can relax.

Control Coach®

WHITE with short blip off every two seconds

Control Coach® "check engine" indicator. This notification is letting you know that helpful **Control Coach®** messages are waiting for you in the Coapt **Complete ControlRoom** software application. Your Coapt 'check engine' light comes on whenever the overall **Control Coach®** rating drops below a set value.

Calibration Undo

Double high-pitch beep after the button has been depressed for 6 seconds (LED is solid CYAN for the first 2 seconds and flashing CYAN from 2 to 6 seconds.

This initiates Calibration Undo. Letting the button go after this double beep will "undo" the most recent calibration activity and return your control to the state it was just before that. Pro Tip: It is important to know Undo can only go back one step.

Calibration Reset

A 6-note, high-pitch jingle after the button has been depressed for 10 seconds.

This initiates Calibration Reset. Letting the button go after this jingle will reset/erase the Coapt system to a blank starting state. The LED will turn solid magenta.

System Updating

Flashing GREEN

System is Updating. When the internal code (firmware) of the Coapt system is going through an update, the LED will be flashing green. This process may take several minutes. Please do not turn off the system during updates.

Critical Error

Solid RED

Critical Error. Not to worry, this usually means the Coapt system had to put itself in a protective state because of something else going on with the system. This can usually be overcome with a quick chat with your prosthetist or Coapt, and you probably don't even need to take the system off.

COMPLETE CONTROLROOM GEN2:
USER INTERFACE

Complete ControlRoom Gen2 is an easy to use and convenient user interface application available to both clinicians and users. It can be downloaded and installed as a PC application or a mobile application in the Apple or Google Play store. **Complete ControlRoom** connects to a **Complete Control** System Gen2 via Bluetooth and is used for setup, configuration, calibration assistance, and controls practice.

INSTALLATION

Windows PC

1. Visit the Coapt website and navigate to the **Complete ControlRoom** download link to save the installer application file to the computer.
2. Navigate to the downloaded installer application file and double-click to begin.
3. Follow the install wizard directions.
4. Once the installation is complete, click on the desktop icon to use the **Complete ControlRoom** application software as needed.

iOS

1. On an iOS device, visit the App Store (To install apps, sign in with an Apple ID or create one).
2. Search for the Coapt **Complete ControlRoom** application by name.
3. Tap the app.
4. Tap GET then tap INSTALL.

Android

1. On an Android device, visit the Google Play Store.
2. Search for the Coapt **Complete ControlRoom** application by name.
3. Tap the app.
4. Tap INSTALL.

UPDATES

Windows PC

The **Complete ControlRoom** application will alert you when a critical update is available.

1. A pop-up window will ask if you want to install – select yes.

2. The update procedure will be initiated and will restart the **Complete ControlRoom** application when complete.

iOS

When an update is available for the **Complete ControlRoom** application, the iOS device should automatically initiate the update when the application is opened.

iOS applications can also be updated manually:

1. From the Home screen, tap **App Store** .
2. Tap **Updates** in the bottom right corner
3. Find **Complete ControlRoom** application and tap the **Update** button next to it.

Android

When an update is available for the **Complete ControlRoom** application, the Android device should automatically initiate the update when the application is opened.

Android applications can also be updated manually:

1. From the Play Store Home screen, tap your Google profile icon (upper-right).
2. Tap **My apps & device**.
3. Tap individual installed apps to update or tap **Update All** to download all available updates.
4. If presented, review App Permissions then tap **Accept** to proceed with app update.

COMPLETE CONTROLROOM GEN2 ENVIRONMENTS

Dashboard

The Dashboard environment appears when **Complete ControlRoom** is launched and presents navigation to the four other **Complete ControlRoom** environments.

Connect

The Connect environment has two main purposes:

