COAPT
COMPLETE CONTROL

COMPLETE CONTROL Handbook

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

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1 User Assistance & Safety

1.1 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, including videos, about connecting and using the COMPLETE CONTROL system can be found online at **coaptengineering.com**.

1.2 Symbol Definitions

The following definitions pertain to all symbols used on device labels and in this handbook.

SYMBOL	DEFINITION
⚠WARNING	**This symbol accompanies a warning regarding possible risk of severe accidents or injury.**
⚠ CAUTION	**This symbol accompanies a warning regarding possible risks of accident or injury.**
NOTICE	**This symbol accompanies a warning regarding possible damage to product or equipment.**
	**This symbols advises the device operator to consult the accompanying documents (e.g., this handbook) prior to use.**
	**This symbols is used as a voluntary visual indication that the marked device complies with all applicable FCC requirements.**
	**This symbol for non-ionizing radiation indicates that the device includes an RF transmitter or applies RF electromagnetic energy.**
Rx Only	**This symbol indicates that Federal law restricts the device to sale by or on the order of a physician.**

1.3 General Warnings and Precautions

For your safety and to prevent damage to your COMPLETE CONTROL system and 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 your warranty.

⚠ CAUTION **Read and follow safety instructions.** Read this entire manual before operating your COMPLETE CONTROL system. Failure to do so could result in suboptimal system performance or injury to you, 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 you have been 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 your device while it is charging (i.e., connected to an A.C Mains supply) unless you have been 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 your 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.

2 System Overview

2.1 Purpose of the Device

The COMPLETE CONTROL system is an advanced control solution designed to enhance the functionality of a powered upper limb prosthesis. COMPLETE CONTROL employs *pattern recognition* technology to revolutionize the way muscle 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 recalibration. COMPLETE CONTROL simplifies electrode placement and allows prosthetists to spend less time adjusting system settings and configurations.

The COMPLETE CONTROL system 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 section 2.7 Compatible Devices). COMPLETE CONTROL does not require an additional battery.

2.2 Indications for Use

The COAPT COMPLETE CONTROL system is to be used exclusively for external prosthetic fittings of the upper limbs.

2.3 Contraindications

None known.

2.4 Limitations

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

2.5 Intended Use

The COMPLETE CONTROL system is suitable for unilateral or bilateral amputations starting with the transradial or transhumeral amputation level or, in the case of congenital limb deficiency (dysmelia), for forearm or upper arm fittings.

Candidates for the COMPLETE CONTROL system include prosthesis users who desire intuitive control, users of multiple–degree of freedom (DOF) prosthetic arms, users with poor myosite isolation, users with weak or unbalanced myosignals, and users with mode switching challenges.

2.6 Description of the Device

The COMPLETE CONTROL system is an embedded system that is used in conjunction with an upper-limb prosthetic device. Prosthetic device may include a combination of a supported elbow, wrist, hand or terminal devices (see section 2.7 Compatible Devices). It contains several modules, one for processing surface EMG signals (CO-AMP), one for processing and translating prosthesis commands (CONTROLLER), one to initiate the controller training routine (CALIBRATE), and

one to permit wireless connection of the system (COMMUNICATOR) to user interface software (CONTROLROOM) for diagnostics and provisioning.

The COMPLETE CONTROL system contains the following components.

1. Device Interface Cable (clinician-specified termination type)
2. COMPLETE CONTROLLER main processor
3. COMPLETE CALIBRATE user interface button
4. COMPLETE CO-AMP consolidated EMG amplifier
5. EMG Interface Cable
6. Fabrication aids for the COMPLETE CONTROLER, COMPLETE CO-AMP, and COMPLETE CALIBRATE
7. Socket cut-out template for the COMPLETE CALIBRATE button
8. COMPLETE COMMUNICATOR USB dongle
9. COMPLETE CONTROLROOM software installation USB dongle

2.7 Compatible Devices

2.7.1 Electrodes

The COMPLETE CONTROL system can be used with commercially available non-filtering EMG electrode contacts from several prosthetics manufacturers. Coapt recommends the use of simple stainless steel electrode domes as contacts. Examples of commercially available electrode domes include the following:

- Remote Electrode (Single) from Motion Control, Inc. (part number 1070001)
- Small Dome Metal Electrodes' Kit (3) from Liberating Technologies, Inc. (part number EL13)
- High, Medium, or Small Dome Metal Electrodes from RSLSteeper (kit of 6; part numbers NEL11, NEL12, and NEL13).
- Gold-plated electrode domes sold with various configurations of the Remote Electrode Kit from Touch Bionics (part numbers PL441012, PL069466, PL06947, PL069468, and PL069469)

Please contact your Coapt representative if you have questions about compatible electrodes.

⚠ 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 that electrode contacts are made of biocompatible material and do not cause an allergic reaction.

2.7.2 Prosthetic Devices

The COMPLETE CONTROL system was designed to operate seamlessly with major manufacturers' prosthetic devices, including the following:

Elbow

- DynamicArm Plus (Ottobock)
- DynamicArm* (Ottobock)
- ErgoArm Hybrid plus (Ottobock)
- ErgoArm Electronic plus (Ottobock)
- AxonArm Hybrid (Ottobock)
- AxonArm Ergo (Ottobock)
- Utah Arm 3+ ("Coapt Ready" version; Motion Control)
- Utah Hybrid Arm (Motion Control)
- Motion E2 Elbow (Motion Control)
- Boston Digital Arm (LTI)
- LUKE arm (Mobius Bionics)

*may require special battery considerations

Wrist

- Electric Wrist Rotator with or without MyoRotronic (Ottobock)
- AxonRotation (Ottobock)
- MC Standard Wrist Rotator (Motion Control)
- ProWrist (Motion Control)
- LUKE arm (Mobius Bionics)

Terminal Device

- SensorHand Speed (Ottobock)
- VariPlus Speed (Ottobock)
- System Electric (Ottobock)
- Electric Greifer (Ottobock)
- Michelangelo Hand (Ottobock)
- AxonHook (Ottobock)
- ProHand (Motion Control)
- ProETD/ETD2 (Motion Control)
- i-limb (Ossur)
- bebionic (Ottobock)
- TASKA (Taska)
- VINCENTevolution 2 (Vincent)
- LUKE arm (Mobius Bionics)

Contact your Coapt representative for an up-to-date listing of all supported devices.

2.8 Conditions for Use

The COMPLETE CONTROL system 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 that would cause excessive strain and/or shock to the prosthetic device (e.g., pushups or mountain biking).

The Coapt COMPLETE CONTROL system 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 Section 1.3 General Warnings and Precautions for more information regarding acceptable conditions for using your device.

3 Home Use Instructions

3.1 Using the System

3.1.1 Setup and Training

Only use your Coapt COMPLETE CONTROL system after it has been set up by your prosthetist. Your prosthetist will train you to properly use the COMPLETE CONTROL system and can answer any questions you may have about operating your device. You may use the following space to record notes from your sessions with your prosthetist.

SPACE FOR YOUR OWN SETUP NOTES:

3.1.2 Powering On

Each time your prosthesis is turned on, the COMPLETE CONTROL system takes about 12 seconds to start. The light on the COMPLETE CALIBRATE button will turn red, green, blue and then green again to tell you that the device is on. The device will beep when it is ready to use.

3.1.3 Calibration

The ability to conveniently calibrate or "train" the COMPLETE CONTROL system is key to successfully using its pattern recognition capabilities. The COMPLETE CONTROL system must be trained to recognize patterns of muscle signals in order to provide intuitive control. This is achieved through the calibration routine.

To calibrate control of your prosthesis, press and hold the COMPLETE CALIBRATE button for about 2 seconds until a beep is heard. This will begin the calibration routine.

The system will then perform the following calibration steps:

1. The prosthesis moves to its starting position and collects "no motion" data for approximately 8-10 seconds. You can keep your muscles relaxed.
2. The prosthesis performs each prosthesis movement two times (about 3 seconds per movement), pausing between each movement. Hold the muscle contraction that you and your prosthetist selected for each movement for the full 3 seconds and then relax between movements.
3. The prosthesis will take 5–10 seconds to performance calculations and will play a short song to tell you it is ready to use.

