

# HERO ARM User Manual

Version 12.0

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# Introduction

Hero Arm is a powered bionic limb controlled by your muscles, with intuitive lifelike precision. Each Hero Arm is bespoke, perfectly formed just for you, with a breathable removable socket for enhanced ventilation and ease of cleaning. Powered by high-performance motors, advanced software and long-lasting batteries, it is lightweight and stylish.

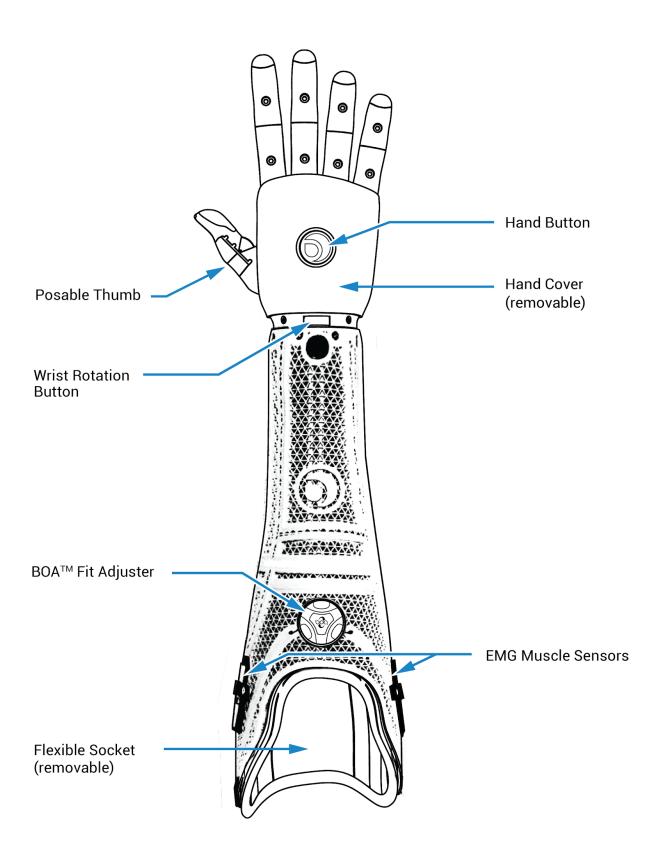
This manual will give you an overview of how to use and look after your Hero Arm, and the important safety considerations to take.

The latest upgrade to the Hero Arm has incorporated Bluetooth connectivity which enables connection to the Sidekick mobile phone app. The Sidekick app is not required to use the Hero Arm, but does provide the user with the ability to configure certain aspects of the Hero Arm's operation and easily access training tutorials. For further information please see the section - Sidekick Mobile App

To search for a specific word or phrase, hit Ctrl + F (on Windows) or  $\mathbb{H}$  Cmd + F (on Mac).

# Hero Arm Overview

Note: Your Hero Arm may look slightly different from the version pictured.



#### What's in the Box

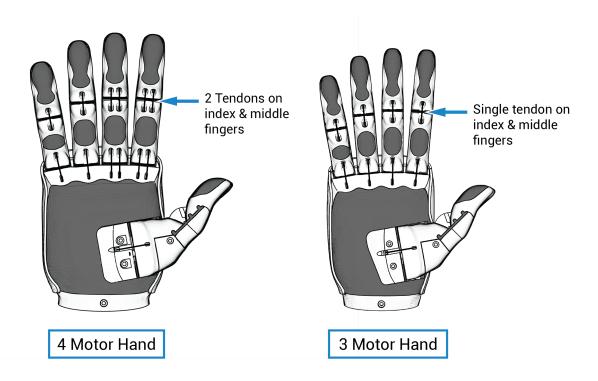
- 1 x Hero Arm
- 1 x Battery
- 1 x Battery Charger
- 1 x Quick Start Guide
- 1 x Hand Cover
- 1 x Battery Cover

# Configurations

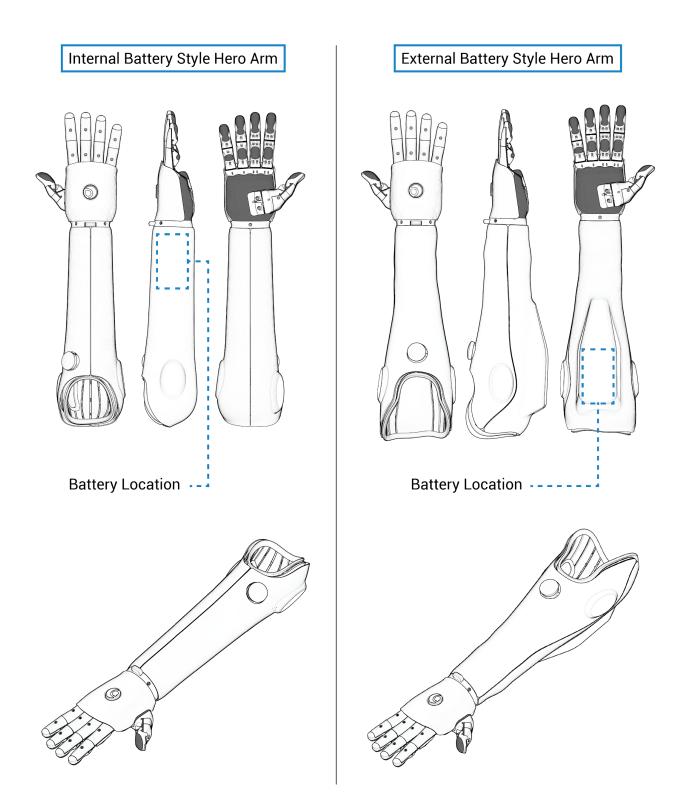
Each Hero Arm is custom built for every individual, and comes in 3 different hand sizes and 2 different arm layouts. As a result, you may see some differences between your Hero Arm and the diagrams in this manual.

The Hero Arm comes with either a 3 Motor or 4 Motor Hand depending on the most suitable size of hand for your arm. The key differences are the reduced size of the 3 Motor version, and the number of tendons.

The 4 Motor versions have 2 tendons on both the index & middle fingers, which allows them to move independently. On the 3 Motor version, the index & middle fingers will always move together.



Every socket is designed and 3D printed for each individual based on a 3D scan of their residual limb, and comes in two different layouts: internal or external battery. The functionality of both layouts are the same, but they have some noticeable cosmetic differences as shown below:



# Getting Started

Before putting on your Hero Arm for the first time, please familiarise yourself with this user manual.

#### When to Use Your Hero Arm

The Hero Arm is intended to be used for day to day activities that require the use of one or two hands. It is intended to be used for light to moderate activities such as:

- Holding objects such as cups, tools, kitchen utensils, trays, bottles, bags
- Performing operations such as opening doors, pressing buttons, getting dressed.

## Precautions and Warnings

The Hero Arm is not intended for use in activities that may result in injury or death to the user or others as a result of it failing to perform the activity as intended. As such, activities which are specifically prohibited include:

- Driving any form of motor vehicle, aircraft or boat,
- the use of firearms, or
- use while partaking in contact sports, watersports or extreme sports.

