

Uncontrolled Copy when printed CV-000917-TC

THE COVVI HAND INSTRUCTIONS FOR USE

CONTENTS SUPERSEDED

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Anything Is Possible

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FOREWORD PERSEDED 1.0

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Our Instructions For Use should be used as a starting point for new users of the COVVI Hand.

The COVVI Hand is referred to as the product in this document.

- Please read this document carefully before using the product and observe the safety notices.
- Please refer to your clinician to safely use the product.
- Please speak to your clinician if you have any questions.
- Report any serious incidents related to the product to your clinician and the manufacturer.



2.0 SAFETY PRECAUTIONS SEDED

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Please read the following safety precautions prior to fitting the product. Please note, we recommend you use the product with COVVI's associated components.

- The product should initially be fit by a Certified Prosthetist.
- Do **NOT** use the product without the integrated glove as this could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.
- Do **NOT** disassemble the product.
- Do **NOT** attempt to change the glove unless you have received written consent from the manufacturer.
- Do **NOT** use an additional glove with the product.
- Do **NOT** attempt to use the product while the batteries are charging. When the batteries are charging, the power will automatically turn off. If for any reason the power does not turn off while charging, using the hand can be potentially unsafe.
- Should the fingers and/or thumb move without an input, stop using the product immediately and contact the manufacturer.
- Do **NOT** use the product if a failure occurs, as it could cause damage to yourself or others.
- Individuals who are exposed to hazardous environments that contain flammable liquid or gas should
 NOT operate the product when in those environments.
- Do **NOT** subject the product to intentional excessive impacts.
- Do **NOT** submerge the product in water.
- Do **NOT** expose the product to an open flame.
- Do **NOT** use the product to operate a firearm.
- Do **NOT** expose the product to chemicals such as solvents, acids, alkalis, corrosive substances, detergents, and similar chemicals as this could damage the components in the product.

COVVI Ltd. and COVVI USA INC have the right to void the warranty of all products that have any type of modification or damage caused by any unauthorised or untrained personnel.



2.0 SAFETY PRECAUTIONS SEDED

2.1 Indications Of Use Make sure to check the newest version

- The product is to be used exclusively for exoprosthetic fittings of the upper limbs.
- Appropriate for all upper limb amputation levels where suitability prescribed by a medical professional.
- Unilateral and bilateral amputations.
- Dysmelia of the upper extremities.

2.2 Contraindications

Everything that contradicts or goes beyond the specifications in this document.

2.3 Conditions Of Use

- The product is for exclusive use by the owner.
- The product was designed and manufactured for everyday use and is NOT suitable for extreme activities
 or sports. These include, but are not limited to: operating a firearm, base jumping, sky diving, downhill/
 endurance mountain biking, motocross, rock climbing, abseiling, bouldering and power lifting. Any sport
 that would involve the product being submerged in a liquid must be avoided. These include, but are
 not limited to: diving, swimming, snorkelling, surfing, kayaking and canoeing.
- Before operating a vehicle with the product, local regulations should be checked, and insurance company
 must be notified. We recommend that the product is fully charged. In the event of an accident occurring
 while operating a vehicle with any COVVI product; COVVI Ltd. and COVVI USA INC shall not be liable
 under any circumstances.
- Avoid remaining in the vicinity of visible strong magnetic or electrical interference, such as theft prevention systems.
- Maintain extra caution when handling sharp objects.
- The product should not be used to carry weight outside the specified load limit.
- The product should not be used, transported, or stored outside the specified boundaries.

COVVI Ltd. and COVVI USA INC have the right to void the warranty of all products that have been used by anyone other than the owner.



3.0 ENVIRONMENTAL CONDITIONS

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Maximum Temperature	104°F / 40°C
Minimum Temperature	-4°F / -20°C
Humidity	Maximum 80%, non-condensing
Pressure	101.3kPa / 14.7psi

4.0 CLEANING

Clean the product with mild soap and a damp lint-free cloth. Abrasive cleaners and cleaning cloths will scratch the dorsal cover. Make sure no liquids get into the EQD. Allow the product to air dry fully before use.

5.0 STORAGE

When you are not using the product; store it in a cool, dry, safe place. Please do not store the product outside of the environmental conditions.



