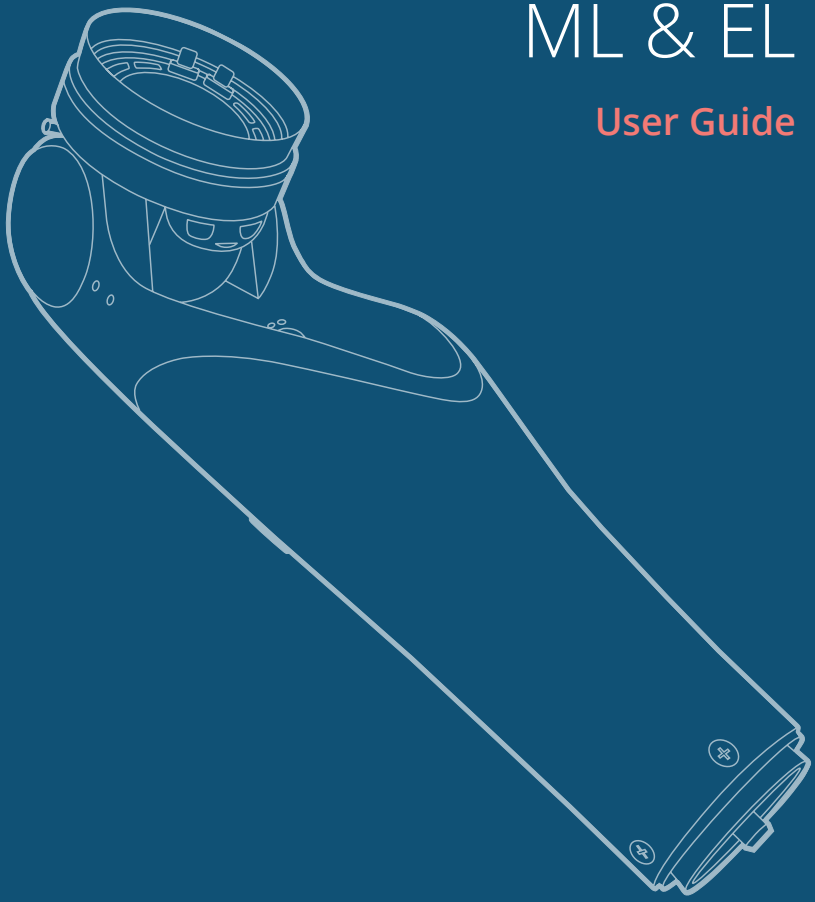
Motion Arm
ML & EL

User Guide



Fillauer®
Motion Control

Motion Arm®

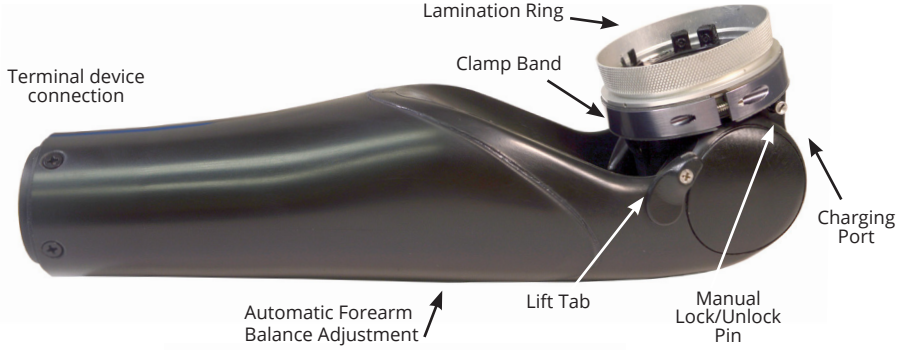
Users Guide

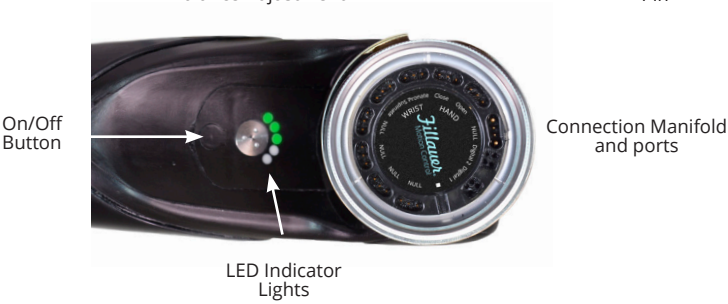
Introduction

The Motion Arm is the first waterproof elbow for use with myoelectric devices. Rated at IP67 dustproof/waterproof certification, with a waterproof terminal device (electric hook or hand) and waterproof wrist attached, the entire prostheses can now be submersed up to the first opening in the prosthetic socket.* No longer fear rainy days, washing the car or even vigorously washing your hands.

