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' 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 with Flex Wrist, Straight Wrist, or Friction Wrist.

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

COVVI Go 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 COVVI Hand 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 COVVI Hand 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 COVVI Hand.

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

2.3 Indications

- The COVVI Hand 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 COVVI Hand is for exclusive use by the owner.
- The COVVI Hand should not be used to carry weight outside the specified load limit stated in the technical information section of the Technical Manual.
- The COVVI Hand should not be used, transported, or stored outside the specified boundaries stated in the mental conditions.
- It is recommended to service the COVVI Hand 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 Hand users should initially be evaluated by their certified clinician to determine eligibility based on physical condition, muscle strength, and ability to effectively use the COVVI Hand. Following this, the hand should then be fitted by a certified clinician, who is also responsible for providing occupational therapy on how to activate and operate the COVVI Hand, as well as adequate training on how to charge and clean it.

- Do **NOT** use the COVVI Hand without the integrated glove, as it protects the device from water ingress and other foreign bodies, which could damage the internal components and cause the COVVI Hand to fail.
- The COVVI Hand has been tested and certified with an IP44 rating, classifying the degree of protection against solids and water of the COVVI Hand 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 COVVI Hand 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 COVVI Hand.
- Do **NOT** disassemble the COVVI Hand.
- Do **NOT** use any other glove from any other manufacturer. Only gloves sold by COVVI are compatible with the COVVI Hand. Cosmetic gloves from other manufacturers restrict the movement of the hand, resulting in lower battery life, reduced grip strength and an increased internal temperature.
- Do **NOT** attempt to use the COVVI Hand 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 COVVI Hand immediately and contact your clinician.
- Do **NOT** use the COVVI Hand 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 COVVI Hand when in those environments.
- Do **NOT** subject the COVVI Hand to intentional excessive impacts. Any damage caused by intentional harm or neglect will not be covered under the warranty.
- Do **NOT** expose the COVVI Hand to an open flame.
- Do **NOT** use the COVVI Hand to operate a firearm.

2.0 SAFETY PRECAUTIONS

- Do **NOT** expose the COVVI Hand to chemicals such as solvents, acids, alkalis, corrosive substances, detergents, and similar chemicals, as this could damage the components in the hand.
- The COVVI Hand 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 COVVI Hand being submerged in a liquid must be avoided. These include, but are not limited to: diving, swimming, snorkelling, surfing, kayaking and canoeing.
- The COVVI Hand 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 COVVI Hand, local regulations should be checked, and the insurance company must be notified. We recommend that the hand 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 COVVI Hand 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 COVVI Hand is subject to natural wear and tear through interaction with the environment. The lifetime of the COVVI Hand 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 COVVI Hand 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 COVVI Hand if there are cracks in the lamination or if there is play between the socket and the Wrist Lamination Ring.

2.8 Liability

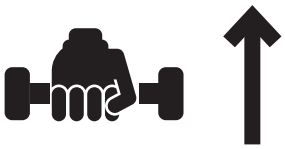
The manufacturer will only assume liability if the COVVI Hand is used in accordance with the descriptions and instructions provided in this Instructions for Use document. The manufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to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

3.0 TECHNICAL INFORMATION

COVVI Hand 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 COVVI Hand before cleaning.
- Clean the COVVI Hand 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 COVVI Hand with a lint-free cloth and then allow it to air dry fully.
- The COVVI Hand can be cleaned three times per day on average.

6.0 STORAGE

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

7.0 PRODUCT HANDLING INFORMATION

7.1 Connecting/Disconnecting The COVVI Hand

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 COVVI Hand to and from the prosthesis.
- Only turn the power on once the COVVI Hand is properly connected to the prosthesis.

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

Remove protective cap

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



If the ball bearings are locked out radially, the COVVI Hand will not plug in

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

7.0 PRODUCT HANDLING INFORMATION

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



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



- To disconnect the COVVI Hand from the socket, twist and pull it.
- If the COVVI Hand 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 COVVI Hand 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 COVVI Hand 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 two seconds activates the Grip Trigger, which must be mapped first in COVVI Go.
- A 10 second press resets the COVVI Hand if you experience Bluetooth connectivity issues.