6.0 INSIDE THE BOX ERSEDED

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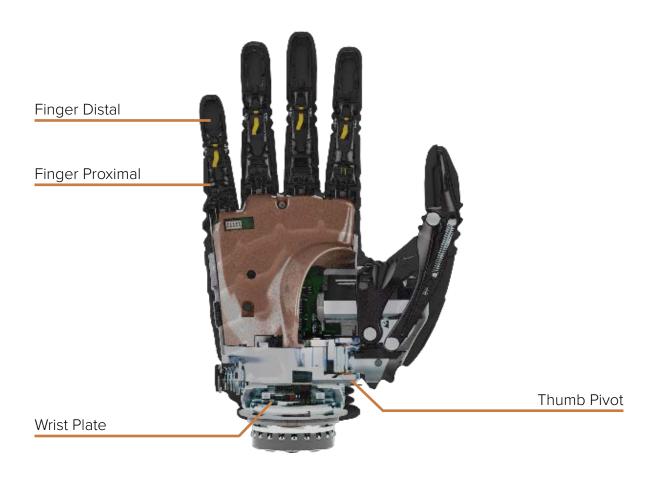
*COVPS-1600 Shown

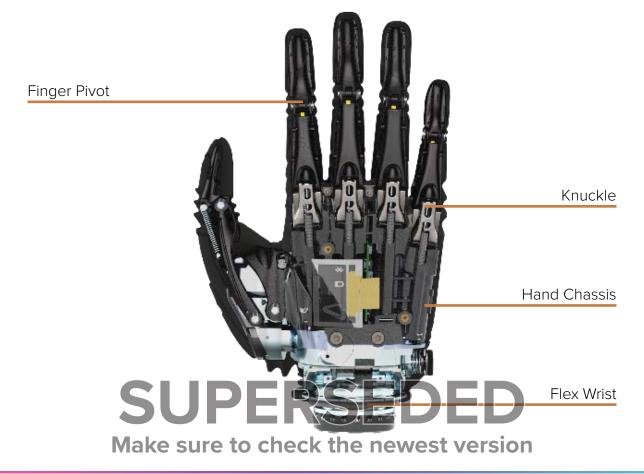
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PRODUCT OVERVIEW S 7.0

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The product is a myo-electric, multi-articulated prosthetic hand with an integrated flex wrist which can be manually locked into 3 positions. The product can be manually rotated 360 degrees in the socket.





PRODUCT OVERVIEW SEDED 7.0





7.0 PRODUCT OVERVIEW SEDED

7.1 Connecting/Disconnecting

- Please make sure the Power Supply is **OFF** before connecting/disconnecting the product to and from the prosthesis as this will avoid any unpredictable spikes in the electric current from the batteries.
- Turn the power on once the product is properly connected to the prosthesis.

Please see the image below for instructions on how to connect the product to the socket.

Remove protective cap





Ensure no debris is inside the EQD core before connecting the product to the socket.











If the ball bearings are locked out radially, the product will not plug in.

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7.0 PRODUCT OVERVIEW SEDED

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If the product is not used for a long period, protect the EQD from debris with the cap. Do NOT use the product if it is visibly damaged.



- Connect the product to the socket by pushing the EQD into the wrist on the socket until you hear the two click together.
- Check the product is properly connected by twisting it 90° clockwise and anticlockwise and lightly pull it away from the socket.
- If the product wobbles in the socket it isn't connected properly.

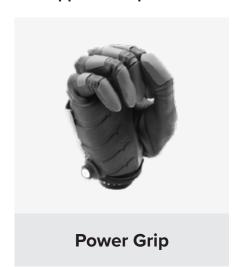


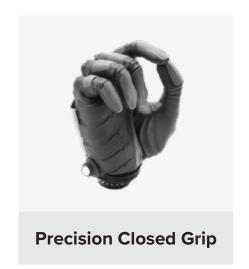
- When you turn the product on, you will hear the start-up beep and the E-Paper screen will display COVVI followed by the first grip in Table A.
- Once you use the product, every time you turn it on again it will display COVVI followed by the last grip and table the product was in when it was turned off.
- To disconnect the product from the socket, rotate it and lightly pull it until the product disconnects.

