



HERO LITE

User Manual

Version 01.00

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Introduction

Hero Lite is a powered bionic limb controlled by your muscles, with intuitive lifelike precision. Each Hero Lite 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.

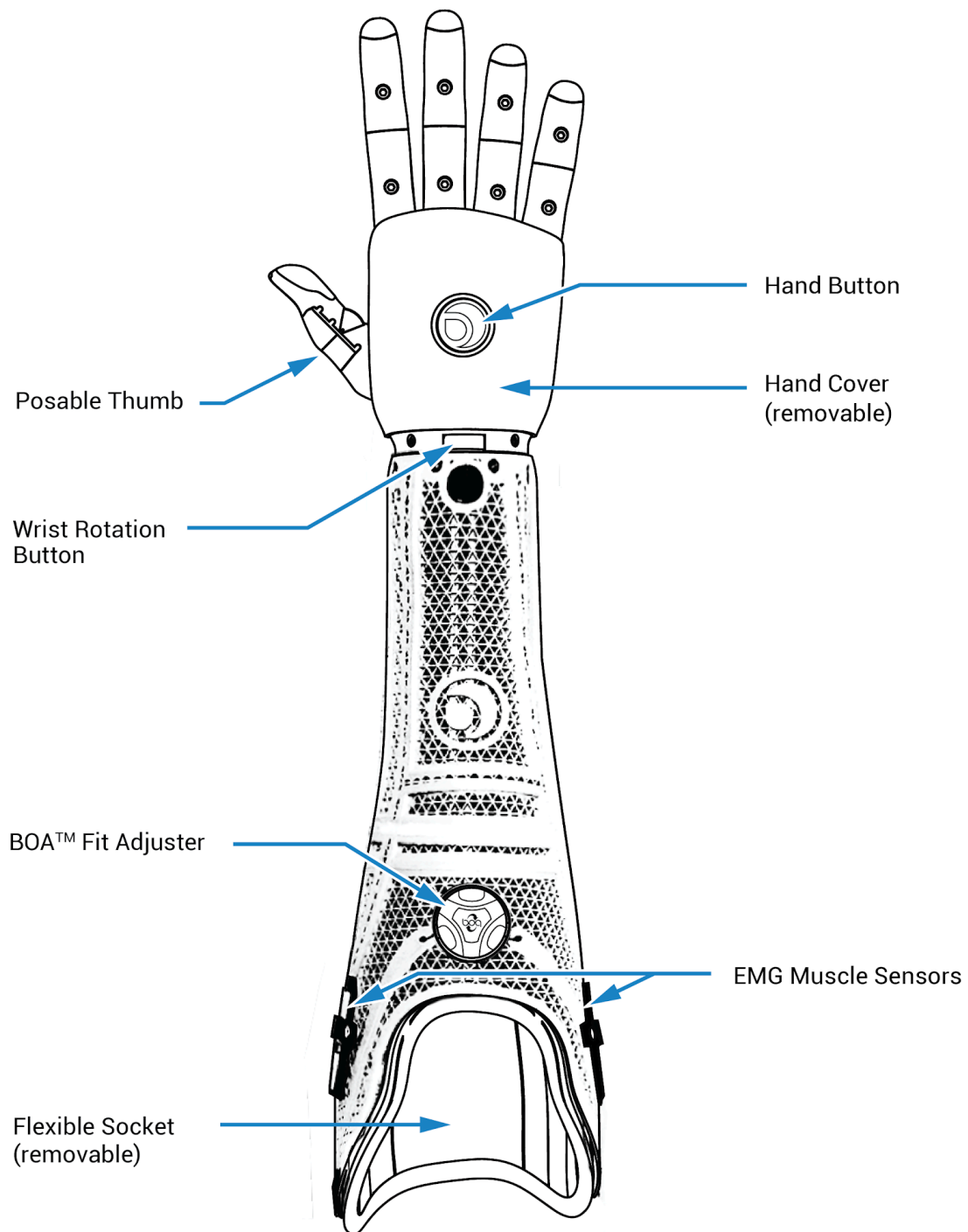
This manual will give you an overview of how to use and look after your Hero Lite, and the important safety considerations to take.

The Hero Lite is an entry level myoelectric prosthesis with a single grip mode, designed to enable the user to become proficient in the use of myoelectric prostheses.

To search for a specific word or phrase, hit Ctrl + F (on Windows) or ⌘ Cmd + F (on Mac).

Hero Lite Overview

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



What's in the Box

- 1 x Hero Lite
- 1 x Battery
- 1 x Battery Charger
- 1 x Quick Start Guide
- 1 x Battery Cover

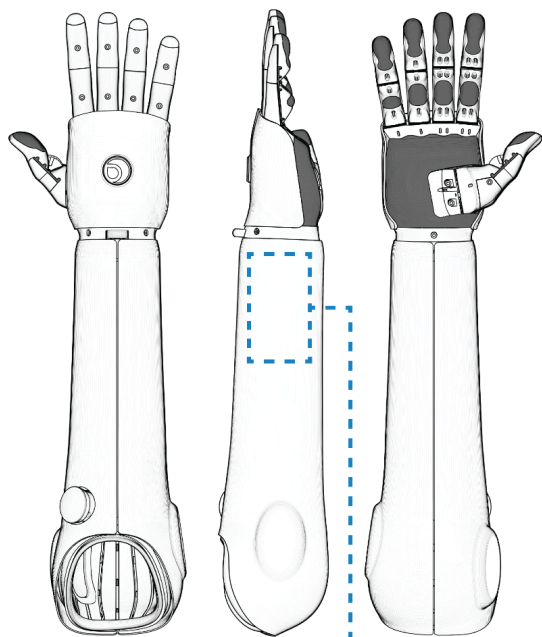
Configurations

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

The Hero Lite is fitted with either a three finger motor block for the small hands or a four finger motor block for the large hands. The key differences are the reduced size and weight on the smaller version, along with the number of tendons for each finger.