Power comes from an internal 3000 mAhr battery, adequate for a full day's charge in most situations. Five LED lights on the front of the arm indicate the level of charge left in the batteries with low battery warnings at 20% and 15% of capacity remaining. No more guessing if you need to charge your battery!

Please read through this User Guide. It contains important precautions and information to get the highest performance from your prosthesis.





When used in conjunction with a waterproof terminal device and waterproof quick disconnect wrist.

Special Precautions

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. The device poses a spark risk and should not be used around volatile gases.

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.

A waterproof terminal device with a waterproof quick disconnect wrist must be installed to make the elbow waterproof. Exposing the elbow to water without a waterproof wrist installed will likely cause damage to the elbow.

Use the battery charger supplied with the elbow ONLY. Do not use generic or other manufacturer's chargers.

Do not remove any covers, screws, plates or any part of the elbow not described in this manual. There are no user serviceable components within the elbow. Removal of these covers will compromise the waterproof seal and void the warranty.

Do not charge the elbow while wearing the prosthesis. Remove the prosthesis before charging the device.

A Low Battery Warning will activate when the battery reaches 20% of full capacity. The wearer should charge the elbow at this point. Once the charge is depleted from the battery, the device will no longer function. Non-Motion Control terminal devices may not be able to release their grasp on an object.

The Motion Arm will support 50 ft-lbs/65 Nm (22.6 kg) with the elbow in the locked position. Forces greater than 50 lbs could damage the elbow and are considered beyond the capabilities of the elbow. This could include but is not limited to lifting heavy loads and/or falls onto the elbow.

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 their regional Fillauer company immediately in the event of any device failure.

Charging

Battery level indicator.

When you receive the Motion Arm elbow it likely will not have a full charge. Upon receiving the device, it should be charged to a full charge. The charger comes with multiple wall plugs for various international power outlets. Choose the correct one for your area and slide it into place. Plug the charger into the outlet and the light on the charger will glow green.

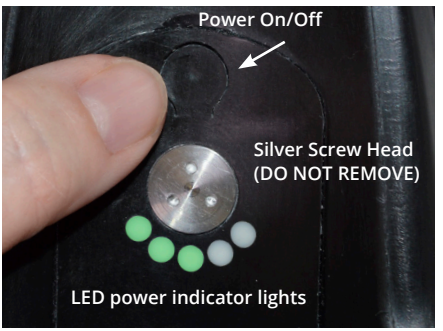
The charge port for the elbow is found on the back of the elbow. It is a simple magnetic connection. Once the connection is made the charger light will change to red as the elbow charges. Once the battery is fully charged, the light will return to green. From full discharge to full charge is usually about 3 hours.

If the charger light glows green but the elbow is not fully charged, check the connection between the charger and the elbow. If it continues to show green, there is a fault in the charging system and you should contact your prosthetist.

Power On/Off

The on/off button is located next to the silver screw on the front of the elbow. To turn the power on/off, press and hold the button for about 2 seconds. When the elbow powers "on" it will beep or buzz (if feedback is enabled) and the 5 LEDs will sequentially flash green, then flash green to indicate the level of charge in the battery. When the on/off button is pressed again for 2 seconds, the LEDs will light red and then sequentially flash red. Once the last red LED is extinguished, the elbow will beep/buzz and the power is now off.


The charge port is located on the back of the elbow and connects with a break-away magnetic charging plug.



The power button and red/green LED indicator lights are located on the front of the elbow.

Battery Level Indicator

The 5 LEDs on the front of the elbow indicate the charge level of the battery. To activate the indicator, the arm must be turned on, the on/off button is pressed momentarily, and the LEDs will light showing the remaining charge. Each light represents 20% remaining charge. The lights will go out in a few seconds.

Low Battery Warning

When the battery charge level drops to 20% of capacity 1 LED will blink and the elbow will beep/buzz 3 times every 5 minutes. This warning can be disabled by pressing the on/off switch momentarily. If the elbow is turned off, and then back on, the warning will reactivate.

