Myo/One

Product Manual

Fillauer®

Contents

Intended Use

Welcome to the Myo/One Electrode System. Designed in conjunction with Coapt™, one small preamplifier provides 2 channels of EMG signal. Controlseal™ by Coapt remote electrode domes require no dummies, are quick to install, and can be easily moved for optimal electrode placement. Snap Electrodes for roll on liners are also available. With Bluetooth connectivity, the gain adjustments for the electrodes are conveniently made via the Motion Arm User Interface (MAUI).

Myo/One is a convenient, small, versatile, package that provides a much simpler system for dual-channel direct EMG control.

Indications

- The Myo/One electrode is intended for non-invasive monitoring of Electromyography (EMG) for use in the control of electrically powered prosthetic devices.

Contraindications

- Contraindicated for patients where myoelectric control is not appropriate.

The device is intended for single patient use only.

Performance Characteristics

Myo/One	
Operating Temperature	-5 – 60 °C (23 – 140 °F)
Transport & Storage Temperature	-18 – 71 °C (0 – 160 °F)
Operating Voltage Range	5 – 20 Vdc

Storage and Handling

It is recommended that Myo/One is stored between -18 – 71 °C (0 – 160 °F) in a clean, dry environment away from harsh chemicals (chlorine, acids, acetone, etc.).

Replacement Parts

Description	Size	Quantity	Product Number
Controlseal™ Domes with Hardware & Tool	Standard	6 ea	**1705002**
Controlseal™ Domes with Hardware & Tool	Large	6 ea	**1705003**
Operating Voltage Range Controlseal™ Dome	Large	1 ea	**1705001**

Warnings and Precautions

NOTICE: Avoid locating electrodes over bony prominences. This could cause discomfort and skin irritation.

NOTICE: Ensure the ControlSeal™ electrode cap assembly remains intact. A missing or broken cap could cause the electrode to short out and not function correctly, especially with the use of carbon fiber forearms.

NOTICE: Use care in routing the wires, especially upon installation or removal of the inner socket into the outer socket. If wires are cut or damaged the system will not function. Damaged wires are not covered under warranty.

NOTICE: The electrodes must all remain in contact with the skin. Any loss of electrode contact will cause unwanted motion of the myoelectric device.

NOTICE: For remote electrode use, the socket wall should be between 1.9 and 5.5 mm thick. For socket walls thicker than 5.5 mm, contact Fillauer Motion Control.

NOTICE: When installing remote electrodes, don't use silicon sealant or Loctite to secure electrodes to screws as they could interfere with the signal. They are unnecessary.

NOTICE: While no dummies are necessary for inner socket fabrication, ensure there is sufficient space between the inner socket and the outer socket to accommodate the electrode cap assembly ⅛ inch (3.2 mm) or snap cap assembly ¼ inch (6.3 mm).

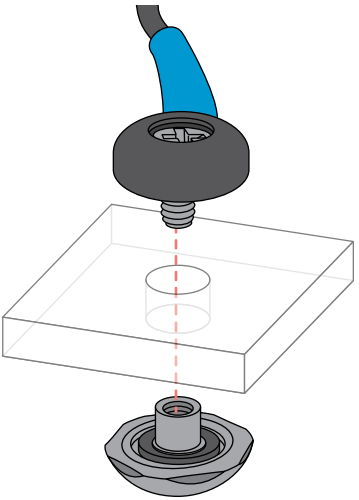
Risk Management

To minimize the risk of device damage or injury to the user while maximizing the functions of this device, follow the instructions for installation, and use this device as described in this manual.

Installation

Controlseal™ Electrode Domes

The ControlSeal™ electrodes provide simple quick and versatile installation into the socket. Please refer to Coapt Electrode Dome Handbook in the link provided on page 11 for more information. The electrode wires are color coded red and blue. These colors correspond to the wires coming out of the preamp and the settings in the user interface.

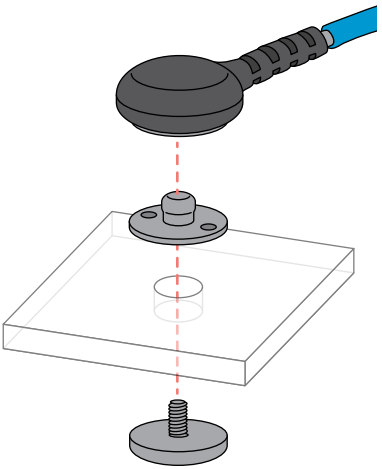


NOTICE: Disregard the instruction on page 13 of the ControlSeal™ manual if it is being used for reference. This applies only when using Coapt control. See more information at the link provided for the Coapt Manual.