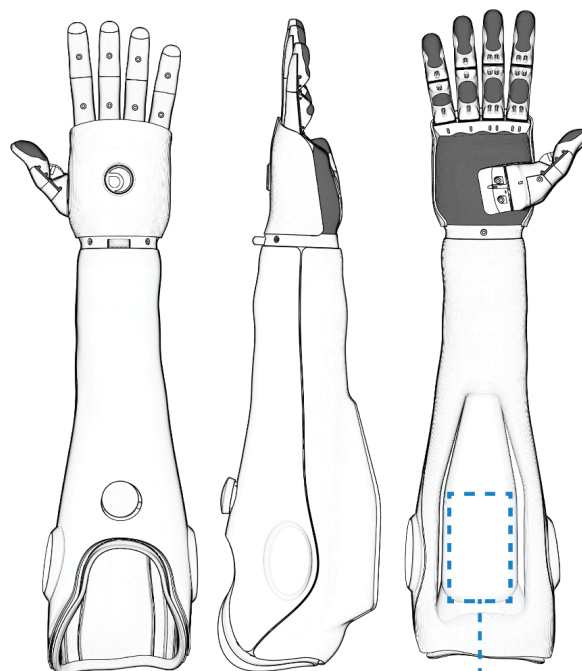
Every socket is designed and 3D printed for each individual based on a 3D scan of their residual limb, and comes in two different layouts: internal or external battery. The functionality of both layouts are the same, but they have some noticeable cosmetic differences as shown below:

Internal Battery Style Hero Lite

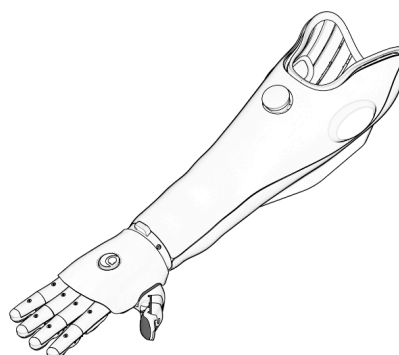
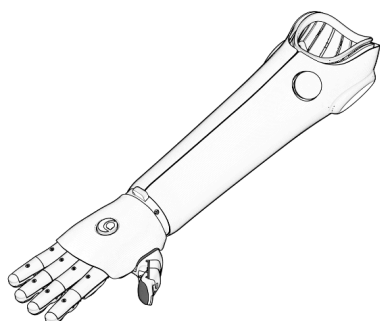


Battery Location

External Battery Style Hero Lite



Battery Location



Getting Started

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

When to Use Your Hero Lite

The Hero Lite 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 Lite 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 Lite 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 Lite losing its grip.
- The Hero Lite moving unintentionally.
- The Hero Lite shifting position on, or coming off your arm.

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

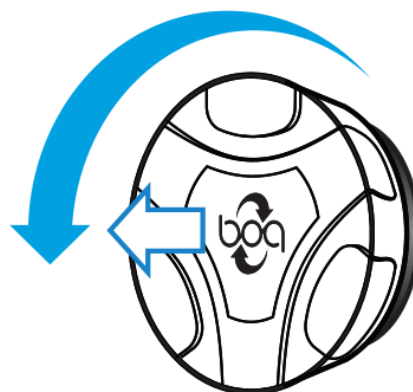
You can use your Hero Lite above -5 °C (23 °F) and below +50 °C (122 °F). You can use it at pressures equivalent to altitudes of up to 4000 m (16,400 ft, that's 600 hPa to be exact), making it safe to use in the cabin of a commercial airliner. Your Hero Lite is IP20 rated. IP is "Ingress Protection" 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 Lite 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 Lite

Your Hero Lite 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 the BOA™ mechanism then rotate clockwise.



To loosen, rotate counter-clockwise or pull to quick release.

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

Switching on

To switch on your Hero Lite, 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.

