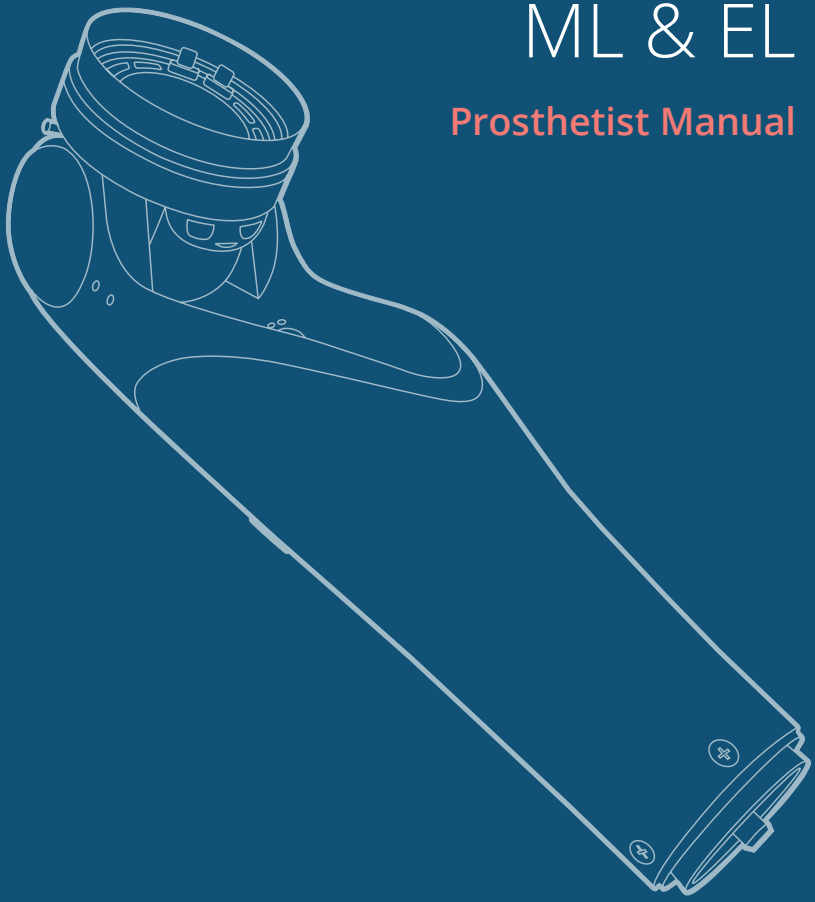
Motion Arm
ML & EL

Prosthetist Manual



Fillauer®
Motion Control

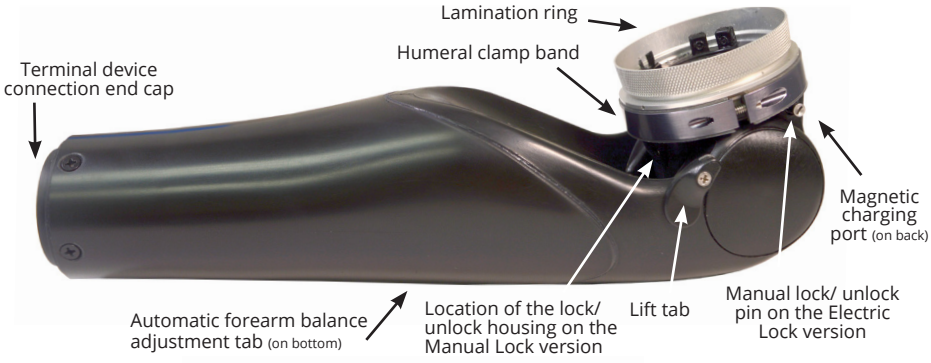
Motion Arm®

Prosthetist Manual

Introduction

Welcome to the next generation of prosthetic elbows. The Motion Arm Manual Lock (ML) and Motion Arm Electric Lock (EL) are the new standard of automatic forearm balance elbows. In continuation with Motion Control, a Fillauer Company philosophy, the new Motion Arm elbows are IP67 dust-proof/waterproof. This allows the elbow to be completely submersed.* This feature is unique to the Motion Arm elbows, and now the wearer has the freedom to wash their hands, wash the car, even bathe their child without concern of water damage.