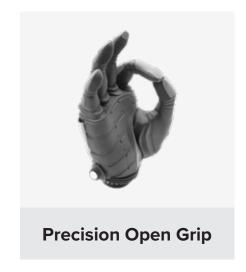
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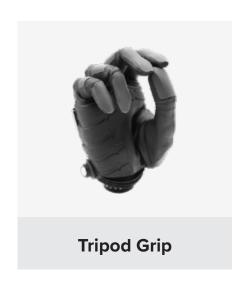
8.0 GRIP PATTERNS ERSEDED

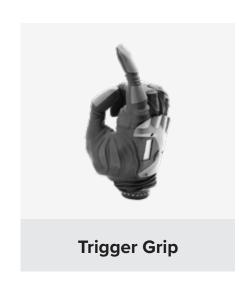
8.1 Opposed Grips Make sure to check the newest version

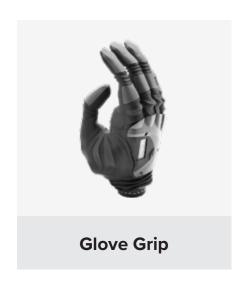








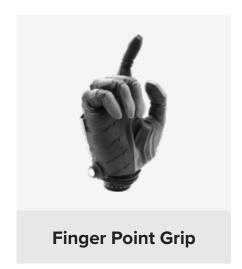


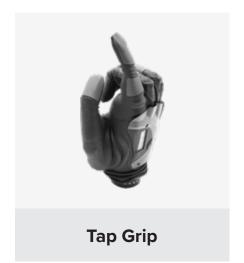


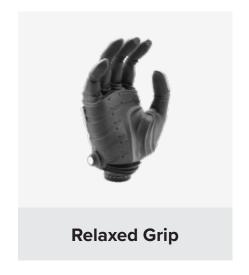
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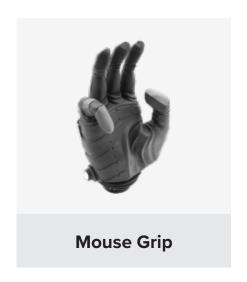
8.0 GRIP PATTERNS ERSEDED

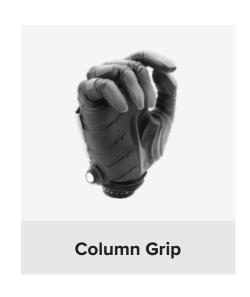
8.2 Non-Opposed Grips Make sure to check the newest version

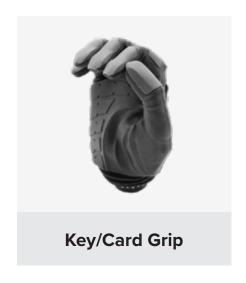












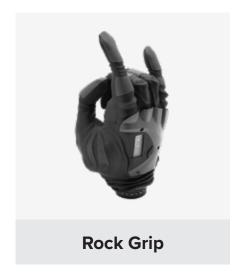
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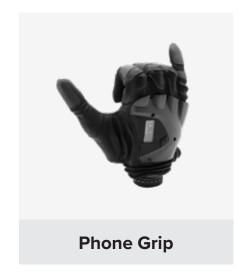
8.0 GRIP PATTERNS ERSEDED

8.3 Gestures

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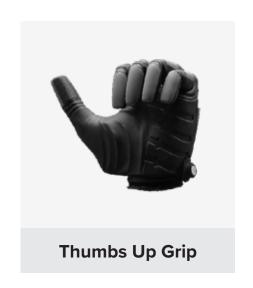
We understand the importance of the product in everyday social interactions, which is why we have incorporated gestures into the available grip patterns. We believe this will not only enhance communication but also encourage social acceptance and community engagement. The available gestures are:

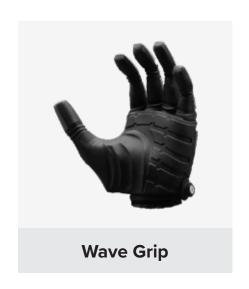












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9.0 PRODUCT FEATURES SEDED

9.1 Integrated Flex Wrist Make sure to check the newest version

The flex wrist can be used in the flexible mode or locked mode which has 3 positions: 30 degrees flexion, extension, and a neutral position.

