



Technical Manual

Anything Is Possible

Foreword

COVVI was founded in 2017 by a passionate and experienced team who wanted to continue to create leading prosthetic designs.

The human hand is amazing and the level of functionality which can be restored through prosthetics has historically been very low; but as engineers and designers we see this as a challenge to continuously improve our designs to meet the needs of users. COVVI started with a blank sheet of paper and a mission to address some of the most prevalent deficiencies of current prosthetic hands.

Fast forward to present day and we now have the best looking and most advanced prosthetic hand in the market.



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1.0 Introduction

1.1 What Defines Us?

COVVI is a portmanteau of the Latin 'Coperor' and 'Vita', translating as 'working together' and 'life'.

CO+[V]VI

Our name was formulated to reflect our single driving intention to change multiple lives together forever through harnessing endless connections to make anything possible. With our name came our 'delta' logo, which also has meaningful origins as a symbol of change and doing things differently.

1.2 The Path to the COVVI Hand

The COVVI Hand was born from a genuine passion for prosthetics and helping others. Through 10 years of working in the industry alongside clinicians and listening to users we have developed a sincere appreciation for how difficult prosthetics are to use and how poor devices do not address or resolve this. After the initial excitement of a new device, these frustrations frequently result in the prosthetic device being rejected, which we see as a personal failure. In today's world there are so many products and designs that we simply do not need, yet in the field of prosthetics so much is still to be done. As a team we could not envisage more rewarding work than developing a cutting-edge prosthetic hand that overcomes as many of these issues as possible, so we made it our absolute mission to do so. We truly want to reduce the restrictions and limitations prosthetic users face every day.

We designed the COVVI Hand with your patient in the forefront of our minds and we want it to be an invaluable tool in their life. Our two main goals were to make it functional and robust, and we are confident it not only enables the easy performance of daily tasks but can withstand anything life throws at it! We always aim to develop desirable products, which is why we use only the best materials and pride ourselves on our unrivalled industrial design. After years of hard work, drive, and passion it makes us immensely proud to see our design working as intended and actively simplifying people's lives.

2.0 What's Inside

2.1 The COVVI Hand and Advantage Kit



*COVPS-1600 Shown

3.0 Safety Precautions



Please read the following safety precautions prior to fitting the COVVI Hand. Please note that the COVVI Hand is recommended with COVVI products.

The COVVI Hand should only be fitted by a Certified Prosthetist. Clinicians can remove the glove from the hand, but no other disassembly can be performed unless you have received training by a COVVI representative and received a certificate. New gloves can be installed by a Certified Prosthetist or Technician once training has been delivered and certification issued by a COVVI representative.

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.

- Do NOT use the COVVI Hand without the integrated glove as this could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.
- 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.
- Do **NOT** use the COVVI Hand if a failure occurs, as it could cause damage to your patient or others.
- Do **NOT** use an additional glove with the COVVI Hand. Cosmetic gloves restrict the movement of the hand, resulting in lower battery life, reduced grip strength and an increased internal temperature.
- The Essential Performance is to move the digits only when an input signal is applied. Should the fingers and/or thumb move without an input, the user should stop using the COVVI Hand immediately and contact COVVI Customer Services.



This symbol is used in instances to warn about hazardous or dangerous materials and/or objects and will be used throughout this document.

- We do not recommend the use of carbon fibre materials in a fabricated socket unless it is grounded to the carbon fibre lamination.
- This product uses semiconductors that can be damaged by electrostatic discharge (ESD).



3.0 Safety Precautions

- 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.
- The COVVI Hand has been tested and certified with IP44 rating, which classifies the degree of protection against solids and water as protected against solid objects over 1mm in diameter and sprays or splashes from all directions.
- The wrist interface is not IP44 water or dust resistant as it is highly dependent on the individual socket build and so should be kept dry at all times.
- 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 water and dust resistance protection for the hand.
- Do **NOT** expose the COVVI Hand to an open flame.
- 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. If the hand needs cleaning, mild soap and a soft damp cloth should be used. Abrasive cleaners and cleaning cloths will scratch the covers.
- Before operating a vehicle with the COVVI Hand, local regulations should be checked, and the user's insurance company must be notified. We recommend that the prosthesis is fully charged. In the event of an accident occurring while operating a vehicle with a COVVI Hand or any other COVVI product; COVVI Ltd. and COVVI USA INC shall not be liable under any circumstances.
- Do **NOT** use the COVVI Hand to operate a firearm.
- The COVVI Hand is not suitable for extreme sports. These include, but are not limited to: base jumping, sky diving, downhill/endure mountain biking, motocross, rock climbing, abseiling, bouldering and power lifting. Any sport that would involve the COVVI Hand getting wet must be avoided. These include, but are not limited to: diving, swimming, snorkelling, surfing, kayaking and canoeing.

4.0 Environmental Conditions

The COVVI Hand is to be used exclusively for upper extremity prosthetic fittings. Based on the environmental conditions below, the user should not use, transport, or store the COVVI Hand outside of the boundaries listed below.

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

5.1 The Hand Box

To remove the COVVI Hand from its box, first slide foam piece 1 vertically out of the box, then slide the rest of the foam pieces along into the gap left by foam piece 1. Lift the hand from the box and remove foam piece 2 from the EQD and foam piece 5 from the fingers. To place the hand back in the box, follow the steps in reverse. Please take care with the orientation of the foam pieces.

