

The cover features a solid orange background. On the left, there is a vertical arrangement of seven white bars of varying heights, creating a bar chart effect. Behind these bars, a black COAPT GEN2 device is visible, showing its side profile and the brand name. A faint, large, orange 'COAPT' logo is also visible in the background, partially obscured by the white bars. In the top right corner, the 'COAPT GEN2' logo is printed in white. In the bottom right corner, the title 'HANDBOOK (V 6.1) COMPLETE CONTROL SYSTEM GEN2' is written in white, stacked vertically.

COAPT[®]
GEN2

HANDBOOK (V 6.1)

COMPLETE
CONTROL
SYSTEM
GEN2

Caution: In the USA, federal law restricts this device to sale by or on the order of a physician.

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USER ASSISTANCE & SAFETY

USER ASSISTANCE

Contact your prosthetist if you have difficulty operating your device. You may also contact Coapt for support (toll free) at 844-262-7800. Additional information about connecting and using the **Complete Control** System Gen2 may be found online at www.coaptengineering.com

GENERAL WARNINGS AND PRECAUTIONS

For your safety and to prevent damage to the **Complete Control** System Gen2, 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 injury to the user or damage to the **Complete Control** System Gen2. The following symbol definitions pertain to warnings in this handbook and on all device labels.

SYMBOL DEFINITIONS



Warning regarding possible risk of severe accidents or injury.



Warning regarding possible risks of accident or injury.

NOTICE

Warning regarding possible damage to product or equipment.



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.



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.



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.



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.



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 ($<-20^{\circ}\text{C}$) or high ($>45^{\circ}\text{C}$) 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.

ADVERSE REACTIONS

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

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

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

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

SUBMITTING ADVERSE EVENT REPORTS TO FDA








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

- Report Online at www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
- 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.

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).
	Serial Number	Signifies the identification information for the device.
	Date of Manufacture	Date the device was assembled at Coapt.
	European Representative	Signifies the European Representative for Coapt.

OVERVIEW

PURPOSE OF THE DEVICE

The **Complete Control** System Gen2 is designed as a control system for upper-limb prosthetic devices. It measures multiple muscle electrical (myoelectric, or “EMG”) signals from the skin of a user and uses machine learning (pattern recognition) algorithms to provide corresponding movement commands to a prosthetic device.

Myoelectric pattern recognition for prosthesis control has a number of benefits:

- **Intuitive Control** – Natural muscle contractions corresponding to the intended prosthesis’ functions are used to control the prosthesis.
- **No Mode-Switching** – No need for “trigger” actions like co-contractions, pulses, fast-slow gestures, etc.
- **Strong muscle contractions are not required** – Avoid fatigue and utilize low intensity muscle contractions as needed.
- **Superior Proportional Control** – Myoelectric inputs are not limited by manual thresholds or speed-limiting “cross-talk” effects.
- **Flexible Electrode Placement** – Less need for precise electrode placements.
- **Calibration and Setup** – Control can be refined and personalized at any time; changes in socket fit, skin condition, fatigue, control choices can be overcome without the need to take the prosthesis off or make extra clinic visits.

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

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 **Complete Control** System Gen2.

DESCRIPTION OF THE DEVICE

The **Complete Control** System Gen2 is a packaged electronic control system for controlling an upper-limb prosthetic device. Its inputs are an array of myoelectric signals from the prosthesis user's limb and its outputs are commands to the prosthesis.

The **Complete Control** System Gen2 allows users to control a prosthetic limb with myoelectric pattern recognition control algorithms. Users personalize their control by calibrating the system whenever necessary. The calibration teaches the electronic system what the myoelectric pattern of the user's intended motions are. For more on myoelectric pattern recognition, please visit: <https://coaptengineering.com/pattern-recognition>

The **Complete Control** System Gen2 main unit is the **Complete Controller** processor coupled to the **Complete Calibrate** button. The oval-shaped **Complete Calibrate** has a pressable button, a Coapt logo, a multi-colored LED, and the ability to make different indicator sounds (see below for the meaning of all LED colors and sounds). This pressable button is NOT a prosthesis on/off switch.