- In the free flex state, the wrist moves freely but always returns to the middle position as it is spring-loaded.
- To lock the wrist in the middle position, click the wrist locking button once.
- To unlock it click the wrist locking button again.
- To lock the wrist in extension or flexion, push the product forward or backward into place and then click the wrist locking to lock it and again to unlock it.



9.2 Dorsal Button

The dorsal button has 3 functions:

- A quick press activates and deactivates standby mode whereby myoelectric signals are ignored, which is useful for certain tasks such as holding a bag.
- Pressing the dorsal button for 2 seconds activates the grip switch trigger which has to mapped first in the COVVI Go App.
- A 10 second press resets the product if you experience Bluetooth connectivity issues.



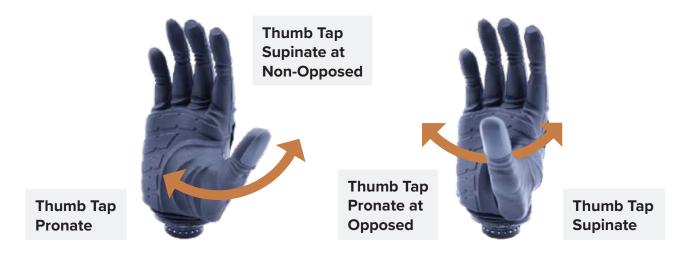
9.0 PRODUCT FEATURES SEDED

9.3 Thumb Tap

Make sure to check the newest version

The product has a novel feature called the thumb tap which is a quick, intuitive way to change grips or tables.

- Laterally tap the side of the thumb to trigger the rocker switch, and depending on what it is mapped to, the grip will change, and the thumb will rotate between non-opposed and opposed positions.
- If you tap the thumb in an opposed grip and the next grip is another opposed grip, the thumb will not rotate but the E-Paper screen will register the change of table/grip.
- If you tap the thumb in a non-opposed grip and the next grip is another non-opposed grip, the thumb will not rotate but the E-Paper screen will register the change of table/grip.



For a Left Hand

Opposed to Non-Opposed - Tap the Right side of the thumb to move it left

Non-Opposed to Opposed - Tap the Left side of the thumb to move it right

For a Right Hand

Opposed to Non-Opposed - Tap the Left side of the thumb to move it right

Non-Opposed to Opposed - Tap the Right side of the thumb to move it left

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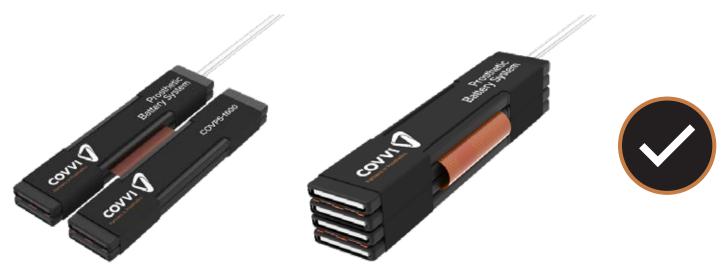
10.0 ACCESSORIES ERSEDED

10.1 Power Supply

Make sure to check the newest version

The product is powered through the power supply.

The 1600mAh Battery is made up of four prismatic cells, that can be folded either way along the brown connecting web.



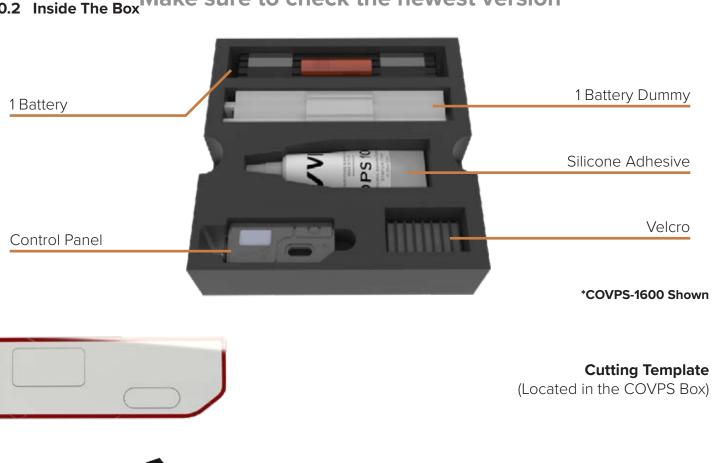
The 2600mAh Battery is made up of two cylindrical cells.

