myomo
my own motion

Instructions for Use

myopro 2X
motion g



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CAUTION

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

CONTACT INFORMATION

UNITED STATES

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For customer support, email: support@myomo.com

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

DEVICE LABELLING AND IFU SYMBOLS

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

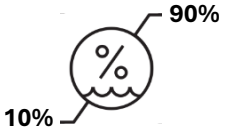
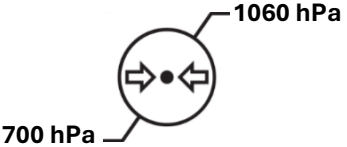
Symbol	Description
	Safety Tested to 60601-1 3rd Edition as amended 1 and 60601-1-2 electromagnetic disturbances.
	RoHS Compliant
	Applied Part Type BF
	Class II construction, does not require a ground

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)

Symbol	Description
⎓	DC Voltage
	UN Transportation Test
	UL Recognized for Canadian and US market

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.

FUNCTIONAL AUDIBLE ALERTS

The following Audible Alerts may be heard when operating the device.

Sound	Trigger	Meaning	Prompted Action
Long Beep	Motor temperature is too hot.	Motor is disabled until it cools down.	Please wait for your motor to cool down. It will resume its function once the motor temperature has cooled enough to resume operation.
Swirl Melody	After overheating, motor temperature has cooled enough to resume operation.	Motor is re-enabled and will begin moving again.	Resume normal use.
Donning Mode Ascending 1	Donning Mode enabled in Myconfig, User holds elbow button for 3 seconds.	Donning mode is entered, hand is about to move.	Place hand into the hand restraints.
Donning Mode Ascending 2	User presses hand button after above.	Handset and elbow are about to move.	Place elbow into elbow restraints.
Donning Mode Ascending 3	User presses elbow button after above.	Donning mode is complete.	Donning mode is complete, device going into standby (or configured start mode). You may begin using your device.
Short beeps at 1second intervals.	Overheat Prevention Alarm has been enabled in MyConfig or Myomo Mobile	After 5 seconds of alerting, Motor is disabled for	Please wait for your device to cool down. It will resume its function once the motor

Sound	Trigger	Meaning	Prompted Action
	App. Device is in Dual Mode, Elbow has been overused in a short period of time.	10 (configurable) seconds to allow it to cool down.	temperature is back to normal.

ABOUT THE DEVICE

The MyoPro 2x consists of a combination of the following components: a custom-made upper limb orthosis (brace), a powered elbow orthosis with surface electromyography (EMG) sensors, a static or manually set multi-articulating wrist (MAW), a static hand orthosis or powered hand orthosis with EMG sensors, and two shoulder harness configuration options for added comfort and secure fit of the MyoPro 2x. The MyoPro 2x also comes with an interchangeable, lithium-ion battery pack with a separate battery charging dock. Depending on device model, the Myomo Mobile App or Myconfig laptop application can be used to view a graphical representation of a muscle's EMG signal while operating the MyoPro 2x. A carrying bag is provided for transporting and storage of the MyoPro 2x.

The MyoPro 2x's EMG-control circuit continuously monitors and senses, but does not stimulate, the User's muscles. The MyoPro 2x 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 User's Provider. The power assist moves the motor with speed proportional to User's exertion. This system enables the MyoPro 2x to assist the User to initiate and complete desired motions.

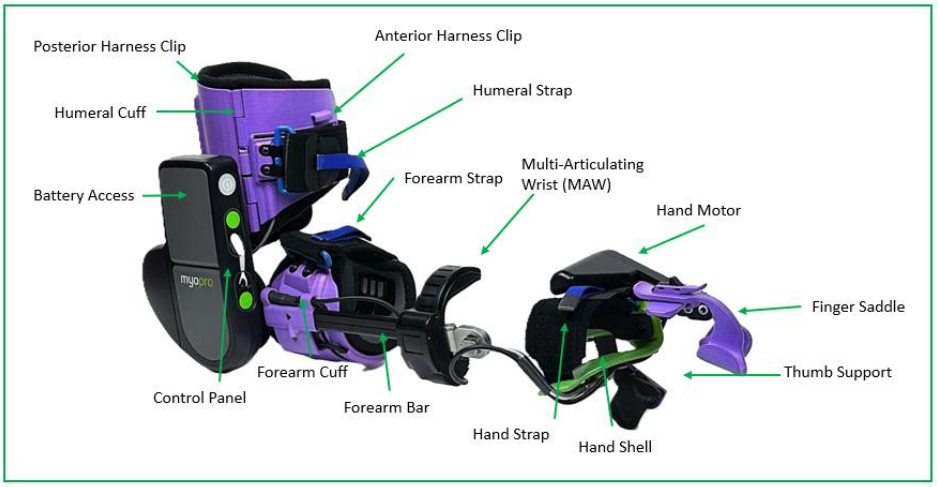
The MyoPro 2x is designed for use in a home or clinical environments away from areas with high flammability risk. Please reference Warnings and Technical Specifications for additional information. It should not be worn while undergoing medical imaging (x-ray, MRI, CT scan, etc.)

INTENDED USE

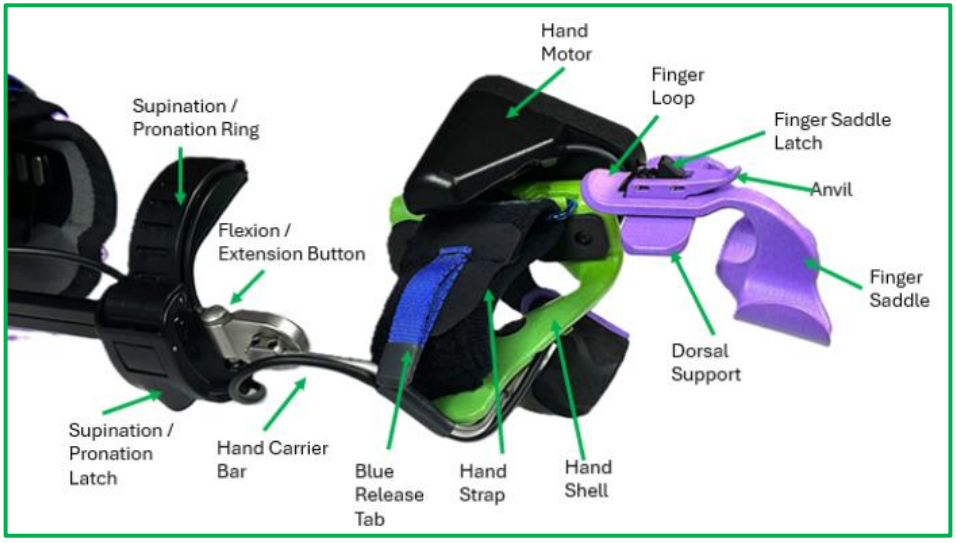
The MyoPro 2x, an upper limb orthosis, is a compensatory device to increase ability to perform functional tasks with the affected limb. The user voluntarily activates movement of the orthotic device with their remaining electromyography (EMG) muscle signal.

DEVICE DIAGRAMS

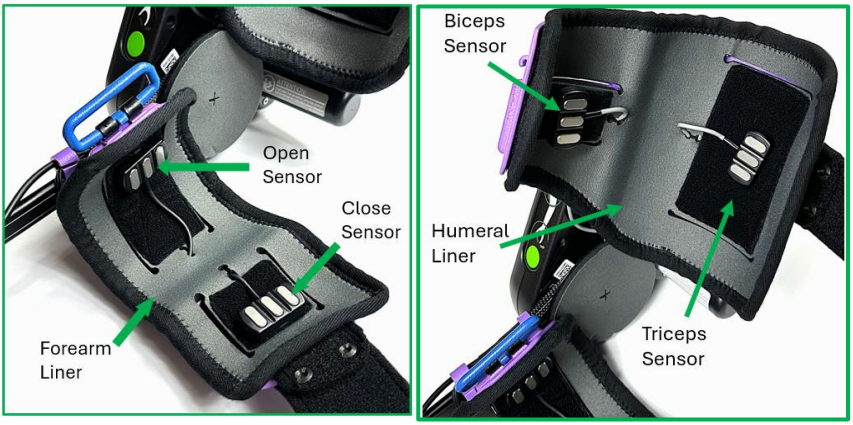
MYOPRO 2X MOTION G COMPONENTS



HAND AND WRIST COMPONENTS



FOREARM AND BICEP/TRICEP SENSORS



INDICATIONS FOR USE

The MyoPro 2x 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.

