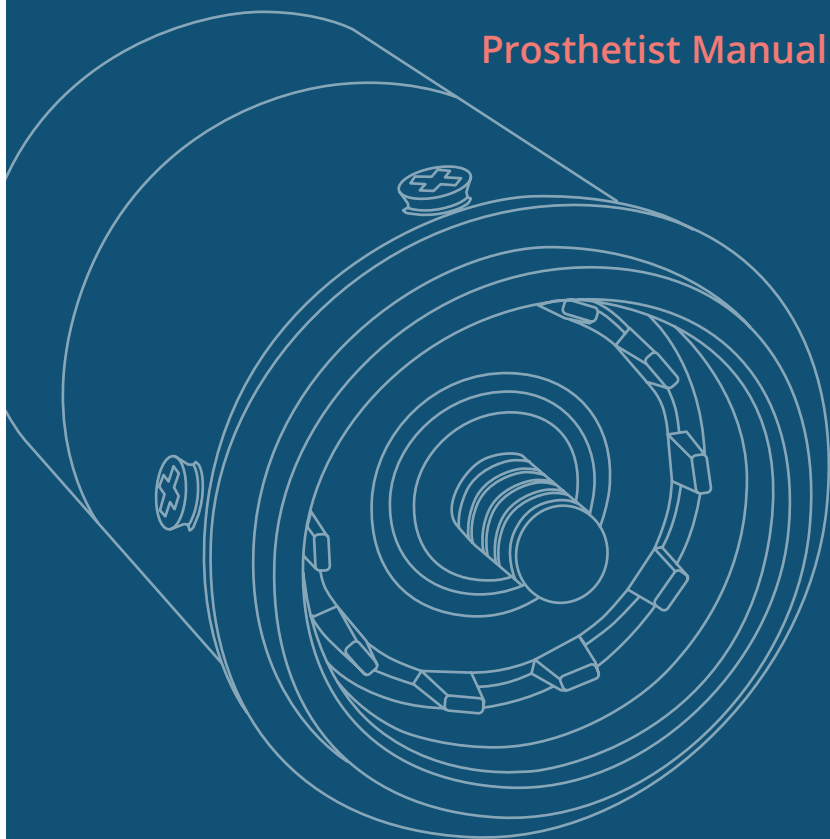


MC Standard Electric Wrist Rotator

Prosthetist Manual



Fillauer[®]
Motion Control

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 MC Standard Wrist Rotator 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 MC Standard Wrist Rotator in environments where it may be subjected to greater than 50 lbs/22.7 kg of force.



When removing the MC Standard Wrist Rotator from the lamination collar, use care to not damage the wires and connectors.



The Standard Wrist 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.

Introduction

The Motion Control (MC) Standard Electric Wrist Rotator (Figure 1) provides powered pronation and supination at twice the torque and twice the speed of previous electric wrist rotators, with less noise. The Standard version of the MC Electric Wrist Rotator **does not** contain a microprocessor, therefore a controller must be “upstream”. The MC Standard Electric Wrist Rotator is used with the ProControl 2, U3, U3+ and Hybrid Elbow. This is also the wrist used in some other manufacturers’ powered elbows such as the LTI Boston Elbow. The MC Standard Electric Wrist Rotator utilizes an industry-standard quick disconnect and coaxial plug, and therefore is compatible with most manufacturers’ terminal devices.



Figure 1

Indications

The MC Standard Electric Wrist Rotator can be used in any case where powered wrist rotation is desired, and adequate space is available in the forearm. An “upstream” controller must be present, as in the Motion Control ProControl 2, U3, U3+, Hybrid Elbow and Boston Elbow.

Contraindications

Inadequate space in the forearm such as wrist disarticulation or long trans-radial amputations. A Motion Control In-Hand Electric Wrist Rotator should be considered in these cases.

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

Cases where the prosthesis is likely to be exposed to environments that may be wet, dirty, dusty and high loads (> 50 lbs/22.7 kg).

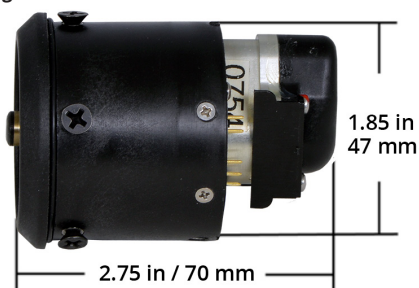
Whenever a controller is not located upstream of the Wrist Rotator, a Motion Control *ProWrist* would be indicated.

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.

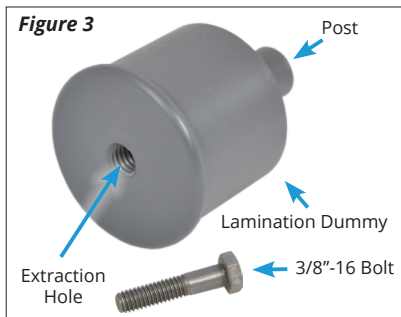
When optimal alignment is achieved, remove all electronics and replace with appropriate dummies that come with each component.

