

Carbonhand®

USER MANUAL

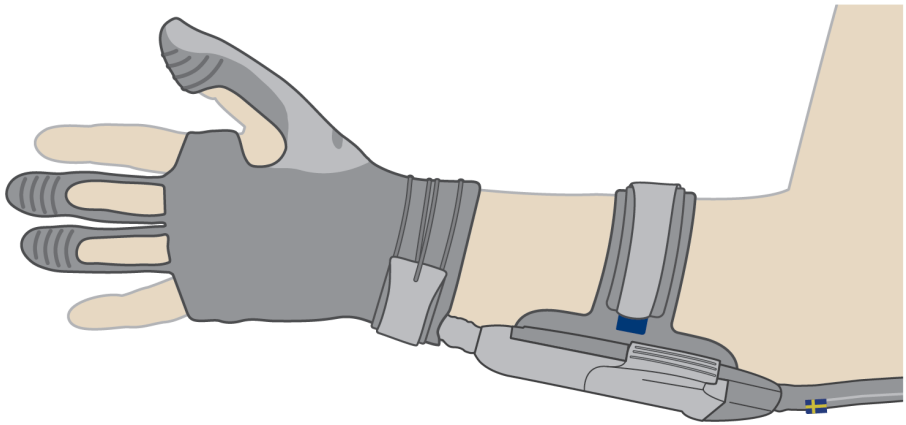


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1. About the product

1.1 Intended use

Carbonhand improves the grip of persons who have a weak or unsteady grip. The condition may be due to orthopedic or neurological problems, from birth or acquired. Carbonhand mimics the user's grip movements and gives your hand additional grip. It is designed to make life easier at work, at home and in everyday life. It is available in several sizes and in both right hand and left hand versions.

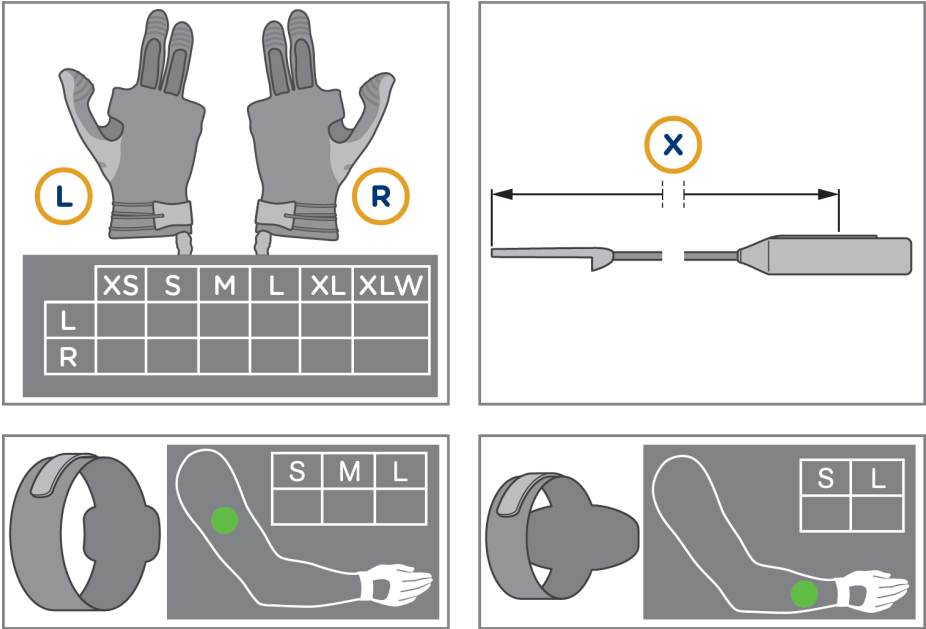
1.2 Conformity

	Standard/Directive	Reference
Carbonhand		
Classification	ISO 9999: 24 18 03	Assistive products for gripping
	ISO 9999: 06 06 07	Hand-finger splints
Compliance	<u>See section 10.2</u> "Declaration of Conformity"	
Charger		
Compliance	See charger manual	
Battery		
Compliance	See battery label	

1.3 Contact information

Bioservo Technologies AB
Torshamnsgatan 35
SE-16440 Kista Sweden
support@bioservo.com
+46 (0)8 21 17 10
www.bioservo.com

1.4 Size guide



Product name	Catalogue number	Explanation	Options
Carbonhand® glove	0010.os	o = orientation s = size	L (left), R (right) XS, S, M, L, XL, XLW
Carbonhand® control unit	0011.x	x = length (cm)	70, 80, 90, 100
Upper arm strap	0017.s	s = size	S, M, L
Lower arm strap	0018.s	s = size	S, L

Example: To order a right-hand glove in size M, use the catalogue number 0010.RM.

1.5 Product overview

1.5.1 Carbonhand

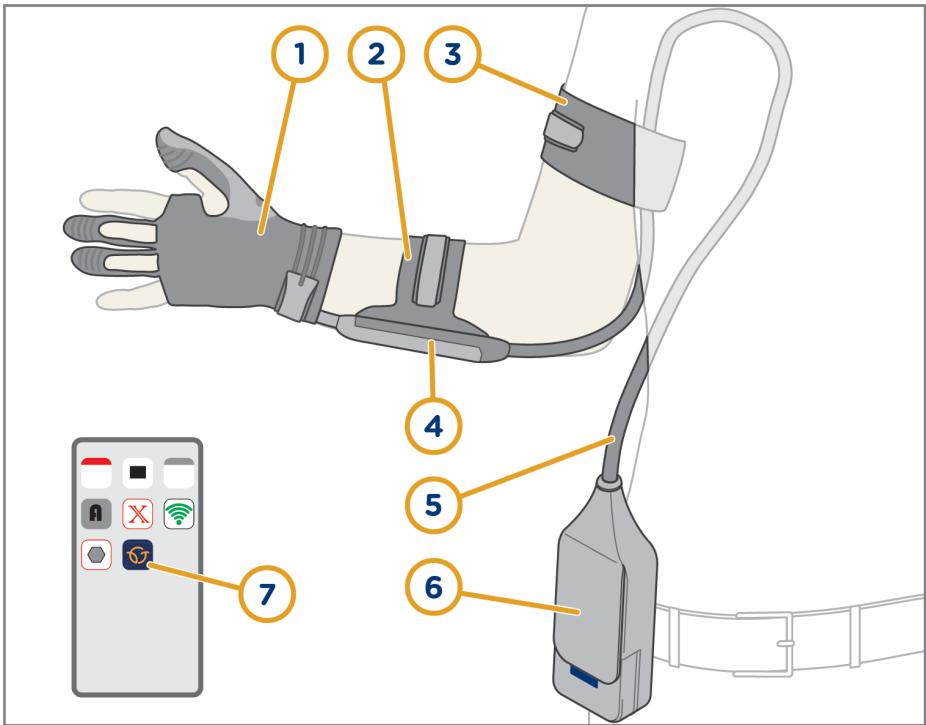


Figure 2: Carbonhand glove and control unit.

