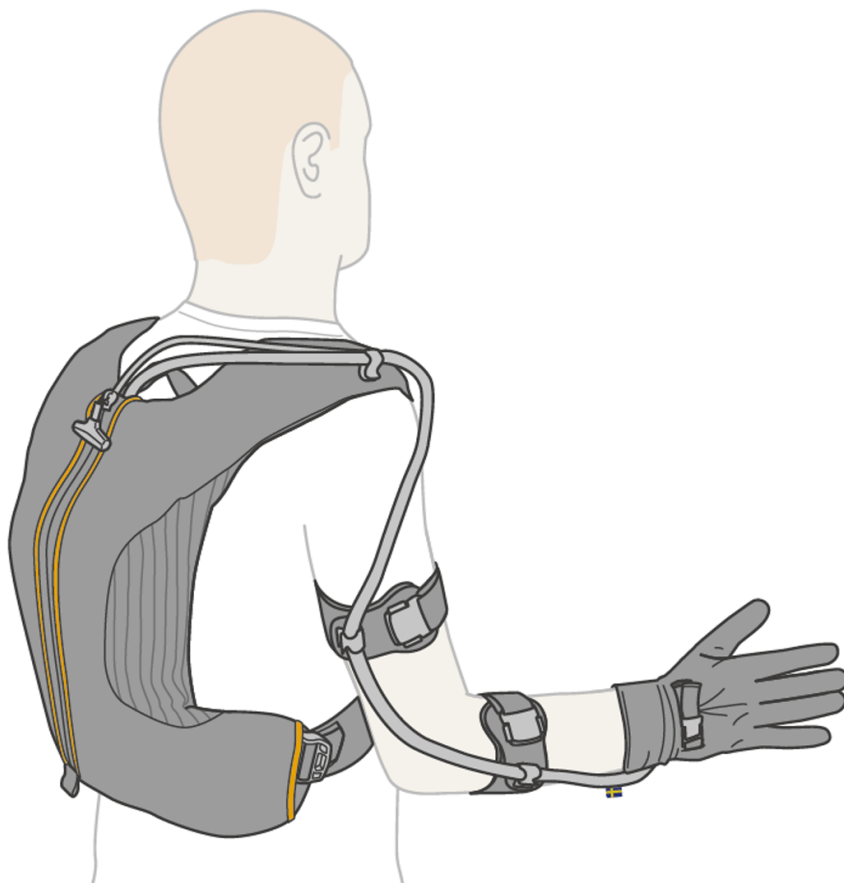


# Ironhand®

## USER MANUAL



TYPE: A1 and A2

 BIOSERVO

# Table of Contents

1.	Introduction .....	4
1.1	About this manual .....	4
1.2	About Ironhand .....	4
1.3	Conformity .....	4
1.4	Symbols on Ironhand .....	5
1.5	Disposal .....	5
2.	Safety .....	6
2.1	Risk assessment .....	6
2.2	Pre-existing hand injuries or other conditions .....	6
2.3	Warning, caution and note definitions .....	6
2.4	Warnings .....	7
2.5	Cautions .....	8
3.	Product overview .....	9
3.1	Ironhand .....	9
3.2	Ironhand power pack .....	10
3.3	Ironhand glove .....	11
3.4	Ironhand remote control .....	12
3.5	Charger .....	13
4.	To assemble Ironhand .....	14
4.1	To charge and insert the battery .....	14
4.2	To connect the glove to the power pack .....	15
4.3	To prepare the Backpack .....	15
4.4	To prepare the Hipcarry .....	16
5.	To use Ironhand .....	17
5.1	Wash your hands and use hand sanitizer .....	17
5.2	To put on and start Ironhand .....	17
5.3	Functionality test .....	22
5.4	To shut down Ironhand .....	23
5.5	To change settings in Ironhand .....	23
5.6	Inspections and service .....	25
5.7	Storage .....	25
6.	To clean Ironhand .....	26
6.1	To clean the glove .....	26
6.2	To clean the arm straps .....	27
6.3	To clean the carry solution .....	27
6.4	To clean the power pack .....	27
7.	Troubleshooting .....	28

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8. Accessories .....	29
9. Technical specifications .....	30
10. Declaration of Conformity .....	31

# 1. Introduction

## 1.1 About this manual

- Read the entire user manual before you operate or do maintenance on the product.
- Always keep the user manual in a place where you can easily find it.
- If you lose the user manual, Bioservo can send you a new manual digitally on request.

## 1.2 About Ironhand

Ironhand is a modular system that consists of a glove, a power pack, a carry solution and two arm straps. The Ironhand glove mimics the user's grasp movements and gives extra strength and endurance to the grasp. This relieves the muscles and conserves the energy of the user.

Ironhand use a function called Smart Assist to learn from the users movements over time, but can also be configured to meet specific needs of each user. To get the best user experience from using Ironhand, make sure to adjust carrying solutions and system configurations.

Ironhand is intended to be used by individuals who are at risk of developing musculoskeletal disorders (MSD's) or who need extra strength and endurance in the grasp.

## 1.3 Conformity

See [Declaration of Conformity](#).

For charger, see included charger manual.

For battery, see battery casing.

## 1.4 Symbols on Ironhand








Symbol	Description	Symbol	Description
	CE mark		Manufacturer's reference number
	Do not discard as household waste		Part that belongs to the Ironhand system
	See user guide for information		See user guide for information
	Serial number and manufacturing year		



Figure 1: The label on the power pack.



Figure 2: The label on the glove.

## 1.5 Disposal

When Ironhand becomes worn out, recycle it as electronic waste. Recycle the battery according to local regulations.

## 2. Safety

### 2.1 Risk assessment

- Qualified personnel must do a risk assessment of the work area and the work environment before Ironhand is used.
- The risk areas include, but are not limited to:
  - The risk to get caught in static or moving objects in the work area.
  - The risk to interfere with personal protective equipment.
  - Possible danger due to malfunction of the product or unintended finger flexion.

