COAPT
GEN2

COMPLETE CONTROL SYSTEM GEN2

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 **Complete Control** System Gen2 may be found online at **www.coaptengineering.com**

GENERAL WARNINGS AND PRECAUTIONS

For safety and to prevent damage to the **Complete Control** System Gen2 and/or prosthetic device, 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 **Complete Control** system. Failure to do so could result in suboptimal system performance or injury, the device, or the connected prosthesis.

⚠ WARNING — **Use with implanted electronic devices**. Do not bring the **Complete Control** system 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 **Complete Control** system and the implanted device could cause the implanted device to malfunction.

⚠ WARNING — **Operation of motor vehicles.** Do not use the **Complete Control** system to operate a motor vehicle. Unintended movements of the prosthesis may cause an accident.

⚠ WARNING — **Operation of industrial machines, heavy equipment, motor-driven equipment, or machinery**. Do not use the **Complete Control** system to operate industrial machines, heavy equipment, motor-driven equipment, or machinery. Unexpected actions of the prosthesis may cause injury.

⚠ WARNING — **Use with firearms.** NEVER use a Coapt **Complete Control** system to operate a firearm. Unintended prosthesis movements during firearm operation could result in death or significant injury.

⚠ WARNING   **Use with sharp objects**. Do not use the **Complete Control** system to handle sharp tools or objects (e.g., knives or blades). Unintended movements of the prosthesis while handling a sharp object could result in death or significant injury.

⚠ WARNING   **Use with power tools.** Do not use the **Complete Control** system to operate power tools. Unintended movements of the prosthesis could cause injury.

⚠ WARNING   **Use of system while charging.** Do not use the device while it is charging (i.e., connected to an A.C Mains supply) unless advised by a qualified healthcare provider that it is safe to do so. Use of the device while charging could cause injury.

⚠ 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 caused by unintended movements of the prosthesis.

⚠ 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 unintended movements of the prosthesis resulting in minor pinch injuries.

⚠ 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, unintended prosthesis movement, 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, unintended prosthesis movement, and minor injury to the user.

⚠ CAUTION   **Crushing of device or socket.** Take care not to allow the device to become smashed or crushed. Crushing of the device can cause device malfunction, unintended prosthesis movement, 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, unintended prosthesis movements, and minor injury to the user.

⚠ CAUTION   **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, unintended prosthesis movement, and injury to the user.

OVERVIEW

PURPOSE OF THE DEVICE

The **Complete Control** System Gen2 is an advanced control solution designed to provide the functionality of a powered upper limb prosthesis. **Complete Control** employs pattern recognition technology to revolutionize the way muscles' bioelectrical activity (electromyogram, EMG) signals are used to control a prosthesis. With **Complete Control**, users can achieve intuitive control of their devices, eliminate control switching, and benefit from quick and powerful calibration. **Complete Control** simplifies electrode location dependence and allows prosthetists to spend less time adjusting system settings and configurations.

The **Complete Control** System Gen2 is designed to work seamlessly with most major manufacturers' devices as an easy plug-and-play add-on (for a list of compatible devices and electrodes, see up-to-date information online or visit the Compatible Devices section of this Handbook). **Complete Control** does not require an additional battery.

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 myoelectic 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—covering the whole area of these underlying muscle contractions—lets 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, and 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 can always be helpful to return to those perceptions when 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 **Complete Control** System Gen2 is to be used exclusively for external prosthetic fittings of the upper limb.

CONTRAINDICATIONS

None known.

LIMITATIONS

Careful evaluation is required to determine if individuals with brachial plexopathy or high-level amputations without targeted muscle reinnervation surgery could benefit from the COMLETE CONTROL System Gen2.

DESCRIPTION OF THE DEVICE

The **Complete Control** System Gen2 is a packaged electronic control system used in conjunction with an upper-limb prosthetic device. The **Complete Control** System Gen2 has been validated for a specific set of prosthetic elbow, wrist, and hand components (see Compatible Devices section). The **Complete Control** System Gen2 is a module for processing EMG and computing pattern recognition algorithms (**Complete Controller**) permanently connected to a user-interface calibration interface button (**Complete Calibrate** button) and connected to the prosthesis and muscle signal inputs by connectable interface cables.

The **Complete Control** System Gen2 contains the following components:

1. **Complete Controller** main processor with a connected **Complete Calibrate** button
2. Device Interface Cable (clinician-specified termination type)
3. EMG Interface Cable (clinician-specified termination type)

Accessories to the **Complete Control** System Gen2 include the following:

1. **Complete Controller** Fabrication Aid (1:1 scale disposable model for use in prosthesis fabrication)
2. Prosthesis socket cut-out template for the **Complete Calibrate** button
3. **Complete Communicator** USB Bluetooth Dongle
4. **Complete ControlRoom** Gen2 User Interface Application

COMPATIBLE DEVICES

Electrodes

The **Complete Control** System Gen2 can be used with commercially available non-filtering, passive EMG electrode contacts. Coapt recommends the use of stainless-steel electrode domes as contacts. The compatible electrodes are shown below. Please contact a Coapt representative with any questions about 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
Manufacturer: Liberating Technologies, Inc. **Product Name:** Small Dome Metal Electrodes **Part Number(s):** EL03	**Proprietary Name:** Joint, Elbow, External Limb **Establishment Number:** Liberating Technologies, Inc., 1220851 **Product Code and Regulation Number:** IRE, 890.3420	none
Manufacturer: Motion Control, Inc. **Product Name:** Remote Electrode (Single) **Part Number(s):** 1070001	**Proprietary Name:** Electric Terminal Device; Motion Control Hand; Motion Control Wrist; Procontrol 2 **Registered Establishment Number:** Motion Control, Inc., 1723997 **Product Code and Regulation Number:** IQZ, 890.3420 **Proprietary Name:** NYElbow; Utah Arm **Registered Establishment Number:** Fillauer, LLC, 1022826 **Product Code and Regulation Number:** IRE, 890.3420	none
Manufacturer: RSLSteeper **Product Name:** Kit of 6 (High/Medium/Small) Dome Metal Electrodes **Part Number(s):** NEL11, NEL12, NEL13	**Proprietary Name: bebionic:** ELEC 60; Prosthesis **Registered Establishment Number:** Steeper Group LTD, 9612243 **Product Code and Regulation Number:** IQZ, 890.3420	none
Manufacturer: Touch Bionics **Product Name:** Remote Electrode kit **Part Number(s):** PL441012, PL069466, PL06947, PL069468, PL069469	**Proprietary Name:** Remote Electrode kit **Registered Establishment Number:** Touch Bionics, 3008018840 **Product Code and Regulation Number:** IQZ, 890.3420	none

⚠ 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.
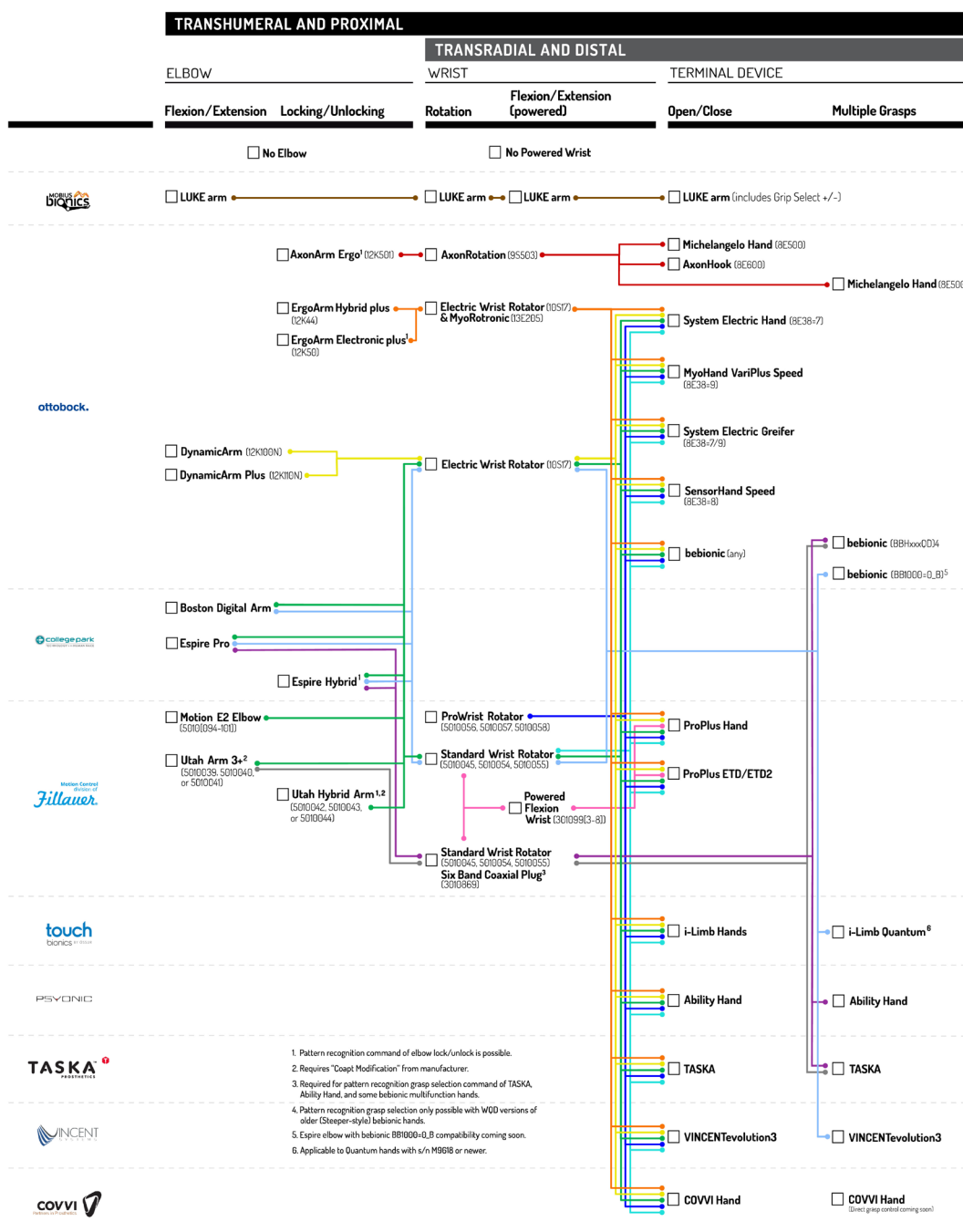
Prosthetic Devices

The **Complete Control** System Gen2 was designed to operate seamlessly with many major manufacturers' prosthetic devices. The chart below depicts the common compatibilities and capabilities of the **Complete Control** System Gen2. Each navigating-line of color in the chart indicates devices that are compatible with each other in a valid **Complete Control** System Gen2 configuration.