For all other activities, you should assess the impact of the following:

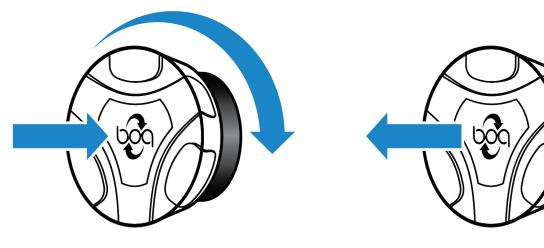
- The Hero Arm suddenly ceases to function (for example if it were to run out of battery). Bear in mind that this could leave the device unable to release.
- The Hero Arm losing its grip.
- The Hero Arm moving unintentionally.
- The Hero Arm shifting position on, or coming off your arm.

If the consequence of using the Hero Arm for any of the above activities is injury or death to yourself or anyone else, the Hero Arm must not be used. In the case of using the Hero Arm to return to work, you should discuss the above points with your Health and Safety representative and conduct a formal risk assessment.

You can use your Hero arm above -5 °C (23 °F) and below +50 °C (122 °F). You can use it at pressures equivalent to altitudes of up to 4000 m (16,400 ft, that's 600 hPa to be exact), making it safe to use in the cabin of a commercial airliner. Your Hero arm is IP20 rated. IP is "Ingress Protection" the first number is a score for solids and dust, the second is for liquids. IP20 means finger-sized objects can't get inside. It is not waterproof. You should avoid exposing it to any water. If your Hero Arm does get wet, turn it off, remove the battery and leave it to dry fully. It can be used in Relative Humidities (RH) between 15% and 90%.

# Putting on your Hero Arm

Your Hero Arm has been designed to perfectly fit your arm, and comes with an adjustable BOA Fit System™ to reach the perfect balance of comfort and secure fit.



To tighten, push in then rotate clockwise

To loosen, pull outwards

You can easily adjust the fit of your Hero Arm throughout the day without removing it, simply by adjusting the BOA Dial.

# Switching on

To switch on your Hero Arm, press the Hand Button for 1 second. The Hand Button will pulse purple while initialising. Once the arm is on and ready to use, the Hand Button pulses white.

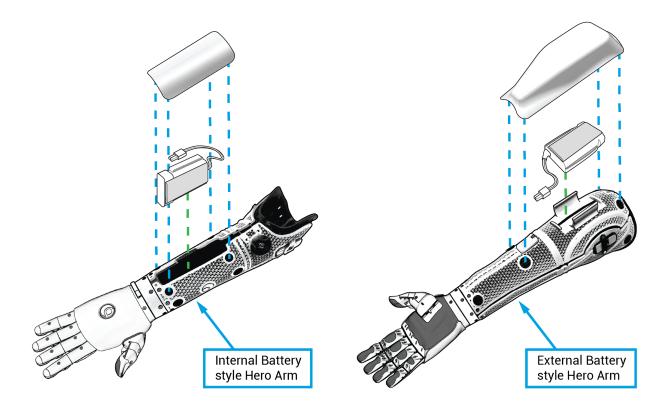
## Charging the Battery

Your Hero Arm comes with a battery and Smart Charger. The battery life of your arm will vary depending on how heavily you use it, but we recommend charging it every night.

You must remove the battery from the arm before charging. For safety reasons, only ever charge your battery using the Smart Charger provided with your arm.

Follow the steps below to charge your Hero Arm battery:

- 1. Switch off your arm by holding down the Hand Button for 3 seconds
- 2. Once switched off, remove the battery cover and unplug the battery, by pressing the latch and pulling on the white connector
- 3. Remove the battery from the arm by gently pulling on it
- 4. Plug the battery into the supplied Smart Charger
- 5. Plug the charger into a mains power outlet
- 6. The status Hand Button of the Smart Charger will flash to indicate that the battery is charging
- 7. When the battery is fully charged, the status Hand Button will stop flashing
- 8. You can now disconnect the battery from the Smart Charger and reconnect it to your Hero Arm



# Checking the Battery Status

To check the status of the battery, with your Hero Arm switched on, hold the Hand Button down for 1 second. The battery life is indicated by the colour of the Hand Button:

Battery Level Indicator			
Hand	<b>Button Colour</b>	Battery Level	
	Green	40%-100%	
	Amber	20%-39%	
	Red	2%-19%	
- 0 -	Red Flashing	Under 2%	

# How to use your Hero Arm

## The Hand Button

The multi-function button on the back of the hand can be used to control a variety of functions of your Hero Arm:

- Hand On/Off
  - o To switch on your Hero Arm, press the button for 1 second.
  - To switch off your Hero Arm, press the button for 3 seconds.
- Change Grip Group
  - Your Hero Arm has multiple grip groups; to change between these, press the Hand Button for 0.5s. See '<u>Grip Modes</u>' for more information on grips.
- Check Battery Status
  - Press the Hand Button for 1s, and its colour will change to indicate the battery level.

# Notifications/Status

The Hero Arm will notify you of a variety of status changes through the Hand Button colour, vibration, and beeper. These are summarised below (in addition to the battery level indicators listed in 'Checking the Battery Status'):



- Indicates a vibration of the Hero Arm

На	nd Button Colour		Notification
	Purple (pulsing)		Initialising / Calibrating
	White (pulsing)		Normal operation
- 6 -	Green (flash)	<b>\\\\</b> \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Grip change (number of flashes indicates grip number)
- 0 -	Purple (flash)	<b>\\\\</b> \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Grip group change (number of flashes indicates group number)
	Purple (solid)	<b>\\\\</b> \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Shutting down
	Blue (pulsing)	<b>\\\\</b>	Freeze Mode active
	Orange (pulsing)	<b>\\\\</b> \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Low battery warning
	Red (pulsing)	<b>\\\\</b> \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Battery too low (followed by automatically powering off)
	Yellow Blue (pulsing)		Hero Arm is getting too hot
	Yellow Red (pulsing)		Hero Arm has reached maximum temperature (followed by automatically powering off)
	Red (solid)		EMG communication failure

## Controlling the Hand

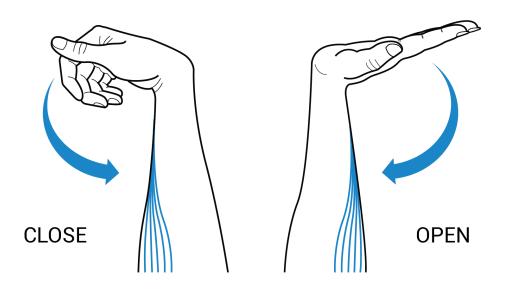
The Hero Arm comes with an advanced myoelectric, multigrip bionic hand. The EMG Sensors in the arm detect your muscle movements, and the hand responds for intuitive control. When being fitted for your Hero Arm, your prosthetist will have found the optimal location of the EMG Sensors for your muscles.



As standard, the Hero Arm uses two EMG muscle sensors to control the hand. However, if you only have one suitable muscle site on your residual limb, your Hero Arm may only use a single EMG sensor. If this is the case, the way you control the arm will be different. The control scheme for single-site users is outlined in Controlling the Hand - Single Site Users.

