

MC ProWrist Rotator

Prosthetist Manual

Special Precautions



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.



The ProWrist should not be used in situations where inadvertent movement or lack of intended motion may cause injury to the user or others such as, driving, operating heavy equipment, use of power tools or handling hot liquids.



Do not use the ProWrist in environments where it may be subjected to greater than 50 lbs/22.7 kg of force.



When removing the ProWrist from the lamination collar, use care to not damage the wires and connectors.



The ProWrist should be adjusted to the patient via the Motion Control User Interface by a qualified prosthetist. Factory default settings are not necessarily the best settings for all patients.



The o-rings on the mounting screws and the o-ring on the rotator provide a waterproof seal for use with the MC Waterproof Collar for Quick Disconnect Wrist and the MC Waterproof Collar on the TASKA HandGen2. These o-rings must be in place for the wrist to be waterproof.



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 at the earliest possible convenience. Clinicians should contact Motion Control immediately in the event of any device failure.

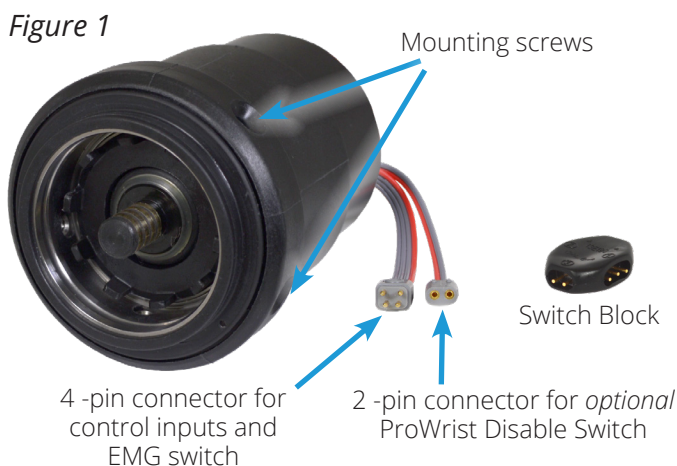


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Introduction

The Motion Control (MC) ProWrist (Figure 1) provides powered wrist rotation with an on-board microprocessor. This controller provides Proportional Control and switching of function between the terminal device and wrist rotation. The ProWrist is to be used in cases of transradial and higher-level amputation. The ProWrist may also be used with body-powered elbows and some other manufacturers' externally-powered elbows for transhumeral and higher-level amputations. When using Motion Control Utah Arms, the MC Standard version of the powered wrist rotator should be used (see MC Standard Electric Wrist Rotator Manual p/n 1910063). The ProWrist provides twice the speed and twice the torque of previous wrist rotators with less noise. By using an industry-standard quick disconnect wrist unit and coaxial plug,



the ProWrist is compatible with almost all available powered terminal devices. The optional Wrist Disable Switch (p/n 3010846, Figure 3) allows disabling of Hand/Wrist switching for times when the patient desires only the terminal device to be operational.

Indications

The ProWrist can be used in almost any case where powered wrist rotation is desired and adequate space is available in the forearm.

Contraindications

Inadequate space in the forearm such as wrist disarticulation or long transradial amputations.

Patients for whom the extra weight of an electric wrist rotator is intolerable.

In cases where the prosthesis is likely to be exposed to high loads (> 50 lbs/22.7 kg).

Cases in which a controller is “upstream” of the wrist rotator such as Motion Control ProControl 2, U3, U3+, Hybrid Elbows, and Boston Elbow applications. The Motion Control Standard Electric Wrist Rotator is indicated in these situations.