COMPONENTS

1. **Complete Controller** main processor
2. **Complete Calibrate** button (permanently attached to the **Complete Controller**)
3. Device Interface Cable
4. EMG Interface Cable

ACCESSORIES

5. Electrode contacts (Coapt **ControlSeal™** electrodes shown)
6. Electrode Dome Assembly Aid
7. Fabrication Aid (1:1 scale disposable model for use in prosthesis fabrication)
8. Prosthesis socket cut-out template for the **Complete Calibrate** button

USER INTERFACE APPLICATION

9. **Control Companion** mobile app (not shown)



COMPATIBLE DEVICES

Prosthetic Hands, Wrists, and Elbows

The **Complete Control** System Gen2 is designed to connect to and control a wide range of commercially available prosthetic devices. For up-to-date prosthetic device compatibility, contact a Coapt representative or visit <https://coaptengineering.com/compatibility-tool>



Electrode Contacts

The **Complete Control** System Gen2 is designed to work with non-filtering, passive electrode contacts. Coapt recommends using these compatible electrode contacts:

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

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

⚠ CAUTION

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

CONDITIONS FOR USE

The **Complete Control** System Gen2 was developed for everyday use and must not be used for unusual activities. These activities include 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 **Complete Control** System Gen2 is intended for single patient use only.

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

INSTRUCTIONS FOR USE

PATTERN RECOGNITION FUNDAMENTALS

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

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

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

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

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

Guidance for Learning and Practice:

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

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

PLANNING PATTERN RECOGNITION ELECTRODE LOCATIONS

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

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



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

Step 1: Discussing User Contractions

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

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



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

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

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

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



TIPS

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

Step 3: Planning Electrode Locations

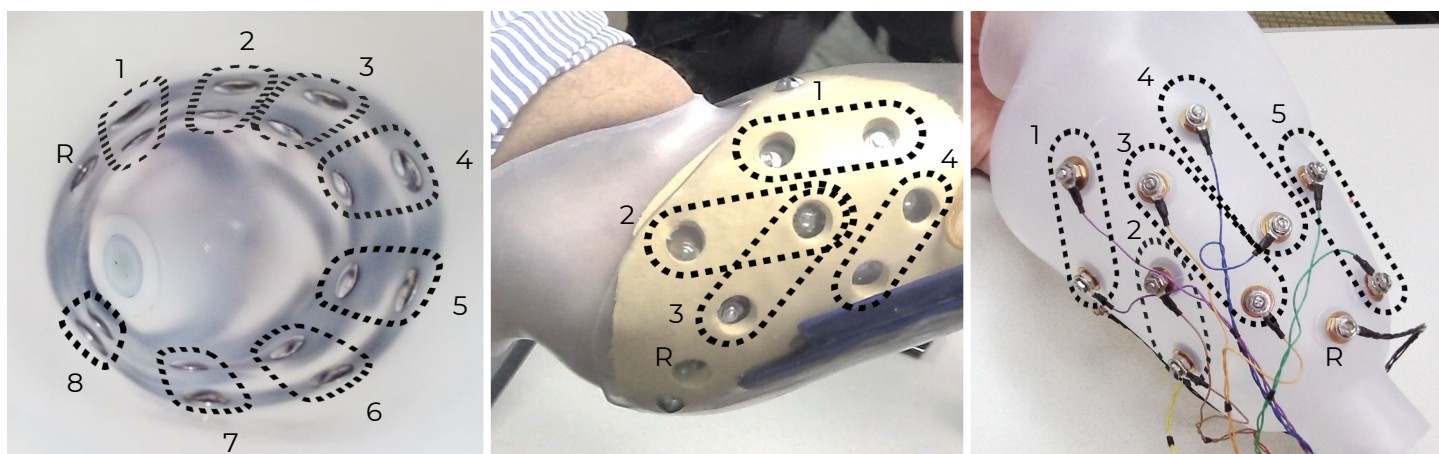
Use the areas of underlying muscle information discovered in Steps 1 and 2 to plan electrode contact locations.

