The Mobile Arm Rehabilitation Kit 2 (MARK2)

User Manual

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CONTACT INFORMATION

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myomo my own motion	For more information about Myomo, visit:	www.myomo.com

⚠ CAUTION: United States Federal Law restricts this device to sale by or on the order of a physician or physical therapist.

The MARK2 mechanical assembly has an expected life of three years. This statement is not a service warranty or a guarantee of access to a service warranty. This information is provided to assist in planning.

CONTENTS

INTRODUCTION

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CUSTOMER SUPPORT

For any support issues, please contact Myomo customer support for assistance. See CONTACT INFORMATION for contact information.

INFORMATION SYMBOLS

WARNING
Warns about situations involving the use of electricity and other situations that could result in bodily harm.

CAUTION
Cautions about actions that may create unsafe conditions that could result in damage to the equipment or loss of data.

NOTE
Note about something to be aware of at this stage of MARK 2 use that will help optimize performance or help avoid a common issue that new Users may face.

INTENDED USE

The Mobile Arm Rehabilitation Kit 2 (MARK2), an upper limb orthosis, is a compensatory device to increase the ability to perform functional tasks with the affected limb. The user voluntarily activates movement of the orthotic device with their remaining electromyography (EMG) muscle signal.

INDICATIONS FOR USE

The MARK2 is indicated for use by adolescents and adults diagnosed with long-term muscle weakness OR partial paralysis. Users must meet physical size specifications and demonstrate capacity to use the device, including sufficient cognitive abilities, per user assessment and clinician evaluation.

INTENDED USER

The MARK2 is intended to be used and donned by a Clinician and cannot be sent home with a patient.

CONTRAINDICATIONS

The MARK2 is contraindicated for use as follows:

1. Insufficient myoelectric signal output from at least one muscle group needed to activate the desired powered joint (for example, biceps or triceps signal to extend the affected elbow).
2. Severe shoulder subluxation.
3. Excessive pain in shoulder, arm or hand during facilitated range of motion.
4. Contraindicated during recovery from acute injury such as trauma, infection, or skin condition.
5. Upper extremity contracture(s) that prevent functional movement to benefit from the orthosis.
6. Rigid spasticity in the affected muscle groups.
7. Arm circumferences and lengths that are outside build specifications required to be fit with the orthosis.
8. Cognitive or behavioral impairment that would inhibit safe use of the orthosis.
9. Other medical issue which interferes with safe use of the device for functional improvement.

MARK2 DESCRIPTION

The MARK2 Kit consists of two custom-fabricated, adjustable upper limb orthoses (braces), one for a left arm and one for a right arm. Each MARK2 device is built with a powered elbow orthosis with surface electromyography (EMG) sensors, a powered hand orthosis with surface EMG sensors, a manually set, multi-articulating wrist (MAW) for wrist flexion, extension, pronation and supination, as well as the following components:

Component
A shoulder harness for added comfort, stability, and ease of supporting the weight of the device
An alternative hand shell for larger hands
An interchangeable, lithium-ion battery pack
A battery charging dock
Carrying bags
Two finger saddle options (small/large)
Straps for tethered connection
A 3mm hex key for size adjustments
An extra parts kit

Depending on device model, a clinical provider can use the Myomo Mobile App or Myconfig laptop application to view a graphical representation of a muscle's EMG signal and adjust the User's settings for optimal performance while operating the MARK2.

The EMG-control circuit of the MARK2 continuously monitors and senses, but does not stimulate, the User's muscles. The MARK2 filters and processes the EMG signal and translates this information into motor movement. Based on the User's needs and abilities, the control parameters are adjusted by the Clinical Provider. The power assist moves the motor with speed proportional to the User's exertion. This system enables the MARK2 to assist the User to initiate and complete desired motions.

The MARK2 is designed for use in a clinical environment away from areas with high flammability risk. Please reference Warnings and Technical Specifications for additional information. It should not be worn while undergoing medical imaging (x-ray, MRI, CT scan, etc.)

WARNINGS

The following statements warn against injury risk when using the MARK2:

⚠ The MARK devices are certified medical devices and should only be used as indicated under clinical supervision.

⚠ ONLY use the MARK2 upper limb orthosis on the prescribed elbow, wrist, and hand joints. Each MARK2 is built specifically for a left arm or a right arm; never wear the MARK2 on the other arm.


⚠ Do not allow the User the MARK2 to drive an automobile or operate machinery.

⚠ Do not allow the User to sleep while wearing the device

⚠ DO NOT expose the MARK2 to flame or excessive heat; personal injury may occur.

⚠ The MARK2 is NOT waterproof. Do not allow the User to shower, swim, or expose the device to rain or other sources of water. Do not wear the device for assistance to wash dishes by hand as risk for water exposure to the grasp motor is high.



⚠ Caution the User when using the device in shoulder positions where it is possible for the User to hit him or herself.

⚠ Do not allow the User to attempt to lift heavy objects with the MARK2; the elbow motor provides at most 5 lbs of lifting assistance.

⚠ Tight straps may restrict the User's circulation. Therefore, always check that the straps are not too tight throughout the User's range of motion.

⚠ Each component of the device is supplied for safety and best performance. Use all provided components for optimal operation.

⚠ No modification or disassembly of the mechanical or electrical components of the MARK2 is allowed as it may expose other dangers.

⚠ If storing the MARK2 for more than one month, remove the battery from the battery compartment.

⚠ If at any time during the use of this device, you notice any of the following, discontinue use and contact Myomo:

- Movement does not match the User's desired motion.
- Persistent redness, swelling, or skin breakdown (bleeding, chafing, etc.)
- Rash on the arm, hand, or fingers.
- Pain associated with wearing the MARK2 orthosis.
- Unusual noises from the orthosis (popping, clicking, etc.)
- Smells from the orthosis (smoking, burning plastic, etc.)
- Odor from the orthosis (sour smells or other indications of bio-contamination.)

⚠ Make any size or component swapping of the device before the MARK is on the User. Acceptable adjustments to make after it is on the User are Forearm Bar length, Multi- Articulating Wrist tensioning, and Thumb Saddle size.

⚠ Some adjustments, such as retracting the Forearm Bar, increase the amount of excess wire around the User's arm. Before powering the MARK on, ensure that any excess wire is not at risk of catching on other objects in the environment. Also check if there is enough wire slack to allow all movement of the MARK device.

Icon Credits

Medical Shield by Josy Dom Alexis, Weight: Deadlift by Scott Lewis, Single Person: Person by Alexander Smith, Group of People: Group Men by Peter van Driel, Arm: Muscle by Jurjen Versteeg; the Noun Project

CAUTIONS

The following cautions apply to the MARK2 device and accompanying components:

⚠ Do not expose to flame or excessive heat.

⚠ Do not incinerate the Lithium Ion battery pack.

⚠ Do not use a hairdryer to dry components of the MARK2.

⚠ Use only the battery and battery charger provided with the MARK2.

⚠ Insert only the battery pack that came with the MARK2 into the MARK2 battery compartment.

⚠ Charge the battery indoors only. The battery and battery charger should only be operated in temperatures ranging from 0-40 °C (32-104 °F).

⚠ The MARK2 and accessories are not waterproof. Take care to protect the device from coming in contact with liquids. Never immerse, pour, or spray water or other liquids directly onto the MARK2. For proper cleaning instructions, see CLEANING THE MARK2.

⚠ Excess force applied to rotate the motors in either direction will permanently damage the motors.

⚠ The MARK2 is not suitable for use in the presence of flammable anesthetic mixtures with air, or flammable anesthetic mixtures containing oxygen or nitrous oxide.

⚠ If you detect fumes, flames, melting of components around the battery or battery charger, or the device is hot to touch, **TURN THE DEVICE OFF IMMEDIATELY** and contact Myomo.

⚠ Protect the MARK2 from damage, always use the carrying bag provided with the unit to store or ship the MARK2.

⚠ When the MARK2 is tethered to a patient, ensure that it is placed on a flat surface away from people as it can move unpredictably and pinch fingers.

⚠ CAUTION: The MARK2 and accessories are not waterproof. Take care to protect the device from coming in contact with liquids. Never immerse, pour, or spray water or other liquids directly onto the MARK2.

⚠ CAUTION: Do not use a hairdryer to dry components of the MARK2.

⚠ CAUTION: Avoid harsh cleaning agents such as bleach and ammonia. NOTE: Take care to prevent the buildup of debris. Let the MARK2 completely dry out before putting it on again.

Icon Credits
Trees: Forest by Simone Fernandes, House: House by Numero Uno; the Noun Project

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BATTERY & CHARGING

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CAUTIONS, REVIEW

⚠ **CAUTION**: Do not expose to flame or excessive heat.

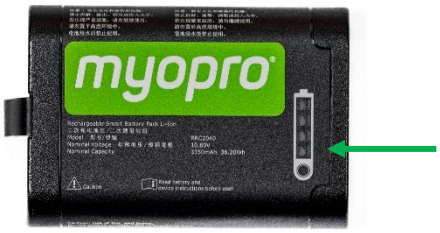
⚠ **CAUTION**: If you detect fumes, flames, melting of components around the battery or battery charger, or the device is hot to touch, TURN THE DEVICE OFF IMMEDIATELY and contact Myomo.

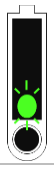
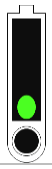
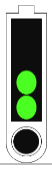
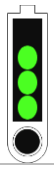
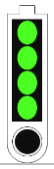
NOTE: Charge the battery before using the device.

NOTE: The battery may arrive in "Shipping Mode." You MUST put the battery on the charging dock to take it out of Shipping Mode. The MARK2 will not turn on if the battery is in Shipping Mode.

CHECK THE BATTERY'S CHARGE LEVEL

Press the black dot on the battery icon to see the battery's charge level.
A light scale (1 to 4 lights) will indicate the battery's current charge range.



Visual Indicator	One light blinks for 1 second and repeats four times	One light illuminated for 4 seconds	Two lights illuminated for 4 seconds	Three lights illuminated for 4 seconds	Four lights illuminated for 4 seconds
Percent Charge	Less than 10%	10-25%	26-50%	51-75%	76-100%
Icon Display					

SETTING UP THE CHARGER

⚠ **CAUTION**: Charge the battery indoors only. The battery and battery charger should only be operated in temperatures ranging from 0-40 °C (32-104 °F).

⚠ **CAUTION**: Use only the battery and battery charger provided with the MARK2.

⚠ **CAUTION**: Do not expose to flame or excessive heat.

1. Plug the charging cable into the charging dock.

2. Plug the 3-prong end into a wall outlet.

3. Locate the row of metal prongs inside the charging dock.

CHARGING THE BATTERY

⚠ **CAUTION**: Charge the battery indoors only. The battery and battery charger should only be operated in temperatures ranging from 0-40 °C (32-104 °F).

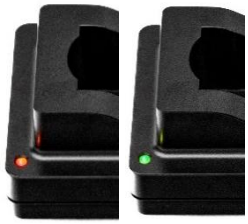
⚠ **CAUTION**: Use only the battery and battery charger provided with the MARK2.

⚠ **CAUTION**: Do not expose to flame or excessive heat.

NOTE: Charging time for a battery with <10% capacity is approximately 3 hours.

1. Locate the “teeth” on the battery.

2. Align the teeth with the prongs inside the charging dock and push down gently to sit the battery fully onto the prongs.



Flashing (blinking) between RED & GREEN

The charger is detecting the battery.

Illuminated ORANGE

The battery is charging.

Illuminated GREEN

The battery is charged.

Illuminated RED

There is a problem with the battery. Remove the battery from the charger and contact Myomo.

OPENING AND CLOSING THE MARK2'S BATTERY COMPARTMENT

To open the battery compartment, **press the eject button**.

To close the battery compartment, **push firmly in the center of the compartment door** until the door clicks shut.

INSERTING THE BATTERY INTO THE MARK2

⚠ **CAUTION**: Insert only the battery pack that came with the MARK2 into the MARK2 battery compartment.