If possible, install the sensing electrodes between 1 and 2 inches (25 – 50 mm) apart. This may not be possible with extremely short transradial fittings. In those cases, make sure the electrodes are not touching. The ground electrode (black lead) can go anywhere in the socket with good electrode contact, at least one inch from sensing electrodes if possible.

Snap Electrodes for Roll-on Liners

Locate the electrode site, using a small awl, make a small hole in the roll-on liner. Insert the electrode and tighten the snap onto the stud. A pair of snap ring pliers can be used to snug it up. Once the position of the electrodes is finalized, a small drop of cyanoacrylate (super glue) to the backside of the snap (in the small holes) will lock the electrode in place. Do not allow glue to get on the threads of the snap.



Instruct your patient to use care when un-snapping the electrode cap from the electrode to prevent tearing the liner. The snap caps are color coded red and blue. These colors

correspond to the wires coming out of the preamp and the settings in the user interface.

Forearm Fabrication for Controlseal™ & Snap Electrodes

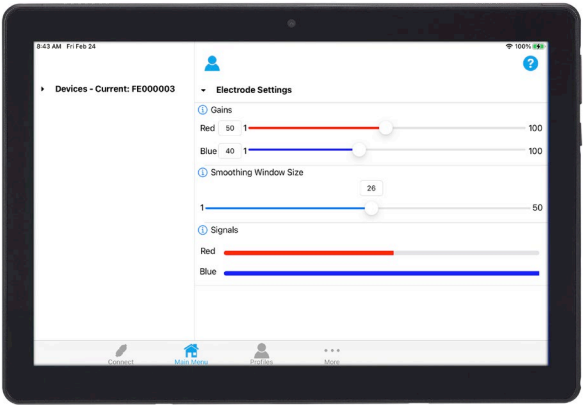
Standard myoelectric forearm fabrication techniques should be used. The forearm must be hollow and the inner socket removable to allow access to the internal electronic components. If there is a pull tube for donning the prosthesis, ensure it is well sealed so perspiration does not enter the forearm. The connections with the wrist components and battery connections are likely not waterproof and prone to damage by perspiration.

Ensure there is ⅛ inch (3.2 mm) space between the inner and outer sockets for the protective plastic caps on the ControlSeal™ electrodes and ¼ inch (6.4 mm) on the electrode snaps for roll-on liners. Also ensure there is a space for the wires and the Myo/One preamp. A dummy has been provided for the preamp.

The Myo/One Electrode wires are held in place by a moveable slide. In most cases there is adequate separation for the wires to reach the electrodes. If the electrode sites are farther apart, simply move the slide down the wire set and gently separate the wires. Conversely, if the wires get separated too much, gently move the slide back toward the connectors.

Adjustment

Myo/One electrodes have the same gain adjustability as traditional electrodes. Rather than using a screwdriver on a small mechanical gain pot accessed at the back of the electrode, gain adjustment is made via Bluetooth on your Apple handheld device.



1. Download MAUI on your Apple device (see page 9)
2. Power cycle the system to “wake up” the Bluetooth transmitter in the electrode.
3. When you open the app and search for devices, any ProPlus device will appear along with the Myo/One electrodes. Tap on the ‘Myo/One’ to connect.

In the user interface, the gain (signal amplification) can be adjusted. The higher the gain setting, the greater the amplification for weak signals. The lower the setting proportional control improves. Filtering can also be adjusted. Increased filtering results in smoother control.

These adjustments are necessary when using devices without a user interface. On devices with a user interface, adjustments in the electrode are “ballpark” adjustment. Adjust the electrodes to get close, then make fine adjustments in the device’s user interface. This is especially true if the wearer is using more than one myoelectric device; e.g., interchanging between a Taska hand and an ETD.

Troubleshooting

Myo/One not found in MAUI

1. Ensure the battery power switch is in the On position.
2. Power cycle the system to “wake up” Bluetooth.
3. Check battery charge.
4. Check all connections and wires.

Erratic, Max, or no signal from electrode

1. Check for electrode contact.
   - **a.** Even if there is slight contact it could be intermittent.
   - **b.** Check signal and contact as the wearer moves through range of motion
2. Check connections, especially the Electrode Cap Assemblies.
3. Check to make sure the screw connections on both remote electrodes or snap electrodes is tight, and threads are free of threadlocker, sealant, or glue.
4. Check other components that may be “upstream” of the device; e.g., electric wrist rotator, powered elbow etc.