Compatibilities and capabilities of the **Complete Control** System Gen2 are subject to change at any time.

The displayed chart may not illustrate full compatibilities and capabilities of the **Complete Control** System Gen2.

Visit the Coapt website or contact a Coapt representative for an up-to-date listing of all supported devices.

TRANSHUMERAL AND PROXIMAL

TRANSRADIAL AND DISTAL

ELBOW		WRIST		TERMINAL DEVICE	
Flexion/Extension	Locking/Unlocking	Rotation	Flexion/Extension (powered)	Open/Close	Multiple Grasps

No Elbow — No Powered Wrist

Mobius Bionics
- LUKE arm — LUKE arm — LUKE arm — LUKE arm (includes Grip Select +/-)

ottobock.
- AxonArm Ergo[1] (12K501) — AxonRotation (9S503)
  - Michelangelo Hand (8E500)
  - AxonHook (8E600)
  - Michelangelo Hand (8E500)
- ErgoArm Hybrid plus (12K44) / ErgoArm Electronic plus[1] (12K50) — Electric Wrist Rotator (10S17) & MyoRotronic (13E205)
  - System Electric Hand (8E38÷7)
  - MyoHand VariPlus Speed (8E38÷9)
  - System Electric Greifer (8E38÷7/9)
  - SensorHand Speed (8E38÷8)
  - bebionic (any)
  - bebionic (BBHxxxOD)[4]
  - bebionic (BBI000÷0_B)[5]
- DynamicArm (12K100N) / DynamicArm Plus (12K110N) — Electric Wrist Rotator (10S17)

college park
- Boston Digital Arm
- Espire Pro
- Espire Hybrid[1]

Motion Control (division of Fillauer)
- Motion E2 Elbow (5010[094-101])
- Utah Arm 3+[2] (5010039, 5010040, or 5010041) — ProWrist Rotator (5010056, 5010057, 5010058)
  - ProPlus Hand
- Utah Hybrid Arm[1,2] (5010042, 5010043, or 5010044) — Standard Wrist Rotator (5010045, 5010054, 5010055)
  - Powered Flexion Wrist (3010991[3-8])
  - ProPlus ETD/ETD2
- Standard Wrist Rotator (5010045, 5010054, 5010055) Six Band Coaxial Plug[3] (3010869)

touch bionics
- i-Limb Hands
- i-Limb Quantum[6]

PSYONIC
- Ability Hand
- Ability Hand

TASKA PROSTHETICS
- TASKA
- TASKA

VINCENT
- VINCENTevolution3
- VINCENTevolution3

COVVI
- COVVI Hand
- COVVI Hand (Direct grasp control coming soon)

1. Pattern recognition command of elbow lock/unlock is possible.
2. Requires "Coapt Modification" from manufacturer.
3. Required for pattern recognition grasp selection command of TASKA, Ability Hand, and some bebionic multifunction hands.
4. Pattern recognition grasp selection only possible with WOD versions of older (Steeper-style) bebionic hands.
5. Espire elbow with bebionic BB1000÷0_B compatibility coming soon.
6. Applicable to Quantum hands with s/n M9618 or newer.

CONDITIONS FOR USE

The **Complete Control** System Gen2 was developed for everyday use and must not be used for unusual activities. These activities include, for example, extreme sports (e.g., free climbing, paragliding, etc.) or activities causing excessive strain and/or shock to the prosthetic device (e.g., pushups or mountain biking).

The Coapt **Complete Control** System Gen2 should only be used by the individual to whom it was prescribed. This system is a custom solution that may not perform well for individuals other than the intended recipient.

See General Warnings and Precautions section for more information regarding acceptable conditions for using the device.

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, that will produce some wonderful benefits.

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.

TIPS

A HELPFUL APPROACH TO LEADING THIS DISCUSSION:

- 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.

TIPS

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.
  - 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 DOME ELECTRODES

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.

Now you are ready to place the electrodes in the socket/liner interface. 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:

- 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 harness as described below.

- Two Dome Electrodes work together to create one "channel" of EMG information.

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

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

The most important thing to remember with electrodes: **Dome 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.

**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).

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.

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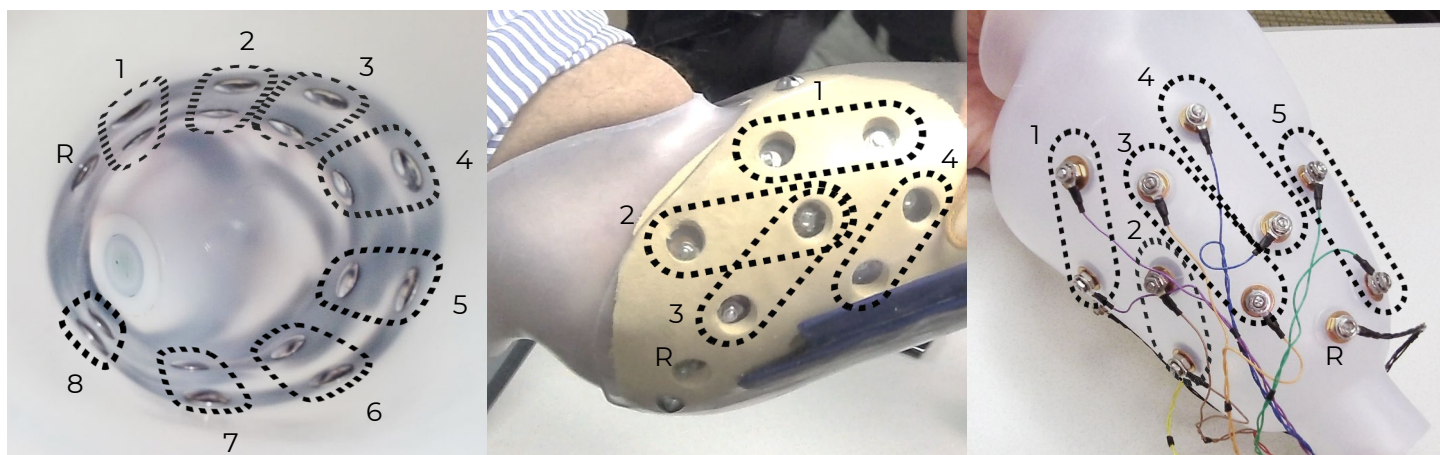
Contact your Coapt representative with any questions about myotesting and/or electrode placement. Coapt is willing and able to assist with placement instruction and suggestion—these can often be accomplished by submitting socket and/or limb shape images to Coapt.

Assembly Instructions for placing Dome Electrodes into the prosthesis

For more information, see Coapt's Dome Electrode Handbook (available on the Coapt website)

1. Push a Dome Electrode through a #4 mounting hole you have made in the prosthesis' inner socket/liner interface. Place it so the dome side will make contact with the skin of the user, and the thread is on the outer side of the socket wall. Ensure the Dome Electrode stud is pushed all the way in the hole.

2. Place a provided Flat Washer on the threaded side of the Dome Electrode.

3. Place the ring terminal of a conductor cable on top of the Flat Washer. Same-color conductor cables should be planned for nearby Dome Electrodes.

4. If you are "sharing" a Dome Electrode, place the other conductor cable(s) ring terminal(s) (different color(s)) on this threaded stud. Keep in mind that same-color conductors must NOT share the same Dome Electrode. Also, make sure the black (ground) connection is connected to its own Dome Electrode.

5. Place a provided Split Lock Washer on top of the ring terminal(s) of the conductor cable(s).

6. Place and tighten a provided 4-40 Threaded Nut to secure the assembly. Make sure it is tight enough that the conductor cable wire cannot be moved side-to-side with your fingers.

7. Repeat these steps for each Dome Electrode that needs to be connected to a conductor.

8. Do NOT leave any Coapt EMG wires unconnected.

9. Do NOT use any liquid thread locker.

10. Where applicable, trim the excess threaded stud of each Dome Electrode once installed and tightened. Make sure to smooth, remove, or cover any sharp edges.

A FEW THINGS TO BE CAREFUL OF WHEN WORKING WITH THE DOME ELECTRODE HARDWARE

- Be careful not to damage other wires when installing the Dome Electrodes.

- If any part of the metal of the Dome Electrodes and the hardware make contact with conductive materials (e.g. carbon fiber outer sockets) the EMG signal will not be as clear. Take caution to avoid that type of contact.

- Make sure the black (ground) connection is connected to its own Dome Electrode.

- Two wire conductors of the same color should NEVER be connected to the same Dome Electrode.

- Do not cross-thread the nuts on the threaded part of the Dome Electrodes. Try starting the nuts with your fingers first and if not easy to tighten, try adjusting the starting orientation of the nut.

- Make sure the Dome Electrodes are installed with the dome side making contact with the user. The threaded side and other components should be secured behind a mounting socket wall or enclosure.

⚠ CAUTION **Trimmed electrode studs.** Ensure any excess length of electrode dome threaded studs are sufficiently trimmed and smoothed. Sharp edges and protrusions can cause damage to other prosthesis wiring, socket materials, and installed components.

NOTICE **Conductive socket material.** It is important to consider electrode interference when using of electrically conductive socket materials, such as carbon fiber laminate. Conductive socket material that comes in contact with electrode dome threaded studs can negatively affect prosthesis performance by reducing the detected EMG signal quality. Take care to electrically isolate the electrode dome threaded stud and/or EMG Interface Cable ring-terminals from contact with any conductive socket materials.

