

MC ProPlus ETD

Prosthetist Manual

Fillauer[®]
Motion Control

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Introduction

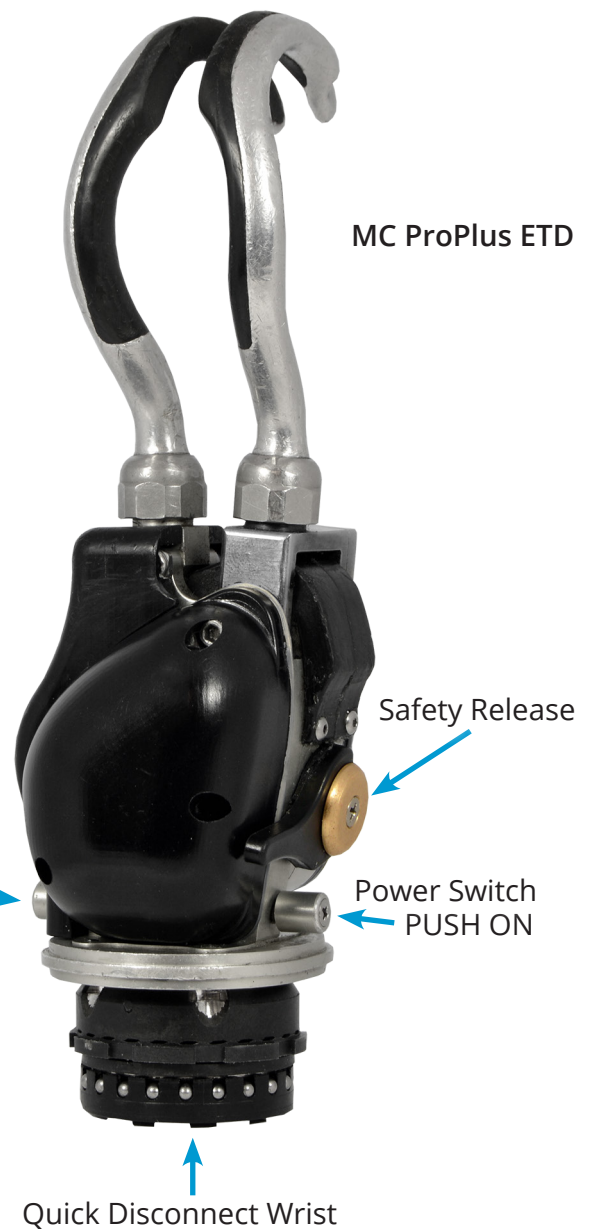
The Motion Control (MC) ProPlus Electric Terminal Device (ETD) is a high performance electric terminal device for persons with upper extremity limb loss. The MC ETD contains a battery-saver circuit for longer battery life, wide-opening fingers, and a unique safety release.

The MC ETD is manufactured as a robust device for high-use wearers. The fingers are lightweight aluminum, but are also available in titanium for increased strength. The MC ETD is water-resistant to the IPX7 standard, allowing it to be submerged to the quick disconnect wrist.

The MC ETD allows the addition of two different types of Motion Control flexion wrists, the Flexion Wrist or Multi-Flex Wrist, without major increases in length. In cases where the residual forearm length is rather long, choose the Wrist Disarticulation version, which is shorter by 2.4 cm (1.0 in) by sacrificing the Q/D and fabricating directly to the forearm.

The MC ProPlus ETD has an ultra long-life brushless DC motor and on-board controller. This versatile microprocessor provides easy adjustability via wireless Bluetooth® communication to iOS devices (iPhone®, iPad®, and iPod Touch®), a variety of input sensors, and high performance. The MC ProPlus ETD can be used with other MC ProPlus components, such as the MC ProWrist Rotator, and easily interchanged with the MC ProPlus Hand, and other manufacturers' devices.

MC ProPlus ETD green coax receptacle (replaces earlier red receptacle)



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 ETD is water-resistant, not waterproof

While the Motion Control ETD is water-resistant, the quick disconnect wrist is not. Do not submerge the ETD beyond the wrist.



