



COAPT GEN2

Gen2 EVALUATION KIT Handbook

v1.0

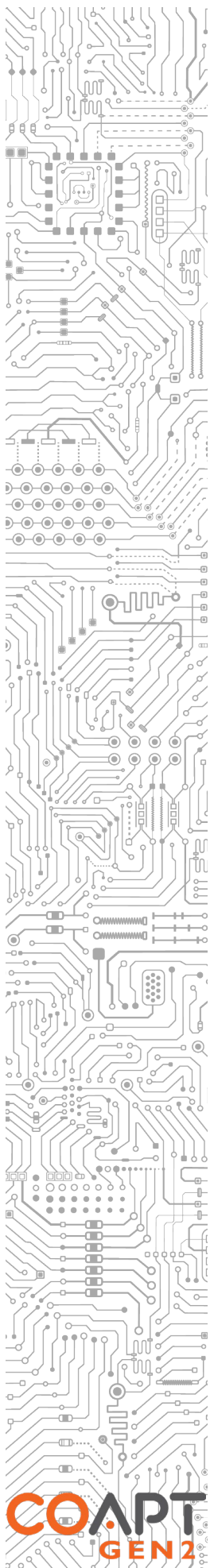
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USER ASSISTANCE & SAFETY

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


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 and other devices. Failure to heed all warnings and precautions could cause injury to the user, patient, damage to the device, or 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.
	Refer to Operating Instructions prior to use.

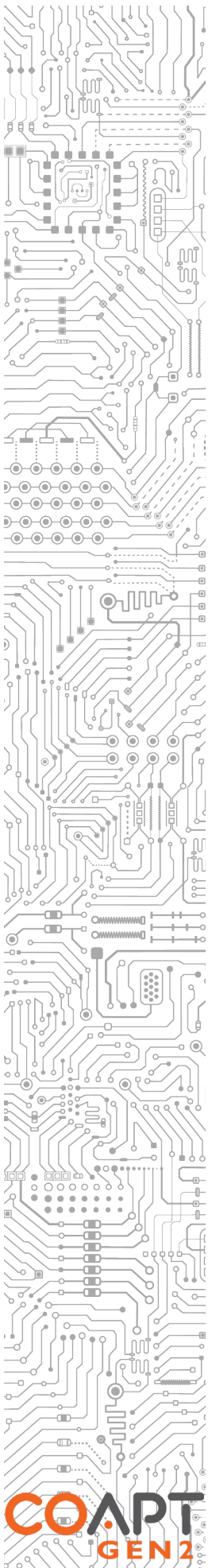
 **CAUTION** **Read and follow safety instructions.** Read this entire manual before operating the Evaluation Kit. Failure to do so could result in suboptimal system performance, injury, or damage to the device.

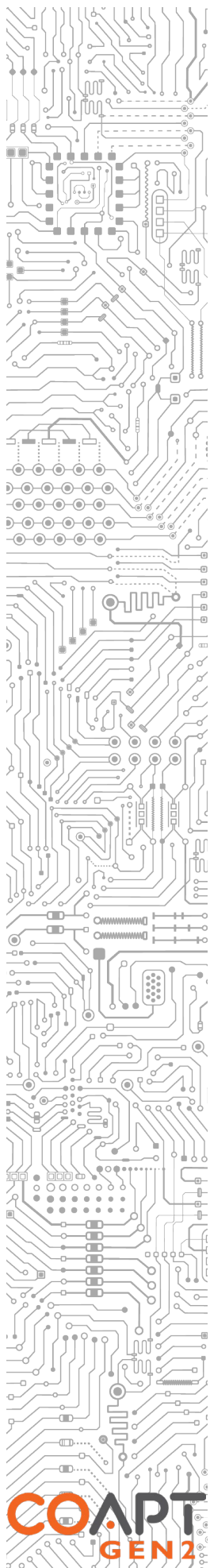
 **WARNING** **NEVER attempt to remove or modify the battery** in any way. Maintenance, repairs and upgrades may only be performed by Coapt, LLC. Unauthorized device modification or disassembly could cause damage to the device resulting in device malfunction, and injury to the user.

 **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 and injury.

- ⚠ CAUTION** **Exposure to extreme temperatures.** Do not expose to extreme low (<math>< -20^{\circ}\text{C}</math>) or high (>math>> 45^{\circ}\text{C}</math>) 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 a 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.

EVALUATION KIT 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 also permits virtual practice and training for pattern recognition myoelectric control.



Figure 1: Features of the Coapt Evaluation Kit

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.

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 medical 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)



Figure 2: Components of the Coapt Evaluation Kit

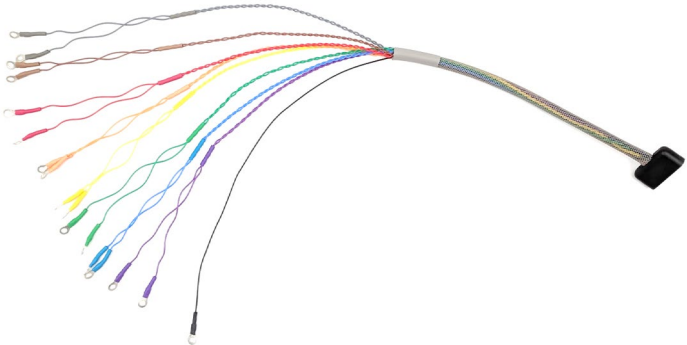
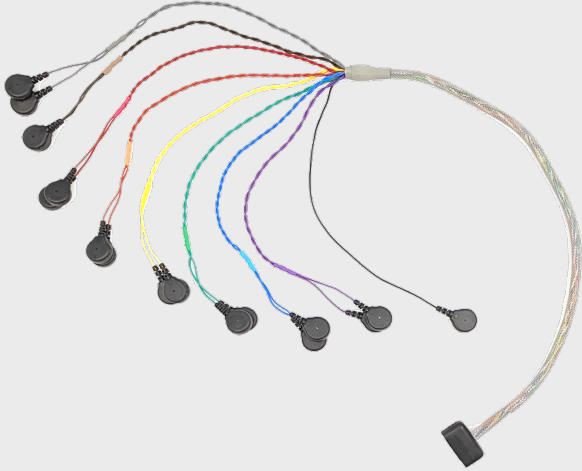
Accessories to the Evaluation Kit and not included but may be required:


1. **EMG Interface Cable(s)** (sold separately)
2. **Coapt Dome Electrodes** (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 CABLE	PART NUMBER	DESCRIPTION
Standard Eyelets EMG Interface Cable	CCEE	17 ring/eyelet terminations for use with Coapt Dome Electrode Set (p/n ELSA) 
Snap Style EMG Interface Cable	CCES	17 snap terminations for use with set of liner-snap electrode contacts (sold by third party) or with disposable, self-adhesive snap contacts 

Evaluation-Style Cuff EMG Interface Cable	CCEC	Wrap-around, Velcro cuff for evaluation use with transradial and small circumference transhumeral limbs 
Osseointegration-Style Cuff EMG Interface Cable	CCEO	Elastic cuff for definitive Osseointegration use only 

Electrodes

Where the Evaluation Kit is used with an Eyelets style EMG Interface Cable (CCEE), Coapt recommends the use of FDA cleared, non-filtering, passive, stainless-steel, electrode domes as EMG contacts. 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 (ELSA) Part Number(s): D37C13T4L50, ELSA	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

PATTERN RECOGNITION INTRODUCTION

WHAT IS PATTERN RECOGNITION?

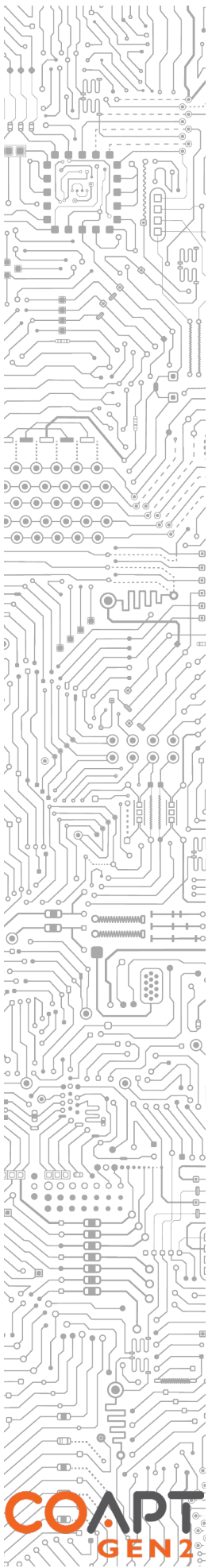
Multiple muscles work together each time we move our arms and hands. The contractions of these muscles create a pattern of activity that is unique to each movement. For example, the pattern of forearm muscle activity for hand opening is different than the pattern for hand closing. Electrodes placed on the skin over multiple muscle areas (which we often call “control sites”) can detect these overall patterns of activity.

HOW IS PATTERN RECOGNITION AN IMPROVEMENT 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:

- *Control motions are intuitive* – With standard myoelectric control, users are often required to make non-intuitive contractions to command prosthesis actions. A good example of this is using wrist extension and flexion contractions to command a prosthetic hand to open and close. With pattern recognition, natural intuitive control is possible: hand open and close contractions will control the prosthetic hand, and wrist contractions will control the prosthetic wrist.
- *Mode switching is eliminated* – With standard myoelectric control, muscle control sites are limited because of the need for signal isolation. This typically means fewer control sites are available than the desired prosthesis functions and users have to use “switches” to cycle between prosthesis functions. Examples include using co-contractions of two control signals to toggle between hand and wrist control or a physical/electrical switch the user must activate with another movement of their body. With pattern recognition, users can directly control each of their prosthesis’s motions without cumbersome and non-intuitive switching.
- *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.
- *Enhanced proportional control* – Because of the difficulty of isolating control sites with standard myoelectric control, much of a user’s ability to modulate the intensity of their prosthesis’s motor speed is often tuned out of the system. With pattern recognition, the system can take full advantage of the user’s ability and relates a wide range of the muscle contraction intensities to prosthesis speeds.
- *Simplified electrode placement* – With pattern recognition, there is much less need to search for, or precisely place control site electrodes over exact muscle locations. This means less time is spent myotesting for isolated signals; clinicians have freedom to place electrodes in socket areas that promote fit and comfort; clinicians can use sockets/liners that may be positioned differently upon each donning; the system is forgiving of changes due to muscle fatigue; and many other benefits. With less time spent in the clinic searching for the muscle



control sites, time available for in-clinic functional practice with the prosthesis is increased – thus helping users accept their prosthesis for increased at-home use.

- *Powerful recalibration* – With standard myoelectric control, changes in socket fit, user skin condition, fatigue, mental state, battery health, and many other factors can diminish the user’s function with their prosthesis. For many of these issues a repair visit or call to a prosthetist is necessary, often resulting in time-consuming prosthesis adjustments and software resetting. With pattern recognition, the control can adapt to changing conditions (such as those listed above and many more) by means of re-calibration that the user can do quickly and efficiently as needed – without travel and time with their clinician.

WHAT IS KEY TO MAKING PATTERN RECOGNITION FUNCTION AT ITS BEST?

Repetition Matters: 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 is Key: Pattern recognition requires the pattern of muscle signals to be different for each distinct motion. Each motion should “feel” different from all other motions.

One at a Time: Only one motion can be performed at a time. The performance of combined/simultaneous motions can temporarily confuse the system.

PRACTICING PATTERN RECOGNITION CONTROL

- No need for extra-hard muscle contractions. Contraction levels should be moderate – like a comfortable handshake.
- Start slow and encourage patience. This new 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, they do not need to “hold” their hand closed while rotating their wrist, as each motion is a separate activity.
- If control becomes erratic, ask the user to relax, close their eyes, and think back to the “feeling” of all their motions. The system doesn’t forget the patterns it was most recently calibrated with, so perhaps the user has changed the way they are performing muscle contractions.

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.

MYOTESTING AND ELECTRODE PLACEMENT FOR PATTERN RECOGNITION

This section describes a 3-step approach to myotesting and electrode contact placement for pattern recognition myoelectric prosthesis control. Pattern recognition utilizes the full spectrum of information contained in multiple EMG signals – as opposed to traditional myoelectric control schemes which rely on comparative amplitude information from singular EMG signals – and for ideal pattern recognition performance, electrode contact locations are strategically planned for areas of reliable contact on the residual limb. The following guidelines describe an approach to how this is accomplished through use of the Coapt Evaluation Kit.