1. Manage Bluetooth connection to a **Complete Controller** System Gen2

2. Guide the correct configuration and physical connections of the **Complete Controller** System Gen2 to the prosthesis.
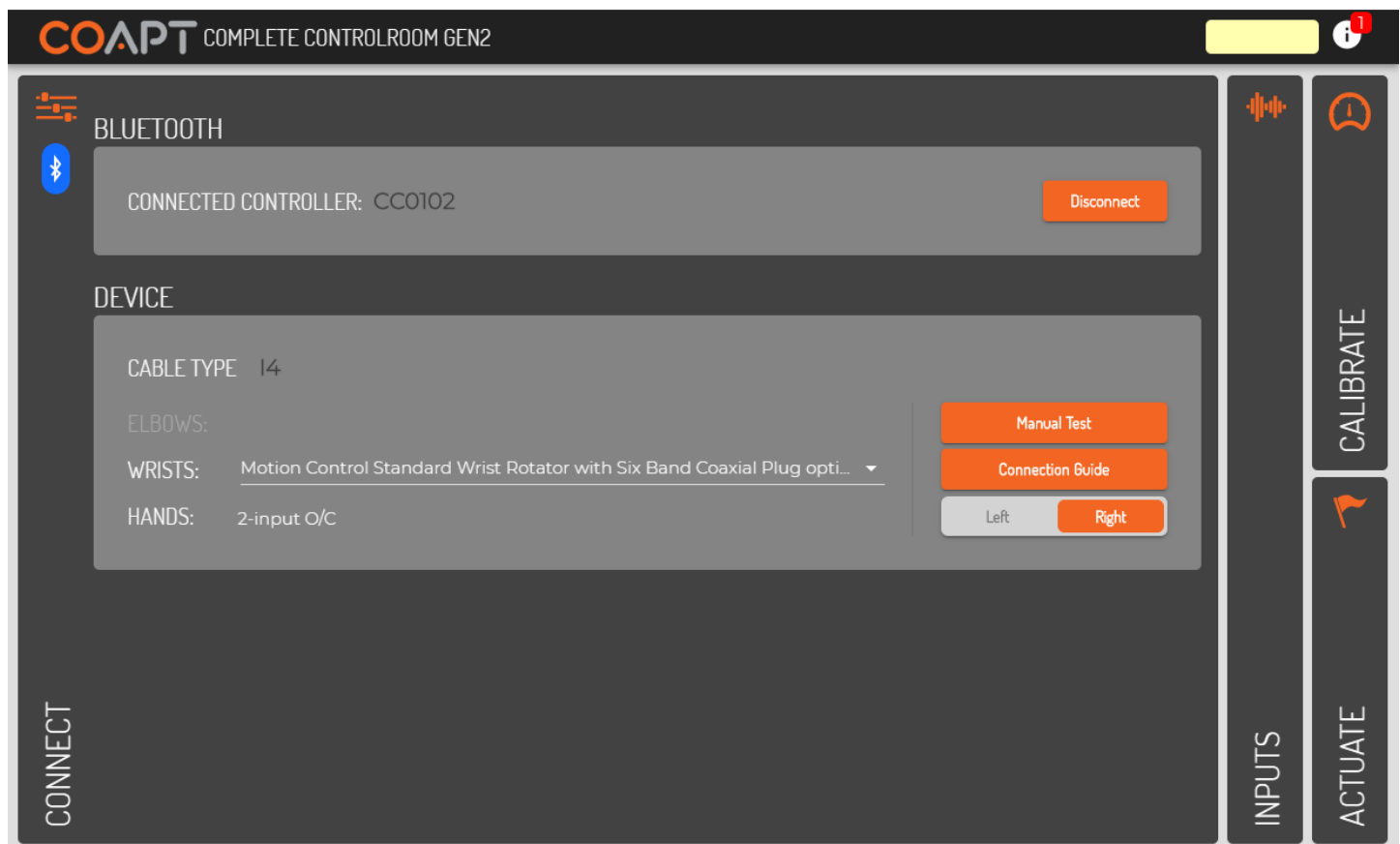
CONNET PANEL ELEMENTS (BLUETOOTH SUB-PANEL)	
CONNECTED CONTROLLER	A Bluetooth-connected **Complete Controller** will be named by its serial number starting with "CC". Check the serial number displayed on the screen and the serial number of the device (located on its label) to ensure you are connected to the correct **Complete Controller**.
SCAN/DISCONNECT – BUTTON	Displays a list of any **Complete Controller** devices currently broadcasting over Bluetooth. Clicking on the serial number identifier of one will establish Bluetooth connection. This button changes to "Disconnect" once Bluetooth connection has been established to a device. Clicking on "Disconnect" will terminate the Bluetooth connection.

TIPS

After a period of inactive Bluetooth communication (e.g. being disconnected from the software application), a **Complete Controller** will stop radio broadcasting in order to save battery power. To have the **Complete Controller** turn its Bluetooth capabilities back on, simply press the **Complete Calibrate** button once quickly or turn the power of the prosthesis off and then back on.