NEED TO CLEAN THE DOME ELECTRODES?

- Coapt recommends cleaning of the Dome Electrodes' skin contact side as needed using isopropyl alcohol on a clean cloth. Avoid using anything abrasive like sandpaper or steel wool.

- These Dome Electrodes are made of a high-grade Stainless Steel. If they appear damaged or corroded, please contact Coapt.

CONNECTING THE COAPT SYSTEM COMPONENTS

The Coapt system is a stand-alone prosthesis control system. Its inputs are EMG signals from the user and its outputs are commands to the prosthesis. This section will guide you through connecting the EMG inputs cable and the prosthesis connection cable to the Coapt main controller unit.

Complete Control System Gen2 Label Symbol Descriptions

SYMBOL	INFORMATION	EXPLANATION
RX Only	RX Only	This device is only intended for sale to a licensed medical professional.
	Consult Accompanying Documents Symbol	Please read the entire instruction manual before using the device.
	FCC Symbol	This device is certified with the United States Federal Communications Commission.
	Non-ionizing Radiation Symbol	This device emits non-hazardous levels of non-ionizing radiation.
	CE Mark	The device is certified with the European Union under the Medical Device Directives (93/42/EEC).
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.

In the Complete Control Kit

The **Complete Control** System Gen2 kit contains the following components:

1. **Complete Controller** main processor
2. EMG Interface Cable (clinician-specified termination type)
3. Device Interface Cable (clinician-specified termination type)
4. **Complete Calibrate** button (part of Complete Controller)
5. Socket cut-out template for the **Complete Calibrate** button
6. Fabrication Aid (disposable mock-up of **Complete Controller**)
7. **Complete Communicator** USB Bluetooth Dongle
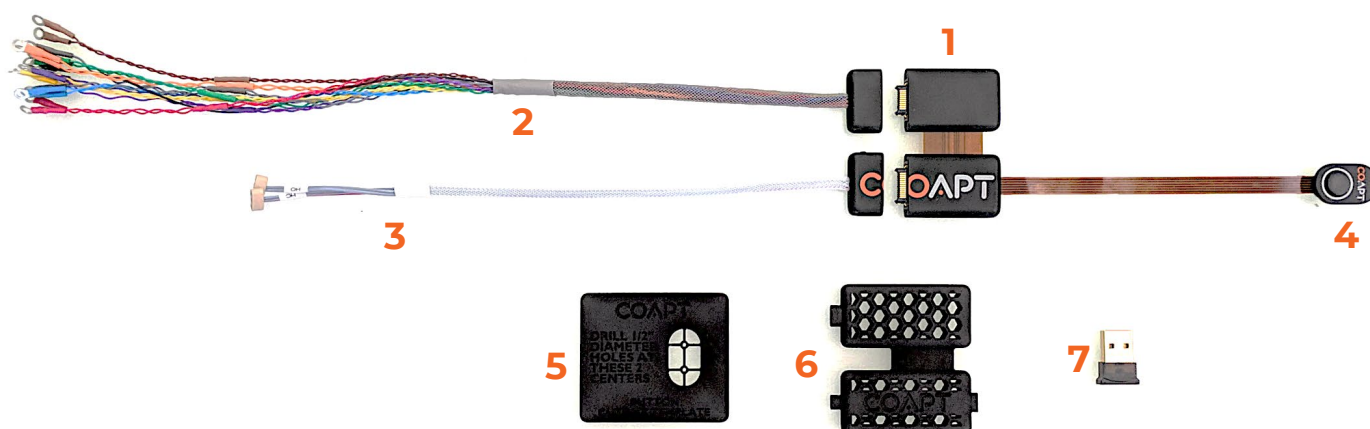
Placing the Complete Control system

The main processing unit of the Coapt system is the **Complete Controller**. Permanently attached to that is the **Complete Calibrate** button. That button is designed to be secured into the outer socket wall of the prosthesis with its button side exposed to the user. You can make good use of the provided fabrication aids to ensure the **Complete Controller** and the **Complete Calibrate** button fit perfectly.

The **Complete Controller** main unit arrives in its box with two cables already attached. One should have white sleeving and the other gray sleeving. If you have not already, feel free to detach those cables for easier fabrication. The logo on one side and some instructive arrows on the other side will help you make sure you will reattach them correctly. These are unique and keyed connectors which also helps.

No access is required for everyday use of the **Complete Controller** and it can be placed accordingly during prosthesis fabrication. Avoid excessive compression of the unit and attempt to locate the **Complete Controller** away from impact or load-bearing areas of the prosthesis.

The **Complete Controller** has two main lobes connected by a semi-flexible bridge. This allows for the unit to conform to the curvature of a prosthetic socket or be folded to fit in distal socket voids. Take care not to cut or damage the flexible bridge with sharp elements.

A disposable plastic fabrication aid is provided and can be used in the fabrication processes. The aid is an exact size and shape match of the **Complete Controller** with the Device Interface Cable and the EMG Interface Cable connected.

The **Complete Calibrate** button is a module connected to the **Complete Controller**. It has one central button, an indicator LED, and the Coapt logo on its top face intended to be accessible to the user. The button is primarily used to initiate the prosthesis calibration process and is NOT a prosthesis power on/off button. The multicolor LED indicator is positioned in the middle of the Coapt logo.

This unit houses sensitive electronics and should be handled with as much care as reasonably expected in a prosthetic fabrication environment. The **Complete Calibrate** button can also be damaged by exposure to excessive sweat or water.

The **Complete Calibrate** button should be secured in the outer socket wall of the prosthesis, in a location where the user can easily see and access it.

To aid in fabrication planning for the **Complete Calibrate** button, a cut-out template is provided as part of the **Complete Control** kit. It can be used to mark the required cut-out hole on the socket wall. The desired cut-out area equates to two overlapping holes of 12.7mm (½ in) diameter.

Instructions for socket mounting hole preparation are embossed on the Cut-Out Template. These instructions explain to drill two 12.7mm (½ in) diameter holes at the center of the two printed holes of the cut-out aid. After drilling these two holes, residual socket material should be trimmed away to allow for secure fit of the **Complete Calibrate** button.

The **Complete Calibrate** button can be secured to the prosthetic socket using general adhesives common in prostheses' fabrication.

⚠ CAUTION   **Adhesive & hardware use.** Use of mounting hardware drilled or screwed into the **Complete Calibrate** button housing could damage the device. Never use mounting hardware drilled or screwed into the **Complete Calibrate** button housing.

The **Complete Calibrate** button unit will protrude about 3.9 mm (0.15 in) below a typical thickness outer socket wall. Please plan accordingly for nearby component clearance.
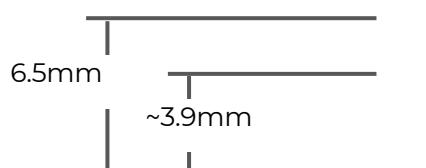
Connect the EMG Interface Cable

The gray jacketed cable is the EMG Interface Cable. One end of this cable has a wide connector that mates with the **Complete Controller** while the other end will be your EMG interface of choice, e.g. a set of ring-terminal eyelets, snap connectors, or perhaps even an EMG cuff. In most assemblies, it will make sense to attach the EMG interface end to Dome Electrodes mounted in the socket/liner first.

To connect the EMG Interface Cable to the controller, line up the arrows on the bottom labels that point directly at each other and push the connector on until it clicks in place. Note there are NO logo parts printed on the EMG Interface Cable connector nor the EMG connection half of the **Complete Controller**.
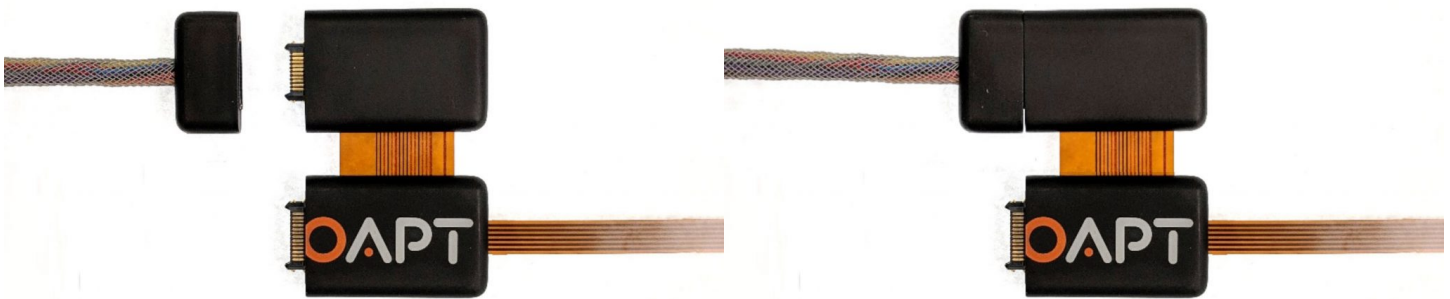
⚠ CAUTION **Foreign material in cable interconnects.** Ensure cable interconnects are free of foreign material before connecting device components together and connecting the device to power or the prosthetic components. Presence of foreign material in cable interconnects can cause damage to the device, resulting in device malfunction and minor injury to the user.

Connect the Device Interface Cable

The Device Interface Cable is the white jacketed cable. The Device Interface Cable connects the **Complete Controller** to the prosthetic device(s) being controlled. One end of this cable has a wide connector that mates with the **Complete Controller** while the other end has variable terminations for connection to the prosthetic device(s) being controlled.

To connect the Device Interface Cable to the controller, line up the arrows on the bottom labels that point directly at each other and push the connector on until it clicks in place. Coapt logo halves printed on the Device Interface Cable connector and the device connection of the **Complete Controller** will combine to complete the logo when properly connected.