Specifications

Length: 2.75 in/70 mm

Diameter (without lamination collar): 1.85 in/47 mm

Weight: 5.9 oz/168 g

Voltage: 7.2 v

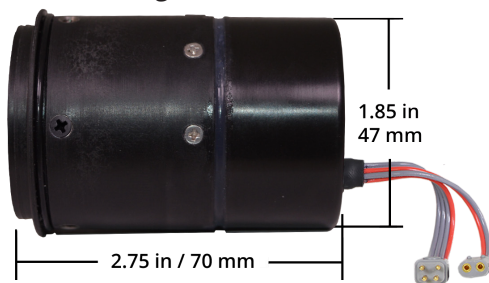
SPL at full speed: 38.5 dB maximum at 1 meter

Speed: 28 rpm @ 7.2 v

Torque: 15 in-lb @ 7.2 v

Static Load: 50 lbs/22.7 kg

Figure 2



Options

Wrist Disable Switch (p/n 3010846)

Disables hand/wrist switching. This switch is useful when a patient wants to operate only the terminal device and prevent all powered wrist function. This would be the case of a patient fearful of inadvertent hand/wrist switching (Figure 3).

Figure 3



ProWrist Option – Multiple Inputs

This special option for the ProWrist provides separate inputs for terminal device function and wrist function. Contact Motion Control for specific applications.

Fabrication

Once a well-fitting evaluation socket is fitted to the patient, a temporary alignment fixture made from PVC pipe can be used to determine optimal alignment of the wrist/terminal device and forearm length. Reinforced with synthetic casting material, this system can be used during trial fitting for short-term training.

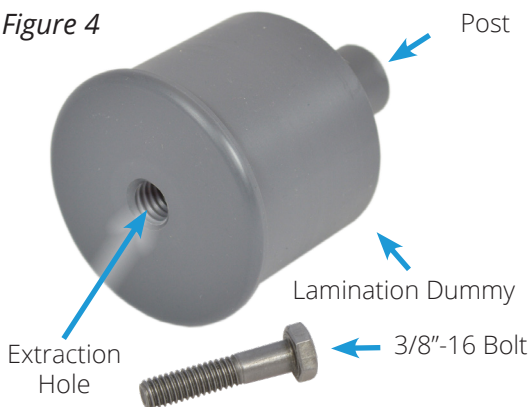
When optimal alignment is achieved, remove all electronics and replace with appropriate dummies that come with each component.

A Wrist Lamination Dummy Kit is required (Figure 4), purchased separately (p/n 3010886). This dummy has an extraction hole that accepts a 3/8"-16 bolt (included).

With this dummy in place of the ProWrist, the entire prosthesis can now be mounted in a vertical transfer fixture (Figure 5).

The prosthetic socket is now filled with Plaster of Paris, and alignment is maintained between the wrist unit and the prosthetic socket.

Figure 4



Remove the temporary alignment fixture.

Pay attention to the post on the proximal portion of the Lamination Dummy, indicating the length of the ProWrist. Reserve space to this length for the wrist component. (see "Post", Figure 4)

Apply adequate parting agent to the inside of the lamination collar and any surfaces not to be bonded to the outer lamination.

Use electrical tape to wrap the screw holes in the lamination collar.

Do not apply parting agent to the outer surface of the lamination collar proximal to the retention screw collar. This area provides the bonding surface to the outer forearm lamination.

Laminate the outer socket using the materials and technique of choice.

After lamination, remove the excess plastic from the distal surface of the wrist unit and thread a 3/8-16 bolt into the extraction hole. (see "Extraction Hole", Figure 4) Firmly pull to remove the Wrist Lamination Dummy.

Carefully cut the lamination proximal to the retention screw collar and remove the lamination to expose the screw holes.

Assembly

1. Attach appropriate connectors (Figure 6).
2. Using the template provided with the Battery Charging Harness, locate the position for the Battery Charging Port and drill a 3/8 in (9.6 mm) hole.
3. Install the Battery Charging Harness by securing the Charging Port into place.
4. Connect the Battery Wire Harness to the Ottobock 13E190 (included).
5. Connect the MC Li-Ion 7.2v Battery to the Battery Wire Harness.
6. Connect the input device (e.g. preamps) into the Ottobock 13E190.
7. Input 1 corresponds to Channel A; Input 2 corresponds to Channel B.
8. Secure the battery and preamps to the wall of the prosthesis with self-adhesive Velcro.
9. Slide the ProWrist into the lamination collar.
10. Align the ProWrist screw holes with the holes in the lamination collar and insert the forearm screws.