CONNECT PANEL ELEMENTS (DEVICE SUB-PANEL)

CABLE TYPE	When **Complete ControlRoom** establishes Bluetooth connection to a **Complete Controller**, the type of Device Interface Cable attached is detected and displayed. The Cable Type is a two-character code that will match the labelling on the Device Interface Cable.
ELBOWS/WRISTS/HANDS	Each unique Cable Type determines the set of pull-down menus and their contents. Available options represent the known possible devices compatible with that particular Device Interface Cable. Take care to select their prosthetic devices accordingly.
MANUAL TEST – BUTTON	Opens a pop-up window where all available prosthesis actions/functions will be listed on individual buttons. Clicking and holding on any of these buttons is intended to result in the corresponding prosthesis action. Direction flipping/reversing is also available.
CONNECTION GUIDE -BUTTON	Opens a pop-up window that displays helpful information for proper physical connection of the Device Interface Cable to the prosthetic devices as well as other devices' suggested software settings (where applicable).
LEFT/RIGHT – TOGGLE	Selects either left-handed or right-handed prosthetic device and virtual arm operation.

NOTE

Manual test is provided to ensure proper operation, connection, and configuration of the prosthetic device(s) has been made. If proper setup with prosthetic devices is not complete, the **Complete Control** System Gen2 will not be able to function at its ideal capacity.

Inputs

The Inputs environment has three main purposes:

1. Verification that EMG inputs have reliable electrode-to-skin contact

2. Allowing for on/off toggle of EMG input channels for diagnostic purposes

3. Display a real-time classification output (when calibrated) corresponding to inputs' patterns
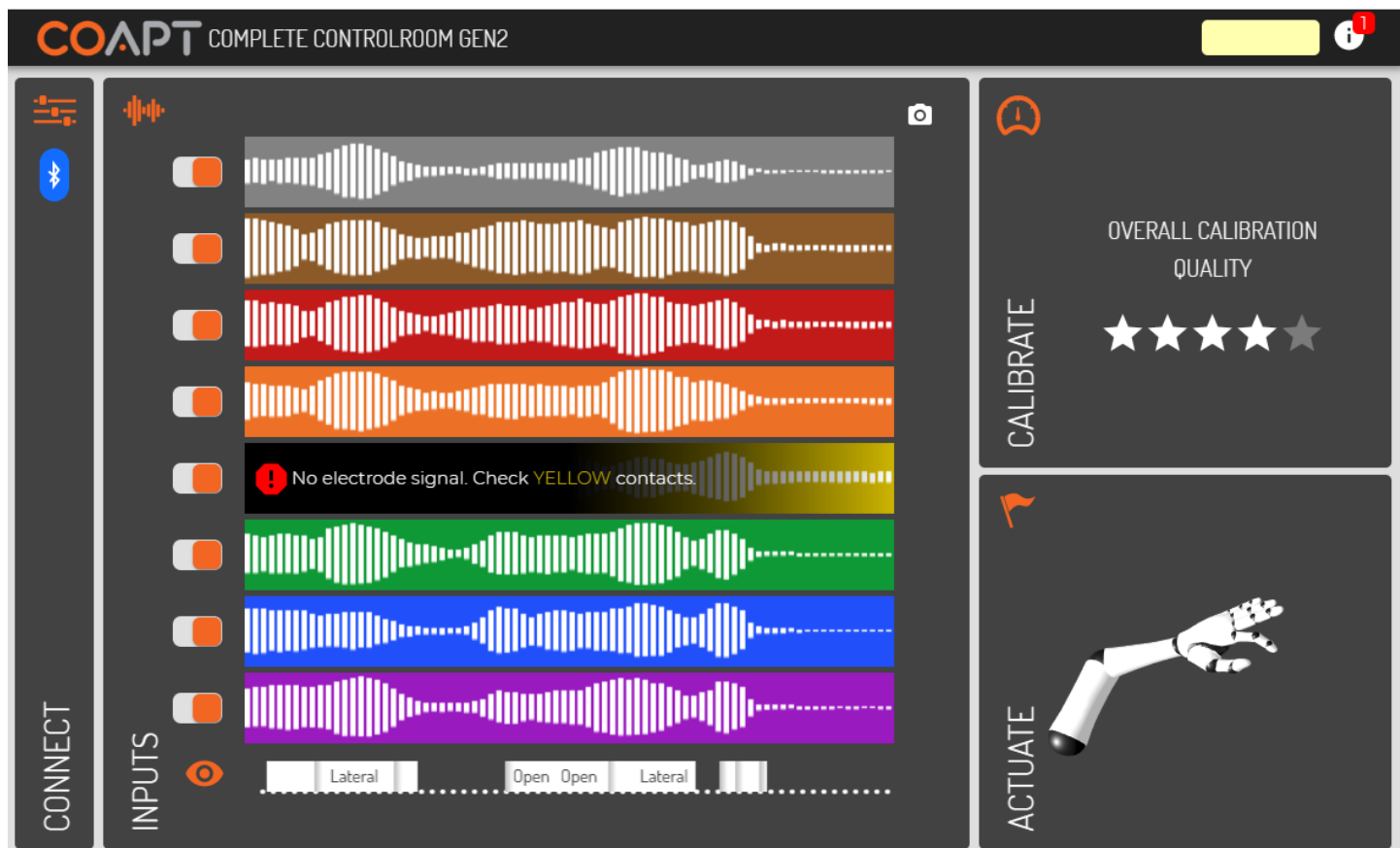
The **Complete Control** System Gen2 is designed to function at its ideal capacity with all eight EMG channel inputs. Any EMG channels that are turned off should be corrected to ensure reliable electrode contact and then turned back on for optimal performance.

