COVVI
Partners in Prosthetics

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COVVI HAND & ASSOCIATED PRODUCTS

Instructions For Use

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Anything Is Possible

1.0 FOREWORD

These Instructions for Use (IFU) are applicable for the following products and accessories: The COVVI Hand, COVVI Hand - Straight Wrist, COVVI Hand - Friction Wrist, COVVI GO, COVVI Power Supply, COVVI Wrist Lamination Kit, COVVI Friction Wrist Lamination Ring, COVVI Friction Wrist Switch Block, COVVI Friction Wrist Installation Tool, Glove Kit and Glove Kit 2.

In this Instructions For Use (IFU), the term ‘COVVI Hand’ and ‘Product’ refers to all wrist variants. If any instructions, warnings, or information apply only to a specific wrist type, this will be clearly stated as applying to the COVVI Hand/Product with Flex Wrist, Straight Wrist, or Friction Wrist.

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

2.1 Intended Use

COVVI Hand

The COVVI Hand is intended for individuals with unilateral or bilateral upper limb loss or congenital limb deficiency. It is designed exclusively for use in exoprosthetic fittings of the upper limbs, providing functional and assistive support to users.

COVVI Hand - Straight Wrist

The COVVI Hand - Straight Wrist is an external, motor-driven prosthetic hand with a Straight Wrist designed to assist individuals with unilateral or bilateral upper limb deficiencies. Specifically crafted with anatomically correct dimensions, the COVVI Hand - Straight Wrist facilitates activities of daily living through controlled movement of programmed grip patterns.

COVVI Hand - Friction Wrist

The COVVI Hand - Friction Wrist is an external, motor-driven prosthetic hand with a Friction Wrist designed to assist individuals with unilateral or bilateral upper limb deficiencies. Specifically crafted with anatomically correct dimensions, the COVVI Hand - Friction Wrist facilitates activities of daily living through controlled movement of programmed grip patterns.

COVVI Go App

The COVVI Go App is software intended to assist users of the COVVI Hand by enabling the selection and customization of grip functions and the adjustment of control settings.

COVVI Power Supply

The COVVI Power Supply is intended to power externally controlled upper limb prosthetic hands.

2.0 SAFETY PRECAUTIONS

COVVI Wrist Lamination Kit

The COVVI Wrist Lamination Kit is intended to transmit power and control signals to upper limb exoprosthetic terminal devices.

Glove Kit

The COVVI Glove Kit is an accessory intended to be worn with the COVVI Hand to protect it from external contaminants and maintain device integrity.

Glove Kit 2

The COVVI Glove Kit 2 is an accessory intended to be worn with the COVVI Hand (Friction and Straight Wrist) to protect it from external contaminants and maintain device integrity.

2.0 SAFETY PRECAUTIONS

2.2 Patient Population

The product is suitable for adult users aged 18 years and above. It may also be used by adolescents aged 14 to 17 years, provided they have the physical ability and cognitive understanding required to operate the product effectively.

Prior to use, adolescents should undergo evaluation by a certified clinician to ensure they have the necessary muscle control and cognitive ability to manage the product.

The patient population is applicable to all products detailed in 1.0.

2.3 Indications

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

Indications are applicable to all products detailed in 1.0.

2.4 Conditions Of Use

- The product is for exclusive use by the owner.
- The product should not be used to carry weight outside the specified load limit stated in the technical information section of the Technical Manual.
- The product should not be used, transported, or stored outside the specified boundaries stated in the mental conditions.
- It is recommended to service the product every year.

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.

2.0 SAFETY PRECAUTIONS

2.5 Contraindications

All COVVI product users should initially be evaluated by their certified clinician to determine eligibility based on physical condition, muscle strength, and ability to effectively use the product. Following this, the product should then be fitted by a certified clinician, who is also responsible for providing occupational therapy on how to activate and operate the product, as well as adequate training on how to charge and clean it.

- Do **NOT** use the product without the integrated glove, as it protects the product from water ingress and other foreign bodies, which could damage the internal components and cause the product to fail.
- The product has been tested and certified with an IP44 rating, classifying the degree of protection against solids and water of the product to solid objects over 1mm in diameter and sprays and splashes from all directions. However, the wrist interface is not IP44 water or dust resistant.
- Do **NOT** submerge the product in water. Any damage caused by intentional submersion in water will not be covered under the warranty. If the glove is punctured, it will affect the IP44 rating of the product.
- Do **NOT** disassemble the product.
- Do **NOT** use any other glove from any other manufacturer. Only gloves sold by COVVI are compatible with the product. Cosmetic gloves from other manufacturers restrict the movement of the product, resulting in lower battery life, reduced grip strength and an increased internal temperature.
- 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 product can be potentially unsafe.
- Should the fingers and/or thumb move without an input, stop using the product immediately and contact your clinician.
- 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. Any damage caused by intentional harm or neglect will not be covered under the warranty.
- 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.