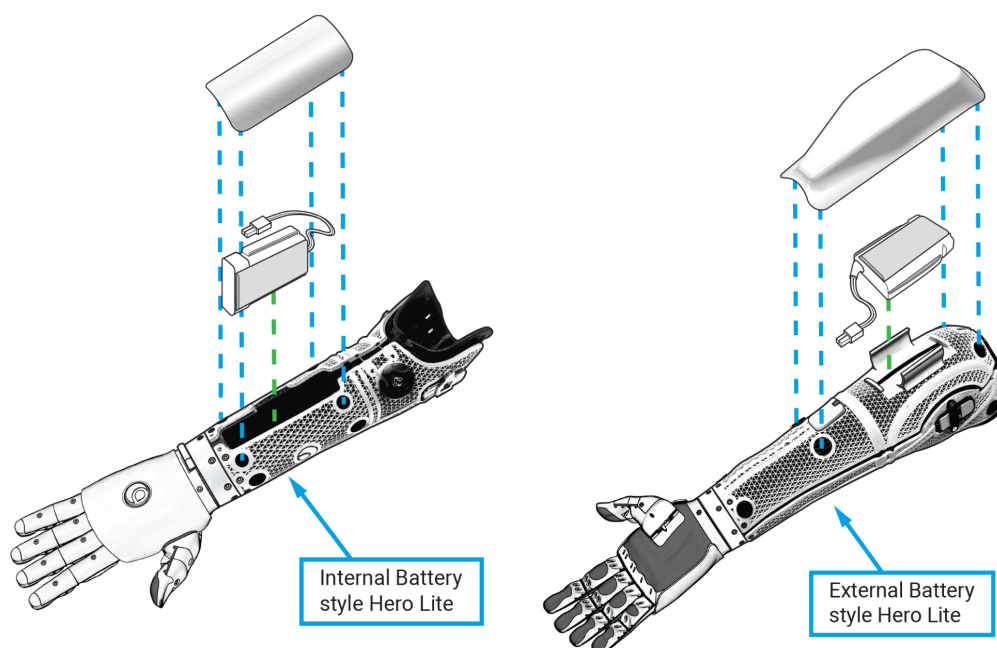
Charging the Battery

Your Hero Lite 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 Lite 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 Lite.



Checking the Battery Status

To check the status of the battery, with your Hero Lite 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 Button Colour		Battery Level
 Green		40%-100%
 Amber		20%-39%
 Red		2%-19%
 Red Flashing		Under 2%

How to use your Hero Lite

The Hand Button

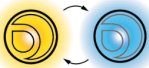
The multi-function button on the back of the hand can be used to control a variety of functions of your Hero Lite:

- Hand On/Off
 - To **switch on** your Hero Lite, press the button for **1 second**.
 - To **switch off** your Hero Lite, press the button for **3 seconds**.
- Check Battery Status
 - Press the Hand Button for 1s, and its colour will change to indicate the battery level.

Notifications/Status

The Hero Lite 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 Lite

Hand Button Colour		Notification
	Purple (pulsing)	Initialising / Calibrating
	White (pulsing)	Normal operation
	Purple (solid) 	Shutting down
	Blue (pulsing) 	Freeze Mode active
	Orange (pulsing) 	Low battery warning
	Red (pulsing) 	Battery too low (followed by automatically powering off)
	Yellow Blue (pulsing)	Hero Lite is getting too hot
	Yellow Red (pulsing)	Hero Lite has reached maximum temperature (followed by automatically powering off)
	Red (solid)	EMG communication failure

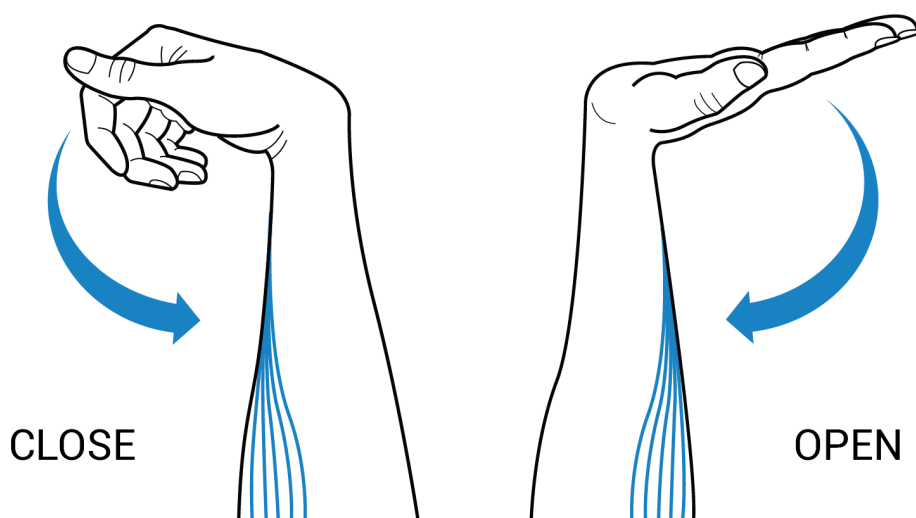
Controlling the Hand

The Hero Lite 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 Lite, your prosthetist will have found the optimal location of the EMG Sensors for your muscles.

As standard, the Hero Lite uses two EMG muscle sensors to control the hand. However, if you only have one suitable muscle site on your residual limb, your Hero Lite 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 Lite'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 [Troubleshooting](#) section on page 31.

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 (p15-16) **only** applies to users with a single muscle site. For the vast majority of Hero Lite users (with two muscle sites) the information in [Controlling the Hand](#) applies instead.