Step 1: Discussion

To begin planning for electrode placement for pattern recognition, start with having a thorough discussion with the user about their current perceptions of missing limb movement and muscle contractions. This discussion will encourage the user to think about control in a new way. It is important to discover what control motions the user will find intuitive to use.



Figure 3: Clinical discussion for pattern recognition

GOALS of the 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.

DISCUSSION TIPS:

- A qualified practitioner should lead the discussion.
- Use demonstrations of the motions for the user to imagine and attempt.
- 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 can 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 might be available for control.
- Discuss one movement group at a time; i.e. discuss and practice hand open/close before moving on to wrist motions.
- Encourage the user to mirror their perceived motions with their sound limb if possible.
- Begin discussing the most intuitive motions and add variations as needed; i.e. try natural hand close for “hand close” and if the user has 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 for the user to perceive, discuss if they can perceive 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 to the user.
- Perform this discussion in a relaxed environment.
- Generate a common vocabulary for motions.
- Incorporate the discussed and practiced motions into a home exercise program for pre-prosthetic control.
- Encourage the user to make and hold the muscle contractions.

Step 2: Palpation

The second stage of planning for electrode placement is to repeat the Discussion activities with the user but do so while feeling for any underlying muscle activity from their residual limb. Palpation for pattern recognition is NOT an exercise in finding one or two isolated myosites; instead, it is a process to feel for all muscle activity areas including the subtle, the co-contracting, the unexpected, etc. The practitioner should feel with as much of their hands as possible and avoid trying to pinpoint activity using only fingertips.

GOALS of Palpation are to:

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.



Figure 4: Clinical palpation activities for pattern recognition

PALPATION TIPS:

- Grasp and cover as much of the user’s limb as possible; do not just use fingertips to feel.
- Have the user perform all the useful motions discovered during the Discussion phase.
 - Encourage the user to make and hold medium, comfortable-intensity contractions.
 - Have the user hold each contraction for about 3 seconds and relax between each.
- 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 only locate areas of strong, isolated contractions; instead sense all “areas of interest”.
- Do not ignore areas of slight/subtle/weak underlying muscle contraction.
- Note any unique and unexpected areas of underlying muscle contraction.
 - For transhumeral amputees this may mean unique muscle activity distal on the residual limb.
- Encourage the user to practicing making and *holding* their muscle contractions.
- 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 user’s residual limb to help remember areas of activity.
- Take time with this process.
- Be patient and listen to the user.
- Perform this exercise in a relaxed environment.

Step 3: Positioning Electrode Contacts

If the Discussion and Palpation steps have been performed with care, most of the information required to locate electrode contacts is known. Discussion helped to identify the intended control contractions and Palpation was used to locate the corresponding areas of underlying muscle activity on the residual limb. The Electrode contacts used for the evaluation will be placed on the residual limb to capture this muscle contraction information.

GOALS of positioning electrode contacts are to:

1. Cover the areas of interest discovered during Palpation.
2. Plan accordingly for future socket/liner constraints.

PLANNING TIPS:

- Consider starting with locations that correspond to existing myosites for retrofitting existing 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 (CCEE), Snaps (CCES), or Osseointegration-style Cuff (CCEO) 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 (CCEC) 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 (CCEC) or Osseointegration-style Cuff (CCEO) EMG Interface Cable:

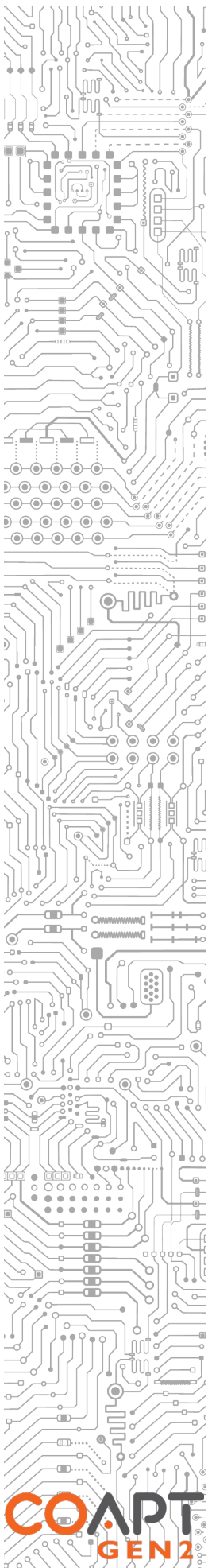
For best results, clean and dampen underlying skin areas before placing the cuff.

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.



Figure 5: Evaluation-style Cuff EMG Interface Cable (CCEC)



Placing the Standard Eyelets (CCEE) or Snaps (CCES) EMG Interface Cable:

Contact Spacing – It is acceptable to position the two electrode contacts for any EMG channel 30–60 mm apart.

This is helpful when fitting a larger residual limb – spacing the contacts apart will ensure that all available EMG control information is captured.

Contact-Pair Orientation – It is acceptable to place some of the EMG channels off-axis from the underlying muscle fiber direction.

This is helpful when fitting a residual limb with unique areas of EMG interest, common for Targeted Muscle Reinnervation patients. This can also be useful for geometrically unique and congenital limb presentations.

Contact Sharing – It is acceptable to have a few of the EMG channels share an electrode contact. Ensure the two wires for the same EMG channel (common color wires) are NOT sharing a single electrode contact. All wires must be connected to an electrode contact.

This is helpful when fitting a smaller residual limb – sharing the electrode contacts will limit the amount of electrode hardware required while capturing all available EMG control information.

Single Reference (Ground) Contact – The COMPLETE CONTROL System Gen2 requires a single 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.

General Symmetric Distribution – It is acceptable in some cases to position electrode contacts in a symmetrical arrangement. This is common for transhumeral Targeted Muscle Reinnervation patients and some transradial patients.

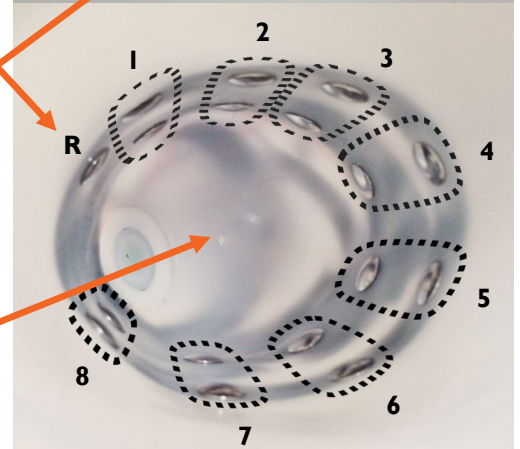
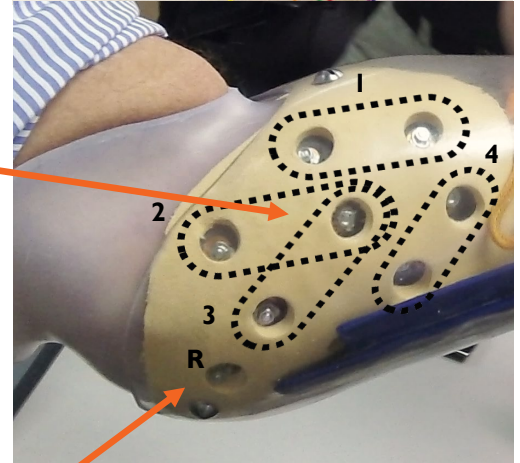
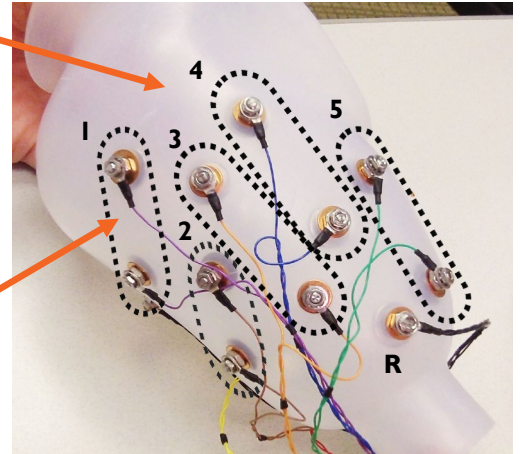


Figure 6: Annotated examples of electrode placement for pattern recognition

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.



Figure 7: Evaluation Kit and micro-USB cable disconnected (Left) and connected/charging (Right)

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 Solid 	Low battery warning. Charge the Evaluation Kit.
Amber Solid 	Evaluation Kit is charging.
Green Solid 	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.

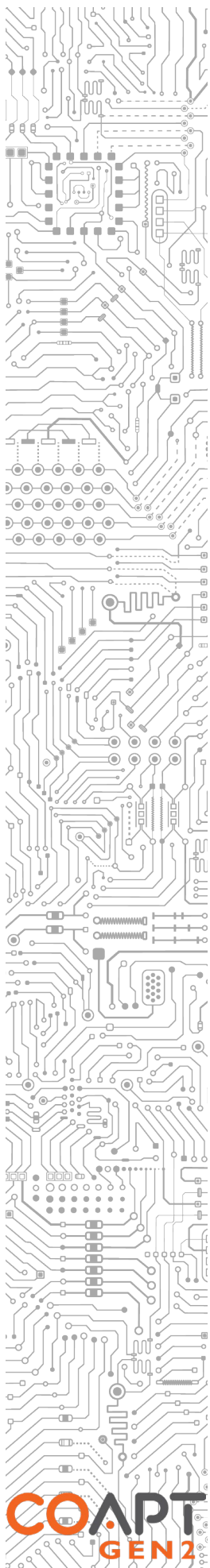


Figure 8: Evaluation Kit powered off (Left) and powered on showing the illuminated orange Power ON LED (Right)

When powered on, the LED light of the COMPLETE CALIBRATE Button on the top of the main unit may also be illuminated. See the table in the COMPLETE CALIBRATE LED Color Indications section for information on COMPLETE CALIBRATE 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.



Figure 9: Connecting an EMG Interface Cable to the Evaluation Kit by removing the EMG Interface Port Cap (Left-to-Center) and plugging in the connector end of the EMG Interface Cable to the EMG Interface Port (Center-to-Right)

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 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 functioning USB port on your personal computer.




Figure 10: Preparing for Bluetooth communication by removing the COMPLETE COMMUNICATOR USB Dongle from its Evaluation Kit holder (Left-to-Center) and plugging it into a personal computer USB port (Right)

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 coming soon to iOS devices. **See the comprehensive instructions in the COMPLETE CONTROLROOM: USER INTERFACE APPLICATION section before using the Evaluation Kit.**

Installation

Windows PC

1. Visit <https://www.coaptengineering.com/gen2setup> and navigate to the COMPLETE CONTROLROOM Gen2 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 Gen2 application software as needed.

iOS

1. Once COMPLETE CONTROLROOM Gen2 is available for iOS devices, navigate from the Home screen to **App Store** . To install apps, sign in with an Apple ID or create one.
2. To browse the App Store, tap **Apps** (at the bottom).
3. Search for the application by name, tap **Search** (at the bottom) then enter the name of the app – COMPLETE CONTROLROOM.
4. Tap the app.
5. Tap **GET** then tap **INSTALL**.
 - For a compatible iPhone with Face ID enabled, double-tap the **Side button** then look at the screen to authenticate.
 - For a compatible iPhone with Touch ID enabled, press the finger used for Touch ID on the **home button** to authenticate.
6. If prompted, sign in to the iTunes Store to complete the install.



Updates

Windows PC


The COMPLETE CONTROLROOM Gen2 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 Gen2 application when complete.

iOS

When an update is available for the COMPLETE CONTROLROOM Gen2 application, the iOS device should automatically initiate the update next time the application is opened.

Alternatively, iOS applications can 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. Alternatively, tap **Update All** in the top right corner to update the COMPLETE CONTROLROOM and other applications awaiting an update.

CALIBRATING PATTERN RECOGNITION CONTROL

Key to successful use of the pattern recognition capabilities of the Evaluation Kit is the ability to conveniently calibrate or “train” the algorithms of the system. Pattern recognition needs to be calibrated to learn the muscle signal patterns the user wants to use for control.