2.0 SAFETY PRECAUTIONS

- 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.
- The product is **NOT** suitable to support body weight on crutches; we recommend that the hand is **NOT** used with crutches.
- Before operating a vehicle with the product, local regulations should be checked, and the 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.
- Do **NOT** subject the product to impact from sharp-edged or pointed objects.
- Maintain extra caution when handling sharp objects.

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

2.6 Lifetime

The product is subject to natural wear and tear through interaction with the environment. The lifetime of the product will diminish or increase depending on the individual level of use. Only when the Instructions for Use are observed is it possible to achieve the maximum product lifetime, dependent on the level of product use.

2.7 Wrist Lamination

Ensure that the wrist is adequately laminated to the socket prior to use. Do not use the product if there are cracks in the lamination or if there is play between the socket and the Wrist Lamination Ring.

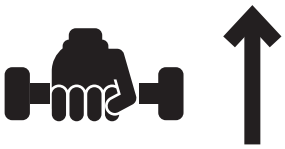
2.8 Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this Instructions for Use document. The manufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to improper use or unauthorised modification of the product.

3.0 TECHNICAL INFORMATION

Product Voltage	7V to 8.4V DC
Maximum Current Draw	5A (Max. Constant) / 7A (Max. peak, 50ms duration)
Maximum Finger Load Limit	16kg / 35 lbs

Maximum Loading Capacity of push-down force
90 kg / 198 lbs over the knuckles



Maximum Carrying Capacity picking weight up
30 kg / 66 lbs

Avoid pressure on thumb

***All conversions into lbs are rounded to the nearest whole number**

4.0 ENVIRONMENTAL CONDITIONS

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

5.0 CLEANING

- Switch off the product before 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 or Friction Wrist Base.
- Dry the product with a lint-free cloth and then allow it to air dry fully.
- The product can be cleaned three times per day on average.

6.0 STORAGE

When you are not using the product, store it in a cool, dry, safe place. Do not use, transport or store the product outside of the environmental conditions.

7.0 PRODUCT HANDLING INFORMATION

7.1 Connecting/Disconnecting The Product

These instructions only apply to the COVVI Hand if a Flex or Straight Wrist is installed

- Make sure the Power Supply is **OFF** before connecting/disconnecting the product to and from the prosthesis.
- Only 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

Please Note: The Wrist Plate marking may vary between variants.

7.0 PRODUCT HANDLING INFORMATION

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

- To connect the product to the socket, push and then twist the EQD into the wrist on the socket.
- To check that the product is properly connected, twist it in the socket and pull lightly. If it wobbles, it isn't properly connected.

- To disconnect the product from the socket, twist and pull it.
- If the product is not properly connected, you may experience BLE connectivity issues or App connectivity issues.

For fitment and removal of the COVVI Hand - Friction Wrist, please refer to the COVVI Hand - Friction Wrist Lamination and Fitment Guide:

www.covvi.com/wp-content/uploads/documents/Friction-Wrist-Lamination-Guide.pdf

7.0 PRODUCT HANDLING INFORMATION

7.2 Integrated Flex Wrist

The Flex Wrist can be used in the Flexible mode or Locked mode, which has three positions: 27 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.

-27° Extension **0° Neutral** **27° Flexion**

The product can also be manually rotated 360 degrees in the socket.

Please Note: The Flexion feature is **NOT** available when using the COVVI Hand - Straight Wrist or COVVI Hand - Friction Wrist.

7.3 Dorsal Button

The dorsal button has three 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 trigger, which must be mapped first in the COVVI Go App.
- A 10 second press resets the product if you experience Bluetooth connectivity issues.

7.0 PRODUCT HANDLING INFORMATION

7.4 Thumb Tap

The product has a novel feature called the thumb tap whereby you laterally tap the thumb, which activates the rocker switch in the base of the thumb and depending on the configuration, a certain action will happen. The default setup has the Non-Opposed Thumb Tap In and Opposed Thumb Tap Out mapped to the next table and previous table, respectively. However, this can be changed in the App to any of the other available actions. Essentially, it allows grip changes without the need for myo inputs.

Non-Opposed Thumb Tap In and Non-Opposed Thumb Tap Out are only available in non-opposed grips Key, Finger Point, Mouse, Column and Phone.

Opposed Thumb Tap Out and Opposed Thumb Tap In are only available in opposed grips Tripod, Power, Trigger and Glove.

Please Note: The thumb tap only works when the product is fully open.

The product is in a non-opposed position

The product is in an opposed position

7.0 PRODUCT HANDLING INFORMATION

7.5 Activating the Power Supply

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.

Press to show for 5 seconds

7.0 PRODUCT HANDLING INFORMATION

7.6 Charging the Power Supply

To charge the Power Supply, connect the Charger to the mains and the USB-C port on the Control Panel and turn on the power. It will now be charging. Please check the Control Panel connections with the battery before you connect the USB-C port on the Control Panel.

Please Note: We recommend you only use the COVVI USB-C Charger to charge the COVVI Power Supply.