The bionic hand is controlled by tensing the same muscles which are used to open and close a biological hand. To close the Hero Arm's hand, and perform the selected grip, imagine flexing the wrist inwards while pulling the fingers into the heel of the hand.

To open the hand, imagine extending the wrist with an outstretched palm.



If you are having trouble getting the hand to respond to your muscle movements, please see the <u>Troubleshooting</u> section on pages 24-25.

# **Speed Control**

The hand will move more slowly when your muscles are tensed gently, and will move more quickly with a firmer tense. This control can be useful for manipulating small or delicate objects.



The information on the following two pages (p11-12) **only** applies to users with a single muscle site. For the vast majority of Hero Arm users (with two muscle sites) the information in <u>Controlling the Hand</u> applies instead.

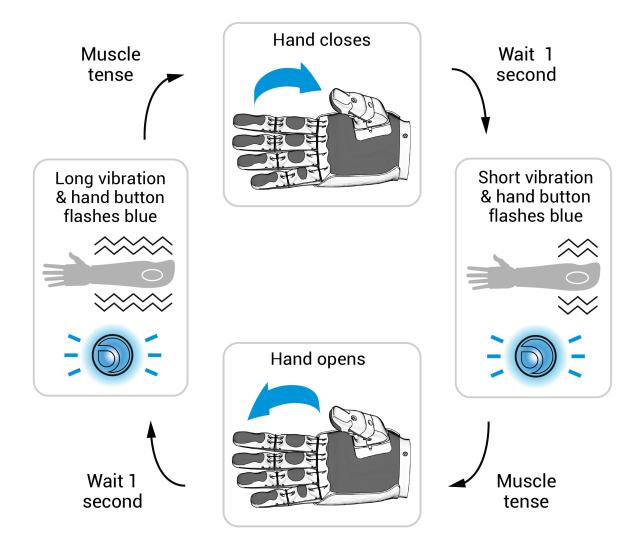
## Controlling the Hand - Single Site Users Only

When you tense the muscles under your sensor, the Hero Arm swaps between opening, then closing the fingers.

If you tense, the fingers will begin by closing.

If you relax and wait for 1 second, the hand will swap to be ready to open on your next signal. It will indicate this by flashing blue and vibrating. Tensing now will cause the fingers to open. Relaxing again will cause the hand to swap back to be ready to close the fingers.

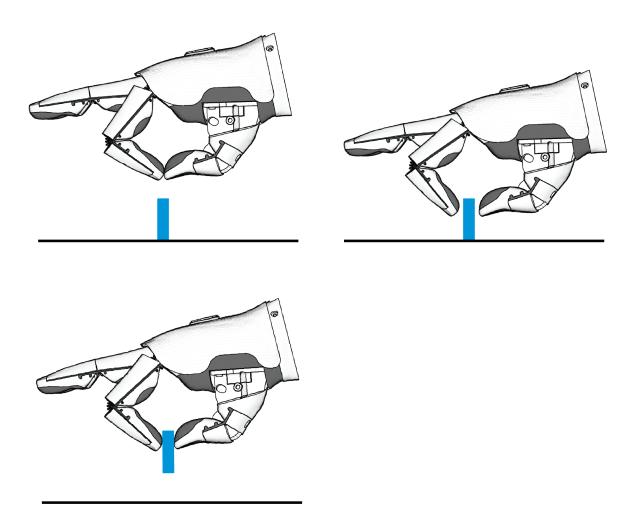
By alternating backwards and forwards like this, you can pick up and put down objects.



The length of the vibration you receive when the hand changes direction provides non-visual feedback about which direction it will go:

- Shorter pulses mean it has swapped to open next.
- Longer pulses mean it will close next.

When picking up small objects, it's useful to pre-position the fingers so that they're spread just a little bit wider than the object. To do this, choose the grip you want, fully close the fingers, then open them so that they are slightly wider apart than the object. The hand will then be ready to close around the object.



Tensing harder causes the fingers to move faster, and tensing softer moves them more slowly.



Do not attempt to tighten your grip on an object you are holding. After picking it up, the hand will swap direction to opening, so your next muscle tense will release it.

To tighten your grip on an object you must put it down (or otherwise support it), release it with your Hero Arm, then re-grip it from scratch.

# Grip Modes

The Hero Hand has 4 different grip patterns in the 3 motor version, and 6 different grips in the 4 motor version. These grips are grouped together in pairs to make switching between them quick and easy.

# **Changing Grips**

To switch between grips within a group, move the hand into the open position, relax, then hold an open signal for more than a second (see <u>Controlling the Hand</u>). You will feel a long vibration, and the Hand Button will flash green a number of times to indicate which grip number you have selected; 1 flash for the 1st grip in the group, and 2 flashes for the 2nd grip in the group.

To switch between the different groups, press and release the Hand Button. You will feel a short vibration, and the Hand Button will flash purple a number of times to indicate which group number you have selected - i.e. 1 flash for group 1, 2 flashes for group 2.

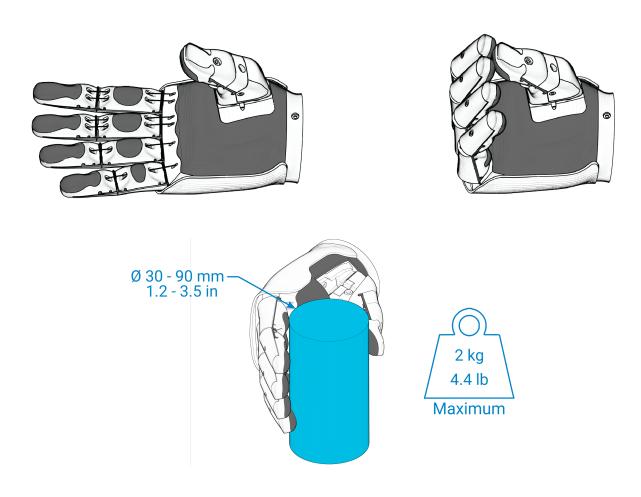
The various grips are described in the following pages.

# Group 1 - Fist and Hook

The primary group contains the **Fist** and **Hook** grips:

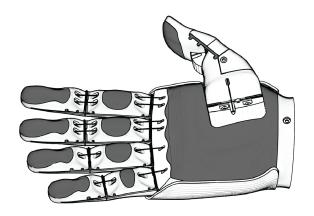
# Fist

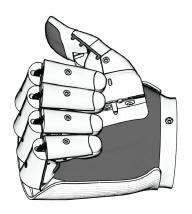
This grip is useful for carrying round objects such as bottles or fruit, for holding utensils and handles, and can also be used for handshakes. First, the thumb closes, followed by all 4 fingers.

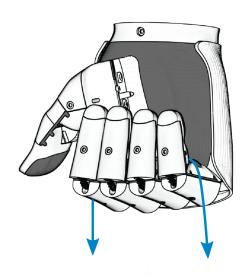


# Hook

Similar to the Fist grip, however the thumb remains open while the four fingers close. This is ideal for carrying a shopping bag or briefcase, and also allows you to do a "thumbs up" gesture.