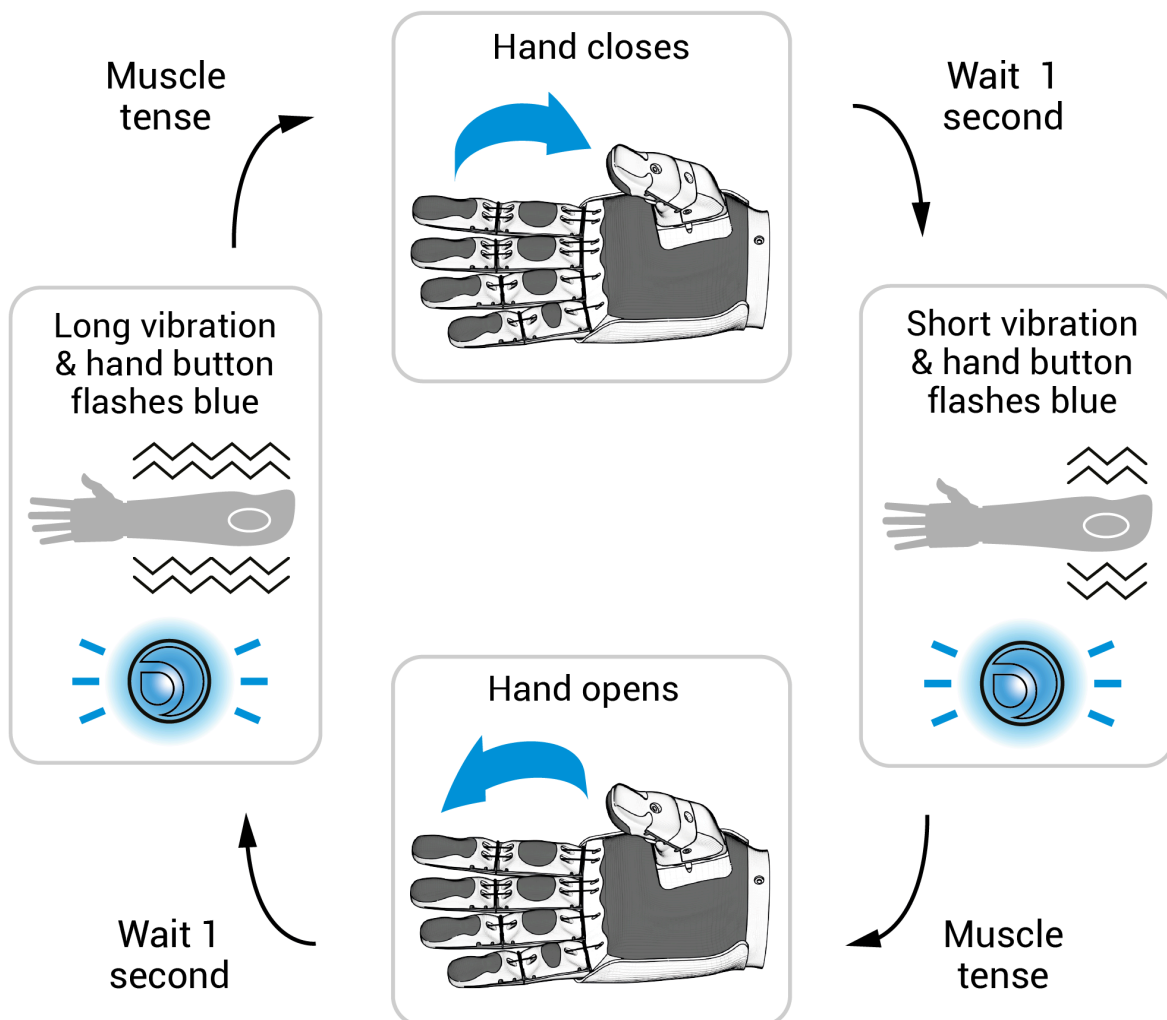
Controlling the Hand - Single Site Users Only

When you tense your muscles under your sensor, the Hero Lite will move between the open and close Positions.

If you tense, the hand will move in the required direction.

When you relax for 1 second, the hand will swap the direction for the next movement (it will also flash blue and vibrate to indicate a direction change)

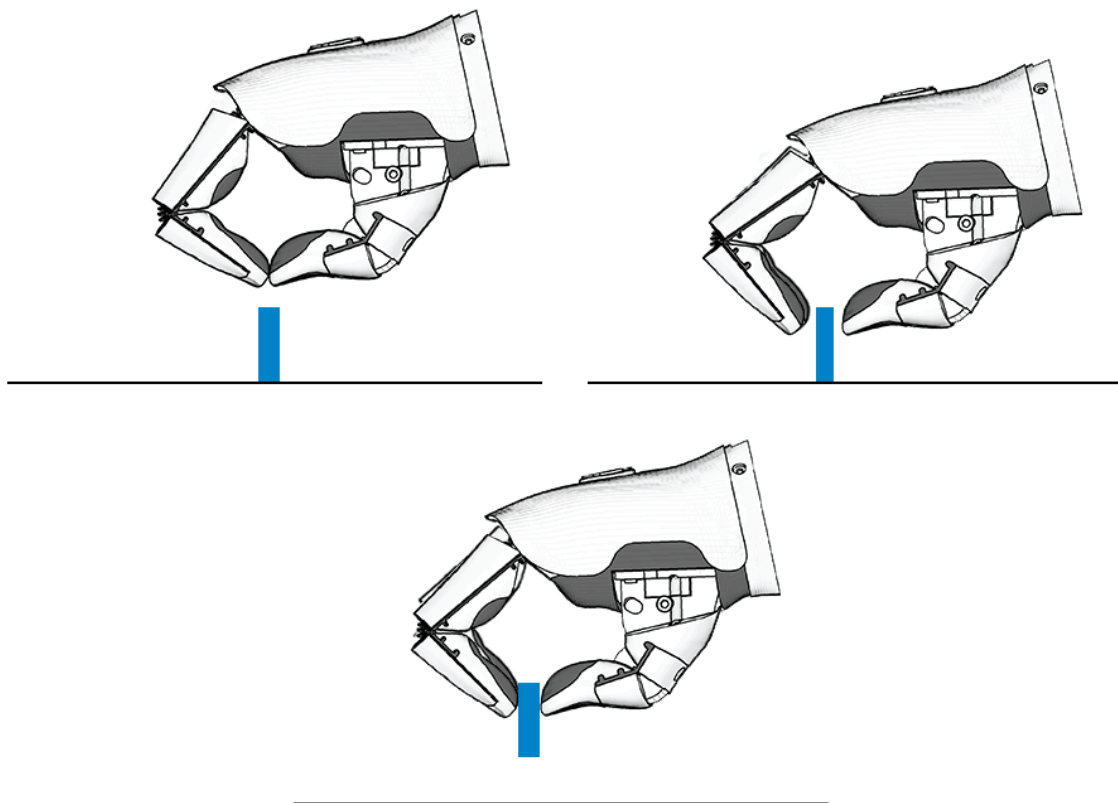
When you tense again, the hand will now move in the new direction.



