MC ProPlus ETD User Guide



MC ProPlus ETD

User Guide

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 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 easily interchanged with other MC ProPlus components, such as the MC ProPlus Hand, and other manufacturers' devices.



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, see your prosthetist.



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.



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.



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.



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 2).

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

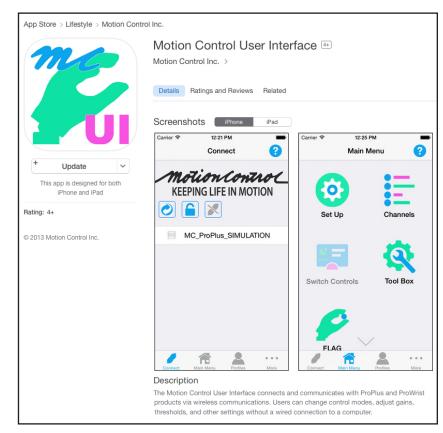
Each of the ProPlus family of Motion Control products contains a microprocessor that can be adjusted and set for a specific individual's needs. Wearers without EMG signals can also be accommodated, but some additional hardware may be necessary. The software necessary to make these adjustments is provided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

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. (i) 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 you will be asked "Patient" or "Prosthetist" – select "Patient". While you as a patient are allowed to navigate the entire application, many of the adjustments are "grayed out" as those can only be changed by your prosthetist.

However, you are still able to see the strength of your EMG, or other input signals, to allow you to exercise those muscles.

Additionally, you may change any adjustments that are not "grayed out". These include such settings as buzzers, and several of the FLAG adjustments (FLAG is an optional feature).

User Profiles

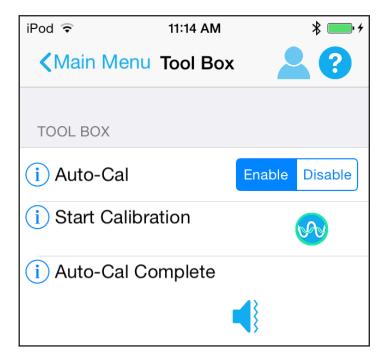
You are able to save your profile in the User Profile section of the iOS User Interface. It is advisable to save your Profile on your device, and your prosthetist is advised to save it on his, also. This will provide a backup in case any repairs or firmware updates are required.

Auto-Cal

Auto-Cal is a feature on every ProPlus device. Use Auto-Cal only at the direction of your prosthetist. Triggering an Auto-Cal event will likely cause loss of the settings your prosthetist has programmed into your device.

If your prosthetist has instructed you in the use of Auto-Cal, you can trigger an Auto-Cal event by tapping the icon at "Start Calibration", then give moderate open and close signals for 7 seconds. The iOS device will prompt you. It is important you make these moderate signals, as too strong a signal will result in the device running slowly. Too weak a signal will result in a device that is difficult to control.

After "Auto-Cal Calibration" you will be asked if you like these settings. Try opening and closing quickly and then attempt lightly grasping objects. If you are able to do both, accept the calibration. If you do not have adequate control, tap "Retry".



Note: When you accept Auto-Cal settings, your previous settings are lost. If your prosthetist has set up custom settings, do *not* trigger Auto-Cal calibration.

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 \sim 3 sec.)**. When FLAG turns on, the wearer will feel one long vibration. A "Hold Open" signal (for \sim 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.

**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)









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 (A)



download and install the MCUI.



- 2. Choose "Patient".
- 3. Open the App and follow the Tutorial.
- 4. Go to the Connect screen



and tap Scan.



- 5. Input the Pairing Key. Your prosthetist will provide this.
- 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 guick 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 (i) provides information about a function
- To repeat the tutorial, go to



and tap Reset on Reset Guided Tutorial

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