TIPS

Do not forget, the Device Interface Cable is how the **Complete Controller** receives power. Batteries already incorporated in the prosthesis will supply switched power through the Device Interface Cable. When you are ready to test that proper connections of the Device Interface Cable to the prosthetic devices are made, use the "Manual Test" section in the Coapt software application.
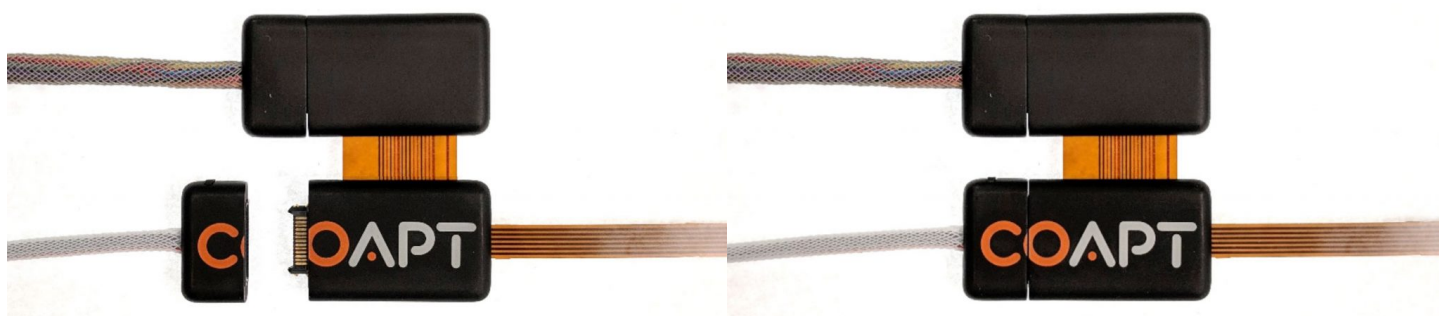
⚠ CAUTION   **Foreign material in cable interconnects.** Ensure cable interconnects are free of foreign material before connecting device components together and connecting the device to power or the prosthetic components. Presence of foreign material in cable interconnects can cause damage to the device, resulting in device malfunction and minor injury to the user.

Making sure the prosthetic components are set up for ideal Coapt control

There are quite a few options for prosthesis users when it comes to terminal devices, wrists, and elbows; not to mention all of the possible different configurations of each. This section will assist with the Coapt setup with your specific configuration.

The Coapt system was designed to be compatible with as many prosthetic components as possible. To do that it stores different communication languages, setups, and profiles in its memory. The system has been engineered to be smart, but it is still VERY IMPORTANT for you to ensure two things for ideal operation:

PROPER PROSTHETIC DEVICE SETTINGS

Make sure the native/onboard settings of the prosthetic devices you are setting up for Coapt control are set and saved to exact parameters recommended by Coapt. For this one-time task, you may have to use the setup software and/or tools from the manufacturer of each device. Plan for enough setup time to accomplish this.

To find guidance for these settings, refer to the visual connection guides for each different cable type available on the Coapt website, or on visual instructions within the Coapt software applications. Pro tip: There is a two-character code on the label of your Coapt Device Connection Cable. Use that code to find and follow the settings and connection diagrams specific to your cable type. Please contact a Coapt representative for assistance if you are not comfortable adjusting any of the settings of the prosthetic components.

PROPER PROSTHETIC DEVICE CONNECTIONS

Connectors coming from the Coapt system (white jacketed Device Connection Cable) need to be properly connected to your prosthetic device(s). To assist, all Coapt terminal connections are labeled and match instructions on illustrative connection diagrams available on the Coapt website, or on visual instructions within the Coapt software applications. Pro tip: There is a two-character code on the label of your Coapt Device Connection Cable. Use that code to find and follow the settings and connection diagrams specific to your cable type. Please contact a Coapt representative for assistance if you are not comfortable making the connections to the prosthetic components

⚠ CAUTION **Use with correct prosthetic components.** Make sure the device is only connected to the prosthetic components indicated during product order. Any use with a prosthetic device that is incompatible with the system, or was not indicated during product order, may cause damage to and/or malfunction of the device and could result in minor injury to the user.

The Device Interface Cable also connects prosthesis power to the **Complete Controller**.

⚠ CAUTION **Proper battery connection.** Ensure proper wiring, proper connection polarity, and use of a suitable battery when connecting the device to power. Improper wiring, reversed polarity, or use of an unsuitable power supply can cause permanent device damage, device malfunction, and minor injury to the user.

NOTICE **Use of "switched" power.** It is important that "switched" power is provided (i.e., the prosthesis and/or battery system must incorporate an on/off switch) otherwise a constant power drain will occur. If no prosthesis power switch is present, please contact a Coapt representative.

GENERAL INSTALLATION PRECAUTIONS

The following safety precautions should be read and followed by the qualified prosthetist responsible for fabricating and configuring the device prior to user use.

⚠ CAUTION **Configuration by a qualified professional**. The Complete Control system must be configured by a qualified prosthetist.

⚠ CAUTION **Use of excessive force.** Do not try to force components/product into socket or cutout holes. Use of excessive force or impact force tools (e.g., hammer) could permanently damage the device and result in device malfunction and minor injury to the user.

⚠ CAUTION **Opening enclosures.** Do not open the device enclosures during fabrication. Opening the enclosures could cause permanent damage to the device 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 close proximity to the device components during fabrication. Overheating can cause damage to the device, resulting in device malfunction and minor injury to the user.

⚠ CAUTION **Use with incorrect or incompatible prosthetic device.** Make sure the device is only connected to the prosthetic components indicated during product order. Use with a prosthetic device that is incompatible with the system, or was not indicated during product order, may cause damage to and/or malfunction of the device and could result in minor injury to the user.

⚠ CAUTION **Compression of connection cables.** Do not force device and cabling into prosthetic socket and ensure connection cables are not compressed between prosthetic layers. Compression of the connection cables could cause the cables to fail resulting in device damage, device malfunction, and minor injury to the user.

⚠ CAUTION **Use of sharp objects during fabrication**. Use caution when using sharp objects (e.g., scissors, blades) during fabrication. Damage to or severing of connection cables could cause device damage, device malfunction, and minor injury to the user.

⚠ CAUTION **Installation in material prone to static buildup.** Do not install device in socket material prone to experiencing a buildup of static electricity (e.g., leather, wool, nylon, and lead). Increased amounts of electrostatic discharge events could cause damage to the device, resulting in device malfunction and minor injury to the user.

MORE INFORMATION

Additional information, including videos, about connecting and using the **Complete Control** System Gen2 can be found online at **www.coaptengineering.com**

GUIDANCE FOR USERS

SETUP AND TRAINING

Only use a Coapt **Complete Control** System Gen2 after it has been set up by a prosthetist. Your prosthetist will train proper use of the **Complete Control** System Gen2 and can answer any questions about operating the device.

First pattern recognition trial or fitting?

When meeting with your prosthetist for a new fitting, your direct input will be an important part of the process. Coapt uses as many as 17 Dome Electrode contacts in a configuration that's unique to you to gather as much information from your muscle signals as possible. As a result, this should help improve your function in a way that comes naturally to you from the start.

Your prosthetist should ask all about what you can feel and/or move with your missing limb—so help them by being as descriptive as possible. They will also feel for these actions on your limb to locate and map out points where the electrodes should be placed. The electrode contacts will work in sets of two to create up to 8 channels for receiving your muscle signals simultaneously. Once these placements are mapped, your prosthetist will assemble Stainless Steel Dome Electrodes within the socket/liner of your prosthesis and wire them to your Coapt **Complete Control** Gen2 controller system.

From here they will fit your prosthesis and help you learn how to calibrate motions and functions. If the fit is correct, all electrodes should stay in contact with your skin. Be sure to let your prosthetist know if you feel any need readjusting.

Maintenance visits with your prosthetist or therapist

Remember, as you wear and independently fine-tune your Coapt **Complete Control** system's calibration, it will continually learn how to better adapt to your natural signals. When meeting with your clinician for any follow-up appointments, inform them on what your ongoing wearing experience has been like to determine if any additional maintenance would be beneficial.

If you are making a clinical visit to add or change a component of your prosthesis, make sure that you and your prosthetist are careful to set it up properly according to Coapt guidelines. If you are adding a new function, no worry necessary—you can calibrate and improve its function just like you have done with other motions in the past.

POWERING ON

The **Complete Control** System Gen2 takes about 1-2 seconds to start each time the prosthesis is powered on. It will signal 'readiness' with a short beep and a synchronized green light flash on the **Complete Calibrate** button.

CALIBRATING PROSTHESIS 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 your prosthesis. The better you calibrate, the easier it will be to control. Calibration should come easy. You will be prompted (either by movements of your prosthesis or instructions on a screen) to make and hold muscle contractions exactly the way you would to naturally replicate the motions of your 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 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 with the press of a button

Somewhere on your socket, you should have access to the Coapt **Complete Calibrate** button. This oval unit has one pressable button, a Coapt logo, and a multi-colored LED. It also makes a series of audio cues when pressed for operation by ear (see below for the meaning of the audible tones and LED colors). This pressable button serves a very important purpose. It lets you calibrate without the software or app. Use this any time you have a desire or need to update and adapt your prosthesis control on-the-go.

TO START THIS STYLE OF CALIBRATION:

- Press and hold the button for two seconds until you hear it beep once.

- Release your hold on the button, and your prosthesis will begin to move on its own.

- The following minute or so is what Coapt calls Prosthesis Guided Calibration (PGC). PGC is when the prosthesis goes through a sequence of motions on its own (like it is being remotely controlled) and you simply follow along with your corresponding muscle contractions. For example, if the prosthetic wrist is turning up, hold your intended muscle motion for an upward wrist. Same for hand actions, and so on. As you hold these corresponding muscle signal contractions, Coapt PGC is recording, building, and adapting the pattern recognition memory to match.

- Once PGC goes through all of its pre-selected motions (these are settable in the Coapt **Complete ControlRoom** application), it will sound a short jingle and then return prosthesis control to you.

> **NOTE**
>
> This is when 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.

TIPS

CALIBRATION UNDO can be performed using the **Complete Calibrate** button on the prosthesis, too. Simply hold it down for 6 seconds (until you hear a double beep and see the LED flashing blue) and let it go. This will jump the calibration back to what it was just before the most recent calibration activity.