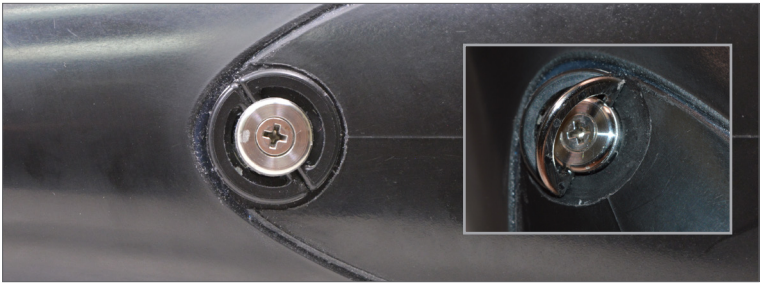
A critical Low Battery Warning will notify the user when the Battery is at 15% of capacity. The elbow will beep/buzz 3 times and the LEDs will flash red. When the battery is completely depleted the terminal device and all components will not function. If the feedback feature has been turned off, you will not get the audible warning. The light will still flash.

When the Low Battery Warning goes off, the wearer should actively begin seeking a charge for the battery. Non-Motion Control terminal devices may not be able to release their grasp on an object when the battery is depleted.

Adjusting Automatic Forearm Balance

The Motion Arm ML and EL have a self-contained automatic forearm balance mechanism. This allows adjustment of the forearm lift force to counteract the weight of the terminal device and/or an electric wrist rotator.

The forearm adjustment is found on the backside of the forearm. To increase the lift assist for heavier terminal devices or the addition of an electric wrist rotator, flex the elbow completely, open the two wings of the adjustment screw and turn it clockwise as if looking directly at the adjustment screw. To decrease the forearm lift, (for example, going from a multi-articulating hand to an ETD) turn the screw counterclockwise. A total of 10 revolutions are possible. The screw will not turn after it reaches its limit. Do not force it further as damage will occur. Once the adjustment has been made, be sure to return the adjustment screw wings to their flattened, locked position



The Automatic Forearm Balance (AFB) mechanism is on the bottom of the arm. Lift the tabs and twist to adjust. A total of 10 revolutions is possible.

A total of 10 revolutions are possible with the adjustment. Do not force as damage will occur.

Flex the elbow completely before making the adjustment

Elbow Electronic Adjustments

Motion Arm ML

The Motion Arm Manual Lock is designed to be a simple, lightweight, low-cost elbow. As such, set up of the elbow is performed by a series long and short depressions of the on/off switch. See the section, Settings Mode (p.8) for the setting codes.

Motion Arm EL

The Motion Arm Electric Lock elbow has sophisticated electronics including Bluetooth for communication with the iOS User Interface. For information on downloading the Motion Arm User Interface (MAUI), see the MAUI for iOS section (p.16). After downloading the App, you will be prompted to view a tutorial. It is highly suggested you follow this tutorial as it only takes 10-15 minutes.

MAUI adjustments affect only the elbow settings. Adjustment of these settings are necessary for ease of lock/unlock of the elbow. Adjustment of the electric wrist rotator and/or terminal device are made in each component's specific user interface.

Manual Lock/Unlock Override

Motion Arm EL only

The Motion Arm EL has a manual lock/unlock override for those situations where you may not be able to hit an unlock trigger, or the battery is depleted, and the elbow is locked. Behind the elbow axis, slightly below the friction band, a slide will lock/unlock the elbow. By pushing on the right side and sliding it to the left, (from the patient's perspective) the elbow will unlock. Sliding from the left toward the right, the elbow will lock.

Mode Adjustments

Elbow Unlock: Wrist/Terminal Device Disable

The Motion Arm can be set so the Terminal Device and wrist rotator (if installed) is disabled upon elbow unlock. This allows the wearer to flex and extend the elbow without the fear of inadvertent opening (or closing) of the terminal device or wrist rotation. It can also be set to allow motion of the TD and wrist rotator while simultaneously flexing and extending the elbow.

Feedback

The elbow will beep or buzz to inform the wearer of several events. The wearer can choose between a beep, buzz, or none by turning off the feedback for these events. If both are turned off, there is no audible low battery warning. The lights will continue to flash.

