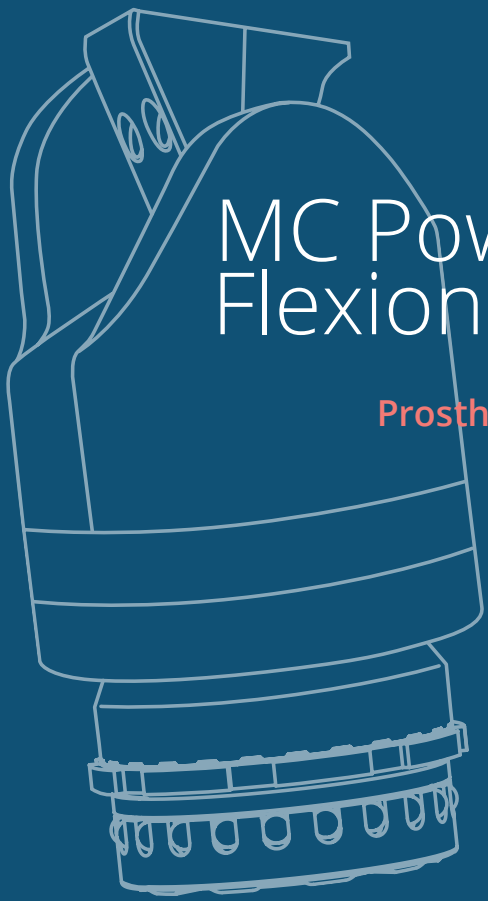
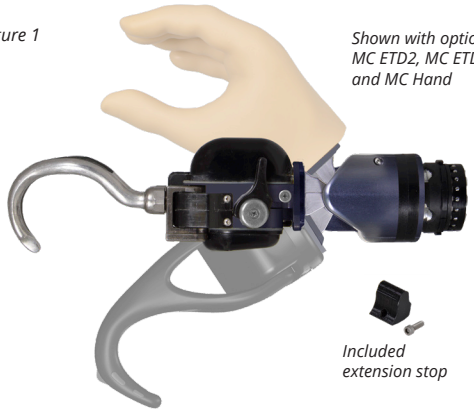


MC Powered Flexion Wrist

Prosthetist Manual

Fillauer®
Motion Control

Figure 1



Shown with optional MC ETD2, MC ETD and MC Hand

Included extension stop

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 Powered Flexion Wrist should be adjusted for each patient using the MCUI iOS user interface. Factory Settings will seldom be the optimal settings for the user.

The Powered Flexion Wrist 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 a vehicle, operating heavy equipment, using power tools or handling hot liquids.

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

The Powered Flexion Wrist has a pinch danger when it is near or at maximum flexion or extension (Figure 3).

Caution should be used when operating the wrist around volatile gases. The wrist utilizes an electric motor that can ignite volatile gases.

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.

MC Powered Flexion Wrist

Prosthetist Manual

The Motion Control Powered Flexion Wrist (PFW) provides powered wrist flexion/extension or radial/ulnar deviation with an on-board microprocessor (Figure 1). This controller provides proportional control and switching of function between the terminal device and powered wrist flexion/extension or radial/ulnar deviation.

Any Motion Control terminal device can be installed on the Powered Flexion Wrist when it is ordered. By using an industry standard quick disconnect, the PFW/TD unit can easily be removed from the prosthesis and another manufacturers' terminal device may be inserted in its place. The Powered Flexion wrist is suitable for the transradial level of amputation or higher.

The Motion Control Powered Flexion Wrist (PFW) provides powered wrist flexion/extension *or* radial/ulnar deviation with an on-board microprocessor (Figure 1). This controller provides proportional control and switching of function between the terminal device and powered wrist flexion/extension *or* radial/ulnar deviation. Any Motion Control terminal device can be installed on the Powered Flexion Wrist when it is ordered. By using an industry standard quick disconnect, the PFW/TD unit can easily be removed from the prosthesis and another manufacturers' terminal device may be inserted in its place.

Indications

The Powered Flexion Wrist can be used in almost any case where powered wrist flexion is desired and adequate length is available.

Contraindications

Inadequate space due to residual limb length such as wrist disarticulation or long transradial amputations.

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

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

Fabrication

There is no special fabrication for the powered flexion unit. When ordered, Motion Control will attach the flexion unit to the desired terminal device (ordered separately). The powered flexion unit will

have a standard quick disconnect coupler for easy plug and play attachment to the socket.