When the system is charging, it will cycle through these screens

7.7 Residual Risk - Battery Depletion

Sudden battery loss may lead to the product shutting down, especially during critical activities such as holding objects. We advise you to monitor the battery level regularly by checking either the dorsal screen on the product or the screen on the Control Panel.

7.8 The Glove Kit

Replacement Glove Kits can be ordered that contain a new COVVI Glove, Dorsal Cover and Retention Ring. The fitting of this glove must only be performed by a trained clinician or a COVVI-certified prosthetist.

Glove Kit: Compatible with the COVVI Hand.

Glove Kit 2: Compatible with the COVVI Hand - Straight Wrist and COVVI Hand - Friction Wrist variants.

For replacement instructions, refer to:

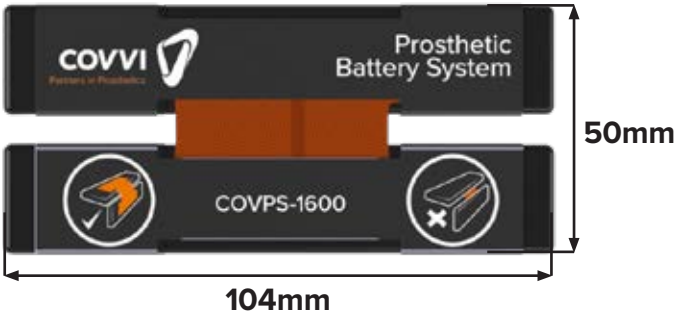
- www.covvi.com/wp-content/uploads/documents/Glove-Replacement-Guide-UK.pdf
- www.covvi.com/wp-content/uploads/documents/Glove-Fitment-Retention-Ring-Guide-UK.pdf
- How To Fit The COVVI Retention Ring (Video Tutorial) - www.youtube.com/watch?v=LSaApG4iXQk

7.0 PRODUCT HANDLING INFORMATION

7.9 System Specification for the COVPS-1600

Typical Battery Capacity	1600mAh
Nominal Voltage	7.4V
Maximum Current Draw	7A Peak
Humidity	Maximum 80% humidity, non-condensing
Charge Temperature Range	10°C to +45°C
Discharge Temperature Range	-20°C to +60°C

COVPS-1600 (Unfolded)



Control Panel

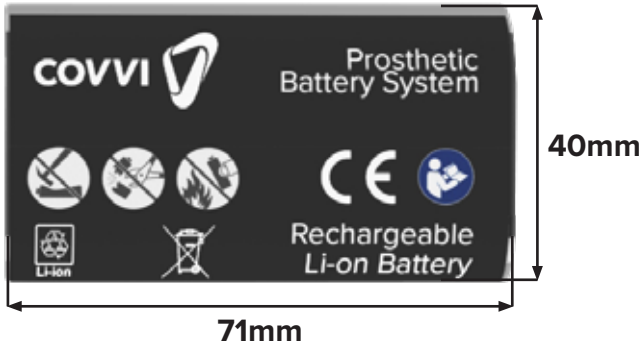
COVPS-1600 (Folded)

7.0 PRODUCT HANDLING INFORMATION

7.10 System Specification for the COVPS-2600

Typical Battery Capacity	2600mAh
Nominal Voltage	7.4V
Maximum Current Draw	8A Peak
Humidity	Maximum 80% humidity, non-condensing
Charge Temperature Range	10°C to +45°C
Discharge Temperature Range	-20°C to +60°C

COVPS-2600



Control Panel

7.0 PRODUCT HANDLING INFORMATION

7.11 E-Paper Screen

When you turn the product on, the E-Paper screen will display the following:

It will then display the following:

7.0 PRODUCT HANDLING INFORMATION

When Auto Grip is enabled, if the product senses an object is slipping it reapplies a small continuous force to grasp the object. Auto Grip works in Power Grip, Tripod Grip, Precision Open and Precision Closed.

Auto Relax moves the product to a relaxed position after a period of inactivity. A user input signal will cause the product to revert to its previous grip, and the icon will be removed.

Both of these features can be enabled and set up by the clinician upon the user's request, or whenever a clinician finds it useful for a particular user.

A short press to the dorsal button (under two seconds) puts the product into Standby Mode, whereby user inputs from the electrodes have no effect on the product. Pressing the dorsal button again will exit Standby Mode, and the icon will be removed.

The CAN bus icon is displayed whenever the product is connected to a CAN-enabled device, such as the COAPT Gen2 system.

Please Note: This icon is only displayed once Bluetooth has turned off (the two icons share the same location on the display).

The warning icon shows that the product has detected a fault. The screen will also display text to identify what the fault is, for example, 1 of 1 Fault Thumb Sensor.

7.0 PRODUCT HANDLING INFORMATION

If this message appears, please disconnect the product and allow it to cool down.

If this message appears, please disconnect the product and allow it to dry in a warm, dry environment.

If the warning icons and messages do not disappear, please get in contact with your clinician and COVVI Customer Services.

The following notifications will appear when you select to update the firmware in the COVVI Go App. The update downloads from the App to the product, and then it updates the product. Do not power off hand during the update; this will cause product damage.