7.0 PRODUCT HANDLING INFORMATION

7.4 Thumb Tap

The COVVI Hand 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 COVVI Hand is fully open.



The COVVI Hand is in a non-opposed position



The COVVI Hand 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 COVVI Hand 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 COVVI Hand 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:

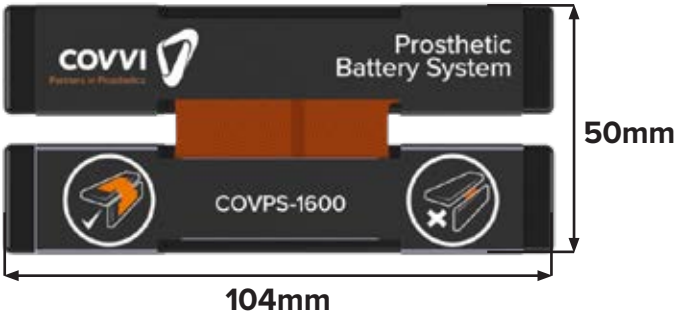
- www.covvi.com/wp-content/uploads/documents/Glove-Replacement-Guide-UK.pdf
- www.covvi.com/wp-content/uploads/documents/Glove-Fitment-Retention-Ring-Guide-UK.pdf
- How To Fit The COVVI Retention Ring (Video Tutorial) - www.youtube.com/watch?v=LSaApG4iXQk

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)

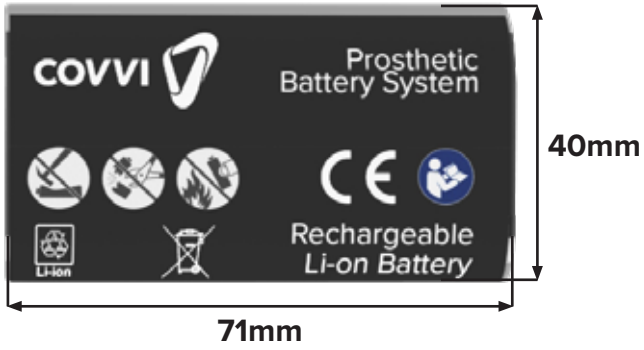


7.0 PRODUCT HANDLING INFORMATION

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 COVVI Hand 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 COVVI Hand 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 COVVI Hand to a relaxed position after a period of inactivity. A user input signal will cause the hand 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 COVVI Hand into Standby Mode, whereby user inputs from the electrodes have no effect on the hand. Pressing the dorsal button again will exit Standby Mode, and the icon will be removed.

The CAN bus icon is displayed whenever the COVVI Hand 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 COVVI Hand 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 COVVI Hand and allow it to cool down.



If this message appears, please disconnect the COVVI Hand 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 COVVI Go. The update downloads from the app to the COVVI Hand, and then it updates the COVVI Hand. Do not power off hand during the update; this will cause 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 COVVI Hand 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.

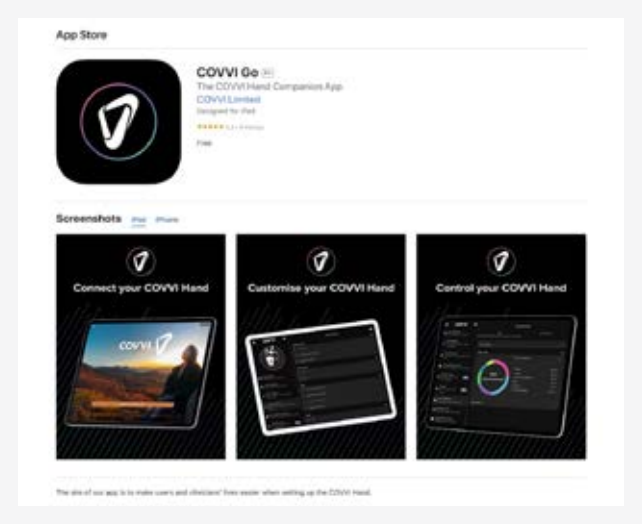
All COVVI products are subject to evaluation for warranty. COVVI is not responsible for normal wear, and/or damage caused by excessive force and/or excessive usage beyond the technical design and/or beyond its reasonable means. COVVI warrants its products against defects in material and workmanship within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

When registered as a User, these accounts will automatically be set to ‘Restricted Mode’, which limits the level of access available on COVVI Go. An account can be de-restricted by an associated Clinician on the COVVI Go app or Web Portal and, where appropriate, can also be actioned by authorised COVVI personnel on request.