Power comes from an internal 3000 mAh Lithium Ion battery. The battery charge level can be determined by the 5 LED lights at the cubital fold of the elbow. Additionally, inputs accept all standard connections with all connections being waterproof. This eliminates the concern for ingress of perspiration into the elbow electronics. Overall, the elbows are designed to be waterproof, robust, and versatile.



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.

The electronic connections at the input manifold of the elbow are waterproof only if a wire is plugged into the connection. Dummy connectors are provided for connections not being used. A small amount of silicone grease (supplied) on all the connectors ensures a waterproof seal and prevents corrosion.

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

Do not remove the forearm cover for any reason. This will damage the waterproof seal. The warranty will be voided for any water damage caused to the elbow if the forearm has been removed by anyone other than authorized personnel. To cut the forearm to length use the Motion Arm Forearm Cutting Tool, part number 3011092. (See Section "Forearm Length Adjustment" pg. 12)

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.

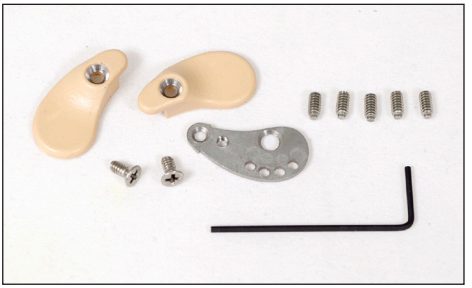
A Low Battery Warning will activate when the battery reaches 20% of full capacity. The wearer should charge the elbow at this point. Once the charge is depleted from the battery, the device will no longer function. Non-Motion Control terminal devices may not be able to release their grasp on an object.

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.

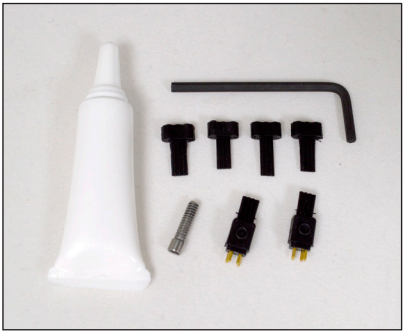
In The Box

Motion Arm ML or EL

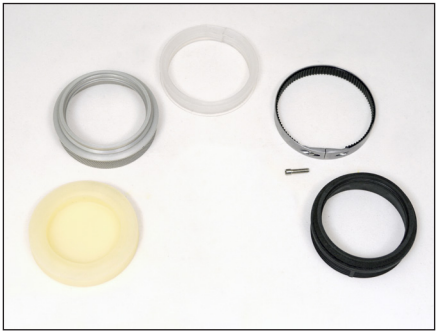


Lift Tab Kit

Battery charger



Spare parts kit with waterproof dummy plugs



Lamination Collar Assembly

Cable Hanger—
Manual Lock only

The following items are included in the box with your new Motion Arm. The box might also include a cutting guide if requested.

Light Indicators

Charging

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. 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 posterior aspect of the humeral section. 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 may be a fault in the charging system. Contact Motion Control for information.

Power On/Off

The on/off button is located slightly distal to the silver screw at the cubital fold 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

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.

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 (if feedback is enabled) and the power is now off.

Battery Level Indicator

The 5 LEDs in the cubital fold 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.

More information about the Motion Arm ML light indicators is available in the Mode Adjustments section.

Setup for the Motion Arm

VIDEO INSTRUCTIONS AVAILABLE ONLINE

The lift tab base-cable pull is attached with a counter sunk screw and then angled and held with a set screw. After the ball terminal is added to the base-cable pull, add the cover and screw down with the second counter sunk screw.