Figure 5 Vertical Transfer

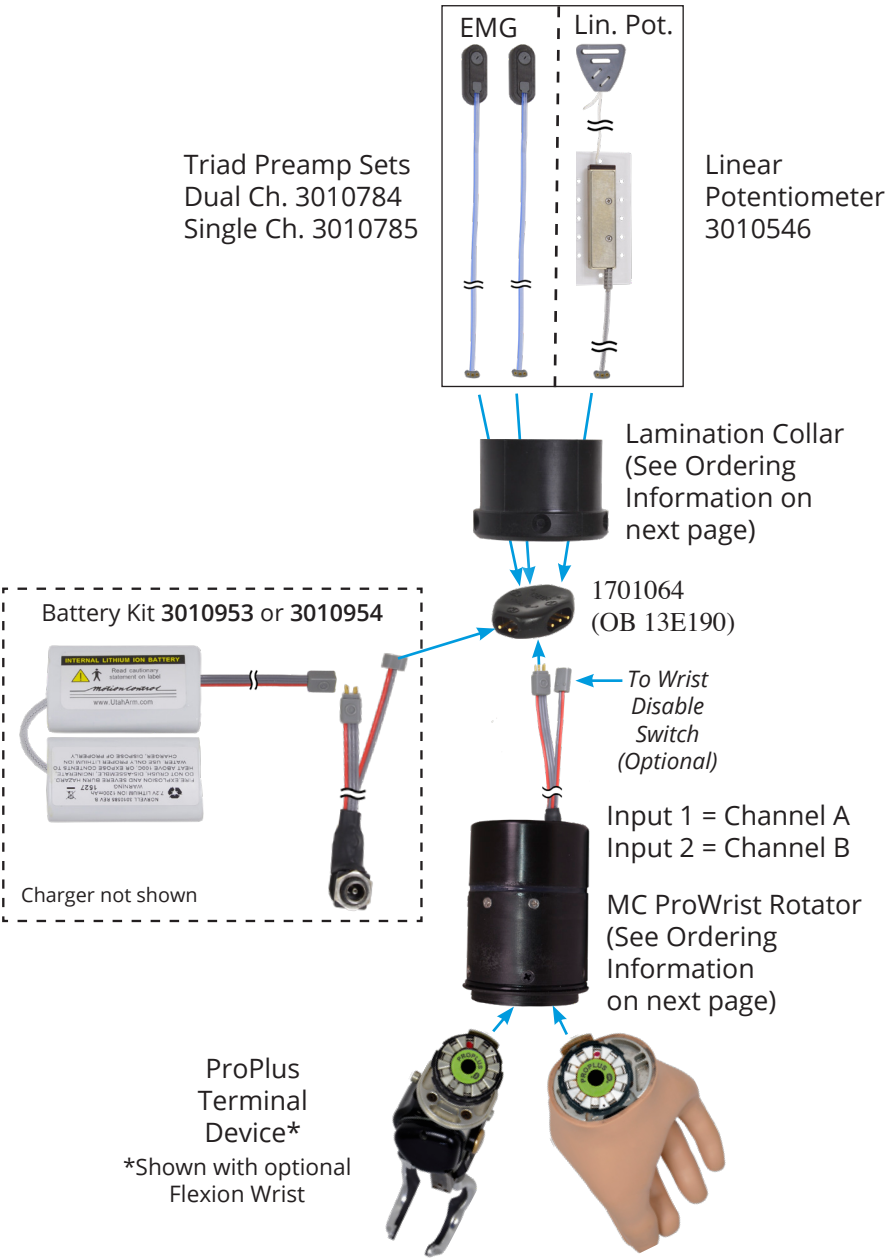
Fixture with temporary alignment fixture fabricated from PVC.



Figure 6

NOT TO SCALE

**ProWrist/Terminal Device
Input Options**



Disassembly

The ProWrist will fit very snugly into the lamination collar. Attach a terminal device to the wrist, remove the five screws and then firmly pull on the terminal device. The ProWrist will slide out of the lamination collar.

Disconnect all the connectors.

Adjustment

See Quick Set up Guide included with this device.