To insert a charged battery into the MARK2's battery compartment:

1. Remove the battery from the charging port & unplug the Charging Dock from the wall outlet.
2. Open the battery compartment.
3. The battery only engages fully in the battery compartment ONE DIRECTION. Locate the "myopro" sticker on the battery – position the logo so that it faces toward the User's arm., with the battery tab pointing up. This will line it up properly for step 4.

4. Gently insert the battery into the battery compartment.
5. Close the battery compartment.

NOTES ON BATTERY HEALTH

⚠ **WARNING**: If storing the MARK2 for more than one month, remove the battery from the battery compartment.

NOTE: If a battery is unused (stored), it should be recharged at least once every 6 months. If uncharged for more than 6 months, the battery could get so depleted that it could be unable to be recharged.

NOTE: Best practices for charging the battery:

- The battery is rated for 300 “charge cycles.” A charge cycle is from less than 10% charge to 100% charge. If you charge once a day, the battery should last for 10 months.
- Lithium ION batteries deteriorate faster when the depth of discharge is higher. Therefore, it is better NOT to fully deplete the battery before charging. Mid-cycle charging (between 40-60% battery charge) will provide the best longevity.

NOTE: Batteries do not last forever. If the battery is not holding a charge for more than 30 minutes, or you have been using the battery consistently for more than 12 months, it may be time for a new battery. Contact Myomo to order a new battery.

NOTE: The battery charger has an expected life of 3 years.

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CONTROL PANEL & SENSITIVITY SETTINGS

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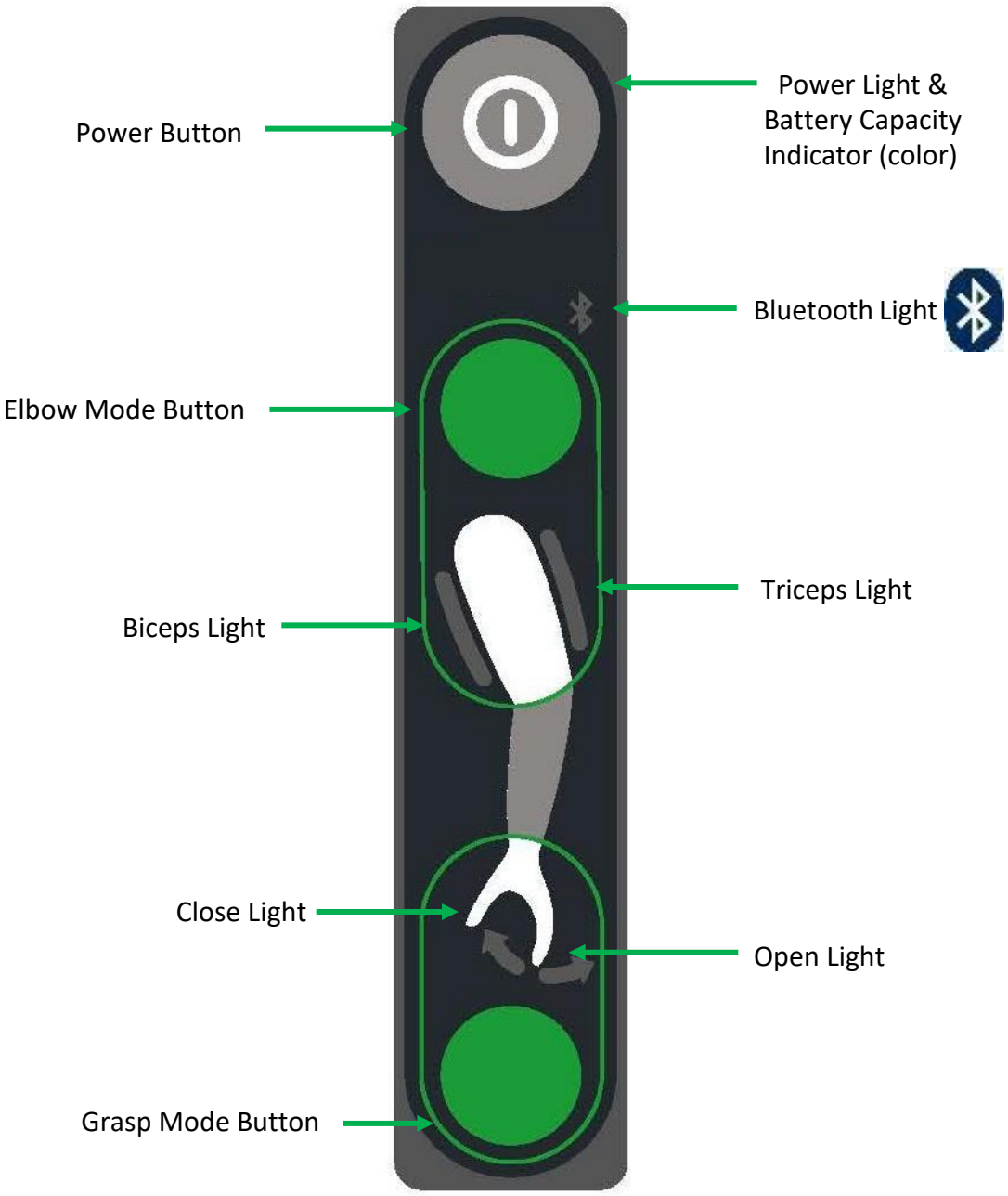
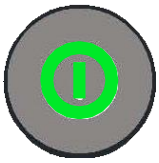
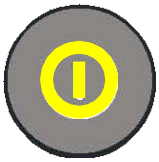
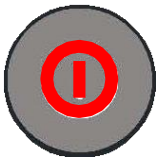
CONTROL PANEL BUTTONS & LIGHTS DIAGRAM



CONTROL PANEL LIGHTS, DESCRIBED

POWER LIGHT & BATTERY CAPACITY INDICATOR COLOR

NOT Illuminated (off)		The MARK2 is powered OFF.
Illuminated Green		The MARK2 is powered ON. The battery has greater than 15% charge remaining.
Illuminated Yellow		The MARK2 is powered ON. The battery has between 15% and 5% charge remaining.
Illuminated Red		The MARK2 is powered ON. The battery has less than 5% charge remaining.
If color is changing in a repetitive pattern…	1. White (may look light blue) 2. Dark Blue 3. Green 4. Red	The MARK2 is experiencing an error. See MARK2 ERROR for instructions.

NOTE: Another way to check the battery capacity level is to eject the battery and check the light indicator on the battery itself (see CHARGING THE BATTERY for instructions).

BLUETOOTH LIGHT

Illuminated (on)		The Bluetooth light indicates the Bluetooth function is on. Please reference the *MyConfig View – Software User Guide* or *Myomo Mobile App User Manual* for more information on Bluetooth connectivity.
Flashing (blinking)		The MARK2 is experiencing an Error. See MARK2 ERROR for instructions.

HOW TO POWER THE MARK2 ON AND OFF

⚠ **WARNING**: Do not allow the User to drive an automobile or operate machinery while wearing a MARK device.

⚠ **WARNING**: The MARK2 is NOT waterproof. Do not allow the User to shower, swim, or expose the device to rain or other sources of water. Do not wear the device for assistance to wash dishes by hand as risk for water exposure to the grasp motor is high.

⚠ **WARNING**: Do not allow the User to attempt to lift heavy objects with the MARK2; the elbow motor provides at most 5 lbs of lifting assistance.

⚠ **CAUTION**: The MARK2 is not suitable for use in the presence of flammable anesthetic mixtures with air, or flammable anesthetic mixtures containing oxygen or nitrous oxide.

POWER ON

NOTE: Only turn the MARK2 on once it is correctly and comfortably positioned on the User's arm. The MARK2 should always be powered OFF while you are putting it on the User's arm. Similarly, ensure the power is OFF before starting to take the MARK2 off the User's arm.

1. Press the Power Button.

2. Observe: When the MARK2 is turning ON, all the lights on the control panel will light up.
3. Observe: After 3 seconds, all the lights will turn off, except for Power Button light.
4. The MARK2 is ready to use!

POWER OFF

1. Press the power button.

2. Observe: All the lights will stop being illuminated, indicating that the MARK2 has successfully powered off.

NOTE: The MARK2 should remain OFF any time the MARK2 is not being worn.

SENSITIVITY SETTINGS

The device **sensitivity settings** can be programmed when the device is on the User. Depending on device model, refer to either MyConfig Set Clinical Guide (28655) and MyConfig View User Guide (28656) or the Myomo Mobile App User Manual - MyoPro User/Caregiver (31310) and the Myomo Mobile App User Manual - Clinician (31311) for more details. All the information in the MyConfig and Myomo Mobile App user guides for the MyoPro apply to the MARK2. These settings below correspond to how the device detects and responds to the User's muscle signal. The sensitivity may be adjusted over time as the User continues to use the device. The different sensitivity settings of the device are described below.

Gain	Gain refers to amplification of EMG signal that takes place through the sensor hardware. The higher the gain, the more amplified the User's EMG signal will be, and the easier it will be to trigger the assistance of the device.
Threshold	Threshold refers to the value that the EMG signal must cross to initiate the motor (in response to either an active muscle signal or a relaxed muscle signal. The threshold can be increased or decreased to the point where the User's EMG signal can get well above it upon activating a muscle, and well below it upon relaxing the muscle.
Range of Motion (ROM)	Another adjustment the Myomo Mobile App or MyConfig can make for the MARK2 is the range of motion for each motor. Ensure the range of motion of the elbow and the grasp are optimized for comfort and utility of the User depending on their current passive range of motion.

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MARK2 COMPONENTS

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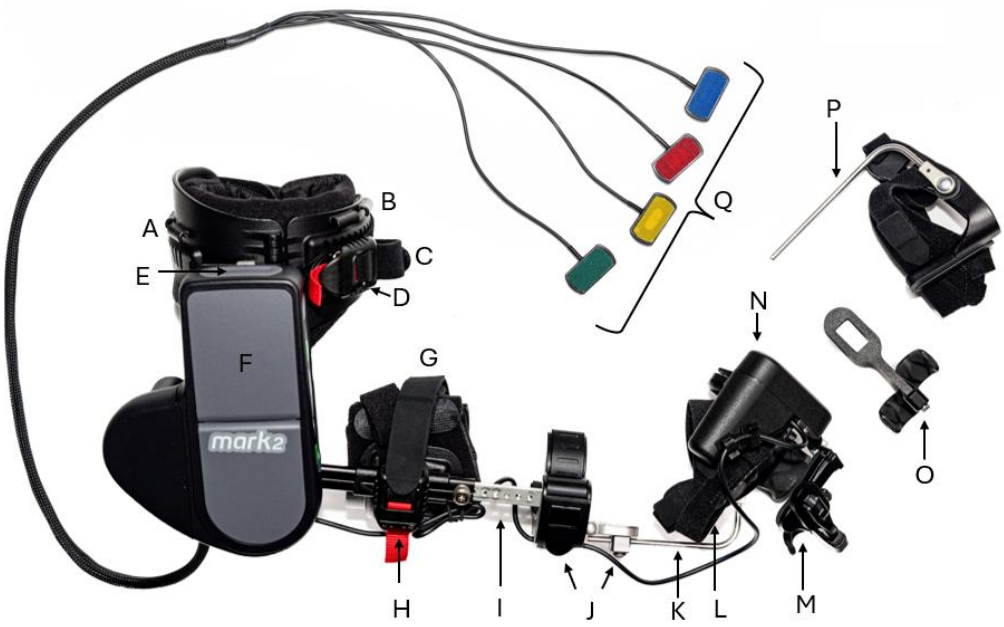
MARK2 COMPONENTS: OVERVIEW

Reference the diagram below to understand the various components of your MARK2 Orthosis.