Very weak signals

1. Check the Myo/One gain adjustment in the User Interface, increase the gain if necessary.
2. Check electrode contact.
3. Check electrode placement.
4. Check connections.

MAUI App for iOS

Quick Setup for Motion Arm User Interface for Apple® iOS (MAUI)

1. From the Apple® App Store download the MAUI app.
2. Enter the Prosthetist Code: **PR-MCAK**. Patients do not require a code.
3. Open the App and follow the Tutorial.
4. Go to the Connect screen and tap Scan.
5. Input the Pairing Key that came with the device. **This key should be kept in the patient's record.**
6. The device is now connected to the MAUI.
7. To disconnect, tap the Connect icon in the lower left corner, then tap Disconnect.

Troubleshooting

- Make sure the battery on the device is fully charged
- Confirm the device is turned on
- Verify that you are not in Simulation Mode by double tapping the Home key, then swiping MAUI off the screen, and reopening the app
- Bluetooth® must be turned on in Settings on the iOS device.
- The Information icon provides information about a function
- To repeat the tutorial, go to and tap on **Reset** Guided Tutorial.

System Requirements

- iOS 11 minimum
- iPad® (5th gen and later)
- iPad mini® (2nd gen and later)
- iPad Air®
- iPad Pro®
- iPod Touch® (6th gen and later)
- iPhone® 5s and later.

Compatibility

The Myo/One electrode is intended for use in the control of electrically powered prosthetic devices sold for use with single, double, and multisite myoelectric control.

Myo/One is incompatible with Espire Elbow Pro and Espire Elbow Hybrid.

Safety Caution

Use caution when using this device in situations where injury to yourself or others may occur. These include but are not limited to activities such as driving, operating heavy machinery, or any activity where injury may occur. Conditions such as a low or dead battery, loss of electrode contact, or mechanical/electrical malfunction (and others) may cause the device to behave differently than expected.

Disposal / Waste Handling

This device, including any associated electronics and batteries should be disposed of in accordance with applicable local laws and regulations. This includes laws and regulations regarding bacterial or infectious agents, if necessary.

All metal components may be removed and recycled at the appropriate recycling facility.

Serious Incidents

In the unlikely event a serious incident occurs in relation to the use of the device, users should seek immediate medical help and contact their prosthetist, local competent authority and Fillauer at the earliest possible convenience. Clinicians should at any time contact their local Fillauer representative and local competent authority immediately in the event of any device failure.

Warranty

Seller warrants to Buyer that the equipment delivered hereunder will be free from defects in materials and manufacturing workmanship, that it will be of the kind and quality described and that it will perform as specified in Seller's written quotation. The limited warranties shall apply only to failures to meet said warranties that appear within the effective period of this Agreement. The effective period shall be one year (12 months) from the date of delivery to the fitting center that has purchased the components. Refer to the shipping receipt for the date of shipment.

Return Policy

Returns are accepted from date of shipment as follows **with the addition of any repairs that may be required to return the product to resalable condition**:

Return Policy	
Up to 30 days	No restocking fee
31 – 60 days	10% restocking fee
61 – 90 days	15% restocking fee
90+ days	Not accepted

Customer Support

Americas, Oceania, Japan

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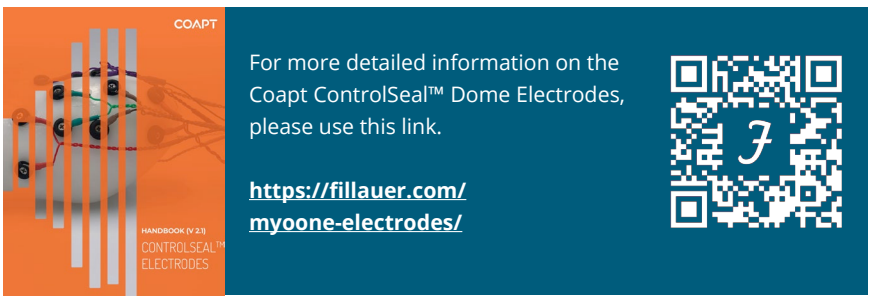
Declaration of Conformity

The product herewith complies with Medical Device Regulation 2017/745 and is registered with the United States Food and Drug Administration. (Registration No. 1723997).



For more detailed information on the Coapt ControlSeal™ Dome Electrodes, please use this link.

https://fillauer.com/myoone-electrodes/

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