The Evaluation Kit provides calibration via the COMPLETE CONTROLROOM Gen2 user interface application. Instead of a prosthesis moving and the user copying its actions (as done with COMPLETE CONTROL System Gen2), a virtual arm and/or a displayed prompt of functions will guide the user through collection of muscle signal patterns.

Calibration can be initiated either by the COMPLETE CALIBRATE Button on the top of the Evaluation Kit main unit, or from within the COMPLETE CONTROLROOM Gen2 user interface application.

Calibration Initialize/Reset

Before any newly connected user calibrates with the Evaluation Kit for pattern recognition control, the system should be initialized/reset to an initial, baseline state.

Initialize/Reset also provides a useful means that allows users to “start fresh” when pattern recognition control is not adequate.

An initialized/reset starting state means the memory of ADAPTIVE ADVANCE will be set to an initial, baseline state.

There are two ways to initialize/reset the system:

USING THE COMPLETE CALIBRATE BUTTON:

1. Press and hold the COMPLETE CALIBRATE Button on top of the Evaluation Kit main unit for 10 continuous seconds.

2. A short jingle will be played and the LED light on the COMPLETE CALIBRATE Button will turn to solid magenta indicating the system was initialized/reset.

USING COMPLETE CONTROLROOM GEN2 USER INTERFACE APPLICATION:

1. Open the COMPLETE CONTROLROOM Gen2 user interface application and connect via Bluetooth to an Evaluation Kit that is powered on.
2. Navigate to the Calibrate environment and click the cogwheel icon to access the settings pop-up menu.
3. Locate and click the “Reset” button near the controls for ADAPTIVE ADVANCE.
4. The LED light on the Evaluation Kit’s COMPLETE CALIBRATE Button will turn to solid magenta indicating the system was initialized/reset.

Starting Calibration from the Software/Application

1. Open the COMPLETE CONTROLROOM Gen2 user interface application and connect via Bluetooth to an Evaluation Kit that is powered on.
2. Navigate to the Inputs environment and verify all EMG channels are not indicating any skin-contact errors.
3. Navigate to the Calibrate environment.
4. Select the desired control actions/functions from the list shown.
5. When ready to perform the calibration sequence, click the on-screen “Calibrate” button to begin.
6. During this style of calibration, an animated orange circle will prompt the user to perform the type and timing of muscle contractions and relax periods. The virtual arm depicted in the Actuate environment may also be performing the coordinated calibration prompts.

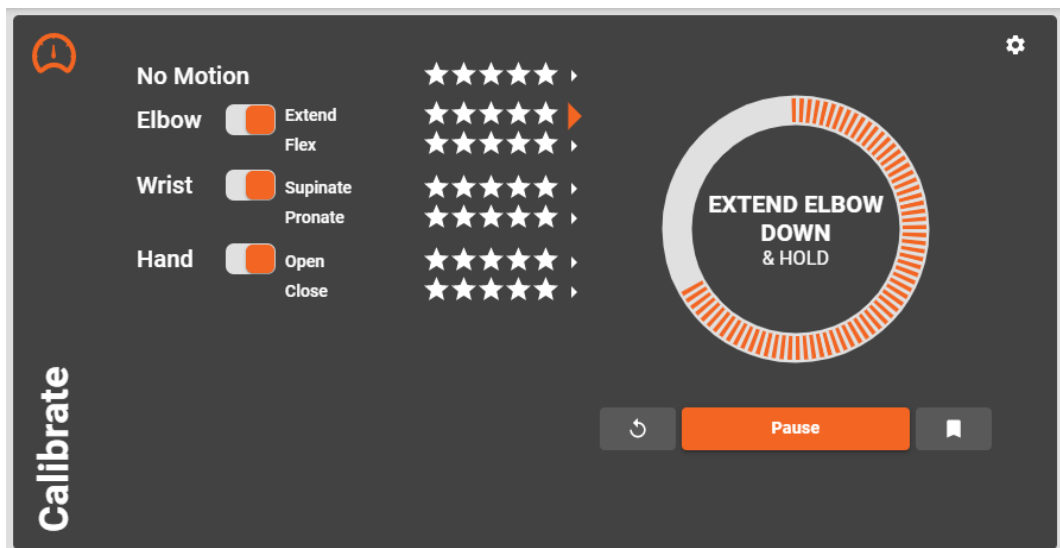


Figure 11: Example of User Interface-Guided Calibration application screen

7. Upon completion of the sequence, and after a few seconds of computation, the calibration success or calibration failure jingle will play from the Evaluation Kit’s COMPLETE CALIBRATE Button.

Starting Calibration from the Evaluation Kit

1. Open the COMPLETE CONTROLROOM Gen2 user interface application and connect via Bluetooth to an Evaluation Kit that is powered on.
2. Navigate to the Inputs environment and verify all EMG channels are not indicating any skin-contact errors.
3. Navigate to the Calibrate environment.
4. Select the desired control actions/functions from the list shown.
5. When ready to perform the calibration sequence, press and hold the COMPLETE CALIBRATE Button located on the top of Evaluation Kit main unit for about 2 seconds until a single beep is heard. Then release the button to let the calibration sequence start.



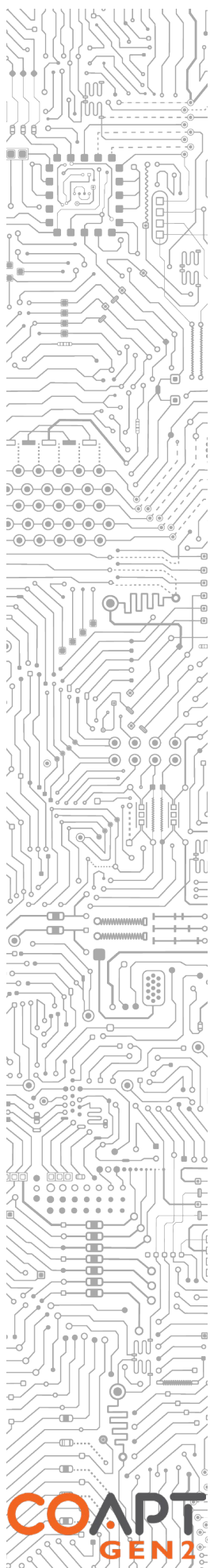
Figure 12: Pressing the COMPLETE CALIBRATE Button located on the top of Evaluation Kit main unit

6. During this style of calibration, the COMPLETE CALIBRATE LED light will illuminate green when the calibration routine begins and will also illuminate green during each of the prompted functions. The LED will be off during the short relax period between each prompted function.
7. If the COMPLETE CONTROLROOM Gen2 user interface application Calibrate environment is on screen, an animated orange circle will prompt the user to perform the type and timing of muscle contractions and relax periods. The virtual arm depicted in the Actuate environment may also be performing the coordinated calibration prompts.
8. Upon completion of the sequence, and after a few seconds of computation, the calibration success or calibration failure jingle will play from the Evaluation Kit's COMPLETE CALIBRATE Button.

Full Sequence Calibration

An example of a full calibration sequence is as follows:

STEP	DESCRIPTION	TIME	USER RESPONSIBILITIES	BUTTON LED COLOR
Starting	Initiating calibration	2 seconds	(COMPLETE CALIBRATE Button) Press and hold for 2 seconds until a single beep is heard, then let it go. (Application) Navigate to the Calibrate tab and press	Cyan while pressed



			on screen “Calibrate” button.	
Homing	Virtual arm will move itself into a known starting position. Calibration prompt circle will say “RELAX”	3-4 seconds	None	Off
“No Motion” recording	Virtual arm will be idle as an indication it is recording the relaxed state of the user. Calibration prompt circle will say “RELAX (Recording)”	3-6 seconds	NO muscle contractions should be made during this recording. It is critical that the system records EMG data representing the relaxed state (where no actions of the virtual arm would be desired).	RECORDING Solid green
Relax period	Virtual arm will be idle. Calibration prompt circle will say “RELAX”	2-4 seconds	None	Off
Prosthesis action recording	Virtual arm will move itself in one action/function. Calibration prompt circle will say “[prompted action] & HOLD”	3 seconds	Make and hold a muscle contraction corresponding to the prompted action. NOTE: do not attempt to match the moving position of the virtual arm, rather hold a steady contraction that relates to that type of motion. e.g. if the hand is slowly closing, make and hold a fully closed hand contraction for the prompt duration.	RECORDING Solid green
Relax period	Virtual arm will be idle. Calibration prompt circle will say “RELAX”	2-4 seconds	None	Off
...	The two steps above will be repeated for every selected/available action.	Variable: 5-7 seconds for each selected/available calibration action.	Make and hold muscle contractions corresponding to each prompted action. Relax during the periods in between each.	RECORDING Solid green during recording phase of each action.
Completion	When all data collection is complete, the system will internally compute its control memory and play an audible jingle when ready.	2 seconds	Once the completion jingle is heard calibration will end.	Off: Calibration data was ok. OR White with short blip every 2 seconds (see CONTROL COACH section): assistant detected something in the calibration data that is noteworthy. Click on an actions’ arrow/chevron to

Single Motion Calibration

A supplemental method of calibration for control is provided to allow calibration of a single action/function instead of a full calibration sequence of all selected actions.

This calibration method is called Single Motion Calibration and is useful for when a user has control challenges for one specific action/function of movement at a time. The user adds calibration data to this single action/function in a “fill-the-bucket” type process.

Single Motion Calibration is only available from within the COMPLETE CONTROLROOM Gen2 user interface application.

Steps to calibrate using Single Motion Calibration:

1. Open the COMPLETE CONTROLROOM Gen2 user interface application and connect via Bluetooth to an Evaluation Kit that is powered on.
2. Navigate to the Calibrate environment.
3. Click on the expansion arrow/chevron next to any action/function label to expand the details about the existing calibration of that specific function.
4. When ready, click the on-screen “Add Data” button to initiate Single Motion Calibration for that function.
5. During this style of calibration, an on-screen circle will fill with orange segments as muscle contraction data is received. The segments only fill in if muscle contraction is detected. Make and hold the muscle contraction corresponding to prompted function. **NOTE:** for Single Motion Calibration, the system is seeking to acquire a set amount of data, not simply record data for a period of time (as with Full Sequence Calibration). Therefore, Single Motion Calibration completes once the on-screen circle is completely filled with orange segments.

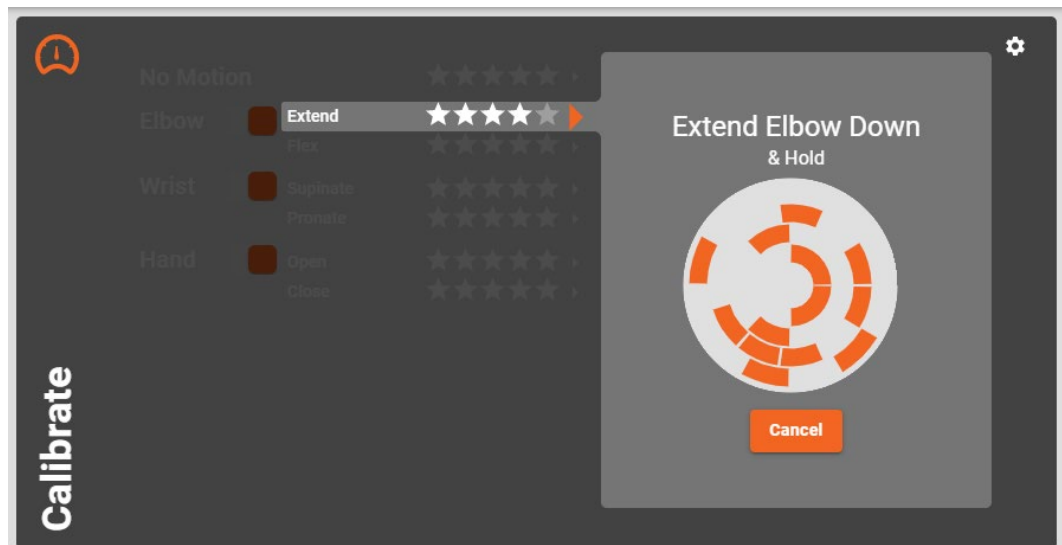
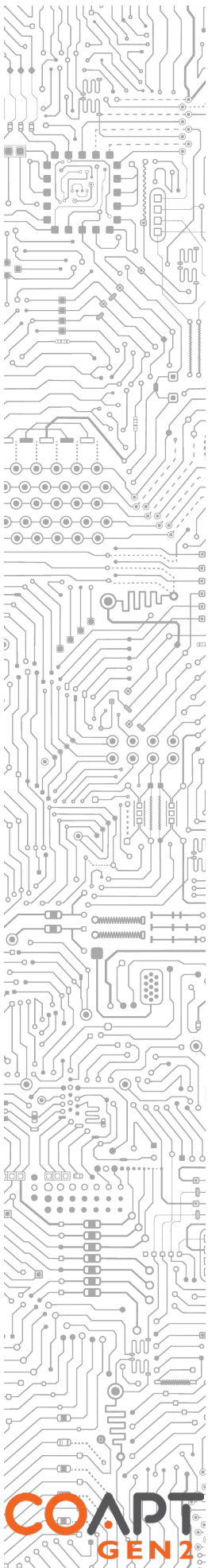


Figure 13: Example of Single Motion Calibration application screen

CONTROL COACH

CONTROL COACH is an Artificially Intelligent assessment system of users’ pattern recognition calibration quality. It monitors for issues that can limit control performance and lets the user know when informative feedback is available.