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

- Shorter pulse; the next movement will be in the open direction.
- Longer pulse; the next movement will be in the closer direction.

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.



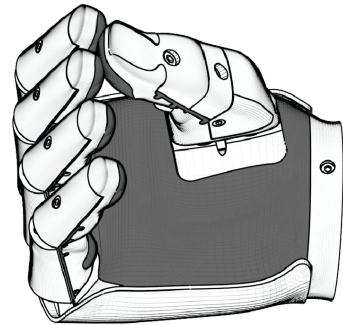
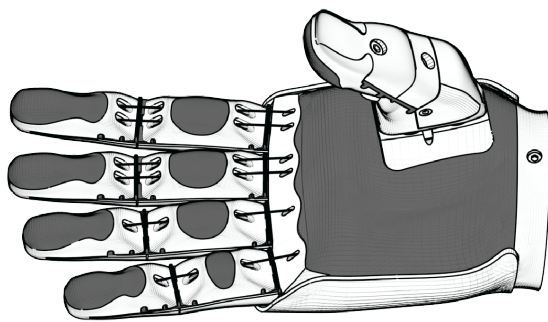
Tensing harder causes the fingers to move faster, and tensing softer moves them more slowly.

Grip Mode

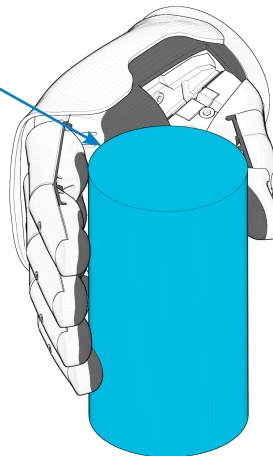
The Hero Lite has only one grip mode

Fist

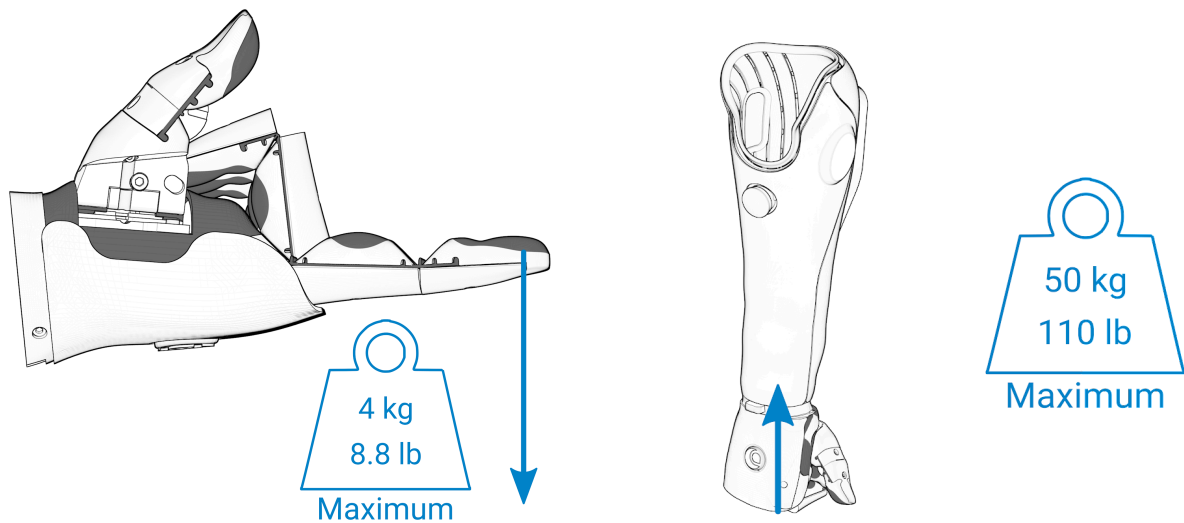
This grip is useful for carrying round objects such as bottles or fruit, for holding utensils and handles, and can also be used for handshakes. First, the thumb closes, followed by all 4 fingers.