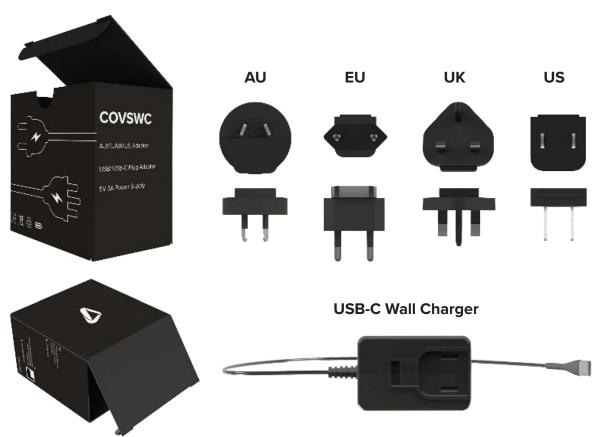


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10.0 ACCESSORIES ERSEDED

10.2 Inside The Box Make sure to check the newest version



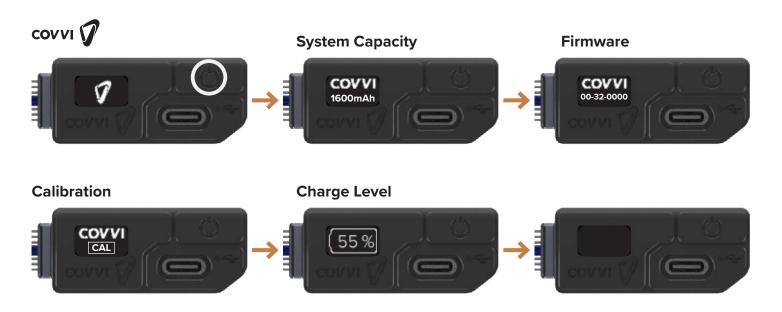




10.0 ACCESSORIES ERSEDED

10.3 Activating The System System

Press and hold the Power Button on the Control Panel for two seconds to turn the Power Supply on. The screen will display COVVI for two seconds and then the current charge level for five seconds. The system is now providing power. To turn the Power Supply off, press and hold the Power Button for two seconds.



To reduce power consumption the screen is blank. To see the charge level, press the Power Button.



10.4 Changing The Display Mode

There are two display modes: bars or a percentage level. To choose the display mode, connect the USB-C Wall Charger to the Control Panel, turn it on and press and hold the Power Button until the screen starts alternating the two styles. Release the Power Button when it shows your preferred display.

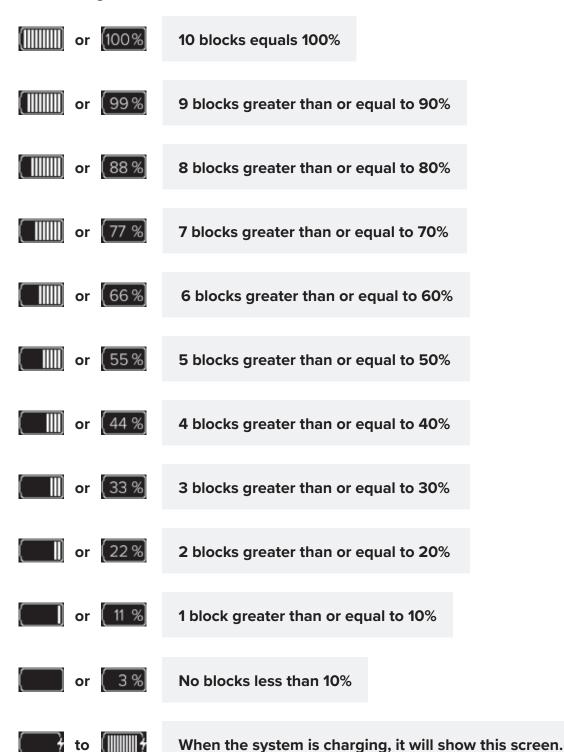
Please Note: The screen will not turn off while the USB is plugged in.