CONTROL COACH algorithms analyze users' EMG calibration data for:

- Excessive amount of EMG level during the recording of the relaxed state “no motion”
- Uncharacteristically empty signals during the recording of the relaxed state “no motion”
- EMG data patterns that are indistinct and/or too similar for one or more actions/functions
- Users' muscle contractions that started significantly late during the calibration prompt(s)
- Users' muscle contractions that ended significantly early during the calibration prompt(s)
- Users' muscle contractions that are very low in contraction strength/intensity
- Users' muscle contractions that are very high in contraction strength/intensity
- EMG data patterns that contain artifacts due to inconsistent or missing electrode-skin contact

Each of these analysis items are known to cause control degradation for some users.

CONTROL COACH combines analyses for each action/function and calculates a 1-5 “star rating” accordingly. A rating of 5 means CONTROL COACH did not determine any concerns with the action/function. Ratings less than 5 mean that one or more analysis items indicated the action/function could be subject to improvement(s). In the COMPLETE CONTROLROOM Gen2 user interface application, detailed information is available for each action/function's star rating. The on-screen information:

1. Identifies the potential sources and reasons for possible control degradation;
2. Has information on suggested approaches to address the challenges upon recalibration;
3. Provides a mechanism to quickly reset and/or recalibrate the action/function of concern.

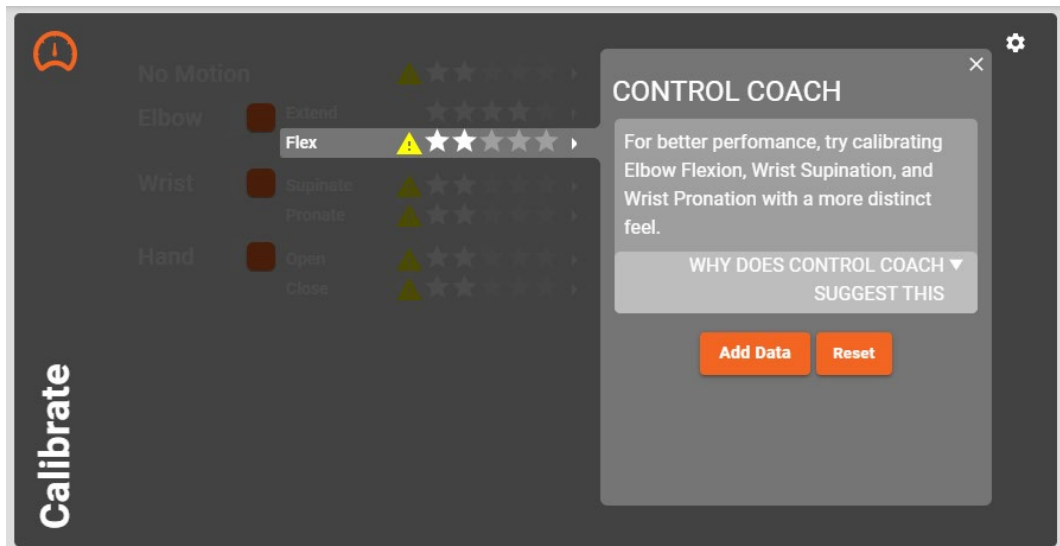
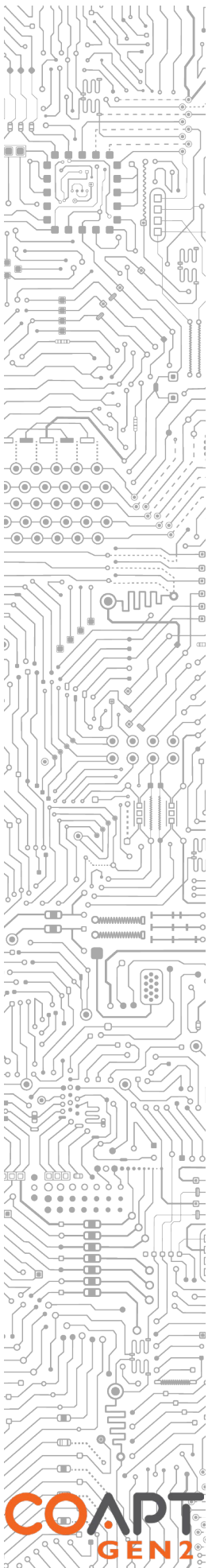


Figure 14: Example of CONTROL COACH information screen

The CONTROL COACH star rating system is designed to help the user quickly determine the areas for greatest possible control improvement. When overall star rating is below a threshold value, the visible LED on the COMPLETE CALIBRATE Button will be white with a short blip every 2 seconds. This encourages the user to connect to the COMPLETE CONTROLROOM Gen2 user interface application for the detailed information and corrective action.

ADAPTIVE ADVANCE

ADAPTIVE ADVANCE is an important feature that is part of calibration when using the Evaluation Kit. It is an automatic, continuous-learning algorithm that knows exactly how to meld new calibration data











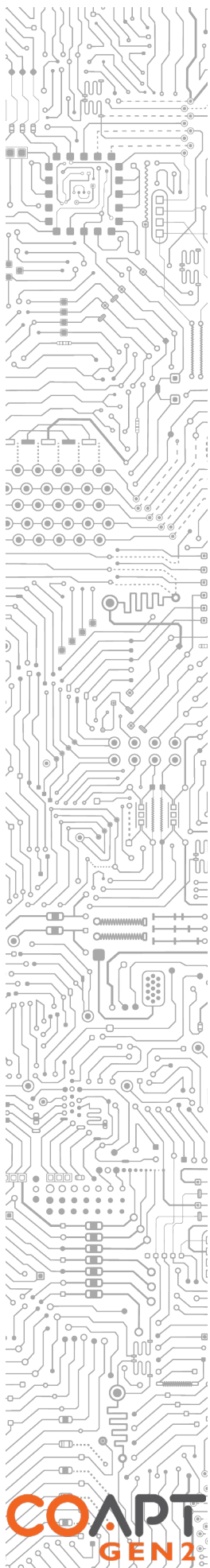
into the existing state of users' control. Since ADAPTIVE ADVANCE adapts and learns along with the user, it acts as a control companion that tracks natural changes over time.

Users are encouraged to take advantage of ADAPTIVE ADVANCE by performing the calibration routine multiple times to effectively “layer” extra information into a robust and functional control scheme.

COMPLETE CALIBRATE LED COLOR INDICATIONS

On the surface of the Evaluation Kit's COMPLETE CALIBRATE Button there is a single, multicolor LED light that provides valuable information and feedback:

LED LIGHT INDICATOR	STATUS
Magenta Solid 	System has been reset or is in an initial state. No pattern recognition output should be expected until calibration is performed.
White with a short blip every 2 seconds 	CONTROL COACH has valuable information waiting in the COMPLETE CONTROLROOM Gen2 user interface application to assist with control improvements.
Cyan Solid 	The COMPLETE CALIBRATE Button is being pressed.
Green Solid 	EMG information is being recorded while this indicator is on, recording pauses when it is off. During calibrations, this green indicator will be turning on and off, corresponding with the recordings of each motion.
Red Solid 	Critical system error. Contact Coapt support for assistance.
Red Double Blink 	The Evaluation Kit battery is too depleted for safe operation. The Evaluation Kit will not operate until battery is charged or charging.
Green Blinking 	Internal firmware of the system is being updated. Do NOT power off the Evaluation Kit until this is complete.
Cyan Blinking 	The COMPLETE CALIBRATE Button has been depressed for greater than 5 seconds and, if released before 10 seconds, will “undo” the last calibration activity. (only when undo is available)



COMPLETE CONTROLROOM GEN2: USER INTERFACE APPLICATION

OVERVIEW

The COMPLETE CONTROLROOM Gen2 user interface application connects via Bluetooth and is used for setup, configuration, and use of the Coapt Evaluation Kit.

COMPLETE CONTROLROOM ENVIRONMENTS

Dashboard

The Dashboard environment appears at the start of the user interface application.

Launch bars shown in the Dashboard help to navigate to the four other COMPLETE CONTROLROOM Gen2 environments:

- Connect
- Inputs
- Calibrate
- Actuate

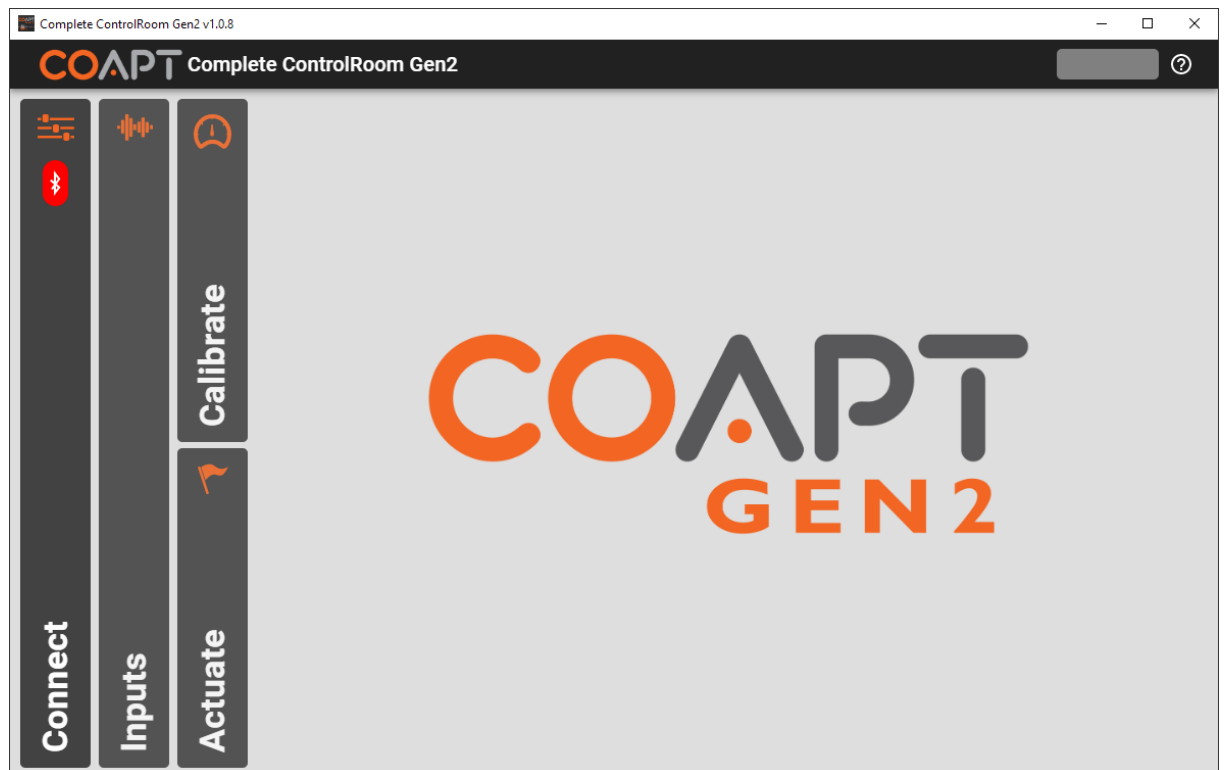


Figure 15: COMPLETE CONTROLROOM Gen2 main dashboard, shown when an Evaluation Kit is not wirelessly connected via Bluetooth – the Bluetooth icon is red, the status indicator is inactive (grey), and the only available environment to click is Connect