Item	Name	Function
1	Glove	Provides grip force
2	Lower arm strap	Keeps the connector attached to your arm
3	Upper arm strap	Keeps the cord attached to your arm
4	Connector	Connects the glove with the control unit
5	Cord	Transmits sensory data and force
6	Control unit	Controls grip force based on sensory data
7	Carbonhand App	Adjusts Carbonhand settings

1.5.2 Carbonhand glove

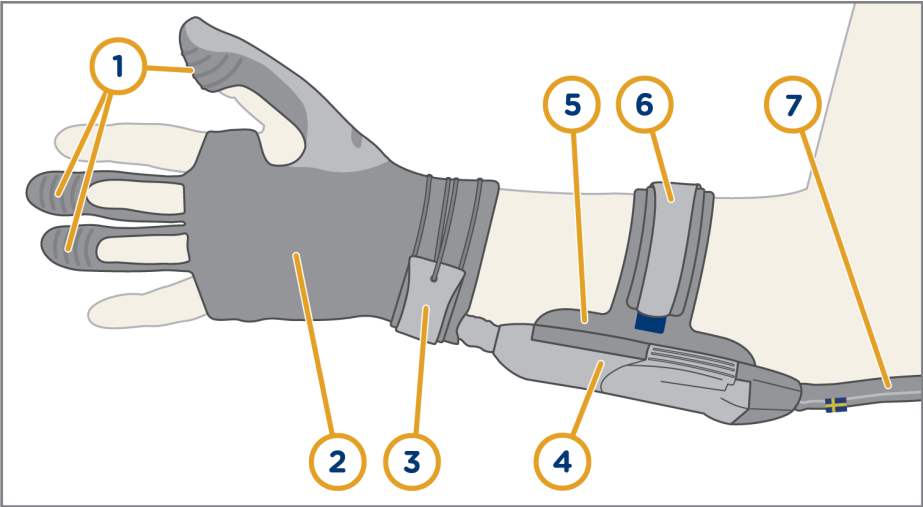


Figure 3: Carbonhand glove and connector.

Item	Name	Function
1	Sensors	Provide data to control unit
2	Glove	Provides grip force
3	Wrist strap	Keeps the glove in position
4	Connector	Connects the glove with the control unit
5	Connector attachment	Keeps the connector attached to the lower arm strap
6	Lower arm strap	Keeps the connector attached to your arm
7	Cord	Transmits sensory data and force

1.5.3 Carbonhand control unit

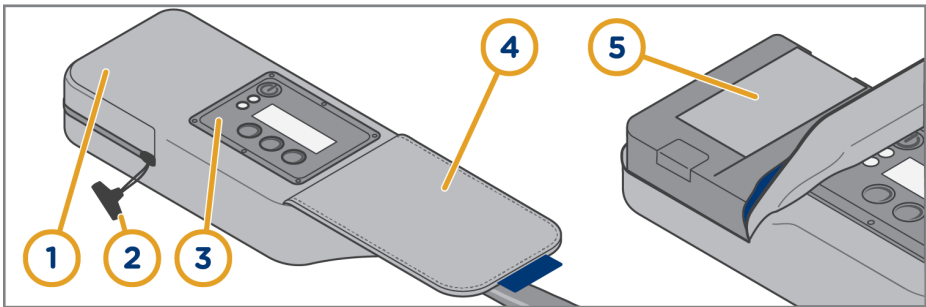


Figure 4: Carbonhand control unit.

Item	Name
1	Battery compartment
2	Zipper
3	Display
4	Lid
5	Batteries

1.5.4 Charger

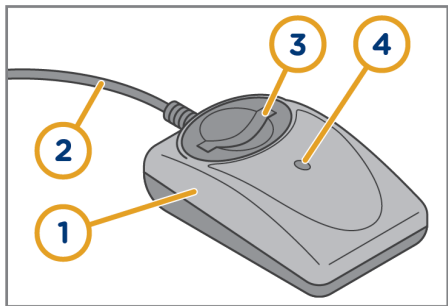










Figure 5: Charger

Item	Name
1	Battery charger
2	Electric cable
3	Battery slot
4	Charging indicator

1.6 Symbols

Symbol	Description	Symbol	Description
	Serial number		Keep the product dry
	Manufacturer's reference number		Do not discard as household waste.
	Manufacturer and date of manufacture		CE mark
	See user guide for information		Medical Device

1.7 Labels

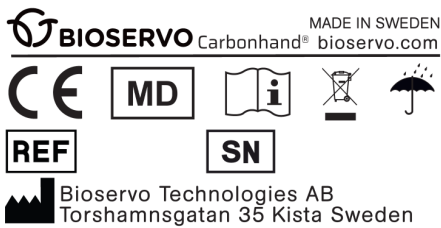


Figure 6: The label on the control unit.

1.8 Disposal

When Carbonhand becomes worn out, recycle it as electronic waste.

2. Safety

2.1 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.

2.2 Warnings

- Do not use Carbonhand for tasks that can cause injury if Carbonhand malfunctions. For example, do not hold a heavy container with hot liquid in it.
- Do not carry burning material or deal with fire while wearing the Carbonhand.
- Use a protective inner glove in Carbonhand if you have cuts or scratches on your hand.
- Wear the Carbonhand as instructed in this manual to avoid entanglement.
- Carbonhand does not provide protection. Use a protective inner or outer glove if it is necessary.
- Always follow the instructions of your doctor or therapist.
- Only use Carbonhand on the hand it is intended for.
- All service work must be done by an approved technician or the supplier.
- Do not do modifications to Carbonhand.
- Stop using Carbonhand if you feel that the use of it causes too great load or an unbalanced load on your body.
- In case of discomfort or pain, stop using Carbonhand and contact your doctor or therapist.
- Do not remove the batteries while Carbonhand is turned on.
- Only use Carbonhand with the supplied batteries.

- Do not short circuit the terminals of the battery.
- Do not expose the batteries to fire. This can cause an explosion.
- Do not expose the batteries to temperatures above 60°C/140°F.
- Do not dismantle the batteries.
- Do not use batteries that show signs of damage.
- Only use the charger specified in this manual.
- Keep batteries out of reach of children.
- Dispose of worn out batteries according to local regulation without delay.
- Unplug the charger when not in use. Pull the plug to disconnect the power cable. Never pull the power cable itself.
- 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.
- It is not possible to guarantee that the charger or any other electric device does not cause interference with other electric devices. Contact the Carbonhand supplier if you encounter a problem.

2.3 Cautions

- Carbonhand is a medical device. Incorrect handling can cause discomfort.
- Keep Carbonhand clean at all times. Do not touch anything that can cause resistant stains.
- Keep Carbonhand away from liquids and small particles. They can cause damage if they enter Carbonhand.
- Do not bend the cord or put heavy objects on it.
- Do not allow metal objects other than batteries to touch metal parts in the charger connector. A short circuit can occur and damage the charger.
- Any serious incident related to Carbonhand should be reported to Bioservo Technologies AB and competent authority where the user holds citizenship.

3. Before first use

When you start using Carbonhand, adjust the glove finger length and do a performance test.