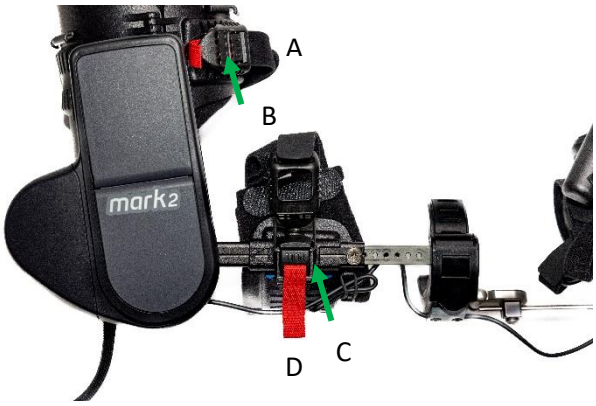
A. Posterior harness retention clip
B. Anterior harness retention clip
C. Humeral straps
D. Humeral closure
E. Battey access
F. Control panel
G. Forearm straps
H. Forearm closure
I. Forearm bar
J. Multi-Articulating Wrist (MAW)
K. Hand carrier bar (Classic hand shell size)
L. Hand straps
M. Medium Finger Saddles
N. Hand motor
O. Large Finger saddle
P. Large hand shell size
Q. Sensors



MARK2 CLOSURE COMPONENTS

Reference the diagram below to understand the various components related to the MARK2 *closures* of the *forearm* and *humeral straps*.

A. Closed position
B. Buckle
C. Magnetic latch
D. Red release tab



MARK2 PADDED INSERTS

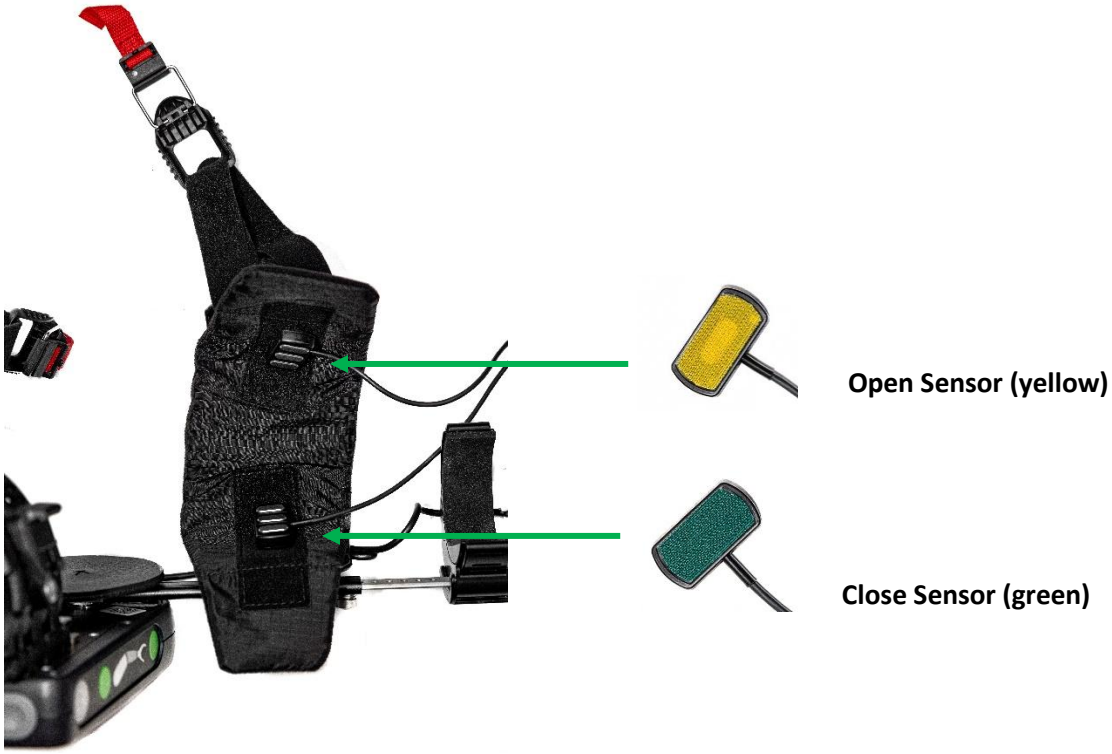
Padded inserts are offered in three thicknesses: 3/16”, 3/8” and ½” thick

Humeral Inserts

Forearm Inserts

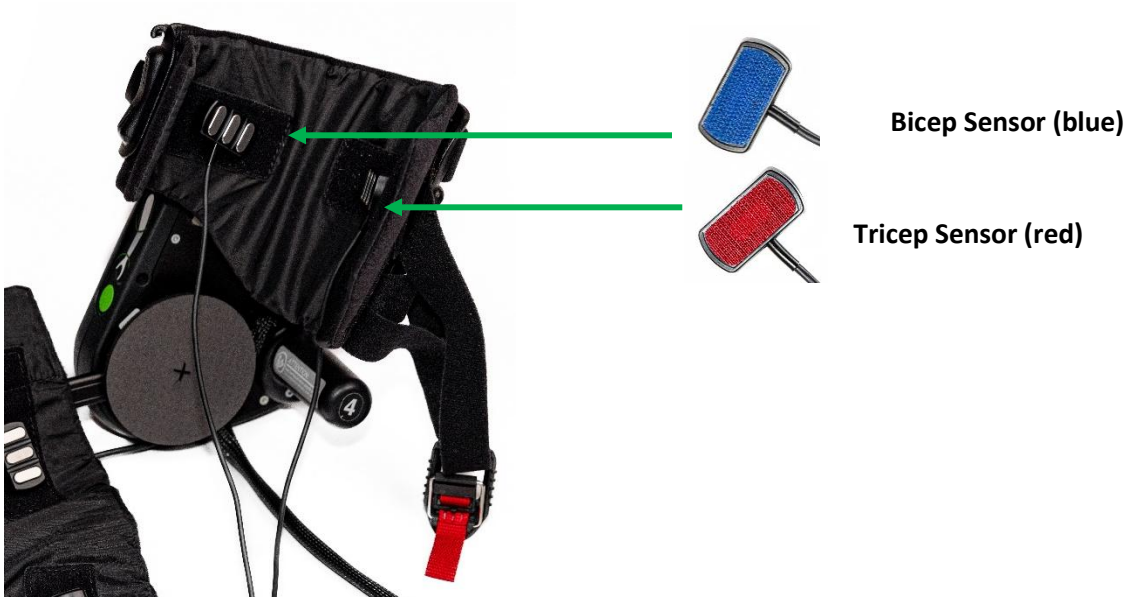
MARK2 FOREARM SENSORS

Reference the diagram below to understand the various components related to the MARK2 *forearm sensors*. Sensors can be moved anywhere along the hook and loop strips.



MARK2 BICEPS & TRICEPS SENSORS

Reference the diagram below to understand the various components related to the MARK2 *biceps & triceps sensors*. Sensors can be moved anywhere along the hook and loop strips

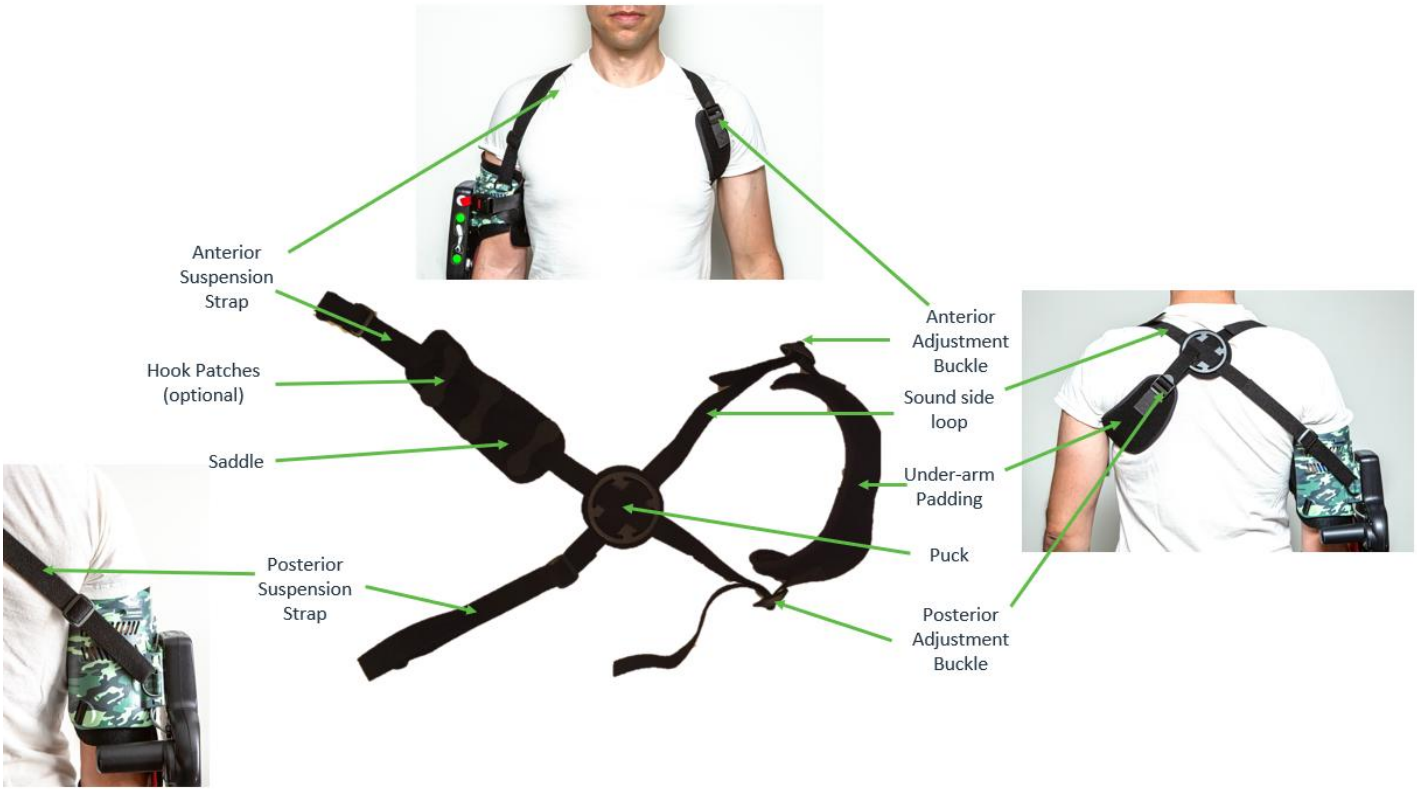


MARK2 CROSS-BODY HARNESS COMPONENTS

There are two harness types, a *cross-body harness* and a *figure 8 harness*. Reference the diagram below to understand the various components related to the MARK2 cross-body harness.

MARK2 FIGURE 8 HARNESS COMPONENTS

Reference the diagram below to understand the various components related to the MARK2 figure 8 harness.



MARK2 HAND OPTIONS

There are two Hand Shell size options - C*lassic* and *Large.* Select the Hand Shell to best match the User's size. The widths are the same, but the hand carrier bar lengths are different. The Classis is 4.4" and the Large is 4.8".

Classic Hand Shell

Large Hand Shell

MARK2 TOOLS

The only tool required for the MARK2 is a 3mm hex key.

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DONNING THE MARK2

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The following pages include step-by-step instructions for putting the MARK2 on, referred to as “donning the MARK2”.

WARNINGS REVIEW

Before donning the MARK2 , review the warnings below:

⚠ **WARNING**: DO NOT expose the MARK2 to flame or excessive heat; personal injury may occur.

⚠ **WARNING**: The MARK2 is a prescription device and should only be used as indicated under clinical supervision of a Provider, or after receiving instruction from a clinical Provider for at-home use.

⚠ **WARNING**: Each component of the device is supplied for safety and best performance. Use all provided components for optimal operation.

⚠ **WARNING**: ONLY use the MARK2 upper limb orthosis on the prescribed elbow, wrist and hand joints. Each MARK2 is built specifically for a left arm or a right arm; never wear the MARK2 on the other arm.

⚠ **WARNING**: Tight straps may restrict the User’s circulation. Therefore, always check that straps are not too tight throughout the User’s range of motion.

⚠ **WARNING**: Do not allow the User to sleep while wearing the MARK2 as straps may alter the User’s circulation.

⚠ **CAUTION**: If you detect fumes, flames, melting of components around the battery or battery charger, or the device is hot to touch, **TURN THE DEVICE OFF IMMEDIATELY** and contact Myomo.