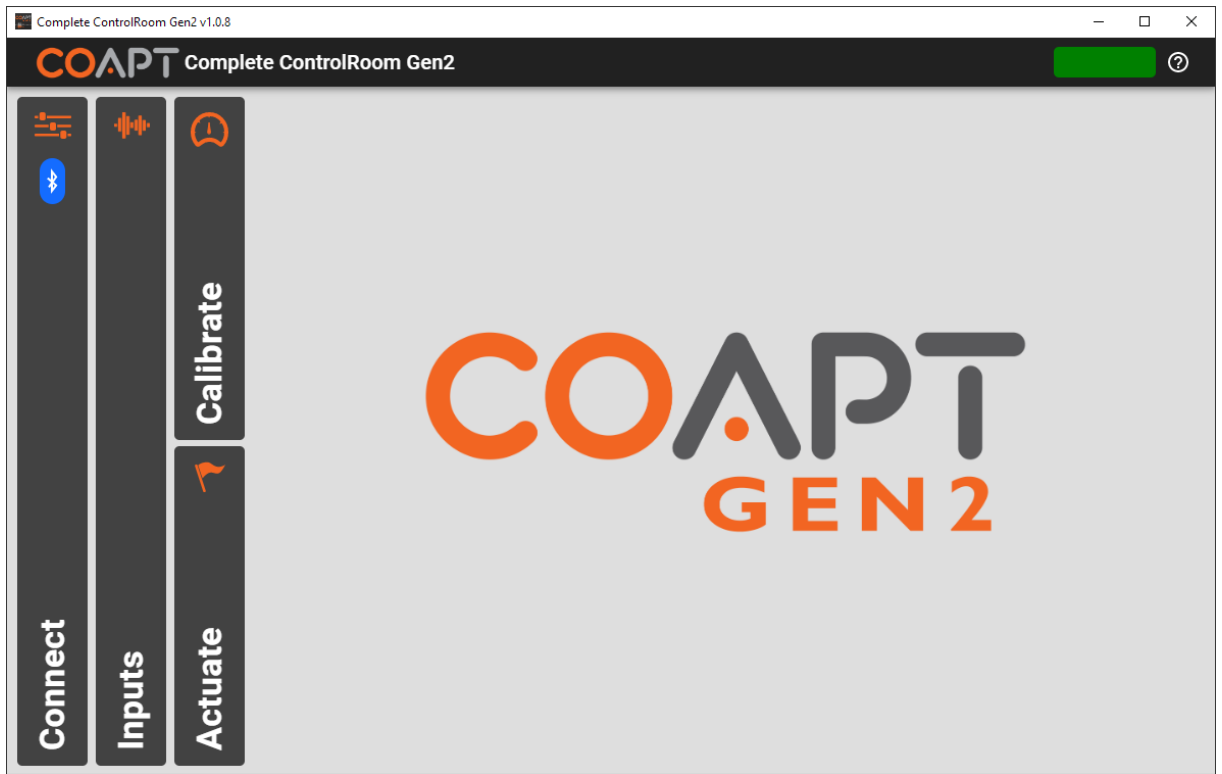


Figure 16: COMPLETE CONTROLROOM Gen2 main dashboard, shown when an Evaluation Kit is wirelessly connected via Bluetooth – the Bluetooth icon is blue, the status indicator is active (green in this example), and all environments are available to click

Connect

The COMPLETE CONTROLROOM Gen2 Connect environment manages the Bluetooth connection to the Evaluation Kit. The Bluetooth logo will be red if the application and Evaluation Kit are not connected. The Bluetooth logo will be blue if connection has been established.

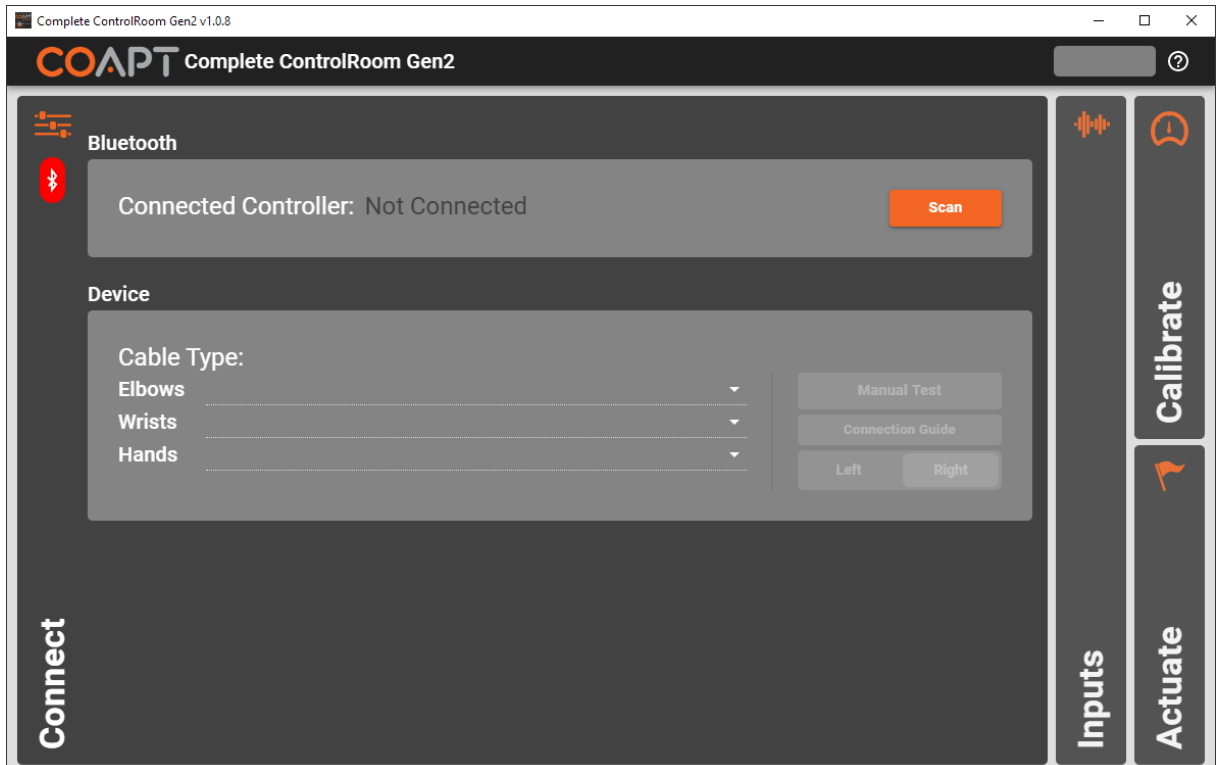


Figure 17: COMPLETE CONTROLROOM Gen2 Connect screen shown when a COMPLETE CONTROLLER or Evaluation Kit is not yet wirelessly connected via Bluetooth – the only clickable item is the Scan button

BLUETOOTH:

Action Button: Scan/Disconnect – Clicking “Scan” displays a list of any Evaluation Kits (or nearby Coapt COMPLETE CONTROL Gen2 controller systems) 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.

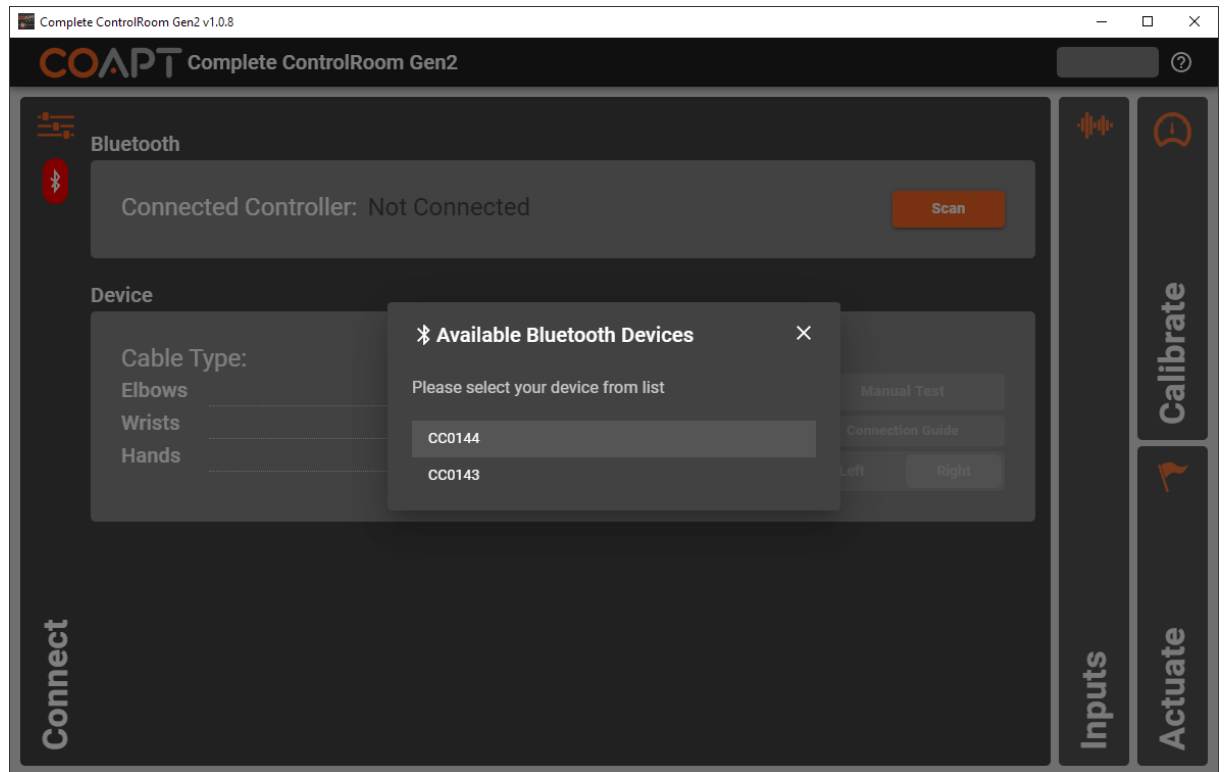


Figure 18: After clicking the Scan button, a selectable menu showing Bluetooth-available devices is shown

The connected Evaluation Kit 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 Evaluation Kit.