The **Complete Control** System Gen2 has 17 electrode contacts to place, where 1 is an independent reference “ground” contact and the remaining 16 are paired to make 8 “signal channels”. Each pair of signal electrode contacts work together to capture the bi-polar, differential measurement of the muscle contraction underlying their location. The two **contacts for a given channel are ideally placed 30-60mm apart** and detect a myoelectric signal from an oval area encompassing their general location. The farther apart the pair of electrode contacts, the larger (and deeper) the sensed area will be, and vice versa.

General Placement - Plan to place the 8 sets of 2 signal electrode contacts so their 8 myoelectric detection “oval areas” fully capture all underlying muscle information. The independent reference contact (the 17th) should be positioned in a location that maintains excellent electrode-skin contact and should NOT be shared or paired with any of the signal contacts.

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

Contact Sharing – For a limb that is too small to reliably fit all 17 electrode contacts, it is ok to have a few of the signal channels share an electrode contact. See the Coapt **ControlSeal™** product handbook for assembly detail when sharing. When connecting the signal conductor wires of the **Complete Control System Gen2** to shared electrode contacts, do NOT place the two wires for the same channel (same color) on the same electrode contact – this will result in zero signal for that channel and not be helpful for pattern recognition performance. Also, do not leave any conductor wires unconnected. That is, always place electrode contacts for all 8 myoelectric signal channels.



TIPS

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

INSTALLING ELECTRODE CONTACTS

The electrode domes of the product must be placed through the wall of an inner socket interface. The domed side will contact the skin surface while the connection wire and hardware components are on the outside of the socket interface. When using Coapt **ControlSeal™** electrode domes, please follow the assembly and care instruction of the **ControlSeal™** product handbook.

The wires of the **Complete Control** System Gen2 EMG Connection Cable have 8 different colored pairs to help with connection to the electrode domes. The wire for the non-paired reference “ground” is the only black wire and must connect to its own electrode dome.

All 17 EMG Connection Cable wires must be connected to an electrode contact for proper operation.



Electrodes MUST MAINTAIN CONTACT WITH THE USER'S SKIN for proper operation.

Electrodes that do not stay in contact with the user's skin will lead to prosthesis control limitations. Take care in planning and be sure to fabricate a well-fitting socket interface.

INSTALLING CONTROLLER COMPONENTS

Controller and Calibration Button Location

The **Complete Controller** is the processing unit of the **Complete Control** System Gen2. It is designed to be installed in an available void between outer and inner socket layers. Its two main lobes are connected by a flexible bridge allowing the unit to conform to socket curvature or to be folded to fit in distal socket voids.

The **Complete Calibrate** button unit is permanently attached to the **Complete Controller** by a longer flexible circuit. This button unit is designed to be secured into the outer socket wall of the prosthesis with its button side exposed to the user, in a location where the user can easily see and access it.

Controller and Calibration Button Installation

The provided fabrication aid is a size match of the **Complete Controller** (with the Device Interface Cable and the EMG Interface Cable connected). Use it as necessary during socket fabrication to ensure a placement location for the **Complete Controller**. When installing, connect the Device Interface Cable and the EMG Interface Cable (see below) to the **Complete Controller** and place into the planned void with care.



Damage to flexible circuit areas. Use caution not to cut or damage the flexible circuit areas during installation.



Excessive force. Avoid excessive compression or blunt object forces and attempt to locate the **Complete Controller** away from impact or load-bearing areas of the prosthesis.

Use the provided button cutout template to mark the **Complete Calibrate** cut-out hole on the socket wall. The cut-out area is made by drilling two overlapping ½ inch diameter (12.7mm) holes at centers indicated on the template. After drilling these two holes, trim residual socket material to allow for secure fit of the **Complete Calibrate** button. Pass the **Complete Calibrate** up through the hole and snap it in place to install. The unit will protrude about 0.15 inch (3.9 mm) under the socket wall once installed. Please plan accordingly for underlying component clearance.