3.1 To adjust the glove finger length

To ensure that Carbonhand works well, the glove should fit tight. Shorten or lengthen the fingers of the glove, as shown in the steps that follow.

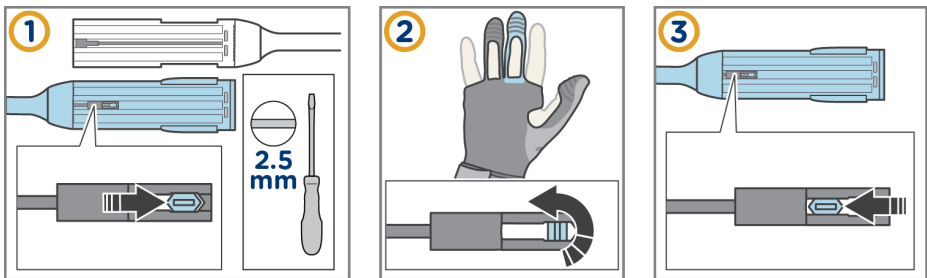


Figure 7: To adjust the glove finger length.

3.2 Performance test

1. Look at the Carbonhand glove. If it is worn down or damaged, contact the supplier.
2. Put Carbonhand on your hand according to the instructions in [section 4.2](#).
3. Hold an object tightly with all your fingers. Make sure that Carbonhand adds extra force to your thumb, middle and ring fingers.
4. Release the object. Carbonhand should stop adding force to your fingers.
5. If Carbonhand does not add force when you hold, or does not stop adding force when you release, see [section 7](#) or contact the supplier.

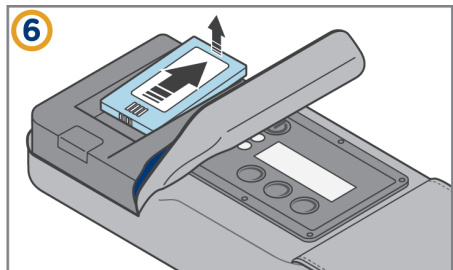
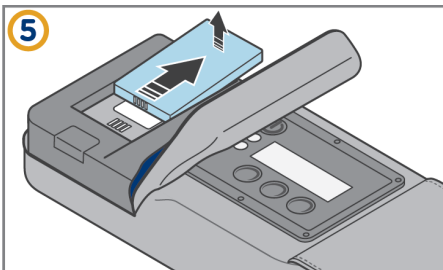
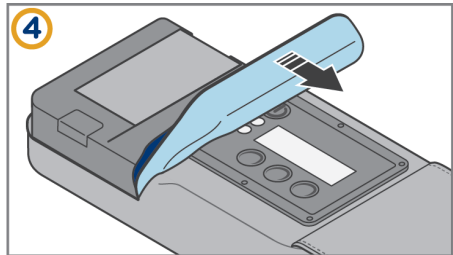
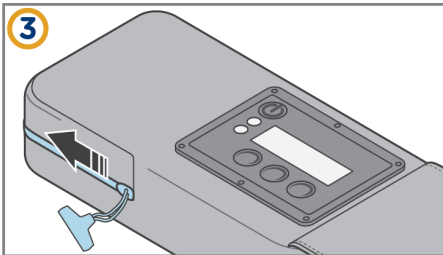
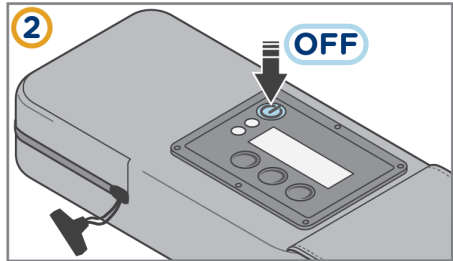
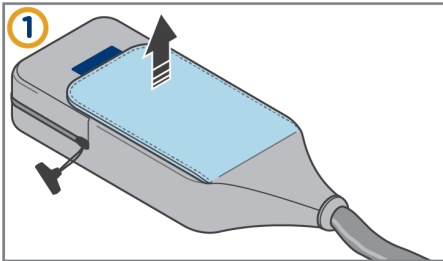
4. To use Carbonhand glove daily

4.1 Before use

4.1.1 To charge and insert the batteries



The charger becomes warm during use.



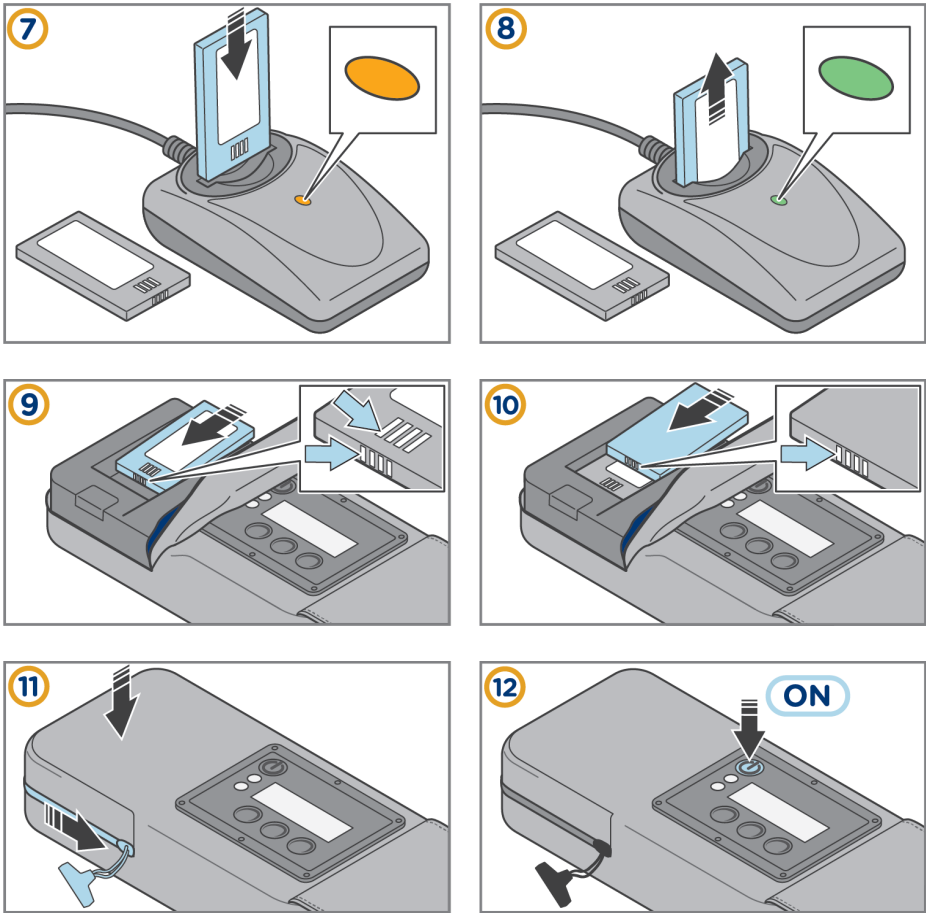


Figure 8: To charge and insert the batteries.

4.2 To connect and put on Carbonhand



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 Carbonhand.