Disassembly

There are no serviceable parts in the Powered Flexion Wrist. The powered flexion unit will need to be returned to Motion Control to exchange terminal devices. Disassembly of the Powered Flexion Wrist, including removal of the terminal device will void the warranty.

Maintenance

The Motion Control Powered Flexion Wrist does not require any routine maintenance. Avoid using any lubricants, liquids, or cleaners on any surfaces of the Powered Flexion Wrist. The coaxial plug may require periodic cleaning. This is accomplished using 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.

Extension Stop

The full range of flexion provided by the Powered Flexion Wrist is sometimes excessive for supporting or carrying objects that are beyond the capability of the wrist's passive resistance to support. The Powered Flexion Wrist includes an extension stop (circled in Figure 4) to limit extension to 30 degrees. This stop can be installed or removed with a 3/32" hex wrench. When the stop is either removed or installed, the range of motion of the wrist must then be recalibrated. Please see section "iOS adjustments of the Powered Flexion Wrist", item 5.

Suggested LCodes

Description	Feature	LCode
MC Powered Flexion Wrist	Wrist Rotator, Electric	L7529
	Microprocessor Control	L6882
	Proportional Control	L7499*
	Brushless DC Motor	L7499*
	AutoCal	L7499*
	Water Resistant	L7499*
	Bluetooth® Adjustment	L7499*

*Contact Motion Control for MSRP regarding L7499 codes

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.

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.

iOS User Interface

The Motion Control Powered Flexion Wrist communicates 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 (Figure 2). **Note:** The MCUI App is ***not*** available for Android devices.

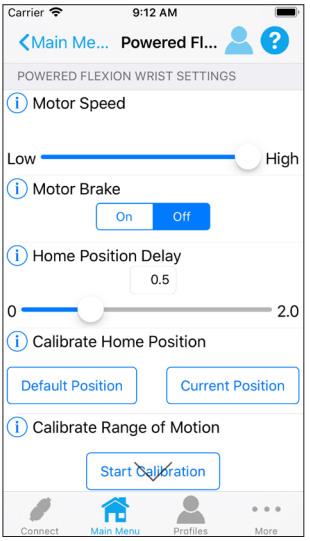


Figure 2

iOS Adjustments for Powered Flexion Wrist

1. **Motor Speed**

   This adjustment allows the user to fine tune the desired speed of the device. Lower speeds result in finer control, higher speeds, quicker response. The slider can be adjusted from Low to High to optimize the speed for the user.

2. **Motor Brake**

   This adjustment allows for enabling/disabling the internal motor brake. When the motor brake is enabled, passive resistance will be increased.

3. **Home Position Delay**

   The PFW will pause at a "Home" position. The length of pause is adjustable. Set Home Position Delay to zero (0) if no pause is desired.

4. **Calibrate Home Position**

   This will determine where the user would like the Home Position centered in the full range-of-motion. Default Position will set the Home Position centered in the full range of motion. To change the Home Position, move the powered flexion unit to desired Home Position and touch the Current Position tab to set a new Home Position.

5. **Calibrate Range of Motion**

   If you remove or add the physical extension stop (Figure 4) a short calibration sequence will find the correct end points for the new range-of-motion.

Figure 3

Figure 4

MCUI User Interface for iOS

Quick Setup Guide*

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. The device should now connect to the MCUI.
6. 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.

Specifications

Operating Temperature: -5° to 60° C (23° to 140° F)
Transport & Storage Temperature: -18° to 71° C (0° to 160° F)
Rating: IPX7
Length: 2.6 in/66 mm
Diameter: 1.84 in/46.74 mm
Weight: 9.12 oz/258.55 gm
Voltage: 6.9 – 7.9 v
ROM – 153°, Flexion – 86°, Extension – 67°
Speed: 180°/sec
Active Torque: 20 in-lb
Passive Torque: Brake – 20 in-lb, No Brake – 10-15 in-lb
Static Holding Torque: 10 in-lb

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)

Customer Support

Americas, Oceania, Japan
Fillauer Motion Control
115 N. Wright Brothers Drive
Salt Lake City, UT 84116
801-326-3434
motioninfo@fillauer.com

Europe, Africa, Asia
Fillauer Europe
Kung Hans väg 2
192 68 Sollentuna, Sweden
+46 (0)8 505 332 00
support@fillauer.com

Fillauer
2710 Amnicola Highway
Chattanooga, TN 37406
423.624.0946
www.fillauer.com

EC REP **Fillauer Europe**
Kung Hans väg 2
192 68 Sollentuna, Sweden
+46 (0)8 505 332 00