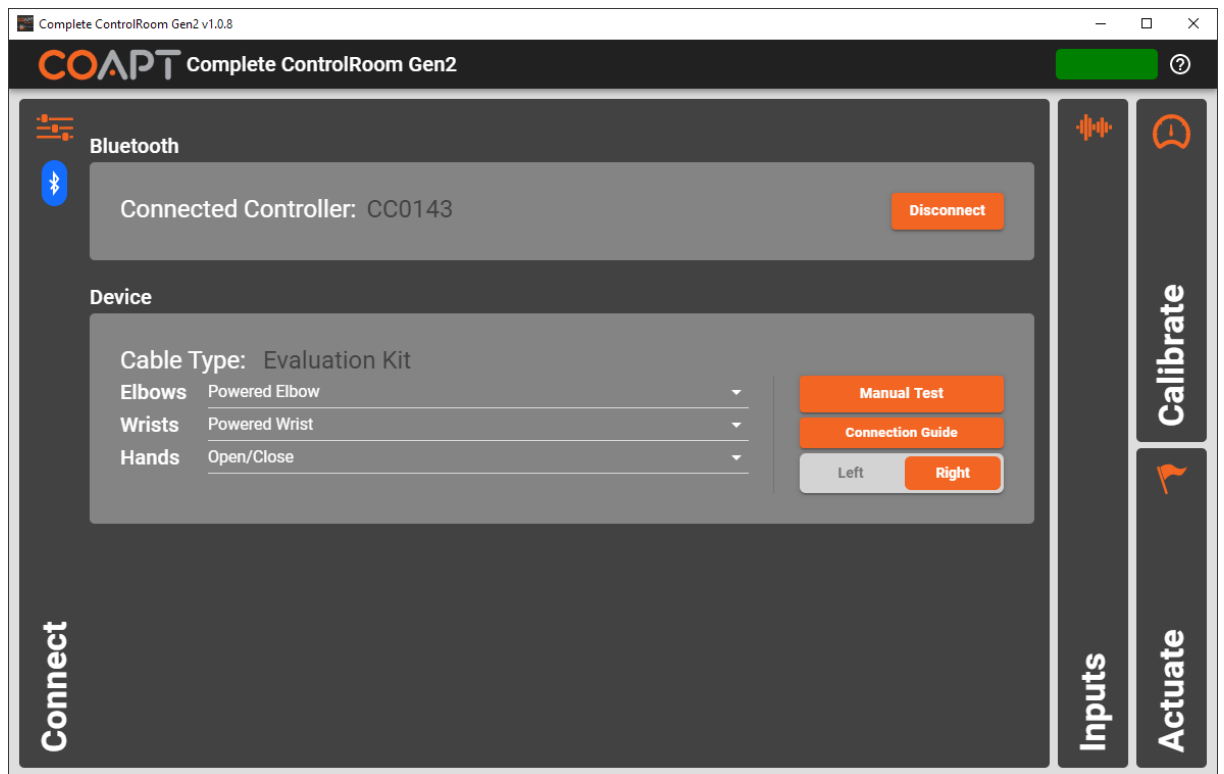


Figure 19: COMPLETE CONTROLROOM Gen2 Connect screen shown when an Evaluation Kit is wirelessly connected via Bluetooth – showing Bluetooth-connected device ID, the connected controller’s cable type, all available action buttons, and the active title bars to enter the other software environments

NOTE: After a period of inactive Bluetooth communication (e.g. being disconnected from the user interface application), an Evaluation Kit will stop radio broadcasting in order to save battery power. To have the Evaluation Kit turn its Bluetooth capabilities back on, simply press the Evaluation Kit’s COMPLETE CALIBRATE Button once quickly or turn the power of the Evaluation Kit off and then back on.

DEVICE:

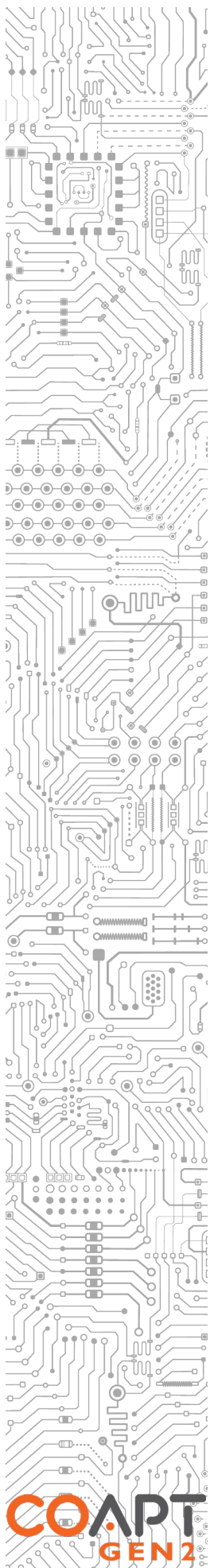
With the Evaluation Kit, a user will be able to select different movements for the virtual hand, wrist, and elbow from the drop-down menus.

Action Buttons:

Action Button: Left/Right – This toggle button is provided to allow the user to test their Evaluation Kit with a left-handed or right-handed virtual arm in the Actuate environment.

Inputs

The COMPLETE CONTROLROOM Gen2 Inputs environment is provided as a means to verify that all electrode-to-skin connections are reliable, and that the EMG information is healthy. Dynamic signal activity on eight horizontal bars of color represent the eight EMG channel inputs of the Evaluation Kit. The on-screen colors correspond to the EMG channel colors of the EMG Interface Cable. Each EMG channel has an on/off toggle button that will determine its inclusion or exclusion from the set of pattern recognition inputs. Wherever possible, it is strongly suggested that all eight EMG inputs are used to ensure optimal performance.



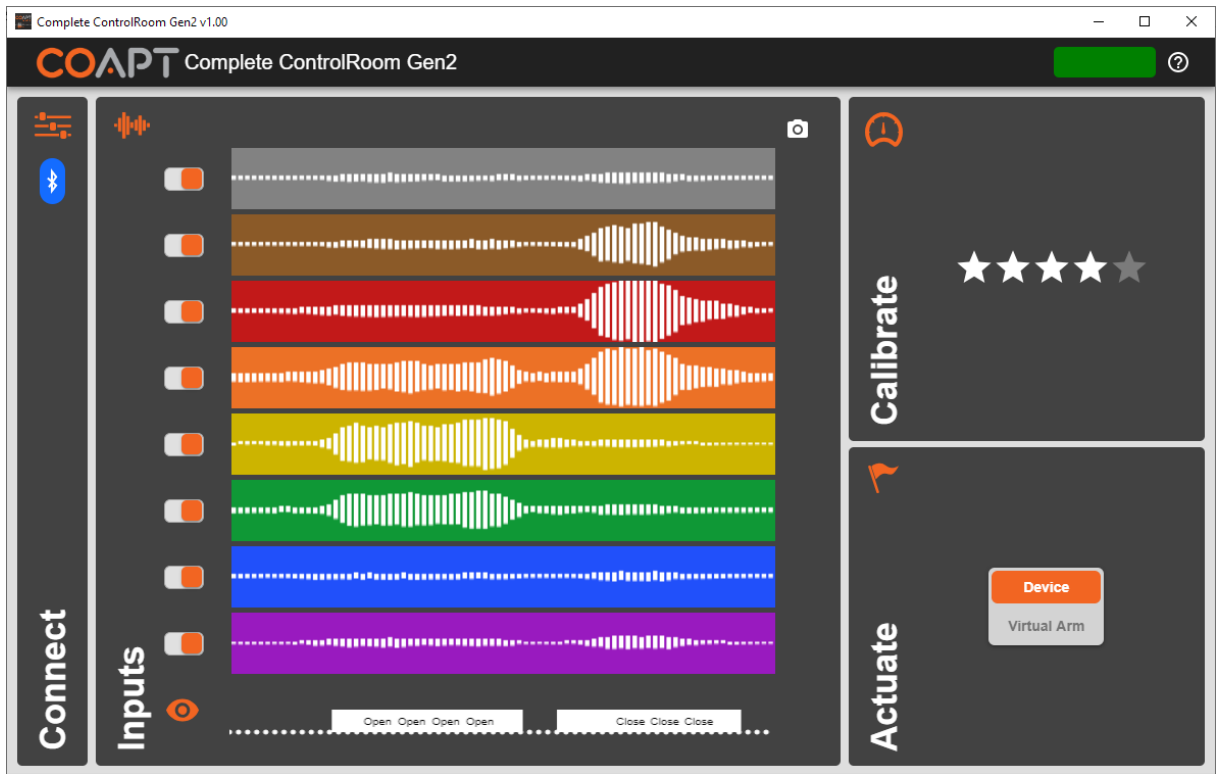


Figure 20: COMPLETE CONTROLROOM Gen2 Inputs screen showing all eight channels of input EMG signals, channel selection toggles, an output notification track at the bottom of the screen, and two 'peek' windows for the Actuate and Calibrate environments

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.

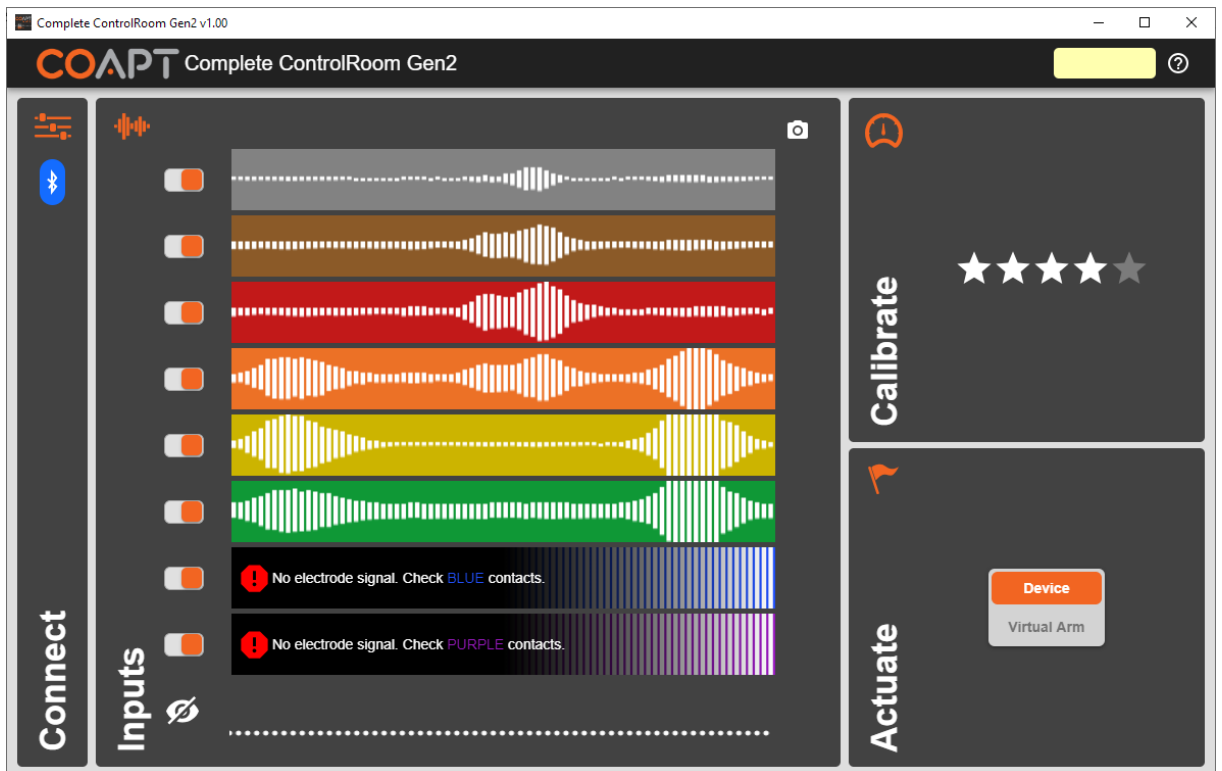


Figure 21: COMPLETE CONTROLROOM Gen2 Inputs screen showing EMG electrode lift-off (loss of contact with user's skin) detection messages for the Blue and Purple EMG input channels

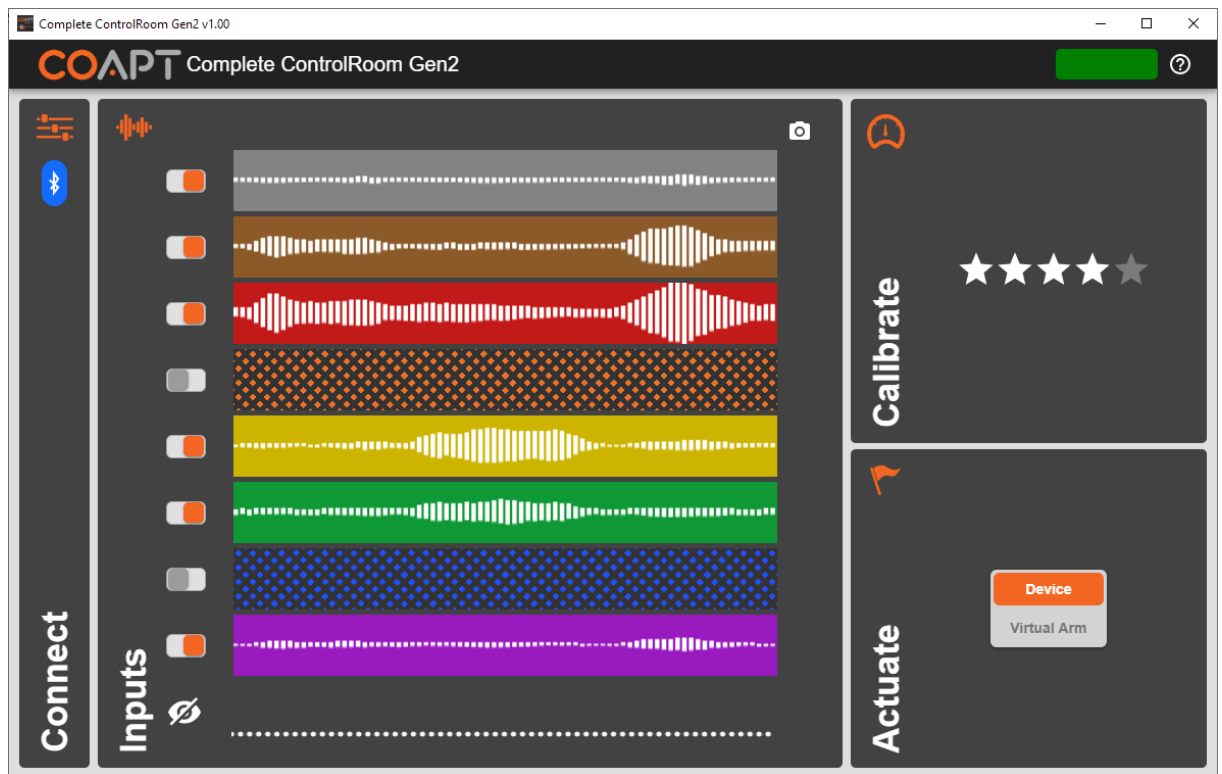


Figure 22: COMPLETE CONTROLROOM Gen2 Inputs screen showing an example of two EMG input channels (Orange and Blue) turned “off”

IMPORTANT: The Evaluation Kit 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.