Ø 30 - 90 mm
1.2 - 3.5 in



Limits

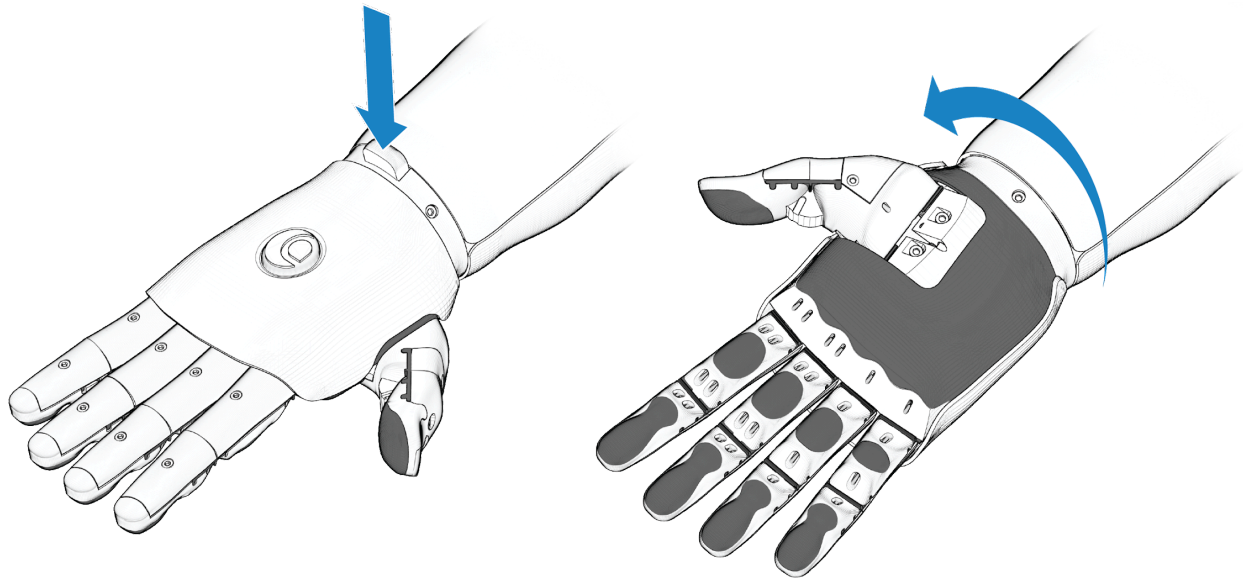


Freeze Mode

Freeze Mode can be used 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 Lite'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.

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.



Calibration

When you power on your Hero Lite 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 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 not 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.

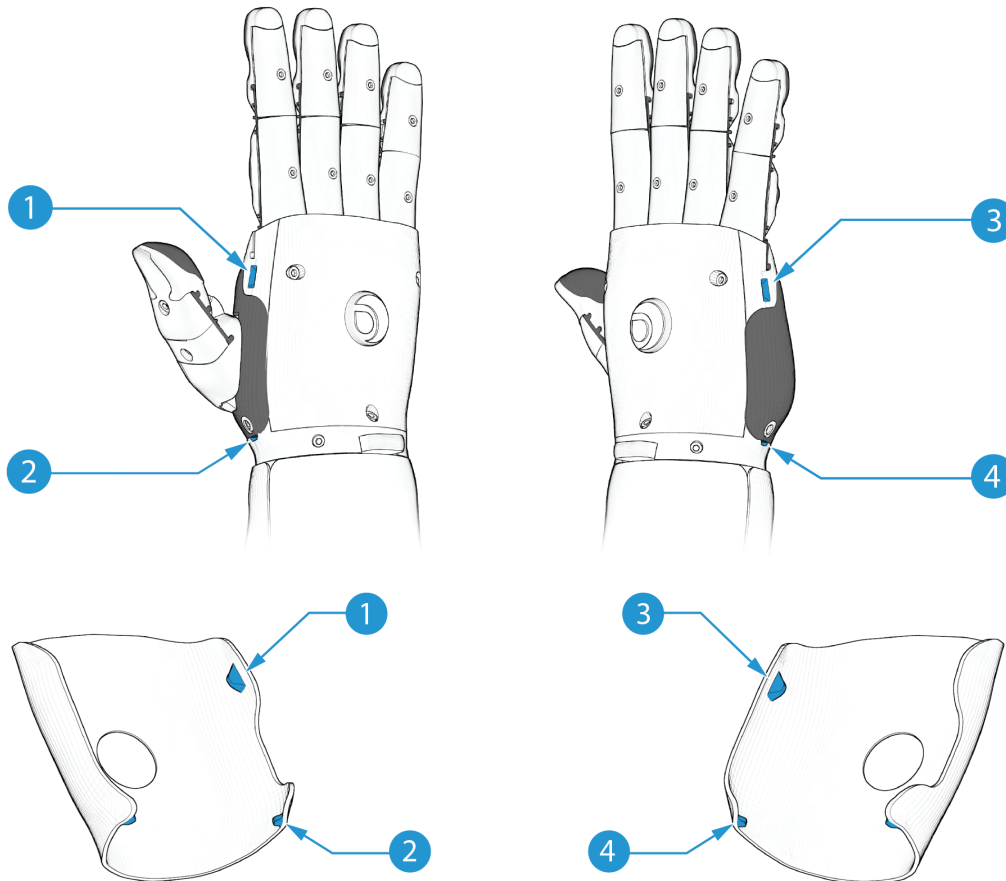
If your hand repeatedly fails to calibrate, please see the [Troubleshooting](#) section of this manual on page 31..

Covers

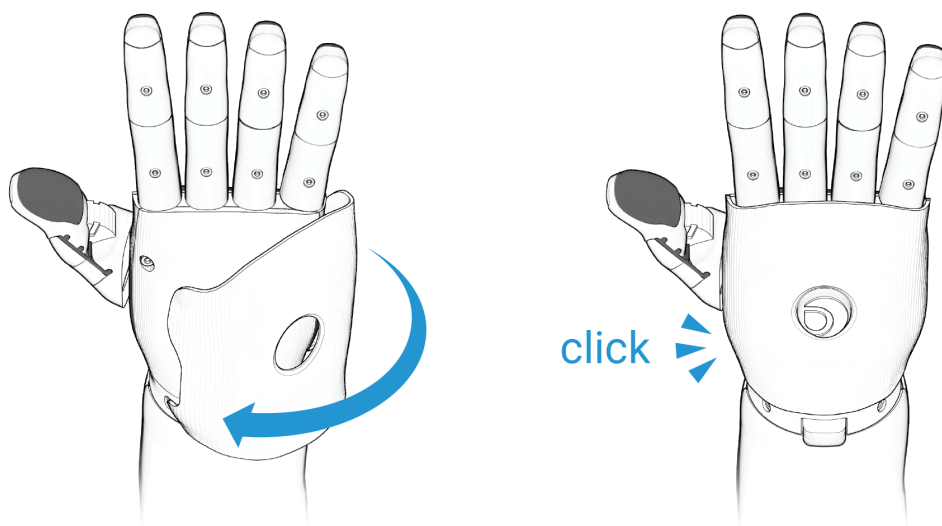
As the entry level model, the Hero Lite does not come with covers. However, covers can be purchased separately for your Hero Lite.

