

# MC Powered Flexion Wrist

Prosthetist Manual

*Fillauer*<sup>®</sup>  
Motion Control



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## Prosthetist Manual

### Introduction

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 manufacturer's terminal device may be inserted in its place. The Powered Flexion wrist is suitable for the transradial level of amputation or higher.

### Powered Flexion Wrist

Figure 1



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 manufacturer's 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).

## Specifications

**Operating Temperature:** -5° to 60° C (23° to 140° F)

**Transport & Storage Temperature:** -18° to 71° C (0° to 160° F)

IPX7 Rating

**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



## 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 individual patients 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.



*Figure 3*



## 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.

## Adjustment

See Quick Setup Guide for PFW, later in this document.

## 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.

Figure 4



## 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

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.

## 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 Powered Flexion Wrist 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 Powered Flexion Wrist 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 Powered Flexion Wrist has been exposed to a corrosive environment or used in any abusive activity. This warranty does not include any prosthetic fitting or clinical expenses.

## Ordering Information \*Terminal Device ordered separately

Description	Part Number
Powered Flexion Wrist Flexion/Extension option for MC Hand	3010993
Powered Flexion Wrist Radial/Ulnar option for MC Hand	3010994
Powered Flexion Wrist Flexion/Extension option for MC ETD	3010995
Powered Flexion Wrist Radial/Ulnar option for MC ETD	3010996
Powered Flexion Wrist Flexion/Extension option for MC ETD2	3010997
Powered Flexion Wrist Radial/Ulnar option for MC ETD2	3010998

## 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. **Note:** The MCUI App is **not** available for Android devices.

# 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

## 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

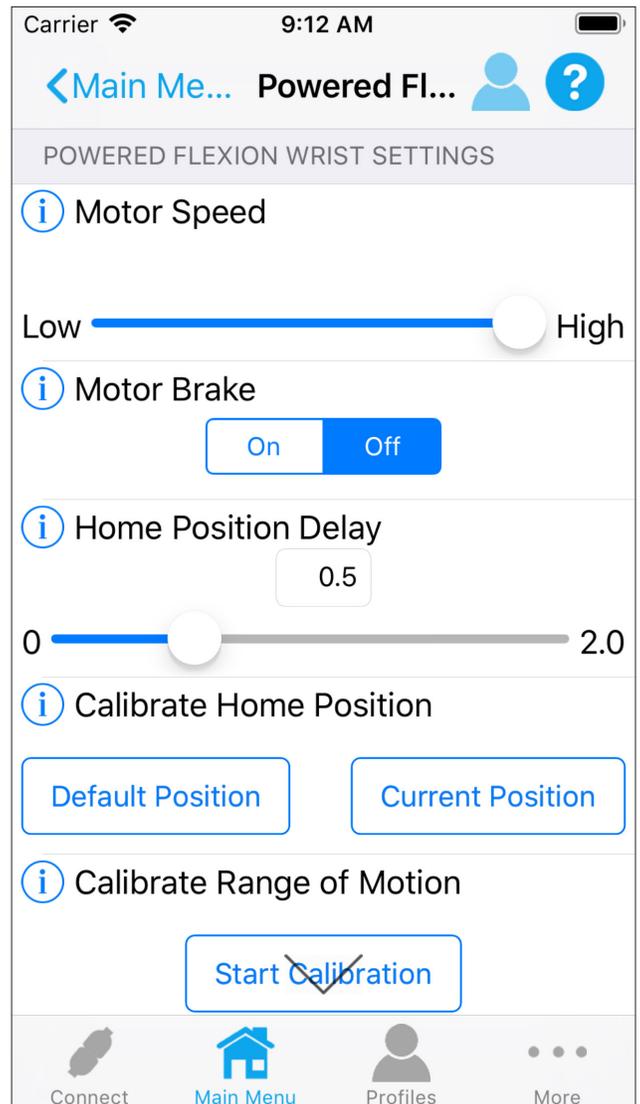
The PFW will pause at a "Home" position. The length of pause is adjustable. Set Home Position Delay to zero (0) if no pause is desired.

### 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.

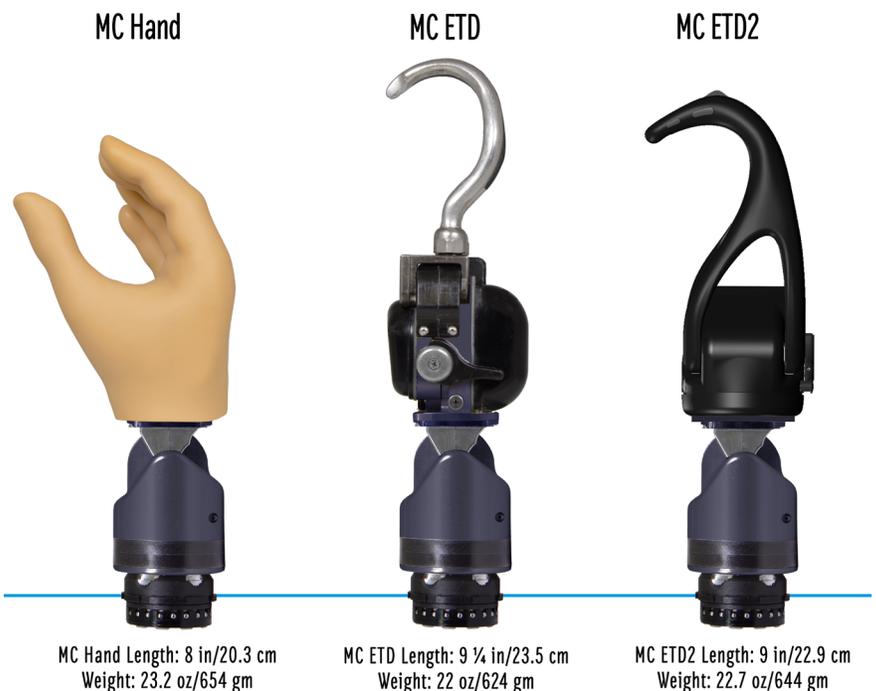
### 5. Calibrate Range of Motion

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.



## 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)



**Fillauer Europe**

Kung Hans väg 2  
192 68 Sollentuna, Sweden  
+46 (0)8 505 332 00



[www.fillauer.com](http://www.fillauer.com)

**Motion Control, Inc.**

115 N Wright Brothers Drive  
Salt Lake City, UT 84116  
801.326.3434  
Fax 801.978.0848