### 2.2 Pre-existing hand injuries or other conditions

- In cases of pre-existing hand injuries or conditions, start at 25% volume and increase slowly. If use causes pain, consult your physician before further use.

### 2.3 Warning, caution and note definitions



Warning! Risk of injury if instructions are not obeyed.



Caution: Risk of material damage if instructions are not obeyed.



Information for optimal use of equipment.

## 2.4 Warnings

### 2.4.1 General

- Only use Ironhand on the hand it is intended for.
- Make sure that the cord is routed close to the body to avoid getting caught in static or moving objects within the work area.
- A protective glove must be worn on top of Ironhand.
- Do not do modifications to Ironhand.
- All service work must be done by an authorized technician.
- Stop using Ironhand if you feel that the use of it causes discomfort.
- If Ironhand malfunctions, pull the red quick stop handle on the remote control to release the grasp.
- Do not use Ironhand for tasks that can cause injury if Ironhand malfunctions.
- Only carry objects that you would otherwise be capable of carrying.
- Be cautious when operating heavy machinery such as cranes and hoists.



### 2.4.2 Battery

- **ELECTRICAL HAZARD.** Change in voltage supply can damage the product and cause a fire. Replace the battery with a battery of the same type and rating.
- Do not short circuit the terminals of the battery.
- Do not expose the battery to fire. This can cause an explosion.
- Do not expose the battery to temperatures above 60°C/140°F.
- Do not dismantle the battery.
- Do not use batteries that show signs of damage.
- Dispose of worn out batteries according to local regulation without delay.

### 2.4.3 Charger

- Only use the charger specified in this guide.
- ELECTRICAL HAZARD. Earthed power supply is vital for the safe use of the battery charger. Never operate the charger without connection to an earthed power supply outlet.
- Never use the charger with a damaged cable or if it has been dropped or damaged.
- Always keep charger and batteries clean.
- Do not dismantle the charger.
- If you have any problems with the charger while it is connected to the electric outlet, disconnect it from the power point immediately to turn off the power.

## 2.5 Cautions

- Use Ironhand according to the instructions. Incorrect handling can cause discomfort and void the warranty.
- Keep Ironhand clean at all times. Do not touch anything that can cause resistant stains.
- Keep Ironhand away from liquids and small particles. Liquids can easily go through the outer glove and cause damage if they enter Ironhand. To clean Ironhand, see [To clean Ironhand](#).
- Do not use portable RF communications equipment, like mobile phones, closer than 30 cm (12 inches) to the Ironhand power pack. Otherwise, the performance of Ironhand can deteriorate.
- Use caution when operating Ironhand in environments with high levels of radio frequency noise, such as near welding equipment.



### 3. Product overview

#### 3.1 Ironhand

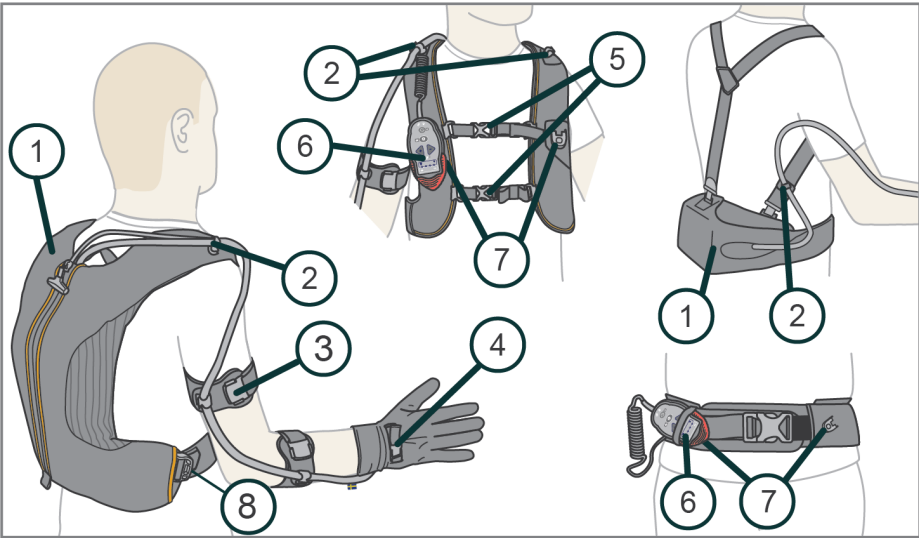



Figure 3: The components of the Ironhand system.

Item	Name	Function
1	Carrying solution with power pack	Protects the power pack
2	Cord clips	Holds the cords in place
3	Arm straps	Keeps the cord attached to your arm
4	Glove	Provides grasp force
5	Sternum straps	Connects the shoulder straps
6	Remote control	User control
7	Remote control mount	Holds the remote control in place
8	Side strap	Used to tighten the backpack

## 3.2 Ironhand power pack

 A carry solution must always be used to prevent damage to the power pack.

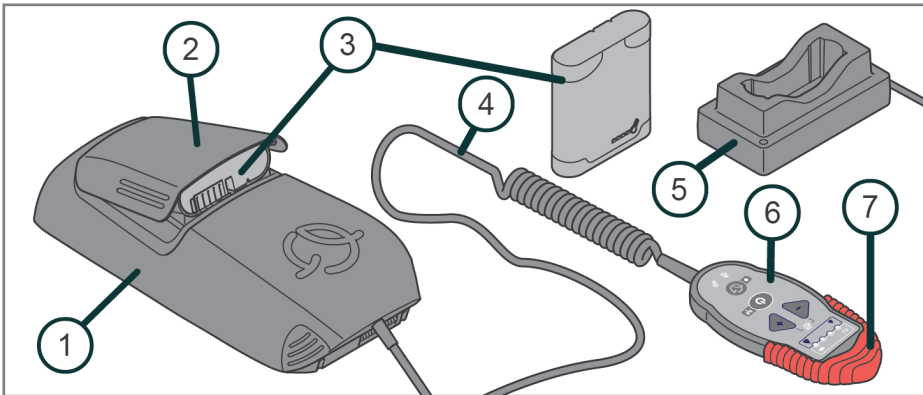


Figure 4: Ironhand power pack, remote control and battery charger.