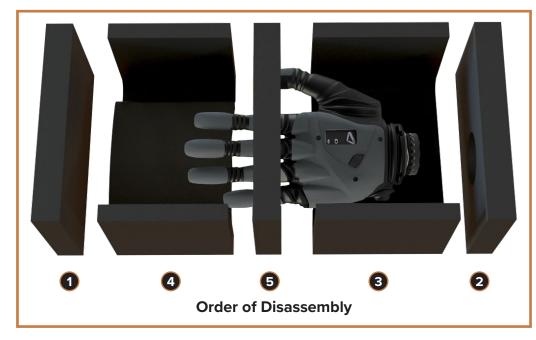
Knuckle Foam

Removable Insert for Medium & Large



Left



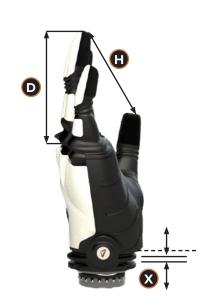


Right



5.2 Dimensions

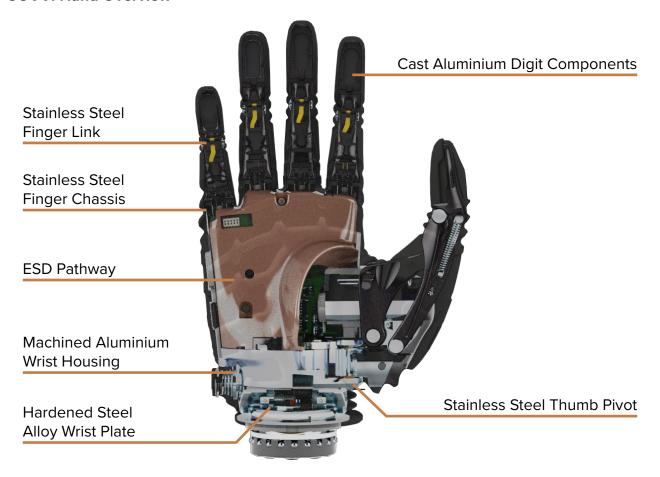


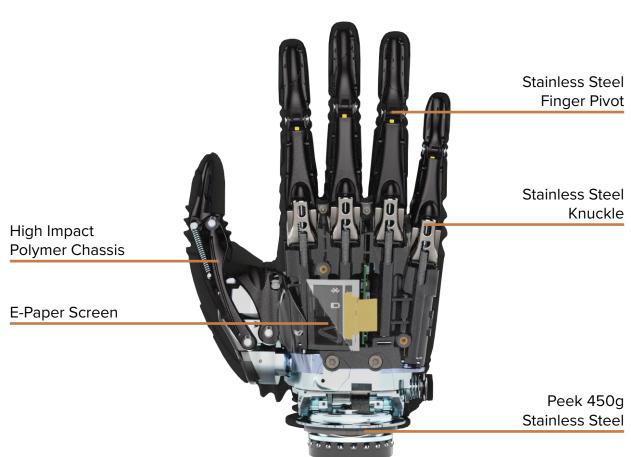


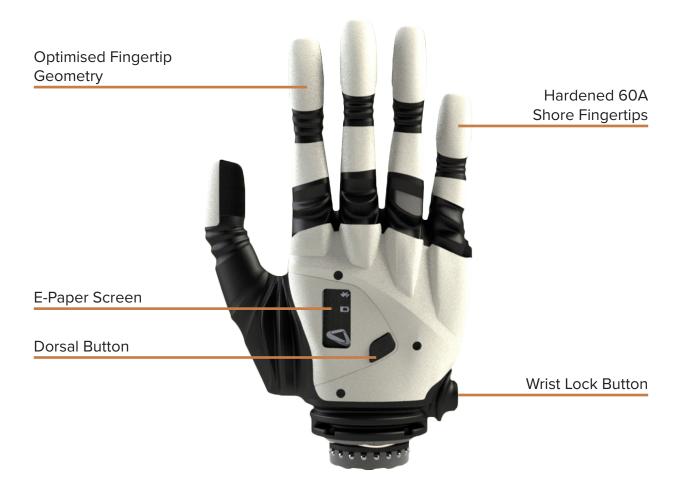
Wrist Flexion Axis

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

5.3 COVVI Hand Overview









5.4 Technical Information

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



Maximum Hand Load Limit (A) with force applied upwards

90 kg / 198 lbs over the knuckles

Maximum Hand Load Limit (B) picking weight up 32 kg / 71 lbs

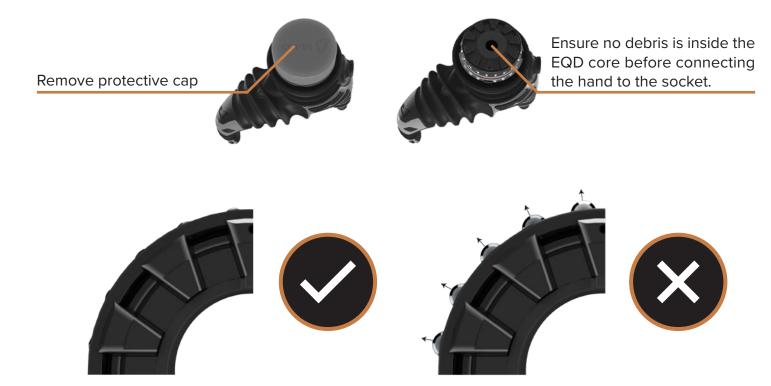


Avoid pressure on thumb

6.1 Connecting/Disconnecting the COVVI Hand

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

Please see the image below for instructions on how to connect the COVVI Hand to your patient's socket.



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



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.



Connect the hand to the socket by pushing the EQD into the wrist on the socket until you hear the two click together.

Check the hand is properly connected by twisting it 90° clockwise and anticlockwise and lightly pull it away from the socket. If the hand wobbles in the socket it isn't connected properly.

When you turn the hand on, you will hear the start-up beep and the E-Paper screen will display COVVI followed by the first grip in Table A. Once you use the hand, every time you turn it on again it will display COVVI followed by the last grip and table the hand was in when it was turned off.

To disconnect the hand from the socket, rotate it and lightly pull it until the hand disconnects.

6.2 E-Paper Screen

The COVVI Hand has an E-Paper screen which shows important hand information. It requires no power to display and little power to change display, so it doesn't drain the user's batteries.