Lift Tab Installation

The lift tab provided with the Motion Arm can be used on either side of the arm for left or right applications. Apply a bead of Locktite 222 to one of the small 4-40 set screws and set it into the distal threaded hole on the side of the arm you need the lift tab. Screw it down until flush with the surface of the arm. Place the base-cable pull plate with the 4-40 countersunk Phillips head screw with a small bead of Loctite in to the proximal hole. Do not tighten all the way.

Position the base-cable pull tab at the angle you need and back out the distal hole set screw counterclockwise until it is tight against the lift tab. Now tighten the countersunk screw. Ensure there is no motion in the tab. If there is, loosen the screws, reposition the tab and re-tighten

Part Number	3/16 Inch Ball Terminal Description
50354-P	Ball Terminal for 1/16 Inch Cable (Pkg 4)
50355-P	Ball Terminal for 3/64 Inch Cable (Pkg 4)
50356-P	Ball Terminal for 3/32 Inch Cable (Pkg 4)
ASPCB1	Ball Terminal for Spectra Cable (Pkg 1)

the screws.

A 3/16" ball terminal is required for cable attachment. Place the ball terminal in the hole in the base-cable pull. Secure the ball terminal with the pull cover and the second countersunk screw. A drop of Loctite is indicated here also. Lastly, insert the extra 4-40 set screws in the opposite side mounting holes. Tighten them down firmly.

The input Manifold is marked with corresponding Degree of Freedom. Note: there is no consistency between manufacturers on polarity. Avoid grease on the label itself.

Input Manifold and Connections

The Input Manifold is marked with the corresponding Degree of Freedom and direction. Keep in mind, there is no consistency between manufacturers on polarity. When setting up the device with the patient the first time, have the patient generate a signal, watch the signal within the User Interface and the direction the component moves. You may need to change the polarity within the component's User Interface.

When inserting connectors into the input manifold at the top of the humeral section of the Motion Arm, add a small amount of dielectric silicone grease (provided) to the connector (caution: don't get grease on the center label). This will aid in waterproofing the connection and prevent corrosion should any perspiration or water seep into the connection. If an input is not being used, install a dummy plug into the connection. This will prevent ingress of water or perspiration and prevent corrosion of the connection.

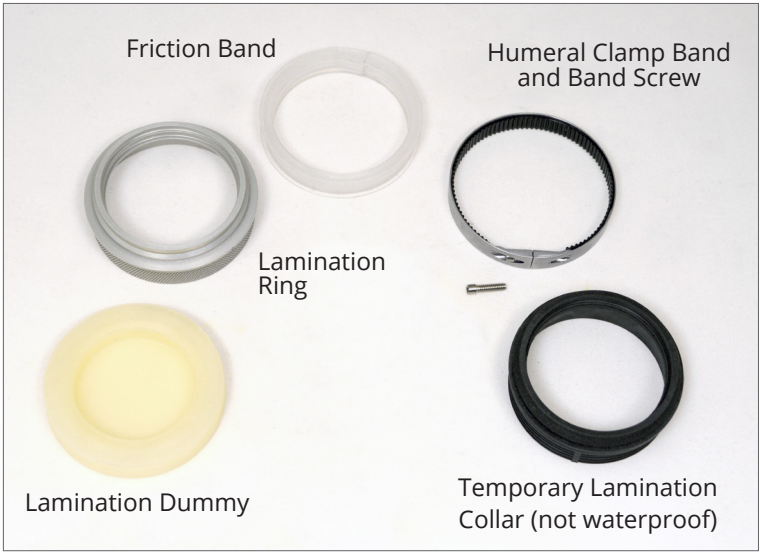
When inserting connectors into the input manifold, add a small amount of dielectric silicone grease (provided) to the connector to aid in waterproofing.

Each connection is to that degree of freedom for simultaneous control. For instance, a system with 4 EMG sites to control pronation/supination and terminal device open/close would be plugged in as listed on the input manifold. If reversed polarity is needed, you can manually change it in the device.

If control is via a 2-site system, with an electric wrist rotator (optional) in sequential control, the inputs are connected to the most distal degree of freedom, in this case the terminal device.