CONTRAINDICATIONS

The MyoPro 2x 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. Upper extremity contracture(s) that prevent functional movement to benefit from the orthosis.
5. Rigid spasticity in the affected muscle groups.

6. Arm circumferences and lengths that are outside build specifications required to be fit with the orthosis.
7. Cognitive or behavioral impairment that would inhibit safe use of the orthosis.
8. Other medical issue which interferes with safe use of the device for functional improvement.

⚠ GENERAL WARNINGS

The MyoPro 2x 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.

The MyoPro 2x is only to be used by the person for whom it is prescribed.

ONLY use the MyoPro 2x upper limb orthosis on the prescribed elbow, wrist, and hand joints. Each MyoPro 2x is built specifically for a left arm or a right arm; never wear the MyoPro 2x on the other arm.

WARNING: Small Parts – Choking Hazard
This device contains small components that may pose a choking hazard. Keep out of reach of young children.

Do not use the MyoPro 2x to drive an automobile or operate machinery.

Do not sleep while wearing the MyoPro 2x as straps may alter the User's circulation.

DO NOT expose the MyoPro 2x or battery to flame or excessive heat; personal injury may occur.

The MyoPro 2x is NOT waterproof. Do not 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.

Do not attempt to lift heavy objects with the MyoPro 2x; 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 MyoPro 2x is allowed as it may expose other dangers.

If storing the MyoPro 2x 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 your Provider:

- 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 MyoPro 2x 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.)

If at any time during the use of this device, you notice any of the following, discontinue use and seek guidance from your Provider.

- 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 MyoPro 2x 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.)

⚠ CAUTIONS

Do not use a hairdryer to dry components of the MyoPro 2x.

Insert only the battery pack that came with the MyoPro 2x into the MyoPro 2x 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 MyoPro 2x 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 MyoPro 2x. For proper cleaning instructions, see cleaning section below.

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

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 your Provider.

DONNING THE MYOPRO 2X

In addition to the below instructions, Myomo offers donning instructional videos for the MyoPro 2x on the Myomo website (www.myomo.com) as well as either on the laptop provided with the device or via the Myomo Mobile App.

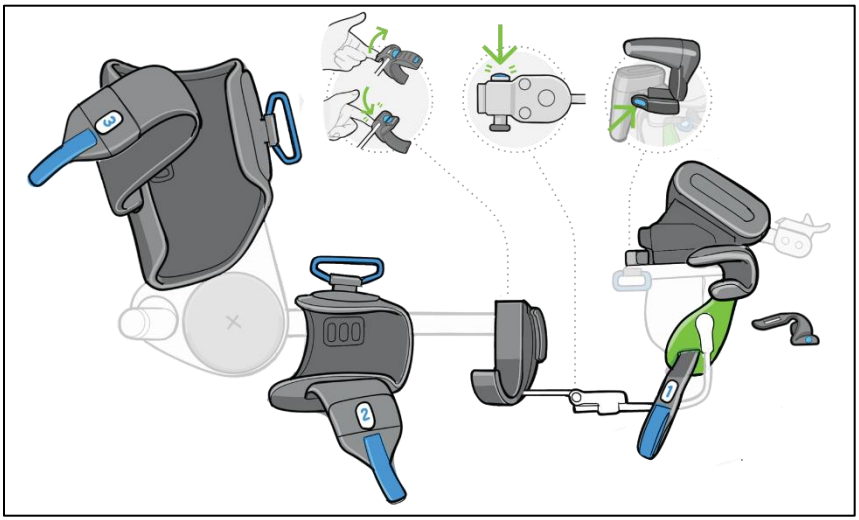
If you still have difficulty donning the MyoPro 2x, consult with your Provider and/or therapist for tips and strategies specific to your situation.

⚠ **WARNING**: A harness should always be worn when the MyoPro 2x is donned, unless directed otherwise by your physician and/or therapist. Failure to wear a harness may result in shoulder joint discomfort, pain, and/or injury.

Before donning your MyoPro 2x, perform the following steps:

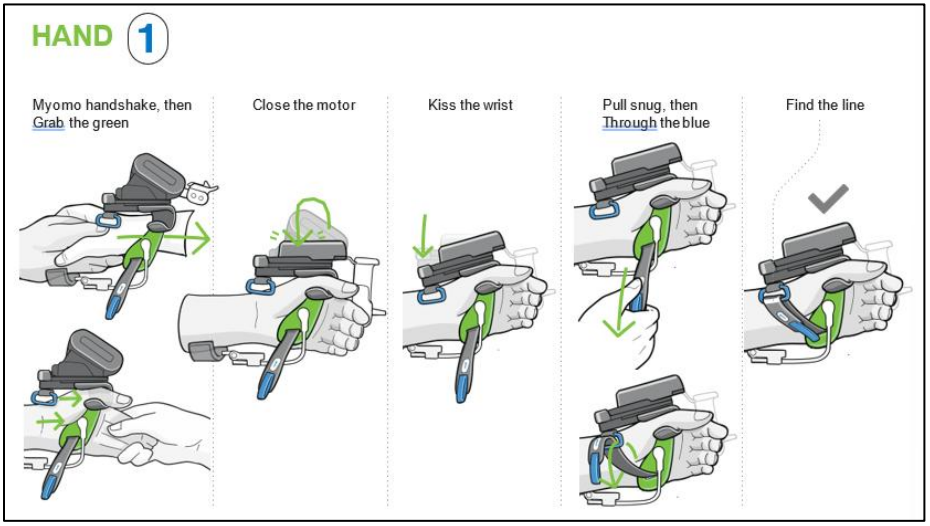
1. Ensure that the MyoPro 2x is powered off.
   - **NOTE:** Pads and straps should be fully air-dried from the previous use.
   - **CAUTION:** Do not use a hairdryer to dry components of the MyoPro 2x.

Setup

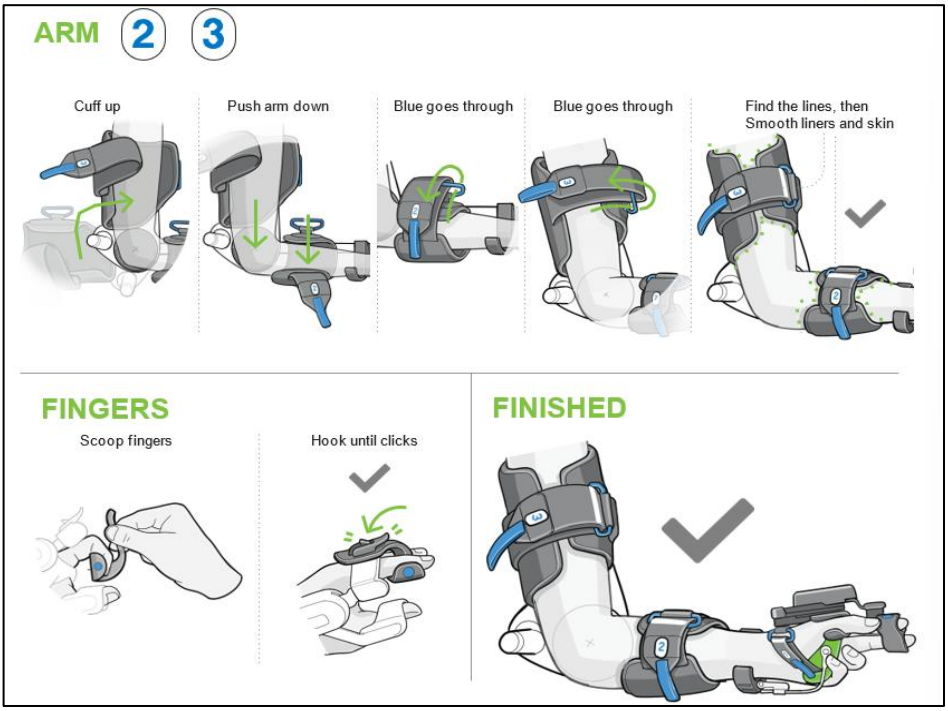


1. Open velcro straps #2 & #3.
2. Locate the black wrist ring. Pull up on the gray latch to unlock the ring. Rotate the ring until the blue stickers line up. Push the latch to lock the ring.
3. Locate the silver wrist joint next to the black wrist ring. Push the blue button to lock in place.
4. Remove the MyoPro finger saddle.
5. Push the blue button to open the MyoPro hand motor.
6. Open velcro strap #1 near the MyoPro thumb. Give slack to the strap on top.