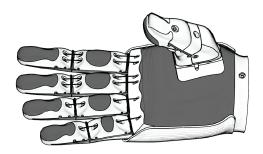


# Group 2 - Tripod

The secondary group contains two **Tripod Grips**. These are useful for picking up and manipulating small objects, such as car keys, coins, jar lids, pens etc.

# Tripod A

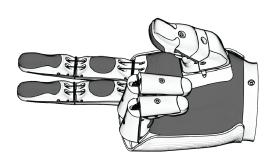
The middle and index fingers close to meet the thumb. The ring and little fingers remain open.

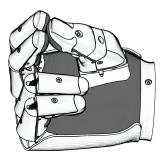


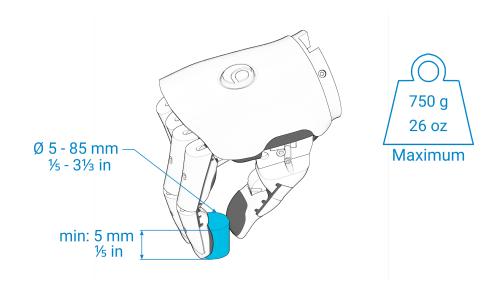


# Tripod B

The ring and little fingers close when selecting this grip, and when sending the close signal, the index and middle fingers then close to meet the thumb. You can make a "peace" hand signal with this grip.





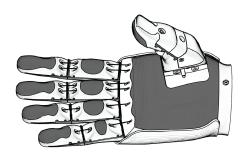


# Group 3 - Pinch

The final group, only available on the 4 Motor versions of the hand, contains two **Pinch Grips**. The Pinch Grips are useful for manipulating small objects or picking things up off a table such as a coin or pen. The pinch grips work with the thumb knuckle in both the closed and open positions - if you're finding it difficult to pick up a small object, try moving the thumb knuckle (see <u>Thumb Flexion</u> on page 18).

#### Pinch A

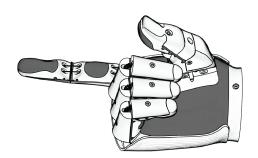
The index finger closes to meet the thumb, all other fingers remain open. You can make an "A-OK" hand sign with this grip.



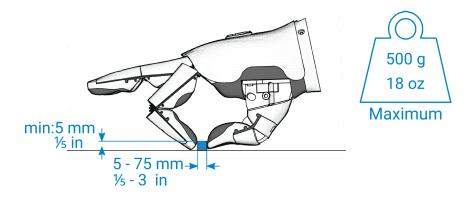


#### Pinch B

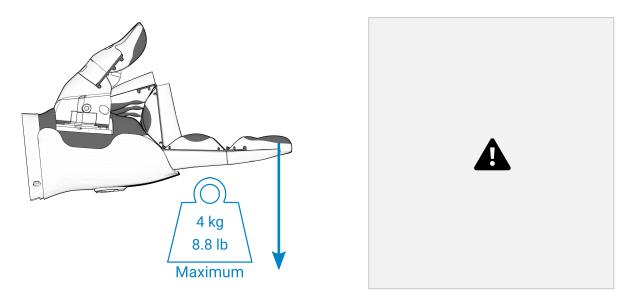
When selecting this grip, the middle, ring and little fingers will close, and when sending the close signal the index finger will then close to meet the thumb. You can use this grip to point, or do a "come here" gesture.







#### Limits



#### Freeze Mode

Freeze Mode can be used with any of the grip patterns to temporarily freeze the position of the hand and disable the muscle control - this allows you to set a grip position without worrying about accidentally sending a muscle signal and releasing your grip. To activate Freeze Mode, close your Hero Arm's hand around an object until the fingers stop moving, then keep tensing for a further 1 second - the Hand Button will change to light blue (aqua) and there will be a vibration to indicate Freeze Mode has been activated. Freeze Mode will remain active until you disable it by pressing the Hand Button. You can also disable Freeze Mode without pushing the button by tensing the 'Close' muscles again for 2.5 s.

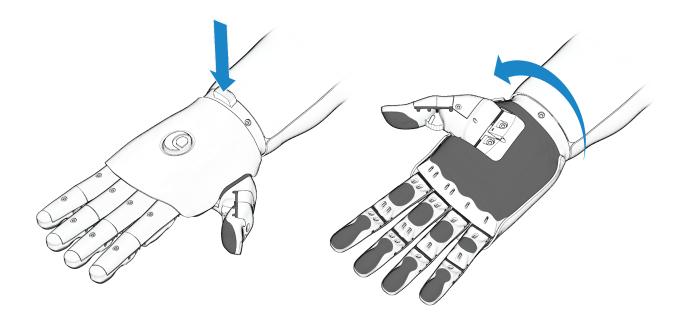
# Older versions

Pre-bluetooth versions of the Hero Arm activated Freeze Mode differently. You can tell if you have a Bluetooth Hero Arm by looking for the Bluetooth logo as described in the <u>'Checking Hero Compatability'</u> section.

If you don't have a Bluetooth arm (no logo), activate Freeze Mode by tensing the 'Close' muscles whilst simultaneously holding down the Hand Button for 1 second.

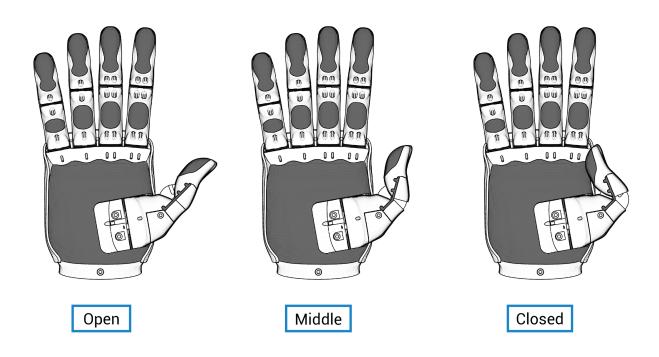
# Wrist Rotation

You can adjust the rotation of the wrist through 180°. To do this, depress the Wrist Button at the base of the wrist (on the back of the hand), and rotate to the desired angle. Release the button to lock the wrist in the new position. The wrist can be locked at any angle within the range of the rotation.

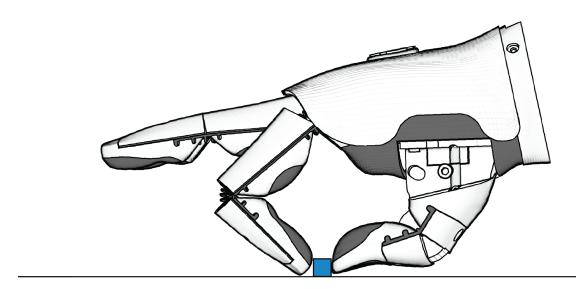


# Thumb Flexion

In addition to the powered movement of the thumb, the knuckle can also be manually adjusted into either the open, middle or closed position.