3.1.4 Layering Calibration

"Layering" is an additional feature of the Coapt COMPLETE CONTROL system that can enhance function and accelerate learning times. Layering refers to the process in which one to four sequential sets of calibration data are combined by the pattern recognition algorithm. Layering is beneficial in several scenarios:

- It can provide extra data to reinforce subtle EMG pattern differences. This is especially useful for users who are new to pattern recognition and whose muscle patterns are still developing differentiation.
- It can provide EMG data that corresponds to various prosthesis positions within the workspace.
- It can enhance the controllable range of proportional speed control.

Before layering is considered, the user and prosthetist should be very familiar with the concept of calibration and ensure that (1) electrode contact is reliable, (2) calibration contractions are performed and held synchronously with the movement prompts (i.e. no delays) and, (3) calibration muscle contractions have been selected and differentiation is understood.

Method:

1. Press and hold the COMPLETE CALIBRATE button for 2 seconds until a single beep is heard. This will begin a new calibration sequence. Any previous calibration data will be erased and the calibration prompts will be provided in the expected order.
2. After the first calibration, press and hold the COMPLETE CALIBRATE button. After 2 seconds a single beep will sound. Continue holding the calibration button for 2 additional seconds and then release when two sequential beeps are heard. This indicates that the system will add the upcoming data to the data from the previous calibration, resulting in two data sets. The calibration prompts will commence and be presented in the expected order. This calibration sequence is a good opportunity to provide contraction data corresponding to any desired control enhancements, including:
    - Similar contractions to the previous set in order to enhance EMG control patterns;
    - Contractions performed with the prosthesis in a different position or with different loading in order to incorporate various positional data;
    - Contractions of different intensities than the previous set in order to enhance the range of proportional speed control;
    - Contractions of slightly different character than the previous set in order to enhance control flexibility
3. To incorporate three calibrations, press and hold the COMPLETE CALIBRATE button while one beep, then two additional beeps, and finally three additional beeps are heard (approximately 6 seconds). The three beeps indicate that the system will incorporate three calibration datasets: the two most recently stored and the one about to be acquired.

The calibration prompts will commence and be presented in the expected order. As above, use this opportunity to provide contraction data corresponding to any desired enhancements.

4. To incorporate four calibrations, press and hold the COMPLETE CALIBRATE button while one beep, then two additional beeps, then three additional beeps, and finally four additional beeps are heard (approximately 8 seconds). This indicates that the system will incorporate four calibration datasets: the three most recently stored and the one about to be acquired. The calibration prompts will commence and be presented in the expected order. As above, use this opportunity to provide contraction data corresponding to any desired enhancements.
5. To cancel a calibrating sequence and prevent the system from erasing any data, press and hold the COMPLETE CALIBRATE button for 2 seconds beyond the four beeps, until one long beep is heard (approximately 10 seconds). This indicates no calibration process will be performed and the button can be released.

Notes:

- Calibration layering is only available via the physical calibration button.
- The maximum number of layers is four.
- Any time calibration is performed after a single beep, the previous data (including any previous layering) will be erased and replaced with the upcoming calibration data.
- The majority of Coapt users do quite well with only a single calibration as they learn how to perform the calibration process. Users seem to improve with the single calibration as they learn the process and their EMG patterns develop. If layering is employed, please note that it may not always be necessary as experience and practice progress.

3.1.5 TROUBLESHOOTING

Please call your prosthetist if you are having trouble with your device. You may also refer to Section 6 Troubleshooting.

4 Clinician Guide

4.1 Pattern Recognition Introduction

WHAT IS PATTERN RECOGNITION?

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

HOW IS PATTERN RECOGNITION AN IMPROVEMENT OVER STANDARD MYOELECTRIC PROSTHESIS CONTROL?

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

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

- *Control motions are intuitive* – With standard myoelectric control, users are often required to make non-intuitive contractions to command prosthesis actions. A good example of this is using wrist extension and flexion contractions to command a prosthetic hand to open and close. With pattern recognition, natural intuitive control is possible: hand open and close contractions will control the prosthetic hand, and wrist contractions will control the prosthetic wrist.
- *Mode switching is eliminated* – With standard myoelectric control, muscle control sites are limited because of the need for signal isolation. This typically means fewer control sites are available than the desired prosthesis functions and users have to use "switches" to cycle between prosthesis functions. Examples include using co-contractions of two control signals to toggle between hand and wrist control or a physical/electrical switch that the user must activate with another movement of their body. With pattern recognition, users can directly control each of their prosthesis's motions without cumbersome and non-intuitive switching.
- *Strong muscle contractions are not required* – Pattern recognition has the advantage of being able to utilize low intensity muscle contractions as needed. This is beneficial for standard myoelectric control users who were required to elicit strong control contractions that tire them out quickly.
- *Enhanced proportional control* – Because of the difficulty of isolating control sites with standard myoelectric control, much of a user's ability to modulate the intensity of their prosthesis's motor speed is often tuned out of the system. With pattern recognition, the system can take full advantage of the user's ability and relates a wide range of the muscle contraction intensities to prosthesis speeds.
- *Simplified electrode placement* – With pattern recognition, there is much less need to search for, or precisely place control site electrodes over exact muscle locations. This means that less time is spent myotesting for isolated signals; clinicians have freedom to place electrodes in socket areas that promote fit and comfort; clinicians can use sockets/liners that may be positioned differently upon each donning; the system is forgiving of changes due to muscle fatigue; and many other benefits. With less time spent in the clinic searching for the muscle control sites, time available for in-clinic functional practice with the prosthesis is increased – thus helping users accept their prosthesis for increased at-home use.
- *Powerful recalibration* – With standard myoelectric control, changes in socket fit, user skin condition, fatigue, mental state, battery health, and many other factors can diminish the user's function with their prosthesis. For many of these issues a repair visit or call to a prosthetist is necessary, often resulting in time-consuming prosthesis adjustments and software resetting. With pattern recognition, the control can adapt to changing conditions (such as those listed above and many more) by means of re-calibration that the user can do quickly and efficiently as needed – without travel and time with their clinician.

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

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

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

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

PRACTICING PATTERN RECOGNITION CONTROL

- No need for extra-hard muscle contractions. Contraction levels should be moderate – similar to a comfortable handshake.
- Start slow and encourage patience. This new method of control can take a little time and practice to get used to.
- Control is not position-based. Example: if a hand is commanded to close (and it does) and the user then wishes to turn the wrist, they do not need to "hold" their hand closed while rotating their wrist, as each motion is a separate activity.
- If control becomes erratic, ask the user to relax, close their eyes, and think back to the "feeling" of all of their motions. The system doesn't forget the patterns it was most recently calibrated with, so perhaps the user has changed the way they are performing muscle contractions.

SUCCESSFUL USE OF PATTERN RECOGNITION CONTROL RELIES ON TWO PRIORITIES:

1. Placing electrodes at locations that make reliable contact with the skin.
2. Good understanding of the concept of *pattern recognition* by the user and the practitioner.

4.2 Myotesting and Electrode Placement for Pattern Recognition

This section describes a proven in-clinic approach to myotesting and electrode contact placement for pattern recognition users. Because pattern recognition utilizes the full information contained in a large number of EMG signals (as opposed to traditional myoelectric control schemes which rely on comparative amplitude information from singular EMG signals), the COMPLETE CONTROL pattern recognition system does not utilize industry standard electrode amplifiers; instead, passive electrode contacts are strategically placed throughout the prosthesis-skin interface. The following guidelines describe how this is accomplished.

4.2.1 Step 1: Discussion

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

The **GOALS** of the Discussion are to determine what muscle contractions (motions) the user feels

1. are intuitive to use for prosthesis control.
2. can be performed consistently.
3. are unique for each intended prosthesis action.