4.2.1 To connect the glove and the control unit

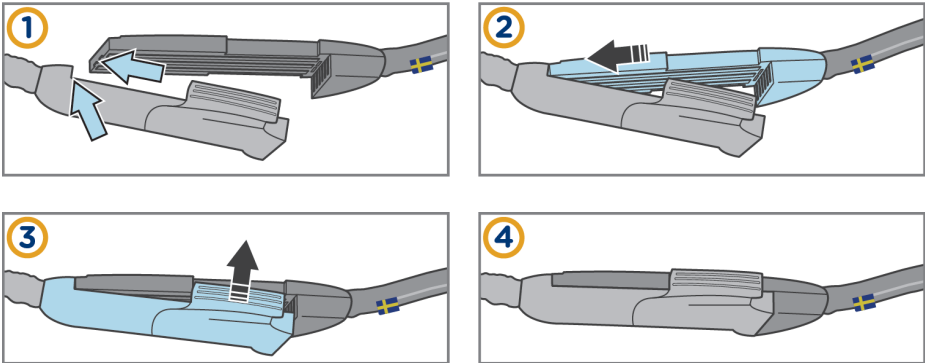


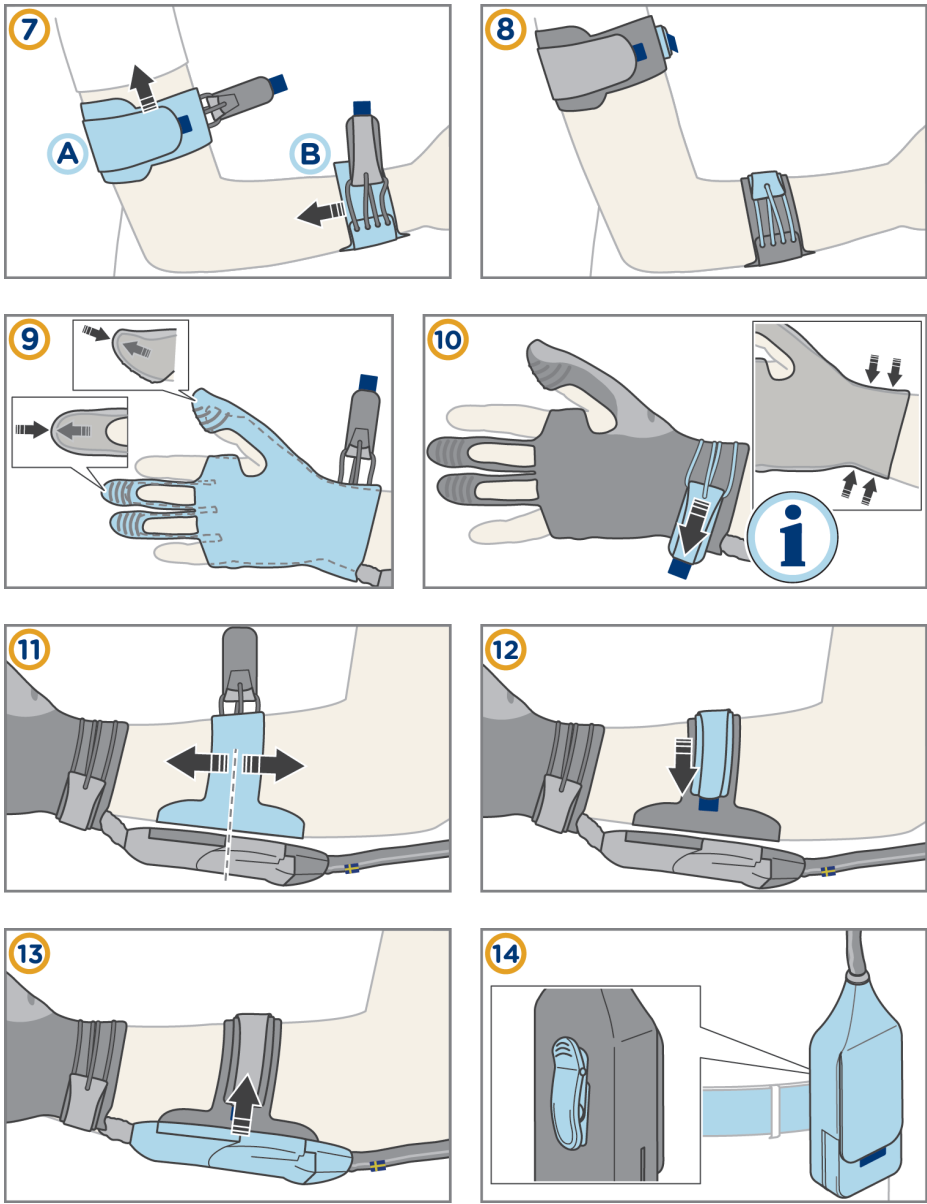
Figure 9: To connect the glove and the control unit.

4.2.2 Wash your hands and use hand sanitizer



Figure 10: Wash your hands and use hand sanitizer.

4.2.3 To put on and start Carbonhand



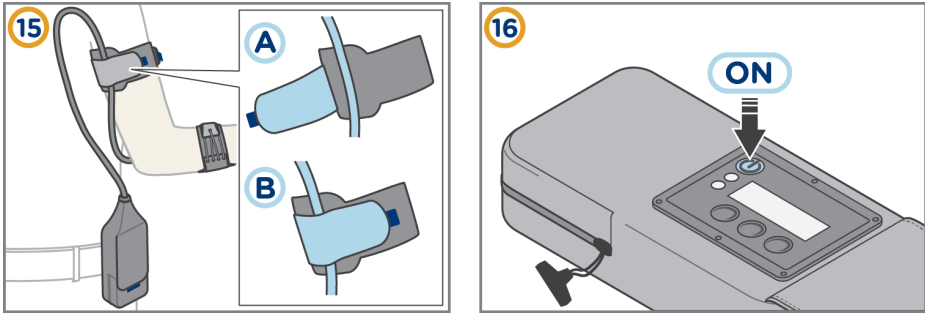


Figure 11: To put on and start Carbonhand

4.3 Protective gloves



Warning! Carbonhand does not provide protection. Use a protective inner or outer glove if it is necessary.



Use a thin glove of latex or cotton inside the Carbonhand glove to prevent direct contact and to keep the Carbonhand glove clean.



Use a protective glove on the Carbonhand glove to keep your hand warm and to keep your hand and the Carbonhand glove clean.

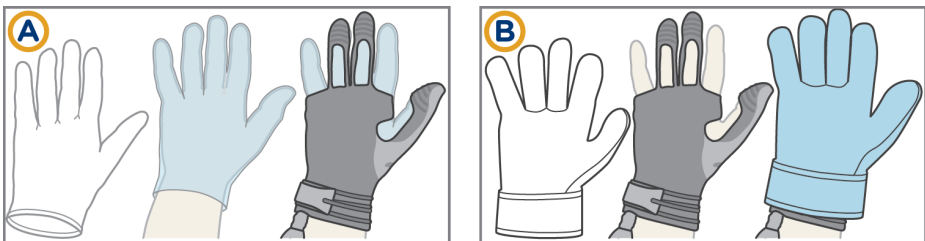


Figure 12: Optional protective glove (A) inside Carbonhand glove and (B) outside Carbonhand glove.

