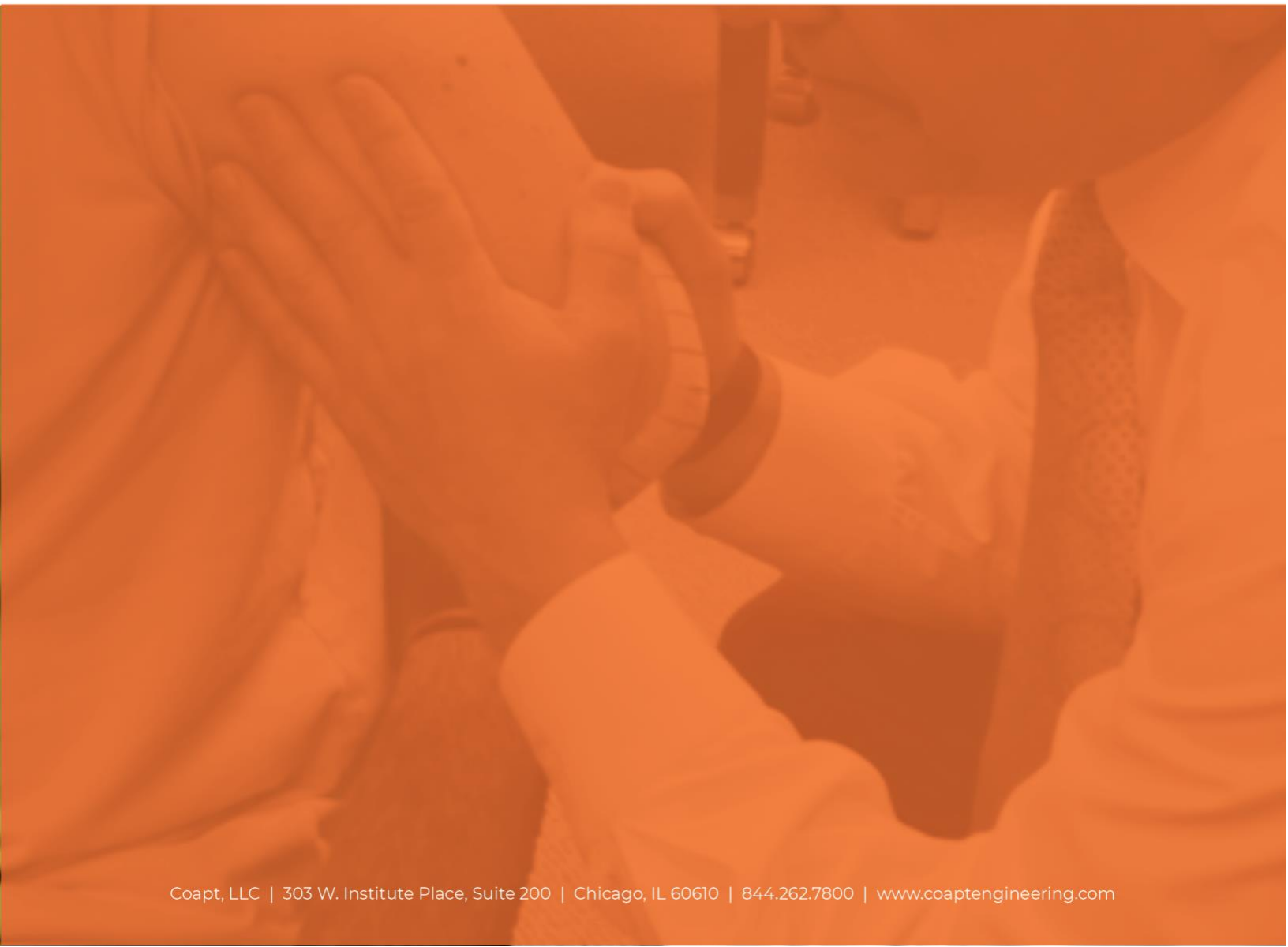
COAPT GEN2

PLANNING EMG ELECTRODE SITES FOR COAPT GEN2® PATTERN RECOGNITION



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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.

NOTE

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.

