

MC ETD2

User Guide

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 ETD2 is water-resistant, not waterproof

While the Motion Control ETD2 is water-resistant, the quick disconnect wrist is not. Do not submerge the ETD2 beyond the wrist.



Flammable Gases

Caution should be used when operating the ETD2 around flammable gases. The ETD2 utilizes an electric motor that can ignite volatile gases.



Do not bend fingers

While the MC ETD2 is robust, body weight represents a great deal of force. Do not apply full body weight on the fingers. A fall with the force directed to the fingers could cause damage. Additionally, when pushing forcefully with the ETD2 do not push on the open, moveable finger. Push only with the ETD2 in the closed position. This includes pushing up from a chair. If the fingers do become bent or out of alignment, return the ETD2 to Motion Control.



Safety Release

Do not force the ETD2 fingers opened or closed. This will result in serious damage to the device. The safety release will allow easy opening and closing of the ETD2. 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 ETD2. This will likely cause damage, additional repairs and void the warranty.



Setup Using the User Interface

While the default settings in the MC ETD2 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.

Single Use Statement

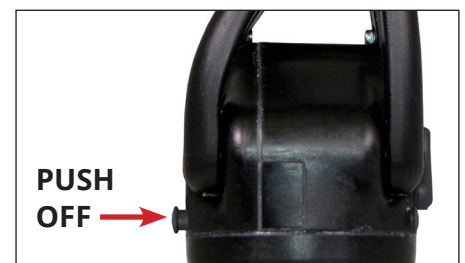
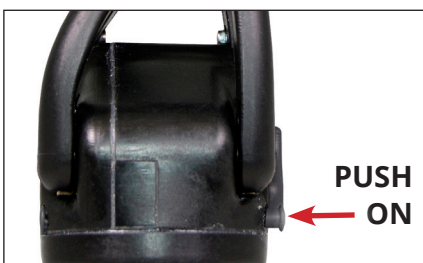
Each amputee is unique. The shape of their residual limb, the control signals each generates and the tasks an amputee performs during the day require specialized design and adjustment of the prosthesis. Motion Control products are manufactured to be fit to one individual.

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.

Power Switch

The power switch is located at the base of the ETD2. Pushing from the side opposite the fingertips will turn the ETD2 ON. Pushing from the fingertip side will turn the ETD2 OFF.



MC ETD2

User Guide

Introduction

The Motion Control ETD2 marks the second generation of the Electric Terminal Device. Continuing the features of the previous ETD, the ETD2 is robust, lightweight and water-resistant to provide a high level of functionality to persons with upper extremity limb loss.

The ETD2 is manufactured with metal inserts in the fingers, over molded with plastic for strength and durability. The result is a sleek, aesthetically integrated form. The Gripping Pads can be quickly and easily replaced by your prosthetist. The safety release allows the fingers to be opened in case of emergency.

The ETD2 is a member of the ProPlus Family of Motion Control devices. The ProPlus on-board microprocessor makes the ETD2 interchangeable with almost all other hands and terminal devices on the market. Additionally, the on-board microprocessor allows use of a brushless DC motor which makes your device quieter and much more dependable.

Bluetooth® provides convenient communication between your ETD2 and an iPhone®, iPad® or iPod® Touch. This allows easy adjustability for your Prosthetist to get the highest level of performance and fine control of your ETD2. Additionally, you can communicate with your ETD2 to make several changes to the device, and use it for training to improve your control.

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.

MC ETD2



Safety Release

On a Left ETD2, the safety release is located on the same side as the fingertips. On a Right ETD2, the safety release is located on the side opposite the fingertips.

To engage the fingers, ensure the safety release lever points toward the fingertips. To release the fingers, rotate the lever 90 degrees, toward the moveable finger.



Finger Lining Replacement

The gripping surfaces on the fingers of the ETD2 can be replaced. This replacement should be performed by your prosthetist.

Instructions for Use

Before attaching the MC ETD2 to the forearm, locate the power switch at the base of the ETD2. Ensure it is switched OFF (see diagram, page 3).