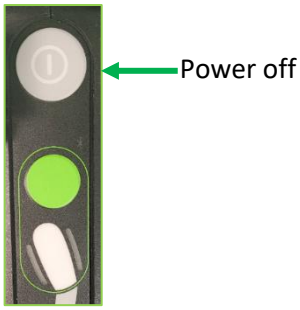
STEPS FOR PUTTING ON MARK2 ORTHOSIS

To ensure proper fit and function, it is essential the MARK2 is donned (put on) correctly before each use. If the MARK2 is donned incorrectly, the User may experience discomfort, soreness, and/or pain. The User is not expected to don the MARK2 device independently.

Myomo offers donning instructions on its website (www.myomo.com). If you have difficulty donning the MARK2 on a User, consult with Myomo.

Consult the illustrations above to reference the individual components of the MARK2, which are identified as *italicized* words in the following instructions.

DONNING PREPARATION



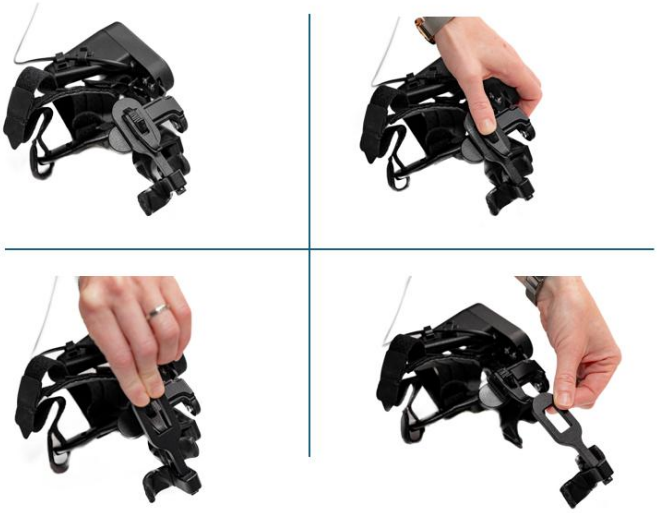
Before donning the MARK2 on a User, perform the following steps:

1. **Ensure that the MARK2 is powered off.**

   NOTE: Pads and straps should be fully air-dried from previous use.

   CAUTION: Do not use a hairdryer to dry components of the MARK2.

2. **Remove the *finger saddle* from the *anvil*.** Simultaneously depress the spring-loaded *finger saddle latch* and remove the *finger saddle* from the *anvil*. First removing the *finger saddle* makes the donning process easier. The *finger saddle* will be re-attached later.

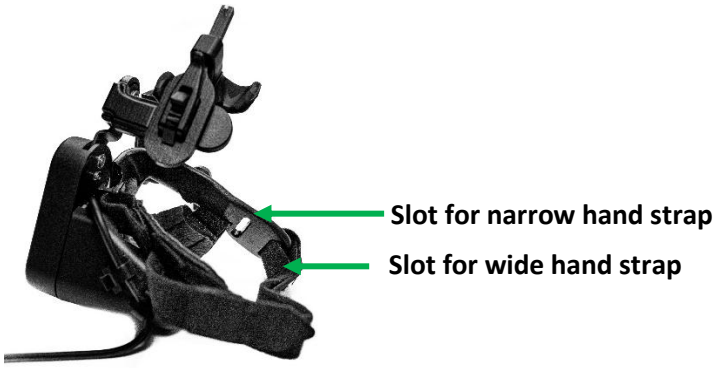


3. **Select the Hand Shell size** based on the User's size. The Classic will fit a majority of Users.

Classic Hand Shell

Large Hand Shell

4. **Configure the hand strap on the hand shell.** There is a narrow and wide option for each hand shell. Select the best configuration based on the User's size.



5. **Connect the Hand Shell**. In many cases, the *Classic* Hand Shell will already be connected to the orthosis as it is optimal for most users. See below for instructions on how to swap the Hand Shell.

1. Loosen screw and pull Hand Bar out, Do not completely remove the screw.

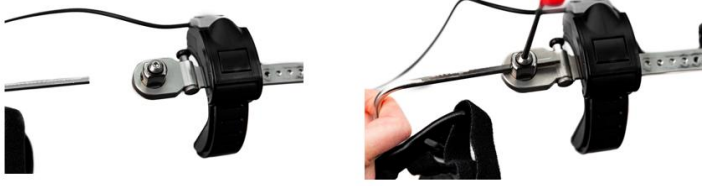
2. Flip hand piece over and loosen screws above the motor. Do not completely remove the screw.

3. Pull Palmer Grip off

4. Slide desired Palmer Grip onto flat rectangular metal piece

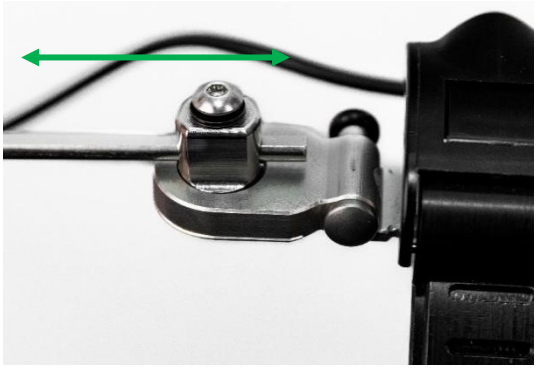
5. Adjust thumb support per patient sizing

6. Tighten screws above the motor to secure Palmer Grip in place.



7. Re-connect Hand Bar and tighten the screw.

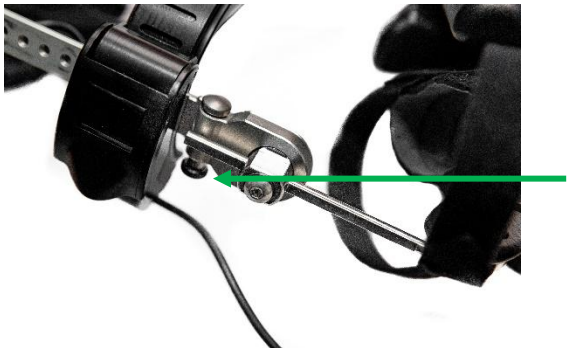
6. **Position the Hand Shell**: Loosen screw (3mm) on wrist joint to slide hand shell proximally/distally. Make sure the screw is tightened down on to the flat beveled side of the hand carrier bar otherwise it may slip out.



7. **Loosen the hand straps** by removing the Velcro alligator tab and pulling and tightening as needed.

Velcro tab to loosen hand strap

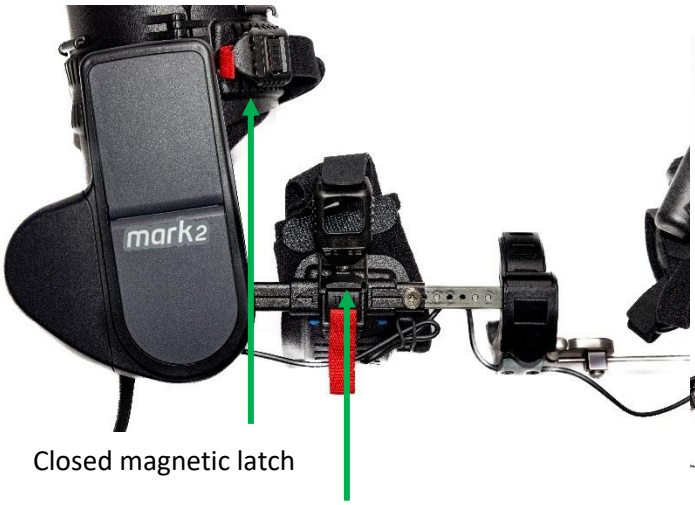
8. **Position the wrist *flexion/extension joint* in a neutral position** (in-line with the rest of the brace). Unlock the joint by depressing the *flexion/extension button* (the black button). Lock the wrist *flexion/extension joint* after positioning in a neutral position.



Push the black button up to unlock the flexion/extension joint

9. **Position the wrist *supination/pronation joint* so the *thumb support* points down.** The wrist/hand should be in the same horizontal position as if the User were holding a bike's handlebars. Unlock the joint by pulling the *supination/pronation latch*. Position the wrist in line with the forearm bar. Secure the *supination/pronation latch* after positioning to lock the wrist joint.

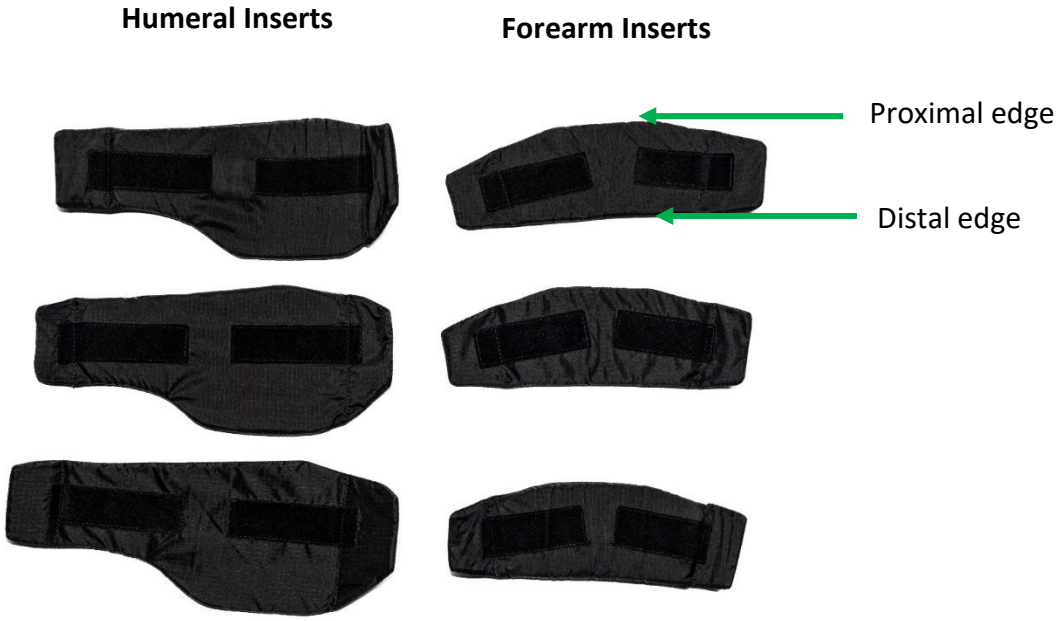
10. **Completely loosen the forearm magnetic latch and the humeral magnetic latch** by pulling on the *red release tabs*. Open the *humeral* and *forearm shells* with their respective *straps* positioned out of the way.



Closed magnetic latch

Open magnetic latch

11. **Place the pads in the forearm and humeral inserts**. Padded inserts are offered in three thicknesses: 3/16”, 3/8” and ½” thick. Thicker inserts can be used for patients with smaller arms. Select the appropriate insert for the patient.

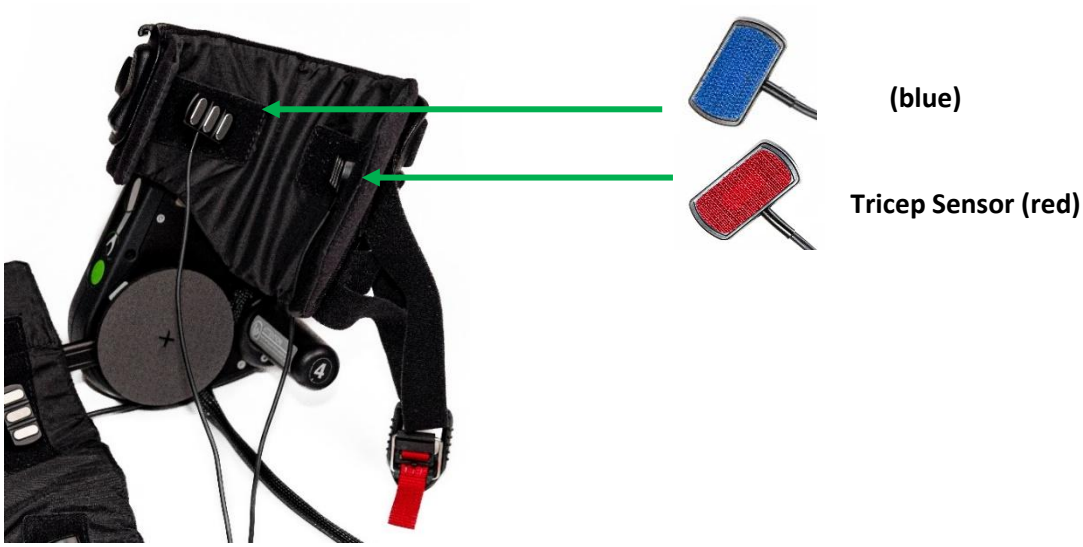


Inserts are attached to the brace with Velcro. Simply stick the insert into the brace, ensuring the shiny side with the hook and loop strip is facing up.