10.0 APP SETUP

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.

Once you have logged in, the app will automatically begin searching for your hand. If there is only one COVVI Hand in range, then a button will appear that allows you to connect. If multiple COVVI Hands are in range, each will show separately with the hand's serial indicating which hand will be connected to.

If you fail to connect before 60 seconds, turn the power to the COVVI Hand off and back on again. Please ensure that the Bluetooth on your device is enabled, and you have accepted the permissions needed for the app.

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

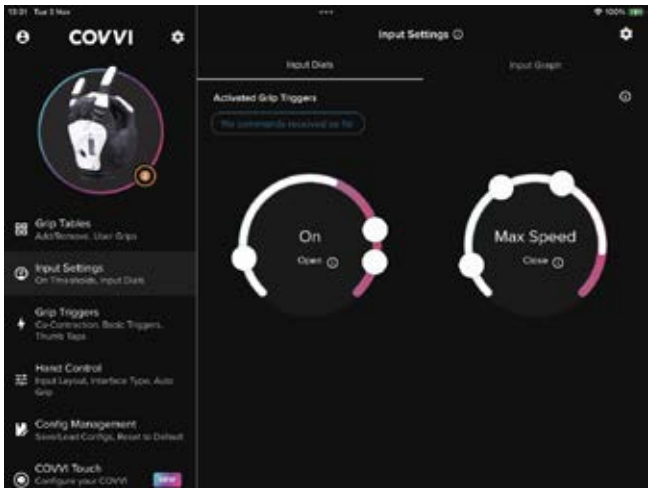
If you experience Bluetooth connectivity issues, please first reset the COVVI Hand by pressing the dorsal button for 10 seconds. If the connectivity issues persist, please ensure the COVVI Hand doesn't have a low battery and that you don't have Bluetooth interference.

10.3 Configuration

The COVVI Hand 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 Input Settings, you can automatically calibrate the COVVI Hand to the input signals you can produce, as well as map the 'On' and 'Max' thresholds to respond to these input signals, to allow you to comfortably operate the COVVI Hand.

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

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

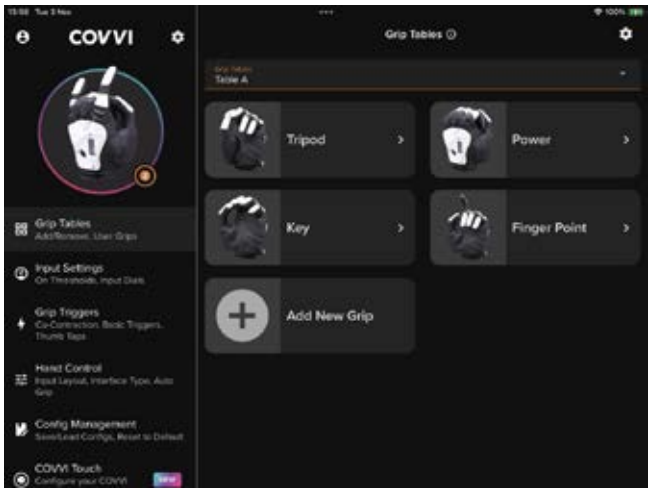
Please Note: If you map co-contraction, an additional threshold will appear for adjustment.

Residual Risk - Device Malfunction

In some cases, the COVVI Hand 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.