TIPS

INPUTS PANEL ELEMENTS

EMG INPUT BARS	Dynamic signal activity on eight horizontal bars of color represent the eight EMG channel inputs of the **Complete Control** System Gen2. The on-screen colors correspond to the EMG wire colors of the EMG Interface Cable.
	A real-time signal quality assistant monitors for EMG electrodes losing contact with user's skin ("lift-off"). When lift-off is detected, a warning message is displayed on the corresponding signal channel.
EMG INPUTS – ON/OFF TOGGLES	Each EMG Input channel has an on/off toggle that will determine its inclusion or exclusion from the set of pattern recognition inputs. It is strongly suggested that all eight EMG inputs are used to ensure optimal performance.
SCROLLING OUTPUTS DISPLAY	Below the set of EMG inputs is a scrolling display that shows real-time control outputs from the current state of the **Complete Control** system's calibrated pattern recognition classifier. No motions will be displayed when the system is in a Reset state.
	For convenience, visibility of this output display can be toggled on or off by clicking the "eye" icon.
SNAPSHOT – BUTTON (CAMERA ICON)	The camera icon opens a pop-up window that contains a snapshot of the EMG Inputs activity at the moment the button was pushed. The pop-up allows for the captured imaged to be saved for later use.

Calibrate

The Calibrate environment assists the user with calibration of their **Complete Control** System Gen2.
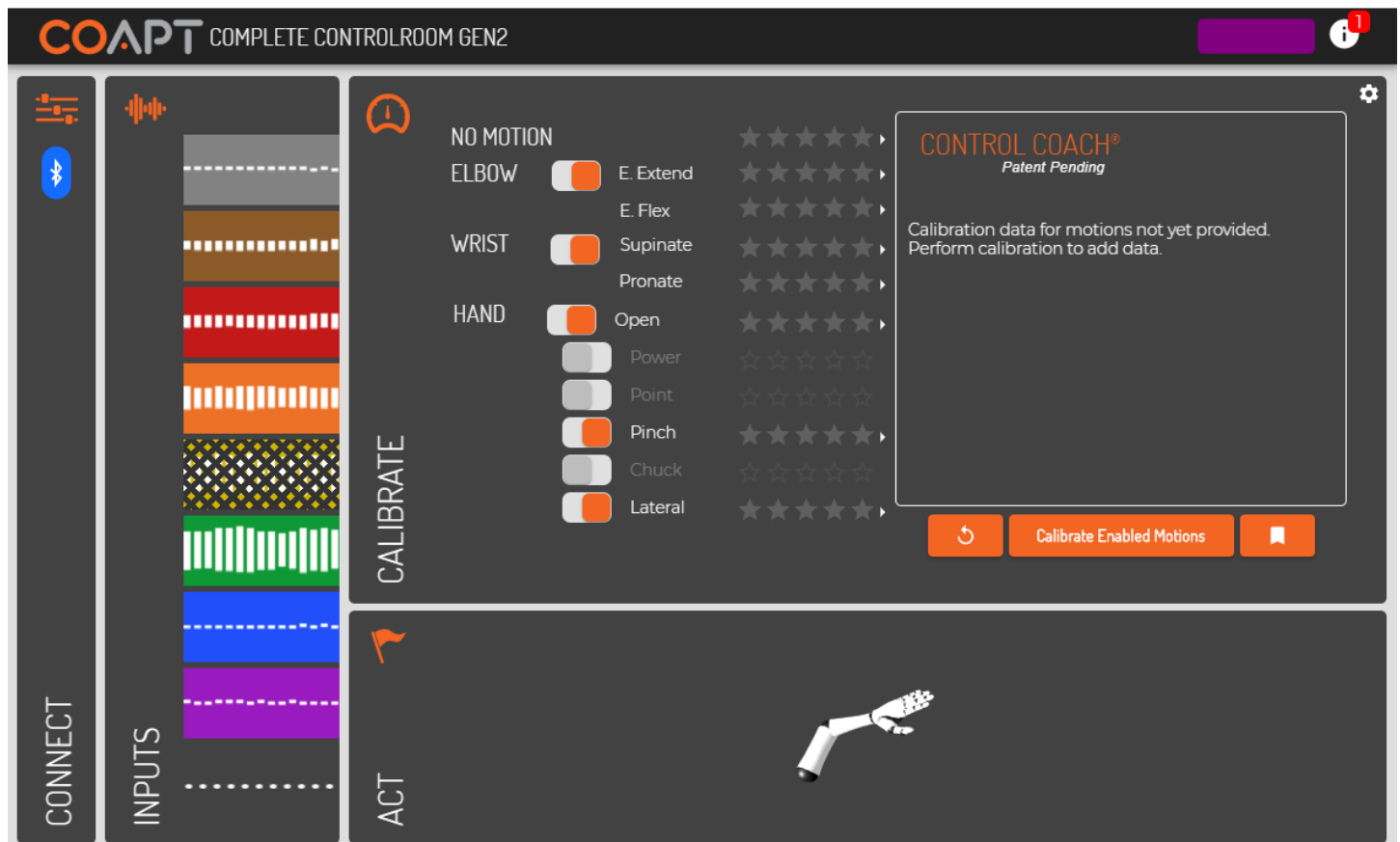
CALIBRATE PANEL ELEMENTS	
ACTION/FUNCTION TOGGLES	Allows selection of which actions/functions are included in calibration for prosthetic control.
ACTION/FUNCTION STAR RATINGS	Displays the A.I. **Control Coach®** estimated calibration quality for each action/function (see **Control Coach®** section for more).