Item	Name	Function
1	Power pack	Controls and powers Ironhand
2	Battery compartment	Keeps the battery in the power pack
3	Battery	Powers the power pack
4	Cord	Transmits commands and power between the power pack and the remote control
5	Battery charger	Charges the battery
6	Remote control	User control
7	Quick stop	Shuts Ironhand down quickly

### 3.3 Ironhand glove

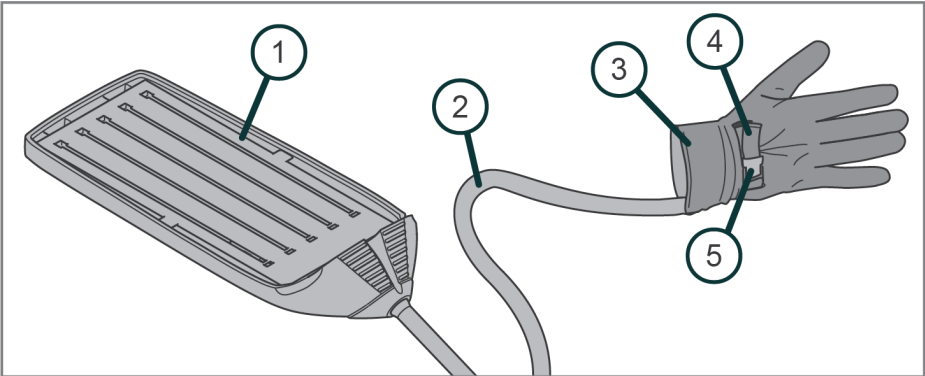


Figure 5: Ironhand glove and connector.

Item	Name	Function
1	Connector	Connects the glove to the power pack
2	Cord	Transmits sensory data and force
3	Glove	Provides grasp force
4	Strap	Secures the glove on the hand
5	Buckle	Holds and loosens the strap

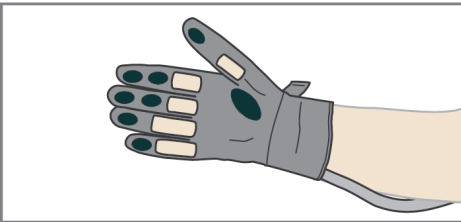


Figure 6: Sensors on Ironhand.

Name	Function
Finger sensors	Provide data to the power pack

### 3.4 Ironhand remote control

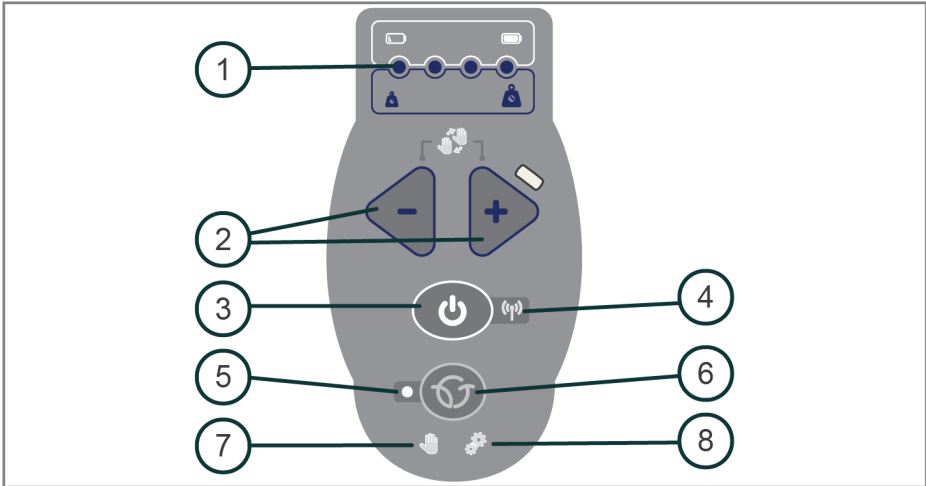


Figure 7: Ironhand remote control.

Item	Name	Function
1	LEDs	Indicates battery level in white or force level in blue
2	Force adjustment	Press to adjust the force level
3	On/off button	Hold for approximately 1 second to turn the system on or off. Double-click to enable/disable WiFi/Bluetooth.
4	WiFi/Bluetooth indicator	Blinking = WiFi/BLE functionality is turned on. Steady light = connected to WiFi/BLE.
5	Profile selection indicator	Off = primary profile, on = secondary profile
6	Profile selection button	Press to select profile
7	Glove status indicator	Indicates glove errors
8	Power pack status indicator	Indicates power pack errors

### 3.5 Charger

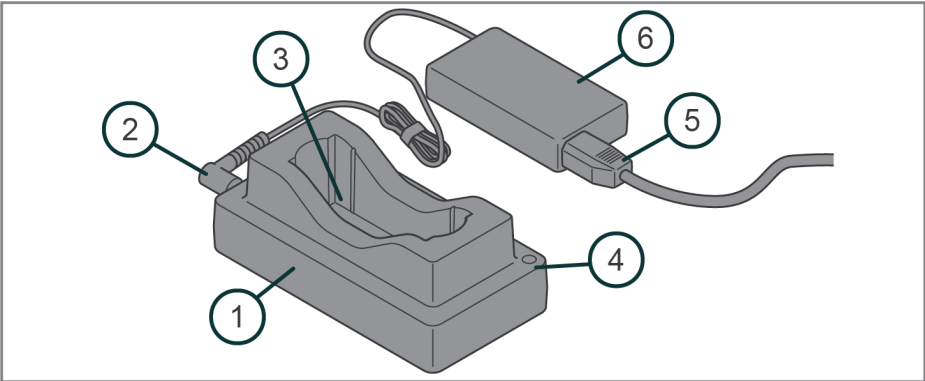


Figure 8: Charger.