NOTICE

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. Use of adhesives common in prostheses' fabrication is acceptable but must not cover the user-pressable button.

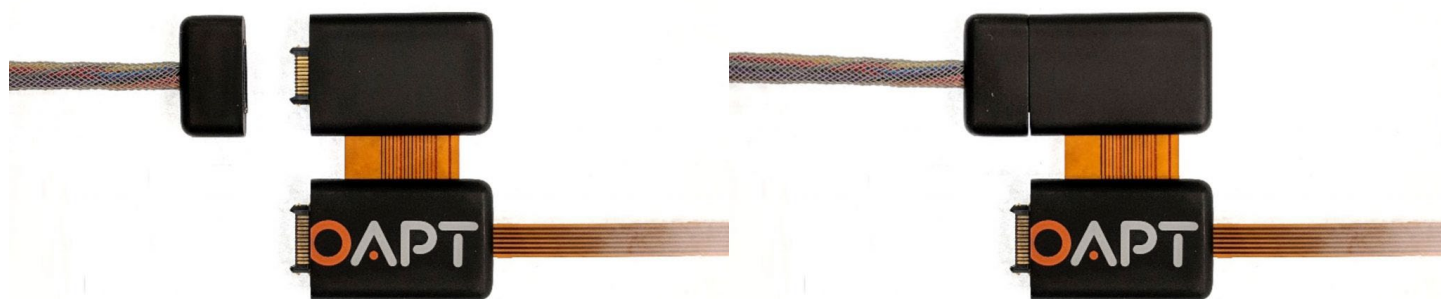
EMG Interface Cable Connections

Myoelectric signals are input to the **Complete Controller** by an EMG Interface Cable (gray cable covering). One end has a wide connector that mates with the **Complete Controller** and the other is suited for receiving EMG.

A definitive socket installation typically uses Coapt's "Ring terminal Eyelets" EMG Interface Cable type and in most cases, it will make sense to attach the ring terminals to socket electrode contacts before connecting to the **Complete Controller** (see the Coapt **ControlSeal™** product handbook for instruction on connecting electrodes).



To connect the EMG Interface Cable to the **Complete 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**.



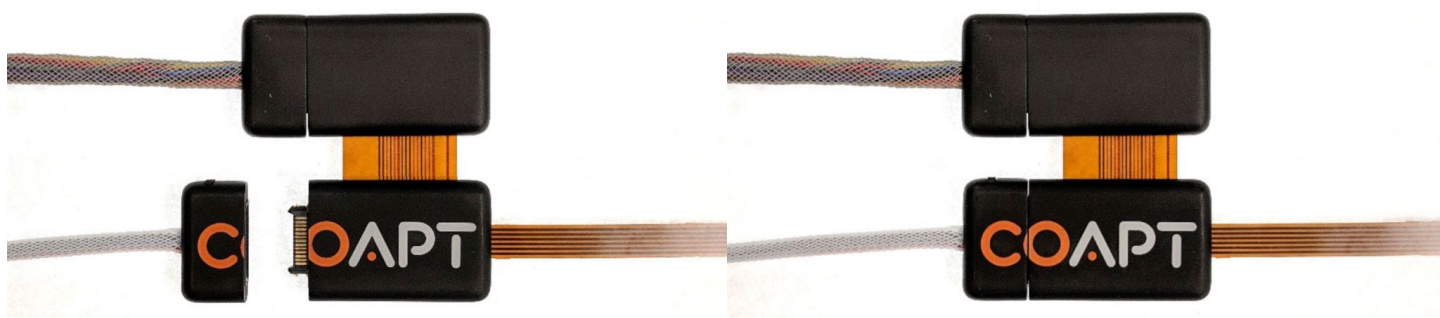
Device Interface Cable Connections

Actuation commands are output from the **Complete Controller** by a Device Interface Cable (white cable covering). One end has a wide connector that mates with the **Complete Controller** and the other end has terminations for connection to the prosthetic device(s) being controlled. To account for connection differences of all compatible prosthetic devices, the Device Interface Cable is available in various “types”. Contact a Coapt representative or visit <https://coaptengineering.com/compatibility-tool> to determine proper Device Interface Cable type for your prosthetic application.