ACTION/FUNCTION CONTROL COACH® ARROWS	Clicking the arrow next to any action/function will expand its specific **Control Coach®** information in the **Control Coach®** sub-panel (see **Control Coach®** section for more).
CALIBRATE ENABLED MOTIONS – BUTTON	Initiates the guided calibration sequence of all of the actions/functions toggled on.

UNDO – BUTTON (COUNTER-CLOCKWISE ARROW ICON)	Reverts the system to the calibrated state it was in just before the most recent calibration activity, that activity either being single-motion or full-sequence calibration.
	The Undo functionality only applies to one calibration step; that is, undoing more than one calibration step is not possible.
RESTORE POINTS – BUTTON (BOOKMARK ICON)	Opens a pop-up window for storing or loading a Calibration Restore Point.

Opens a pop-up window for **Complete Control** calibration settings:

SETTINGS – MENU (COGWHEEL ICON)	CALIBRATION PACE – SELECTOR	Sets the pace at which prompts will be spaced during a calibration sequence.
	ADAPTIVE ADVANCE® – TOGGLE	When "On" (default), enables the **Adaptive Advance®** continuous-learning algorithms to meld any new calibration data into the existing state of users' control (see **Adaptive Advance®** section for more).
	CONTROL COACH® LED SENSITIVITY – SELECTOR	Adjusts when the **Control Coach®** white LED on the **Complete Calibrate** button will come on. For example, when set to 2 stars, the **Complete Calibrate** button indicator will only come on when the overall **Control Coach®** star rating is a 2 or less (see **Control Coach®** section for more).
	SINGLE-CLASS CALIBRATION DATA AMOUNT – SLIDER	Determines how much calibration data users will be tasked to provide in order to 'fill-the-bucket' during any Single Class Calibrations.
	RESET ALL – BUTTON	Sets the **Complete Control** system to a blank starting state. The control memory will be emptied and will need at least one new calibration to actuate the prosthesis.