Figure 2



A Wrist Lamination Dummy Kit is required (Figure 3), 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 wrist, the entire prosthesis can now be mounted in a vertical transfer fixture (Figure 4).



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

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 3).

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 3). 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.

Figure 4 - Vertical Transfer Fixture with temporary alignment fixture fabricated from PVC.

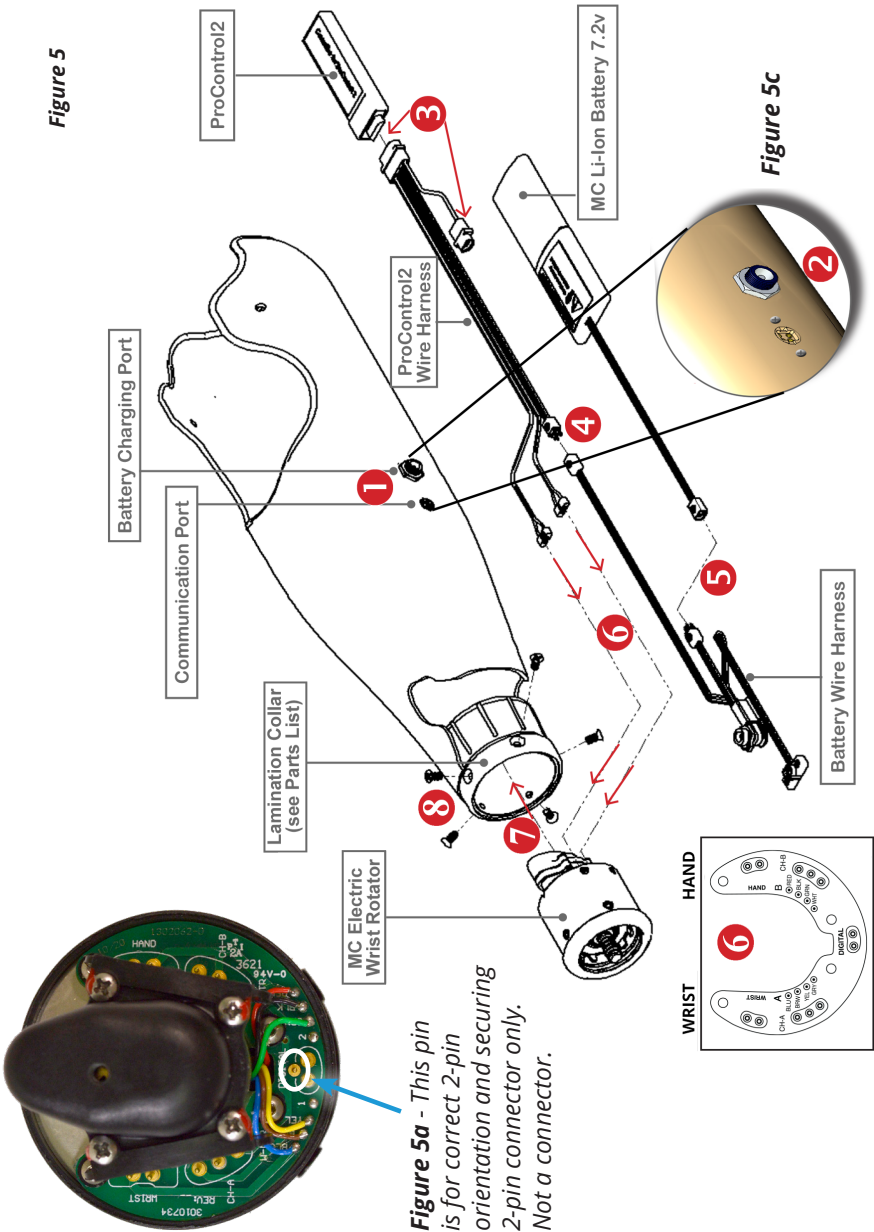
Assembly

Attach appropriate connectors (Figure 5 and insets 5a, 5b and 5c).

1. 1. Using the template provided with the Battery Charging Harness, locate the position of the Battery Charging and Communication Ports, and drill holes.
2. Install the Battery Charging Harness by securing the Charging Port and Communication Port into place (inset Figure 5b).
3. Connect ProControl 2 and input device (e.g. preamps) to the ProControl 2 Wire Harness.
4. Connect the ProControl 2 Wire Harness to the Battery Wire Harness.
5. Connect the MC Li-Ion 7.2 v Battery to the Battery Wire Harness.
6. Connect the Hand and Wrist output from the ProControl 2 Wire Harness to the back of the MC Wrist Rotator (inset Figure 5c).
7. Insert the entire assembly into the prosthesis, including the Wrist Rotator.
8. Align the screw holes, and fasten the screws.