Detailed instruction about connecting the Device Interface Cable to the prosthetic device(s) is organized by Device Interface Cable here: <https://coaptengineering.com/clinicians>



To connect the Device Interface Cable to the **Complete 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

The Device Interface Cable is how the **Complete Controller** receives power. Batteries already incorporated in the prosthesis will supply power through the Device Interface Cable. Validate connections of the Device Interface Cable to the prosthetic devices using “Manual Test” in the **Control Companion** mobile app.

⚠ 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.

SETTING UP THE PROSTHETIC COMPONENTS

A detailed “Connection Guide” corresponding to each Coapt Device Interface Cable type can be found at: <https://coaptengineering.com/clinicians>. Connection Guides are organized by a two-character type code. The first two characters after “SN” on the Device Connection Cable label indicate its type code (H2, I4, or J4, etc.).

Proper Prosthetic Device Settings

Follow the “Software Settings” of the Connection Guide corresponding to the Device Connection Cable in use to set the native/onboard settings of connected prosthetic devices to recommended parameters. For this one-time task, the setup software and/or tools from the manufacturer of each device may be required. Plan for enough setup time.

Contact a Coapt representative for assistance as required if not comfortable adjusting any of the settings of the prosthetic components.

Proper Prosthetic Device Connections

Follow the “Physical Connections” diagrams of the Connection Guide corresponding to the Device Connection Cable in use when connecting the connectors of the Device Connection Cable to prosthetic device(s). To assist, All Device Connection Cable connections are labeled and match instructions on Connection Guide diagrams.

Contact a Coapt representative for assistance as required if 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 Gen2 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 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. Using 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

TROUBLESHOOTING

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

Contact Coapt toll free at 844-262-7800

Technical support is available at support@coaptengineering.com

Clinical support is available at clinical@coaptengineering.com

Engineering support is available at engineering@coaptengineering.com

GUIDANCE FOR USERS

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.

The **Complete Control** System Gen2 uses an array of skin-contacting electrodes to learn and detect the specific pattern of your muscle electrical (myoelectric, or “EMG”) signals corresponding to desired prosthesis actions.

New users should read the Purpose of the Device and Pattern Recognition Fundamentals above for more information.

SETUP AND TRAINING

First Pattern Recognition Trial or Fitting

When meeting with your prosthetist for a new pattern recognition evaluation or fitting, your feedback will be an important part of the process. Coapt uses as many as 17 electrode contacts in a configuration that’s unique to you, to gather as much information from your muscle signals as possible.

Your prosthetist should ask all about what you can feel and/or move with your missing limb – help by being as descriptive as possible. They will also feel for these actions on your limb to locate and map out points where the electrode contacts should be placed. Your prosthetist will assemble the electrode contacts within the socket/liner of your prosthesis and connect them to your Coapt **Complete Control** System Gen2.

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 think any need readjusting.

Maintenance Visits with your Clinician

As you wear and personalize your **Complete Control** System Gen2 via calibration, it will adapt to your muscle patterns.

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, you can calibrate it in addition to your existing motions.

PATTERN RECOGNITION CALIBRATION

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

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



TIPS

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



NOTE

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

Calibrating All Motions in a Sequence

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

USING THE PHYSICAL BUTTON

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

The prosthesis moves itself through a sequence of motions (like it is being remotely controlled) and you follow along with your corresponding muscle contractions. For example, if the prosthetic wrist is rotating palm up, hold your intended muscle contraction for wrist supination. If the prosthetic hand is opening, hold your muscle contraction for hand open. If the prosthesis pauses for a moment, be sure to relax your muscle contractions. As you hold and relax muscle contractions corresponding to the prosthesis motions, the system is learning and adapting its pattern recognition memory. Note: the first few seconds of the sequence may be the prosthesis getting into a starting position and do not need corresponding contractions.