Actuate

The Actuate environment assists the user with on-screen prosthesis control practice using their **Complete Control** System Gen2.
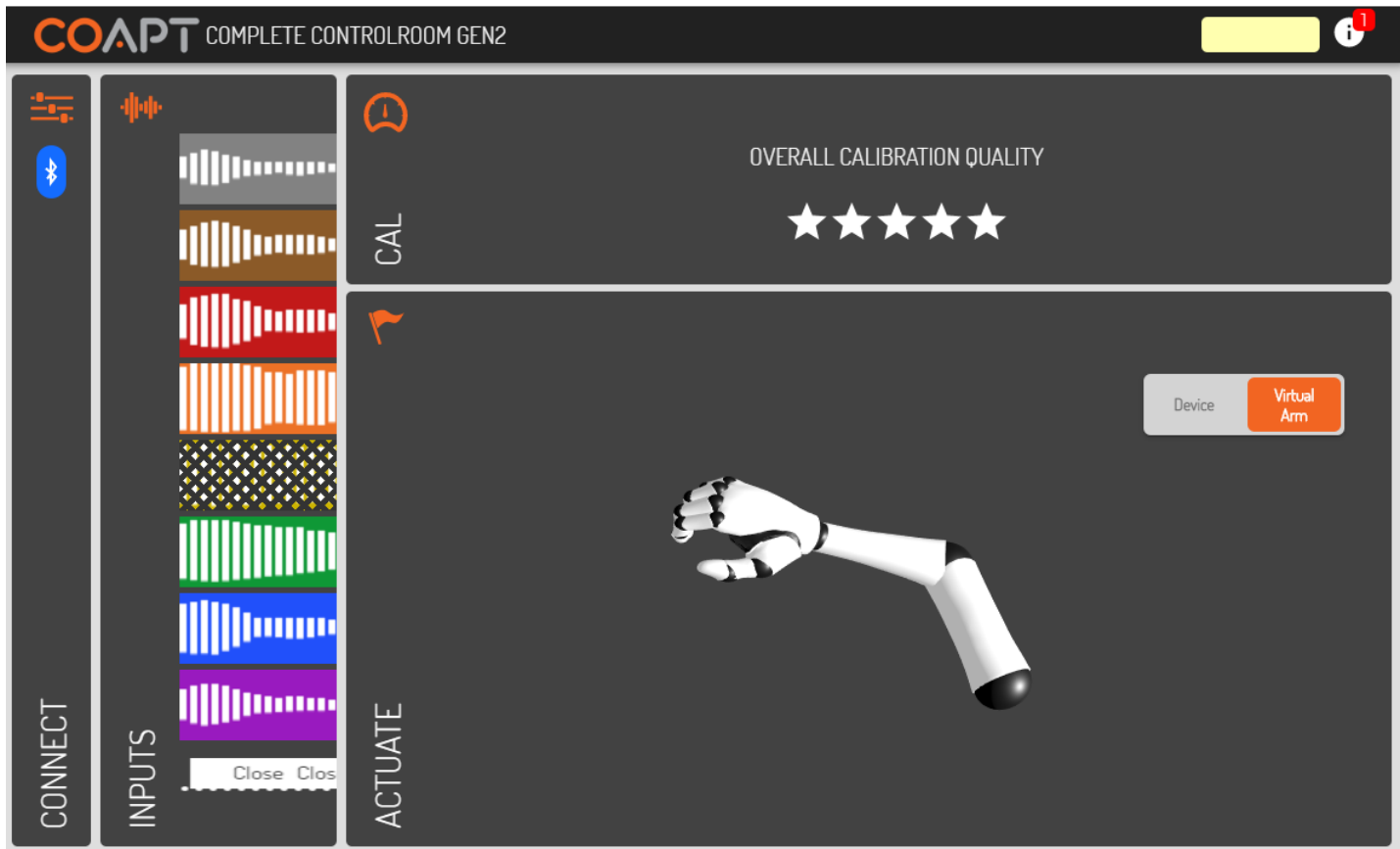
VIRTUAL ARM/DEVICE – TOGGLE	Allows the user to direct their real-time pattern recognition control to either the on-screen arm or their prosthesis.