12. **Place the sensors on the on the Velcro pads.** Sensors can be moved anywhere along the hook and loop strips

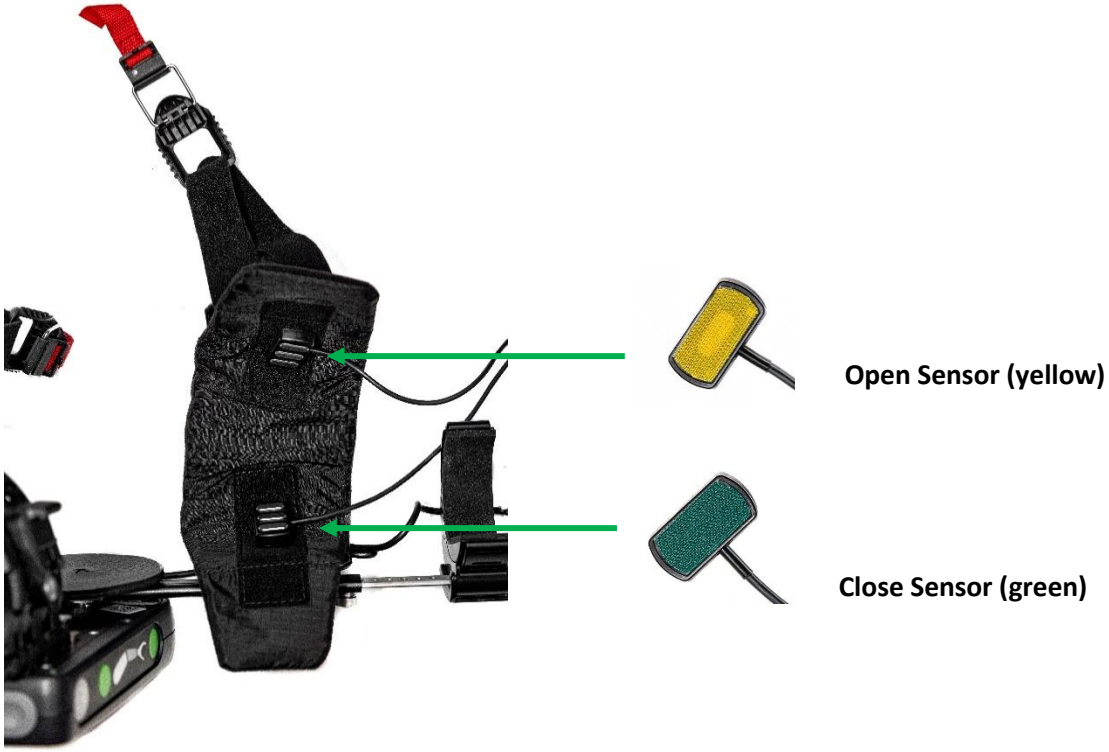
    Sensors for the biceps and triceps muscles are placed into the Upper Cuff. They are attached with Velcro so they can be repositioned but will stay in place for the User. The Velcro is color coded. Generally, optimal sensor place will be on the muscle belly.

    - Blue Velcro sensor is for elbow flexor (“blue” for “biceps”)
    - Red Velcro sensor is for elbow extensor (triceps)



Sensors for the wrist flexors and extensors attach to the Forearm Cuff. This cuff sits proximal to the MAW.

- Green Velcro sensor is for the forearm flexors (“green” for “grab”)
- Yellow Velcro sensor is for the forearm extensors



NOTE: Sensors can be oriented horizontally or vertically on the skin; the most important thing is to have even contact and pressure across all of the metal surface

13. **Forearm bar adjustment.** Loosen the spring screw on the forearm bar to allow it to telescope. The bar can be lengthened or shortened to match the length of the patient's forearm. When the bar has been adjusted to the desired location, tighten the screw to secure the forearm bar to the housing.

14. **Forearm cuff adjustments.** Forearm can slide up and down the forearm bar. Loosen the thumb screw to shift the forearm cuff proximally/ distally along forearm bar. Cuff should be positioned under the widest part of forearm.

15. **Forearm/Humeral Strap Adjustment and Buckles**. Change tension by pulling/relieving strap ends through the mounts.

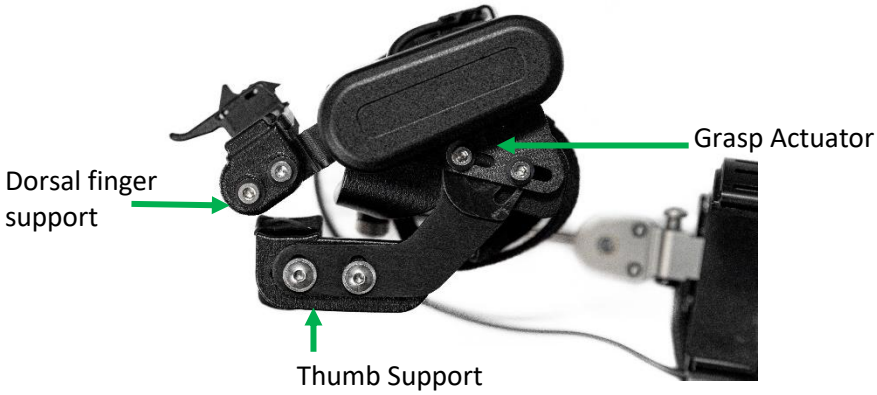
16. **Humeral Cuff Adjustments:** Loosen screw (3mm hex) to adjust cuff higher or lower depending on the length of the patient's arm and optimal sensor placement.

17. Hand Shell Adjustments

Grasp Actuator: Loosen screws (3mm hex) to either shift actuator distally/proximally in channels or rotate thumb to change angle.

Thumb support: Loosen screws (3mm hex key) to shift thumb distally/proximally in channel.

Dorsal finger support: Loosen screws to raise or angle the dorsal finger support



DONNING INSTRUCTIONS

Prep: If the User has tone/spasticity in their hand/fingers, it may be beneficial to employ various techniques to relax their wrist flexors/extensor muscles before proceeding with donning. Consult Myomo for tone/spasticity management solutions.

1. When donning, position the MARK2 on a surface with adequate friction to prevent it moving, such as the User's lap.

⊙ **NOTE**: The motor and battery case should rest on the outside of the arm. If the motor and battery case is aligned along the interior of the arm, you may be donning upside down or on the wrong arm.

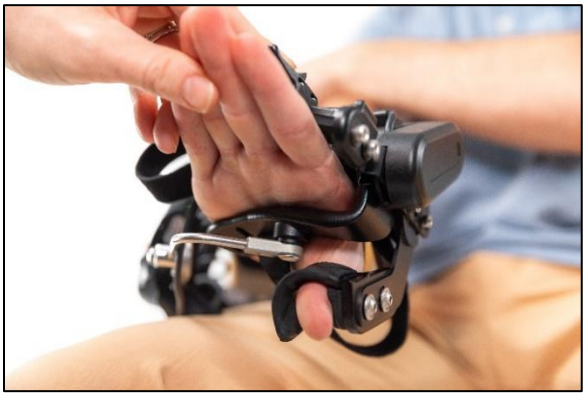
2. Ensure the *hand motor* and *hand strap* are cleared.

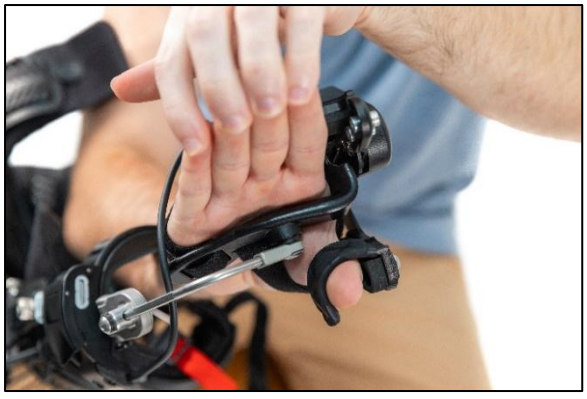
3. Begin by placing the affected hand onto the *hand shell*. It may be easiest to focus on guiding the thumb into the opening.

4. Position the thumb into the *thumb support*.

5. If the hand is tight, you will have to uncurl the User's fingers to pull the hand sufficiently into the hand shell.

6. Position the hand so the base of the thumb is in full contact with the *hand shell*. **Everything is aligned in comparison to the thumb being fully seated against the hand shell.** The majority of fit issues occur here.





7. Secure the *hand strap*. The hand should be locked in place and unable to remove without releasing. If the hand can slip out, tighten the *palmar hand strap* and/or *dorsal hand strap* as necessary.

⚠ FIT CHECK ⚠

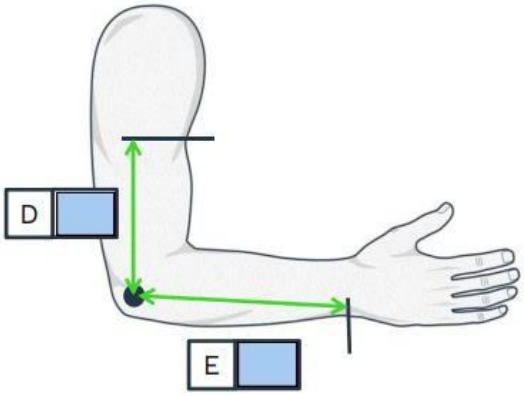
CONFIRM THE *HAND SHELL* PLASTIC IS AGAINST THE THUMB WEB SPACE AND THAT THE KNUCKLES ARE PAST THE PALMAR CREASE. MAKING CHANGES TO THE FIT OF THE HAND PAST THIS POINT IS IMPOSSIBLE WITHOUT REMOVING THE BRACE AND STARTING OVER. THE HAND SHOULD BE LOCKED

IN THE CORRECT POSITION AT THIS POINT.

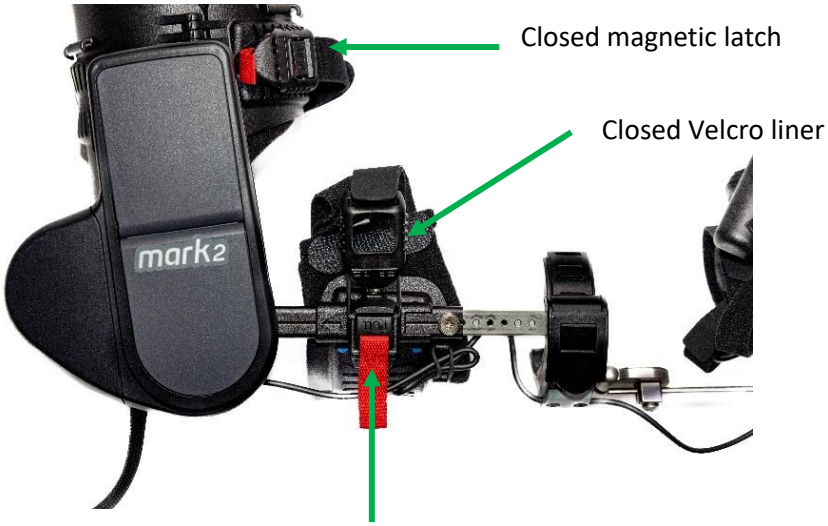
8. Select the appropriate finger saddle.