Instructions



1. Using your helping hand, place the affected hand on the black wrist ring.
2. Reach your helping hand through the MyoPro hand. Pull the affected hand through to “grab the green” bar. Push the thumb down into the thumb piece.
3. Find strap #1. Pull down on the strap until it is snug against the top of the hand
4. Feed strap #1 through the blue ring.
5. Fold the strap and fasten to the palm when you find the white line.
6. Push the hand motor closed and kiss the wrist with the blue ring.



7. Slide the forearm into the black wrist rotation ring and forearm cuff.
8. Pull the upper cuff up to hug the arm.
9. Push the elbow and forearm down into the MyoPro.
10. Feed strap #2 through the blue ring.
11. Fold the strap and fasten when you find the white line.
12. Move your elbow away from your body. Reach your helping hand through to find strap #3.
13. Feed strap #3 through the blue ring.
14. Fold the strap and fasten when you find the white line.
15. Smooth out any folded liner edges and skin.

16. Attach the MyoPro finger saddle.
    a. When using the **2-finger saddle**, start by positioning the saddle on the end of your index and middle fingers.
    b. (*If Provided*) When using the **4-finger saddle**, start by positioning the saddle on the end of your index, middle, ring, and pinky fingers.



2-Finger Saddle



4-Finger Saddle

DONNING AND DOFFING THE HARNESS

The MyoPro 2x is available with two harness models depicted below. Following the appropriate instructions, depending on which harness model you have.

If necessary, the provided O-ring(s) can be placed over the end of the harness D-ring to secure the D-ring in the MyoPro clip. Refer to MyoPro 2x Harness Instructions or visit www.myomo.com for more information.

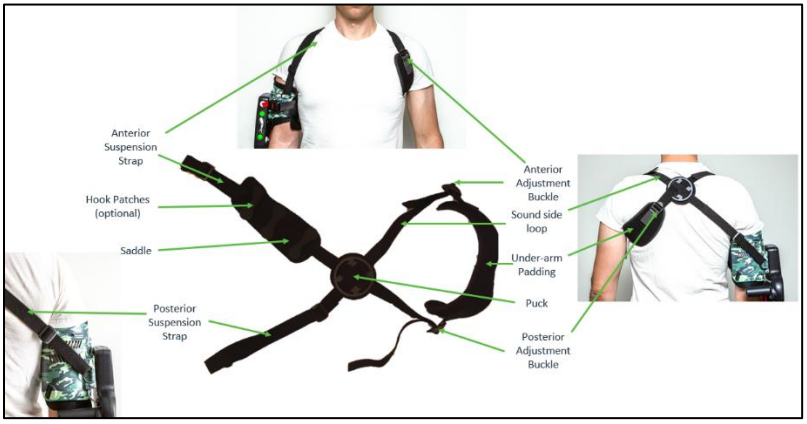
CROSS-BODY HARNESS



FIGURE 8 HARNESS



FIGURE-8 HARNESS - DONNING (METHOD 1)



1. Orient harness, noting that the puck's gray surface will face your back; ensure straps are untwisted.

2. Place non-affected side arm through sound side loop with puck facing toward you.



3. Lift harness over and behind head. The puck will settle between your shoulder blades and the saddle in your armpit.



4. Adjust straps to rest between neck and shoulders.







FIGURE-8 HARNESS - DONNING (METHOD 2)

1. Hold harness behind your back with puck's gray surface toward your back.





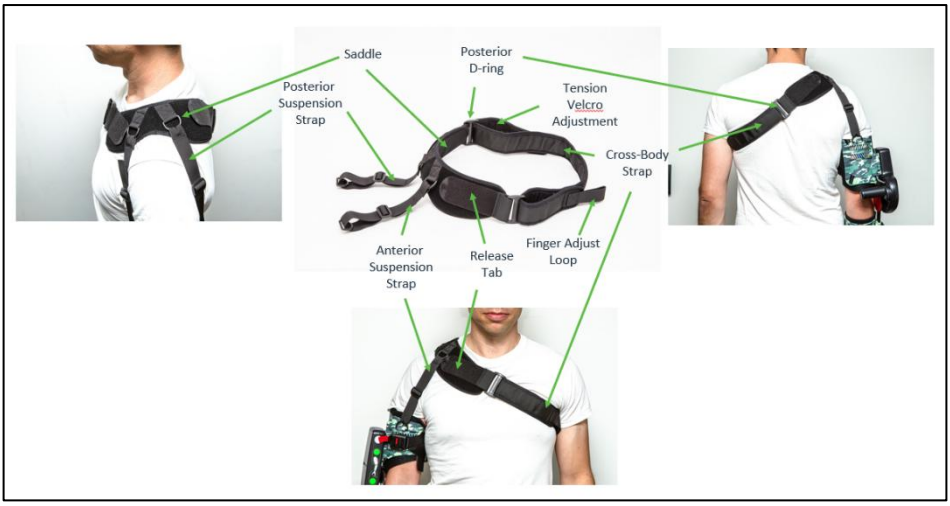
2. Thread non-affected side arm into loop and wriggle up toward your shoulder. Shrug to help straps over your shoulders to the front of your body.



3. Adjust front suspension strap to rest comfortably.



CROSS-BODY HARNESS - DONNING



1. Place harness saddle on affected-side shoulder. Keep centered on the midline of the shoulder, touching neither your neck nor shoulder joint.




2. Reach behind your back and pull strap under non-affected side arm. Hold the saddle with your chin as needed.





3. Secure strap using release tab, adjusting angle as needed so saddle rests flat against the chest.



4. Lift affected-side arm, or use furniture to help lift, and pull finger-adjust loop to set tension.



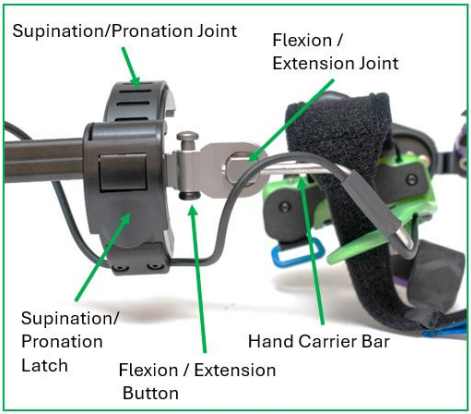

CROSS-BODY HARNESS - DOFFING

1. Pull release tab to unclip cross-body strap. Do not detach harness clips from MyoPro unless laundering.



ADJUSTING WRIST MODULE

ADJUSTING PRONATION/SUPINATION (SP JOINT)



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

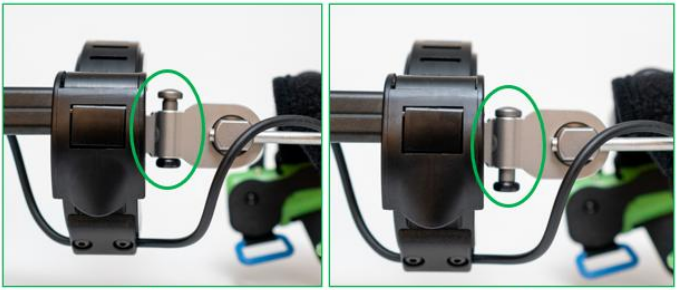
⚠ **CAUTION**: The SP latch should be closed when the device is not in use to avoid accidental damage to the components.