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



FW: The high-level Firmware. The image shows Version 4 followed by the date it was created.

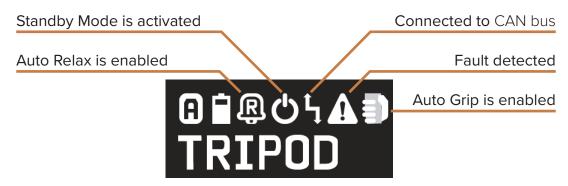
GW: The low-level Gateware. The image shows Version 4 followed by the date it was created.

It will then display the following:



It always shows the current grip, table and battery life. The Bluetooth icon will be displayed for 60 seconds and then it will disappear as Bluetooth will automatically turn off, this is a battery saving feature. If you connect to the App the Bluetooth icon will remain on the E-Paper screen until you disconnect from the App.

6.3 System Notifications



When Auto Grip is enabled, if the 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 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.

A short press to the dorsal button (under two seconds) puts the hand into Standby Mode where 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 hand is connected to a CAN enabled device, such as the COAPT Gen2 system. 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 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.



When the COVVI Hand is too hot, outside of its normal operating temperature (see section 4.0), the following warning message and icon will appear. If this message appears, please disconnect the hand, and allow it to cool down.



When the COVVI Hand is too humid, outside of its normal operating humidity (see section 4.0) the following warning message and icon will appear. If this message appears, please disconnect the hand, and allow it to dry in a warm, dry environment.

Any function that refreshes the screen, for example a grip change, will change the message displayed but the warning icon will remain visible.

If the warning icons and messages do not disappear, please get in contact with 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 hand and then it updates the hand.





A list of all fault codes can be found on our website: www.covvi.com

The COVVI Hand has an array of features to facilitate your patient's life, providing them with a high level of functionality and a captivating design.

7.1 Passively Flexing Fingers and Thumb

All fingers and the thumb have passive flex which increases durability as the spring-loaded feature provides impact protection. The digits fold out of the way reducing the likelihood of damages and repairs.

All digits are manufactured from a combination of stainless steel and aluminium to increase resilience.

The COVVI Hand has 5 actuators all located low in the palm where they are protected from the mechanical frame of the hand. The weight is also more proximal and therefore better distributed allowing for better overall control of the prosthesis.





7.2 Integrated Flex Wrist

Every COVVI Hand has an integrated flex wrist with a single locking button mechanism which can lock the wrist into three positions: 30° flexion, 30° extension or neutral. It is spring-loaded to the neutral position; click the button once to lock the wrist, again to unlock it.



7.3 Thumb Tap/Powered Rotation

The thumb has powered rotation so automatically switches between non-opposed and opposed positions. But it also has a novel thumb tap which is a quick, intuitive way to change grips or tables. Laterally tap the side of the thumb to trigger the rocker switch and activate the powered rotation without the need for a myo-input. The thumb will rotate between non-opposed and opposed positions depending on which grip is assigned next.



For a Left Hand

Thumb Tap Pronate - Tap the left side of the thumb to move it inwards from a non-opposed position to an opposed position. If the next grip is non-opposed, the thumb will remain in the same position.

Thumb Tap Supinate - Tap the right side of the thumb to move it outwards from an opposed position to a non-opposed position. If the next grip is opposed, the thumb will remain in the same position.

Thumb Tap Pronate at Opposed - Tap the left side of the thumb to rock it inwards on the rocker switch. If the next grip is opposed, the thumb will remain in the same position; if the next grip is non-opposed, the thumb will rotate to a non-opposed position.

Thumb Tap Supinate at Non-Opposed - Tap the right side of the thumb to rock it outwards on the rocker switch. If the next grip is non-opposed, the thumb will remain in the same position; if the next grip is opposed, the thumb will rotate to an opposed position.

For a Right Hand

Thumb Tap Pronate - Tap the right side of the thumb to move it inwards from a non-opposed position to an opposed position. If the next grip is non-opposed, the thumb will remain in the same position.

Thumb Tap Supinate - Tap the left side of the thumb to move it outwards from an opposed position to a non-opposed position. If the next grip is opposed, the thumb will remain in the same position.

Thumb Tap Pronate at Opposed - Tap the right side of the thumb to rock it inwards on the rocker switch. If the next grip is opposed, the thumb will remain in the same position; if the next grip is non-opposed, the thumb will rotate to a non-opposed position.

Thumb Tap Supinate at Non-Opposed - Tap the left side of the thumb to rock it outwards on the rocker switch. If the next grip is non-opposed, the thumb will remain in the same position; if the next grip is opposed, the thumb will rotate to an opposed position.

8.1 Opposed Grips

Power Grip

This is a stable grip for when holding heavier items, but it is also great for daily and manual tasks such as carrying bags, pushing a shopping trolley, or mowing the lawn.



Precision Grip (Open & Close)

These two grips use the thumb and index finger to give a reliable and fast method of picking up, holding, and using small objects with precision.

In precision open the fingers remain extended and allow you to get the hand close to the object. In precision closed, the fingers close to give you better visibility of the item you are picking up.



Trigger Grip

This grip is for the use of trigger operated objects such as hairdryers, spray bottles, a power drill or electronic garden tools.



Tripod Grip

This grip is useful for grasping a variety of everyday items. Active finger tracking ensures a reliable and stable grip.



Rock Grip

This grip is not a functional grip. It allows you to do the 'rock' sign.



Glove Grip

This grip is to aid dressing and undressing. It makes the hand as slim as possible to make it easier to put on clothing, for example, pulling a jacket sleeve onto your arm.



8.2 Non-opposed Grips

Finger Point Grip

This grip enables you to press buttons, ring a doorbell, use a smartphone, or point out directions.



Tap Grip

This grip is very similar to the finger point grip but has the additional function of an active button press.

The index finger moves up and down.