Flammable Gases

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



Do not bend fingers

While the MC ETD is robust, body weight represents a great deal of force. Do not apply full body weight on the fingers. Additionally, a fall with the force directed to the fingers could cause damage. If the fingers do become bent or out of alignment, return the ETD to Motion Control.



Safety Release

Do not force the ETD fingers opened or closed. This will result in serious damage to the device. The safety release will allow easy opening and closing of the ETD. If the release mechanism does not allow motion, the device requires service by Motion Control.



Setup Using the User Interface

While the default settings in the MC ProPlus ETD may allow the patient to operate the system, it is highly recommended the prosthetist utilize the User Interface to customize the settings for the wearer.



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.



Repairs or Alterations

Do not attempt to repair or alter any of the mechanical or electronic components of the MC ETD. This will likely cause damage, additional repairs and void the warranty.

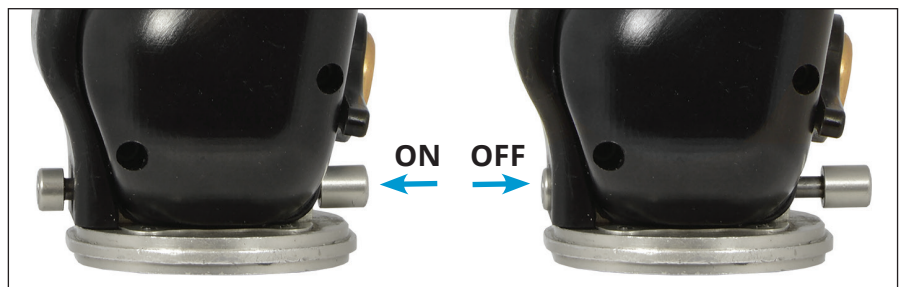


Serious Incidents

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.

Power Switch

The power switch is located at the base of the ETD, on axis with the opening of the fingers. Pushing on the same side as the safety release turns the ETD ON. Pushing on the opposite side turns the ETD OFF.



Safety Release

Pushing the safety release lever UP disengages the fingers, allowing the ETD to be easily opened.



Quick Disconnect Wrist

The Quick Disconnect wrist is a universal design that allows interchangeability with our other terminal devices, such as the MC ProPlus Hand, and other manufacturers' devices.

Instructions for Use

Before attaching the MC ETD to the forearm, locate the power switch at the base of the ETD. Ensure it is switched OFF (see diagram, page 3).

Insert the quick disconnect wrist on the ETD into the wrist on the forearm. While pushing it in firmly, rotate the ETD until an audible click is heard. It is advisable to rotate the ETD both directions several clicks, then attempt to pull the ETD off to ensure it has attached firmly.

Now, push the power switch in the opposite direction and the ETD is ON and ready for use.

To disconnect the ETD, first turn it OFF, then rotate it either direction until a slightly more difficult click is felt. Overcoming this click will disconnect the ETD from the forearm. This allows interchangeability with another terminal device, such as the MC ProPlus Hand.

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 additional hardware may be necessary. The software needed to make these adjustments is provided at no charge to the prosthetist or end user.

Motion Control 5.3.1

Motion Control 5.3.1 is the Windows-based version of the User Interface which is available for download at: <http://www.utaharm.com/files/wl/?id=c&filename=UserInterfaceInstallation.exe>.

Either a hard-wired USB cable (P/N 5010075) or Bluetooth® Firefly (P/N 5010037) is required to connect the MC ProPlus Hand to the Windows PC. The ProPlus Adapter T-Cable (P/N 3010444) may be necessary in some applications.

Motion Control 5.3.1 instructions can be found at:

<http://www.utaharm.com/files/wl/?id=f&filename=1910010-QUICK-SET-UP-GUIDE-for-ProPlus-ProWrist-ProControl2-10-09-2019 EN.pdf>.

Note: Adjustments for the optional FLAG feature (discussed later) are *not* available in the Windows version of the User Interface.

iOS User Interface

MC ProPlus ETDs 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.

Instructions for loading the MCUI application onto your Apple® device, and pairing the device using Bluetooth®, can be found on page 8.