Fully closing the thumb makes it easier to pull the Hero Arm through the sleeves of clothing. The middle thumb position can be useful for picking up small objects:



#### Calibration

When you power on your Hero Arm for the very first time, the hand may perform a calibration routine - this will involve closing each of the fingers and the thumb in order to check everything is working correctly. It is important that the fingers are not obstructed during calibration, as this could cause the calibration to fail. The Hand Button will pulse purple to indicate the hand is calibrating. A successful calibration is indicated by the Hand Button turning white once the movement of the hand has stopped.

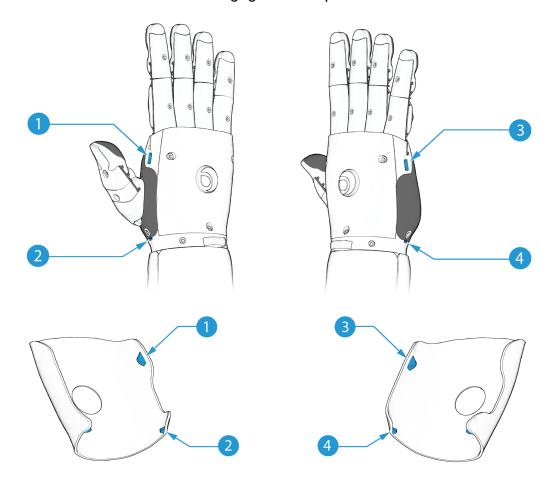
If the calibration is unsuccessful for some reason, such as an obstruction preventing the full movement of any of the fingers, the hand will repeat the calibration a second time - ensure any obstruction is cleared before the process repeats. If any finger fails calibration, it will remain in the open position and will not respond to muscle inputs. If you disconnect the battery before powering off the hand, it will need to recalibrate the next time you power it on. You should therefore always switch off your hand, if it is working correctly, by holding down the Hand Button, before disconnecting the battery.

There may be some situations when you want to force the hand to calibrate, such as if a finger is no longer closing or opening fully - in this scenario it is then acceptable to disconnect the battery with the hand powered on in order to initiate a calibration.

If your hand repeatedly fails to calibrate, please see the <u>Troubleshooting</u> section of this manual on pages 24-25.

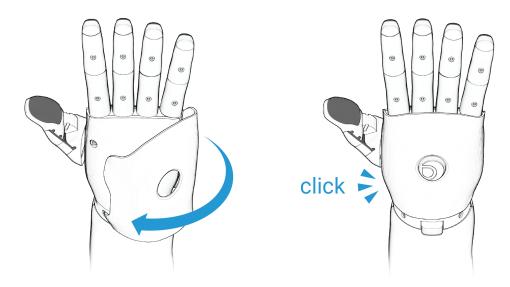
# Covers

Your Hero Arm can be customised with swappable covers, to match your style or mood. There are 3 types of cover: hand cover; arm covers (split into two halves) and battery cover. Each cover is custom designed to fit your Hero Arm perfectly. The Hero hand has 4 slots which engage the 4 clips on the hand cover.



Engage the clips on one side of the hand first (Clips 1 & 2, or clips 3 & 4). Then push the cover onto the hand until the other two clips "click" into place.



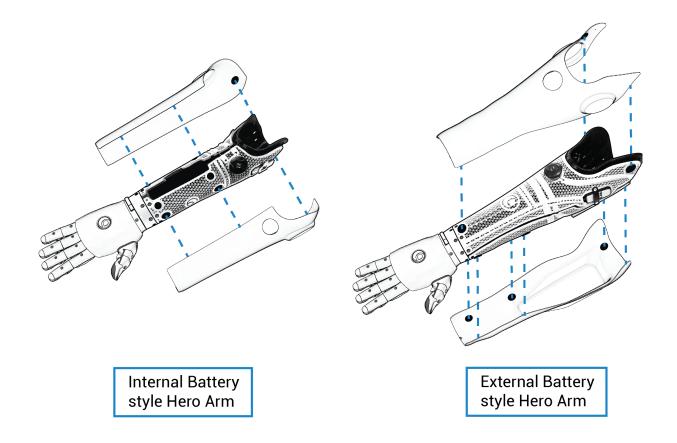


Depending on whether you have an internal or external battery style Hero Arm, your arm covers will look slightly different.

Older versions of the Hero arm use a hook-and-loop pad to attach the covers. To attach the battery and arm covers, line up the fastening pads on your cover with those on your arm, and press the cover firmly into place - you should hear a click when the fastening pads have engaged. To remove the cover, gently pull it free from your arm.

Newer versions of the Hero arm use magnets to attach the covers. To attach them, line up the magnets and they should click into place. To remove, gently full the cover free from your arm.

The magnets are nickel plated. People with a nickel allergy should avoid direct contact with the magnets on the arm and corresponding metal disks on the covers.



To ensure your battery is protected, you **must** wear the battery cover when using the Hero Arm if not wearing any other arm covers.

For more cover options go to <a href="https://shop.openbionics.com/">https://shop.openbionics.com/</a>

# Looking after your Hero Arm

# Safety

Although the Hero Arm has been engineered to be strong and robust, you should treat it as if it were your own limb - please read this section of the manual for general safety information and guidance on how to care for your arm.

Avoid subjecting your arm to excessive loads or impacts - your safety should not rely on the arm at any time.

You must always have at least the battery cover on your Hero Arm in use.

You should not attempt to lift or carry objects heavier than 13 kg.

If you have a particular activity or sport that you want to play whilst wearing your Hero Arm which might subject it to excessive impacts or force, we would recommend first discussing this with your prosthetist.

Please refer to the When to Use Your Hero Arm section for advice.

Your Hero Arm can withstand splashes of water (such as light rain), however it is not water resistant. Do not submerge your Hero Arm in water - it should be protected from moisture at all times. If any water reaches the internal components of the hand or arm they are likely to cause damage and eventual failure. Water damage is not covered by the standard 12 month warranty.

Do not expose it to a naked flame or subject it to excessive heat. If the hand temperature reaches 50°C, the hand will warn you by flashing the Hand Button yellow and blue. At 55°C, the Hand Button will flash yellow and red, and you will be notified with a beep before the hand shuts itself off.

## Storage

The Hero Arm can be stored between -25°C and +70°C with the battery removed (see <u>How to Store the Battery</u>)

The covers have a more limited temperature range and should be kept between -5°C and 30°C, out of direct sunlight.