Key/Card Grip

This grip is ideal for holding thin objects like keys, credit cards or paper, but it can also be used in domestic tasks such as carrying plates or holding a knife.



Mouse Grip

This grip is specifically designed for using a mouse.



Column Grip

This grip is ideal for a variety of tasks such as pressing buttons, calling lifts, or turning light switches on and off.



Relaxed Grip

This grip provides a natural resting position for when the hand is not in use.



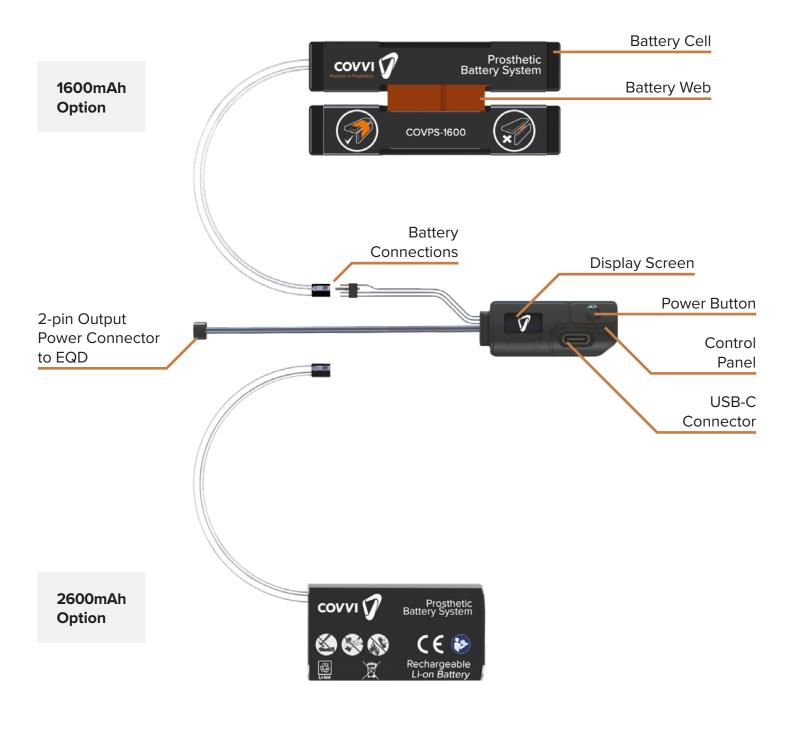
Phone Grip

This grip is not a functional grip. It is to imitate holding a phone.

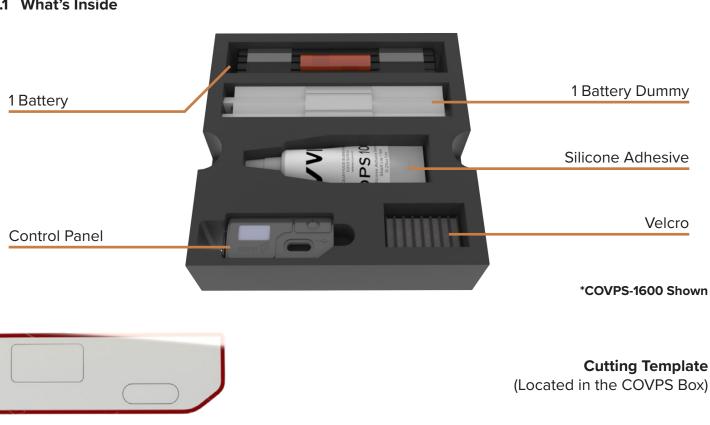


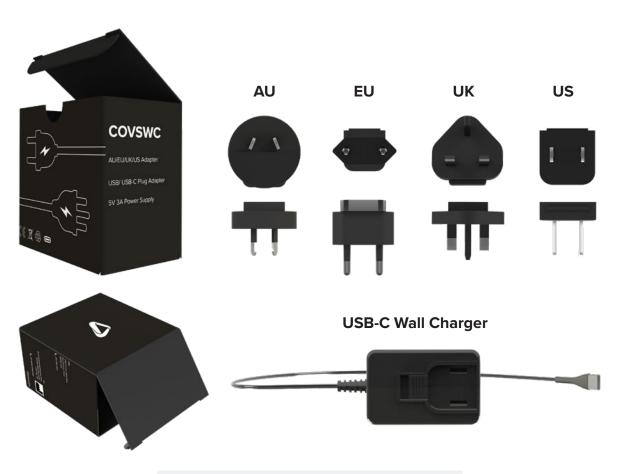
There are two Power Supply systems available: 2600mAh cylindrical cells with a system weight of 104 grams ideal for users with a short residual limb, and 1600mAh prismatic flat cells with a system weight of 74 grams and a web connecting the cells. This web allows the batteries to be folded, without bending the cells, to follow the contours of the inside of the prosthetic socket. This system is ideal for users with a long residual limb.

Both Power Supplies come with a Control Panel which weighs 16 grams. It has USB-C charging, the 1600mAh Power Supply takes under three hours to charge and the 2600mAh Power Supply takes four hours to charge.



9.1 What's Inside





Only use with COVVI Batteries

9.2 Safety Precautions

Please read the following safety precautions prior to fitting the COVVI Power Supply.