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ACCESSORIES ERSEDE 10.0

10.5 Charge Indication Make sure to check the newest version





If there is a fault with the Power Supply, the screen will show the following warning icon. Please turn off the Power Supply and contact the manufacturer.

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APP SETUP PERSEDED 11.0

11.1 Registration

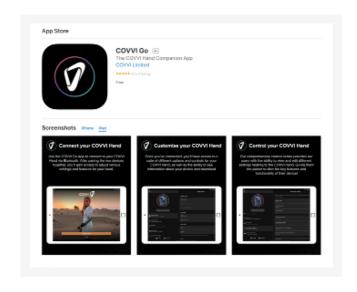
Make sure to check the newest version

Register for a COVVI Go Account by filling out the form on the COVVI website, www.covvi.com, and download the App onto your smart device from the Apple Store or Google Play Store. Your clinician is responsable for accepting your account.

11.2 Connection

Please Note: the first setup should be performed by your clinician and any subsequent changes to the configuration should be approved by them.

Open the App, sign into your account and click on Get Started and then on Connect next to the serial number of your hand. Bluetooth only stays activated on the product for 60 seconds as a battery saving feature. If you fail to connect before 60 seconds, turn power to the product off and back on again.



11.3 Configuration

The product has a default configuration saved but you can make changes.

11.4 Hand Control

In Hand Control, choose the interface type, number of inputs you use, whether input A is the open signal and B the close signal (AB) or vice versa (BA) and the operating mode. If you use two inputs you can only choose dual site open/close, if you choose one you can select your preferred mode.

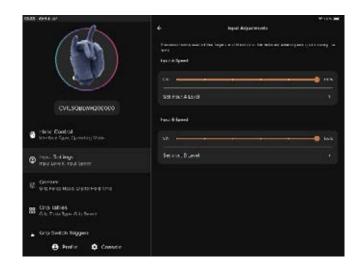


11.0 APP SETUP PERSEDED

Make sure to check the newest version

11.5 Input Settings

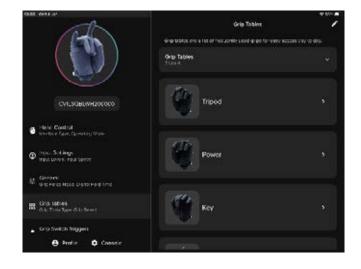
In Input Settings your clinician will help you set your input levels and thresholds. The input level adjusts the input range to the signals you can produce, and the input thresholds are the levels within this range that the product operates. To set the input range, click on the icon in the top right of the screen and then on Set Input A Level / Set Input B Level and for 5 seconds give your strongest open and close signal respectively, assuming the interface layout is AB. To adjust the On and Max thresholds, move the circles on the dials and graph. The On threshold shows the signal strength needed for the product to move and the Max threshold shows the signal strength needed for the product to move at full speed.



11.6 Grip Tables

You can populate up to four tables with up to six grips in each table. Tables B, C and D can be empty, but Table A must contain at least one grip. This grip is called the primary grip. If you are a new user, its recommended to start with one or two grips in either one or two tables. More advanced users may like to separate the grips between tables for daily activities for example one table for grips used at home, another for grips used when at work.

To add a grip, select the table you'd like to populate and click on the + sign, choose the desired grip from the list and then click the back button at the top left. The grip will now appear in the next available position. Grips are added one-by-one.. If you are unsure of



what a particular grip does, select one to see a video showing the hand closing and opening with that grip.

To remove a grip, click on the pencil symbol in the top right of the screen then on the trash icon. The grip will no longer appear in the table.

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11.0 APP SETUPERSEDED

11.7 Grip Switch Triggers Make sure to check the newest version

There are 3 options to change grips and tables through myo-inputs and there are 8 options to change grips and tables with features on the hands. All available triggers are shown in the list and all actions can be seen when you make a selection. The action assigned to a trigger can be seen in orange below its name. Any trigger can be assigned to any action, you can only assign a grip switch trigger once, but you can assign the same action to multiple grip switch triggers.