4.4 To shut down Carbonhand

Press and hold the **on/off** button to shut down Carbonhand.

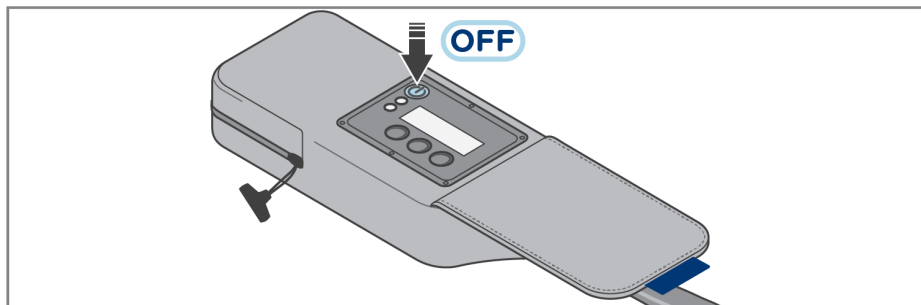


Figure 13: To shut down Carbonhand.



If the Carbonhand glove malfunctions, disconnect the connector to shut it down quickly.

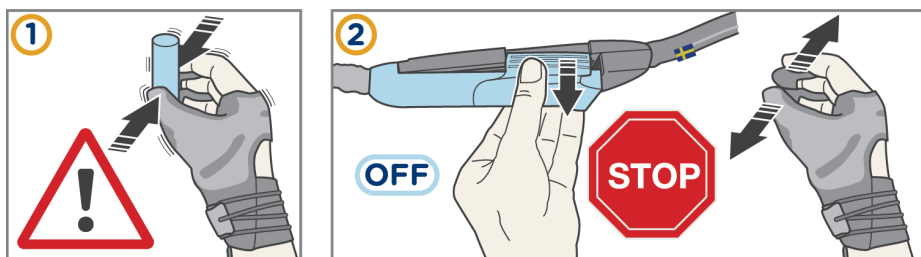


Figure 14: Quick release.

4.5 To change the glove

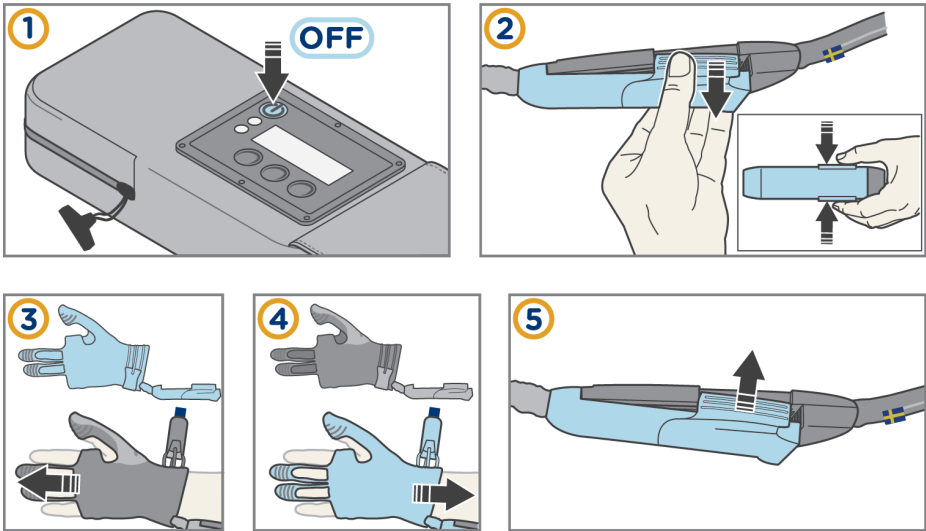


Figure 15: To change the Carbonhand glove.

4.6 To clean Carbonhand

1. Use a lint roller or soft brush to remove dust or other loose particles from Carbonhand.
2. Remove stains on the Carbonhand glove and control unit with a damp cloth. Do not make the glove wet, as this can cause malfunction.
3. Spray the Carbonhand glove with alcohol-based disinfectant to disinfect them.

4.7 Storage

Remove the batteries if you are not going to use Carbonhand for more than one week. When you keep the batteries in Carbonhand, they will slowly drain. Store the batteries in room temperature away from direct sunlight.

5. To use the Carbonhand control unit



Warning! Carbonhand is a medical device. Use it according to the instructions. Incorrect handling can cause discomfort.

Most settings on the Carbonhand are adjusted in the Bioservo Carbonhand App. Download the free app from regular app stores. Some settings are made directly in Carbonhand.

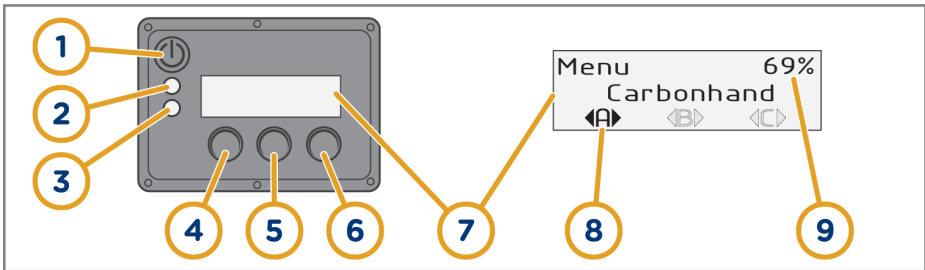


Figure 16: Display, buttons and indicators on the control unit.

Item	Name	Function	Function in Settings mode
1	On/off button	Press to start Carbonhand. Press and hold to shut it down.	Cancel or go back one step
2	Yellow/ blue indicator	See section 5.3	
3	Green/ red indicator	See section 5.3	
4	Button A	Press to select profile A	Go to the left
5	Button B	Press to select profile B	Select and confirm
6	Button C	Press to select profile C	Go to the right
7	Display	Displays information	
8	Active profile	Displays the current grip profile	
9	Battery level	Displays the remaining battery capacity	

5.1 Switch between profiles

Carbonhand has preset profiles that are accessed with the buttons on the control unit. Press button **A**, **B** or **C** to activate the profile you want to use, or activate a profile in the control unit menu.



The profiles have names to identify them easily. You can also add your own profiles if you wish. You do this in the Carbonhand App.

Adjust the profile settings to make it suit the users need. Adjust the sensitivity, maximum force and other settings as described in [section 6](#). Carbonhand comes with pre-set profiles with different settings.

Name	Description
Johan soft	Imitates normal soft hand grip patterns and only applies force in the finger or fingers you press with.
Johan strong	Imitates normal strong hand grip patterns and only applies force in the finger or fingers you press with.
Erik soft	Activates all the fingers for a stable grip.
Erik strong	Activates all the fingers with a strong force to get a stable grip.