10.0 APP SETUP

10.5 Grip Tables



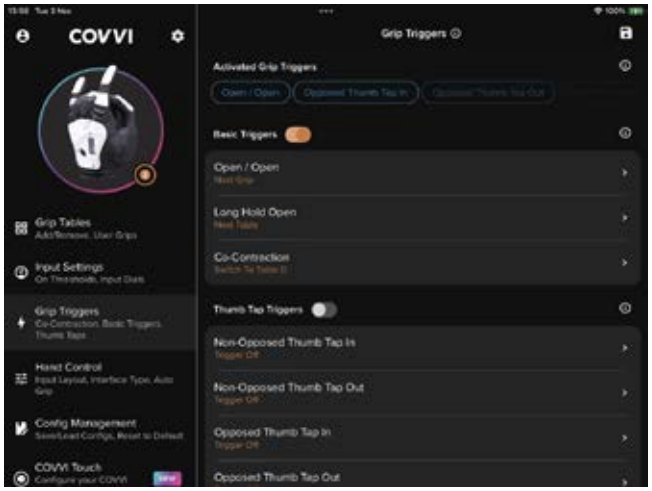
There are four tables available, each of which can be populated with up to six grips. All tables can be empty apart from Table A, which must always have one grip set as the hand's primary grip. You can separate grips between tables for different activities of daily life, for example, one table for grips 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 on the back arrow to return to the table. 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 COVVI Hand performing the selected 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 COVVI Hand, all listed below. Clicking on any Grip Trigger brings up the list of actions. The action assigned to each Grip Trigger is shown in copper underneath it. You can only assign a single action to a specific Grip Trigger; however, the same action can be set to multiple Grip Triggers if you desire.

The available Grip Triggers with myo-inputs are:

1. An Open/Open signal
2. A Long Hold Open signal
3. A Co-Contraction signal

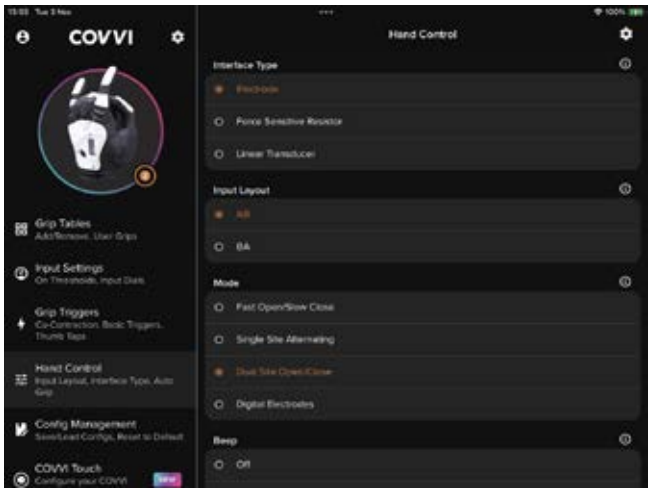
The available Grip Triggers with features on the COVVI Hand are:

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, Toggle Auto Grip, Toggle COVVI Touch Enabled and Toggle COVVI Touch Repeat.

10.0 APP SETUP

10.7 Hand Control



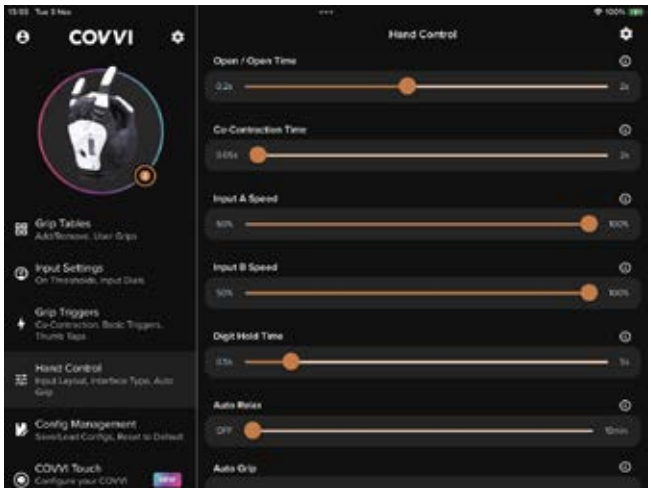
In this section, you have all the features you can program to adjust the performance of your COVVI Hand.

The available options are:

1. Interface Type - Choose what control interface you are using.
2. Input Layout - Order the open and close signals.
3. 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.