SETTING	RED LED	GREEN LED
Disable Wrist/TD Elbow Unlocked	Wrist/TD Enabled when elbow is unlocked	Wrist/TD Disabled when elbow is unlocked
Buzz	Disabled	Enabled*
Beep	Disabled	Enabled*

*Note, all Buzzers and Beepers, including low battery buzzers, are disabled when both buzz and beep are turned off.

Settings Mode—Motion Arm ML

Lacking Bluetooth communications, settings for the manual locking elbow are made with the power switch. To enter the settings mode, with the arm powered on, press the on/off button twice, quickly and then hold the button on the third press. The LEDs will now dance green. Pushing the power button once, the settings will now cycle through as listed in the feedback chart. Quickly pressing the power button twice enables
or disables a setting.

Exit Settings Mode the same way as entering it, push the power switch twice quickly and hold on the third push. The LEDs will now dance red. The settings mode will time out and exit after 5 minutes of no activity.

Feedback Indicators

Many events will trigger a beep or buzz and flashing lights. See the below chart for an indication of those events.

EVENT	FEEDBACK
Power On	One long buzz or beep
Lock/Unlock	One quick buzz or beep
Low Battery Indication	1 Green LED ramp-up (20% battery remaining). Three quick buzzes or three quick beeps
Critical Battery Level	1 Red LED ramp-up (15% battery remaining). Three quick buzzes or three quick beeps
Enter Settings Mode	LEDs dance green
Exit Settings Mode	LEDs dance red

MAUI App for iOS

Quick Setup for Motion Arm User Interface for Apple® iOS (MAUI)

- From the Apple® App Store download the MAUI app.
- Enter the Prosthetist Code: **PR-MCAK**. *Patients do not require a code.*
- Open the App and follow the Tutorial.
- Go to the Connect screen and tap Scan.
- Input the Pairing Key that came with the device. *This key should be kept in the Patient's record.*
- The device is now connected to the MAUI.
- To disconnect, tap the Connect icon in the lower left corner, then tap Disconnect.

Troubleshooting

- Make sure the battery on the device is fully charged
- Confirm the device is turned on
- Verify that you are not in "Simulation Mode" by double tapping the Home key, then swiping MAUI off the screen, and reopening the app
- 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

System Requirements

- iOS 11 minimum
- iPad® (5th gen and later)
- iPad mini® (2nd gen and later)
- iPad Air®
- iPad Pro®
- iPod Touch® (6th gen and later)
- iPhone® 5s and later

Declarations

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, a Fillauer Company 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.

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, local competent authority and Fillauer at the earliest possible convenience. Clinicians should at any time contact their regional Fillauer representative and local competent authority immediately in the event of any device failure.

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 two years years (24 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.

Rental Program

Fillauer offers a rental program for trial fittings up to six months. A product is rented with your regional Fillauer office's signed rental agreement, and a portion of the rent is applicable towards purchase using a sliding formula. Contact us for details.

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.

Microprocessor Software Information

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RoHS COMPLIANT CE Bluetooth®

Technical Specifications

Operating temperature: 0° to 44° C (32° to 110° F)

Transport & storage temperature: -18° to 60° C (0° to 140° F)

Load limit (elbow locked): 50 ft-lbs/65 Nm, all directions (+/- 10%)

Range of motion: 0° to 145°

Humeral rotation: 360 degrees, adjustable friction resistance

Weight: 1.7 lbs / 771 grams

Weight with lamination collar/friction band: 1.8 lbs / 816 grams

Build height: 1.75 in / 45 mm

Dimensions (from elbow center of rotation)

- Standard length: 10 in / 254 mm
- Minimum length: 8 in / 203 mm

Optional Features

MC Electric ProWrist Rotator

MC ETD or ETD2, MC Hand

Compatible with TASKA®, i-limb® and bebionic® hands, and other manufacturers' terminal devices

Battery Pack Specifications

Nominal Voltage:	7.2 V
Rated Capacity:	3000 mAhr
Charge Time:	3 Hours
Ingress Protection Rating:	IP67

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)

Safety Warning

Bluetooth 2.0 and 4.0 devices like the Motion Arm emit low levels of nonionizing radiation. Exposure to low amounts of this type of radiation is not harmful to humans.

Motion Arm operations and education

VIDEO INSTRUCTIONS AVAILABLE ONLINE

Documentation and videos for operation of the Motion Arm ML and EL, along with best practices, can be found online:

www.fillauer.com/motion-arm-education

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