9. Attach the *finger saddle*. First position the *finger saddle* on the end of the User's index and middle fingers with the *finger loop* emerging from between your fingers. Then position the *finger loop* around the *anvil*- **you may pull the anvil down towards the loop without damaging the motor**. Push on the back of the *finger loop* while pulling up on the finger saddle. Once the *latch* toggles, the *finger saddle* is locked in place.

10. Align the point of elbow rotation of the device with the User's elbow center. Double check by passively flexing and extending the User's arm in the device while the device is turned OFF.



11. Secure the *forearm shell*. Velcro the *forearm liner* ends together. Close the *forearm shell* and attach the *forearm magnetic latch* to the *forearm buckle base*. Secure the *forearm strap* completely by closing the *forearm buckle.* Lock the *forearm buckle clasp*.



12. Secure the *humeral shell*. Reach under the armpit to grab and then close the Velcro lining with light tension, ensuring the EMG sensors are not covered by the liner. Secure and attach the *humeral magnetic latch* to the *humeral buckle base*. Lock the *humeral buckle clasp*. (see picture above)

CHECKING THE FIT

- Passively (and slowly) open and close the fingers; ensure that knuckles are not rubbing on the plastic edges of hand or finger supports.
- Passively flex and extend the wrist to check alignment; wrist should not hit hand plastic or MAW.
- Passively pronate and supinate the wrist to check alignment.
- Double check that no support padding trim lines are bunched or folded underneath the patient's arm.
- Passively flex and extend the elbow to check alignment.
- Sensor Placement & Strap Tension Reminders
  - Sensors should be on the skin over a palpable muscle belly; some trial and error for the best placement is normal.
  - Straps should neither be too tight or too loose, but comfortably snug.
- Check for any pinching of the skin through all active and passive motions of elbow, wrist, and hand.

- Check for any abrasion of the skin through all active and passive motions of elbow, wrist, and hand.
- Check for any loose wires and straps.

The MARK2 is now applied. For instructions on donning the harness, please reference the instructions below to determine which harness is optimal and the instructions for application.

STEPS FOR PUTTING ON MARK2 HARNESS

A harness is provided with the MARK2. It serves to both protect the shoulder joint and to suspend the MARK2 in correct position on the arm, so it does not slide off.

WARNING: A harness should always be worn when the MARK2 is donned, unless directed otherwise by a physician and/or therapist. Failure to wear a harness may result in shoulder joint discomfort, pain, and/or injury.

The MARK2 is available with two harness models depicted below. Following the appropriate instructions, depending on which harness model your donning on the User.

CROSS-BODY HARNESS	*FIGURE 8 HARNESS*
	

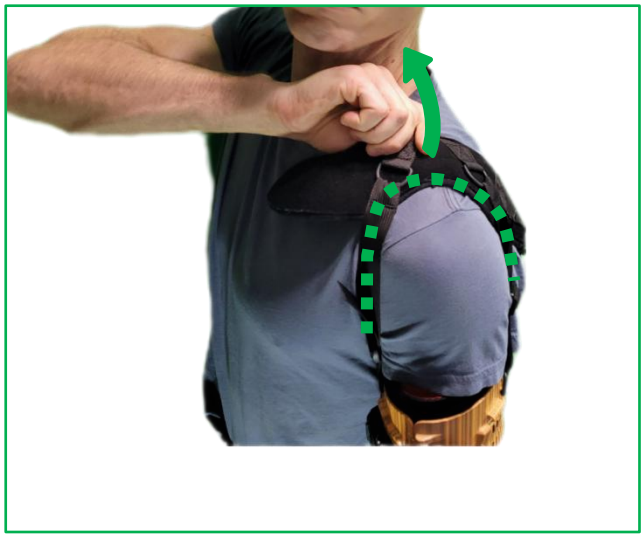
HARNESS CLIPS

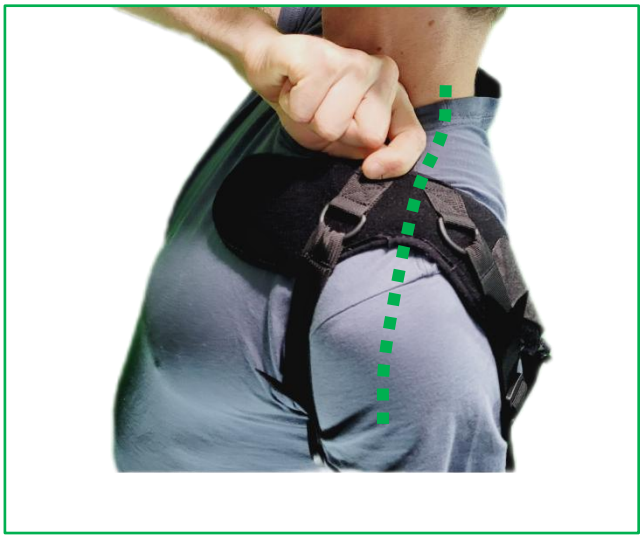
Having the harness connected to the appropriate retention clip will influence the alignment of the MARK2. Ensure the anterior and posterior retention clips are securely locked in place before donning the harness. Each harness option will use (1) anterior retention clip and (1) posterior retention clip.

CROSS-BODY HARNESS DONNING

For donning the *cross-body harness*, follow the steps below:

1. Place the harness saddle on their shoulder. The suspension straps should straddle their shoulder. The middle of the saddle should be at the midline of the shoulder, touching neither the neck or shoulder joint. You may have to lift the arm out to the side in order to move the saddle into the correct position.





2. Grab the *cross-body strap* behind the User's back and pull it underneath their armpit on the side opposite the MARK2. It may help to instruct the User to hold the *saddle* in place with their chin to prevent migration.

3. Secure the *cross-body strap* using the *release tab*. The *saddle* should lay flat against the User's body. Adjust the angle of the fastened *release tab* to make the *saddle* sit evenly and comfortably. There should be slack in the *finger adjust loop* at this point.

4. Abduct the shoulder with the MARK2 (lifting it to the side). When the arm returns to the torso, the User should feel the tension of the harness saddle on their shoulder, indicating the MARK2 is suspended from their shoulder girdle, not the shoulder joint. Make minor adjustments to the *finger adjust loop* tension until a good balance is reached between suspension and comfort. The Velcro will secure the tension.

FIGURE 8 HARNESS DONNING

For donning the *figure 8 harness*, following the steps below:

Orient the harness and check for twists in the strapping. The *puck* has a surface covered in red fabric, while the other surface is an intersection of the strapping. The red surface of the *puck* indicates the side that will lay against the User's back once the harness is donned, while the straps face away from the User.

Method 1 (flexibility-dependent)

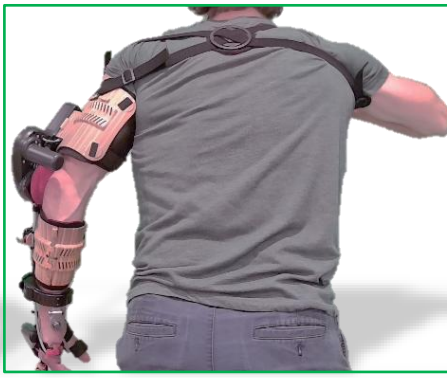
1. Place the intact-side arm through the *sound side loop* with the fabric of the *puck* facing the User.

2. With the arm against the saddle, lift the harness over and behind the User's head. Gravity will do most of the work as they let it slide down towards their shoulder. The harness is done once it's nestled in the User's axilla (armpit).

3. Adjust the *sound side loop* so it rests between the chest and shoulder, protecting the collar bone. It shouldn't make contact with the neck. The *anterior suspension strap* coming off the front of the MARK2 may require small adjustments to rest similarly.

Method 2 (back-pack method)

1. Starting with the harness behind the User's back, locate the puck. Orient the puck so that the fabric side is towards their back, while the straps face away from the them. This will keep the harness oriented in the correct position as you move your hand into the *sound side loop*. Take note that both of the harness straps from the MARK2 begin around the back of the device. The *anterior suspension strap* will be moved into position at the end.



2. With the *sound side loop* around the User's intact-side wrist, begin to wriggle the loop up the arm, towards the shoulder. The final motion will require a shoulder shrug to help the strapping cross the User's shoulders to the front of their body.

3. Adjust the *sound side loop* so it rests between the chest and shoulder, protecting the collar bone. It shouldn't make contact with the neck. The *anterior suspension strap* coming off the front of the MARK2 may require small adjustments to rest similarly.

FIGURE 8 ADJUSTMENT

The harness can be made looser by pulling forward on the *anterior adjustment buckle*

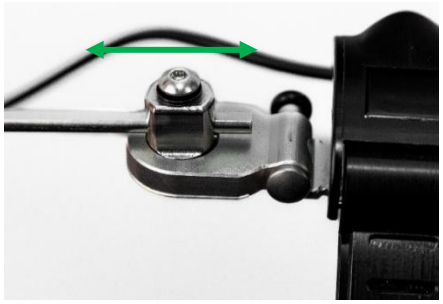
The harness can be tightened by pulling back on the *sound side loop* strap that exits the *anterior adjustment buckle*

ADJUSTING WRIST MODULE

The wrist module position along the user's forearm (proximal-distal) can be adjusted two different ways.

1. Method 1: Move the Hand Carrier Bar in the Flexion/Extension Joint. This can be done by loosening and retightening these set screws with a 3 mm hex key.
2. Method 2: Move the wrist module along the forearm bar. This can be done by loosening the spring screw and adjusting the position.

Method 1

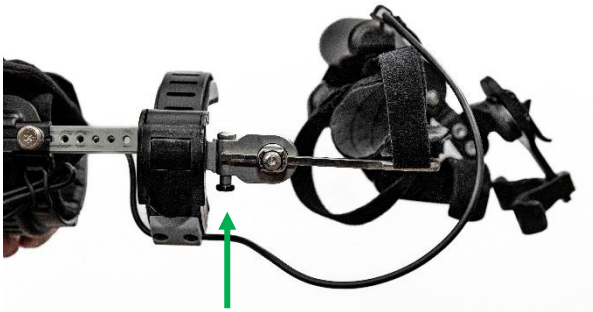


Method 2

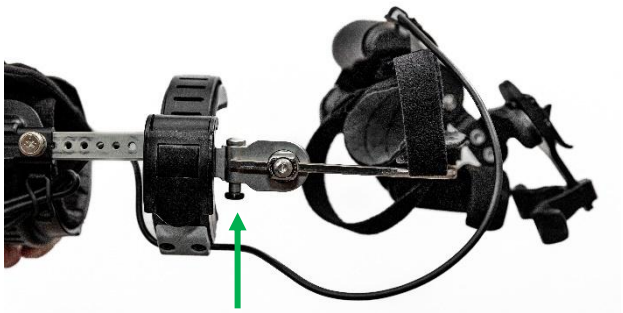
ADJUST Open the Supination/Pronation (SP) Latch to adjust the pronation and supination of the supination/pronation joint. Close the SP Latch once the joint is in the desired location.

⚠ **Caution:** The SP latch should be closed when the device is not in use to avoid accidental damage to the components.

ADJUST Push the Flexion/Extension Button to the unlocked position (shown below) to unlock the Hand Carrier Bar, then adjust the Hand Carrier Bar. Push the Flexion/Extension Button to the locked position to lock the Hand Carrier Bar in the desired position.



Joint locked



Joint unlocked

TETHERED SET-UP

CAUTION, REVIEW

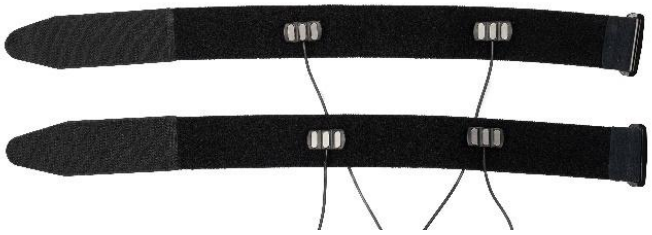
⚠ When the MARK2 is tethered to a patient, ensure that it is placed on a flat surface away from people as it can move unpredictably and pinch fingers.