CALIBRATION RESET can be performed using the **Complete Calibrate** button on the prosthesis, as well. To reset ALL calibrated motions using the Coapt button, hold it pressed for about 10 seconds (until you hear it play a short melody) then release. This will reset the system back to a starting state and turn the button's LED magenta. Don't expect control of the prosthesis when the LED is magenta—the control memory is empty and it will have to get at least one calibration to operate a prosthesis again.

Calibrating control on-screen (via mobile or desktop)

In case you would prefer to calibrate your Coapt system by watching on-screen prompts, great calibration tools are provided in the Coapt **Complete ControlRoom** software interface or app.
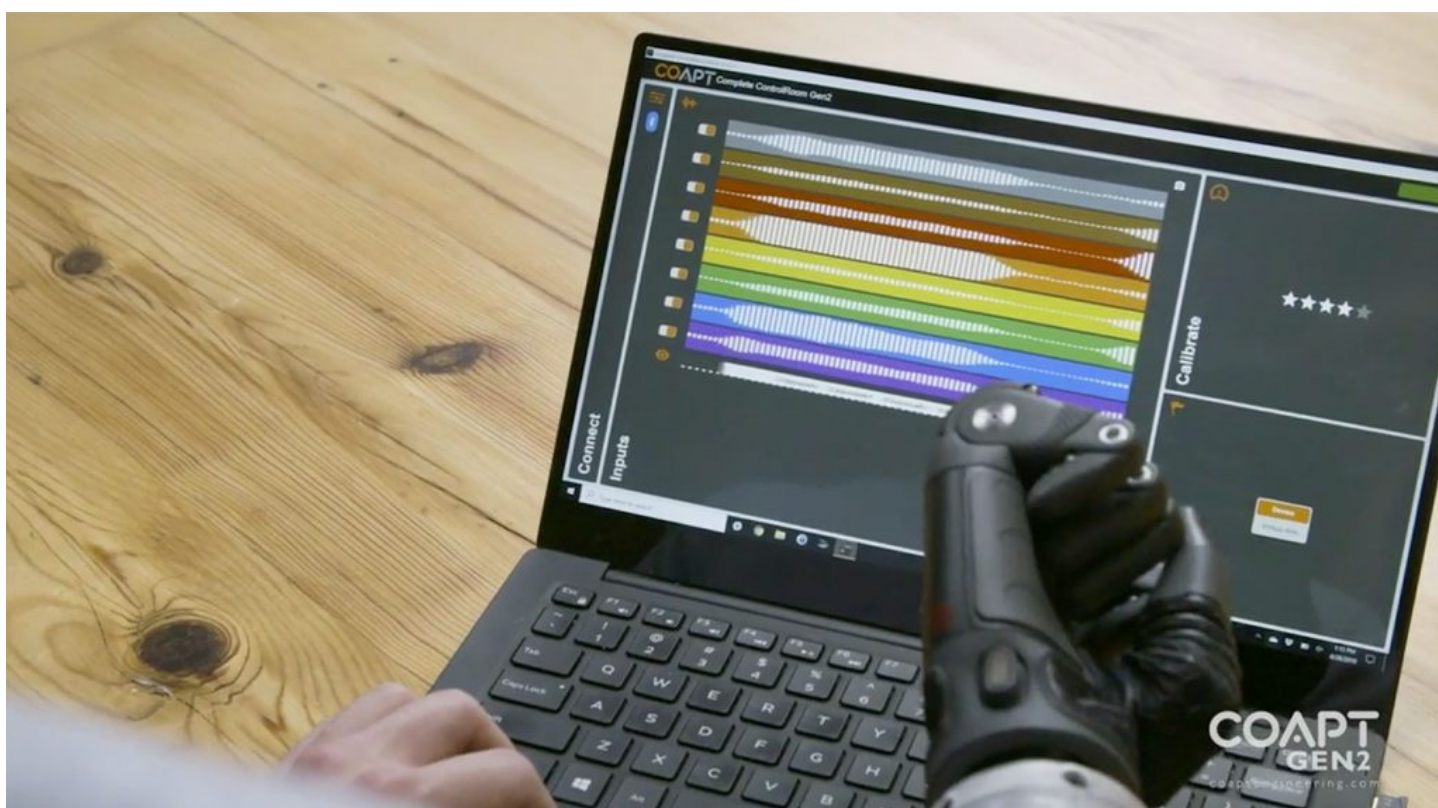
To use the PC software, make sure that you have an available Coapt **Complete Communicator** Bluetooth radio dongle, and then make sure you download and install the Coapt **Complete ControlRoom** application software from the Coapt website. To use the iPhone/iPad application, visit the Apple store for the Coapt **Complete ControlRoom** app.

CALIBRATING ALL MOTIONS USING THE SOFTWARE:

Once you've established a Bluetooth connection to your Coapt system in the **Complete ControlRoom** application, navigate to the "Calibrate" panel. This is a screen area where your available prosthesis 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, prosthesis control will be returned to you, and your **Control Coach®** quality ratings will be updated.

CALIBRATING INDIVIDUAL MOTIONS FROM THE SOFTWARE:

While you are in the "Calibrate" panel, you will see that each available prosthesis 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.
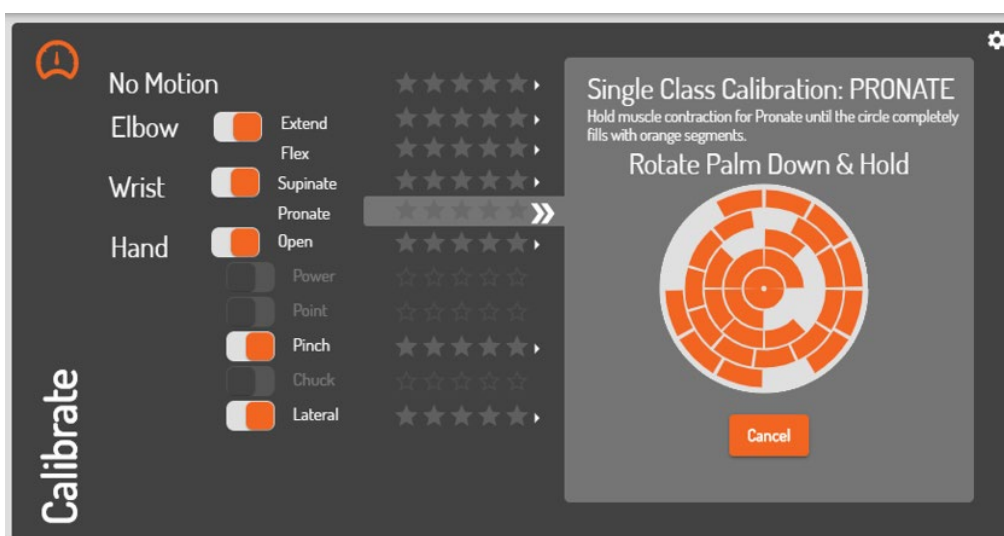
CALIBRATION ADAPTATION: **ADAPTIVE ADVANCE**®

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 a major socket change (such as electrode relocation) 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 on the prosthesis or use 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 prosthesis when the LED is magenta—the control memory is empty and it will need at least one new calibration to operate a prosthesis 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 prosthesis when the LED is magenta—the control memory is empty and it will need at least one new calibration to operate a prosthesis 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 would like to begin fresh 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 to a blank starting state while leaving the other calibrated motions as-is. The control memory for the affected motion is now empty and it will have to get at least one calibration to be controlled again.

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 prosthesis control back to you.
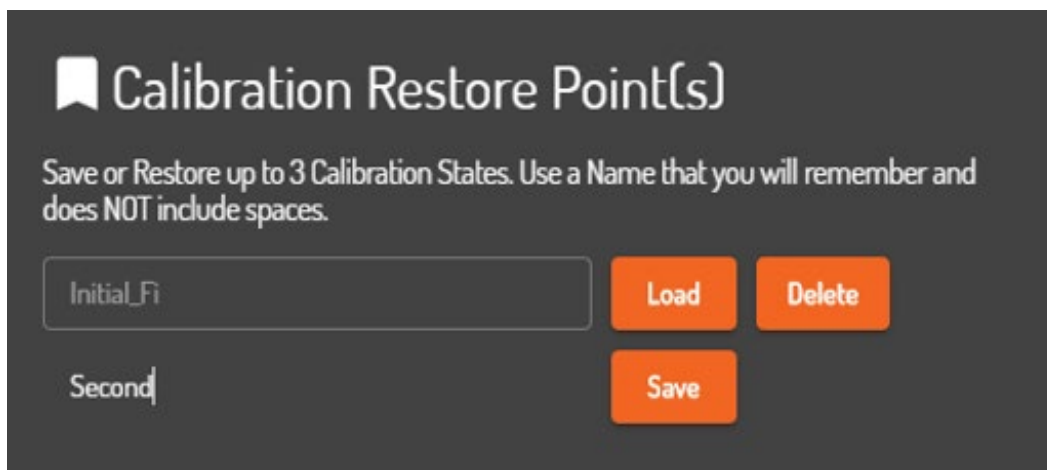
CALIBRATION UNDO USING THE SOFTWARE APPLICATION