Item	Name	Function
1	Battery charger	Charges the battery
2	Charger power cable	Transmits DC voltage to the charger
3	Battery slot	Holds the battery
4	Charging indicator	Indicates the status of the charger
5	Mains power cable	Transmits AC voltage to the power adapter
6	Power adapter	Converts AC to DC

#### 3.5.1 Charger indicators

Light indicator	Meaning
One blink series RED/ORANGE/GREEN	Self test: the charger is ready for use.
Blinking RED/GREEN	The battery is identified.
Solid ORANGE	The battery is charging.
Solid GREEN	The battery is fully charged and can be removed.
Blinking RED	The battery is too hot or too cold to be charged.
Solid RED	The battery is damaged or of a wrong type.

## 4. To assemble Ironhand

### 4.1 To charge and insert the battery



The charger becomes warm during use.

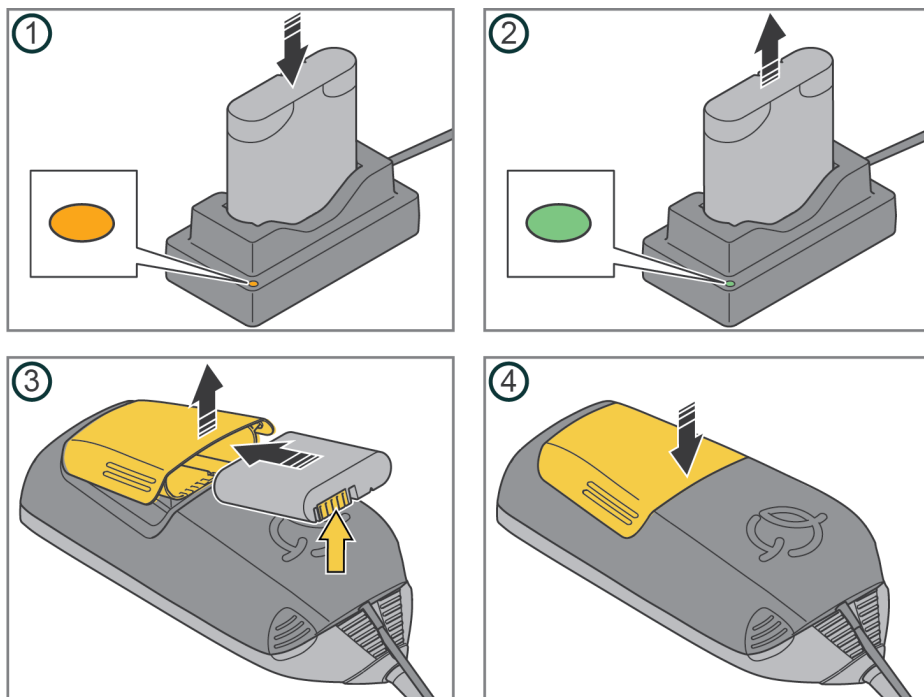


Figure 9: To charge and insert the battery.

Make sure that the battery is fully charged. The four white battery indicators on the remote control show the battery status, see [Ironhand remote control](#). You can also check the battery status on the charger.

## 4.2 To connect the glove to the power pack

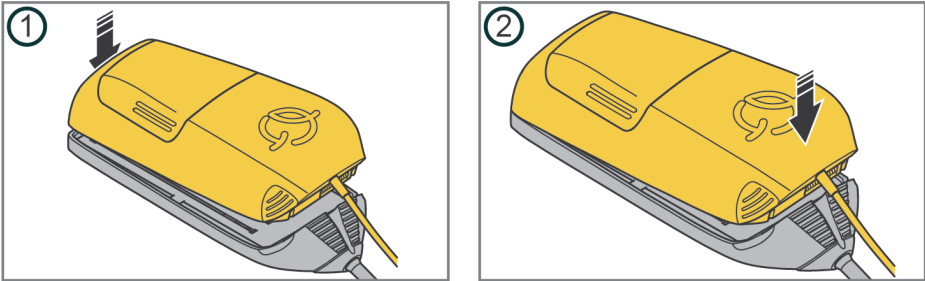


Figure 10: To connect the glove connector to the power pack.