8.0 GRIP PATTERNS

8.1 Opposed Grips

You can find more opposed grips in the User Grips section of the App.

Power Grip

Precision Closed Grip

Precision Open Grip

Tripod Grip

Trigger Grip

Glove Grip

8.0 GRIP PATTERNS

8.2 Non-Opposed Grips

You can find more non-opposed grips in the User Grips section of the App.

Finger Point Grip

Tap Grip

Relaxed Grip

Mouse Grip

Column Grip

Key/Card Grip

9.0 WARRANTY

9.1 24-Month Manufacturer's Warranty

The product has a 24-month manufacturer's warranty included, and the glove has a 3-month manufacturer's warranty included, which takes effect from the date of invoice.

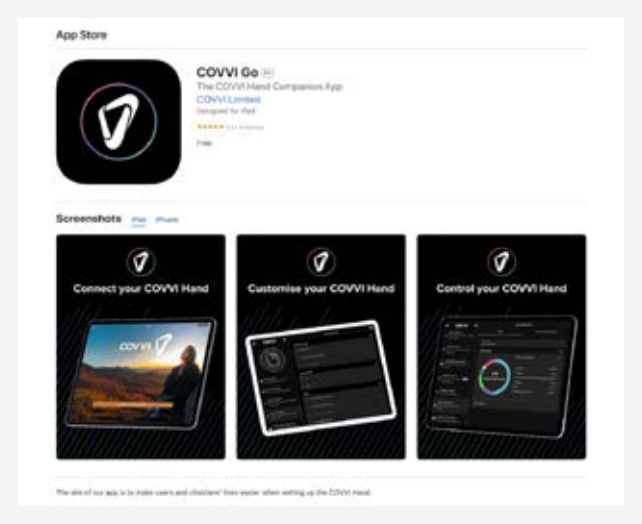
All COVVI products are subject to evaluation for warranty. COVVI is not responsible for normal wear, and/or damage caused by excessive force and/or excessive usage beyond the technical design and/or beyond its reasonable means. COVVI warrants its products against defects in material and workmanship within the warranty period.

10.0 APP SETUP

10.1 Registration

In order to register your COVVI Go Account, start by downloading our official App via the Apple iOS Store or the Google Play Store. Open the COVVI Go App, click on ‘Get Started’, then ‘Sign Up’. Choose either ‘Prosthetic User’ or ‘Clinician’ and then click on ‘Next’ to fill out all the fields that are relevant to your account type. Once you complete all the required sections, you will receive an email with a link to validate your email and set your password. After this, you will be able to log in to the App.

Please Note: If your account is in Restricted Mode, certain features will be disabled within the App. Please speak to your clinician if you would like to change this.



10.2 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 product. If you fail to connect before 60 seconds, turn the power to the product off and back on again.

There is an option to reset your password in case you forget it.

If you experience Bluetooth connectivity issues, please first reset the product by pressing the dorsal button for 10 seconds. If the connectivity issues persist, please ensure the product doesn’t have a low battery and that you don’t have Bluetooth interference.

10.3 Configuration

The product has a default configuration saved but you can make changes to the configuration to programme it to suit your daily needs.

10.0 APP SETUP

10.4 Input Settings

Please Note: We recommend that your clinician only make changes in this section. Any further changes should be approved by them.

In the Advanced Input Graph Settings, you can automatically calibrate the product to the input signals you can produce, and in the Input Settings, you can map the On and Max thresholds to respond to these input signals, to allow you to comfortably operate the product.

- The On threshold is the signal strength required for the product to move.
- The Max threshold is the signal strength required for the product to move at full speed.

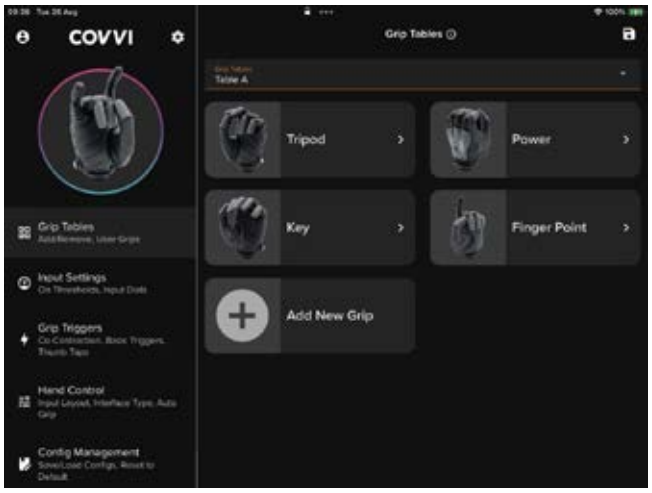
You can view these thresholds on either the dials or a graph.

Please Note: If you map co-contraction, an additional threshold will appear for adjustment.

Residual Risk - Product Malfunction

In some cases, the product may have trouble detecting muscle signals due to external environmental factors such as sweating. If this occurs, clean the electrodes in the socket with a damp lint-free cloth.