Maintenance

The Motion Control ProWrist does not require any routine maintenance. Avoid using any lubricants, liquids, or cleaners on any surfaces of the ProWrist.

The coaxial plug may require cleaning periodically. This is accomplished with a Q-tip and a very small amount of rubbing alcohol.

Follow up visits should be made to the Prosthetist at least yearly to ensure the User Interface settings do not require readjustment.

Single Patient Use

Each amputee is unique. The shape of their residual limb, the control signals each generates and the tasks an amputee performs during the day require specialized design and adjustment of the prosthesis. Motion Control products are manufactured to be fit to one individual.

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.

Limited Warranty

The Motion Control ProWrist is warranted for 12 months from the date of shipment from Motion Control. Items under warranty will be repaired or replaced (at Motion Control's discretion) at no charge. The warranty will be void if the ProWrist has been fabricated or installed outside Motion Control's recommendations, or altered mechanically, electronically, or structurally in any way. The warranty is also void if the ProWrist has been exposed to a wet, or corrosive environment, or used in any abusive activity. This warranty does not include any prosthetic fitting or clinical expenses.



Rental Program

Motion Control offers a rental program for trial fittings up to six months. A product is rented with Motion Control's signed rental agreement, and rent is applicable towards purchase using a sliding formula. Contact Motion Control for details.

Return Policy

In all cases, if reconditioning or repairs are required, costs for returning the product to resalable condition will be charged.

Products returned within 30 days after sale, in resalable condition, are credited the full value without a restocking fee.

Products received 31-60 days after sale will be charged a 10% restocking fee.

Products received 61-90 days after sale will be charged a 15% restocking fee.

Products returned over 90 days after sale will not be exchanged or credited.

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)



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.

User Interface Adjustments

Each of the ProPlus family of Motion Control products contains a microprocessor that can be adjusted and set for a specific individual's needs. Wearers without EMG signals can also be accommodated, but some hardware may be necessary. The software necessary to make these adjustments is provided at no charge to the prosthetist or end user.

iOS User Interface

MC ProWrists produced since 2015 communicate via Bluetooth® directly with Apple® iOS Devices. The MCUI App is available at no charge from the Apple® App Store*. No additional hardware or adapters are necessary with the iOS Interface. ***Note:** The MCUI App is **not** available for Android devices.

Ordering Information

Description	Tan	Brown	Jet Black
MC ProWrist Rotator	5010057	5010058	5010056
Lamination Collar for MC Wrist, 7 ¼ Hand	1100292	1100296	1100288
Lamination Collar for MC Wrist, 7 ¾ Hand	1100293	1100297	1100289
Lamination Collar for MC Wrist, 8 ¼ Hand	1100294	1100298	1100290
Lamination Collar for MC Wrist for Hosmer Prefab (Large), Boston or AFB	1100295	1100299	1100291

Suggested LCodes

Description	Feature	LCode
MC Electric Wrist Rotator	Electric Wrist Rotator	L7259
	Hi-Speed, Hi-Torque Motor Drive	L7499*
MC ProWrist Controller	Microprocessor Control (use above codes plus):	L6882
	Proportional Control	L7499*

*Contact Motion Control for MSRP regarding L7499 codes



MCUI User Interface for iOS

Quick Setup Guide

Quick Setup for Motion Control User Interface for Apple® iOS (MCUI)

1. From the Apple® App Store  download and install the MCUI. 
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. *This key should be kept in the Patient's record.*
6. The device is now connected to the MCUI.
7. To disconnect, tap the Connect icon in the lower left corner,  then tap  Disconnect.

System Requirements

Apple® App Store account, and any of the following devices:

- iPad® (3rd gen and later)
- iPad mini™, iPad Air®, iPad Air® 2
- iPod touch® (5th gen and later)
- iPhone® 4S and later.

Troubleshooting

- Make sure the battery on the device is fully charged
- Check connection of the device in the quick disconnect wrist
- Confirm the device is turned on
- Verify that you are not in “Tutorial Mode” by double tapping the Home key, then swiping MCUI off the screen, and reopening MCUI
- 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 **Reset** on Reset Guided Tutorial

Customer Support

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