5.2 Menu

5.2.1 Settings mode

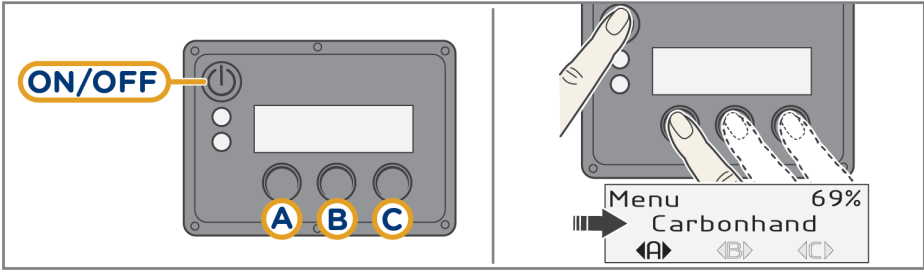


Figure 17: The Carbonhand unit display and buttons.

Use the control unit menu to adjust settings and to display information about the system. Launch the control unit in Settings mode to access the menu.

Press and hold button **A**, **B** or **C** and the **on/off** button to launch the control unit in Settings mode.

5.2.2 Profiles

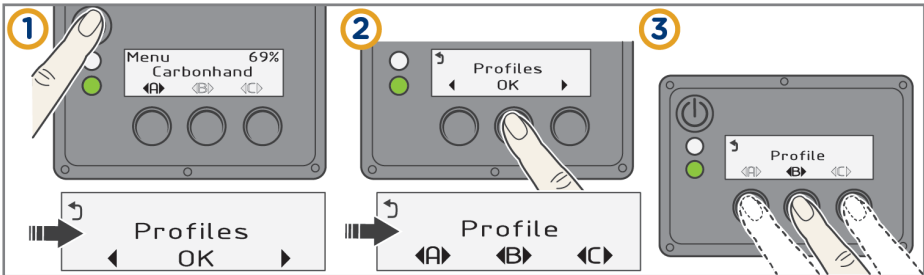


Figure 18: Profiles

5.2.3 Wi-Fi

See [section 6.1](#).

5.2.4 System info

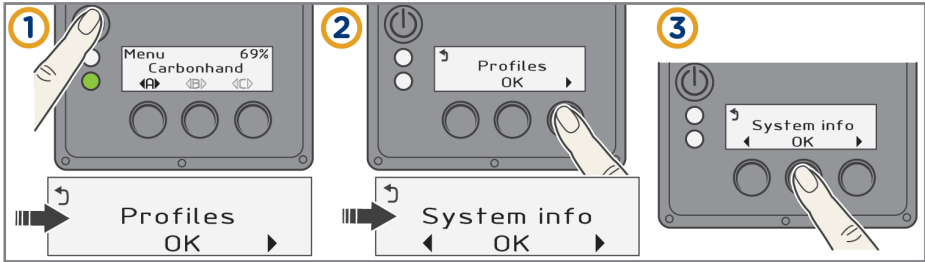


Figure 19: System information

5.2.5 Display error

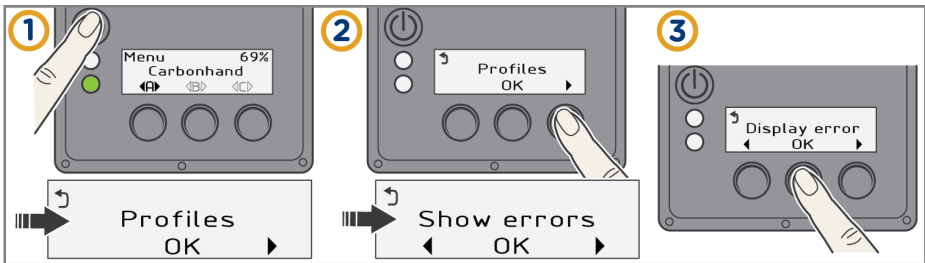


Figure 20: Display error

5.2.6 Settings

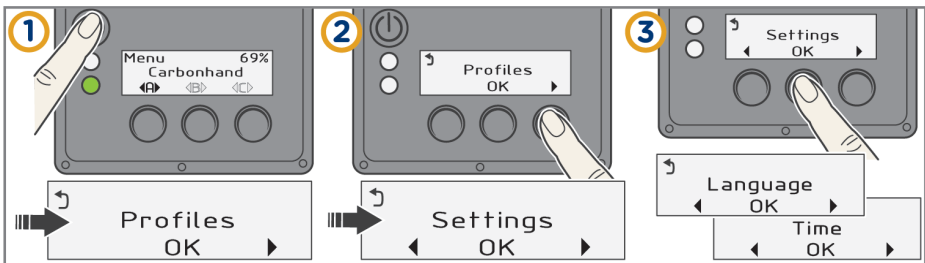


Figure 21: Settings

5.3 Control unit indicators and error messages

Indication	Meaning
Green light, slowly pulsing	Carbonhand is ready to use.
Green light, rapid blinking	<ul style="list-style-type: none">• The system is booting.• The system is turning itself off.• The connector is open.• The connector has been closed incorrectly. Open the connector, wait a few seconds and then close it again.
Red light, rapid blinking	The battery level is critically low. Carbonhand is about to turn off.
Yellow light, solid	Error warning. The system has detected that a component is not working as it should. Carbonhand can continue to be used, but will not perform optimally. See section 5.2.5 .
Yellow light, slowly blinking	Battery level is low. Charge the batteries.
Blue light, slowly blinking	Carbonhand is ready for Wi-Fi connection.
Blue light, slowly pulsing	Wi-Fi connection established.

Display messages	Meaning
DISCONNECT GLOVE	The Carbonhand glove has been connected incorrectly. Disconnect the Carbonhand glove from the Carbonhand control unit and reconnect the glove.
CHARGE BATTERY!	The battery level is low. Charge the batteries as soon as possible.

5.4 Charger indicators

Light indicator	Meaning
Solid ORANGE	The battery charges.
Solid GREEN	Power on and no battery connected or battery fully charged.
Blinking RED	An error has occurred.

6. To use the Bioservo Carbonhand App



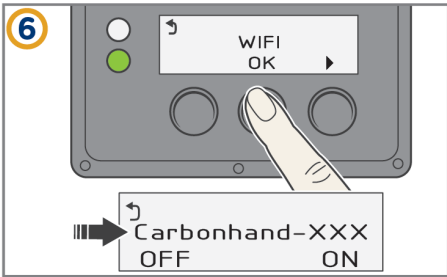
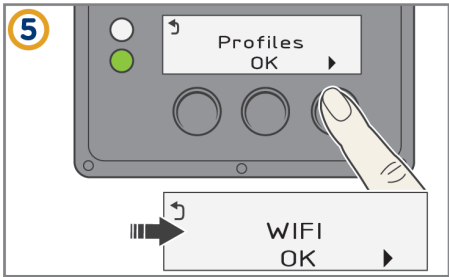
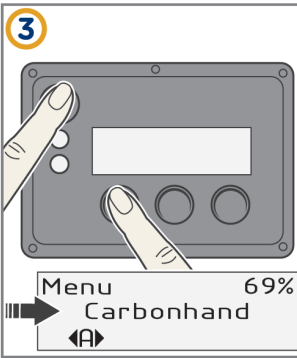
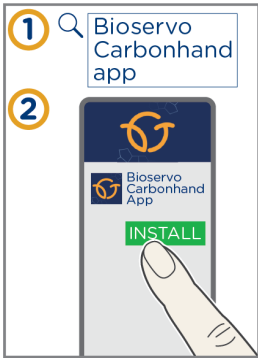
Warning! Do not increase the power setting to maximum in one step. If it is set too high, you can feel discomfort. Gradually increase the power until it feels right for the user.