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 prosthesis 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 that control state and return to that control setup.
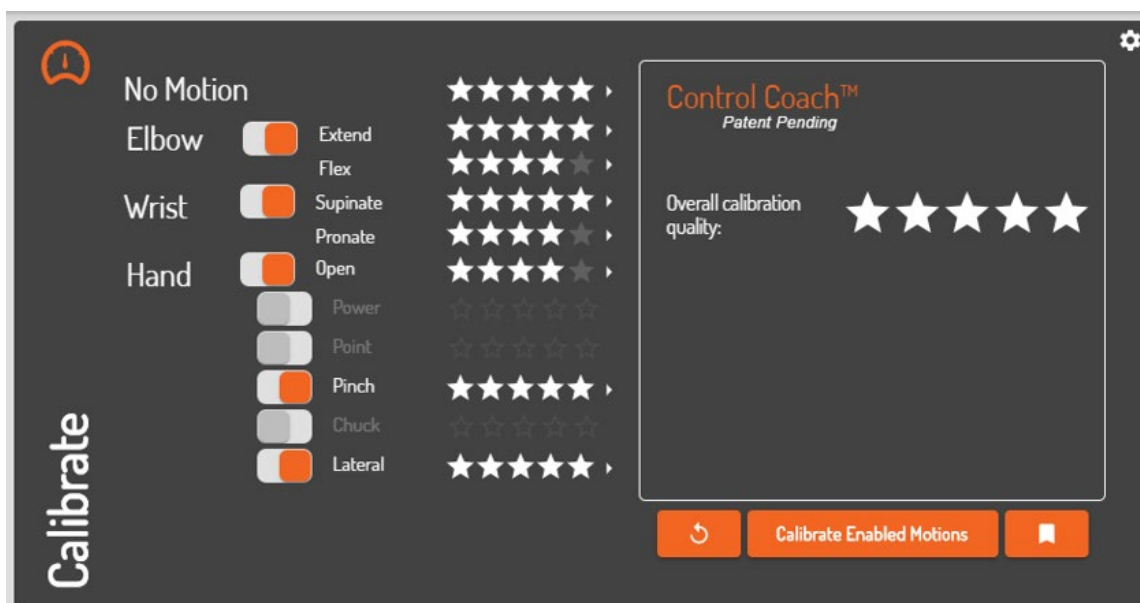
CONTROL COACH®

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—getting 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 that you may be interested in. Ratings of 2 stars or lower typically mean **Control Coach®** has some helpful insights that 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.
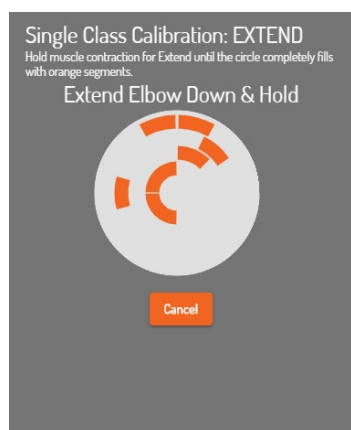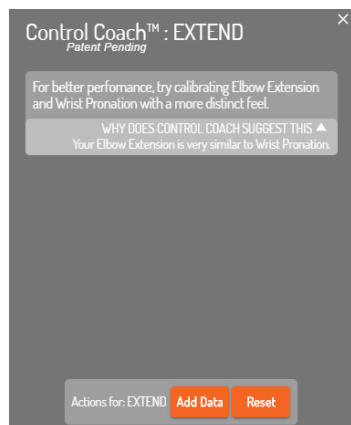
ADD DATA

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 affected 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

When sensors in your car determine there is something important that you need to know for improving the performance and reliability of your ride, you get a Check Engine light to let you know. **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

Somewhere on the surface of the prosthesis, 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 prosthesis is turned on.

Low Power Source

Double RED Blink

Low power source. The Coapt system won't have as much view into the health of your battery as the other prosthesis components should, but 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 prosthesis.

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 Prosthesis 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.

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 prosthesis 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 prosthesis. This can usually be overcome with a quick chat with your prosthetist or Coapt, and you probably don't even need to take your prosthesis 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 found in the Apple store as an iOS app. **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.

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.

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.
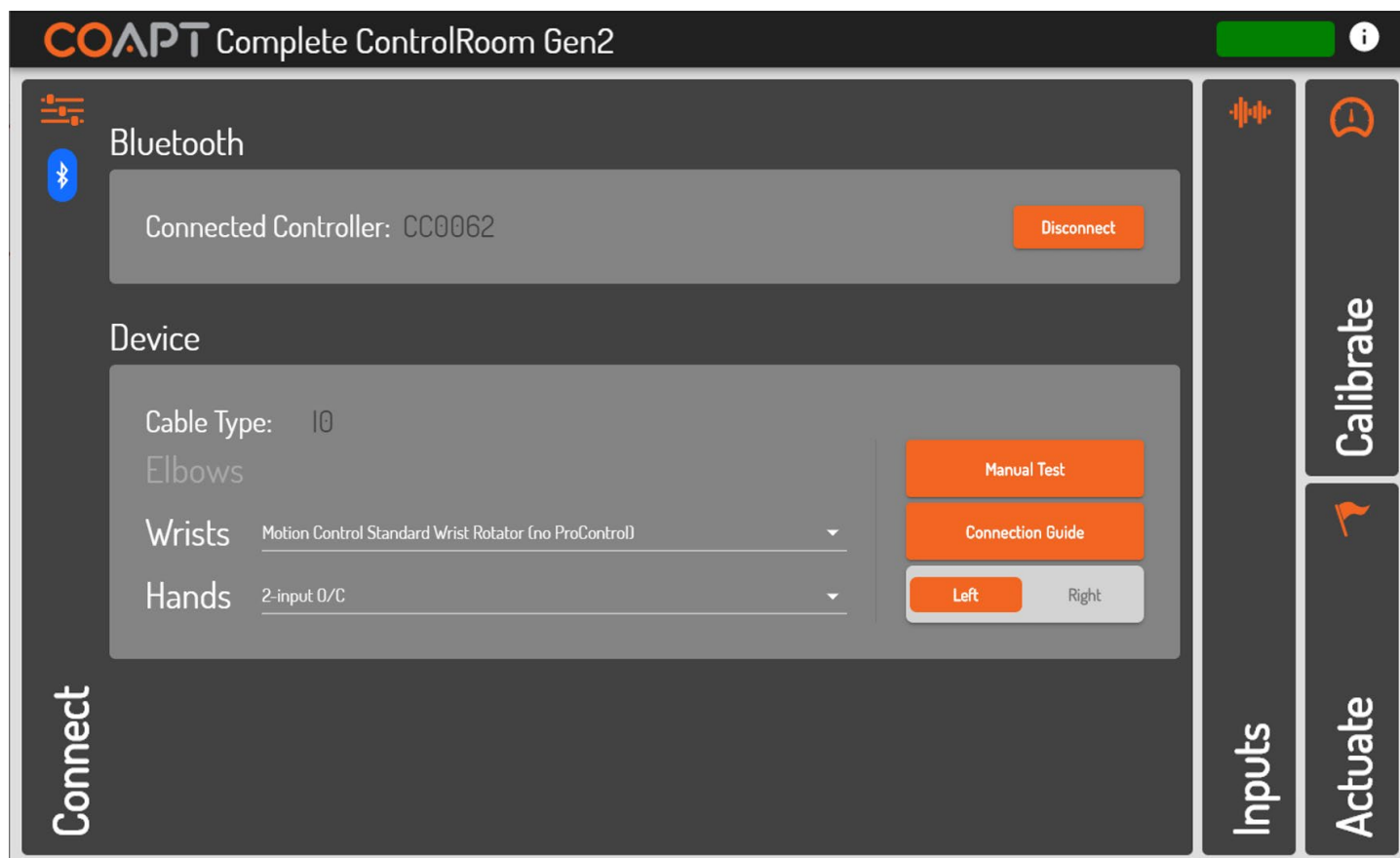
CONNET PANEL ELEMENTS (BLUETOOTH SUB-PANEL)	
CONNECTED CONTROLLER	A Bluetooth-connected **Complete Controller** will be named by its serial number starting with "CC". Check the serial number displayed on the screen and the serial number of the device (located on its label) to ensure you are connected 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

---
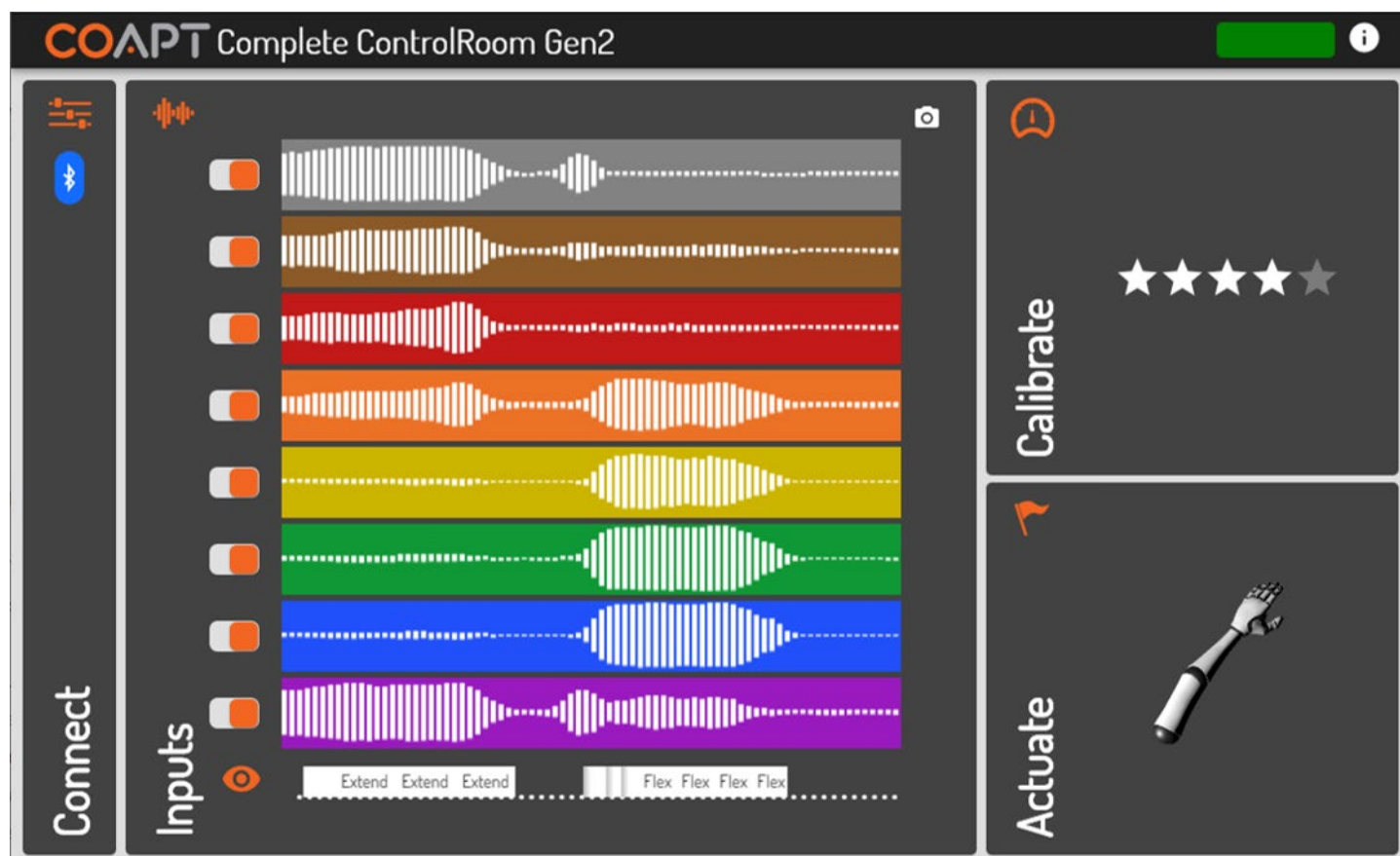
TIPS

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.