TIPS:

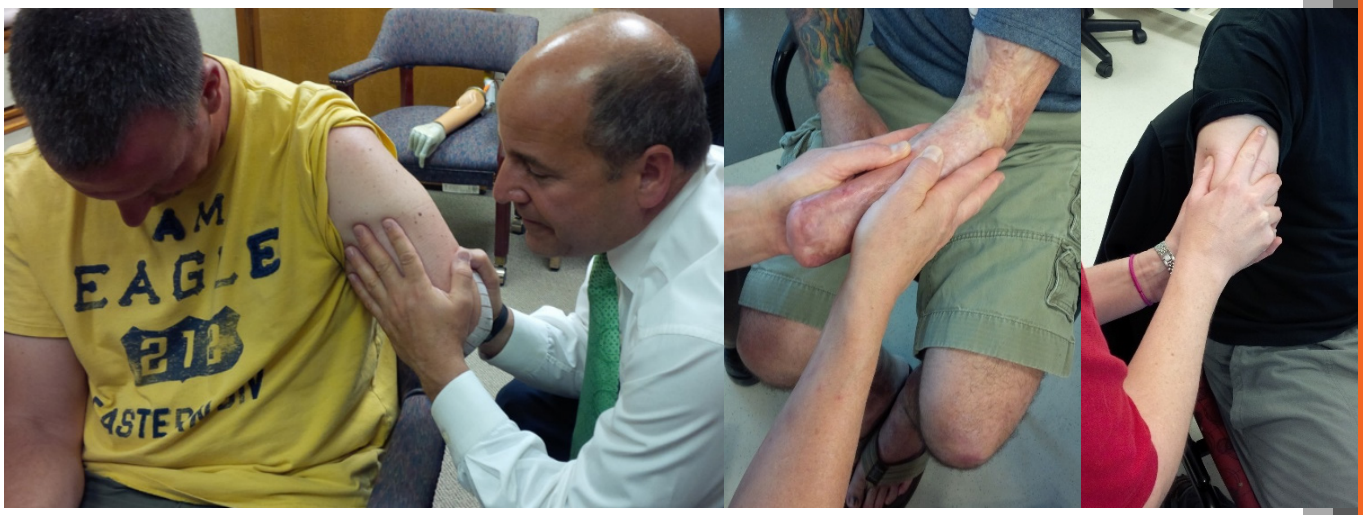
- Lead the discussion.
- Demonstrate motions you would like the user to attempt.
- Ask questions such as:
  - "Can you feel your hand? Which fingers can you feel you can move?"
  - "Can you imagine making a fist? What about opening your hand with your fingers spread apart?"
  - "Does it feel like your hand is squeezing down on something?"
  - "Do you feel like you can turn your wrist? Does your hand stay relaxed?"
  - "Does your thumb move? How far? Which direction?"
  - … and so on. Remember, the goal is to learn, together, what might be available for control.
- Discuss one movement group at a time; i.e. discuss and practice hand open/close before moving on to wrist motions.
- Encourage the user to mirror their perceived motions with their sound limb if possible.
- Begin discussing the most intuitive motions and add variations as needed; i.e. try natural hand close for "hand close" and if the user has poor perception of hand close but good perception of one specific finger (for example), try practicing the use of that finger perception for "hand close." In another example, if wrist rotation is difficult for the user to perceive, discuss if they can perceive thumb or pinky finger ab/adduction to accentuate rotation.
- Focus on motions that are distinct and repeatable.
- Take your time with this process.
- Be patient and listen to the user.
- Perform this discussion in a relaxed environment.
- Generate a common vocabulary for motions.
- Incorporate the discussed and practiced motions into a home exercise program for pre-prosthetic control.

4.2.2 Step 2: Palpation

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

The **GOALS** of Palpation are to

1. feel for all "areas of interest" corresponding to underlying muscle activity related to the control motions.
2. note/remember these "areas of interest" as good locations to place electrode contacts.



TIPS:

- Grasp and cover as much of the user's limb as possible with both of your hands.
- Do not only use your fingertips to feel.
- Have the user perform all of the useful motions discovered during the Discussion phase.
  - Encourage the user to make medium, comfortable-intensity contractions.
  - Have the user hold each contraction for about 3 seconds and relax between each.
- Feel for the overall muscle activity – similar to what the pattern recognition algorithm does – by sensing the patterns of activity at multiple areas simultaneously.
- Do not only locate areas of strong, isolated contractions; instead sense all "areas of interest".
- Do not ignore areas of slight/subtle/weak underlying muscle contraction.
- Note any unique and unexpected areas of underlying muscle contraction.
  - For transhumeral amputees this may mean unique muscle activity distal on the residual limb.
- If the user is tensing all of their muscles quite hard for all of their motions, ask them to make their contractions a little more softly.
- Make temporary markings on user's residual limb to help remember areas of activity.
- Take your time with this process.
- Be patient and listen to the user.
- Perform this exercise in a relaxed environment.

4.2.3 Step 3: Positioning Electrode Contacts

If the Discussion and Palpation phases have been performed with care, the majority of the information required to locate the electrode contacts will have been acquired. Discussion helped to identify the intended control contractions of the user and Palpation was used to locate the corresponding areas of underlying muscle activity on the residual limb. The placement of pattern recognition electrode contacts should now be planned to capture all of this muscle contraction information.

The **GOALS** of positioning electrode contacts are to

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

TIPS:

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

The COMPLETE CONTROL system utilizes eight EMG signals and each signal requires two passive electrode contacts. These 16 contact points, plus one more for a system-wide reference/ground signal are the 17 contacts that need to be placed. Each pair of electrode contacts that make up one EMG signal pick up an oval-shaped area of muscle signal centered with the two contacts. The closer the two contacts are to each other, the smaller the area of detected EMG.

TIPS:

- SPACING: It is acceptable to position the two electrode contacts for any one EMG channel 30–60 mm apart.

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

- MUSCLE FIBER DIRECTION: It is acceptable to place some of the EMG channels off-axis from the underlying muscle fiber direction.

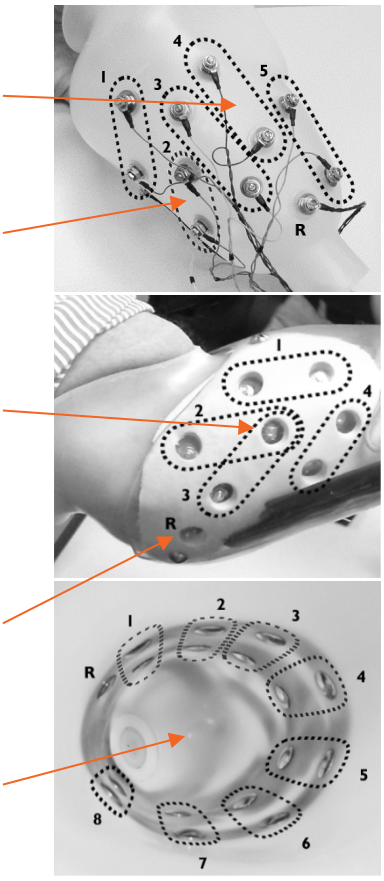
  This is helpful when fitting a residual limb with unique areas of EMG interest, common for Targeted Muscle Reinnervation patients. This can also be useful for geometrically unique and congenital residual limbs.

- CONTACT SHARING: It is acceptable to have a few of the EMG channels share an electrode contact. Ensure that the two wires for the same EMG channel (common color wires) are NOT sharing a single electrode contact.

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

- SINGLE REFERENCE: The COMPLETE CONTROL system requires a single electrode contact for purposes of EMG reference/ground. This contact should not be shared with any other EMG signal wires. The reference contact should be positioned in a location that maintains excellent electrode-skin contact.

- GENERAL SYMMETRIC DISTRIBUTION: It is acceptable in some cases to position electrode contacts in a symmetrical arrangement. This is common for transhumeral Targeted Muscle Reinnervation patients and some transradial patients.



4.3 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 that 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 that 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.