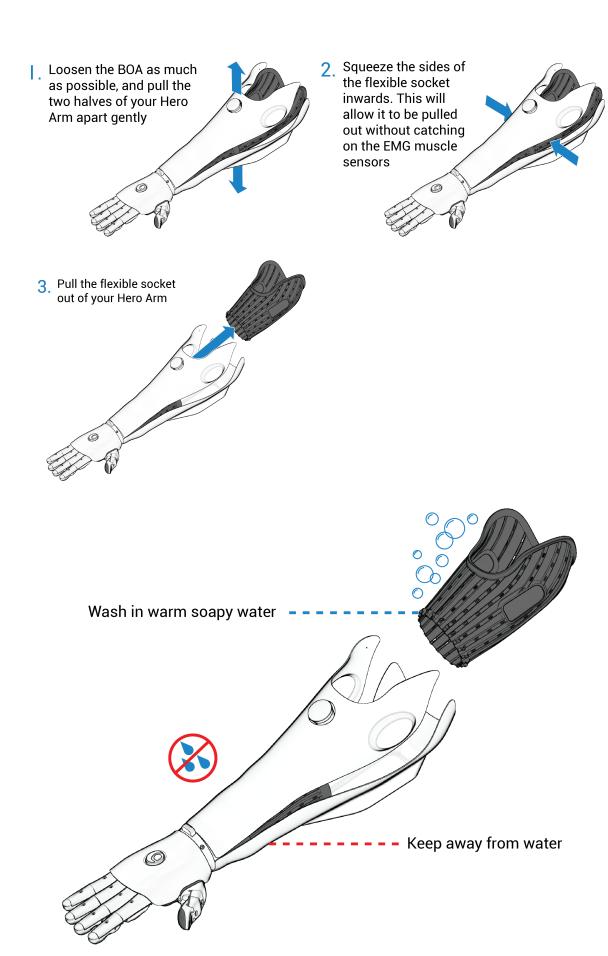
### Maintenance

Do not attempt any maintenance or modification of your Hero Arm by yourself. If you think your arm is not functioning as it should, or has been damaged, you can contact your prosthetist to arrange for repair or replacement.

Your prosthetist will arrange an appointment with you annually to perform the required annual maintenance. This allows us to keep your Hero Arm in top condition throughout its five year service life.

# Cleaning

The Hero Arm can be cleaned using alcohol-free antibacterial wipes. In addition, the flexible internal socket is easily removable from the frame of your Hero Arm to make cleaning easy. You should clean the flexible socket using warm, soapy water on a regular basis. The steps below apply to both Internal & External Battery style Hero Arms.



Ensure the socket is thoroughly rinsed after washing, and never use anything marked as irritant to clean the socket (such as bleach), to prevent irritation from residue.

The socket should be thoroughly dried before the next use, the best method for this is leaving it to air dry overnight.

We recommend you clean your socket daily, and the rest of the device as needed. If you find that you struggle to clean part of your Hero Arm, discuss the matter with your prosthetist.

## Growing out of your Hero Arm

If you are still growing, your Hero Arm may eventually become too small. While the BOA Fit System $^{\text{TM}}$  allows you to adjust the tightness of your socket, the length is not adjustable. This means that when your arm grows in length, the EMG muscle sensors may no longer be in the correct position relative to your muscle sites, and your Hero Arm may struggle to detect when you send an open or close signal.

You may also find that it becomes difficult to put your Hero Arm on.

If you think that you have outgrown your Hero Arm, speak to your prosthetist who can advise you about a re-fit. You can get your Hero Arm resized for substantially less than the cost of buying a whole new unit.



Do not dispose of your Hero Arm in the household waste. Arrange with your prosthetist to have it returned to Open Bionics for disposal.

# Battery

Your Hero Arm comes with a Li-lon 7.5V 2600mAh battery (Friwo FB2S1P18650-26).

Only use the battery issued with your Hero Arm, or another purchased from the Open Bionics store. Only charge the battery according to the guidance provided in the 'Charging the Battery' section of this manual, using the provided charger.

Do not expose the battery to water, or leave it in an extremely hot environment such as in a hot car, or exposed to direct sunlight.

Battery performance is dependent on how you use the arm, but also on the environment - battery performance may decrease in cold temperatures.

# How to Store the Battery

If you are not planning on using your Hero Arm or its battery for a long period of time, we recommend you fully charge the battery before storing it in a cool dry place. To maintain the battery's function, you should fully run down and recharge the battery at least once a year.

## **Battery Life**

The battery life is dependent on use but should last most users a full day. We recommend you charge it each night.

The battery is expected to last at least one year. If your battery life is too short to get you through a whole day before this point, it is covered under your Hero warranty. After a year of use, you will need to contact Open Bionics or your prosthetist to order a replacement.

## Disposal



This symbol on the battery indicates that it is not to be treated as household waste. Do not dispose of batteries in a normal bin. This could lead to a fire when the waste is compacted. By disposing of the battery correctly, you'll be helping minimise any negative consequences for the environment. Please contact your local authority for information on where you can recycle the battery. Please recycle old batteries after discharging them.

# Safety

Please follow these guidelines in regards to the battery for your Hero Arm

Do not bend or crush the battery

- Do not pierce the battery
- Do not try and disassemble the battery in any way
- Do not expose to excessive heat or leave in a vehicle
- Do not leave in direct sunlight
- Do not attempt to modify the connector or wiring of the battery in any way
- Do not use a damaged charger with the battery
- Do not use any charger other than the one provided
- Do not attempt to use the battery with any device other than your Hero Arm
- Do not dispose of the battery in regular waste you must recycle it
- Do not attempt to connect the two terminals of the battery

#### **WARNING:**

If you observe any leaking from your battery, or it has swollen in any way, you must:

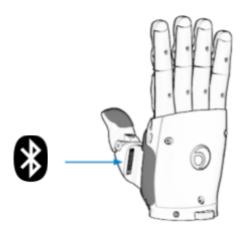
- Immediately disconnect it from the Hero Arm or the battery Charger
- Move the battery to a safe place and keep a minimum distance for 30 minutes
- Do not attempt to reuse the battery you must dispose of it according to local regulations
- Contact your prosthetist to inform them of the situation

# Sidekick Mobile App

The Sidekick mobile application is a companion to the Hero Arm which contains interactive training tools, training videos, configuration options and data tracking.

## Checking Hero Arm Compatibility

In order to connect your Hero Arm to the Sidekick App, your device must have Bluetooth installed. To check if bluetooth is installed on your Hero Arm, inspect the area behind the thumb.



The Bluetooth logo present on the back of the thumb indicates the Hero Arm has Bluetooth enabled and can connect to the Sidekick App. If your hand does not have Bluetooth enabled, you can still use some features of the Sidekick App. Please contact Open Bionics at <a href="mailto:support@openbionics.com">support@openbionics.com</a> if you would like to unlock the full functionality of the app.

The Open Bionics Sidekick app is downloadable from the <u>Google Play Store</u> and the <u>Apple App Store</u>.



A mobile phone with Android 5.0 or iOS 12.0 or later is required. Additionally, the mobile must support Bluetooth 4.2 (introduced in 2014) or later.