In some cases, you may only want to place the sensors on the User instead of donning the full orthosis. These circumstances could include:

1. EMG signal strengthening and/or assessment
2. Sensor site evaluation
3. Biofeedback training in therapy clinic
4. Patient's arm is too small or too large for the MARK

To don in a tethered set-up, follow the instructions below.

1. Obtain the tethered straps.
2. Velcro the biceps and triceps sensors (blue and red) to one strap and the forearm sensors (green and yellow) to another strap.



3. Wrap the straps around the candidate's upper and lower arms. The biceps sensor should line up with the bicep muscle belly, the triceps sensor should line up with the triceps lateral head. The forearm sensors should sit over the flexor and extensor muscle bellies in the proximal end of the forearm.

4. It may be helpful to wrap the straps around the arm first and then tuck the sensors in afterwards.
5. Make sure the straps are snug.
6. Power on the MARK and connect to Myconfig.
7. To remove, unvelcro the straps

TAKING OFF MARK2 (“DOFFING”)

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WARNINGS REVIEW

⚠ WARNING: If at any time during the use of this device, you notice any of the following, discontinue use and seek guidance from Myomo.

- Movement does not match the User's desired motion.
- Persistent redness, swelling, or skin breakdown (bleeding, chafing, etc.)
- Rash on the arm, hand, or fingers.
- Pain associated with wearing the MARK2 orthosis.
- Unusual noises from the orthosis (popping, clicking, etc.)
- Smells from the orthosis (smoking, burning plastic, etc.)
- Odor from the orthosis (sour smells or other indications of bio-contamination.)
-

CROSS BODY HARNESS DOFFING:

When doffing the Cross Body Harness, remove the cross body strap by pulling the *release tab from the front portion of the shoulder saddle*.

Note: Do not remove the harness clips from the MARK2 unless you are removing for laundering purposes.

FIGURE 8 HARNESS DOFFING

Slide the *anterior suspension strap* off of the MARK2-side shoulder. There should then be enough slack to remove the *sound side loop* off the intact side.

Resting the User's intact arm at their side will allow the *sound side loop* to fall down their arm. It may take minor maneuvering, but once the loop is past their elbow, simply lifting the sound side arm will finish removing the harness.

DOFFING MARK2 DEVICE

To remove the MARK2, referred to as "doffing the MARK2", follow the steps below:

1. Ensure that the MARK2 is turned OFF.
2. Place the MARK2 in the User's lap, or on a flat surface that is not slippery.
3. Remove the finger saddle .
4. Loosen the hand strap.
5. Align the multi-articulating wrist into a neutral position using the flexion/extension joint and supination/pronation ring.
6. Open the forearm cuff. Pull on the forearm red release tab to release the forearm buckle from the forearm buckle base.
7. Open the humeral cuff. Note, once the humeral cuff is loose, the MARK2 may fall away from the User's arm. Be sure to secure the MARK2 first so that it does not fall. Pull on the humeral red release tab to release the humeral buckle from the humeral buckle base.
8. Gently slide the hand back through the loosened hand straps and the hand shell.

9. Attach the finger saddle to the anvil so it does not become lost.
10. Rest the MARK2 in a clean, dry location to ensure it will fully air-dry before next use.
11. Place the MARK2 into the carrying case for travel or storage.

⚠ **CAUTION**: After doffing the MARK2, check the User's arm and hand for areas of persistent redness and/or swelling. If there are fit problems, contact Myomo for support.

⊙ **NOTE**: The MARK2 should remain OFF any time the MARK2 is not worn.

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OPERATING MARK2

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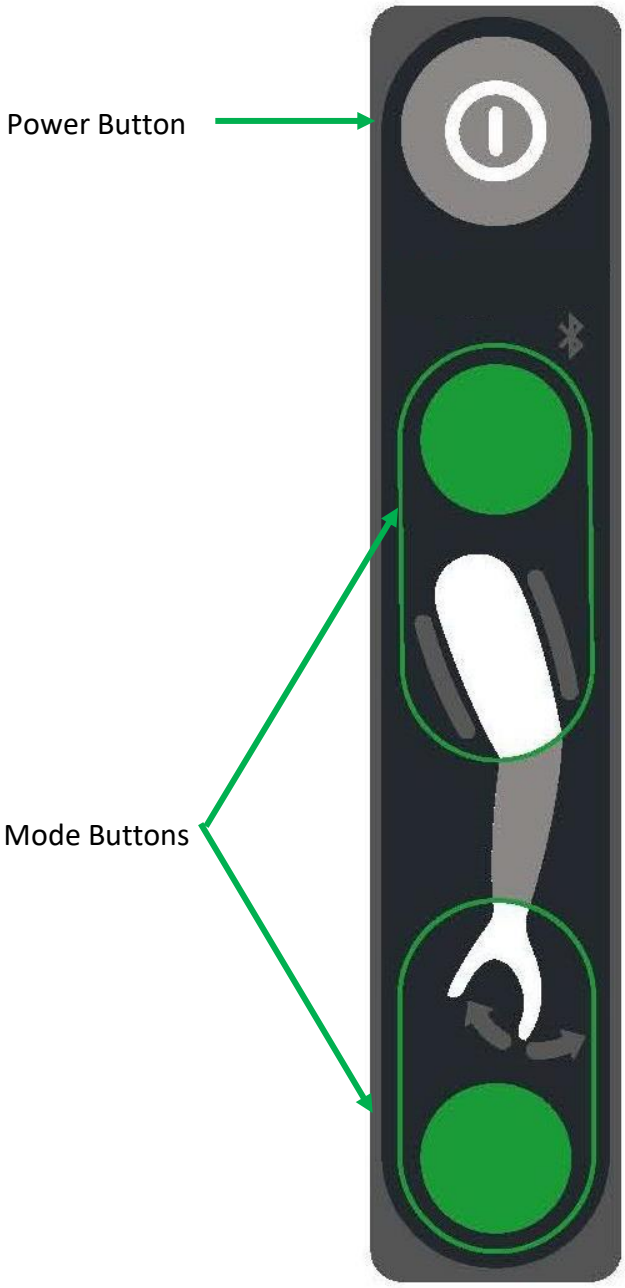
CONTROL PANEL

See the *User Manual – Sections for All MARK2 Models* document for a comprehensive Control Panel Buttons & Lights Diagram.



MODES OF USE

⚠ **WARNING**: Caution the User when using the device in shoulder positions where it is possible for the User to hit him or herself.

The MARK2 may be used in a variety of **modes**. The different modes allow the User to operate the MARK2 by tensing or relaxing different muscles. You may find that you want the User to use different muscles – and therefore different modes – when performing specific tasks with the MARK2. Modes may be changed using the buttons on the control panel.

When the device is fit to the User, you will need to optimize the sensitivity settings within each mode depending on the strength of the User's EMG signal at that time.

START MODE

When you first power on the MARK2, the elbow and grasp will be in Standby Mode.

ELBOW MODES

The elbow has four distinct modes of use when the MARK2 is powered on.

1. Standby mode
2. Biceps mode
3. Triceps mode
4. Dual mode

These are explained in the following pages.

GRASP MODES

The grasp has four distinct modes of use when the MARK2 is powered on.

1. Standby mode
2. Open mode
3. Close mode
4. Dual mode

These are explained in the following pages.

⊙ **NOTE**: The User may experience a slight vibration of the finger support when the grasp reaches a fully closed or fully open position. This would be caused by the hand motor turning on and off as it detects the limits of its range of motion. This is normal operation, and nothing to worry about.

ELBOW MODES

Standby mode	In this mode, neither the Biceps or Triceps Light will be illuminated. The elbow motor will not respond to the User's EMG signal from either muscle group. Though the MARK2 is powered on, no assistance is being given to your elbow, and the arm will neither flex nor extend. The sensors will be reading your EMG signal from both biceps and triceps, but the motor response is paused. Actions: • This can be useful as a resting mode if straps or sensors need to be adjusted, or if you want to take a short break without turning the device off.	
Biceps mode	In this mode, the Biceps Light will be illuminated. The elbow motor will respond to the User's biceps EMG signal. Actions: • When they relax their biceps, the device will extend. • When they contract their biceps, the device will flex.	

Triceps mode	In this mode, the Triceps Light will be illuminated. The elbow motor will respond to the User's triceps EMG signal. Actions: • When the User's relax their triceps, the elbow will flex. • When the User's contract their triceps, the elbow will extend.	
Dual mode	In this mode, both the Biceps and Triceps Light will illuminate. The elbow motor will respond to the User's biceps *and* triceps EMG signal. The elbow will only respond to muscle contraction (not relaxation, as in other modes) to assist the User's with active flexion and active extension of their elbow. The User must engage both muscle groups in order for their arm to move in both directions. The MARK2 will respond to whichever muscle signal is stronger at a given moment in time. In order for Dual mode to be most effective, the User should be able to isolate the desired muscle (biceps or triceps) and have a limited number of co-contractions prior to using Dual mode. When used well, this mode should allow the User greater ability to hold an arm position at a mid-point between fully flexed and fully extended. Actions: • When the User contracts their biceps, the elbow will flex, aslong as their biceps signal is greater than their triceps signal. • When the User contracts theirr triceps, the elbow will extend, as long as their triceps signal is greater than their biceps signal.	

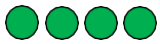
GRASP MODES

Standby mode	In this mode, neither the Close or Open Light will be illuminated. The grasp motor will not respond to their EMG signal. Though the MARK2 is powered on, no assistance is being given to their hand, and the grasp will neither open nor close. The sensors will be reading their EMG signals from both wrist flexor and extensor muscle groups, but the motor response is paused. Actions: • This can be useful as a resting mode if straps or sensors need to be adjusted, or if they want to take a short break without turning the device off.	
Close mode	In this mode, the Close Light will be illuminated. The grasp motor will respond to their wrist flexor EMG signal. Actions: • When the User relaxes their wrist flexors, the grasp will open. • When the User contract their wrist flexors, the grasp will close.	

Open mode	In this mode, the Open Light will be illuminated. The grasp motor will respond to the User's wrist extensor EMG signal. Actions: • When the User relaxes their wrist extensors, the grasp will close. • When the User contracts their wrist extensors, the grasp will open.	
Dual mode	In this mode, both the Close and Open Light will illuminate. The grasp motor will respond to the User's wrist flexor *and* wrist extensor EMG signal. The grasp will only respond to muscle contraction (not relaxation, as in other modes) to assist the User with active close and active open of your hand. The User must engage both muscle groups in order for their hand to move in both directions. The MARK2 will respond to whichever muscle signal is stronger at a given moment in time. In order for Dual mode to be most effective, the User should be able to isolate the desired muscle group (wrist flexors or wrist extensors) and have a limited number of co-contractions prior to using Dual mode. When used well, this mode should allow you greater ability to hold a hand position at a mid-point between fully closed and fully open. Actions: • When the User contracts their wrist flexors, the grasp will close, as long as their wrist flexor signal is greater than their wrist extensor signal. • When the User contracts their wrist extensors, the grasp will open, as long as their wrist extensor signal is greater than their wrist flexor signal.	

CHANGING ELBOW MODE WITH THE CONTROL PANEL

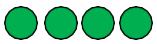
The elbow mode button cycles through the 4 elbow modes, moving to the next mode each time you press the mode button.

When the MARK2 is turned ON, the elbow will be in Standby mode unless it has been changed by Myomo.	
	Press the elbow mode button one time to put the elbow into **Biceps mode**
	Press the elbow mode button again (a second time) to put the elbow into **Triceps mode**
	Press the elbow mode button again (a third time) to put the elbow in **Dual mode**
	Press the elbow mode button again (a fourth time) to return the elbow **Standby mode**

Repeat the above cycle to scroll through and change to another mode at any point during your MARK2 use.

CHANGING GRASP MODE WITH THE CONTROL PANEL

The grasp mode button cycles through the 4 grasp modes, moving to the next mode each time you press the mode button.

When the MARK2 is turned ON, the grasp will be in Standby mode unless it has been changed by Myomo.	
	Press the grasp mode button one time to put the grasp into **Close mode**
	Press the grasp mode button again (a second time) to put the grasp into **Open mode**
	Press the grasp mode button again (a third time) to put the grasp in **Dual mode**
	Press the grasp mode button again (a fourth time) to return the grasp **Standby mode**

Repeat the above cycle to scroll through and change to another mode at any point during your MARK2 use.