The first time the application is opened, a tutorial is offered. This overview will take 10 to 15 minutes and is recommended. Additionally, located throughout the application is a context-sensitive information icon. Tapping this icon ⓘ will briefly explain the function of that adjustment.

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

Patient/Prosthetist Controls

Upon opening the iOS Application, the user responds as “Patient” or “Prosthetist”. If “Patient” is chosen, many of the adjustments are grayed out. EMG signals are visible for training purposes. Several adjustments such as buzzers, some FLAG adjustments, and Auto-Cal are accessible to the wearer. Familiarize your patients with these adjustments.

If “Prosthetist” is chosen, a code is requested (located on page 8 with iOS instructions). This allows access to all the adjustments of the device.

User Profiles

User Profiles can be saved on your Apple® device. It is advisable to save the settings not only on the prosthetist’s device as a part of the wearer record, but also on the wearer’s Apple® device so they can reset their ETD if the settings are lost.

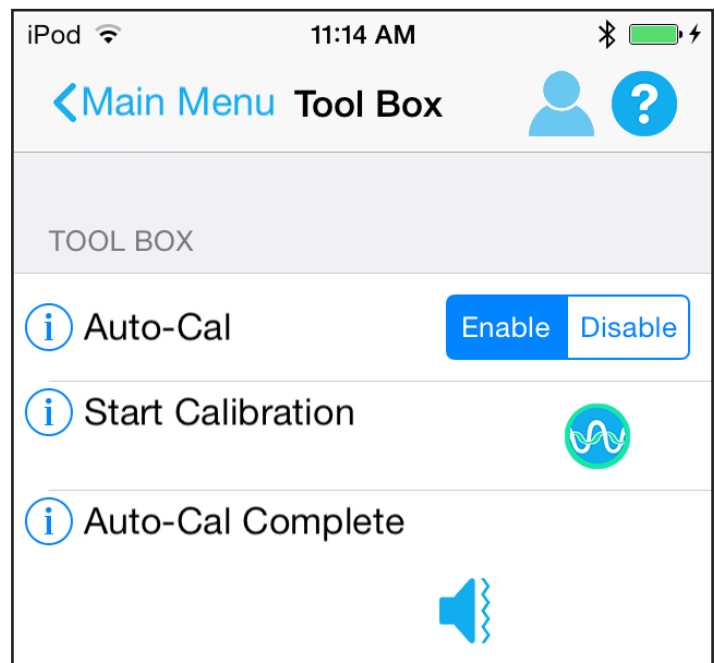
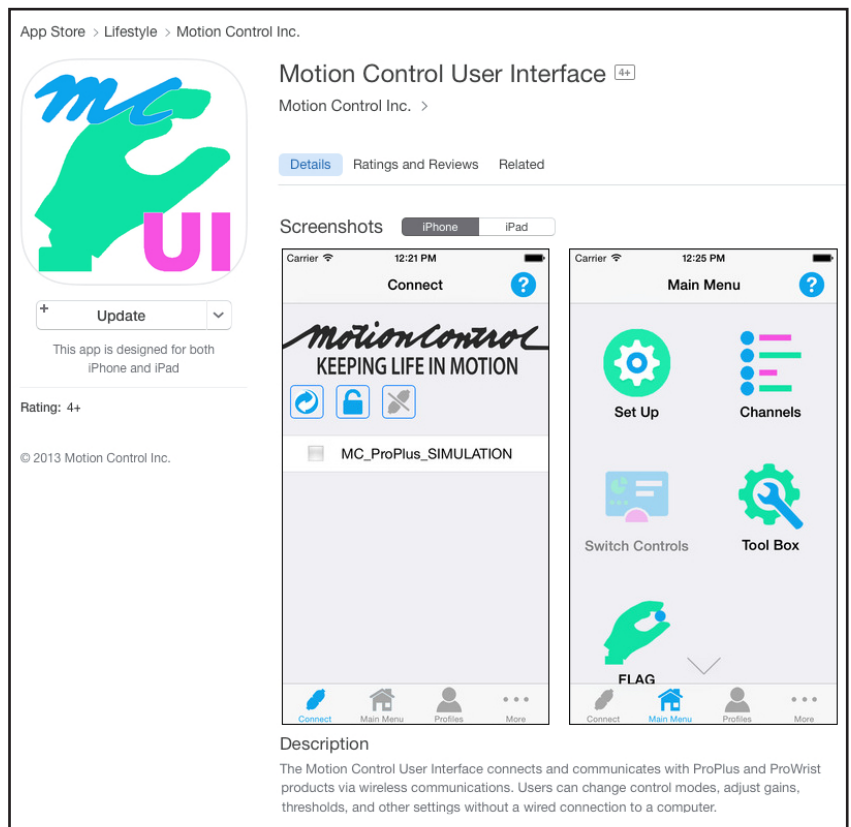
Auto-Cal