## 4.3 To prepare the Backpack

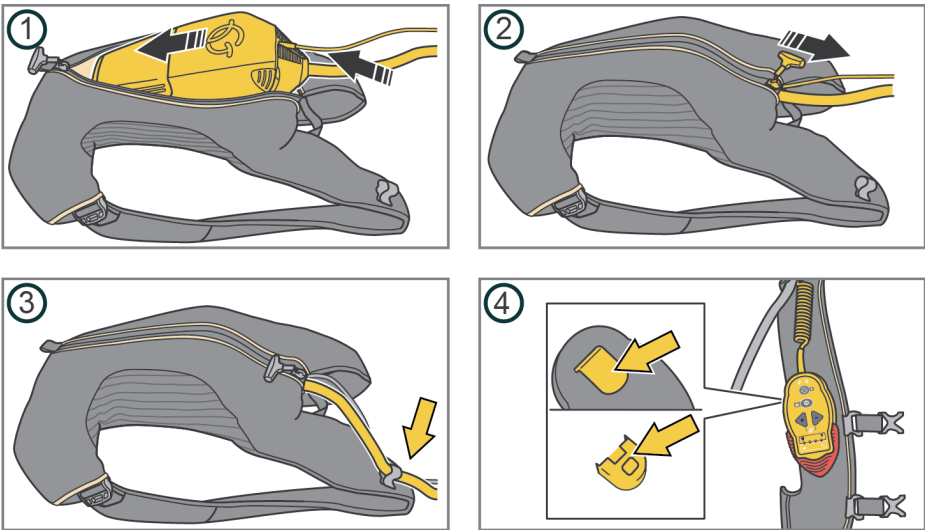


Figure 11: To prepare the Backpack

## 4.4 To prepare the Hipcarry

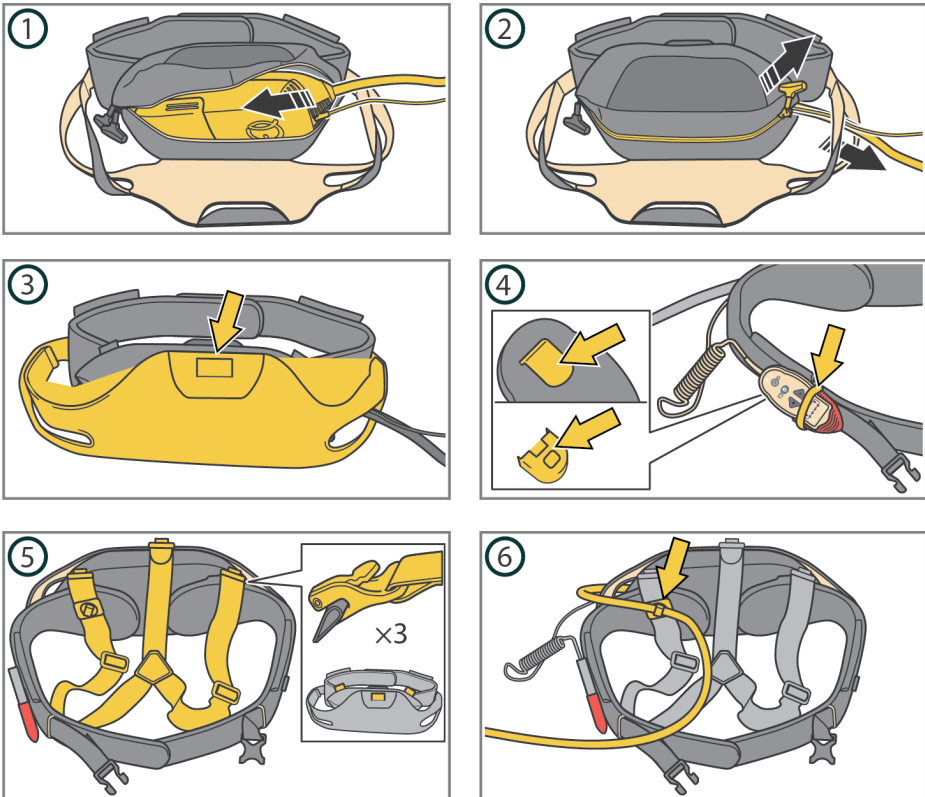


Figure 12: To prepare the Hipcarry



## 5. To use Ironhand



Warning! Use Ironhand according to the instructions. Incorrect handling can cause discomfort.

### 5.1 Wash your hands and use hand sanitizer



Figure 13: Before you use Ironhand, wash your hands and use hand sanitizer.

### 5.2 To put on and start Ironhand



If the Ironhand glove malfunctions, pull the red stop handle on the remote control. This shuts down the system quickly.



Warning! A protective glove must be used on top of the Ironhand glove.



Caution: The added force can be surprising for a new user. Make sure you familiarize yourself with this extra force before you start making full use of Ironhand.

## 5.2.1 To put on the Backpack

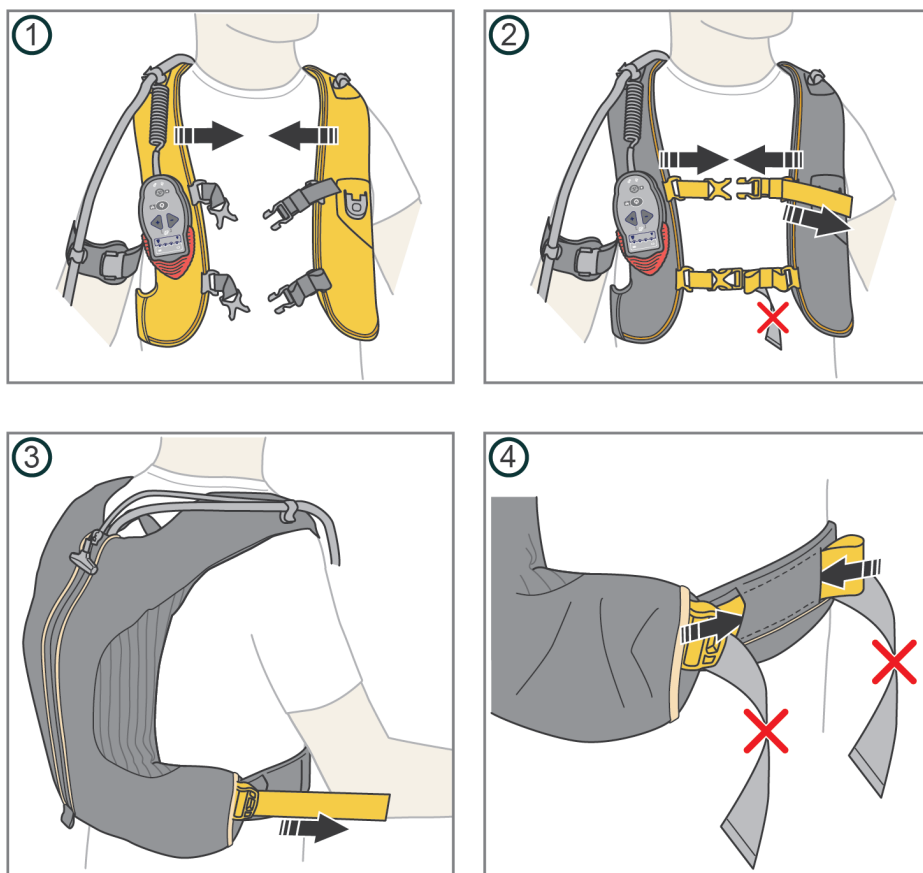


Figure 14: To put on and adjust the Backpack.