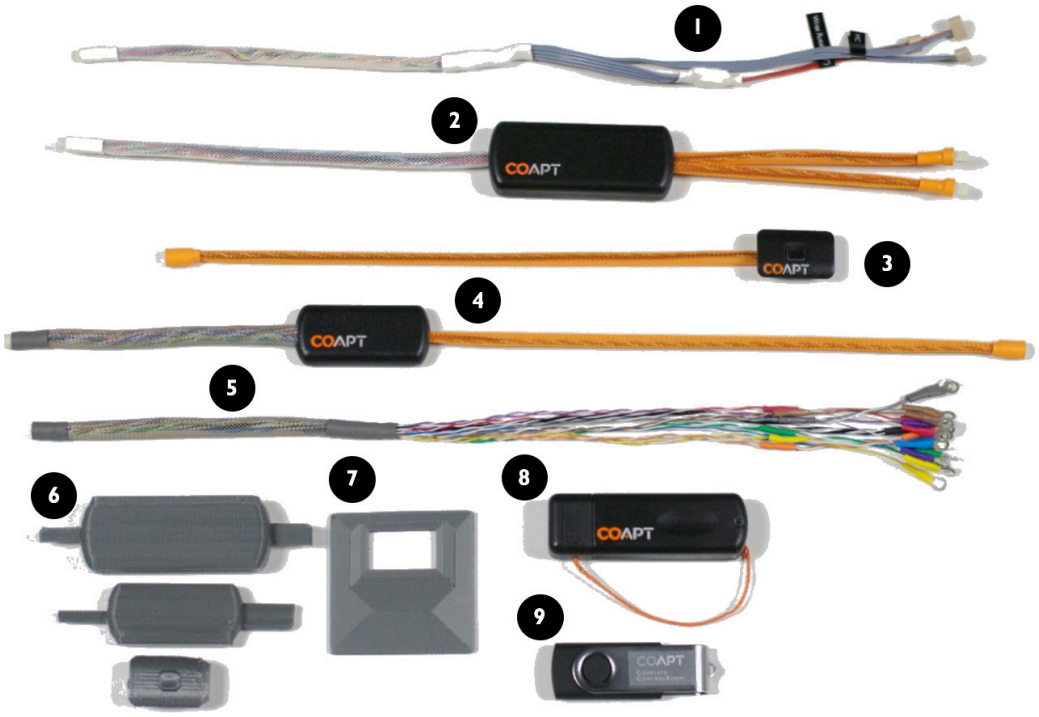
⚠ CAUTION **Use of sharp objects during fabrication**. Use caution when using sharp objects (e.g., scissors, blades) during fabrication. Damage to or severing of connection cables could cause device damage, device malfunction, and minor injury to the user.

⚠ CAUTION **Installation in material prone to static buildup.** Do not install device in socket material that is 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.

4.4 Component Descriptions & Placement

4.4.1 In the COMPLETE CONTROL Kit

1. Device Interface Cable (clinician-specified termination type)
2. COMPLETE CONTROLLER main processor
3. COMPLETE CALIBRATE user interface button
4. COMPLETE CO-AMP consolidated EMG amplifier
5. EMG Interface Cable
6. Fabrication aids for the COMPLETE CONTROLLER, COMPLETE CO-AMP, and COMPLETE CALIBRATE
7. Socket cut-out template for the COMPLETE CALIBRATE button
8. COMPLETE COMMUNICATOR USB dongle
9. COMPLETE CONTROLROOM software installation USB dongle



4.4.2 COMPLETE CONTROLLER Unit

The COMPLETE CONTROLLER is the central brain of the system – where the pattern recognition computation happens. This unit houses a tiny, powerful computer and should be handled with as much care as reasonably expected in a prosthetic fabrication environment.

Placement of the COMPLETE CONTROLLER:

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 contains sensitive electronics and can be damaged by exposure to excessive sweat or water.

A fabrication aid is provided with your kit and can be used in fabrication mock-ups.

Connections of the COMPLETE CONTROLLER:

Throughout the system, color-coded cables indicate cable pairings; like colors should be connected together. As a result, the WHITE cable should be connected to the corresponding WHITE cable that is attached to the prosthesis's inputs.

Connect the pair of ORANGE cables to the corresponding ORANGE cables of the COMPLETE CALIBRATE and COMPLETE CO-AMP. Both ORANGE cables are identical and it does not matter which is connected to the COMPLETE CALIBRATE and COMPLETE CO-AMP.

4.4.3 COMPLETE CO-AMP CONSOLIDATED EMG UNIT

The COMPLETE CO-AMP is a high-quality, consolidated EMG collection system. It is responsible for amplification, filtering, and digitization of up to eight EMG channels. This unit should be handled with as much care as reasonably expected in a prosthetic fabrication environment.

Placement of the COMPLETE CO-AMP:

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

The COMPLETE CO-AMP contains sensitive electronics and can be damaged by exposure to excessive sweat or water.

A fabrication aid is provided with your kit and can be used in fabrication mock-ups.

Connections to the COMPLETE CO-AMP:

The ORANGE cable should be connected to one of the two ORANGE cables coming out of the COMPLETE CONTROLLER.

The GRAY cable should be connected to a corresponding GRAY cable that is connected to electrode-skin contacts.

4.4.4 COMPLETE CALIBRATE BUTTON

The COMPLETE CALIBRATE button gives the power and convenience of system calibration to the user. It is a small, simple button that should be fabricated in the outer socket wall in a place where the user can easily access it. The unit has one central button that is used to initiate the calibration process. This button is NOT a prosthesis power on/off button.

The COMPLETE CALIBRATE button contains sensitive electronics and can be damaged by exposure to excessive sweat or water.

A fabrication aid is provided with your kit and can be used in fabrication mock-ups.

Connection to the COMPLETE CALIBRATE:

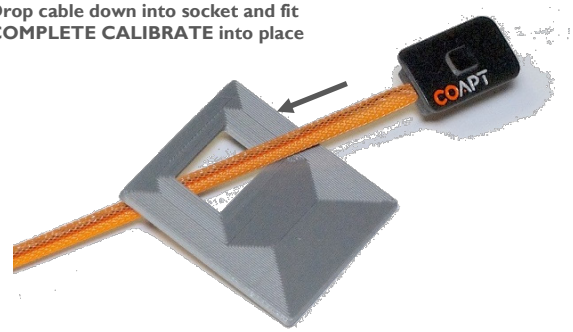
The ORANGE cable should be connected to one of the two ORANGE cables coming out of the COMPLETE CONTROLLER.

Socket Cut-out

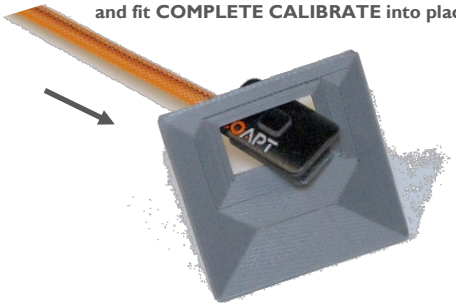
To aid in fabrication planning for the COMPLETE CALIBRATE button, a cut-out template is provided as part of the COMPLETE CONTROL kit. Simply use this to mark the required cut-out hole on the socket wall. If use of the template is not desired, please mark a hole that is 14 mm x 24 mm.

The COMPLETE CALIBRATE button fits through its mounting hole when turned on its side. That way it can be mounted from either the face side of the socket wall or the underside of the socket as shown here:

Drop cable down into socket and fit COMPLETE CALIBRATE into place



Pass unit from inside socket to outside, turn and fit COMPLETE CALIBRATE into place



⚠ CAUTION **Adhesive & hardware use.** Use of excessive adhesive or mounting hardware drilled or screwed into the COMPLETE CALIBRATE housing could damage the device. Use caution not to let adhesive surround the button center when securing the button flanges to the socket. Never use mounting hardware drilled or screwed into the COMPLETE CALIBRATE housing.

The COMPLETE CALIBRATE button unit will protrude about 5 mm (0.20 in) below a typical thickness socket. Please plan accordingly for nearby component clearance.

4.5 Connecting the System

The COMPLETE CONTROL system does not require any component assembly but all the system cables must be connected together for proper use. For your convenience, all cables are color matched with their counterparts. The cables' connectors are also matched and are unique for each color; no connectors are capable of being joined in error.

⚠ CAUTION **Foreign material in cable interconnects.** Ensure that 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.

4.5.1 Connecting for EMG

The EMG connections of the system are GRAY:

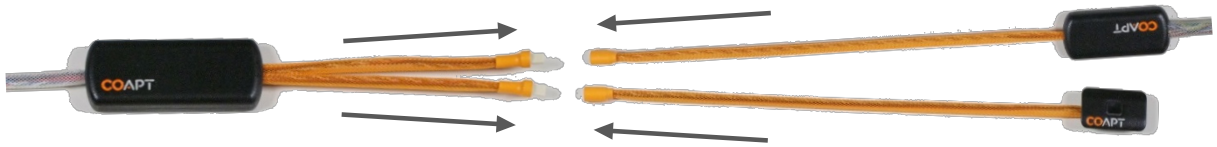
Connect the gray EMG cable to the gray cable of the COMPLETE CO-AMP unit.

The EMG cable is terminated with ring terminals ("eyelets") that connect easily to third-party remote electrode domes (see section 2.4.2). Contact your Coapt representative for up-to-date information on EMG termination options.