10.0 APP SETUP



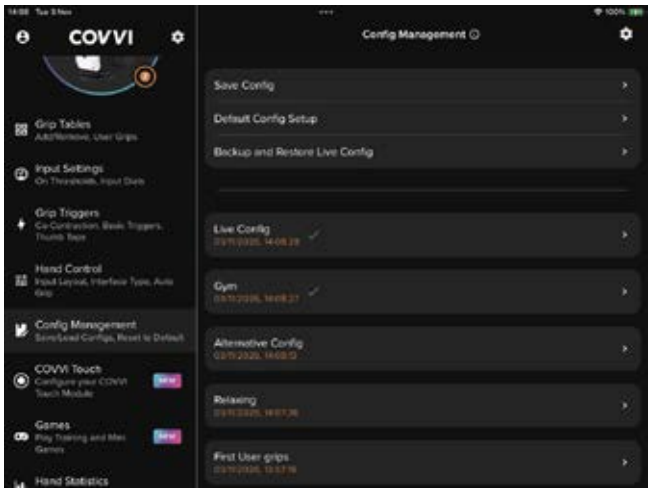
11. Fast Open/Slow Close Time - A signal sent within the time you set is interpreted as an open signal; a signal sent after the time is interpreted as a close signal.
12. Direction Change Time - A signal sent within the time you set will keep the direction of the COVVI Hand the same; a signal sent after 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 COVVI Hand 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 COVVI Hand is fully opened and automatically swings into the correct position when a close signal is detected.

10.0 APP SETUP

10.8 Config Management



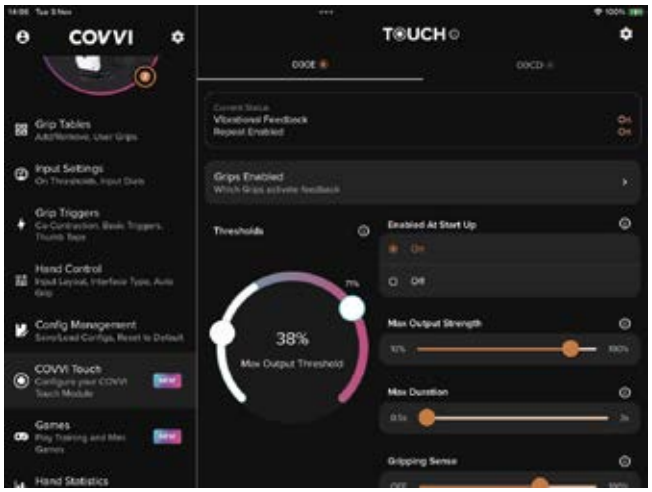
In Config Management, you have three options:

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 allows you to select a COVVI configuration from a range of options, including configurations that are compatible with third-party control systems, such as COAPT.
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 COVVI Hand. To restore a configuration, click on the desired one and then on ‘Restore’.

10.0 APP SETUP

10.9 COVVI Touch



COVVI Touch works in tandem with the COVVI Hand to produce vibrational feedback, which is sent to a user's prosthetic socket when their COVVI Hand comes in contact with an object.

With sensors already present in each digit of the hand, COVVI Touch unlocks the technology for a new purpose - letting users know when their COVVI Hand is touching or holding an object without the need to rely solely on visuals. This provides a better sense of spatial awareness and grasp when handling objects. The more fingertips that come into contact with an object when clasping, the stronger the touch sensing feedback will be.

Settings can be adjusted in this section of the app for elements like deciding which grips to receive feedback in, the strength of the vibration, and how the feedback is relayed (a single pulse, continuous vibration when in contact, or a recurring pulse).

Each COVVI Touch system is identified by its serial number within the app, where the configuration for each system is saved alongside the associated COVVI Hand. Where two COVVI Touch systems are in use, the app allows configs for each system to be saved and swapped independently.

To restore a COVVI Touch config, navigate to the Configuration Management section, select the desired config and press 'Restore'. This will restore the COVVI Hand and COVVI Touch system(s) to the selected config. COVVI Touch Systems can also be restored to factory settings by selecting 'Reset to Default'.