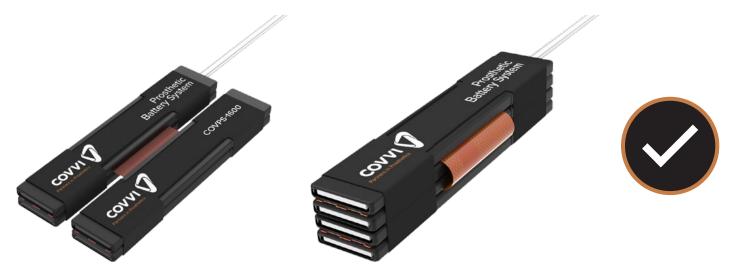
- The Power Supply should only be fitted by a certified prosthetist.
- This product is not designed to be disassembled or serviced. COVVI Ltd. and COVVI USA INC have the right to void the warranty of all products that have any type of modification or damage caused by any unauthorised or untrained personnel. Any damage caused by intentional harm or neglect will not be covered under the warranty.
- Please make sure the Power Supply is **OFF** before connecting/disconnecting the prosthetic device as this will avoid any unpredictable spikes in the electric current from the batteries.
- Do **NOT** attempt to use the prosthetic device 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 prosthetic device can be potentially unsafe.
- Do **NOT** use the Power Supply if there is any visible sign of damage to the Power Supply charger, Power Plug and/or Cables.
- Do **NOT** expose the Power Supply to an open flame or submerge it in water. This could damage the screen and affect the battery's ability to hold charge.
- Do **NOT** use any solvents or abrasives to clean the Control Panel as this might damage the paint finish, the clarity of the screen or integrity of the silicone moulding.
- Do NOT fit the batteries into a small, enclosed space. The batteries are designed to inflate when they fail. Stopping this inflation may cause the generation of excessive heat, injury, or death.
- Individuals who are exposed to hazardous environments that contain flammable liquid or gas should **NOT** use the COVVI Power Supply when in those environments.
- Ensure access to wall plug to enable easy isolation if required.



This product uses semiconductors that can be damaged by electrostatic discharge (ESD).

9.3 1600mAh Batteries

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



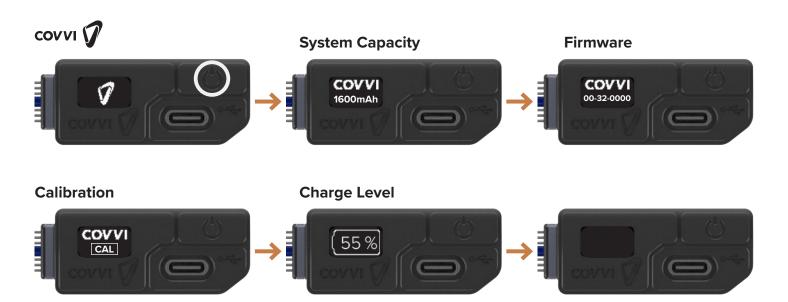
9.4 2600mAh Batteries

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



9.5 Activating the System

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



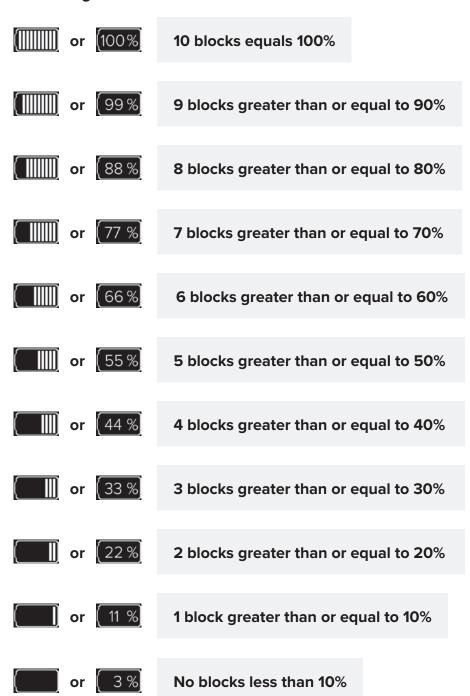
9.6 Changing the Display Mode

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

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



9.7 Charge Indication





to #

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

I Page 34

When the system is charging, it will show this screen.

9.8 Fitting the COVVI Power Supply

The Control Panel should only be fitted by a Certified Prosthetist or Technician once certification training has been delivered by a COVVI representative.

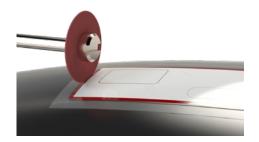
The information below is to be used as a guide, individual prostheses will differ from patient to patient.

We recommend the Control Panel is placed on the upper side of the prosthetic socket away from any area which may be loadbearing when carrying heavy items. Lamination dummies are provided if recesses are required in the outer socket wall.

Control Panel Aperture



Apply the cutting template to the top side of the prosthetic socket.



Carefully cut along the red outline with a cutting disc. File down any sharp edges.



Remove the cutting template and apply a small bead of silicone adhesive to the edge of the aperture.



Insert the wires through the aperture before gently pressing the Control Panel into place.

The batteries can either be connected to the Control Panel prior to being fitted to the limb or after it is fitted if there is sufficient access space.

To ensure correct function it is important to inspect the Control Panel carefully and ensure that the USB-C port is free of debris. If any debris is discovered please carefully remove it with a thin, but non-metallic object to ensure the port is not damaged.

If the Control Panel needs cleaning, mild soap and a soft damp cloth should be used. Abrasive cleaners and cleaning cloths will scratch the covers.

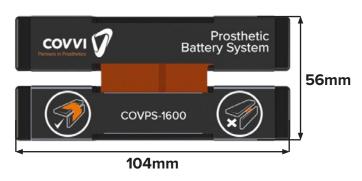
9.9 System Specification

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

Control Panel



1600mAh Battery



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

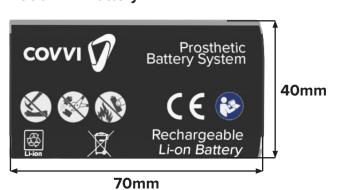
9.0 The COVVI Power Supply

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

Control Panel



2600mAh Battery



9.0 The COVVI Power Supply

9.10 Battery Replacement

As with all batteries the capacity will degrade overtime, we expect this to become noticeable after 12 months of use. The COVVI Power Supply will support 300 charge and discharge cycles. After this, the time it takes to fully flatten the batteries will become shorter. Replacement cells are available for both Power Supply versions.