Insert the quick disconnect wrist on the ETD2 into the wrist on the forearm. While pushing it in firmly, rotate the ETD2 until an audible click is heard. It is advisable to rotate the ETD2 both directions several clicks, then attempt to pull the ETD2 off to ensure it has attached firmly.

Now, push the power switch in the opposite direction and the ETD2 is ON and ready for use.

To disconnect the ETD2, first turn it OFF, then rotate it either direction until a slightly more difficult click is felt. Overcoming this click will disconnect the ETD2 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.

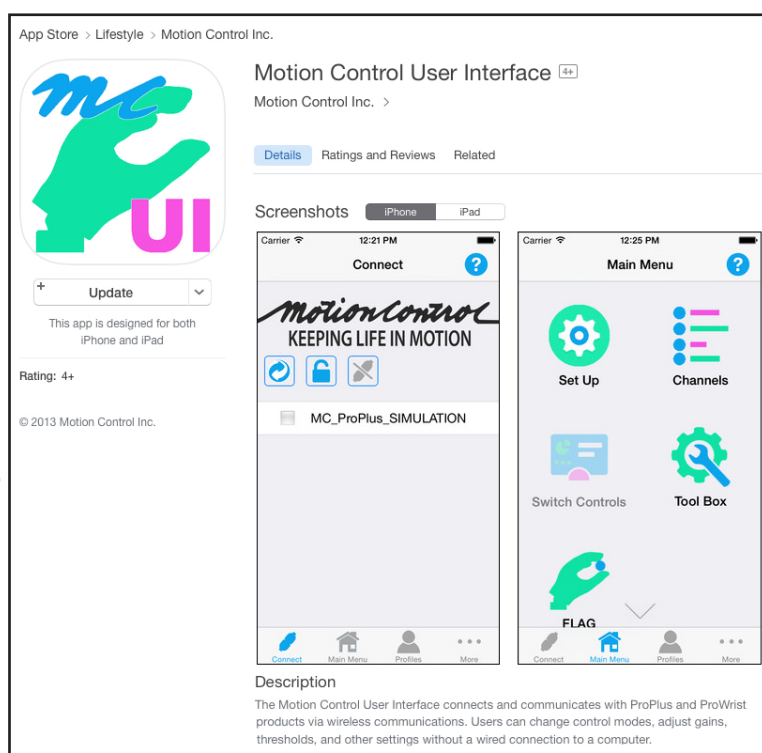
iOS User Interface

The MC ETD2 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.

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 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

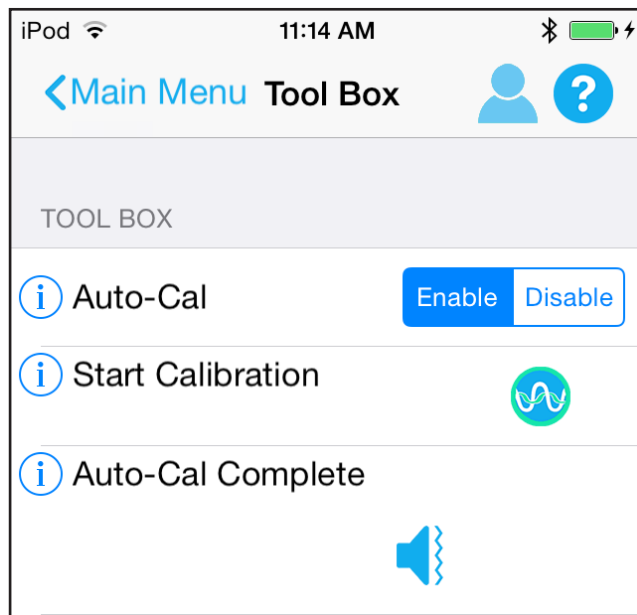
You are able to save your profile in the User Profile section of the iOS User Interface. It is advisable to save your profile on your device, and your prosthetist is advised to save it on his, also. This will provide a backup in case any repairs or firmware updates are required.

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, ETD and ETD2 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.

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



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. 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 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



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 ETD2

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)



Customer Support

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