# Troubleshooting

If you experience any issues with your Hero Arm, please try the following solutions. If you are unable to solve the problem, please contact your prosthetic provider, or Open Bionics at <a href="mailto:support@openbionics.com">support@openbionics.com</a>

Problem	Solutions
Fingers are not moving/responding to my signals	Check to make sure the Hand Button is pulsing white to show the hand is on and ready
	Press gently on the back of the EMG sensors, to make a better skin contact
	Check the battery is fully charged and plugged in correctly
Fingers are not closing/opening fully	Try calibrating the the Hero Arm by disconnecting the battery with the power still ON (see the <u>Calibration</u> section)
There is a loose tendon attached to one of the fingers	A tendon has become damaged from excessive wear or load, please discuss with your prosthetist to arrange for your Hero Arm to be repaired
One finger stays open whilst the other fingers/thumb move normally	The finger that remains open has likely failed calibration. Try calibrating the Hero Arm by disconnecting the battery with the power still ON (see the <u>Calibration</u> section). If this issue continues, contact your prosthetist
The button is not responding to presses but the arm is on	Try disconnecting and reconnecting the battery
The grip patterns are not performing normally	Try calibrating the the Hero Arm by disconnecting the battery with the power still ON (see the <u>Calibration</u> section)
Fingers are moving erratically	Try cleaning the EMG pads with an alcohol-free wipe, remove and reattach

#### your Hero Arm

Problem	Solutions
Fingers are responding intermittently to signals	Try cleaning the EMG pads with an alcohol wipe, remove and reattach your Hero Arm
Hand Button is flashing different colours	Please see the table in 'Notifications/Status' for information on what the Hand Button colours mean
The Hero Arm has got wet	Immediately disconnect and remove the battery. Dry off any visible water. Leave the hand to dry completely before trying to switch on again

## Indications

The Hero Arm is indicated to replace some of the function of a hand for transradial or wrist-disarticulation amputees. The device can be used by congenital or acquired amputations. The device is suitable for bilateral amputees.

#### Contraindications

The Hero Arm is non-invasive and is not designed to be in contact with damaged or irritated skin. Some transradial amputees may be unsuitable due to the shape of their residual limb. For detailed information on this, see our Design Guidelines (d100319). The Hero Arm should not be used if the user has weak EMG signals with the device. The user should be free of comorbidities that could interfere with function of the prosthesis (neuromuscular disease, etc.). Users must have good neurological and cognitive function to operate the prosthesis effectively. The Hero Arm should not be used by people who's skin is sensitive to nickel as the EMG pads are stainless steel, a metal containing nickel as an alloy.

## Service Life & Shelf Life

The Hero Arm has a 5 year service life. The Hero Arm is custom built specifically for each user so is not intended to sit in storage. As such the Shelf Life is the same 5 year span as the Service Life.

## Warranty & Returns

The Hero Arm, its battery and Smart Charger are covered by a standard 12 month warranty. This guarantees against any manufacturing defects or defects with your Hero Arm which arise out of normal use.

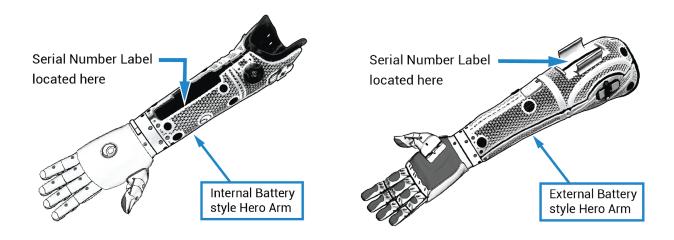
You can purchase additional warranty packages to extend the length of coverplease discuss this with your prosthetic provider.

If you think there is a problem with your Hero Arm, please first carefully read through this manual in case any of your issues are addressed, before contacting <a href="mailto:support@openbionics.com">support@openbionics.com</a> or your prosthetic provider.

The warranty does not apply to any components that have been subject to misuse, excessive loads, subject to water damage, deliberate damage or modification by

uncertified persons unless otherwise permitted in this user manual or given written permission from Open Bionics Ltd.

Please quote the serial number for your Hero Arm when requesting any warranty repairs or returns. This can be found on the product information sticker located under the battery on your arm. When returning your Hero Arm to us, please ensure you package it appropriately - the original packaging in which you received your arm is great for this purpose.





There's a lot to take in in this document, so we've pulled out all the warnings in this document and put them here for your convenience:

- The Hero Arm is not intended for use in activities that may result in injury or death to the user or others as a result of it failing to perform the activity as intended.
- The EMG Pads are stainless steel which contains nickel as an alloy. The magnets for attaching covers on newer arms are nickel coated. The Hero Arm should not be used by people with a nickel skin sensitivity (nickel allergy).
- You must wear at least a battery cover when using the Hero Arm. The
  batteries are designed to be tough, but the covers give them a little extra
  protection against knocks. Not wearing a cover could mean you need to get a
  replacement battery.
- You should not carry objects heavier than 13 kg. You could damage your Hero Arm and the object could fall.
- Your Hero Arm is not water resistant and should be protected from heavy rain and moisture. Your Hero Arm could get damaged.
- Do not expose the Hero Arm to a naked flame. Your arm won't catch fire, but it will be burned and disfigured. Plastic fumes should not be inhaled.
- You should not attempt any maintenance or modification of your Hero Arm (that doesn't include the covers, customise away!)
- You should clean your Hero Arm with alcohol-free antibacterial wipes on a regular basis. The flexible socket can be removed and washed with soapy water.
- Do not dispose of your Hero Arm in household waste. Please return it to Open Bionics via your prosthetist. It contains electrical components that need to be recycled properly or they'll damage the environment.
- Only use the batteries supplied by Open Bionics for the Hero Arm. Other batteries might damage your Hero Arm, or be damaged by the Hero Arm. Other batteries may not have all the safety features that ours does, batteries can cause fires.
- Do not expose the battery to water, or leave it in an extremely hot environment such as in a hot car, or exposed to direct sunlight. Doing so could damage the battery leading to a fire.
- Do not dispose of batteries in household waste. They need to be recycled properly to avoid damaging the environment. They could also cause a fire.
- See the <u>Battery Safety</u> section for a full list of battery warnings.
- The Electromagnetic compatibility test standard EN 60601-1-2 requires that the Hero Arm is tested to be immune from interference from mobile

communication equipment including mobile phones with a transmitted power of 2 W at a distance of 0.3 m. The Hero Arm conforms with this requirement. Operation of the Hero Arm with a separation distance of less than 0.3 m between it and the communication equipment of transmit power of 2 W may result in interference to the operation of the Hero Arm.

Standard EN 60601-1-2 requires that the user is warned of the risk of operation with mobile communication equipment at separation distances of less than 0.3 m.

Mobile phones have a typical maximum transmit power of less than 0.25 W, when operating at maximum distance from the transmitter mast, less when closer to the mast. Use of a mobile phone held in the Hero Hand has not in practice been found to cause any interference to the operation of the Hero Arm.

# Important Warning

If your Hero Arm has Bluetooth connectivity, it must be considered to be a
mobile device, and switched off during aircraft flight, at times when mobile
phones are requested to be used in flight mode or turned off.

# EU & UK Regulatory Compliance

The Hero Arm is fitted with a Bluetooth Low Energy module that meets the appropriate European Union and United Kingdom standards for design, manufacture and supply of prosthetic products and user software.

Continued compliance with the standard is monitored by a programme of internal and external testing and audits.

EU Regulation MDR 2017/745 & UK Statutory Instrument 2002 No. 618 - amended (UK MDR 2002) Applicable Standards:		
IEC BS EN 60601-1	Medical electrical equipment - General requirements for basic safety and essential performance	
IEC BS EN 60601-1-2	Medical electrical equipment - General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests	
IEC BS EN 60601-1-6	Medical electrical equipment - General requirements for basic safety and essential performance. Collateral standard: Usability	
IEC BS EN 60601-1-11	Medical electrical equipment - General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	

When the Hero Arm is fitted with the Bluetooth Low Energy module it is compliant with the requirements of the EU Radio Equipment Directive and the UK Radio Equipment Regulations through certified compliance with the following standards.