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 Lite perfectly.

The Hero hand has 4 slots which engage the 4 clips on the hand cover.



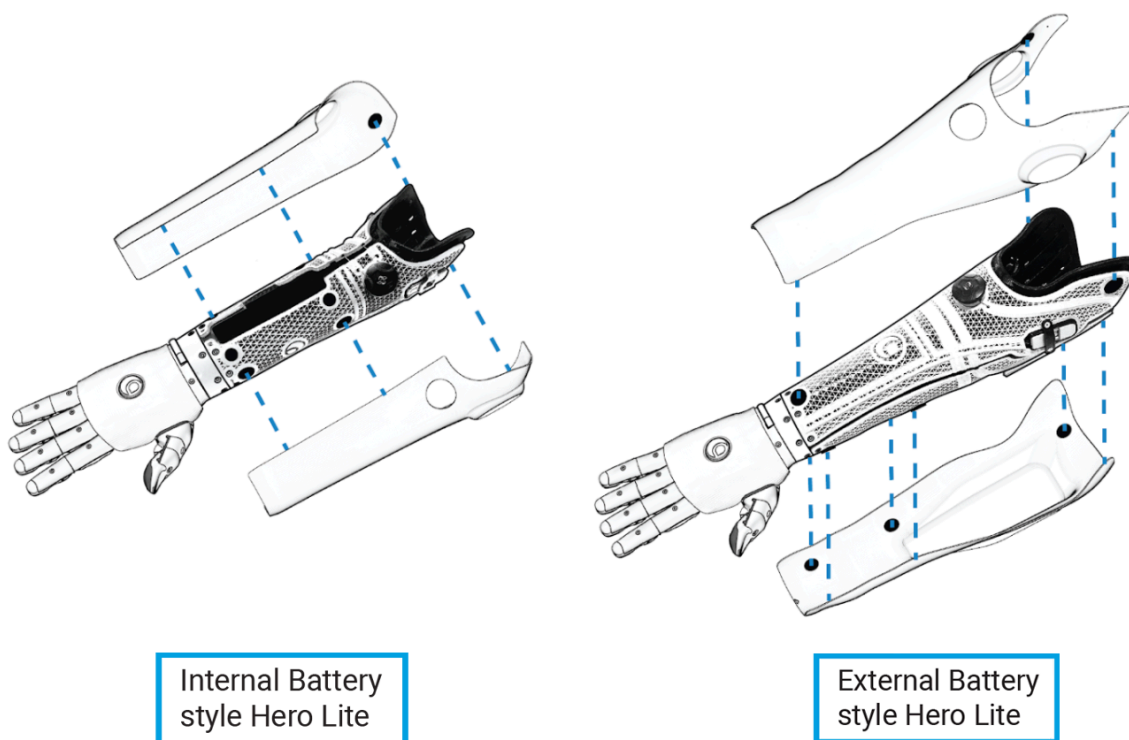
Engage the clips on one side of the hand first (Clips 1 & 2, or clips 3 & 4). Then push the cover onto the hand until the other two clips “click” into place.



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

Magnets are used to hold the covers in place against the Hero Lite. To attach them, line up the magnets and they should click into place. To remove, gently pull 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 Lite if not wearing any other arm covers.

For more cover options go to <https://shop.openbionics.com/>

***Please note that Marvel and Disney covers are currently not available for the Hero Lite**

Looking after your Hero Lite

Safety

Although the Hero Lite 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.

The battery cover should be fitted whilst using your Hero Lite.

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 Lite 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 Lite](#) section for advice.

Your Hero Lite can withstand splashes of water (such as light rain), however it is not water resistant. Do not submerge your Hero Lite 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. The Hero Lite has an [IP20](#) rating.

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 Lite can be stored between -25°C and +70°C with the battery removed (see [How to Store the Battery](#))

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

Maintenance

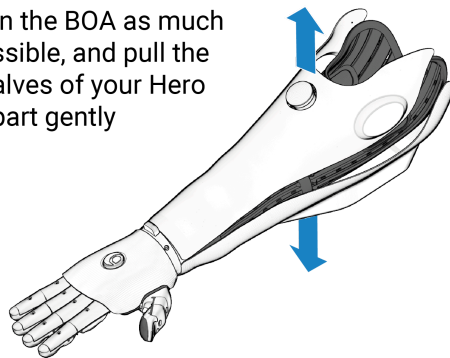
Do not attempt any maintenance or modification of your Hero Lite by yourself. If you think your arm is not functioning as it should, or has been damaged, you can contact your prosthetist to arrange for repair or replacement.

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

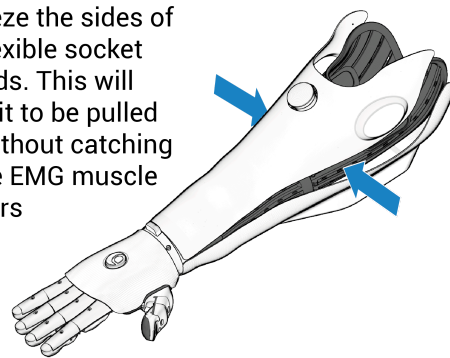
Cleaning

The Hero Lite can be cleaned using alcohol-free antibacterial wipes. In addition, the flexible internal socket is easily removable from the frame of your Hero Lite 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 Lites.