If pattern recognition using the Evaluation Kit has been successfully calibrated (see Calibrating Pattern Recognition Control section), a scrolling display of real-time outputs of the system will be shown below the eight EMG signals. This display allows general association of the EMG activity with the user’s control outputs. For convenience, visibility of this output display can be toggled on or off.

Calibrate

The COMPLETE CONTROLROOM Gen2 Calibrate environment is the centralized location of tools to assist the user with calibration using their Evaluation Kit.

Various elements are associated with each action/function:

- **Selection:** Each action/function (or logical pairing) possible for current device configuration has a toggle selector that allows users to set these functions “on” or “off”. Actions/functions that are de-selected (turned off) will be removed from active control outputs and will not be included in any calibration. Turning these items back on will re-enable the function (if prior EMG pattern data existed for them) and will be included in following calibration activity.
- **CONTROL COACH Star Rating:** CONTROL COACH analyses calibration data and produces a quality estimate for each action/function (See CONTROL COACH section for detailed description of analyses). The estimated quality is displayed via a 5-star rating. 4 or more bright stars indicate high quality while 2 or less bright stars indicates low quality.
- **CONTROL COACH Info Call-out:** Next to each action’s Star Rating is a small arrow/chevron that invites the user to click. Clicking this call-out arrow/chevron expands an area of the screen that contains written information specific to that action/function’s CONTROL COACH evaluation.

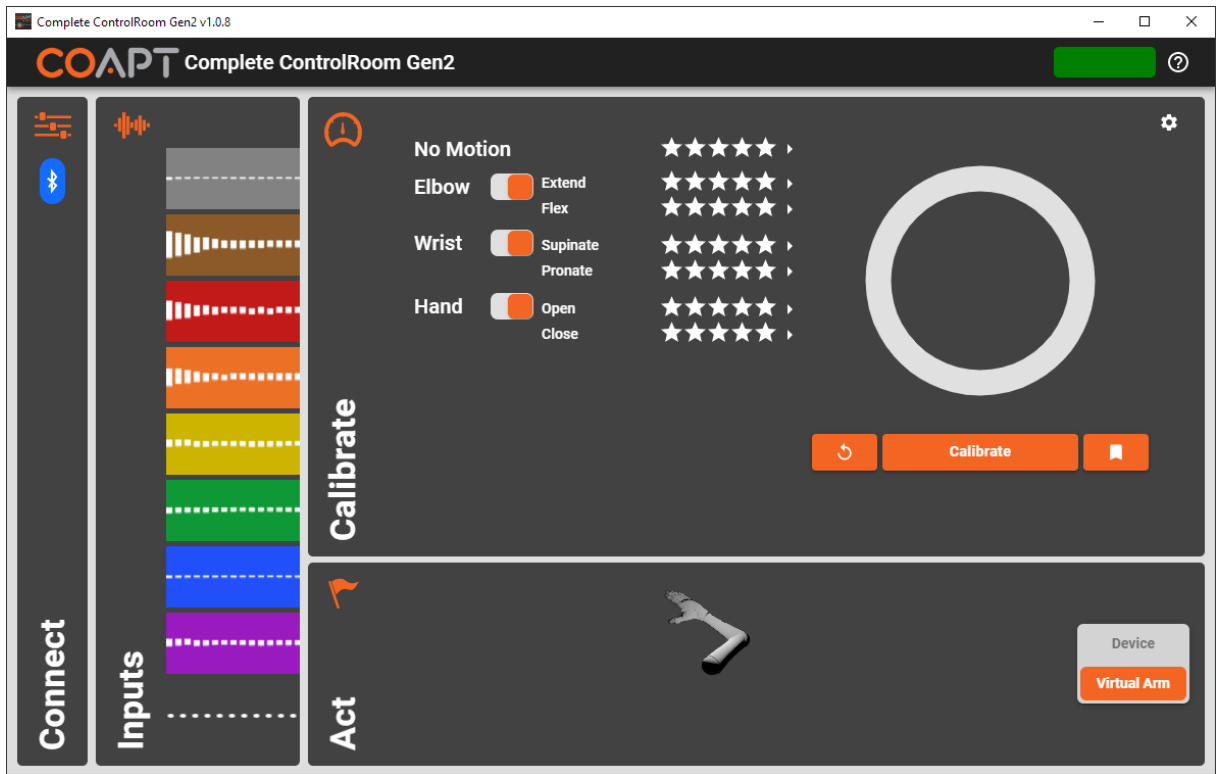


Figure 23: COMPLETE CONTROLROOM Gen2 Calibrate screen showing a list of available and selectable classification actions, their associated CONTROL COACH star-ratings, a calibration prompt area, and two 'peek' windows for the Inputs and Actuate environments

Action Buttons:

Action Button: Calibrate – This single-press button initiates User Interface-Guided Calibration

Action Button: Undo (counterclockwise arrow icon) – This single-press button allows a user to undo the effect of the last completed calibration activity. Thus, returning the control of the device to the state it was just before the most recent calibration activity. Undo functionality only applies to one calibration step and undoing more than one calibration step is not possible.

Action Button: Favorites (bookmark icon) – This single-press button opens a small pop-up window where it is possible to store or recover a state of the control system calibration.

- **Save:** Users may have an instance of excellent control feel and want to store that calibration memory for use later.
- **Load:** Users may want to recall an instance of excellent control that was previously stored.

Three favorites storage/recall locations are available. A previously filled location can be replaced (overwritten) or deleted.

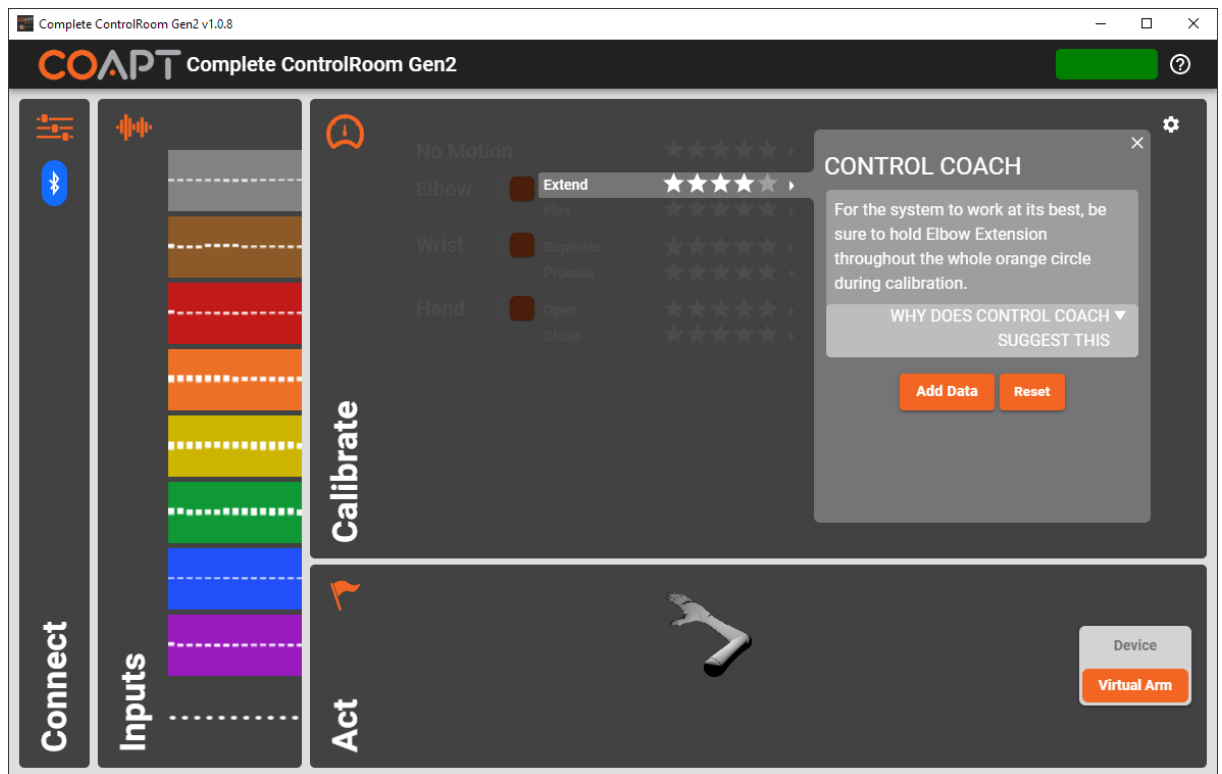


Figure 24: COMPLETE CONTROLROOM Gen2 Calibrate screen showing the CONTROL COACH call-out for one motion – CONTROL COACH presents its helpful findings and analysis as well as instructive tips for functional improvement and an action button that allows the user to bolster his/her motion with additional EMG contraction data

The COMPLETE CONTROLROOM Gen2 Calibration environment has a settings menu accessible via click of the cogwheel icon at the top right of the environment. The settings provide helpful, additional controls for user benefit of calibration:

Settings Menu Control: Calibration Pace – This 3-position selector allows a user to choose the pace at which Calibration will happen. “Slow” means there will be 3 seconds of rest between each prompted muscle contraction, “Medium” means 2 seconds of rest between each prompted muscle contraction, and “Fast” means 1 second of rest between each prompted muscle contraction.

Settings Menu Control: Adaptive Advance – The On/Off toggle selector selects if the ADAPTIVE ADVANCE algorithms will be enabled or not. When “Off”, each new calibration will ‘start fresh’ and overwrite the existing control set. When “On” (default), ADAPTIVE ADVANCE is an automatic, continuous-learning algorithm that knows exactly how to meld new calibration data into the existing state of users’ control (see ADAPTIVE ADVANCE section for more). The “Reset” button allows a user to reset to a starting state for calibration. A starting state means the memory of ADAPTIVE ADVANCE will be set to an initial, baseline state (see Calibration Initialize/Reset section).

Settings Menu Control: CONTROL COACH LED Sensitivity – This sliding selector allows a user to adjust the sensitivity of the CONTROL COACH white LED indication on the COMPLETE CALIBRATE Button (see CONTROL COACH section for more). 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. When set to 4 stars, the COMPLETE CALIBRATE Button indicator will come on when the overall CONTROL COACH star rating is a 4 or less.

Settings Menu Control: One-Class Calibration Data Amount – This sliding selector is a control specifically related to Single Motion Calibration (see Single Motion Calibration section for more). Adjusting this toward “Less” means the user will be tasked to provide less total EMG contraction data during the “fill-the-bucket” type process of Single Motion Calibration (the minimum is 3 seconds of valid contraction data). Adjusting this toward “More” means the user will be tasked to provide more

EMG contraction data during the “fill-the-bucket” type process of Single Motion Calibration (the maximum is 10 seconds of valid contraction data).