### 5.2.2 To put on the Hipcarry

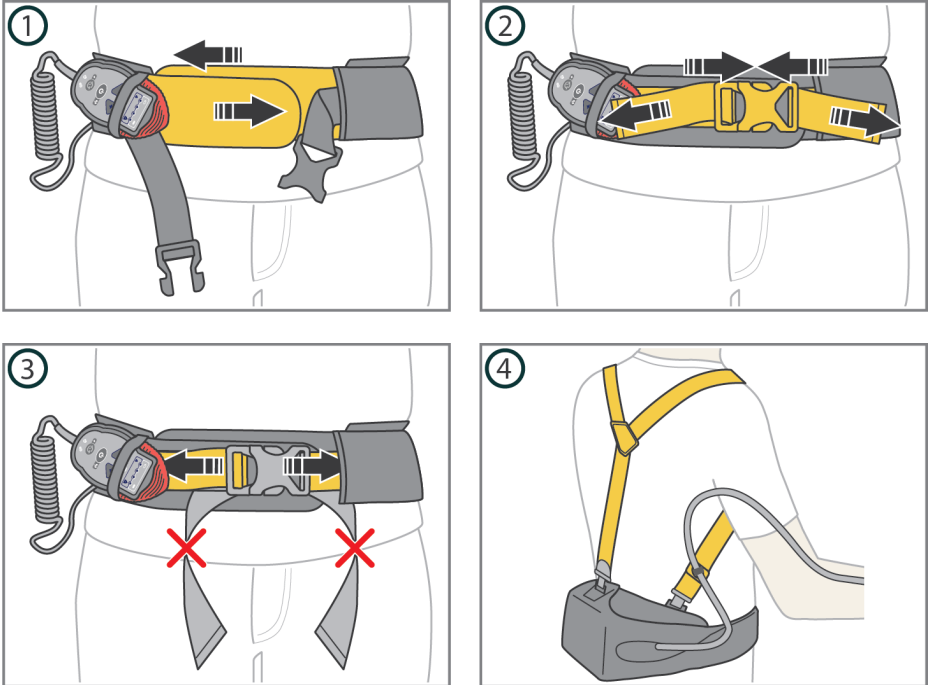


Figure 15: To put on and adjust the Hipcarry.

### 5.2.3 To put on the glove

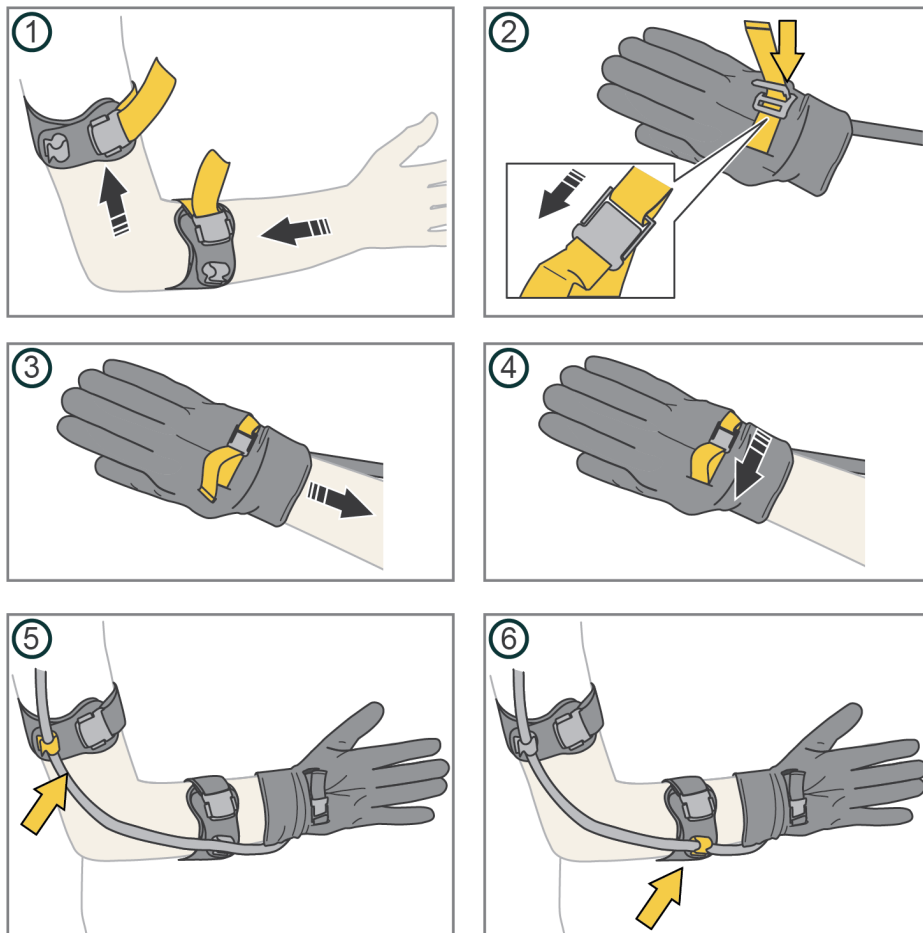


Figure 16: To put on the glove.

The glove should be tight on your wrist but not hurt. To loosen the strap, lift the buckle.



Before use, do a functionality test. See [Functionality test](#).

### 5.2.4 To put on an outer glove

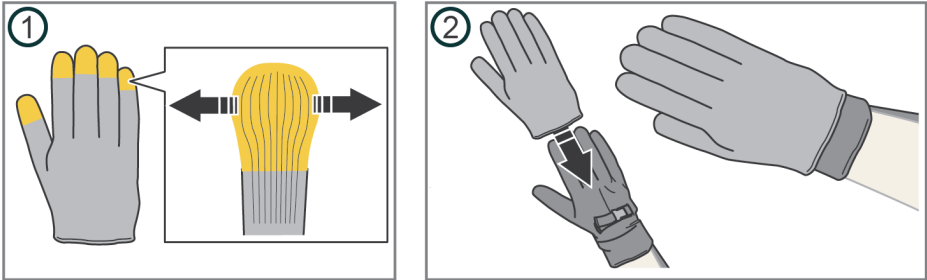


Figure 17: To put on the outer glove.

Put on the outer glove. If you experience problems with getting your fingers into the glove, try extending the fingertips of the outer glove.