4.5.2 Connecting System Components

The digital connections of the system are ORANGE:

Connect one orange cable of the COMPLETE CONTROLLER to the orange cable of the COMPLETE CO-AMP unit. Connect the second orange cable of the COMPLETE CONTROLLER to the orange cable of the COMPLETE CALIBRATE unit. It does not matter which of the orange cables from the COMPLETE CONTROLLER connects to each device.

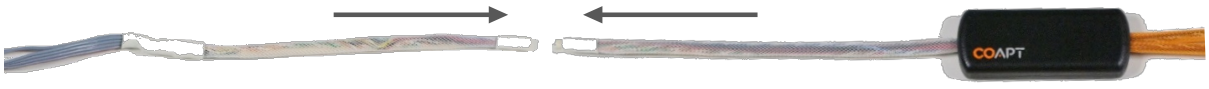


4.5.3 Connecting Prosthetic Devices

⚠ CAUTION **Use with correct prosthetic components.** Make sure that 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 that 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-side connections of the system are WHITE:

Connect the white Device Interface cable that is terminated by the types of connectors specific to the prosthetic device(s) connections to the white cable of the COMPLETE CONTROLLER.



4.5.4 Connecting Power

The white Device Interface cable (see section 4.5.3.) 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 your Coapt representative.

4.6 Other Manufacturer's Device Settings

The pattern recognition algorithms of the COMPLETE CONTROLLER have the ability to automatically adjust the device's control settings (e.g. gain, boost, dynamic range, etc.). Therefore, in order to get the most from your COMPLETE CONTROL system, it is suggested that the settings for each of the connected prosthetic devices be set once and then generally ignored. Contact your Coapt representative for suggested settings for each of the connected devices.

4.7 More Information

Additional information, including videos, about connecting and using the COMPLETE CONTROL system can be found online at **coaptengineering.com**.

5 Software Instructions

5.1 Overview

Your COMPLETE CONTROL system is accompanied by an easy-to-use clinician's software tool that can be installed on most Windows PCs. The software system is intended for use in the clinic by a trained professional. The COMPLETE CONTROLROOM software suite helps to guide the in-clinic process of getting the most from pattern recognition. COMPLETE CONTROLROOM provides five basic environments that provide the access and control that you need.

We recommend that you install COMPLETE CONTROLROOM on a PC computer with at least a 1 GHz processor, 2GB of RAM, DirectX 9 graphics support, and Windows 7 or later.

5.2 Installation

Installing the Software Using the COMPLETE CONTROLROOM Installer USB

1. Connect the COMPLETE CONTROLROOM Installer USB flash drive to an available USB port on your PC.
2. Browse to the files of the COMPLETE CONTROLROOM Installer USB flash drive and double-click on the "Complete ControlRoom Installer" application.
3. Follow the install wizard directions. On the final screen, ensure "Launch the program" is checked and press Finish.
4. Follow the on-screen instructions for setting up the COMPLETE COMMUNICATOR wireless communication dongle.
5. Click on the desktop icon  to use the COMPLETE CONTROLROOM software as needed. Note that the COMPLETE CONTROLROOM software should be launched within 10-20 seconds of powering on the prosthetic system that has the COMPLETE CONTROLLER fully connected.

Installing the Software via the Internet

1. Visit the Resources section at **coaptengineering.com** and click on the Software Download link to save the installer application file to your computer.
2. Navigate to the downloaded "Complete ControlRoom Installer" application and double-click to begin.
3. Follow the install wizard directions. On the final screen, ensure "Launch the program" is checked and press Finish.
4. Follow the on-screen instructions on setting up the COMPLETE COMMUNICATOR wireless communication dongle.
5. Click on the desktop icon  to use the COMPLETE CONTROLROOM software as needed. Note that the COMPLETE CONTROLROOM software should be launched within 10-20 seconds of powering on the prosthetic system that has the COMPLETE CONTROLLER fully connected.

Manual COMPLETE COMMUNICATOR Setup

NOTICE If the steps above were completed, it should not be necessary to perform the remainder of activities in this section. Only continue for manual setup of COMPLETE COMMUNICATOR device if necessary.

COMPLETE CONTROLROOM is only used to communicate with a user's COMPLETE CONTROLLER device. Wireless communication is directed between the PC and the COMPLETE COMUNICATOR USB dongle. To setup this wireless communication manually, follow these steps:

Using the setup application:

1. Navigate to your PC's Start Menu and select All Programs
2. In the programs list, find and expand the "Coapt" folder
3. Click "Setup Complete Control System"
4. Follow the on-screen instructions on setting up the COMPLETE COMMUNICATOR radio communication dongle

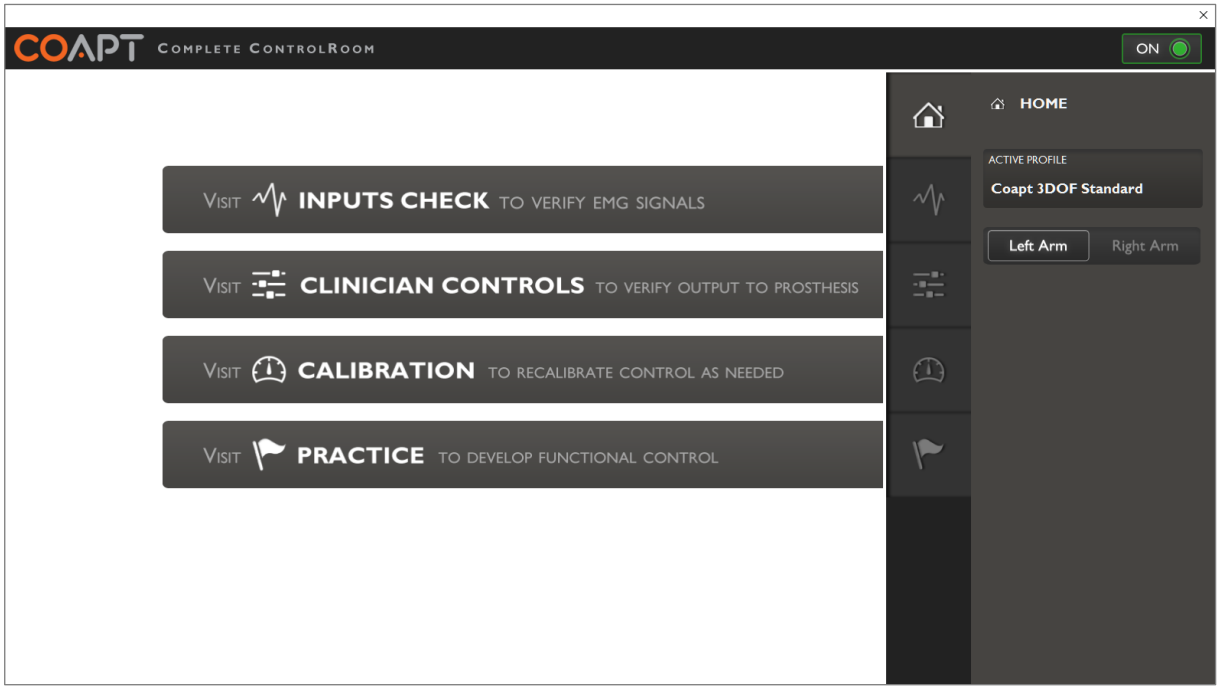
5.3 COMPLETE CONTROLROOM ENVIRONMENTS

5.3.1 HOME

The first environment that is presented provides a section that serves as the home screen for the session. Here, the automatically detected user/device profile is indicated (in the near top right) once it is loaded.

Right vs. Left arm can be set for the session. This selection is saved in the selected user profile when changed.

Launch tabs shown in the main screen area help guide you to the other four COMPLETE CONTROLROOM environments.



5.3.2 Inputs Check

The Inputs Check environment is provided as a quick and simple means to verify that all electrode connections and information is healthy. Each signal line represents one of eight EMG channels. The on-screen colors correspond to the EMG wire colors in the user's socket.

Clicking anywhere on the EMG signals display or on the lower left play button will pause/play the scrolling EMG.

Each signal can be adjusted in size according to the contraction strength of the user. The Signal Control slider for each channel will effectively increase or decrease the corresponding signal's viewable range.