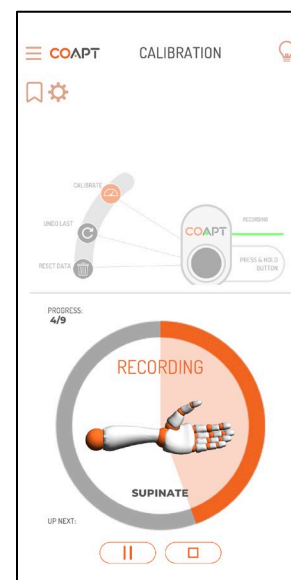
At the end of the sequence of motions (and pattern recognition computations), the button will sound a short jingle to indicate prosthesis control is returned to you.

USING THE MOBILE APP

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

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

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



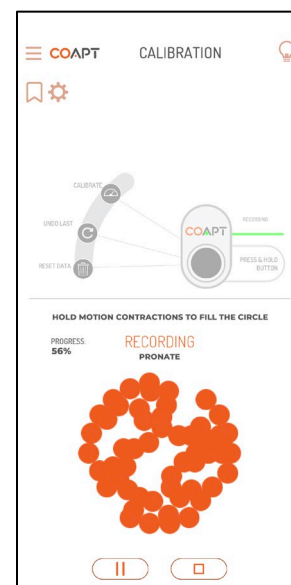
Calibrating Individual Motions

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

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

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

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



ADDITIONAL CALIBRATION TOOLS

Undoing Last Calibration

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

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



USING THE PHYSICAL BUTTON

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



USING THE MOBILE APP

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



NOTE

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

Clearing/Resetting All Calibrated Motions

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

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



USING THE PHYSICAL BUTTON

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



USING THE MOBILE APP

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



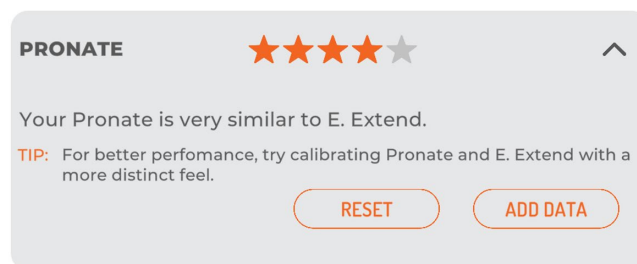
NOTE

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

Clearing/Resetting Individual Motions

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

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

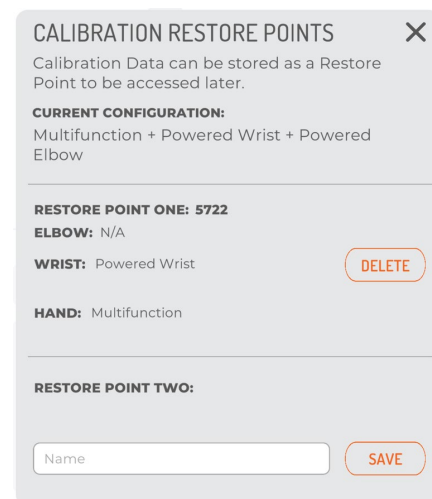


The prosthesis’ action for an individual motion that has been reset will not be available until at least one calibration for that motion is performed. Other actions that were not reset may remain available.

Calibration Restore Points

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

From the Calibration screen of the **Control Companion** mobile app, press the Restore Points button (bookmark icon). In the menu that appears, follow the guidance to save or load a pattern recognition Restore Point.