Closed Latch | Open Latch

ADJUSTING WRIST FLEXION/EXTENSION POSITION

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.



Unlocked *Locked*

DOFFING THE MYOPRO 2X

To remove the MyoPro 2x, follow the steps below:

1. Ensure that the MyoPro 2x is turned OFF.
2. Place the MyoPro 2x in your lap, or on a flat surface that is not slippery.
3. Remove the *finger saddle.*
4. Undo 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 blue tab to unstrap the forearm.

7. Open the *humeral cuff*. Note, once the *humeral cuff* is loose, the MyoPro 2x may fall away from your arm. Be sure to secure the MyoPro 2x first so that it does not fall. Pull on the *blue tab* to release the *humeral cuff.*
8. Gently slide your 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 MyoPro 2x in a clean, dry location to ensure it will fully air-dry before next use.
11. Place the MyoPro 2x into the carrying case for travel or storage.

⚠ **CAUTION**: After doffing your MyoPro 2x, check your arm and hand for areas of persistent redness and/or swelling. If there are fit problems with your MyoPro 2x, contact your provider for adjustments.

⊖ **NOTE**: The MyoPro 2x should remain OFF any time the MyoPro 2x is not being worn.

BATTERY & CHARGING

⊖ **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 MyoPro 2x will not turn on if the battery is in Shipping Mode.

⚠ **CAUTION:** Use only the battery and battery charger provided with the MyoPro 2x.

⊖ **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

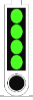
charge for more than 30 minutes, or you have been using the battery consistently for more than 12 months, it may be time for a new battery. Contact your Provider to order a new battery.

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

CHECK THE BATTERY'S CHARGE LEVEL

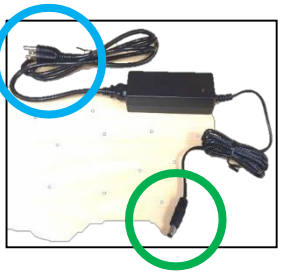
Press the black dot on the battery icon to see the battery's charge level. A light scale (1 to 4 lights) will indicate the battery's current charge range.



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

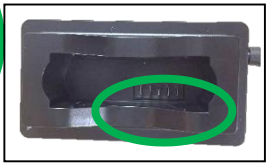
CHARGING THE BATTERY

1. Plug the charging cable into the charging dock.

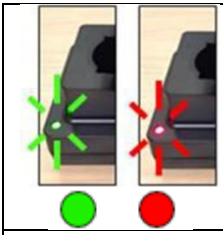




2. Plug the 3-prong end into a wall outlet.
3. Align the teeth on the battery with the prongs inside the charging dock and push down gently to sit the battery fully onto the prongs.

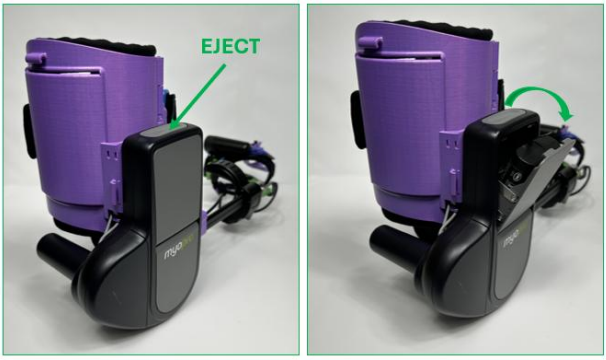




4. Check the light on the charging dock.

			
Flashing (blinking) between RED & GREEN The charger is <u>detecting the battery.</u>	Illuminated ORANGE The battery is <u>charging.</u>	Illuminated GREEN The battery is <u>charged.</u>	Illuminated RED There is a <u>problem</u> with the battery. Remove the battery from the charger and contact your provider

INSTALLING THE BATTERY

To open the battery compartment, press the eject button.

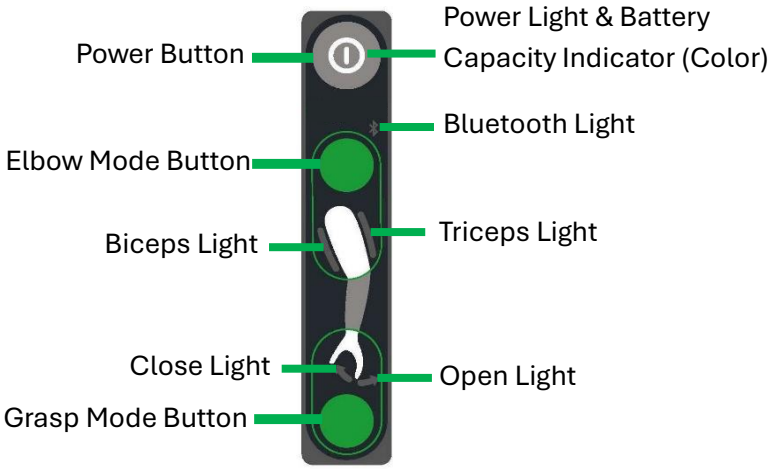


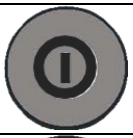
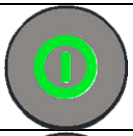
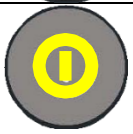
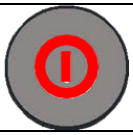
Locate the “myopro” sticker on the battery – position the logo so that it faces toward your arm, with the battery tab pointing up.



Gently insert the battery into the battery compartment and push on the center of the compartment door until it clicks shut to close.

CONTROL PANEL



NOT Illuminated (off)		The MyoPro 2x is powered OFF.
Illuminated Green		The MyoPro 2x is powered ON. The battery has greater than 15% charge remaining.
Illuminated Yellow		The MyoPro 2x is powered ON. The battery has between 15% and 5% charge remaining.
Illuminated Red		The MyoPro 2x 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 MyoPro 2x is experiencing an error. See *MyoPro 2x Error* section.

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 MyoPro 2x is experiencing an Error. See *MyoPro 2x Error* section for instructions.

HOW TO POWER ON AND OFF THE MYOPRO 2X

POWER ON

NOTE: Only turn the MyoPro 2x on once it is correctly and comfortably positioned on your arm. The MyoPro 2x should always be powered OFF while you are putting it on your arm. Similarly, ensure the power is OFF before starting to take the MyoPro 2x off your arm. See your User Manual Appendix for further guidelines.

1. Press the Power Button. 
2. Observe: When the MyoPro 2x 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 MyoPro 2x is ready to use!

POWER OFF

1. Press the power button.
2. Observe: All the lights will stop being illuminated, indicating that the MyoPro 2x has successfully powered off.

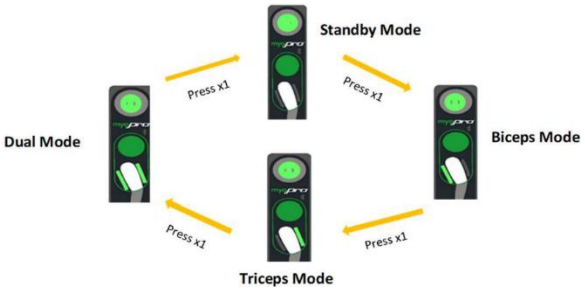
NOTE: The MyoPro 2x should remain OFF any time the MyoPro 2x is not being worn.

MODES OF USE

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

The MyoPro 2x has two powered joints (elbow and hand), and each joint has four modes described below and on the following pages. Modes determine which muscle signals control movement and how the device responds. You can switch modes using the buttons on the control panel as shown.