The available grip switch triggers with myo-inputs are:

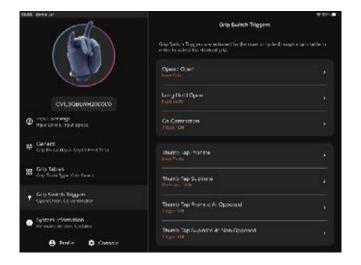
- 1. an open/open signal
- 2. a long hold open signal
- 3. a co-contraction signal

The available grip switch triggers with features on the hand are:

- 1. thumb tap pronate (tapping the thumb inwards)
- 2. thumb tap supinate (tapping the thumb outwards)
- 3. thumb tap pronate at opposed (tapping the thumb inwards when in an opposed position)
- 4. thumb tap supinate at non-opposed (tapping the thumb outwards when in a non-opposed position)
- 5. the dorsal button hold.
- 6. index hold (sensor on the index finger)
- 7. thumb hold (sensor on the thumb)
- 8. four finger hold (sensor on al fingers)

The available actions are trigger off, next grip, previous grip, next table, previous table, switch to table A/B/C/D, map to grip and toggle auto grip.

Click on the grip switch trigger and choose the action you would like to assign it to.



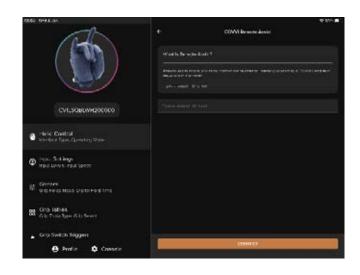
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11.0 APP SETUP PERSEDED

11.8 Remote Assist Make sure to check the newest version

Within the App there is the Remote Assist feature that allows you to request configuration changes or technical support should you ever experience an issue with your product. With this feature we can connect to your hand to make live adjustments and perform some analysis and troubleshooting.

We can ONLY connect to your hand if you notify your clinician and/or us and a meeting time is confirmed. Connect to your hand, go into the console by clicking on the settings icon, and then click on COVVI Remote Assist. Keep the window open in the App and we can then connect to your hand. You will know when we are connected to your hand as under technician status it will say connected in green.



11.9 Hand Statistics

In Hand Statistics you can see data metrics about the hand. You can filter it between grips and grip switch triggers and the time period too. If you choose grips it will show you the total grip time, which is the total time of actuation. If you choose grip switch triggers, it is the number of times that grip switch trigger has been performed. It shows you the Top 5 used grips or grip switch triggers but if you click on view more, you can see all the grips and grip switch triggers and filter it by most used, least used, A-Z or Z-A. If you click on one of the grips or grip switch triggers, it will display the data history on a graph which you can filter by year or total time.



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11.0 APP SET PERSEDED

11.10 System Information Make sure to check the newest version

In the last section in the App, it shows the hand's serial number and basic information about the hand on the top half of the screen and in the bottom half there are 4 important options:

- 1. Config Library shows all the configurations that you, your clinician, or the manufacturer have saved to the hand. You can save more, but you can't delete any.
- 2. Default Config Setup lets you choose COAPT for if you are using a COAPT system with your prosthesis.
- 3. Backup and Restore Live Config is transfer configurations between hands.
- COVVI SETUP O COVVI DEFAULT

4. Check for Updates es where you can look if there is a remote software update available.

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TECHNICAL INFORMATION 12.0

12.1 Product Specifications Make sure to check the newest version

COVVI Hand Voltage	7V to 8.4V DC
Maximum Current Consumption	5A (Max. Constant) 7A (Max. peak, 50ms duration)
Device Weight	570g / 1.25 lbs
Maximum Hand Load Limit (A)	90kg / 198 lbs across knuckle
Maximum Hand Load Limit (B)	32kg / 71 lbs across the fingers
Maximum Finger Load Limit	16kg / 35 lbs
Full Open to Full Close	0.7 seconds to achieve grip
Tripod Grip	0.4 seconds to achieve grip
Tripod Grip Force	45N / 10 lbf
Power Grip Force	80N / 18 lbf
Key Grip Force	22N / 5 lbf