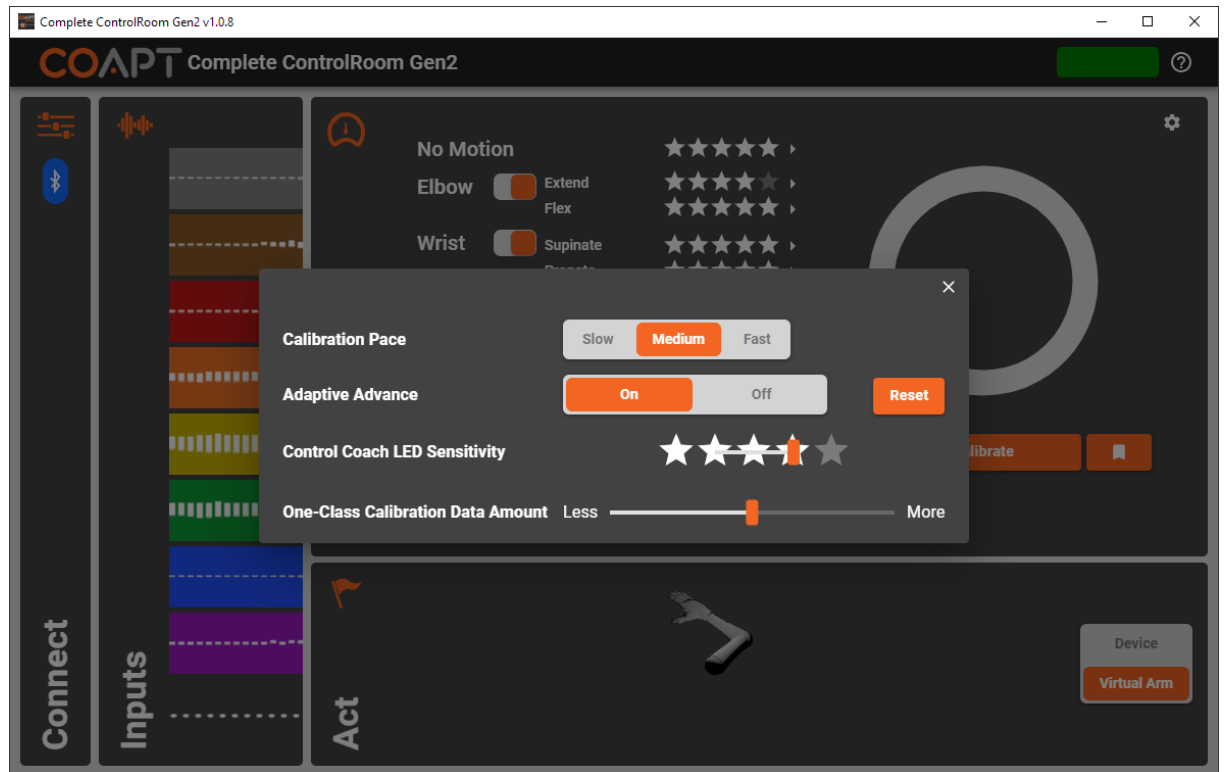


Figure 25: COMPLETE CONTROLROOM Gen2 Calibrate screen settings pop-up showing controls for Calibration Pace, Adaptive Advance, Control Coach LED Sensitivity, and One-Class Calibration Data Amount

Actuate

The COMPLETE CONTROLROOM Gen2 Actuate environment assists users with on-screen prosthesis practice using the Evaluation Kit. The main area of this environment displays a first-person perspective virtual arm.

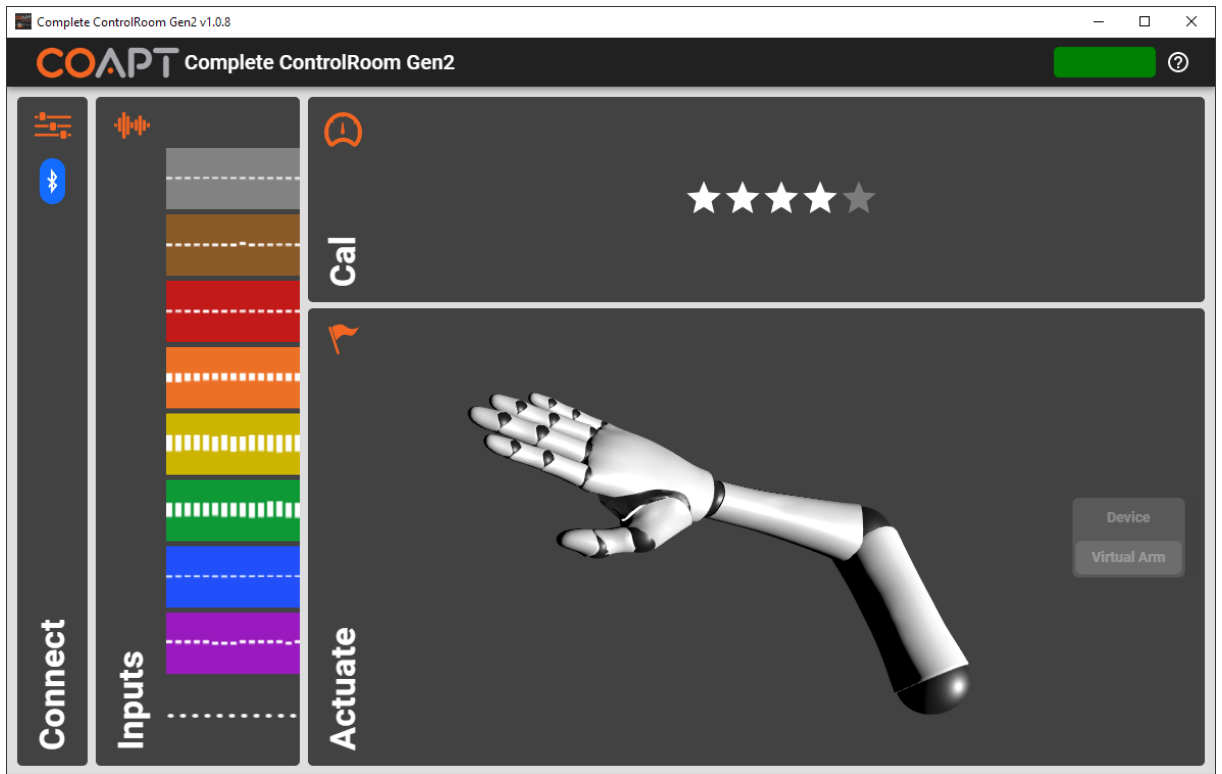


Figure 26: COMPLETE CONTROLROOM Actuate screen showing active virtual arm area and two ‘peek’ windows for the Inputs and Calibrate environments

Action Buttons:

Action Button: **Virtual Arm/Device** – This toggle button will be set to “Virtual Arm” and be inactive when using the Coapt Evaluation Kit.

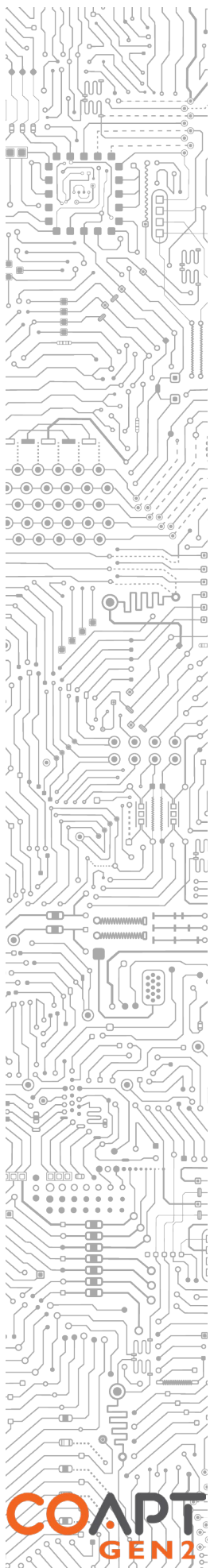
TROUBLESHOOTING

PATTERN RECOGNITION TROUBLESHOOTING

ISSUE	PROBABLE CAUSES	ACTIONS
Virtual Arm in Actuate environment doesn't respond with movements after calibration	Poor electrode-skin contact	Ensure good electrode contact with user's skin
	Poor calibration quality	Ensure user is providing adequate-strength muscle contractions during calibration
	Calibration data/signals were inadequate	Ensure user is correctly following the pace and prompts of the calibration
The Evaluation Kit plays a negative-sounding jingle at the end of Calibration	User is not matching the cadence of the calibration prompts	Ensure user is providing adequate-strength muscle contractions during calibration with the right timing
	Calibration data/signals were inadequate	Ensure user is correctly following the pace and prompts of the calibration
	No EMG data provided during calibration	Ensure EMG Interface Cable connection cable is connected
	Weak EMG data provided during calibration	Ensure user is providing adequate-strength muscle contractions during calibration
	Corrupt EMG data during calibration	Ensure good contact of ground/reference electrode
Control seems to be ok for a while and then changes after a short period	The electrode contacts may have adapted to new skin conditions of the user	Recalibrate

HARDWARE TROUBLESHOOTING

ISSUE	PROBABLE CAUSES	ACTIONS
Nothing happens when the COMPLETE CALIBRATE Button is pressed	Button hold was not long enough	Press and hold (~2 seconds) until release beep is heard
The Evaluation Kit plays a negative-sounding jingle at the end of Calibration	Quality of user's calibration is poor	Recalibrate the system Ensure user is correctly following the pace and prompts of the calibration See Pattern Recognition Troubleshooting for more tips
	EMG Interface Cable has become disconnected	Ensure EMG Interface Cable is connected
The scrolling EMG signals in the Inputs Check environment of the COMPLETE CONTROLROOM Gen2 software are very jumpy and seem to lag	The Evaluation Kit and computer are far apart from each other and/or there are large items between them that are degrading Bluetooth radio communication	If possible, move the Evaluation Kit and computer closer together and remove any large objects that may be in between the communicating devices





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, fire, flood, 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 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. The Items must be accompanied by written evidence of the date of purchase, such as invoice. 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 Federal and State mandated shipping policies, 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 or covered by Coapt.

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 from state to state in the U.S., 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
222 W Ontario St., Suite 300
Chicago, IL 60654

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.

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)

TRANSPORT TEMPERATURE:

- -20°C – 45°C (-4°F – 113°F)

HUMIDITY:

- 5 – 95% RH (Non-Condensing)

ALTITUDE:

- 10,000 feet Maximum

PHYSICAL DIMENSIONS:

- L: 83.11 mm (3.27 in)
- W: 59.51 mm (2.34 in)
- H: 22.10 mm (0.87 in)

REGULATORY INFORMATION

FDA:

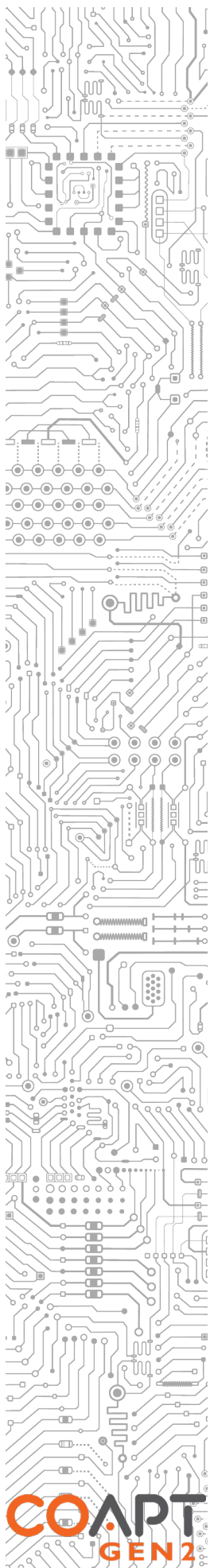
Coapt, LLC is registered with the Food and Drug Administration of the United States Government (Registration Number: 3010605876; Owner Operator Number: 10045459) for the manufacture and supply of prosthetics and orthotics products.



The Coapt 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





IEC:

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



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

CE:

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