Auto-Cal is a useful feature in every ProPlus device. By triggering an “Auto-Cal event” via the iOS User Interface, the wearer can readjust the gain settings throughout the day.

Auto-Cal does have limitations:

- Auto-Cal is only available in Dual Channel control
- Auto-Cal automatically sets Control Type to First Over
- Thresholds are automatically set at 21% (adjustable by the prosthetist)

Auto-Cal will automatically save the previous settings and ask the wearer if they would like to return to previous settings. Performing multiple Auto-Cal events will delete custom settings. Wearers should be advised to **not** Auto-Cal if you have customized the settings.



FLAG (Optional)

FLAG (Force Limiting, Auto Grasp) is an optional feature for the MC ProPlus Hand and ETD terminal devices. FLAG provides two functions:

- **Force Limiting**, to prevent crushing objects due to excessive pinch force
- **Auto Grasp**, which slightly increases the grip on an object if an inadvertent open signal is detected by the controller

Turn FLAG On/Off

Upon power up, FLAG is turned off. The TD should be closed, then opened, before using FLAG. To turn FLAG on, give the device a “Hold Open” signal (for ~ 3 sec.)**. When FLAG turns on, the wearer will feel one long vibration. A “Hold Open” signal (for ~ 3 sec.)** will turn FLAG off, and two short vibrations will be felt by the wearer.

Note: If a series of **5 vibrations** is felt upon a “Hold Open”, it could indicate a malfunction in the FLAG sensor. Turn the device off, and back on, then completely open and completely close the device. Retry the “Hold Open” signal to activate FLAG. If 5 vibrations are felt again, the device will still function but FLAG will be disabled. The device must be returned to Motion Control for the FLAG sensor to be repaired.

Dual Channel FLAG

Force Limiting

1. With FLAG on, closing is still proportional, with maximum speed lowered by 50%**.
2. On closing, when the fingers contact an object, force will be limited to ~ 2 lbs/9N of grip force – then the wearer feels one short vibration.
3. To increase force, the wearer relaxes below threshold, followed by a strong close signal** for a short effort** and the grip force “pulses” up.
4. Grip force can be pulsed up to 10 times to a maximum of ~ 18 lbs/80N of pinch force**.
5. An open signal will open the terminal device proportionally.

Auto Grasp

With FLAG on, a quick, inadvertent opening signal will result in a single “pulse” increase in grip force to prevent dropping an object.**

Single Channel FLAG

With Single Channel Control, FLAG is best used in Alternating Direction Control Mode.

Force Limiting

1. With FLAG on, the terminal device will close at approximately 50% speed**, proportionally.
2. When the device contacts an object, force will be limited to ~ 2 lbs/9N.
3. A quick and strong signal** above the threshold, then relaxation below the threshold, will create one pulse in the force**.
4. This can be repeated up to 10 times for ~ 18 lbs/80N of pinch force.
5. A sustained signal of about 1 second will open the terminal device.

Auto Grasp

With FLAG on, any quick, inadvertent signal will result in the terminal device closing, preventing the object from being dropped.

Using FLAG with Alternate Inputs (including Touch Pad, Linear Potentiometer or Force Sensor)

In the User Interface, set Control Type to Alternate Input, and choose Single or Dual Channel. The Gain settings must be set so the wearer’s output signal is high enough to exceed the Hold Open Threshold** necessary to turn FLAG on or off.

**Note: These settings are adjustable in the iOS MCUI application

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.