10.5 Grip Tables



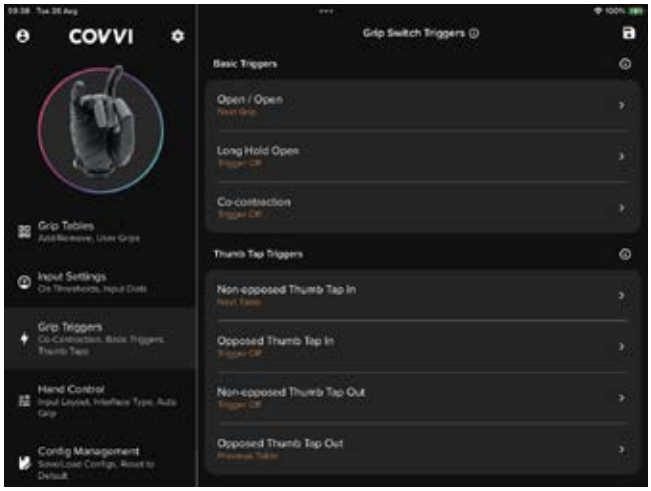
There are four tables available, each of which can be populated with up to six grips. All tables can be empty apart from Table A, which must always have one grip in: the primary grip. You can separate grips between tables for different activities of daily life, for example, one table for grips used at home, another for grips used at work.

To add a grip, select the table you would like to populate and click on ‘Add New Grip’. Choose the desired grip from the list and then click back. 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 product closing and opening in that grip.

To remove a grip, click on it and then select ‘No Grip’. The grip will no longer appear in the table. There is the option for you to save these changes to any configurations saved in the Config Library, or by adding a new config, by clicking on the save icon at the top of the screen.

10.0 APP SETUP

10.6 Grip Triggers



There are 13 available grip triggers, 3 myo inputs and 10 passive input triggers on the product, all listed below. Clicking on any grip trigger brings up the list of actions. The action assigned to each grip trigger is shown in orange underneath it. You can assign a grip trigger once but the same action to multiple grip triggers.

The available grip triggers with myo-inputs are:

1. An open/open signal
2. A long hold open signal
3. A co-contraction signal

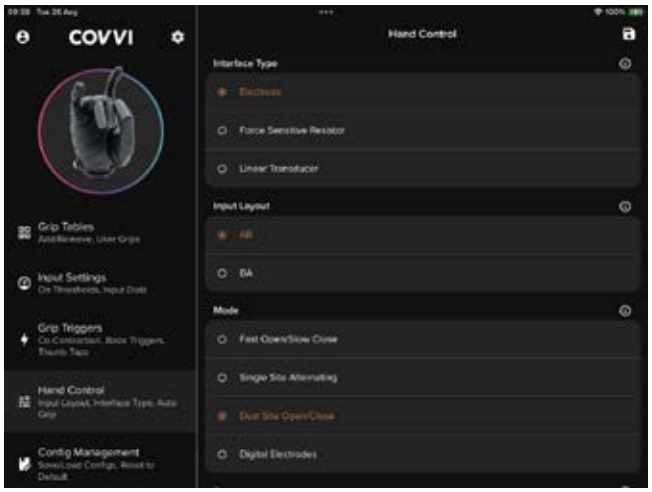
The available grip triggers with features on the product are:

1. Non-Opposed Thumb Tap In (tapping the thumb inwards from a non-opposed position)
2. Non-Opposed Thumb Tap Out (tapping the thumb outwards when in a non-opposed position)
3. Opposed Thumb Tap In (tapping the thumb inwards when in an opposed position)
4. Opposed Thumb Tap Out (tapping the thumb outwards from an opposed position)
5. Dorsal Button Hold
6. Thumb Tip Hold (sensor on the thumb)
7. Index Finger Tip Hold (sensor on the index finger)
8. Middle Finger Tip Hold (sensor on the middle finger)
9. Ring Finger Tip Hold (sensor on the ring finger)
10. Little Finger Tip Hold (sensor on the little finger)

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.

10.0 APP SETUP

10.7 Hand Control



In this section, you have all the features you can program to adjust the performance of your product.

The available options are:

1. Interface Type - Choose what control interface you are using.
2. Input Layout - Order the open and close signals.
3. Operating Mode - One mode available for dual site control (dual site open/close), two modes available for single site control (fast open/slow close or single site alternating), and digital electrodes for pattern recognition control.
4. Beep - Audible alert for activity; can be set for all functions, power on only, or turned off.
5. Vibration - Vibratory alert; assignable like the beep.
6. Grip Strength - Set grasp force between 20% and 100%.
7. Grip Force Mode - Choose proportional (grip matches signal strength) or fixed (grip strength fixed to a set level).
8. Long Hold Open Time - Set how long an open signal must be held to activate the long hold trigger.
9. Open/Open Time - Set time for sending a second open signal to trigger open/open.
10. Co-Contraction Time - Time both inputs must pass thresholds after the on threshold.