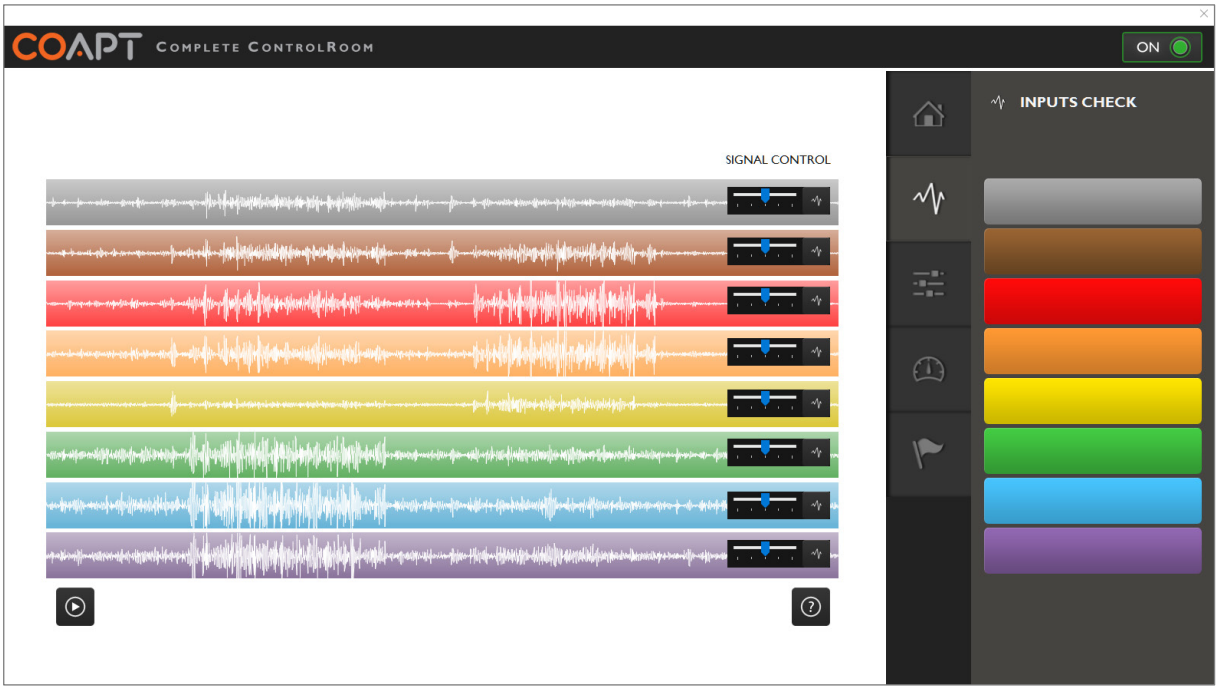
Problematic EMG channels can be eliminated from the system by toggling the signal deactivate button. Deactivated signals will be greyed out. To re-active a deactivated signal, toggle the same button. IMPORTANT: To apply this change, visit the Calibration environment and calibrate the control by clicking the on-screen "Calibrate" button.

The Real Time Signals Check feature (patent pending) is an automated, always-running, signal-testing routine aimed at helping the clinician locate and solve electrode contact and EMG signal quality issues. Any channel exhibiting an issue will have a cautionary message automatically presented over the corresponding signal color in the right panel. For example, if the green channel has a high signal, it will recommend that the clinician lower the corresponding slider.

Similarly, if the green channel is not making contact with the user's skin, it will recommend that the issue be addressed.

Once all electrode contacts are making reliable contact with the user's skin and signal sizes are adjusted properly, any cautionary messages will fade away, leaving the tiles in the right side of the software blank – as seen below.

The Clinician Assistant can be invoked by pressing the info button on the lower right. This feature provides clinical support by guiding the user through an EMG data submission process.



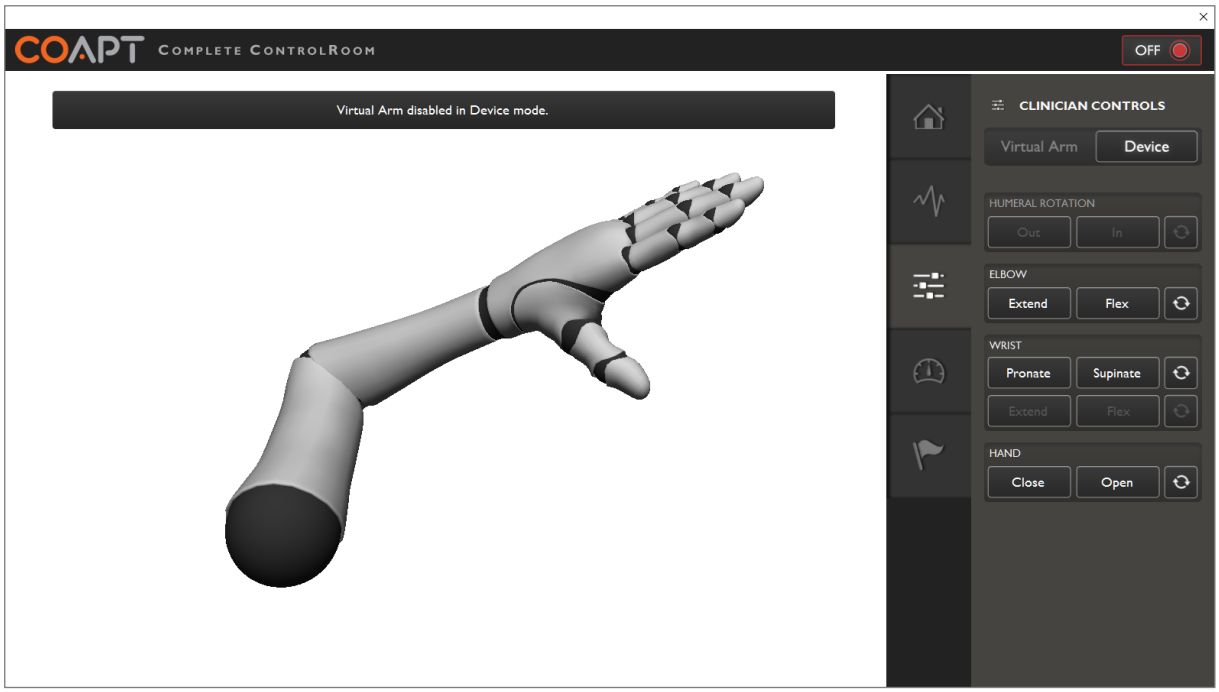
5.3.3 Clinician Controls

The Clinician Controls environment is provided to help test the connected prosthetic device(s)'s operation. Each active degree of freedom (DOF) is represented by buttons for each of its actions. When pressed and held, these buttons command the corresponding prosthetic action to move at constant speed until the left mouse button is released. If a button is pressed, and the corresponding prosthetic movement is not observed, check the output connections and the health/power of the prosthetic device.

If a prosthetic device operates in the reverse motion of the pressed button (example: the wrist pronates when the supinate button is pressed), use the reverse-direction button to correct the output.

In the Clinician Controls environment, the Virtual Arm may also be selected for manual control. This can be useful to help demonstrate to a user what each virtual motion will look like on screen.

IMPORTANT: User control of the physical prosthesis is temporarily suspended while in the Clinician Controls environment; control is only generated by use of the Clinician Controls action buttons.