For more information regarding the Limited Warranty, see the MC FACT SHEET - Limited Warranty.

Return Policy

Returns are accepted for a full refund (not including any repairs that may be required) for up to 30 days from date of shipment. Returns 31-60 days from date of shipment will be accepted, subject to a 10% restocking fee. Returns 61-90 days from date of shipment will be accepted, subject to a 15% restocking fee. Returns must be in re-saleable condition. Beyond 90 days, returns are not accepted.

Technical Specifications

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

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

Pinch Force: At 7.2 volts nominal: 11 kg (24 lbs, or ~ 107N)

Operating Voltage Range: 6 to 8.2 Vdc - MC ProPlus ETD

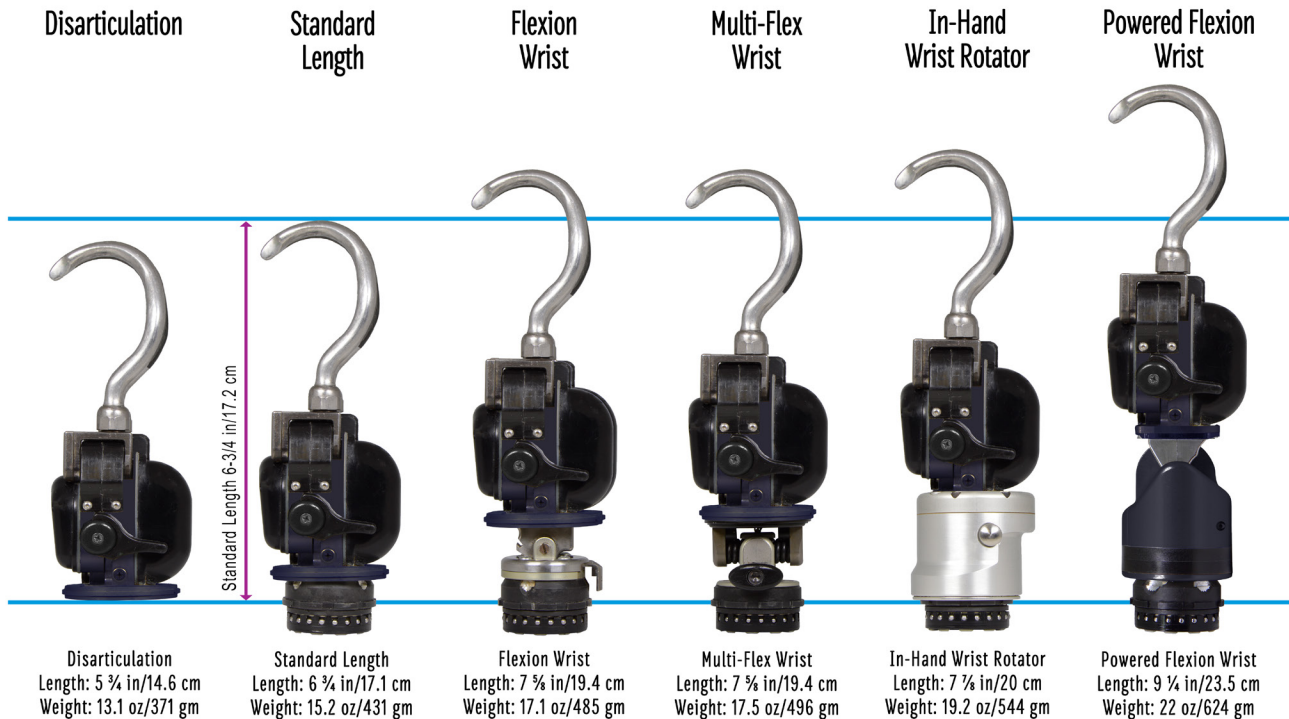
Load Limit: 22 kg / 50 lbs in all directions (+/- 10%)

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)









MC ETD Size and Weight Chart



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:

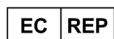
- iPad® (3rd gen and later)
- iPad mini™, iPad Air®, iPad Air® 2
- iPod touch® (5th gen and later)
- iPhone® 4S and later.

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

Fillauer Europe

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



www.fillauer.com

Motion Control, Inc.

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