Please Note: The above times only need to be adjusted if you map the triggers in the Grip Triggers section.

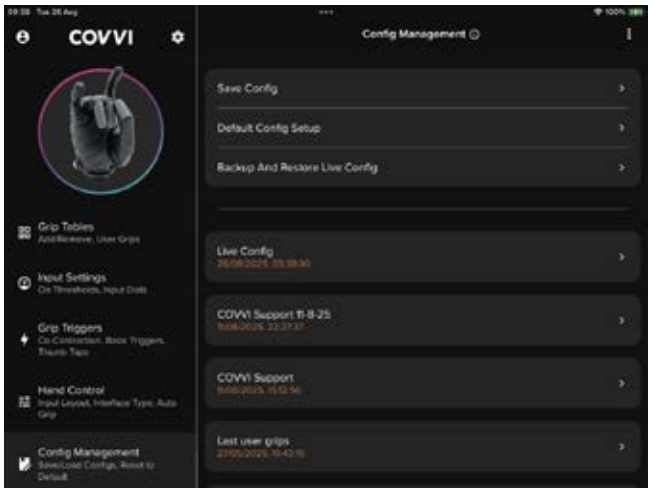
11. Fast Open/Slow Close Time - A signal sent within the time you set is interpreted as an open signal; a signal sent after the time is interpreted as a close signal.
12. Direction Change Time - A signal sent within the time you set will keep the direction of the product the same; a signal sent after the time will change its direction.

Please Note: The above time can only be adjusted if you use single-site alternating.

13. Input Speed (A & B) - Set max digit speed from 50% to 100%.
14. Digit Hold Time - Set duration (0.5-5s), pressure must be applied to activate the grip.
15. Auto Relax - Set inactivity time before the product moves to Relaxed Grip.
16. Auto Grip - When activated, if the fingers sense an object is starting to slip, they reapply a small continuous force or pulse to gently grasp it. It monitors the grip every half a second. (Works in Power Grip, Tripod Grip, Precision Open and Precision Closed Grips only.)
17. Switch to Primary Grip - Set inactivity time before the grip resets to the primary (first in Table A).
18. Thumb Mode - You can set the position of the thumb to latched or dynamic mode. In Latched Mode, the thumb is positioned in either a non-opposed or opposed position according to the selected grip. In Dynamic Mode, the thumb rotates to a mid-position when the product is fully opened and automatically swings into the correct position when a close signal is detected.

10.0 APP SETUP

10.8 Config Management



In Config Management, you have three options:

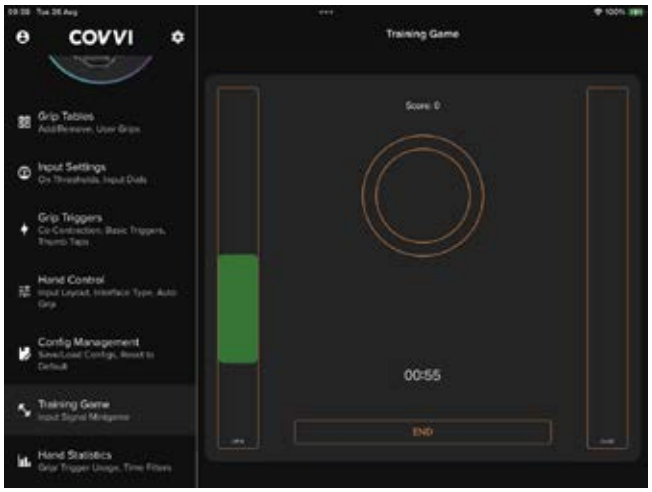
1. Save Config allows you to save a new configuration to the cloud or overwrite an existing config, so there is always a backup available. If a config is saved with a name that already exists, a confirmation message will appear to ask if you want it to be overwritten.
2. Default Config Setup lets you choose COAPT for if you are using a COAPT system with your prosthesis.
3. Backup and Restore Live Config is to transfer configurations between devices.

Underneath these options, there is the Config Library, where you can see all configurations that you have saved to the product. To restore a configuration, click on the desired one and then on Restore.

10.0 APP SETUP

10.9 Training Game

This is a resource for you to practice your open and close signals. The aim of the game is to get your signal into the green box and hold it for the necessary time. You can choose an easy, medium, or hard mode.