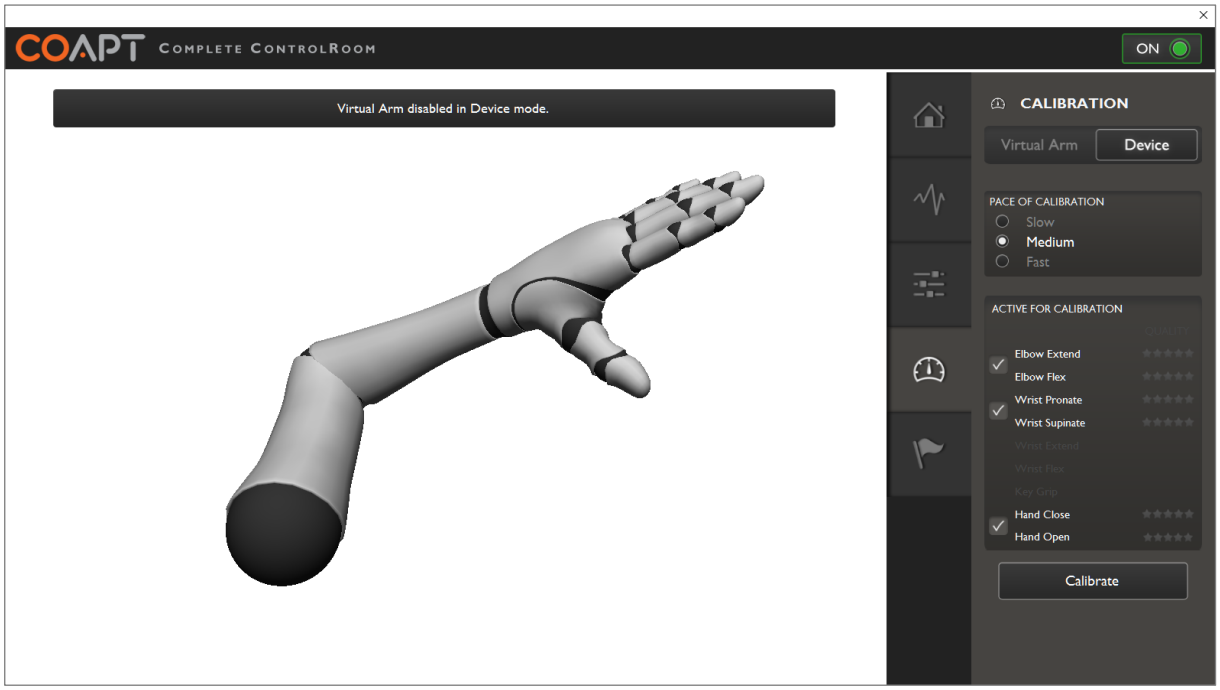
5.3.4 CALIBRATION

The COMPLETE CONTROLROOM Calibration environment has several aids for COMPLETE CONTROL calibration, including:

- On-screen (Virtual Arm) option for recalibration.
- A user-experience setting (beginner, intermediate, experienced) that will alter the pace of the recalibration prompts.
- The ability to calibrate selected DOFs, which allows the user to focus on problematic areas. This is helpful when users are new to the concept of calibration. A user can select/deselect a DOF group by toggling the associated checkbox(es) ☑.
- Calibration quality for each DOF – provides tips to help the user sort out problematic DOFs.

The on-screen calibrate button [Calibrate] will initiate the control calibration routine. When the text in this button glows orange, calibration is required in order to apply a system setting that was changed.

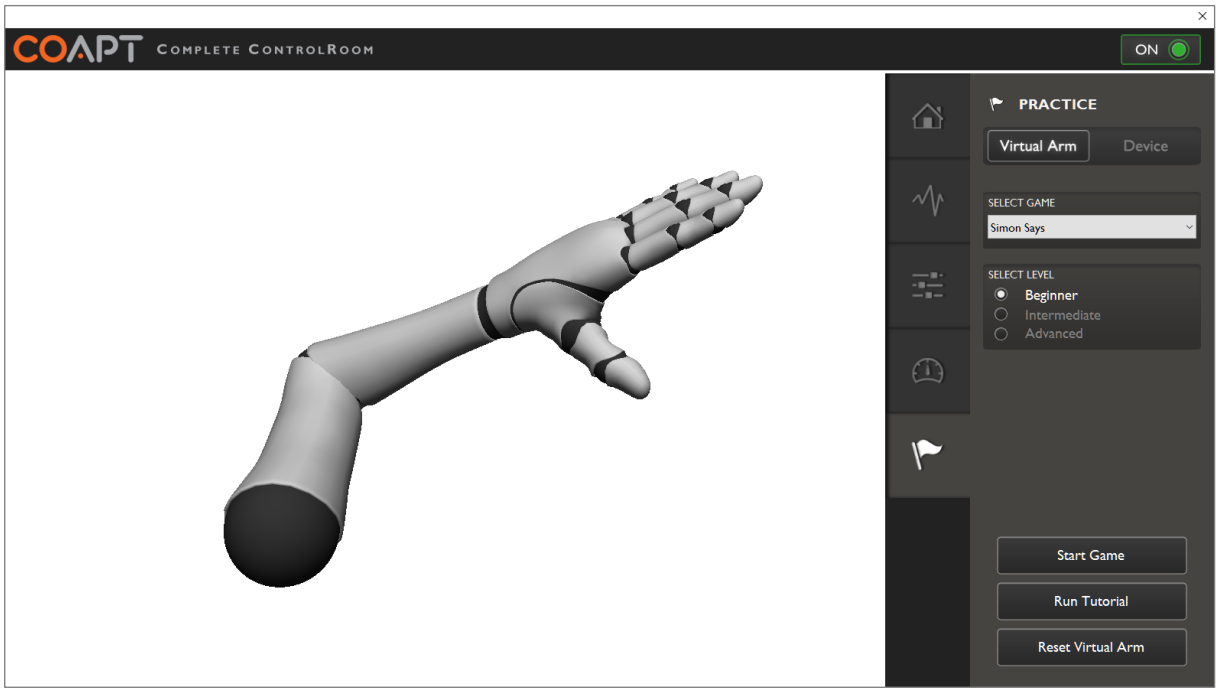
When calibrated, the virtual arm will move according to the user's control if Virtual Arm is selected. When Device is selected, user's control will be directed to the physical prosthesis.



5.3.5 PRACTICE

The COMPLETE CONTROLROOM Practice environment provides users with both virtual and real-world practice of pattern recognition control. When Device is selected, user's control will be directed to the physical prosthesis, and the games will be hidden.

With the system calibrated and Virtual Arm selected, the games will be accessible, and the virtual arm will move according to the user's intent.



Two games are available in the COMPLETE CONTROLROOM Practice environment: "Simon Says" and "In the Zone." The user may select a game by clicking on the pull-down menu in the Selected Game panel. The user can then elect to run a tutorial to see how each game is played.

"Simon Says" helps users practice isolating their individual prosthesis motions from each other. During the game, a shadow arm is displayed. When the user moves the virtual arm to match the shadow arm's position, the shadow arm turns green. If the user is able to hold the virtual arm in the same position as the shadow arm for one full second, the arm turns bright green, and the game moves on to the next motion.

"In the Zone" helps users practice controlling the intensity of their muscle contractions – and the speed of their prosthesis. In the game, a black ring is overlaid on top of any active joint on the virtual arm; this ring grows and shrinks with the intensity of the corresponding muscle contraction. During the game, shaded zones will be displayed. The goal is to have the user elicit their corresponding muscle contraction and keep the ring inside the zone. If the user is able to hold the ring in the zone for one full second, the zone turns bright green, and the game moves on to the next motion.

Both of these games are useful for improving users' control of their prosthesis with the COMPLETE CONTROL system both pre and post-prosthetic-fitting.

6 Troubleshooting

6.1 Pattern Recognition Troubleshooting

Issue	Possible Causes	Actions
Prosthesis doesn't respond with movements after calibration	Poor electrode-skin contact	Ensure good electrode contact with user's skin
	Poor calibration quality	Ensure user is providing adequate-strength muscle contractions during calibration
	Calibration data/signals were inadequate	Ensure user is correctly following the pace and prompts of the calibration
	Hardware issue	See Hardware Troubleshooting section
The COMPLETE CONTROL system plays a negative-sounding jingle at the end of Calibration	User is not matching the cadence of the prosthesis movement prompts	Ensure user is providing adequate-strength muscle contractions during calibration with the right timing
	Calibration data/signals were inadequate	Ensure user is correctly following the pace and prompts of the calibration
	No EMG data provided during calibration	Ensure EMG connection cable is attached to COMPLETE CO-AMP
	Weak EMG data provided during calibration	Ensure user is providing adequate-strength muscle contractions during calibration
	Corrupt EMG data during calibration	Ensure good contact of ground/reference electrode
Some or all prosthesis movements are slow	Weak EMG signals given during calibration	Ensure user is providing adequate-strength muscle contractions during calibration
	Competing settings on prosthetic hardware	Ensure that the on-board settings (gains, thresholds, speeds, etc.) are set to recommended or default values for use with the COMPLETE CONTROL system
Some or all prosthesis motors are moving when user is relaxed (i.e., "ghost" movements)	Weak EMG signals for contraction corresponding to the "ghost" movement were given during calibration	Ensure user is providing adequate-strength muscle contractions during calibration
One prosthesis motion is continuously happening when the user is relaxed	The user's calibration data/signals for that movement are not differentiated enough from the "No Motion" data/signals	Ensure user is providing adequate-strength muscle contractions during calibration with special focus on increase in strength for that one motion Ensure good relax state of user during initial "No Motion" recording phase of calibration Have the user try a variation/modification of that motion during calibration to make that data more unique and distinct
Two prosthesis motions seem to get confused with each other	The user's calibration data/signals for those movements are not differentiated enough from each other	Have the user try a variation/modification of those motions during calibration to make their data more unique and distinct
Control seems to be ok for a while and then changes after a short period	The prosthesis and electrodes have adapted to new skin conditions of the user	Recalibrate the prosthesis