![COAPT GEN2]

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.
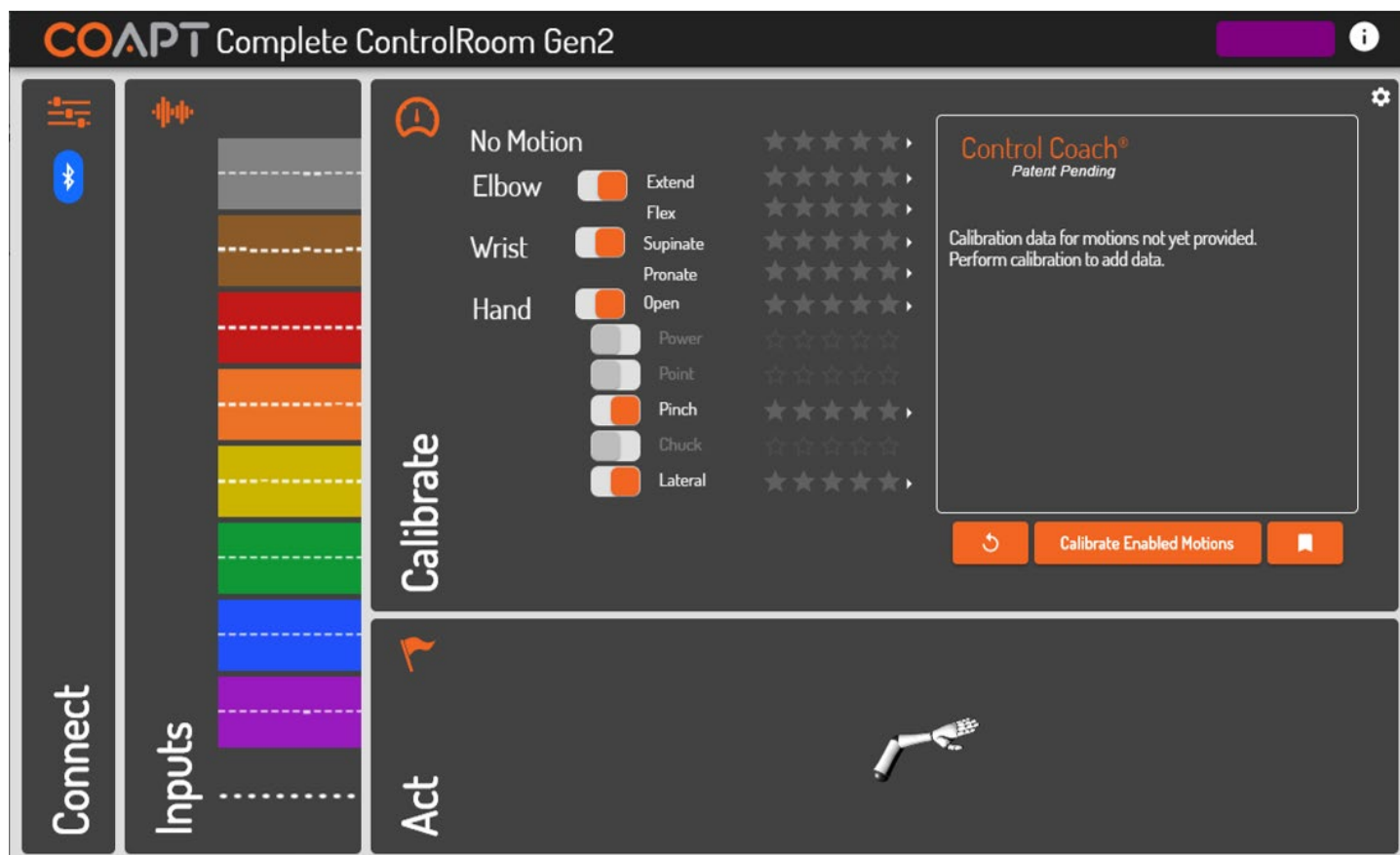
CALIBRATE PANEL ELEMENTS	
ACTION/FUNCTION TOGGLES	Allows selection of which actions/functions are included in calibration for prosthetic control.
ACTION/FUNCTION STAR RATINGS	Displays the A.I. **Control Coach®** estimated calibration quality for each action/function (see **Control Coach®** section for 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.
SETTINGS – MENU (COGWHEEL ICON)		Opens a pop-up window for **Complete Control** calibration settings:
	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.
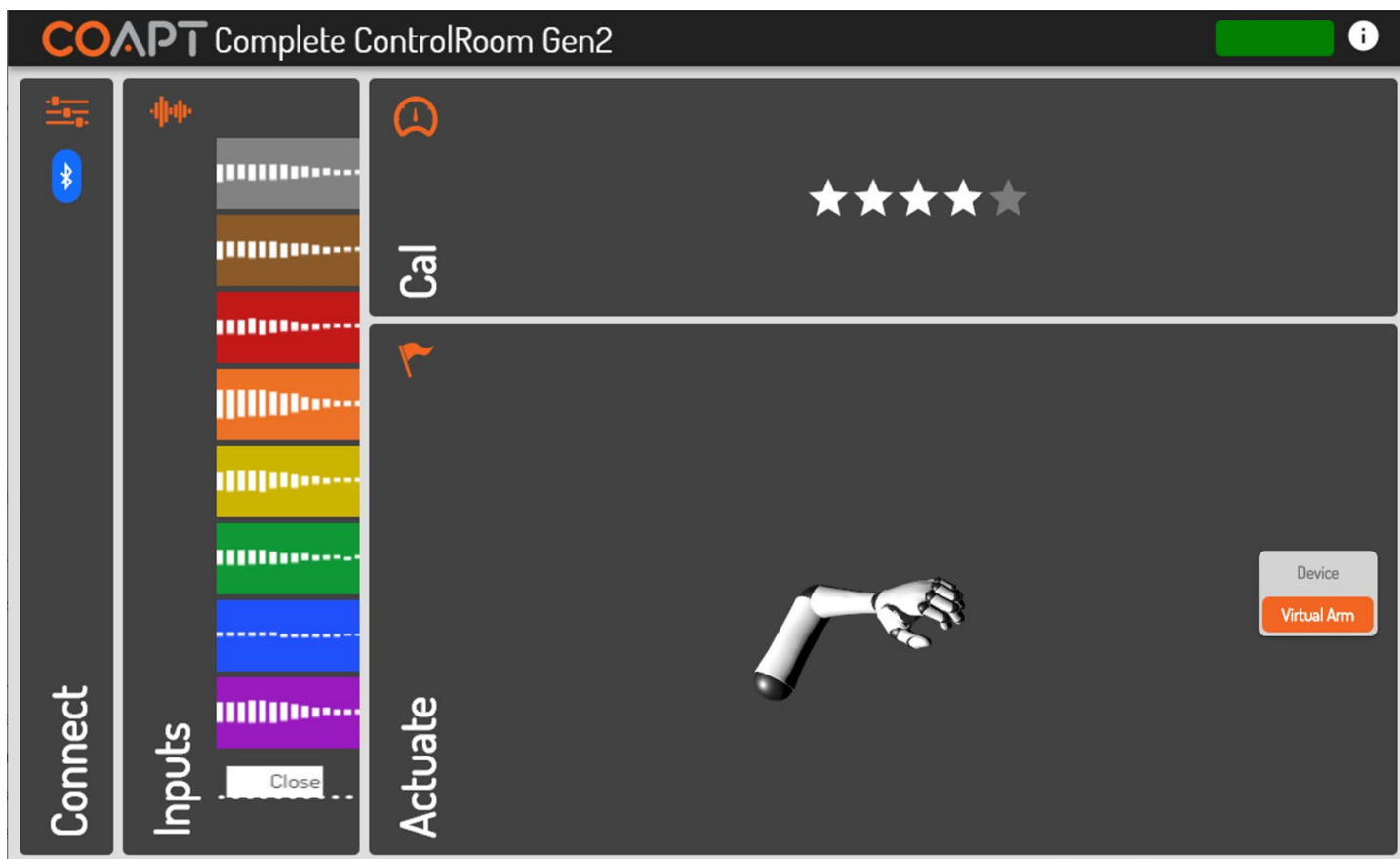
ACTUATE PANEL ELEMENTS

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.

Only one aspect of the system—the **Complete Calibrate** button—needs to be exposed to the user and the connections are also intended to be straightforward. If you are looking for insight into making EMG connections or Dome Electrodes' placement, please refer to those sections. For help with Coapt connections to your specific prosthetic devices, enjoy the helpful connection diagrams Coapt has created, available online or withing the **Complete ControlRoom** software application.

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

Where do I find my cable type so I can reference the correct connection guide and manufacturers recommended settings?

Each specific Coapt Device Connection Cable Type has a helpful connection diagram and instructive settings guides for other manufacturers' components. All of these guides, organized by Coapt cable type, can be found in the Clinician Resources section of our website. To determine your cable type, check the printed label on your Coapt Device Connection Cable – the first two characters after SN are the type (e.g. "H2").