10.10 Hand Statistics

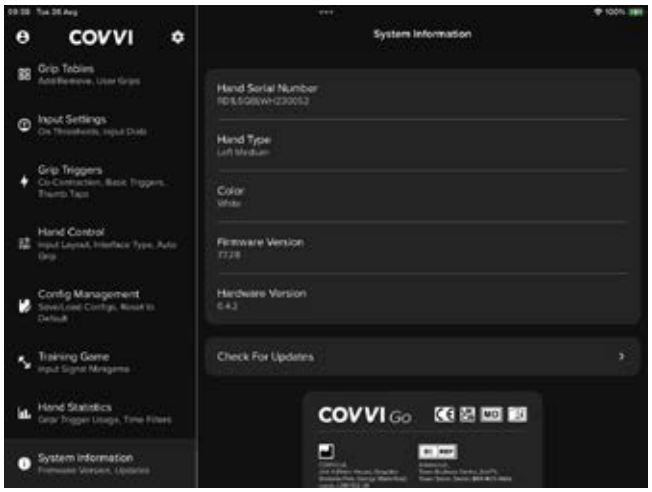
This section shows you the top five grips and grip triggers you use, which can be filtered by month or year. In View More, it shows you the complete stats history for each grip and grip trigger. Selecting one, it shows you the detailed history of this information, displayed on a graph.

It is advised to connect the product to the App more frequently in order to provide more accurate statistics.

10.0 APP SETUP

10.11 System Information

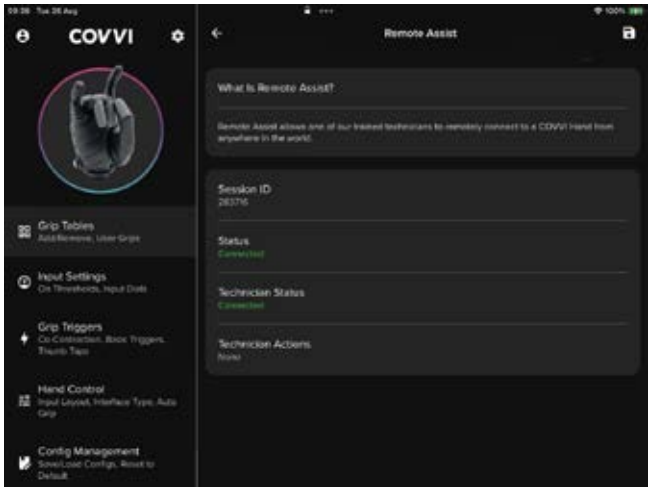
In the last section of the App, it shows you basic information about the product, including its serial number and underneath there is the option to ‘Check For Updates’, where you can check if there is a remote software update available.



10.12 Remote Assist

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 the product to make live adjustments and perform some analysis and troubleshooting.

We can **ONLY** connect to your product if you notify your clinician and/or COVVI, and a meeting time is confirmed. Connect to your product, 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 product. You will know when we are connected, as under technician status, it will say connected in green.



11.0 REGULATORY COMPLIANCE

The product complies with the relevant international regulations and standards to ensure the highest level of safety and performance.

The CE mark may be applied on packaging, accompanying literature, or an enclosure, rather than directly on the product itself. This mark indicates that the product meets the regulatory requirements for medical devices in the European Union under the Medical Device Regulation (MDR 2017/745).

In addition, the product is in full compliance with US FDA regulations for medical devices, ensuring its safety and efficacy in the United States market.

All individual products are marked to indicate their compliance with both EU MDR and US FDA regulatory requirements.

Applicable Harmonised Regulations

EU Regulations:

- MDR 2017/745 (Medical Device Regulation)
- RoHS Directive 2011/65/EU (Restriction of Hazardous Substances)
- WEEE Directive 2012/19/EU (Waste Electrical and Electronic Equipment)

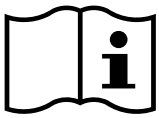
US Regulations:

- US FDA 21 CFR Part 820 (Quality System Regulation)

12.0 SYMBOLS USED

Below are the symbols used to convey information about the COVVI product which is derived from standards EN 980:2008, ISO 15223, IEC 60417 and IEC 60878:

Indicates that the product conforms with the essential requirements and provisions of MDR 2017/745.



Indicates that the user should refer to the instruction manual or consult the instructions for use before operating the medical device. It directs the user to read the accompanying documentation for safety, operational, or maintenance instructions.

Identifies the entity responsible for the design, production, packaging, and labelling of the product.

A unique identifier assigned to each product that differentiates it from others. Used for tracking and recalls.

A unique identifier assigned to each product that differentiates it from others. Used for tracking and recalls.

Indicates that the product is part of a specific lot or batch, and the accompanying number identifies that particular lot or batch for tracking purposes.

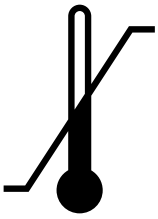
Indicates that the medical device is a specific product from the manufacturer’s catalogue, and the accompanying number identifies that particular product for reordering or reference purposes.

Indicates that the product is classified as a medical device under relevant regulatory requirements, such as EU Medical Device Regulation (MDR) 2017/745. It helps distinguish medical devices from other products.

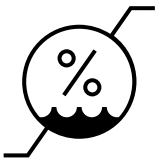
Indicates that the product must be protected from water or moisture exposure, which could damage the internal components.

12.0 SYMBOLS USED

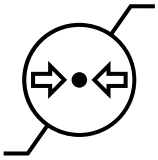
Indicates that the product should not be disposed of with regular household waste and must comply with WEEE regulations for proper electronic waste disposal.