Warning! Do not increase the sensitivity setting to maximum in one step. If it is set too high, it can be difficult to open the grip. Gradually increase the sensitivity until it is right for the user.

Configure the Carbonhand profile settings in the Bioservo Carbonhand App. Download the free app to your smartphone from the regular app stores.

6.1 To connect a smartphone to Carbonhand



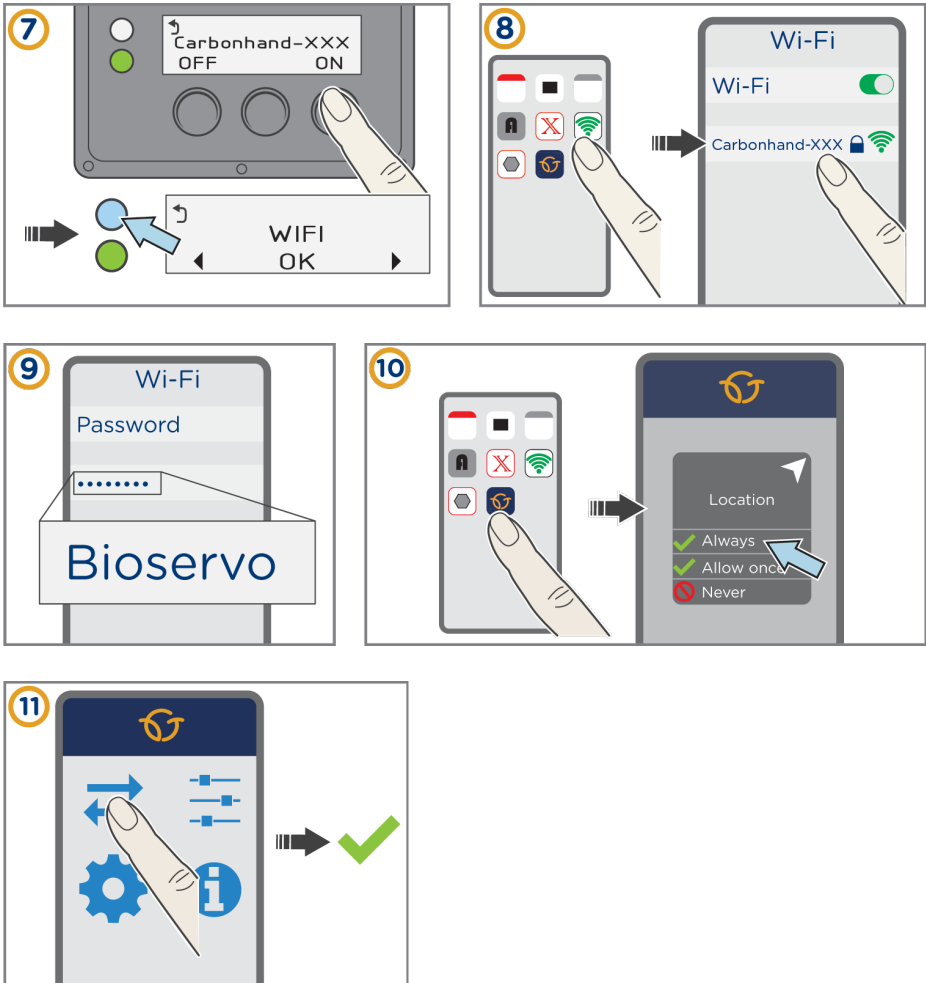


Figure 22: To connect a smartphone to Carbonhand.

Please note that you might be asked to allow the app to use your location, accepting this request will enable the app to find the Carbonhand via WIFI. Bioservo does not collect privacy data. If you deny location permission, the app will not work.

6.2 To turn off Wi-Fi

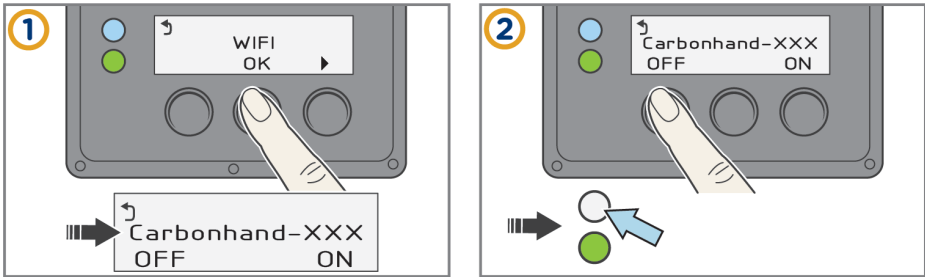


Figure 23: Turn off Wi-Fi to prolong battery life.

6.3 To assign a profile to a button

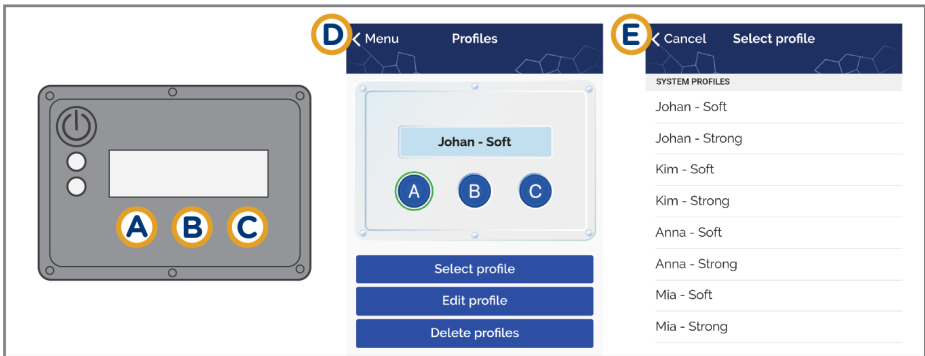



Figure 24: The Carbonhand App. To assign a profile to a button.

 Make sure Simulation mode is disabled before you modify and save profiles. You can not save changes to profiles when in Simulation mode. Simulation mode gives you access to **Profiles** in the app, for demonstration purpose.

1. Switch Carbonhand on. Connect it to the Wi-Fi and to the Carbonhand App.
2. In the app, go to **Profiles**.
3. Select the button you want to assign a profile to (**A**, **B** or **C**). The selected button will be highlighted with a green circle (figure 24 D).
4. Go to **Select profile**. Select the profile you want to use with the activated button (figure 24 E).
5. Tap Menu to exit the Profiles menu.

6.4 To modify a profile

1. Switch Carbonhand on. Create the connection to the Carbonhand App. See [Section 6.1](#)
2. In the app, go to **Profiles**.
3. Select button **A**, **B** or **C** to choose the profile you want to modify. The selected button will be highlighted with a green circle.
4. Go to **Edit profile**.
5. Select the feature to modify (Figure 25 F-I).
6. Adjust the setting to the users preference. Carbonhand will react immediately to your modifications.