It is imperative that you replace the batteries with those of the same capacity, COVSB-1600 is only compatible with the 1600mAh Power Supply and COVSB-2600 is only compatible with the 2600mAh Power Supply. Deplete the old batteries until flat and the limb no longer moves.

Disassemble the limb and replace the batteries. Reassemble the limb, connect the batteries to the USB-C charger and allow them to fully charge. If this initial charge is not conducted properly, it can negatively affect how the system calculates the remaining charge.

Check your local waste regulations to safely dispose of your old batteries.

10.0 Component Compatibility



The use of incompatible prosthetic components can cause injury due to unexpected errors. See the table below to show product compatibility. Any device or component that is not listed below is NOT recommended to be used with the COVVI Hand.

Company	Product	Part Number	Compatibility	Recommendations
		Electrodes		
Ottobock	Electrode	13E200=50	Yes	
Ottobock	Electrode	13E200=60	Yes	
Ottobock	Suction Socket Electrode	13E202=50	Yes	
Ottobock	Suction Socket Electrode	13E202=60	Yes	
Steeper	Electrode	Elec 50	Yes	
Steeper	Electrode	Elec 60	Yes	
Steeper	Seal-in Electrode	ELSK50	Yes	
Steeper	Seal-in Electrode	ELSK60	Yes	
Ossur	Compact Electrode Kit, 50Hz (300mm Cable)	PL091050	Yes	
Ossur	Compact Electrode Kit, 50Hz (600mm Cable)	PL091127	Yes	
Ossur	Compact Electrode Kit, 60Hz (300mm Cable)	PL091060	Yes	
Ossur	Compact Electrode Kit, 60Hz (600mm Cable)	PL091128	Yes	
IBT	Element	TBC	Please speak with your local COVVI representative	
		Batteries		
Ottobock	MyoEnergy Integral	757B35=5	Yes	
Steeper	S-Charge System	SCBP2200	Yes	
Touch Bionics	Replaceable Battery Assembly Kit	PL238149	Yes	
Touch Bionics	Replaceable Battery Assembly Kit w/ switch block	PL238163	Yes	
Ossur	2000mAh battery	PL000335	Yes	
IBT	FlexCell	TBC	Yes	
Vincent	Vincentaccu Flex	flex1290	Yes	

10.0 Component Compatibility

Company	Product	Part Number	Compatibility	Recommendations
		Elbow		
Fillauer	Utah Arm 3 Base	TBC	Please speak with your local COVVI representative	
Fillauer	Utah Arm 3	TBC	Please speak with your local COVVI representative	
Fillauer	Utah Arm 3+	TBC	Please speak with your local COVVI representative	
Fillauer	Utah Hybrid Arm	TBC	Please speak with your local COVVI representative	
Steeper	Espire Pro Elbow	TBC	Yes	
Steeper	Espire Hybrid Elbow	TBC	Yes	
Steeper	Espire Classic Elbow	TBC	Yes	
Steeper	Espire Classic Plus Elbow	TBC	Yes	
Steeper	Espire Basic Elbow	TBC	Yes	
Ottobock	ErgoArm Hybrid Plus	12K44 (All Sizes)	Please speak with your local COVVI representative	
Ottobock	ErgoArm Electronic Plus	12K50 (All Sizes)	Please speak with your local COVVI representative	
Ottobock	DynamicArm Elbow	12K100N (All Sizes)	Yes	Needs an analog adapter
Ottobock	DynamicArm Plus Elbow	12K110N (All Sizes)	Yes	Needs an analog adapter
Ottobock	Analog Adapter	13E100	Yes	
Glaze	Whizzlink		Yes	
		Connection Cables	3	
Ottobock	Electrode Cable	13E129 (All Sizes)	Yes	
Ossur	3-way Cable 300mm	PL091029	Yes	
Ossur	3-way Cable 600mm	PL091030	Yes	

10.0 Component Compatibility

Company	Product	Part Number	Compatibility	Recommendations
		Wrist		
Ottobock	MyoRotronic	13E205	Yes	
Ottobock	Electric Wrist Rotator	10S17	Yes	
Fillauer	MC Standard Wrist Rotator	ТВС	Yes	
Fillauer	MC ProWrist Rotator	TBC	Yes	
Fillauer	MC Powered Flexion Wrist	TBC	Yes	
		Pattern Recognition	1	
COAPT	COAPT		Yes	Must use Motion Control wrists
IBT	Sense	TBC	Please speak with your local COVVI representative	
Ottobock	MyoPlus TR	13E520	No	
		Charger		
Ottobock	MyoCharge Integral	757L35	Yes	If corresponding MyoEnergy Integral battery pack is used
		Lamination Rings		
Ottobock	Lamination Ring	10S1 (All Sizes)	Yes	
		Coaxial Plug		
Ottobock	Coaxial Plug	9E169	Yes	
		Coupling Piece		
Ottobock	Coupling Piece	1054	Yes	

All systems which are compatible with a standard EQD and can deliver 0 to 5V input signals and 7 to 8.4V power supply.

WARNING: Use of the COVVI Hand adjacent to or stacked with other equipment not listed should be avoided because it could result in improper operation. If such use is necessary, the COVVI Hand and the other equipment should be observed to verify that they are operating normally.