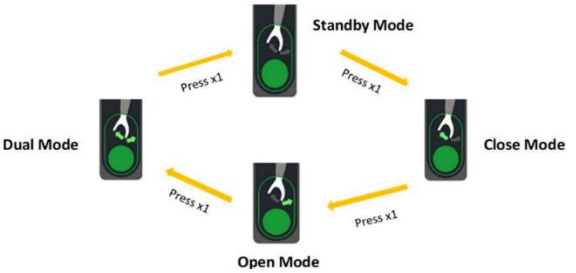
ELBOW MODES



Mode	Description	Control Panel
Standby Mode	Motor does not move. EMG is still read, but the elbow remains still. Useful for resting, pausing, or adjusting straps.	
Biceps Mode	Elbow responds only to biceps EMG. Relax → extend, Contract → flex. Good when the biceps signal is stronger or easier to control.	

Mode	Description	Control Panel
Triceps Mode	Elbow responds only to triceps EMG. Relax → flex, Contract → extend. Used when triceps activation is more reliable.	
Dual Mode	Elbow responds to both biceps and triceps. Biceps → flex, Triceps → extend. The stronger signal determines movement. Enables mid-range positioning and more natural movement.	

GRASP (HAND) MODES



Mode	Description	Control Panel
Standby Mode	Motor does not open or close the hand. EMG is still monitored. Used for rest or repositioning.	

Mode	Description	Control Panel
Close Mode	Responds only to flexor EMG. Relax flexors → open. Contract flexors → close.	
Open Mode	Responds only to extensor EMG. Relax extensors → close. Contract extensors → open.	
Dual Mode	Responds to both flexors and extensors. Flexors → close. Extensors → open. Stronger signal controls movement. Allows mid-range hand positioning. Like the elbow, dual mode is most effective when the user can reliably isolate flexor vs. extensor activation.	

Additional Notes About Modes

- You may feel a slight vibration when the grasp reaches full open or full close — this is normal.
- If movement feels weak or inconsistent, contact your provider — sensitivity settings may need adjustment.

ZOOM

ON YOUR DESKTOP or TASK BAR (at the bottom of your screen):

1. Double click on this icon to open Zoom



2. Click “JOIN MEETING” (Do not sign in)

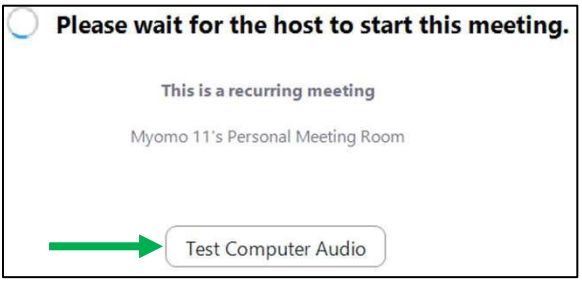


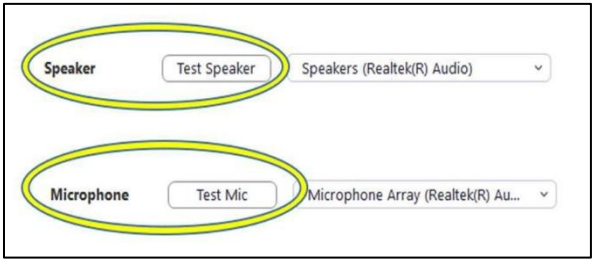
3. Enter the code that you received on your Telehealth email OR click the link within your email. Do not click the boxes for “Do not connect to audio” or “Turn off my video.”



4. Click “Join”

5. While you wait for the host, test your computer audio and computer microphone to ensure that it is working.





6. Join with Video and Audio.



7. You should then be connected to the Myomo Representative and you will be added to the meeting.

MYCONFIG VIEW (USER – MYOMO LAPTOP ONLY)

MyConfig View is a software application pre-installed on the Myomo laptop to visualize what your muscles are doing and how the MyoPro is interpreting them. *If a laptop was not included with MyoPro 2x delivery, please refer to* ***MYOMO MOBILE APP below.***

MyConfig View lets you:

- See your muscle signals (EMG) while using MyoPro
- Check how well MyoPro responds to your muscle activation
- Troubleshoot issues with movement
- Change your device's Start Mode

It is a view-only tool for users. Your provider adjusts the clinical settings.

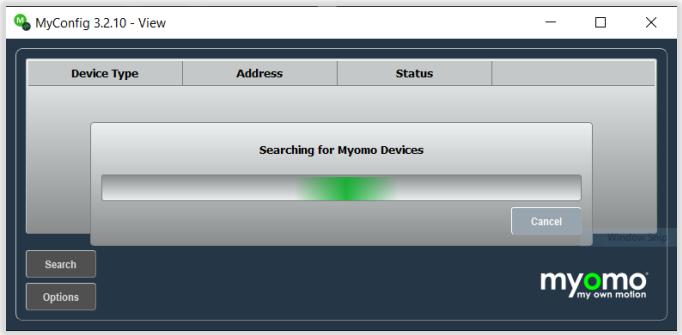
GETTING STARTED WITH MYCONFIG VIEW

1. Turn on your MyoPro: Power on the device using the control panel.

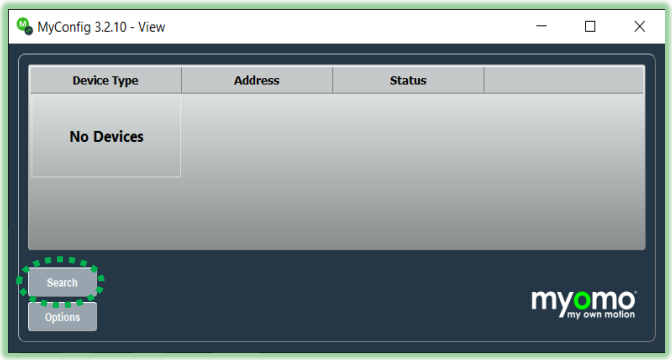
2. Open MyConfig View: Double-click the MyConfig View icon on the device laptop desktop.



3. Wait for automatic Bluetooth connection



- MyConfig will search for your MyoPro automatically.
- If it doesn't connect, press Search and move the device closer to the laptop. It may take a couple of attempts to connect.

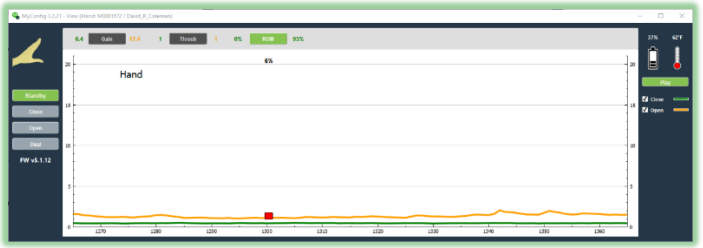


When connected successfully, the below two windows appear:

- Elbow EMG window



- Hand EMG window (Motion G models only)



UNDERSTANDING THE EMG GRAPH

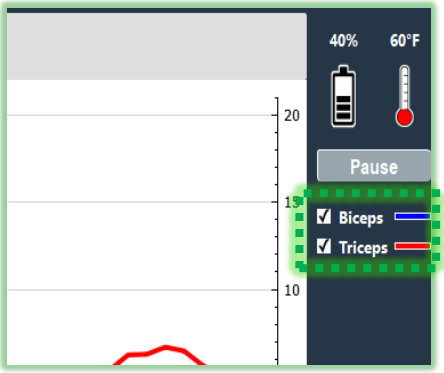
The EMG signals are the lines of the graph to watch because they show what the muscles are currently doing, how that may differ from what they're trying to do, and if MyoPro is being suitably responsive. Each muscle has its own color:

Muscle	Color on Graph
Biceps	Blue
Triceps	Red
Wrist/Hand Extensors	Orange
Wrist/Hand Flexors	Green

What the graph shows:

- How active each muscle is.
- Whether your signal rises enough to trigger motion.
- Whether the MyoPro is reading clean, stable signals.