Once you are connected to the **Complete ControlRoom** application, connection and settings guides can also be found by pressing the "Connection Guide" button in the Connect screen.

I'm using the Manual Test buttons in the Coapt application but the prosthesis doesn't seem to make the corresponding movements.

1. Make sure you are pressing and holding the buttons in the Manual test pop-up window and not just single-clicking them.
2. Ensure all wired connections to the prosthetic device(s) are correct according to the Coapt Device Cable Connection Guide for the cable type of your prosthesis (e.g. "H0", I4", etc.)
3. Ensure all of the settings on the other manufacturers' devices are set exactly as shown in the Coapt guidance documentation specific to the components connected by the cable type of your prosthesis (e.g. "H0", "I4", etc.)

I'm sure all the electrodes are making good skin contact but the Coapt application says "No electrode signal" and to "Check contacts".

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 damp cloth and mild soap).

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.

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 damp cloth and mild soap).

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.

Some of the prosthesis' motions are backwards/opposite.

1. Ensure all wired connections to the prosthetic device(s) are correct according to the Coapt Device Cable Connection Guide for the cable type of your prosthesis (e.g. "H0", "I4", etc.)

2. If necessary or preferred, you can flip direction in the **Complete ControlRoom** application:

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

b. On the Connect screen, verify that the correct selection is made on the Left/Right toggle button.

c. If still not fixed, find and press the "Manual Test" button.

d. In the Manual Test pop-up window, clicking an orange button with arrows, beside a function group, will flip the direction for that function.

The Coapt application doesn't give the option for grips for my multifunction hand; it shows up as 2–input O/C.

This is typically caused because of one or more of the following:

1. The multifunction hand is not a Coapt-grasp compatible version. Please check with Coapt for further detail on compatibility. Note that some prosthetic elbows are not able to pass the grasp command information and will not allow for Coapt-grasp control.

2. The multifunction hand and the Coapt system are not establishing the necessary digital connection.

    a. Ensure all of the settings on the other manufacturers' devices are set exactly as shown in the Coapt guidance documentation specific to the components connected by the cable type of your prosthesis (e.g. "H0", "I4", etc.).

    b. In the case of the multifunction hands that require 6-band wrist connection, ensure proper wrist connection componentry is in place.

3. The grasp-control functionality on the hand may have not yet been setup via the software interface of that device. Ensure all of the settings on the other manufacturers' devices are set exactly as shown in the Coapt guidance documentation, specific to the components connected by the cable type of your prosthesis (e.g. "H0", "I4", etc.)

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 prosthesis' 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.

There are no lights or sounds coming from the Coapt Complete Calibrate button.

1. Ensure all wired connections to the prosthetic device(s) are correct according to the Coapt Device Cable Connection Guide for the cable type of your prosthesis (e.g. "H0", "I4", etc.).

2. Ensure the prosthesis' battery is charged and the prosthesis is turned on.

3. If the Coapt system will connect via Bluetooth to the **Complete ControlRoom** application, the **Complete Calibrate** button unit may be damaged and subject for replacement.

4. If the Coapt system will NOT connect via Bluetooth to the **Complete ControlRoom** application, the Coapt system does not appear to be receiving power. Ensure the power connection with the prosthesis is correct.

FUNCTION/CALIBRATION

Control of the Virtual Arm in the Coapt application is fine but the prosthesis doesn't move.

1. Make sure "Device" is selected on the toggle in the Actuate panel of the **Complete ControlRoom** application.

2. Ensure all wired connections to the prosthetic device(s) are correct according to the Coapt Device Cable Connection Guide for the cable type of your prosthesis (e.g. "H0", "I4", etc.)

3. Ensure all of the settings on the other manufacturers' devices are set exactly as shown in the Coapt guidance documentation specific to the components connected by the cable type of your prosthesis (e.g. "H0", "I4", etc.)

The [specific function/motion] is not working correctly.

1. Ensure the prosthesis' battery is charged and the prosthesis is turned on.

2. Ensure all wired connections to the prosthetic device(s) are correct according to the Coapt Device Cable Connection Guide for the cable type of your prosthesis (e.g. "H0", "I4", etc.)

3. Ensure all of the settings on the other manufacturers' devices are set exactly as shown in the Coapt guidance documentation specific to the components connected by the cable type of your prosthesis (e.g. "H0", "I4", etc.)

The prosthesis is moving on its own when I'm wearing it and relaxed.

1. Verify in the **Complete ControlRoom** application that none of your EMG inputs are showing warnings for electrode lift-off. Address any that are.

2. It is possible that the Coapt system sees your data for that motion (the one that is moving when you are relaxed) as very similar to your data for the actual relax state. A few things that may help:

   a. Calibrate the motion that is moving when you don't want it to with muscle contractions that are a little harder/stronger.

   b. Calibrate "No Motion" while being sure not to be making muscle contractions.

Nothing works after Calibration.

1. Ensure the prosthesis' battery is charged and the prosthesis is turned on.

2. Ensure all wired connections to the prosthetic device(s) are correct according to the Coapt Device Cable Connection Guide for the cable type of your prosthesis (e.g. "H0", "I4", etc.)

3. Ensure all of the settings on the other manufacturers' devices are set exactly as shown in the Coapt guidance documentation specific to the components connected by the cable type of your prosthesis (e.g. "H0", "I4", etc.)

4. Add additional calibration data.

When I try to control a specific motion, my prosthesis 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 with your prosthesis in slightly different arm positions.

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

4. Ensure that muscle contractions during any calibration feel different enough for each different prosthesis 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.

When I calibrate everything works fine but if I move/ go about my day it sometimes changes.

There are a number of things that can change your muscle signals over time. Some are natural, like muscle fatigue or how much sweat might be on your skin. Socket/fit changes can occur and the Dome Electrode sensors might have shifted to a new place on your limb. Mentally, your intuitive control actions may have also changed over time. Adding calibration data after these changes can very often help to bring back great control and will also help the **Adaptive Advance®** system to build a more robust picture of how you wear, and control, your prosthesis.

When I swap hands they seem to respond differently.

If you are swapping between a multifunction and an open/close hand, take care to remember that the open/close device will have its own calibration data for "hand close" that differs from the grasps' calibration data of the multifunction device, and vice versa. If swapping devices for the first time, or from a new/blank calibration state, you may need to provide calibration data for the differing actions.

If you are swapping between two devices of the same type (two different open/close hands for example), some performance difference can be expected due to the different mechanical or settings nature of those hands.

Reminder: it is always good practice to power down your prosthesis before swapping hands.

The range of speed control of my prosthesis seems to be limited.

1. Ensure all wired connections to the prosthetic device(s) are correct according to the Coapt Device Cable Connection Guide for the cable type of your prosthesis (e.g. "H0", "I4", etc.)

2. Ensure all of the settings on the other manufacturers' devices are set exactly as shown in the Coapt guidance documentation specific to the components connected by the cable type of your prosthesis (e.g. "H0", "I4", etc.)

3. Consider calibrating motions with additional, and varied contraction intensities.

Note: different manufacturer's prosthetic components can have different viable speed ranges. Some devices will respond with a wide range of control speed while others will be narrow. Contact a Coapt representative for additional information.

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 "i" at the top of the software?

Clicking on the "i" 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 "i" 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

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 that 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 that 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 "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 "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.

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 prosthesis' battery is charged and the prosthesis 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.

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 prosthesis' battery is charged and the prosthesis is turned on.
2. Close the **Complete ControlRoom** application.
3. Cycle the power of the prosthesis 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.

Coapt makes sure that 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 that power to your prosthesis stays on and your Bluetooth connection is maintained throughout any update.

I was prompted to do an update but I didn't have time, is it really important to do the update?

Coapt makes sure that 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 that 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, 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 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 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 **Complete Control** System Gen2 components directly to their clinician.

Clinicians should return all unserviceable **Complete Control** System Gen2 components directly to their regional distributor. In the United States, Clinicians should return all unserviceable **Complete Control** System Gen2 components directly to Coapt, LLC at:

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

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.

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 Requirements

- The **Complete Control** System Gen2 does NOT have an internal battery
- The **Complete Control** System Gen2 is NOT provided with a battery
- The **Complete Control** System Gen2 will operate on supply voltages between 5–20 V_{DC}
- The **Complete Control** System Gen2 consumes approximately 50 mA at 7.4 V (370mW)

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

- **Complete Controller** (with Device Interface Cable and EMG Interface Cable connected)

  Width: 60.3 mm (2.37 in)   Length: 52.2 mm (2.05 in)   Thickness: 8.0 mm (0.31 in)

- **Complete Calibrate** button

  Width: 16.9 mm (0.67 in)   Length: 26.9 mm (1.06 in)   Thickness: 9.6 mm (0.38 in)

  Depth below socket wall: 3.9 mm (0.15 in)   Protrusion above socket face: 3.6 mm (0.14 in)

  Socket mount hole cut-out: An elongated circle 12.7mm (0.50 in) diameter, 22.7mm (0.89 in) length

- **Complete Communicator** USB Bluetooth Dongle

  Width: 15.8 mm (0.62 in)   Length: 21.8 mm (0.86 in)   Thickness: 6.0 mm (0.24 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 **Complete Control** System Gen2 has been cleared as substantially equivalent to a legally marketed predicate device as a Class II device via Section 510(k) premarket notification; K191083.

FCC Warning Statements

- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
    1. This device may not cause harmful interference, and
    2. This device must accept any interference received, including interference that may cause undesired operation.
- Radiation Exposure Statement for Portable Devices: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment is in direct contact with the body of the user under normal operating conditions. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- This equipment was tested and found to meet the radio interference radiated emission requirements of FCC "Rules and Regulations," Part 15, subpart B, Section 15.109a for Unintentional Radiators, Class B digital devices.
- Any changes or modifications not expressly approved by Coapt, LLC could void the user's authority to use this device.
- FCC ID: T9JRN4020

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). Coapt, LLC's European Union Authorized Representative (EC REP) is Fillauer Europe AB.

COAPT