### 5.2.5 To adjust the length of the cord

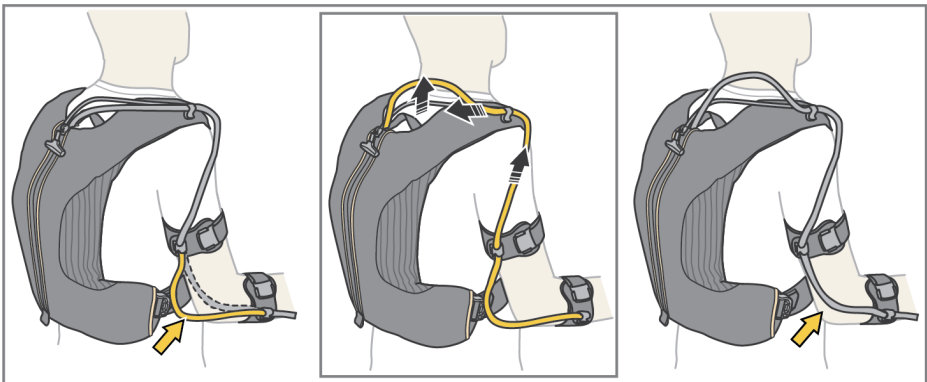


Figure 18: To adjust the length of the cord.

Slide the cord in the cord clips to adjust the length of the cord.

## 5.2.6 To start Ironhand

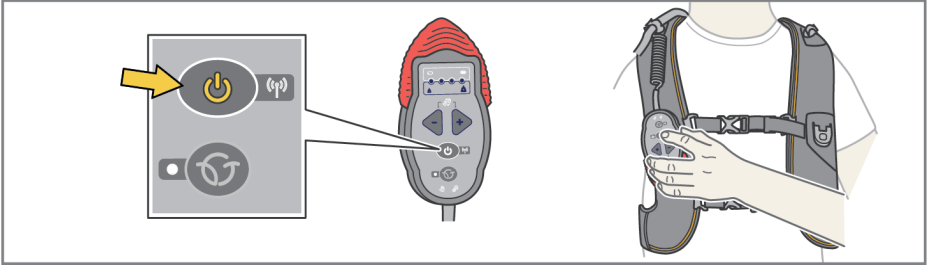


Figure 19: To start Ironhand.

Press and hold the on/off button on the remote control for approximately 1 second to start Ironhand.

## 5.3 Functionality test

Before use, do a functionality test:

1. Inspect the Ironhand system. If it is damaged, contact the supplier.
2. Put Ironhand on according to the instructions in [To put on and start Ironhand](#).
3. Make sure that the glove status indicator and the power pack status indicator are not lit. If they are lit, Ironhand has detected an error. Contact the supplier.
4. Hold an object tightly with all your fingers. Make sure that Ironhand reacts as intended according to installed profiles.
5. Release the object. Ironhand should stop adding force to your hand.
6. If Ironhand does not add force when you hold, or does not stop adding force when you release, see [Troubleshooting](#) or contact the supplier.

## 5.4 To shut down Ironhand

Press and hold the on/off button on the remote control for approximately 1 second to place Ironhand in stand-by mode, press and hold for 6 seconds to shut down Ironhand.

### 5.4.1 Quick stop

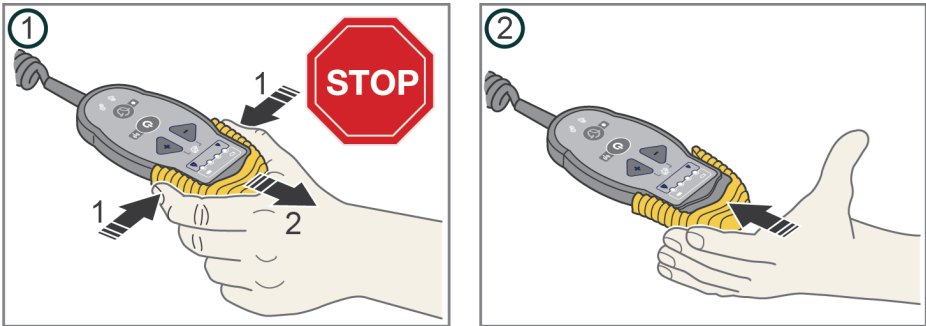


Figure 20: Quick stop.

If the Ironhand on/off button does not respond, pull the red stop handle on the remote control. This releases the grip and shuts down the system quickly. To reset the quick stop, press the red handle to its normal position.

## 5.5 To change settings in Ironhand

### 5.5.1 To adjust the force level

You can increase or decrease the grasp force with the plus and minus buttons on the remote control.

- Press the plus button to increase the grasp force.
- Press the minus button to decrease the grasp force.



The four blue force level indicators on the remote control show which force level you have chosen, see section [Ironhand remote control](#).

## 5.5.2 To switch between profiles

Ironhand has two preset profiles are accessed with the profile selection button on the remote control. Press the profile selection button to activate the profile you want to use.



By default, Ironhand uses a profile called Smart Assist that learns from the operator and optimizes the control system based on the user behavior.

A blinking LED indicates that a Smart Assist profile is being used.

The profile selection indicator (blue LED) shows which profile is active:

Off = primary profile

On = secondary profile



The profile settings can be configured by the operator using the Bioservo App.

## 5.5.3 To connect to the Bioservo App

You can modify the profile settings on Ironhand using the Bioservo app.

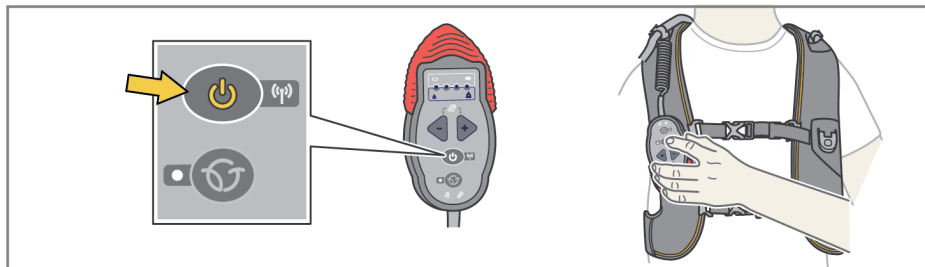


Figure 21: Double click to activate/deactivate Bluetooth/Wifi.