Specifies the temperature range within which the product can be safely stored or operated.



Indicates the range of humidity within which the product can be safely exposed or operated.



Specifies the range of atmospheric pressure to which the product can be exposed.

Indicates the name and address of the Authorised Representative in the European Community (EC) for the medical device. The authorised representative acts on behalf of the manufacturer in ensuring that the manufacturer meets regulatory requirements in Europe, especially for non-EU manufacturers.

Indicates the name and address of the Authorised Representative in the Switzerland for the medical device. The authorised representative acts on behalf of the manufacturer in ensuring that the manufacturer meets regulatory requirements in Switzerland.

The UKCA marking is the conformity marking used for products being placed on the market in Great Britain.

12.0 SYMBOLS USED

Indicates that the electronic device complies with the FCC regulations regarding electromagnetic interference (EMI) and radio frequency emissions, as defined under Title 47 CFR Part 15 (and other applicable parts)

Indicates that the product has a Type BF (Body Floating) applied part that provides a degree of protection against electric shock.

Non-ionising radiation

Li-ion

Indicates that the product contains a Lithium-Ion (Li-ion) battery and must be recycled properly. It is a general environmental symbol that emphasizes the need to dispose of the battery in an environmentally responsible manner.

This symbol warns against crushing the product or battery. Crushing the product could cause internal damage, including potential battery rupture, which may lead to fire or explosion.

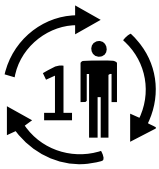
Indicates that the product or battery should not be disassembled. Opening or tampering with the internal components can result in dangerous conditions, such as exposure to chemicals, electric shock, or fire hazards.

Warns against exposing the battery or product to fire or high temperatures. Doing so could cause the battery to overheat, catch fire, or even explode.

A line with a solid line above a dashed line, indicating that the product operates on direct current (DC).

A battery icon with a lightning bolt or an arrow, indicating that the product or battery is charging or capable of being recharged.

12.0 SYMBOLS USED



Indicates that the medical device is intended for use by a single patient, but for multiple times.

Indicates to not load or transport package if damaged

Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information

Indicates that the packaging material or product can be collected, processed, and reused in recycling systems rather than disposed of as waste. The symbol encourages proper disposal through recycling channels according to local regulations.

Indicates that the user must consult the instructions for use (IFU) or user manual for important information on safe and effective use, warnings, precautions, or installation and maintenance procedures.

Indicates that the product conforms to the applicable Technical Regulations of Ukraine, as established by the Cabinet of Ministers of Ukraine, and that the manufacturer has successfully completed the required conformity assessment procedure. It confirms that the product meets essential safety and performance requirements and can be lawfully placed on the market of Ukraine.

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

Japan: 005-101150

South Korea: MSIP-CRM-mcp-BM71BLES1FC2

CCAN16LP0011T7

13.0 PRODUCT PROBLEM REPORTING

In the event of any serious incident involving the product, it is essential that it is reported promptly to the manufacturer and the competent authority of the member state in which the user is established, to maintain the highest standards of safety and compliance. Please report any incident to COVVI Ltd. or COVVI USA INC by emailing customerservice@covvi.com.

Please ensure you include the serial number of the product(s) affected when you reach out to us, which can be found on the base of the device, starting with ‘CV’ and continuing clockwise. If you have a loaner or demo hand, then this serial number begins with ‘LN’.

Ensuring that any issues are reported helps maintain the highest standards of safety and compliance.

Flex Wrist

Straight Wrist

Friction Wrist

14.0 DISPOSAL

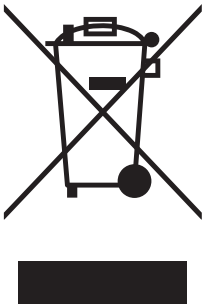
COVVI products should not be disposed of with regular household waste. Proper disposal of COVVI products will avoid having a detrimental impact on health and the environment. For more details on collection and proper disposal, please check with your local authority.

COVVI packaging should be disposed of through your local facilities. By disposing of the packaging in the proper manner, you help to avoid possible hazards for the environment and public health. Observe national registration requirements for importers according to the EU WEEE Directive 2012/19/EU

All the components of this product and articles contained within have been chosen and evaluated in accordance with compliance with the EU RoHS directive 2011/65/ EU: The products are produced with restricted use of hazardous substances to protect the environment.

All the components of this product and articles contained within have been chosen and evaluated in accordance with compliance for the Regulation (EC) 1907/2006 of the European Parliament, “Registration, Evaluation, and Authorization of Chemicals (REACH): The product and articles contained within **DO NOT CONTAIN** any of the 247 REACH - Substances of Very High Concern (SVHC) as updated by ECHA on January 21, 2025.

For the full declaration of conformity statements, please use the links below view the documents:
www.covvi.com/about/declaration-of-conformity



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CE

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EC REP
Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

CH REP
Johner Medical Schweiz GmbH, Tafelstattstrasse 13a, 6415 Arth, Switzerland

v1.3.1 | February 2026