1. Loosen the BOA as much as possible, and pull the two halves of your Hero Lite apart gently



2. Squeeze the sides of the flexible socket inwards. This will allow it to be pulled out without catching on the EMG muscle sensors



3. Pull the flexible socket out of your Hero Lite





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 on a regular basis, and the rest of the device as needed. If you find that you struggle to clean part of your Hero Lite, discuss the matter with your prosthetist.

Growing out of your Hero Lite

If you are still growing, your Hero Lite may eventually become too small. While the BOA Fit System™ 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 Lite may struggle to detect when you send an open or close signal.

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

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



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

Battery

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



Only use the battery issued with your Hero Lite, 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 Lite 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 Health

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

The battery life is expected to last at least one year at a minimum. If (after a full charge) your battery health is too short to get you through a whole day, it is covered under your Hero warranty. If this occurs 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 Lite

- 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 Lite
- Do not dispose of the battery in regular waste - you must recycle it
- Do not attempt to short 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 Lite or the battery charger
- Move the battery to a safe place, preferably outside and away from anything flammable 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

Troubleshooting

If you experience any issues with your Hero Lite, please try the following solutions. If you are unable to solve the problem, please contact your prosthetic provider, or Open Bionics at support@openbionics.com

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 Lite by disconnecting the battery with the power still ON (see the Calibration 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 Lite to be repaired
The button is not responding to presses but the arm is on	Try disconnecting and reconnecting the battery
Fingers are moving erratically	Try cleaning the EMG pads with an alcohol-free wipe, remove and reattach your Hero Lite

Problem	Solutions
Fingers are responding intermittently to signals	Try cleaning the EMG pads with an alcohol wipe, remove and reattach your Hero Lite
Hand Button is flashing different colours	Please see the table in

[‘Notifications/Status’](#) for information on what the Hand Button colours mean

The Hero Lite 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 Lite 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 Lite 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 Lite 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 Lite should not be used by people whose 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 Lite has a 5 year service life. The Hero Lite 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

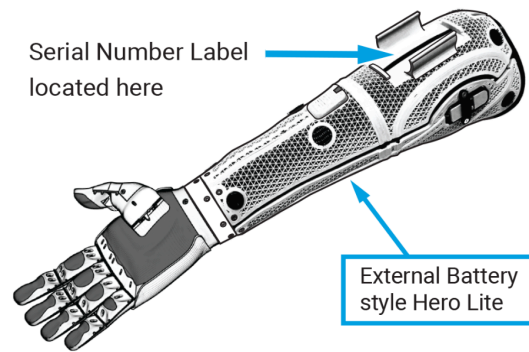
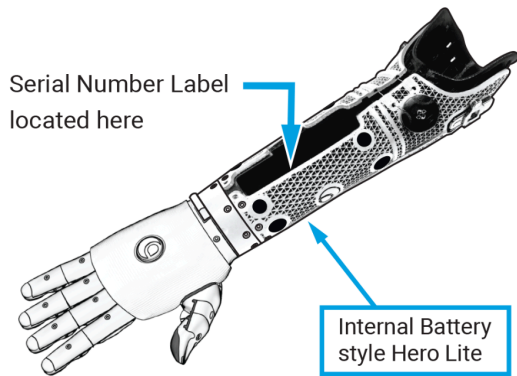
The Hero Lite, its battery and Smart Charger are covered by a standard 12 month warranty. This guarantees against any manufacturing defects or defects with your Hero Lite which arise out of normal use.

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

If you think there is a problem with your Hero Lite, please first carefully read through this manual in case any of your issues are addressed, before contacting support@openbionics.com 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 Lite 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 Lite to us, please ensure you package it appropriately - the original packaging in which you received your arm is great for this purpose.



Warnings

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 Lite 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 Lite 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 Lite. 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 Lite and the object could fall.
- Your Hero Lite is not water resistant and should be protected from heavy rain and moisture. Your Hero Lite could get damaged.
- Do not expose the Hero Lite 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 Lite (that doesn't include the covers, customise away!)
- You should clean your Hero Lite 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 Lite 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 Lite. Other batteries might damage your Hero Lite, or be damaged by the Hero Lite. 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 [Battery Safety](#) section for a full list of battery warnings.
- The Electromagnetic compatibility test standard EN 60601-1-2 requires that the Hero Lite 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 Lite conforms with this requirement. Operation of the Hero Lite 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 Lite.

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 Lite.

EU & UK Regulatory Compliance

The Hero Lite Socket and accompanying documentation are **CE** marked indicating that it is compliant with the requirements of EU Regulation MDR 2017/745 (MDR) and UK statutory instrument SI 2002 No 618 - amended (UK MDR 2002)

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

The Hero Lite 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 Lite 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 Lite does 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)-I	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 Lite's service life, the Hero Lite 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 Lite 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 its 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 Lite 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>

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/>

FDA Compliance

The Hero Lite 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)



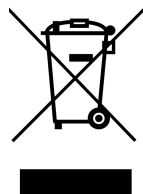
This mark indicates the manufacturer

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



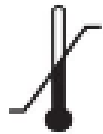
Indicates a type BF (Body Floating) Part complying with IEC 60601-1

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



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