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MAINTENANCE & TROUBLESHOOTING

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BEST PRACTICES FOR SMOOTH PERFORMANCE

Several factors can result in erratic movement of the orthosis.

> **NOTE**: The metal components of each sensor must have contact with the skin in order to properly read EMG signal.

FACTOR A: STRAP TENSION

Make sure the Humeral and Forearm Closures are comfortably snug – not too tight, not too loose.

FACTOR B: SENSORS PLACEMENT

Check that the sensors are centered on the correct muscle site. Some placement adjustment may be made by shifting how the strap is wrapping around the User's arm.

> **NOTE**: Velcro on the back of each sensor and on the liners allows it to be detached and reattached to the sensor cuffs in a more optimal position.

FACTOR C: STATIC

Due to static build up and environmental factors, it can take up to 5 minutes for some Users' resting muscle signal to stabilize. If the User experiences no response from the device, wait 5-10 minutes after donning orthosis to begin using.

> **NOTE**: If the User experiences pain or discomfort, turn off the MARK2 and check that the straps and pads are not twisted or bunched up. Have the User sest and try again. If pain or discomfort continues, discontinue use of the MARK2 and consult Myomo.

CLEANING THE MARK2

Clean the parts of the MARK2 which touch the User's skin (e.g. control panel, orthosis, liners, and sensors) after each use. Clean sensors after each use with a clean dry cloth.

Clean sensors 1x/week with an alcohol wipe, then let sit overnight. Do not saturate sensors with alcohol.

⚠ CAUTION: The MARK2 and accessories are not waterproof. Take care to protect the device from coming in contact with liquids. Never immerse, pour, or spray water or other liquids directly onto the MARK2.

⚠ CAUTION: Do not use a hairdryer to dry components of the MARK2.

⚠ CAUTION: Avoid harsh cleaning agents such as bleach and ammonia. NOTE: Take care to prevent the buildup of debris. Let the MARK2 completely dry out before putting it on again.

REPAIRING THE MARK2

Repairs should be made only by Myomo, directly. To ensure absolute safety of device and personnel, **only** Myomo staff may address repairs to the mechanical or electrical components of the MARK2. If such a repair is needed, please contact Myomo Customer Service. Myomo will conduct the repair, and send your MARK2 back to you.

This repair strategy provides the safest and most reliable pathway for returning the MARK2 to the user in optimal condition.

⊘ **NOTE**: Disassembling the MARK2 will void the warranty.

⚠ **WARNING**: No modification or disassembly of the mechanical or electrical components of the MARK2 is allowed as it may expose other dangers.

STORING THE MARK2

After taking the device off, rest in a clean, dry place to allow the MARK2 to dry.

⚠ **CAUTION**: Do not use a hairdryer to dry components of the MARK2.

⚠ **CAUTION**: Protect the MARK2 from damage, always use the carrying bag provided with the unit to store or transport the MARK2.

NOTE: Ensure the MARK2 is completely dry before storing.

Place in the carrying bag for travel and storage. The device may need to be repositioned in order to fit properly into the carrying bag. Gently bring the upper and lower arm frames closer together so the device is in a fully flexed elbow position. This will require moving the elbow motor while the device is powered off. **Move the motor as slowly and as gently as possible, with minimal force.** This is the best practice for avoiding damage to the motor.

Storage Environment

The MARK2 should be stored:

- In a dry location
- Away from direct sunlight
- In temperatures between 0 to 40 °C (32 to 104°F)

The battery is recommended to be stored at or below 20 °C (68 °F), in low humidity environment, free of dust and corrosive gasses. It is best to keep the battery with a state of charge between 50-80%, particularly for longer-term storage.

⚠ **WARNING**: If the MARK2 is not intended to be used within one month, remove the battery from the battery compartment.

NOTE: Even if it is in storage, the battery should be recharged every 6 months.

DISCARDING THE MARK2

⚠ **WARNING**: Do not incinerate the battery.

Contact Myomo to facilitate proper disposal or recycling.

AVOIDING DAMAGE TO THE MARK2

The MARK2 is designed to facilitate voluntary movements. It can be damaged by excessive force, either from a User forcibly moving the motor too hard, or if something (such as the arm of a chair) restricts the MARK2's movement as it is trying to assist the User.

⚠ **CAUTION**: Excess force applied to rotate the motors in either direction will permanently damage the motors.

NOTE: If you move the elbow or grasp motors to change the orthosis' position when it is in Standby mode or off, do so as gently as possible, with minimal force.

NOTE: Stall Detection Feature:

If the MARK2's motor gets stuck, for example, by the User's strength or by the arm of a chair, the motor will momentarily shut off. The User would feel that the MARK2 stops trying to move the User's arm. The device will stop responding to EMG signal and the motor will be able to move passively (as if the device were turned off). This feature prevents the motor from overheating and drawing excessive power from battery when the motor's movement is restricted. The User should relax and try to reposition the MARK2 away from any interfering objects. The motor will restart on its own, and the device will once again be listening for the User's EMG signal to direct it.

TROUBLESHOOTING

TROUBLESHOOTING TIPS

For additional clinical or technical questions or issues relating to the device, contact Myomo. See CONTACT INFORMATION for contact information.

SYMPTOM	POSSIBLE CAUSE	SOLUTION
Device is behaving erratically/oscillating in a distinct repeating pattern	Inappropriate sensitivity settings	Talk to Myomo to adjust sensitivity settings
	Poor MARK2 fit	Check that cuffs and closures are snug, sensors are sitting flat on the skin, and the MARK2 is aligned correctly on the arm
	Poor sensor conductivity	Check that cuffs and closures are snug, sensors are sitting flat on the skin, and the MARK2 is aligned correctly on the arm
Discomfort	The straps are too tight	Discontinue use and contact Myomo to ensure proper fit
	Poor MARK2 fit	Discontinue use and contact Myomo to ensure proper fit
Device appears to fight or resist your movement	Low battery	Charge battery
	Incorrect MARK2 Use	Contact Myomo to learn correct usage techniques
	Inappropriate sensitivity settings	Talk to Myomo to adjust sensitivity settings.
There is a clicking/grinding sound or frame of device appears “loose” when not in use	There is a mechanical problem	Contact Myomo
Device “locks up” or movement is slow/stiff when in a mode	Low battery	Charge the battery
	Inappropriate sensitivity settings	Talk to Myomo to adjust sensitivity settings.
	Device is in Standby mode	Use the buttons on the Control Panel to change out of Standby mode

MARK2 ERROR

⚠ **CAUTION**: If you detect fumes, flames, melting of components around the battery or battery charger, or the device is hot to touch, **TURN THE DEVICE OFF IMMEDIATELY** and contact Myomo.

RECOGNIZING WHEN THE MARK2 IS EXPERIENCING AN ERROR

When the MARK2 detects an error and initiates an error code, it will not function normally. An electrical or mechanical failure is indicated by the following:

- The Bluetooth light will be flashing (blinking).
- The Power light will be slowly changing color in a repeating pattern – White (which may look Light Blue), Blue, Green, Red, repeat.
- The 4 Mode lights will be turning on and off each time the Power light changes color.

The combination of the Power light color and the 4 mode lights create an **Error Code**. *You do not need to know what the Error Code means; it is intended only for the manufacturer.*

WHAT TO DO ABOUT AN ERROR

1. Turn the MARK2 off.
2. Wait a few moments.
3. Turn the MARK2 back on.
4. Check the control panel lights – are you still seeing an error code? YES or NO?

If NO: continue working with your MARK2 as usual.

If YES, or if the error comes back: contact Myomo, and relay the following information:

When the power button is **White**, what mode lights are illuminated?	□ Biceps	□ Triceps	□ Close	□ Open
When the power button is **Blue**, what mode lights are illuminated?	□ Biceps	□ Triceps	□ Close	□ Open
When the power button is **Green**, what mode lights are illuminated?	□ Biceps	□ Triceps	□ Close	□ Open
When the power button is **Red**, what mode lights are illuminated?	□ Biceps	□ Triceps	□ Close	□ Open

Contact Myomo for assistance with a continuing error.

LOCATION OF IDENTIFYING NUMBERS

Elbow Motor Unit

The primary identifying number for each individual MARK 2 is located on the back of the battery and electronics case: it is the serial number for the elbow motor.

It is written as “M000” followed by a 3 or 4 digit number.

Charger

The identifying information for the charger is located on the underside of the charger.

TECHANICAL SPECIFICATIONS & MARKINGS

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TECHNICAL SPECIFICATIONS

⚠ **WARNING**: The MARK2 is not suitable for use in the presence of flammable anesthetic mixtures with air, or flammable anesthetic mixtures with oxygen or nitrous oxide.

ENVIRONMENTAL REQUIREMENTS

Temperature	**MARK2 Device** Operating: 0 to 40 °C (32 to 104 °F) Storing: -10 to 60 °C (14 to 140 °F)
Humidity	10% - 90% relative humidity, non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa

POWER ELEMENTS

Electrical Characteristics	
Battery Power Source	External/interchangeable 11.25V 2950mAh 33.2Wh Lithium Ion rechargeable battery pack
Battery Charger	Battery Charger: 20-26VDC / 2.8A max Power Supply: 100-240VAC / 50-60Hz
Internal Clock Memory Battery	Internal 3.0 V 40mAh Lithium Coin battery
Environmental Requirements	
Temperature	**Battery Charger** Operating: 0 to 40 °C (32 to 104 °F) Storing: -10 to 70 °C (14 to 158 °F) **Power Supply** Operating: 0 to 40 °C (32 to 104 °F) Storing: -10 to 70 °C (14 to 158 °F) **Battery** For charge: 0 to +45 °C (32 to 113 °F) For discharge: -20 to +60 °C (-4 to 140 °F) Storage < 1 year: -20 to +20 °C (-4 to 68 °F) Storage < 3 months: -20 to +45 °C (-4 to 113 °F) Storage < 1 month: -20 to +60 °C (-4 to 140 °F)

ELECTROMAGNETIC COMPATIBILITY

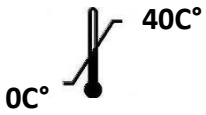
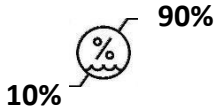
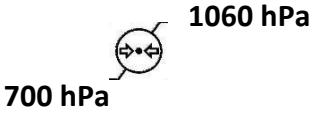
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. Only Myomo personnel may inspect or repair mechanical or electrical components of the MARK2 in order to maintain basic safety and essential performance with regard to electromagnetic disturbances. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the User is encouraged to try to correct the interference by one or more of the following measures:

- Re-orient or re-locate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

ON-DEVICE MARKINGS

Symbol	Description
	Attention – Refer to the accompanying instructions
	Power “On/Off” (push-push) IEC 60417-5010
	The product should be disposed of according to local guidelines
	Complies with FCC Part B Standards- Medical Equipment
	Safety Tested to 60601-1 3rd Edition as amended 1 and 60601-1-2 electromagnetic disturbances.
	RoHS Compliant
	Applied Part Type BF
	Class II construction, does not require a ground

ADDITIONAL INFORMATION

Symbol	Description
	Keep dry
IP21	Ingress Protection rating 21
	Operating Temperature Range: 0 to 40 °C (32 to 104 °F)
	Operating Humidity Range: 10% to 90% non-condensing
	Operating Atmospheric Pressure Range:700 hPa to 1060 hPa
	Manufacturer: Myomo Inc.

BATTERY AND CHARGER MARKINGS

Symbol	Description
	General warning sign
	Instructions for use
	For indoor use only
	The battery and battery charger comply to the current regulations of the EU guidelines
	The battery complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
	The product should be disposed of according to local guidelines
	Recycling Symbol
	For USA and Canada: Please call 1-800-822-8837 for information on how to recycle this battery
	Charger RoHs (China)
	Battery RoHs (China)
	DC Voltage
	UN Transportation Test

	UL Recognized for Canadian and US market