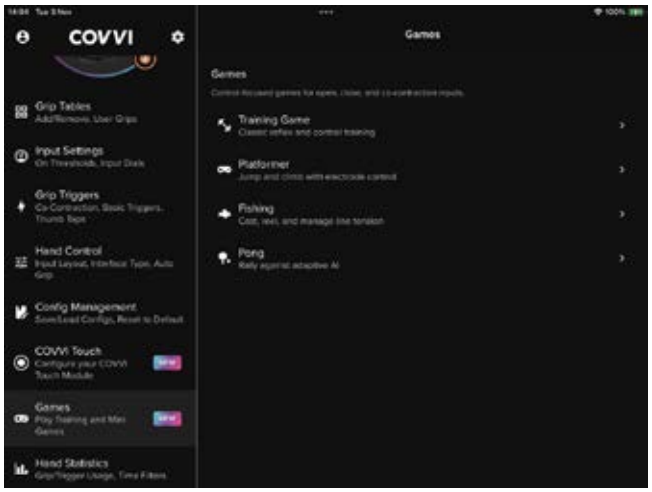
Please Note: COVVI Touch is not compatible when fitted with the COVVI Hand Friction Wrist. It can only be installed on prosthetic systems that feature the COVVI Hand, with either a Flex Wrist or a Straight Wrist.

For more information about being fitted with COVVI Touch, please visit our website: www.covvi.com/covvi-hand/covvi-touch

10.0 APP SETUP

10.10 Games

This section provides you with a range of training programs to practice different operations of the COVVI Hand. For example, our Training Game is focused on fine-tuning your open and close signals by holding a certain signal within a fixed area for different lengths of time. All the games have additional options to customise your experience, as well as multiple difficulty options, so you can build up your competency with the COVVI Hand at your own pace.



10.11 Hand Statistics

This section displays a range of useful statistics about the COVVI Hand. You can see the top five Grips and Grip Triggers you've used in the current month, but this can be filtered to show other periods of time as well.

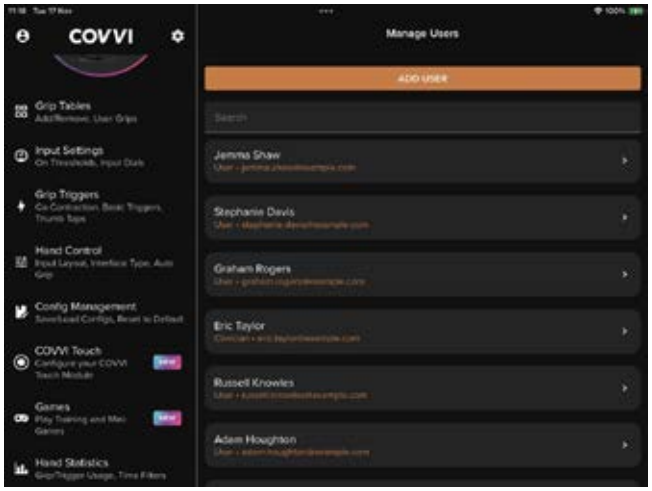
By pressing 'View More', you can see the complete stat history for each individual Grip and Grip Trigger. Selecting any one of these then shows you the detailed history of this information, displayed on a graph.



10.12 Manage Users

This section is only available for accounts with Clinician-level access or above. Here you can add and view the details of different users connected to your account, and change a range of options, such as their name, role, address and whether Restricted Mode is enabled or not. You can also see the devices associated with a user, as well as view their saved configs, with the option to load previous configs to the currently connected device to help with making any necessary changes.

These settings and options are also accessible to view and edit in the COVVI Web Portal.