Maximum Hand Load Limit (A) with force applied upwards

90kg / 198 lbs over the knuckles



Maximum Hand Load Limit (B) picking weight up

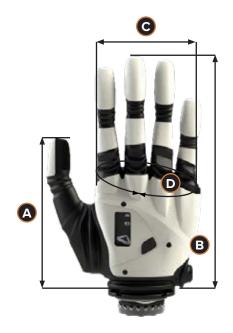
32kg / 71 lbs



Avoid pressure on the thumb RSEDED

12.0 TECHNICAL INFORMATION |

12.2 Product Dimensions Make sure to check the newest version





Wrist Flexion Axis

Dimensions	Key	Small		Medium		Large	
Differsions		Inches	mm	Inches	mm	Inches	mm
Thumb Tip to Base of Hand (excluding EQD)	А	4.46	110	4.5	114.5	4.8	124
Middle Finger to Base	В	6.61	165	7.25	184	7.75	196
Max. Chassis Width	С	2.76	70	3	75	3.1	80
Palm Circumference	D	7.3	190	7.6	195	7.8	200
Maximum Opening Width - Tripod Grip	Е	4.4	110	4.4	115	4.8	120
Length of EQD	X	0.98	3	0.98	3	0.98	3

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12.0 TECHNICAL INFORMATION DED

12.3 1600mAh Battery Dimensions to check the newest version

Power Supply	COVPS-1600
Typical Battery Capacity	1600mAh
Nominal Voltage	7.4V
Maximum Current Draw	7A Peak
Battery Unfolded / Folded (Inches)	4.1 × 2.2 × 0.35 / 4.1 × 0.74 × 0.89
Battery Unfolded / Folded (mm)	104.1 × 55.8 × 8.9 / 104.1 × 18.8 × 22.9
System Weight	74 grams
Humidity	Maximum 80% humidity, non-condensing
Charge Temperature Range	10°C to +45°C
Discharge Temperature Range	-20°C to +60°C

Control Panel



1600mAh Battery



Note: The battery size in mm is subject to +/- 2mm due to manufacturing tolerances.

SUPERSEDED Make sure to check the newest version

12.0 TECHNICAL INFORMATION DED

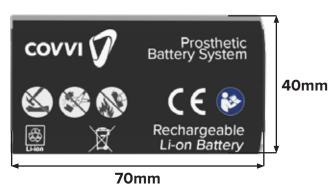
12.4 2600mAh Battery Dimensions to check the newest version

Power Supply	COVPS-2600
Typical Battery Capacity	2600mAh
Nominal Voltage	7.4V
Maximum Current Draw	8A Peak
Battery Dimensions (Inches)	2.6 × 1.6 × 0.8
Battery Dimensions (mm)	70 × 40 × 20
System Weight	104 grams
Humidity	Maximum 80% humidity, non-condensing
Charge Temperature Range	10°C to +45°C
Discharge Temperature Range	-20°C to +60°C

Control Panel



2600mAh Battery



SUPERSEDED

13.0 MAINTENANCE ERSEDED

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Do NOT use the product if the glove is punctured.

It is recommended to service the product every year. A service a year after fitting is included in the 2-years manufacturer's warranty. If you notice any problem with the product, contact your clinician and the manufacturer.

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SYMBOLS USED ERSEDEL



















This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

United States/FCC ID: A8TBM71S2

Canada IC: 12246A-BM71S2

Europe/CE

China/SRRC: CMIIT ID: 2016DJ5890



R 005-101150



MSIP-CRM-mcp-BM71BLES1FC2



注意!

依據 低功率電波輻射性電機管理辦法 第十二條 經型式認證合格之低功率射頻電機, 非經許可,

公司、商號或使用者均不得擅自變更頻率、加大 功率或變更原設計

之特性及功能。

-四條 低功率射頻電機之使用不得影響飛航安 全及干擾合法通信;

經發現有干擾現象時,應立即停用,並改善至無 干擾時方得繼續使用。

前項合法通信,指依電信規定作業之無線電信。 低功率射頻電機須忍受合法通信或工業、科學及 醫療用電波輻射性 電機設備之干擾。

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