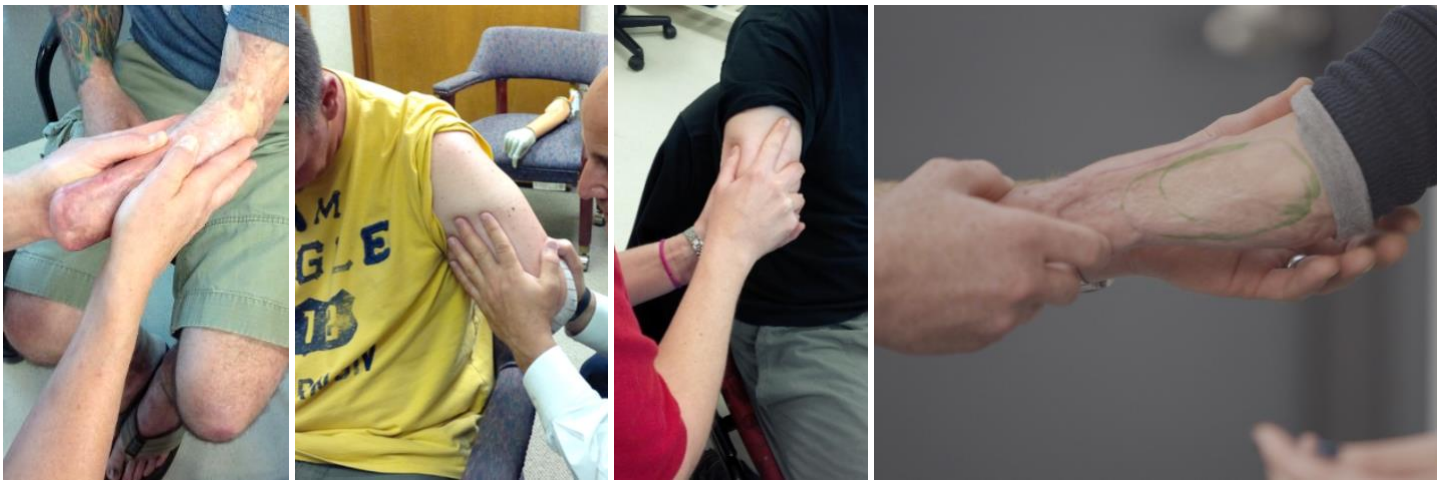
TIPS

- 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

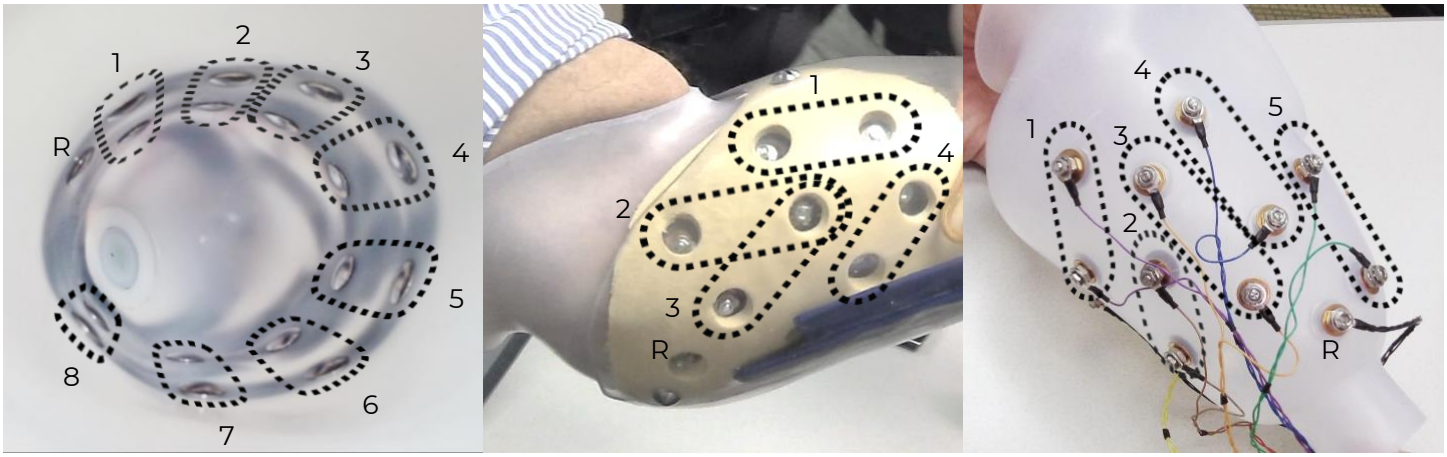
Use the areas of underlying muscle information discovered in Steps 1 and 2 to plan electrode contact locations.

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.

NOTE

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.

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

NOTICE **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

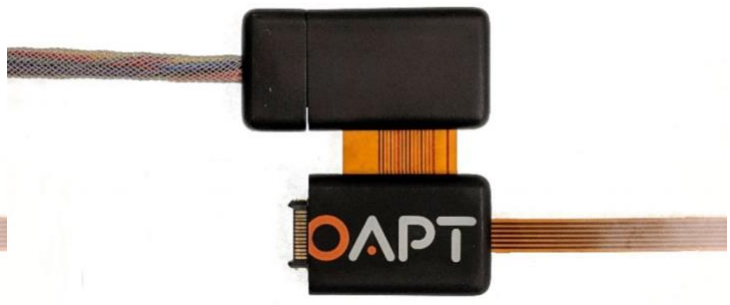
Adhesive & hardware use. Use of mounting hardware drilled or screwed into the **Complete Calibrate** button housing could damage the device. Never use mounting hardware drilled or screwed into the **Complete Calibrate** button housing. Use of adhesives common in prostheses' fabrication is acceptable 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**.

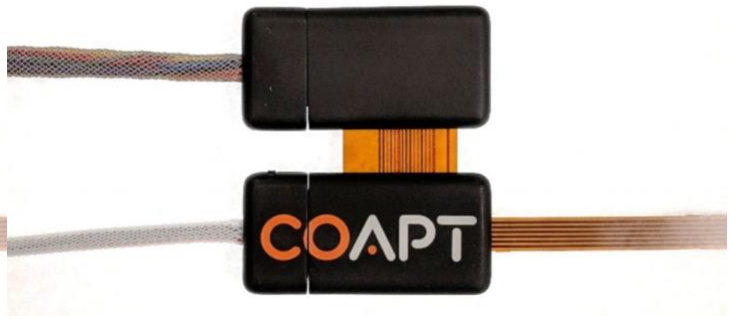


Device Interface Cable Connections

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 **Complete ControlRoom** software app or **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

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