TROUBLESHOOTING

Under the hood, the Coapt system is made of some very advanced technology. However, Coapt has worked hard to make it as easy as possible to implement. If you are encountering an issue that seems out of the ordinary, Coapt hopes you will find the guided troubleshooting in this section helpful.

SETUP

I'm sure all the electrodes are making good skin contact but the Coapt application says, "No electrode signal" and to "Check contacts", or The EMG Inputs display is showing warnings on some of the channels, what do I need to do?

The Coapt system has built-in detection to know if any EMG channel is not receiving signals from the skin. Before you can expect good prosthesis control performance, corrective action for any EMG channel showing this warning should be made. Finding the root of the issue is best, but any EMG channel can be toggled off temporarily until further diagnosis can be made. Coapt does not recommend leaving EMG channels turned off long term nor turning too many channels off at once; a limited number of active EMG inputs can significantly limit control performance and prosthesis function.

A few things to look for when diagnosing problematic EMG signal contact:

1. Ensure all Dome Electrodes are clean and free of residue (clean as necessary with isopropyl alcohol).
2. If skin is significantly dry or hair-covered, allow a few minutes for 'settle-in'. Speed up this process by dampening the skin area before prosthesis donning.
3. Ensure all Dome Electrodes maintain reliable contact with the user's limb throughout their range of motion and during their muscle contractions.
4. Ensure all EMG wire connections to the Dome Electrodes are tight. Always tighten and secure with the provided split-lock washers to prevent loosening.
5. Ensure the EMG Connection Cable is fully connected to the Coapt controller main unit.

LIGHTS AND SOUNDS

The light on the Coapt Complete Calibrate button changes colors, what do they mean?

A helpful guide to the light colors and the different sounds of the **Complete Calibrate** button can be found in the BUTTON SOUNDS & LED COLORS section of this handbook and the User Resources section of the Coapt website.

There's a solid red light on the Coapt Complete Calibrate button.

This means there was a significant power interruption error and the Coapt system put itself in a temporary self-protect state. Ensure the battery is adequately charged.

You should be able to get it going again with these steps:

1. Bluetooth connect to your Coapt system in the **Complete ControlRoom** application

2. On the Connect screen, find and press the "Reset" button (it is be located near a message, "Your Coapt Controller is in an error state.")

3. If this does not resolve the issue, please contact Coapt technical support at 844.262.7800 x2.

FUNCTION/CALIBRATION

When I try to control a specific motion, the virtual arm will sometimes instead do a different one.

This is commonly caused if the Coapt system has data for different motions that it sees as very similar. Specifically, similar for the ones that are getting confused.

1. Try adding additional calibration data to the motions that are causing the most inconsistency.

2. Try calibrating your motions with additional, and varied contraction intensities.

3. Ensure muscle contractions during any calibration feel different enough for each different motion.

Control Coach® is giving low star-ratings but control seems fine, is that okay?

Yes. Coapt is all about getting you great function. **Control Coach®** can be a great help to achieve that but it also assesses other key calibration things, such as making sure you are making calibration contractions at the correct times.

SOFTWARE/APPLICATION

I'm trying to download the Coapt software, but my computer keeps taking me to the app store.

If you are looking to install the PC version of **Complete ControlRoom**, make sure you download the installer file from the Coapt website. If you are looking for the **Complete ControlRoom** iOS app, visit the app store.

What information is contained in the ⓘ icon at the top of the software?

Clicking on the ⓘ icon in the **Complete ControlRoom** application will display current version information of the controllers internal code (firmware) as well as the version number for the **Complete ControlRoom** application.

How do I know what version of software/firmware I have?

Clicking on the ⓘ icon in the **Complete ControlRoom** application will display current version information of the controllers internal code (firmware) as well as the version number for the current **Complete ControlRoom** application.

Does the Complete ControlRoom application work on a Mac?

The **Complete ControlRoom** application has been designed for Windows operating systems. Some Mac users have emulation software (e.g. Parallels) that will also them to run **Complete ControlRoom**. Mac family users will be able to access the iOS version of **Complete ControlRoom** via the App Store.

BLUETOOTH

Can't seem to get Bluetooth to connect: when I press Scan in the Coapt application, a circle appears that just spins but nothing happens.

This means that the **Complete ControlRoom** application cannot find any Coapt systems to Bluetooth connect with.

1. Ensure the battery is charged and the system is turned on.

2. If your Coapt system has been powered on for a while, it may have turned off its own Bluetooth radio to save power. You can wake it back up by pressing the **Complete Calibrate** button once quickly.