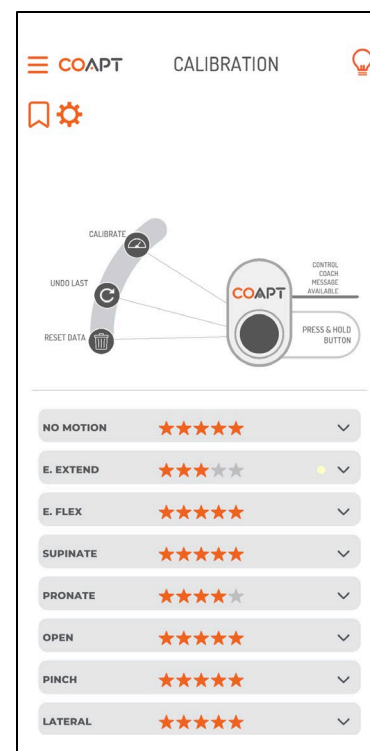


CONTROL COACH[®]

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

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

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



ADAPTIVE ADVANCE[®]

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

Adaptive Advance[®] is enabled by default but can be turned off in the **Control Companion** mobile app.



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 BUTTON UNIT: SOUNDS & LED COLOR MEANINGS



One short beep and a corresponding GREEN flash

Power Up

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



Double RED blink

Low Power Source

Indicates the power supplying the Coapt system is very low.



Solid MAGENTA

Reset State

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



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

Calibration Start

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



Solid GREEN periods

Recording EMG Data

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



WHITE with short blip off every two seconds

Control Coach® Messages Available

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



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

Calibration Undo

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



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

Calibration Reset

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



Flashing **GREEN**

System Updating

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



Solid **RED**

Critical Error

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

CONTROL COMPANION

Control Companion is a mobile app available for both iOS and Android devices. The app wirelessly communicates with the **Complete Controller** and can be used for setup, configuration, calibration assistance, and other pattern recognition controls practice.

INSTALLATION

Search for “Coapt” in the App Store (iOS) or Google Play Store (Android).

CORE APP USES

Configuration

Configuration screens facilitate scanning, connection, and disconnection of nearby, powered-on **Complete Controller** units. Once communication is established to one, the app will display the connected controller number and its associated Device Connection Cable type.

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

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

In applicable cases, a Connection Guide corresponding to the connected Device Connection Cable is available.



A **Complete Controller** is discoverable for about 3 minutes after any power on. To make it discoverable after that, press the **Complete Calibrate** button once.

When multiple **Complete Controller** units are discoverable, the app will display a selection list by serial number.

Output Validation

Before performing calibration for prosthesis control, validate correct connection of the **Complete Controller** to output prosthetic devices and that the devices have correct native settings applied (see Setting up the Prosthetic Components).

In the app, press and hold the “Manual Test” button for each control output to generate the corresponding action of the connected, physical prosthesis. When output actions are not as expected, check all wired connections and device settings.

Input Validation

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

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

EMG Pattern Exploration

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

Calibration

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

Practice and Games

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

ADDITIONAL INFORMATION

LIMITED WARRANTY

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

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

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

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

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

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

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

EXTENDED WARRANTY

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

RETURNS

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

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

PRODUCT RETURN POLICY

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

INTELLECTUAL PROPERTY DISCLAIMER

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

TECHNICAL INFORMATION

CATEGORY	SPECIFICATION
POWER REQUIREMENTS	<ul style="list-style-type: none"> The product does NOT have an internal battery The product is NOT provided with a battery The product will operate on supply voltages between 5–20 V_{DC} The product 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
PHYSICAL DIMENSIONS	<p>Complete Controller (with Device Interface Cable and EMG Interface Cable connected)</p> <p>Width: 60.3 mm (2.37 in) Length: 52.2 mm (2.05 in) Thickness: 8.0 mm (0.31 in)</p> <p>Complete Calibrate button</p> <p>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</p>

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) and 2017/745 Medical Device Regulation (MDR). Coapt, LLC's European Union Authorized Representative (EC REP) is Fillauer Europe AB, Kung Hans väg 2, 19268, Sollentuna, Sweden





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