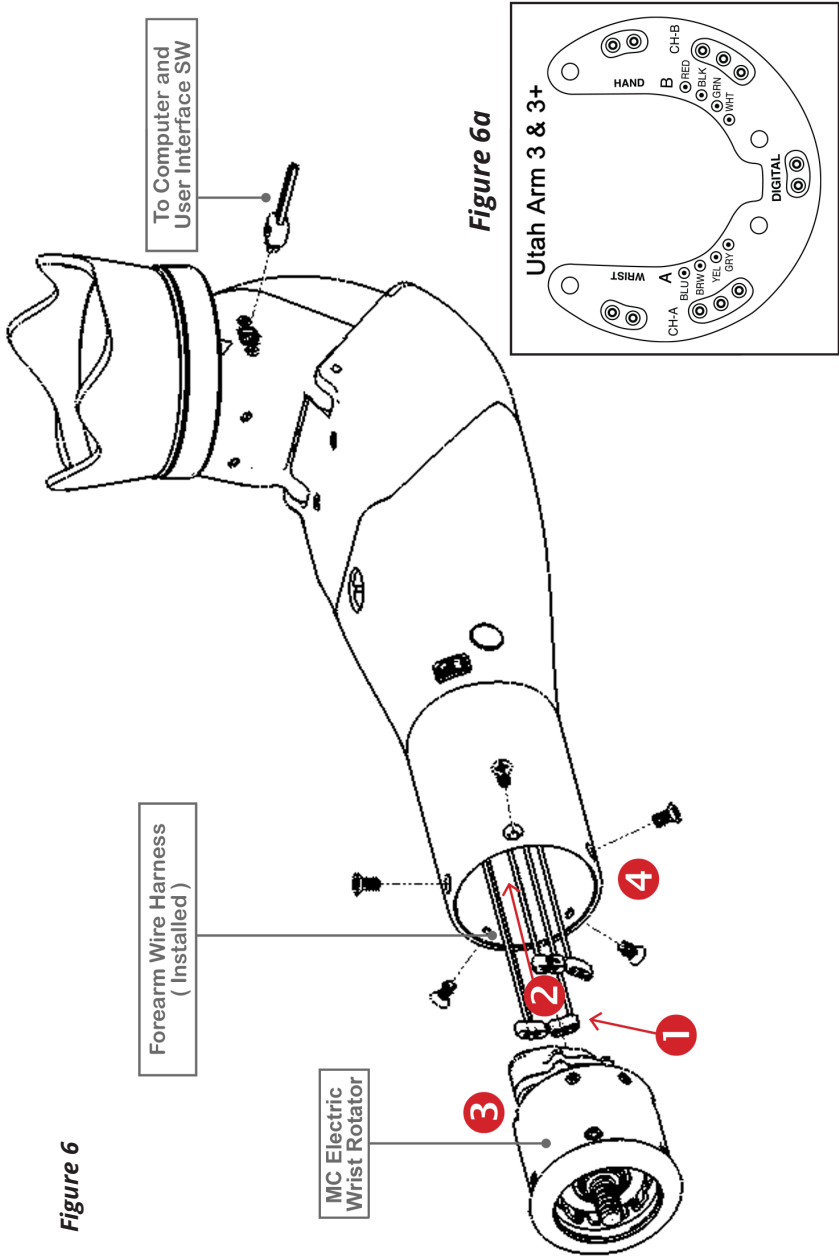
Assembly (Socket)

Attach appropriate connectors (Figure 5 and insets 5a, 5b and 5c).



Assembly (U3, U3+, and Hybrid Elbows)

Attach appropriate connectors (Figures 6 and 6a).



Installing the Motion Control Wrist

1. Attach wires according to the diagram (inset Figure 6a).
2. Insert the Wrist into the forearm cover.
3. Orient the motor to align with the notch in the Ring Connector inside the forearm cover. Be careful to not pinch any wires between the spring clip and the motor. Twisting the wires will help coil the wires around the motor. The wires will also be easier to position with the forearm cover removed from the Arm.
4. Secure the Wrist to the forearm using the five attachment screws.

Disassembly

The MC Wrist Rotator will fit very snugly into the lamination collar or forearm. Attach a terminal device to the wrist, remove the five screws and then firmly pull on the terminal device. The MC Wrist Rotator will slide out of the lamination collar. Disconnect all the connectors.

Follow the User Interface instructions for the controller upstream from the wrist.

Maintenance

The MC Standard Electric Wrist Rotator does not require any routine maintenance. Avoid using any lubricants, liquids, or cleaners on any surfaces of the MC Wrist Rotator.

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

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

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.

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

Returns are accepted for a full refund up to 90 days from date of shipment as long as the item is in resalable condition. Beyond 90 days, returns are not accepted.

Suggested LCodes

MC Standard Electric Wrist Rotator L7259, Hi-Speed, Hi-Torque Motor Drive L7499.

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)

Specifications

Length: 2.75 in/70 mm

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



Weight: 5.03 oz/143 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-lbs @ 7.2 v

Static Load: 50 lbs/22.7 kg

Customer Support

Americas, Oceania, Japan

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