Am I supposed to use the big Coapt USB dongle or the small Coapt USB dongle?

Coapt's Gen2 system uses a small USB Bluetooth radio dongle. It protrudes from a USB port less than 1 cm. If you have the larger, Gen1 USB dongle it will not communicate to a Gen2 Coapt system and vice versa.

I get a "NO COMPATIBLE USB 4.0 DEVICE FOUND" error when I start the Complete ControlRoom application on my computer.

This can mean you do not have the Coapt **Complete Communicator** USB Bluetooth radio dongle plugged into a USB port on your computer or that the necessary USB Bluetooth drivers did not automatically install.

1. Ensure you have plugged the Coapt **Complete Communicator** USB Bluetooth radio dongle into a USB port on your computer.

2. To manually install the necessary drivers:

   a. Unplug the Coapt **Complete Communicator** USB Bluetooth Dongle ("BT Dongle") from the computer.

   b. Close the **Complete ControlRoom** Gen2 software application if it is open.

   c. Ensure your Windows computer is connected to the internet.

   d. Open Device Manager (type "Device Manager" in the search bar at the lower left of the Windows Desktop, then Press Enter).

   e. With the Device Manager window open and visible, plug the BT Dongle into an available USB port and watch for the Device Manager to refresh the "Universal Serial Bus devices" section.

   f. Note the name of the new device (it is likely to appear as "Generic Bluetooth Device" or "CSR...").

   g. Right Click on the name of the new device and select Update driver.

h. Select Search automatically... and wait for the driver to be found.

3. If the issue persists:

a. On the same Windows computer that is experiencing the unable to find the BT Dongle issue, download and install Zadig (https://zadig.akeo.ie/).

b. Open the Zadig program once installed:

c. Select Options, then select List all devices:

d. In top drop down select the "Generic Bluetooth Device" or "CSR..." noted from above.

e. Use the small up and down arrow buttons to navigate to "libusb-win32 (v1.2.6.0)":

f. Press Replace Driver and allow the resulting process to complete.

g. Close the Zadig program.

UPDATES

I clicked start update, but now the progress bar is stuck at 0%.

This is likely an update time-out issue.

1. Ensure the battery is charged and the system is turned on.
2. Close the **Complete ControlRoom** application.
3. Cycle the power of the system off and then back on again.
4. Reconnect via Bluetooth to **Complete ControlRoom** and attempt the update again.
5. If the issue persists, consider asking your company's IT support if there are firewall restrictions on your computer preventing software updates. If so, have them assist in permitting the Coapt update.

I just completed an update, but it is asking me to do another update, or, I was prompted to do an update but I didn't have time, is it really important to do the update?

Coapt makes sure updates are never more frequent than necessary and each one contains important changes to enhance the performance of your Coapt Gen2™ system. Some of the updates are for the software of the **Complete ControlRoom** application while other updates will be for the code (firmware) that lives on the Coapt hardware system inside the prosthesis. This second type of update can take longer to complete and typically requires about 10 minutes. Please make sure power to your prosthesis stays on and your Bluetooth connection is maintained throughout any update.

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 MERCHANTIBLITY, 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. Please contact a Coapt representative for pricing and terms.

RETURNS

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

Clinicians should return all unserviceable Evaluation Kit components directly to their regional distributor. In the United States, Clinicians should return all unserviceable Evaluation Kit components directly to Coapt, LLC at:

**Coapt, LLC
ATTN: Returns
303 W Institute Pl., Suite 200
Chicago, IL 60610**

If sending the Evaluation Kit to Coapt 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.

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

ADVERSE EVENTS

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

- 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

- 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.

TECHNICAL INFORMATION

Power

The Evaluation Kit has a self-contained, IEC 62133 certified, 3.7 V_{DC}, 900 mAh rechargeable Lithium-Ion battery that is charged via micro-USB connection.

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.

⚠ 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.

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

Minimum System Requirements for Complete ControlRoom Application

- Operating System: Windows 10 (64-bit or 32-bit) or newer
- RAM: At least 1GB of system memory
- Storage: At least 1GB of available space
- Screen Resolution: Minimum 1280 x 960

Physical Dimensions

- Length: 83.1 mm (3.27 in)
- Width: 59.5 mm (2.34 in)
- Height: 22.1 mm (0.87 in)

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.