You can check/uncheck boxes to show or hide each signal.



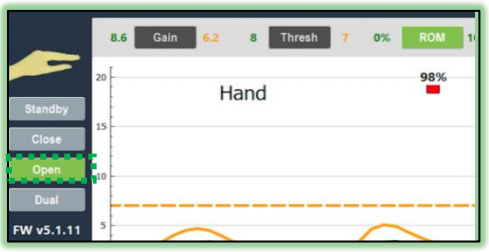
MODES DISPLAYED IN MYCONFIG VIEW

The mode you select on the MyoPro (Standby, Biceps, Triceps, Dual, etc.) is reflected in the MyConfig screen. These modes are defined in the Modes of Use section of this IFU.

What changes on the graph with each mode:

- The selected mode will appear in green on the screen.
- Only the muscles used in that mode are highlighted.
- Threshold lines appear only for the active muscle(s).





There are also Advanced Dual modes available which let you use a different control strategy for increased control.

- Constant Speed – one set speed into hand close and open
- Proportional – motor speed is directly related to measured effort
- Ramped – rate of motor speed increases with effort (exponential)

MYCONFIG SETTINGS

NOTE: If you believe any of the below settings (Gain, Threshold, or ROM) are incorrect, please inform your therapist or the clinician responsible for your MyoPro Management.

Gain (Visual Only in User Mode):

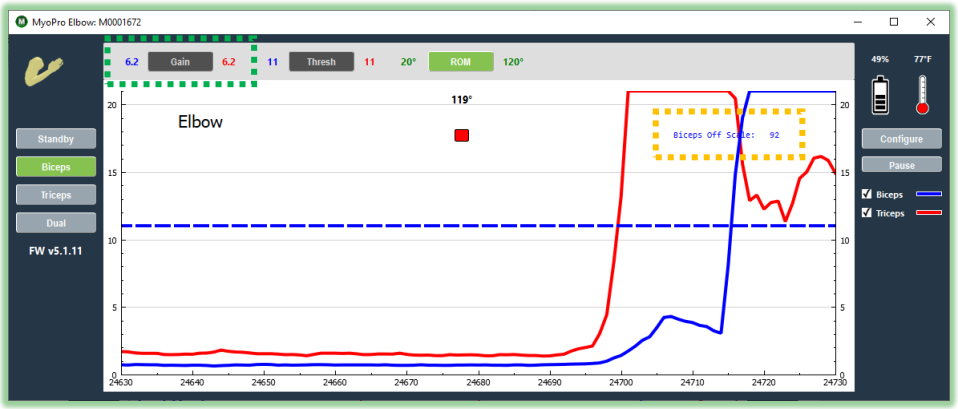
Gain controls how much your EMG signals are amplified by the device.

How Gain Affects What You See

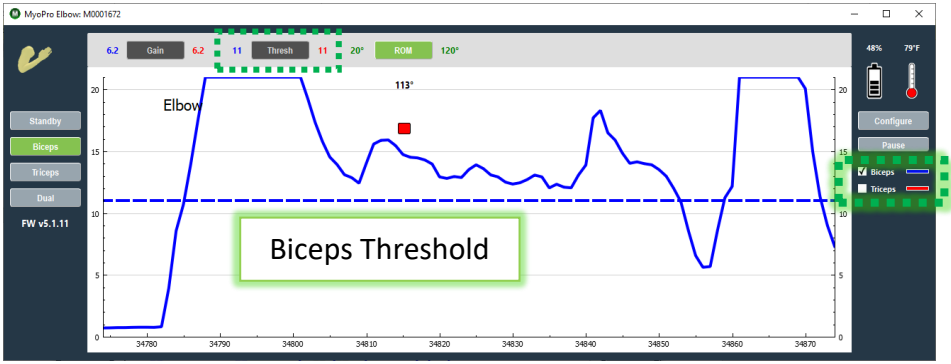
- Higher gain makes the EMG line taller (more amplified)
- Lower gain makes the line shorter

What Proper Gain Looks Like

- At rest, signal stays in the bottom quarter of the graph.
- At maximum effort, signal rises near the top but does not significantly extend past the top of the screen. If the signal goes off screen, a text box will show the current value (shown in orange below).



Threshold (Shown in User Mode):



Threshold is the “line” your muscle signal must cross to trigger movement. You will see a horizontal dashed line, as shown above, in the color of the active mode signal. When you activate your muscle, your EMG signal should cross above the threshold, causing the MyoPro 2x to move. When you relax, it should fall well below the threshold, and the MyoPro will move back to the starting position.

Range of Motion (ROM) Display

Range of Motion (ROM) defines the limits of how far the MyoPro 2x will allow your elbow or hand to move. Your provider sets these limits to keep your movement comfortable, functional, and safe. MyConfig View lets you see your ROM, but it does not allow you to change it. The screen helps you understand:

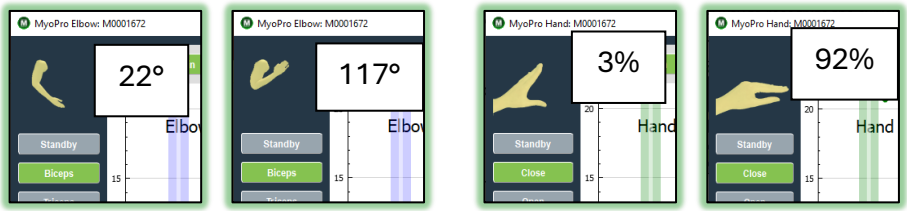
- Where your elbow or hand currently is.
- What the device considers the “start” and “end” of movement.
- Whether the device is reaching its programmed limits.

Elbow ROM is shown in degrees (shown below as 0°=full extension, 135°=full flexion). Hand ROM is shown in % (shown below as 0%=open,

100%=closed). The current position is indicated by the red square between the ROM sliders.



A graphical representation of the current joint position is in the top-left corner of each window. This is a quick way to recognize the current joint position while looking at the computer screen, without having to interpret the numbers.



Please refer to your clinician or visit www.myomo.com for more information and user manuals related to the Myconfig laptop application.

MYOMO MOBILE APP

The Myomo Mobile App is a companion application for the MyoPro. The app displays real-time EMG and depiction of arm/hand movement so users and clinicians can see muscle activity and how the MyoPro interprets those signals. *If your MyoPro 2x was delivered with a laptop, please refer to the **MYCONFIG VIEW (USER – Myomo Laptop only)** section above.*

The Myomo App lets you:

- View arm or hand movement in real time
- See your muscle signals (EMG) while using the MyoPro
- Track repetitions during movement
- Select MyoPro device modes

While the MyoPro can be used without the app for daily activities, the app enhances understanding, practice, and clinician-guided training.

DOWNLOADING THE MYOMO APP

1. **Open your device's app store**
    a. On **Apple devices**, open the **Apple App Store**
    b. On **Android devices**, open the **Google Play Store**
2. **Sign in to your account**
   Sign in using your Apple ID or Google account if you are not already signed in.
3. **Search for the app**
   In the search bar, type **"Myomo"** and select the app published by **Myomo, Inc.**
4. **Download the app**
    a. On Apple devices, tap **"Get"**
    b. On Android devices, tap **"Install"**

   Wait for the download to complete before opening the app.
5. **Email verification (if required)**
   Some devices or accounts may require email verification before downloading or opening the app. Follow the on-screen instructions if prompted.
6. Create your Myomo App Account
   Follow the on-screen instructions to create an account using your email address and password

Forgot your Apple ID or Google account password?

If you cannot sign in:

- Select **"Forgot password"** or **"Sign in & forgot password"** on the App Store or Play Store sign-in screen.
- Enter the email address associated with your Apple or Google account.

- Follow the instructions sent to your email to reset your password.

The Myomo Mobile App is **free to download and use** for both patients and clinicians.

CONNECTING THE MYOPRO TO THE MYOMO MOBILE APP

Before attempting to connect to the Myomo Mobile App, make sure your MyoPro device is properly charged, donned, and ready for use.