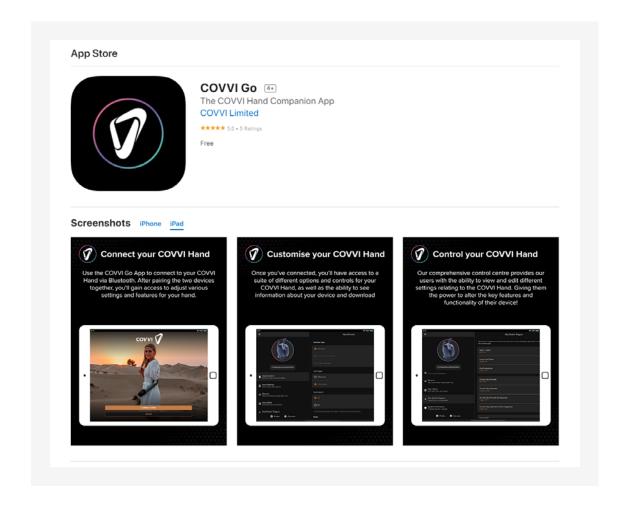
WARNING: Use of accessories, transducers, and cables other than those specified or provided by COVVI Ltd. and COVVI USA INC could result in increased electromagnetic emissions or decreased electromagnetic immunity of the COVVI Hand and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the COVVI Hand, including cables specified by COVVI Ltd. and COVVI USA INC as this could result in degradation of the performance of this equipment.

11.1 COVVI Go

Everything you need to configure a COVVI Hand is within the COVVI Go App, which is compatible with iOS version 12.0+ and Android version 8.0+. The App has been designed to support you and your patient through every step of their journey, being designed from the ground-up to be easy to configure, which helps your patients get the most out of the hand. For those users who have experience with prosthetics, the COVVI Hand has a default setup combining the functionality of other prosthetic devices on the market for efficient interchangeability. For new users, as they become more familiar with their hand, they can test out different setups and make any changes in the App to best suit their daily activities and lifestyle

To download the COVVI Go App, go to our website www.covvi.com, click on the 'COVVI GO APP' dropdown section in the side menu to find links to the Apple Store (for iOS) and Google Play Store (for Android), where you can download the App. You can also search for the App directly in both stores by typing in 'COVVI Go'. When the App has downloaded and installed, the icon will appear on your device's home screen.



11.2 Registration

To access all the features in the App, you first need to register an account with COVVI. On our website www.covvi.com, in the 'COVVI GO APP' dropdown section in the side menu, click on Register Your Interest. Fill out the registration form with all the information requested and click on Submit Request.

You will receive an email within 24 hours with an activation link and a temporary password. Click on the link to verify your email. This will then take you to the sign in page for our Web Portal. Use your email and temporary password to sign in. You

will then be asked to verify your details and create a new password. After entering your new password and pressing 'Submit', your account will be activated, and you can then use your email address and new password to sign into the COVVI Go App on your phone or tablet.

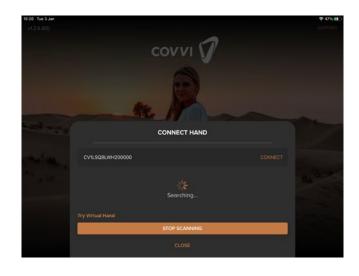
The COVVI Web Portal operates on an invite-only basis. You need to add your patients for them to be able to create an account. Go to our Web Portal portal.covvi.com, on the left-hand side there is an option that says Users, which only appears if you have clinician or distributor access. Click on Users and a list of all the users you have added so far will appear.

Click on the '+' button near the top of the page and you will be taken to a screen where you can add a new user. Fill out and submit the form, then an email invitation with the activation link and temporary password will be sent to your patient. You can choose what access level to give to your patient, which determines what changes they can make. The App can be accessed without an account, but only to view settings, update the firmware and report bugs. No changes can be made to the setup without an account.

11.3 Hand Selection

When you open the App, the initial screen shows you three options, Sign In, Connect Hand and Support. First click the 'Sign In' button to access your account. If you have forgotten your password, click on Forgot Password option, put in your email address, and click on Send Link. Follow the instructions in your email to reset your password.

If you do not currently have a COVVI Hand or account and would like to try out the App to have an idea of the functionality, you can use the Virtual Hand feature. This feature allows you to go through the App and make changes to a configuration as if you were connected to a hand. Click on 'Connect Hand' then on 'Try Virtual Hand'. Clicking the Support button



at the top right will open the Support Console, which will give you additional options such as resetting the Bluetooth settings for the app, opening the video tutorials hub or submitting a support ticket.

Once you have logged in, click on Connect Hand. The Hand Selection box will appear and automatically begin searching for your hand. The COVVI Hand communicates with your device via Bluetooth. Make sure Bluetooth is enabled on both the COVVI Hand and your device. If Bluetooth isn't enabled on your device, the App will notify you.

When you turn the COVVI Hand on, Bluetooth is enabled for 60 seconds before turning off to save battery life. To reactivate Bluetooth, you will need to power the hand off and on again. If you experience connectivity issues you can reset the Bluetooth communication by erasing the data in the BLE module and resetting it. This will set the communication channel back to default and fix all damaged connections. This can be done in the App by selecting the 'Reset Bluetooth Settings' option inside of the Support Console. In addition to this, the settings need to be reset on the hand which can be done by pressing and holding the dorsal button on the back of the hand for 10 seconds. The E-Paper screen will display 'RESET?'. Keep pressing the dorsal button until you hear the start-up beep. This will have cleared the memory and reset the communication channels. If you still have issues connecting to the hand after trying this, please get in contact with COVVI Customer Services.

The hand's serial number will appear as shown in the image above. You can also locate the hand's serial number on the face of the EQD wrist.

When you connect to a hand it takes you to the Hand Overview screen, which shows you a list of the configuration groups that can be changed on the hand, for example, Hand Control and Input Settings. On tablet this section is shown on the left of the screen, with the right side showing your currently selected section.

If you or your patient experiences an issue with their hand, you can click on the 'Console' button at the bottom of the Hand Overview section and select 'Submit A Support Ticket' option. This will allow you to fill out the form, which will be sent to us along with the hand's serial number so we can assist them.

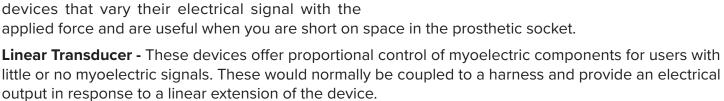
11.4 Hand Control

The first option in the Hand Overview section is Hand Control. This section allows you to select multiple parameters which define how the hand is operated. Below are the parameter which can be set inside of the Hand Control section and what the different options are.