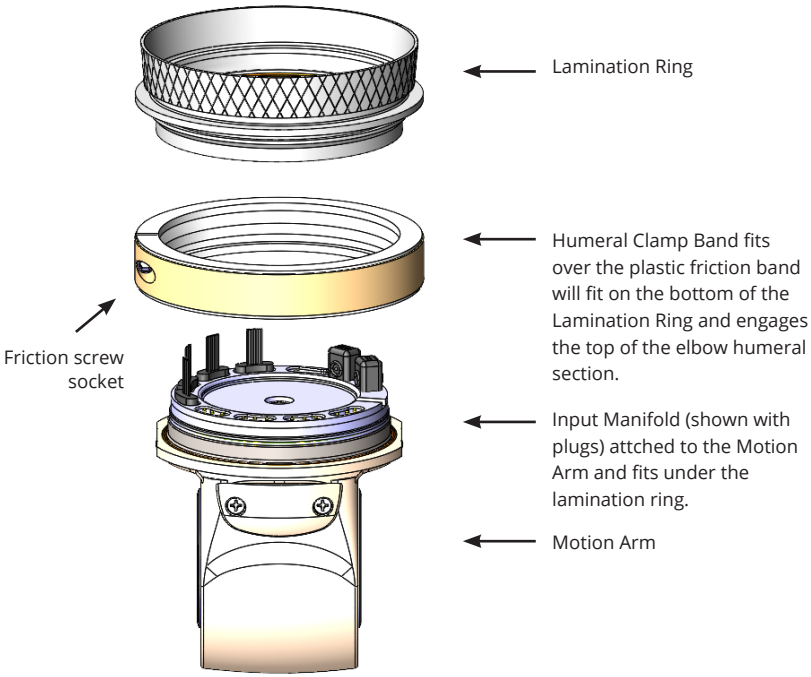
Pattern Recognition Systems

Motion Arm elbows are compatible with COAPT pattern recognition systems. When ordering the elbow and a pattern recognition system, inform both Motion Control and the pattern recognition system manufacturer of all the components to be used, e.g., Motion Arm EL or Motion Arm ML, electric wrist rotator and all terminal devices, especially multi-articulating hands including the manufacturer and model of the device.

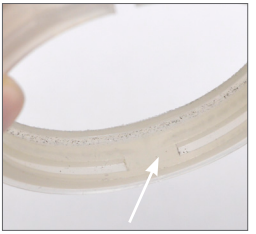


The lamination dummy and collar come as separate items in the box. The rest of the items ship on the elbow and will need to be removed prior to lamination to the socket.

Lamination Collar Assembly



Attachment to the socket



Friction band tab should be placed down near the elbow socket.

Attachment of the Motion Arm elbow to the outer lamination of the socket is accomplished by a 4-part system (plus a lamination dummy) that also adjusts the amount of friction for humeral rotation.

Apply parting agent to the lamination ring where the friction band engages and the inside area of the o-rings.

Install lamination dummy and shape the outer socket by whatever means your fabrication department utilizes. The humeral section must be hollow to allow passage of wires from the inner socket to the input manifold.

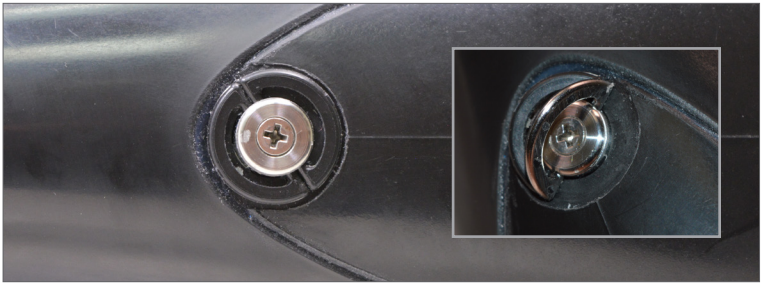
When removing the lamination dummy and any excess plastic, use care not to damage the friction ring or the O-rings of the lamination collar. The O-rings are what protect the elbow from the ingress of water and perspiration.