The Bioservo App can be downloaded from Google Play Store for Android devices and the App Store for iOS devices. For more information see separate Bioservo-App user manual.



## 5.6 Inspections and service



**Warning!** All service work must be done by an authorized technician.

Inspect Ironhand with regular intervals to make sure that it functions correctly and that there are no damages on the system components.

There are no parts in the power pack that can be replaced by the user. Contact the supplier for all service work.

## 5.7 Storage

Remove the battery if you are not going to use Ironhand for more than one week. When you keep the battery in Ironhand, it will slowly drain.

## 6. To clean Ironhand



No other maintenance of the product than cleaning can be performed by the user.

### 6.1 To clean the glove



Do not use fabric softener



Always wash the glove in a padded wash bag approved by Bioservo AB. This prevents damage to the glove and the washing machine.

Hand wash or machine wash the glove according to the below instruction.

	Gentle cycle for synthetics
	Do not centrifuge
	Do not use detergent with bleach
	Do not tumble dry
	Do not iron
	Do not dry clean
	Do not wring
	Hang dry in room temperature

Before use, make sure that the glove and its parts are completely dry. Straighten the fingers on the glove by pulling gently at the fingers, and attach the Power pack. Check the functionality, see [Functionality test](#).

## 6.2 To clean the arm straps

Hand wash or machine wash the arm straps in a padded wash bag approved by Bioservo AB.



Gentle cycle for synthetics

## 6.3 To clean the carry solution

Clean the carry solution according to the cleaning instructions on the label of the carry solution.

## 6.4 To clean the power pack

Clean the power pack and the remote control with a damp cloth. If necessary, use mild detergent. Do not use any abrasive detergents or cleaning equipment such as scouring pad.

# 7. Troubleshooting

Problem	Solution
Ironhand does not start	Make sure that the battery is fully charged and inserted correctly.
Nothing happens when I grasp an object	Make sure that the force adjustment is not set to minimum and that the stop handle is not pulled down.
The system is unresponsive	If none of the above solutions are successful, press and hold the on/off button for 10 seconds to shut Ironhand down. Restart the system.

## 8. Accessories

You can order these accessories from the supplier:

Name	Catalogue number	Description
Powerpack	041.0	Ironhand Powerpack
Battery	RRC2054	Ironhand® Battery
Battery charger	RRC-SMB-MBC	Ironhand® Battery charger
Connection Straps	046.0	Double Carry System Connection Straps
Hard Carry Case Small	045.S	For Ironhand® Kit with up to 2 gloves
Hard Carry Case Large	022.13	For Ironhand® Demokit with up to 6 gloves
Measuring Tape	022.14	Ironhand® branded Measuring Tape
Wash bag	022.9	Ironhand® Wash bag

The below products are ordered in specific sizes:

Name	Catalogue number	Explanation	Options
Ironhand glove	040.os	o = orientation s = size	L (left), R (right) S, M, L, XL
Backpack	042.s	s = size	S-M, L-XL
Hip Carry	043.s	s=size	S, M, L
Arm strap	044.s	s = size	S-M, L-XL

Example: To order a right-hand glove in size M, use the catalogue number 040.RM.

## 9. Technical specifications

Rated voltage	15 V DC
Type of battery	15 V DC Li-ion
Battery life	Approx. 8 hours, depending on usage
IP class	IP4X
Altitude	Max 2 000 m
Weight	Power pack, battery & glove 2.1 kg (4.6 lbs), Backpack 0.6 kg (1.3 lbs), Hipcarry 0.4kg (0.9 lbs)
Max total added force	80 N
Contact material	
Ironhand glove	Polyethylene, polyamide, elastane, viscose, polyurethane, leather
Powerpack/Remote control	Polyamide, polyethylene, polyurethane
Carry Solution&Armstraps	Polyamide, Polyurethane, elastane, leather
Ambient temperature	
Use	-5°C to +40°C (23°F to 104°F)
Storage	-20°C to +50°C (-4°F to 122°F)
Ambient humidity	
Use	10% to 80% relative humidity, non-condensing
Storage	5% to 90% relative humidity, non-condensing
Warranty	
Power pack	1 year or 1 000 000 cycles
Glove	3 months or 100 000 cycles
Chager	See separate manual for specifications
Wifi/Bluetooth	
Frequency	2.4 to 2.5 GHz
Protocols	802.11 b/g/n / Bluetooth 5.1
FCC ID	VPYLB1DX
Radio	
Technology	3G/4G/GNSS
FCC ID	N7NEM75S

# 10. Declaration of Conformity



## DECLARATION OF CONFORMITY

MANUFACTURER                    **Bioservo AB**

ADDRESS                            **Torshamnsgatan 35, 164 40 Kista, Sweden**

DECLARE THAT THE FOLLOWING PRODUCT:

MODEL NAME                      **Carbonhand®**

TYPE                                **C0**

BASIC UDI-DI                      **735008216CH2DP**

INTENDED USE                    **Grasp assistance**

PRODUCT CLASSIFICATION   **Class I (rule 1 & 13)**

SERIAL NUMBER

MAIN HARMONIZED STANDARDS

USED:                                **EN 60601-1, EN 60601-2**

FOLLOWING THE PROVISIONS OF DIRECTIVE:                    **2014/30/EU, 2012/19/EU, 2011/65/EU**

We hereby assure that the product above is in accordance with the European medical device regulation EU 2017/745.

PLACE AND DATE OF ISSUE   **Kista 2024-02-20**

A handwritten signature in blue ink, appearing to read "Ibrahim Deregård".

Ibrahim Deregård  
QA&RA

A handwritten signature in blue ink, appearing to read "Petter Bäckgren".

Petter  
Bäckgren CEO

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