1. Power on the MyoPro
2. Make sure that Bluetooth is turned **ON i**n your phone's settings
3. Open the Myomo Mobile App
4. Select "Click here to connect"
5. Select "Tap to Scan" under "Available Orthoses". Wait for your device to appear in the white text box.
6. Click on your MyoPro after it appears under "Available Orthoses". Wait a few seconds.
7. The app will automatically return to the home page after connecting.

⚠ **Important:**

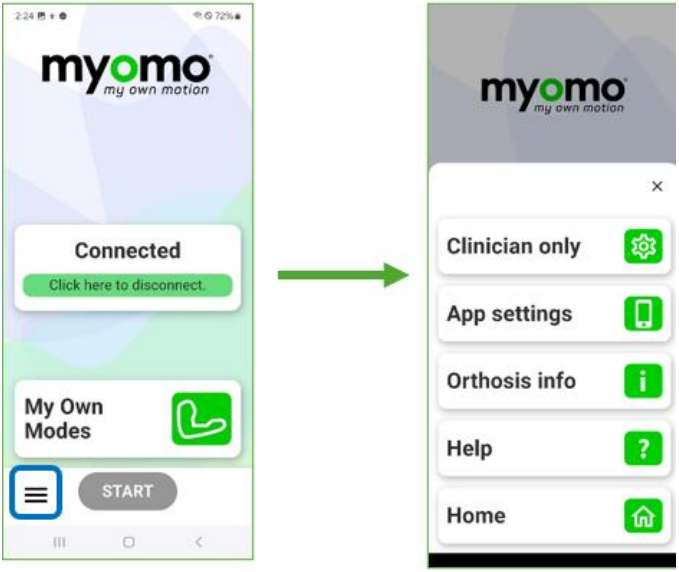
If you are using the Myomo Mobile app, **do not press any additional buttons on the MyoPro® control panel**. All interactions should be made through the app to prevent delays or mismatches between the app display and device operation.

ACCESSING THE MENU

The Home screen shows connection status, access to My Own Modes, and the Start button.



From the Home screen, select the **collapsed menu icon** (also known as the “hamburger button”) located in the **bottom left-hand** corner of the screen. This opens a drop-down menu with additional options, such as Clinician Only configuration settings and Help options.



MY OWN MODES

My Own Modes is a user-friendly feature that allows you to use the MyoPro as prescribed by your clinician while receiving real-time visual feedback. After clicking the **“My Own Modes”** icon on the home screen,

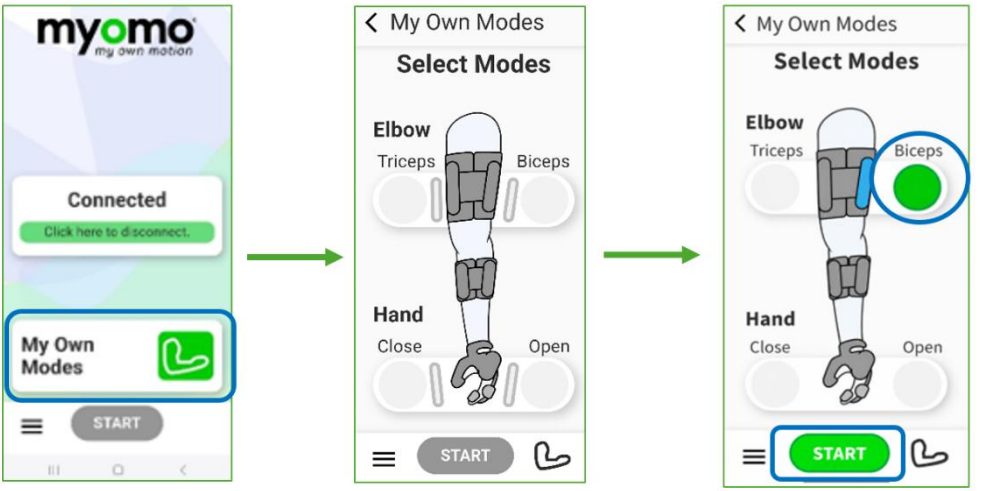
the “Select Modes” page will appear. Here, the desired device mode can be selected.

Note: Be sure your MyoPro is Standby before selecting a mode. This means the Start button is grayed out, and no modes are selected.

After confirming that the MyoPro is in Standby, the desired mode can be selected. This is done by selecting the large circle under the title of the desired mode.

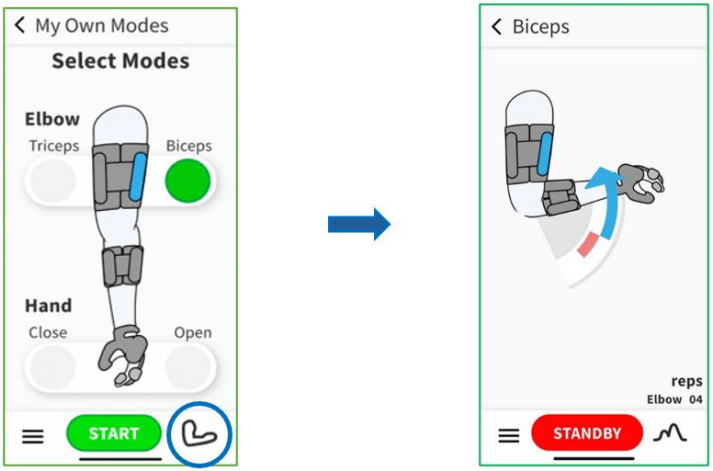
For example, the “**Biceps”** mode was selected in the image below. After it is clicked, the circle will turn green to show that it has been selected.

Afterwards, the “Start” button should be clicked. This will put the device into an active state. The MyoPro is now ready to operate.



OPTIONAL VIEWS IN MY OWN MODES

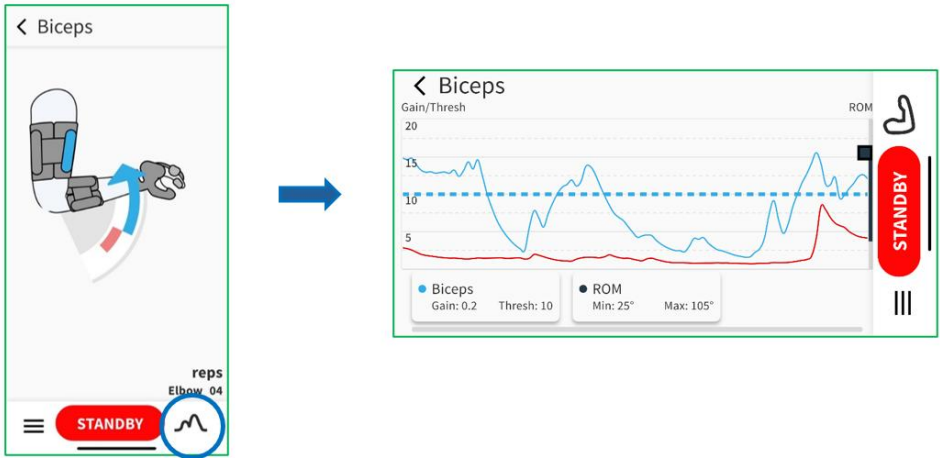
Anatomical Screen – Tap the arm icon in the bottom, right hand corner of the screen to access.



The **Anatomical Screen** shows:

- Live model of the arm or hand that responds to your muscle activity
- Graphic arrows that show the direction of movement and which muscles are firing
- Repetition counter that tracks how many reps have been completed

EMG Screen – Tap the EMG signal in the bottom, right hand corner while in the Anatomical Screen.



Note: The EMG Screen can be viewed in landscape (horizontal) orientation for improved viewing of EMG signals.

The **EMG Screen** shows:

- Live, color-coded muscle activity in a more technical format
  - Blue = Biceps
  - Red = Triceps
  - Green = Hand Close (forearm flexors)
  - Yellow = Hand Open (forearm extensors)
- These colors also correspond with the colors seen in the Anatomical Screen

Please refer to your clinician or visit www.myomo.com for more information and user manuals related to the Myomo Mobile App.