Once the lamination is complete, remove the lamination dummy. Make sure the lamination collar seats completely, otherwise the friction band cannot be installed correctly..

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 ulnar surface 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, 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

Forearm Length Adjustment

Standard Length Forearm

The Motion Arm comes in the “Standard” forearm length of 10 inches (25 cm) from center of the elbow to the distal quick disconnect wrist. This is the shortest available length when using an electric wrist rotator.

Short Forearm

The standard length forearm can be shortened up to 1 in/2.5cm (9 in/ 23 cm from elbow center). This is accomplished with the Forearm Cutting Tool part number 3011092. This tool must be used to ensure a watertight seal at the End Cap.

If shortening the forearm, do not remove the forearm cover from the elbow. The waterproof seal will be compromised, and the warranty will be voided in the case of water ingress.

Ultra Short Forearm

In cases where the forearm must be shorter than 9 inches (23 cm) in length, the elbow must be returned to Motion Control for length adjustment. The shortest the forearm can be is 8 ¼ inches (21 cm).

*Minimum length to include a wrist rotator

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.13) 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. Adjustments 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 the patient may not be able to hit an unlock trigger, or the battery is depleted, and the elbow is locked. Posterior to 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.

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.

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.

Feedback Indicators

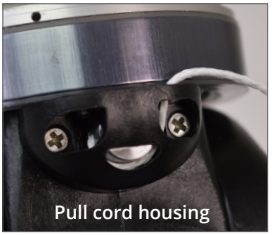
Many events will trigger a beep or buzz and flashing lights. See the below chart for an indication of those events.

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

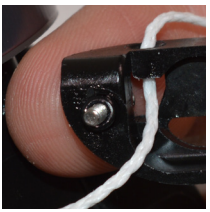
Replacing Spectra Cable

Motion Arm ML

Normal wear and tear will eventually result in the lock/unlock cable fraying and eventually breaking. The cable can be replaced with Spectra Cable from TRS, P/N SPECTRA 400 ULTRA.


Pull cord housing

1. Remove the lock/unlock cover Examine the small O-rings around the screws to insure they are in
   place and in good condition. If they are compromised, replace them (call Fillauer Motion Control).
2. Remove the remnants of the worn cable.
3. Tie an overhand knot in the new cable and gently burn the end to prevent fraying.
4. Insert cable into the lock/unlock pulley, the knot should disappear completely into the hole. If not, re-tie the knot and/or trim it.
5. Loop the cable around the pulley in a counterclockwise direction.
6. Insert the cable through the hole in the cover and replace it. Use care that the cable does not get captured between the pully and the cover.
7. Re-tighten the screws.
8. Tie the ½ inch Spectra Cable Hanger onto the cable with a double half-hitch knot, adjust the length, tie an overhand knot in the end of the cable and gently melt the end with a flame to keep it from fraying.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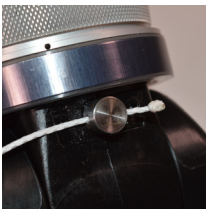
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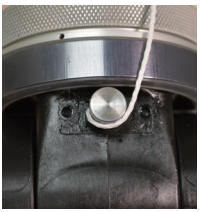
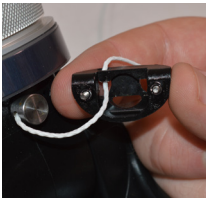

STEP 5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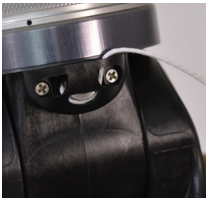
STEP 7


STEP 8

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. Fillauer 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.

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 local 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.

Customer Support

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support@fillauer.com

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Motion Arm setup, operations and education

VIDEO INSTRUCTIONS AVAILABLE ONLINE

Documentation and videos for set up and operation of the Motion Arm ML and EL, along with best practices for it's configuration and function, can be found online:

www.fillauer.com/motion-arm-education

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Customer Support

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