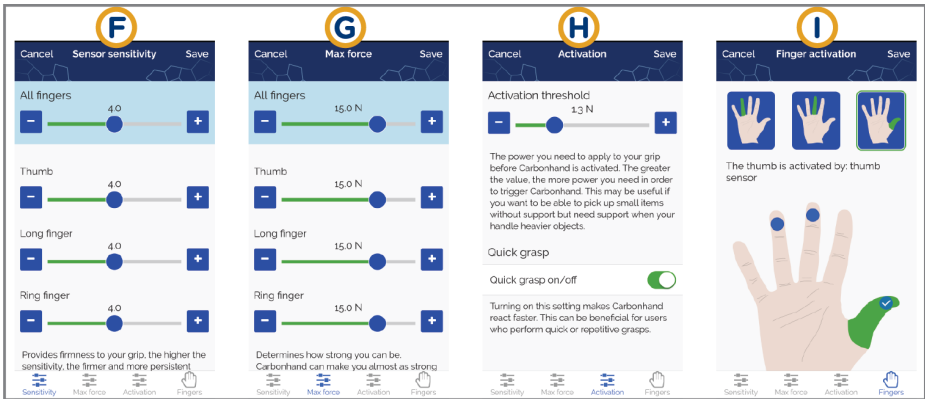


Figure 26: The Carbonhand App. The features that can be modified.

6.5 Sensitivity



Do not increase the sensitivity setting to maximum in one step. If it is set too high, the grip can become locked. Gradually increase the sensitivity until it is right for you.

1. Select **Sensitivity** (figure 26 F).
2. Drag the slide bar to adjust the sensitivity of the finger sensors. You can adjust a single finger, or all three fingers at the same time.

6.6 Maximum force



Under optimal conditions, Carbonhand can give the user approximately 15N force per finger. However, this may vary depending on the users anatomy and hand function.

1. Select **Max force** (figure 26 G).
2. Drag the slide bar to adjust the strength of the grip. You can adjust a single finger, or all three fingers at the same time.

6.7 Activation threshold



You can set an activation threshold for Carbonhand, so that Carbonhand only responds when a certain amount of force has been applied by the user.

1. Select **Activation** (figure 26 H).
2. Drag the slide bar to adjust the necessary minimum effort to activate the grip.

6.8 Quick grasp



Quick grasp makes Carbonhand respond faster, which is helpful during quick and repetitive gripping tasks.

1. Select **Activation** (figure 26 H).
2. Set the **Quick grasp** switch to the **on** or **off** position to enable or disable the quick grasp function.

6.9 Finger activation

1. Select one of the three hand icons (figure 26 I) at the top of the display to select a finger.
2. Select the sensor(s) that will activate that finger.
3. Repeat the steps for the other two fingers.

7. Troubleshooting

Problem	Solution
Carbonhand does not start.	Make sure that the batteries are fully charged and inserted correctly.
The glove does not add force when I grip an object.	The object you grip must be in contact with the sensors on the finger tips. If nothing happens when you put pressure on the sensors, ensure that the fingers are not disabled. See section 6.9 . If the problem persists, contact the supplier for support.
Carbonhand behaves erratically.	Try changing the active profile (see section 5.1) or modify the profile (see section 6.4). If the problem persists, contact the supplier for support.
The display shows an error message.	See section 5.3 . If the error persists, contact the supplier
The system starts but the glove does not respond.	Ensure that the glove connection has been closed.
I cannot close the glove connection.	<ol style="list-style-type: none"> 1. Straighten the cord so that it is not twisted. 2. Turn the control unit off. 3. Reconnect the glove. 4. Restart the control unit.

8. Replacement parts

Order replacement parts from the supplier.

Name	Product number
Battery	EZPack L
Battery charger	EZP06DC005
Upper arm strap	0017
Lower arm strap	0018

9. Technical specifications

9.1 Carbonhand specifications

Max added force	
Thumb and fingers	Approximately 15 N
Batteries	
Type of batteries	3.7V Li-polymer
Number of batteries	2
Battery life	Approx. 8 hours, depending on usage
Storage temperature	-20°C to +50°C
Dimensions	
Carbonhand glove	XS-XL Wide (XLW)
Carbonhand control unit	17 × 8 × 4 cm
Cord	80/90/100 cm depending on model
Weight	
Carbonhand glove	85 g
Carbonhand control unit	600 g
Total weight	700 g
Included outer material	
Carbonhand glove	Polyester, polyamide, polyethylene, PTFE and silicone rubber.
Carbonhand control unit	Polyester, polyamide, acetal and polyurethane.
Ambient temperature (Control Unit)	
Use	-5°C to +30°C
Storage	-35°C to +50°C
Ambient humidity	
Use	10% to 80% relative humidity, non-condensing
Storage	5% to 90% relative humidity, non-condensing

10. Appencices

10.1 Warranty

Warranty terms

Carbonhand consists of a Carbonhand glove and a Carbonhand unit. The Carbonhand glove and the batteries are considered consumables and have therefore shorter warranty than the Carbonhand unit.

Terms for the Carbonhand unit

These terms apply to the Carbonhand unit and the battery chargers, but not the batteries.

The warranty

1. Is valid for two years from date of delivery.
2. Is valid for all failures not caused by incorrect or careless handling, for example:
 - o Something heavy has been placed on the Carbonhand unit (someone has been sitting on it);
 - o It has been soaked or washed by water or other liquids;
 - o The carts in the connection have been manipulated;
 - o The steel wires in the connection have been pulled out of position.
3. Does not apply to wear of the outer materials (textile and plastic).

Terms for the Carbonhand glove

The warranty

1. Is valid for six months from date of delivery.
2. Is valid for all failures not caused by incorrect or careless handling, for example:
 - o It has been soaked or washed by water or other liquids;
 - o The sensors in the fingers have been exposed to violence, folding or been punctured (sharp tip);
 - o Electric wires have been pulled and loaded with force.
3. Does not apply to wear of the outer materials (textile and plastic).

Terms for the batteries

The warranty

1. Is valid for six months from date of delivery.
2. Does not apply if the batteries have been discharged completely, e.g. by being left in their container for several weeks.
3. Does not apply if the batteries have been used for other purposes than intended by the manufacturer.

10.2 Declaration of Conformity



DECLARATION OF CONFORMITY

MANUFACTURER **Bioservo Technologies AB**

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

BASIC UDI-DI **73 5008216**

DECLARE THAT THE FOLLOWING PRODUCTS:

MODEL NAME **Carbonhand®**

PRODUCT VERSION **Rev. 1**

INTENDED USE **Grasp assistance**

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

CONFORMITY ASSESSMENT **Annex I**

SERIAL NUMBER

MAIN HARMONIZED STANDARDS USED:
EN 60601-1, EN 60601-1-2

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 2020-05-19**

Ibrahim Derogård
Quality Assurance Manager

Martin R. Wahlstedt
Development Director

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