MYCONFIG OR MYOMO APP TROUBLESHOOTING

Watching MyConfig View or Myomo App EMG View, I see my EMG signal floating high on the graph, and/or is unresponsive to my attempts to activate it or relax my muscles. If the EMG signals in MyConfig View or within the Myomo App do not mimic your muscle activation and relaxation, consider the following:

1. **Relax**: Ensure you are relaxed. Try taking your mind off your arm and your MyoPro, the signal, or anything else related to the orthosis for a minute or two and see if your signal changes.
2. **Sensor Position:** Check to make sure the sensors are flush on your skin (not tilted partially off your skin or partly on a bony structure).
3. **Sensor Cuff Tension:** Sensor cuffs may be too loose or too tight – ensure the sensor cuffs are comfortably snug.
4. **Oily Skin:** If your skin is oily, wipe skin and sensors with dry cotton cloth or alcohol wipe. If an alcohol wipe is used, the skin and sensor must be completely air dried prior to sensor reapplication.
5. **Dry Skin**: If your skin is dry and/or scaley, use a paper towel or cotton towel to lightly wipe the skin so it becomes a dull pink, and any extraneous dry skin has been removed. If dry skin persists in the area, apply a minimal amount of water to towel, and then

lightly moisten the area. No build-up of water should be visible on the skin.

⚠ **Caution:** If your skin appears fragile, take great care with wiping your skin to avoid skin injury.

6. **Perspiration:** Check for perspiration. If floating EMG continues to be an issue try an antiperspirant wipe (e.g., Certain Dri).
7. **Hair:** Check for hair interference – if floating EMG continues to be an issue, try trimming your arm hair for better sensor-to-skin contact.

Please refer to *CLEANING THE MYOPRO 2X* on the following page for more information.

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 Upper Sensor Cuff and Upper Cuff Closure 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 your arm.

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 you experience no response from the device, wait 5-10 minutes after donning orthosis to begin using.

⊖ **NOTE**: If you experience pain or discomfort, turn off the MyoPro 2x and check that the straps and pads are not twisted or bunched up. Rest and try again. If it continues, discontinue use and consult your Provider.

CLEANING THE MYOPRO 2X

Clean the parts of the MyoPro 2x (control panel, orthosis, and sensors) which touch your skin once a week, or more frequently if dirt or debris has accumulated. 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**: Avoid harsh cleaning agents such as bleach and ammonia.

⊖ **NOTE**: Take care to prevent the buildup of debris. Let the MyoPro 2x completely dry out before putting it on again.

REPAIRING THE MYOPRO 2X

Repairs should be made only by your Provider, or 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 MyoPro 2x. If such a repair is needed, your Provider will send your MyoPro 2x to Myomo, Inc. Myomo will conduct the repair, and send your MyoPro 2x back to your Provider.

It is considered a Minor risk for a user to be without his or her MyoPro 2x for an extended period. This repair strategy provides the safest and most reliable pathway for returning the MyoPro 2x to the user in optimal condition.

⚠ **WARNING**: No modification or disassembly of the mechanical or electrical components of the MyoPro 2x is allowed as it may expose other dangers.

⊖ **NOTE**: Disassembling the MyoPro 2x will void the warranty.

STORING THE MYOPRO 2X

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

⚠ **CAUTION**: Do not use a hairdryer to dry components of the MyoPro 2x.

⚠ **CAUTION**: Protect the MyoPro 2x from damage, always use the carrying bag provided with the unit to store or transport

the MyoPro 2x.

NOTE: Ensure the MyoPro 2x 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 MyoPro 2x 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 a 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.

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

DISCARDING THE MYOPRO 2X

WARNING: Do not incinerate the battery.

Contact your Provider to facilitate proper disposal or recycling. SEE TECHNICAL SPECIFICATIONS & DEVICE MARKINGS FOR ADDITIONAL INFORMATION.

AVOIDING DAMAGE TO THE MYOPRO 2X

The MyoPro 2x 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 MyoPro 2x's movement as it is trying to assist the User.

NOTE: If you move the elbow or grasp motors to change the orthosis's

position when it is in Standby mode or off, do so as gently as possible, with minimal force.

NOTE: Stall Detection Feature:

If the MyoPro 2x's motor gets stuck, for example, by a user's strength or by the arm of a chair, the motor will momentarily shut off. The user would feel that the MyoPro 2x 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 MyoPro 2x 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.

MYOPRO 2X ERROR

Recognizing when the Myopro 2x is experiencing an error:

When the MyoPro 2x 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 MyoPro 2x off.
2. Wait a few moments.

3. Turn the MyoPro 2x back on.
4. Check the control panel lights – are you still seeing an error code? YES or NO?

If NO: continue working with your MyoPro 2x as usual.

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

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

TECHNICAL SPECIFICATIONS

⚠ **WARNING**: The MyoPro 2x 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	**MyoPro 2x 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 10.80V 3350mAh 36.20Wh 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 MyoPro 2x 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.

CLIENT INFORMATION GUIDE

Included in this IFU:

1. MEDICARE SUPPLIER STANDARDS

Available in the full device user manual provided on the device laptop or www.myomo.com/users-and-caregivers/manuals/ :

1. CLIENT BILL OF RIGHTS
2. CLIENT RESPONSIBILITIES
3. HOME SAFETY INFORMATION
4. INFECTION CONTROL
5. DISASTER PREPAREDNESS
6. ADVANCE DIRECTIVES INFORMATION
7. CLIENT COMMUNICATION FORM

MEDICARE DMEPOS SUPPLIER STANDARDS

NOTE: This is an abbreviated version of the supplier standards every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. 424.57(c).

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
3. A supplier must have an authorized individual (whose signature is binding) sign the enrollment application for billing privileges.
4. A supplier must fill orders from its own inventory, or contract with other companies for the purchase of items necessary to fill orders. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or any other Federal procurement or non-procurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site and must maintain a visible sign with posted hours of operation. The location must be accessible to the public and staffed during

posted hours of business. The location must be at least 200 square feet and contain space for storing records.

8. A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards.
9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll-free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.
11. A supplier is prohibited from direct solicitation to Medicare beneficiaries. For complete details on this prohibition see 42 CFR § 424.57 (c) (11).
12. A supplier is responsible for delivery of and must instruct beneficiaries on the use of Medicare covered items, and maintain proof of delivery and beneficiary instruction.
13. A supplier must answer questions and respond to complaints of beneficiaries and maintain documentation of such contacts.
14. A supplier must maintain and replace at no charge or repair cost either directly, or through a service contract with another company, any Medicare-covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.

16. A supplier must disclose these standards to each beneficiary it supplies a Medicare-covered item.
17. A supplier must disclose any person having ownership, financial, or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number, i.e., the supplier may not sell or allow another entity to use its Medicare billing number.
19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and regulations.
22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment for those specific products and services (except for certain exempt pharmaceuticals).
23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.
24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
26. A supplier must meet the surety bond requirements specified in 42 CFR § 424.57 (d).

27. A supplier must obtain oxygen from a state-licensed oxygen supplier.
28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 CFR § 424.516(f).
29. A supplier is prohibited from sharing a practice location with other Medicare providers and suppliers.
30. A supplier must remain open to the public for a minimum of 30 hours per week except physicians (as defined in section 1848(j) (3) of the Act) or physical and occupational therapists or a DMEPOS supplier working with custom made orthotics and prosthetics.

CUSTOMER SUPPORT

For any support issues, please contact your treating clinical Provider. A Provider may be a physical or occupational therapist, a physician, a prosthetist, an orthotist, or other in the medical field who has been trained in providing clinical care with the MyoPro 2x. Your Provider is the first resource for all fit and operational issues.

If your Provider is unable to address an issue, he or she may contact Myomo customer support for assistance. See contact information section.

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The MyoPro 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.