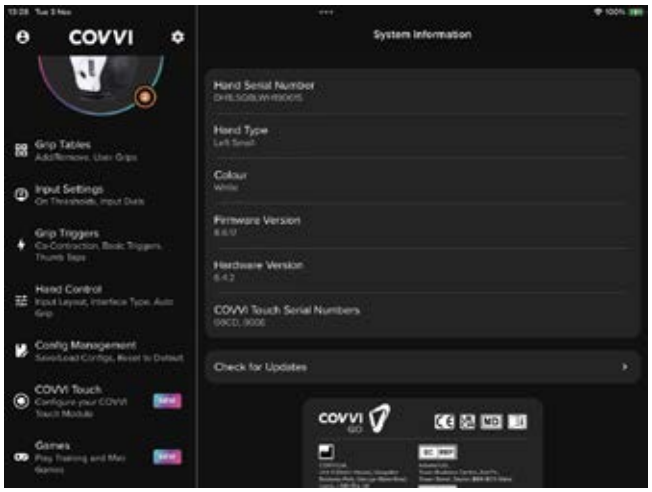


10.0 APP SETUP

10.13 System Information

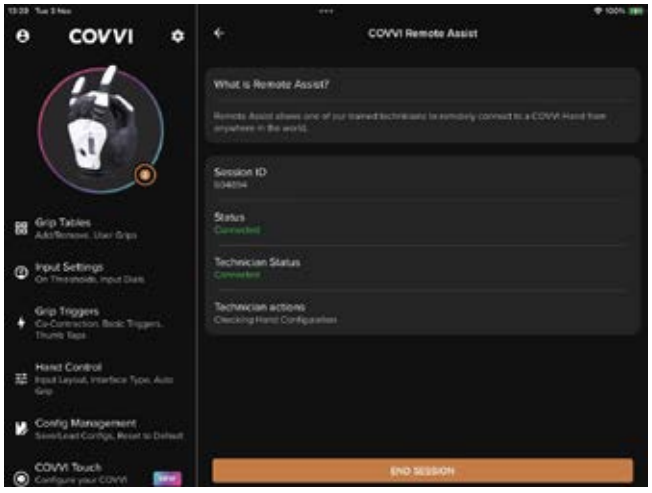
In this section of the app, you can find basic information about the COVVI Hand, including the hand's Serial Number and the current Firmware Version.

There is also the option to 'Check For Updates', which will look to see if there are any software updates that are currently available. If there are any software updates, the app will then guide you through this process of updating.



10.14 Remote Assist

From the main menu of the app, you can access the Remote Assist feature by tapping the 'Gear' icon in the top right corner, and then selecting ' COVVI Remote Assist' from the Console. This feature allows you to request configuration changes or technical support should you ever experience an issue with your hand. A trained COVVI technician can connect to the COVVI Hand from anywhere in the world to make real-time adjustments, as well as perform any configuration analysis and troubleshooting.



Please Note: We can **ONLY** connect to your COVVI Hand if you notify your clinician and/or COVVI, and a meeting time is confirmed. Ensure that you keep the window open in the app while we connect to your hand. You will know when we are connected, as under technician status, it will say 'Connected' in green.

11.0 REGULATORY COMPLIANCE

The COVVI Hand 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 COVVI Hand itself. This mark indicates that the COVVI Hand meets the regulatory requirements for medical devices in the European Union under the Medical Device Regulation (MDR 2017/745).

In addition, the COVVI Hand 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:

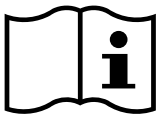
- US FDA 21 CFR Part 820 (Quality System Regulation)

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.



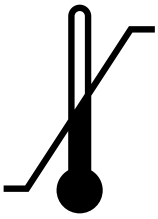
Indicates that the product must be protected from water or moisture exposure, which could damage the internal components.

12.0 SYMBOLS USED

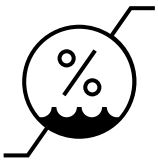


Indicates that the product should not be disposed of with regular household waste and must comply with WEEE regulations for proper electronic waste disposal.

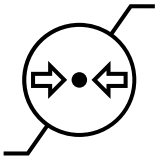




Specifies the temperature range within which the product can be safely stored or operated.



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 Union (EU) 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.

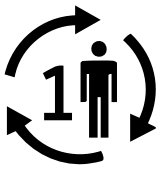


A line with a solid line above a dashed line, indicating that the product operates on direct current (DC).



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 DEVICE PROBLEM REPORTING

In the event of any serious incident involving the COVVI Hand, 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 device(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

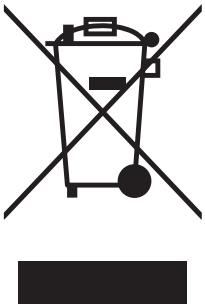
All the components of the COVVI Hand and articles contained within have been chosen and evaluated in accordance with compliance with the EU RoHS directive 2011/65/ EU: The products are produced with restricted use of hazardous substances to protect the environment.

All the components of the COVVI Hand 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 COVVI Hand 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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facebook.com/covvi

linkedin.com/company/covvi



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CE

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

CH REP
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