6.2 Hardware Troubleshooting

Issue	Possible Causes	Actions
Prosthesis does not move	Various	Ensure the system power is on Ensure the user's muscle contractions are adequate and that the user is performing the contractions consistent with their calibration signals Ensure there is good electrode contact with the user's skin Ensure all COMPLETE CONTROL components are properly connected Recalibrate the system Visit the Clinician Controls environment of the COMPLETE CONTROLROOM software and use the manual controls to check prosthesis motions – if still not moving, check all connections and settings of other manufacturer's devices
The COMPLETE CONTROL system beeps and stops working, only to beep again about 10 seconds later and repeats	Power/battery system reset	Ensure battery is fully charged Contact Coapt representative for service
The COMPLETE CONTROL system plays a negative-sounding jingle as soon as it turns on and boots up	Some system components may not be connected	Ensure all cables and wires are connected
	System battery level may be very low	Ensure battery has adequate charge
	System error	Check for component damage Contact Coapt representative for service
Nothing happens when the COMPLETE CALIBRATE button is pressed	Button hold was not long enough	Press and hold (~2 seconds) until release beep is heard
	Disconnected COMPLETE CALIBRATE	Ensure COMPLETE CALIBRATE (orange) cable is connected to rest of system
Some or all prosthesis movements are slow	Weak EMG signals given during calibration	Ensure user is providing adequate-strength muscle contractions during calibration
	Competing settings on prosthetic hardware	Ensure that the on-board settings (gains, thresholds, speeds, etc.) are set to recommended or default values for use with the COMPLETE CONTROL system
Some or all prosthesis movements are erratic	Competing settings on prosthetic hardware	Ensure that the on-board settings (gains, thresholds, speeds, etc.) are set to recommended or default values for use with the COMPLETE CONTROL system
	Quality of user's calibration is poor	Recalibrate the system Ensure user is correctly following the pace and prompts of the calibration See Pattern Recognition Troubleshooting for more tips
The COMPLETE CONTROL system plays a negative-sounding jingle at the end of Calibration	Quality of user's calibration is poor	Recalibrate the system Ensure user is correctly following the pace and prompts of the calibration See Pattern Recognition Troubleshooting for more tips
	EMG wire harness has become disconnected	Ensure EMG wire harness (gray) cable is connected to rest of system

6.3 Software Troubleshooting

Issue	Possible Causes	Actions
Plugged the Coapt USB radio into computer but the software did not seem to install	The COMPLETE COMMUNICATOR USB radio dongle was plugged in instead of the COMPLETE CONTROLROOM software installation USB dongle	Use the COMPLETE CONTROLROOM software installation USB dongle to find the software installer or visit www.coaptengineering.com for the latest software download
COMPLETE CONTROLROOM closes unexpectedly and displays error message saying "d3dx9_42.dll is missing"	The computer being used does not have an updated version of DirectX installed	Ensure that you have run the "Setup Complete Communicator" application, which can be found in Start Menu > All Programs > Coapt > Setup Complete Communicator
Physical prosthesis isn't moving while COMPLETE CONTROLROOM software is running	User is in the Clinician Controls environment of the software	Select any COMPLETE CONTROLROOM environment other than Clinician Controls to regain prosthesis control
	"Virtual Arm" is selected in COMPLETE CONTROLROOM software	Select "Device" in COMPLETE CONTROLROOM software to regain prosthesis control
The scrolling EMG signals in the Inputs Check environment of the COMPLETE CONTROLROOM software do not correspond to the user's contractions.	Electrode contacts are not making good contact with the user's skin	Ensure adequate socket fit Ensure no signal errors are displayed in the Inputs Check environment of the software.
	EMG wire harness is not attached to the rest of the Coapt COMPLETE CONTROL system	Ensure EMG wire harness (gray) cable is connected
	User's skin is very dry/hairy	Consider dampening skin to speed up skin-electrode adjustment process
The scrolling EMG signals in the Inputs Check environment of the COMPLETE CONTROLROOM software are very jumpy and seem to lag	The prosthesis and computer are far apart from each other and/or there are large items between them that are degrading radio communication	If possible, move the prosthesis and computer closer together and any remove large objects that may be in between the communicating devices

7 Additional Information

7.1 Warranty

Limited US Warranty:

For purposes of warranty, the "Customer" is defined as the entity that Coapt, LLC ("Coapt") has invoiced for the custom ordered component(s) ("Items"). The 1 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 that the reported problem(s) is actually associated with a product or component that was not supplied by Coapt, a "Non-Warranty Evaluation Charge" may be invoiced to the Customer.

Coapt warrants that its Items will be free from defects in material and/or workmanship for a period up to one (1) year. 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 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 abuse, mishandling, accident, or failure to follow operating instructions; b) damage by water, perspiration, sand or abrasive materials, or leaking batteries; c) use in a way not recommended by the manufacturer/distributor; d) 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); e) damage by improper installation; 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 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 that are returned within this Limited Warranty Period. It is the Customer's responsibility to adhere to all Federal and State mandated shipping policies, especially in regard to 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:

An additional two-year extended warranty and a five-year warranty are both available for purchase. Please contact your Coapt representative for pricing and terms.

7.2 RETURNS

Users should return all malfunctioning, damaged, or undesired COMPLETE CONTROL system components directly to their clinician.

Clinicians should return all unserviceable COMPLETE CONTROL system components directly to Coapt, LLC at

Coapt LLC
ATTN: Returns
222 W Ontario St., Suite 300
Chicago, IL 60654

7.3 Technical Information

Power Requirements: The COMPLETE CONTROL system will operate on supply voltages between 5.3–16.8 VDC.

The COMPLETE CONTROL system consumes approximately 115 mA at 7.4 V.

Operating Temperature: 0ºC – 35ºC (32ºF – 95ºF)

Transport Temperature: -20ºC – 45ºC (-4ºF – 113ºF)

Humidity: 5 – 95% RH (Non-Condensing)

Altitude: 10,000 feet Maximum

Physical dimensions: COMPLETE CONTROLLER

- W: 25.9 mm (1.02 in)
- L: 66.1 mm (2.60 in)
- H: 13.5 mm (0.53 in)

COMPLETE CO-AMP

- W: 21.4 mm (0.84 in)
- L: 47.8 mm (1.88 in)
- H: 9.6 mm (0.38 in)

COMPLETE CALIBRATE

- W: 17.8 mm (0.70 in)
- L: 27.6 mm (1.09 in)
- H: 11.7 mm (0.46 in)
- Depth below socket face: 7.6 mm (0.30 in)
- Protrusion above socket face: 4.0 mm (0.16 in)
- Socket mounting hole cut-out size: 14 x 24 mm (0.55 x 0.94 in)

COMPLETE COMMUNICATOR

- W: 21.8 mm (0.86 in)
- L: 69.2 mm (2.72 in) including USB end-cap
- H: 16.1 mm (0.63 in)

7.4 Regulatory Information

FDA:

Coapt, LLC is registered with the US Food and Drug Administration (FDA) with Registration Number 3010605876. The COMPLETE CONTROL system has been cleared by the FDA for marketing in the with Device Listing Number D293047 and 510(k) Number K162891.

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: 2ABS8CBM0114IL32

IEC:

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

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

Health Canada:

Coapt, LLC operates under Medical Device Establishment License number 7579 in Canada as a manufacturer of class I medical devices for distribution.

ISED Canada:

The COMPLETE CONTROL system was fully tested and found to meet the requirements of the Industrial, Scientific and Medical (ISM) Radio Frequency Generators Interference-Causing Equipment Standard ICES-001, Issue 4, June2006.