EU Radio Equipment Directive 2014/53/EU & UK Statutory Instrument 2017 No. 1206 The Radio Equipment Regulations 2017 Applicable Standards:		
ETSI EN 300-328	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum	
ETSI 301-489-1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility	
ETSI 301-489-17	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility	

The Hero Arm Battery pack is certified as compliant with the following international standards:

Battery Pack Applicable Standards:		
IEC 62133-2	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems	
UN 38.3	TRANSPORT OF DANGEROUS GOODS - Lithium metal and lithium ion batteries	

The Hero Arm Battery Charger is certified as compliant with the following international standards:

Battery Charger Applicable Standards:		
IEC 60335-1	Household and similar electrical appliances - Safety - Part 1:General requirements	
IEC 60335-2-29	Household and similar electrical appliances - Safety - Part 2-29: Particular requirements for battery chargers	
EN IEC 55014-1	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission	
EN IEC 55014-2	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 2: Immunity - Product family standard	

For full national compliance information please refer to the UK, EU and US signed declarations of conformity available on request from Open Bionics.

#### Declaration of Conformity to EU & UK RoHS 2 & 3

In compliance with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 as amended by delegated directive (EU) 2015/863 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and the UK adoption of the directive UK Statutory instrument 2012 No.3032 "The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012" subsequently amended by "The Hazardous Substances and Packaging (Legislative Functions and Amendment) (EU Exit) Regulations 2020", The Hero Arm and BLE module do not contain the substances listed in the table below, in concentrations greater than the listed maximum value, other than in the cases where component manufacturers are using specific permitted exemptions for the use of lead from Annex III of Directive 2011/65/EU & schedule A2 of UK statutory instrument 2020 No. 1647.

Substance	Maximum Limit (ppm)
Lead (Pb)	1000
Cadmium (Cd)	100
Mercury (Hg)	1000
Hexavalent Chromium (Cr6+)	1000
Polybrominated Biphenyls (PBB)	1000
Polybrominated Diphenyl Ethers (PBDE)	1000
Bis(2-Ethylhexyl) phthalate (DEHP)	1000
Benzyl butyl phthalate (BBP)	1000
Dibutyl phthalate (DBP)	1000
Diisobutyl phthalate (DIBP)	1000

2011/65/EU Annex III Exemption		Usage
6(a)	Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35 % lead by weight	Steel PCB standoffs
6(c)	Copper alloy containing up to 4 % lead by weight	Brass PCB pins
7(a)	Lead in high melting temperature type solders (i.e. lead based alloys containing 85 % by weight or more lead)	Diode and NFET dies
7(c)-l	Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound	Surface mount resistors
34	Lead in cermet-based trimmer potentiometer elements	Surface mount potentiometers

#### EU REACH & UK REACH

In accordance with supplier obligations defined in EU REACH regulation (EC) No. 1907/2006 article 33; Open Bionics declare the presence of the Substance of Very High Concern (SVHC) Lead (CAS No. 7439-92-1) at concentrations above 0.1% (w/w). Lead has been used in articles compliant with RoHS by the use of currently permitted exemptions 6(a), 6(c), 7(a), 7(c)-I & 34. These articles are all electronic components mounted on internal printed circuit boards. In all cases there is no possibility of user contact with the lead content, and there is subsequently no risk of exposure to the user.



To ensure continued safety of the user and others at the end of the Hero Arm's service life, the Hero Arm must be disposed of in accordance with local Waste Electronic Equipment disposal regulations. This can be arranged with your prosthetist, who will return it to Open Bionics for safe disposal. Do not dispose of the Hero Arm in domestic rubbish collection bins.

To the best of Open Bionics's knowledge, based upon the material declarations and compliance statements provided to Open Bionics by it's suppliers, with exception of Lead used in electronic components using the permitted RoHS 2011/65/EU Annex III exemptions 6(a), 6(c), 7(a), 7(c)-I & 24, the Hero Arm does not contain, at concentrations above 0.1% (wt/wt), any Substances of Very High Concern (SVHC) listed on the ECHA Candidate List of Substances of Very high Concern for Authorisation. https://echa.europa.eu/candidate-list-table last published on 10/06/2022

# California Proposition 65 Warning



This product contains Lead & Nickel, known to the State of California to cause cancer, birth defects and other reproductive harm.

Failure to follow correct disposal procedures may result in exposure of the user, or others, to these substances.

For more information visit: https://www.p65warnings.ca.gov/

## FCC Compliance

The Hero Arm 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.

Caution: Any changes or modification not explicitly approved by Open Bionics Ltd may cause the Hero Arm to cease to comply with FCC rules part 15 thus void the user's authority to operate the equipment.

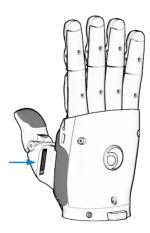
Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate 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:

- —Reorient or relocate 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.

When the Hero Arm is fitted with a Bluetooth Low Energy module, the presence is indicated by this label placed on the inner face of the thumb.





The Canadian identification IC 8595A-ANNAB1 has been omitted as the Hero Arm is not marketed in Canada.

## FDA Compliance

The Hero Arm meets all applicable FDA regulations and medical device effectiveness and safety standards.

# Symbols

CE mark



This mark indicates the product conforms with the essential requirements and provisions of Regulation MDR 2017/745.

**UKCA** mark



This mark indicates the product conforms with the essential requirements and provisions of UK statutory instrument SI 2002 No 618, as amended (UK MDR 2002)

Caution



Indicates the need for the user to consult the instructions for use for important information such as warnings and cautions

Manufacturer (adjacent to company name)



This mark indicates the manufacturer

Refer to instruction manual



Indicates the user must refer to the instruction manual before operating the device.

Wheelie Bin (WEEE) mark



This mark indicates that the product falls under the WEEE Directive (2012/19/EU)

Type BF Applied Part



Indicates a type BF (Body Floating) Part complying with IEC 60601-1

Class II Equipment



Identifies equipment meeting the safety requirements for Class II equipment according to IEC 61140

Rechargeable battery



This mark indicates that the product is designed to be used with rechargeable batteries

#### Temperature Range



This symbol indicates the products temperature range

Serial Number



Indicates the serial number that uniquely identifies the device

Date of Manufacture

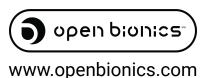


Indicates the date the medical device was manufactured

Use-by-date



Indicates the date after which the device is not to be used



# Contact Open Bionics

#### UK Head Office and Clinic

Open Bionics, Programme, Tower Lane, Bristol, UK BS1 2NB

Email: hello@openbionics.com Phone: +44 (0)117 428 5752 Website www.openbionics.com

#### USA Office and Clinic

200 Union Blvd, Suite 440 Lakewood, CO 80228

Email: <a href="mailto:hello@openbionics.com">hello@openbionics.com</a> Phone: 1-877-HEROARM

Website www.openbionics.com

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