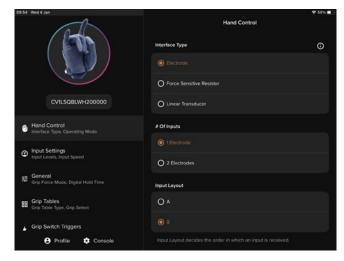
Interface Type: There are three interface types.

Electrodes - These are sensors that detect the user's muscle contractions. A proportional voltage controls the opening and closing of the hand with variable speed and force.

Force Sensitive Resistors - These are resistive



Electrodes are the most commonly used interface type.



of Inputs - The COVVI hand can be controlled by single or dual site strategies.

Input Layout - With dual site control, the default setup is Input A for the open signal and Input B for the close signal, but this can be inverted if the electrodes are wired the other way around.

Mode - The COVVI Hand can be controlled using three different operating modes. The modes available will depend on your selection for '# of Inputs'.

If your patient has single site control, a strategy is required to open and close the hand. There are two available methods.

Fast Open/Slow Close - Fast Open/Slow Close is a signal sent and whether that signal crosses the On threshold before or after the Fast Open/Slow Close Time (a time parameter customisable by the user) determines if it is interpreted as an open or close action.

A signal sent before the time parameter is considered a 'fast signal' and interpreted as an open action. A signal sent after the time parameter is considered a 'slow signal' and interpreted as a close action. Once the On threshold is exceeded, the direction is locked and the speed is proportional to the magnitude of the input signal, which works the same as with dual site control.

Single Site Alternating - Single Site Alternating is an initial signal sent which from powering on the hand is interpreted as a close action and the hand therefore starts to close. When this signal is released, the Direction Change Time (a timer customisable by the user) starts and whether the next signal crosses the On threshold before or after the timer determines whether it will be interpreted as an open or close action. If the second signal crosses the On threshold before the timer it will continue the direction of the hand and so is interpreted as a close signal. If the second signal crosses the On threshold after the timer it will change the direction of the hand and so is interpreted as an open signal.

The Direction Change Time only starts once the signal has been released. Therefore, to change grips the user must send a signal after the Direction Change Time to change the direction of the hand from closing to opening, maintain that signal until the hand is fully open and either keep it maintained to activate a Long Hold Open grip switch trigger, or release the signal and reapply another signal before the Direction Change Time, so it is interpreted as another open signal to activate the Open/Open grip switch trigger.

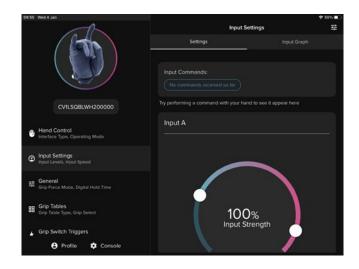
If your patient has dual site control, independent signals open and close the hand. There is one method available.

Dual Site Open/Close: - This is the most common operating mode used with the COVVI Hand. It has two input sites, the default setup is Input A for an open signal and Input B for a close signal. All grip switch triggers work in this mode and give the user the most flexibility.

11.5 Input Settings

We advise that you start by setting the Input Settings before programming the grip tables and grip switch triggers, to ensure your patient can first comfortably operate the hand without fatiguing themselves.

There are two available views for the current input signals; a line graph and input dials with the latter being the default. There are three adjustable thresholds for both Input A and Input B; the On, Max and Co-contraction thresholds. The On threshold shows the signal strength needed for the hand to move and the Max threshold shows the signal strength needed for the hand to move at full speed. The Co-contraction threshold will only appear in the Input Settings if you map Co-contraction in the Grip Switch Triggers section.



At the top right of the screen, you will see an icon which when clicked takes you to a new screen that allows you to set the Input Speed for both Input A and Input B, which can also be adjusted if you click either 'Set Input A Level' or 'Set Input B Level'. The input level adjusts the input range to the signals the user can produce, and the input thresholds are the levels within this range that the hand operates. Click on setup Input A level to automatically set your patient's levels for their input. Once you click on 'Start', your patient will need to give a signal for 5 seconds as the timer counts down. This needs to be the strongest signal they can comfortably produce. It will then notify you that the setting input levels is complete. Click on 'Set Input B Level' to do the same for their close signal.

In the Input Dials view of the Input Settings, you will see round dials which get filled as a signal on either of the inputs is provided. On each of the dials you will see either 2 or 3 sliders which represent the On, Co-contraction and Max thresholds, with Co-contraction being optional depending on if the co-contraction trigger is enabled. Commonly, prosthetic users have background noise also known as baseline interference, which are low level signals detected from the electrodes as they are highly sensitive sensors. Adjusting the On threshold to just above the background noise signals will avoid inadvertent hand movements. If your patient were to send a signal and only reach 50%, the Max threshold can be adjusted to 50% so that they can still move the hand at full speed. If they were to have cross talk where they send input A but show artefacts of input B, this would indicate that their muscle for input B is stronger and has more control, so you can move the On and Max thresholds for input B out of the realm of input A so they have two clean readings.

Two typical threshold setups are High Control and Easy Speed, both allow the user to exceed the Max threshold without excessive strain. High Control has a large difference between the On and Max thresholds and offers great control over a wide speed range, but it does require the user to be able to achieve high magnitude signals without fatigue.

Easy Speed has a small difference between the On and Max thresholds and offers high speed without the need for high magnitude signals, but this setup can make it more challenging to get fine control of the hand at lower speeds. The closer the On and Max thresholds are, the less speed control the user will have of their hand.



To change the layout from dials to the line graph, click on the 'Input Graph' at the top of the Input Settings screen. This layout is useful as it shows historic data. When your patient fires a signal, you will see what percentage signal strength they can comfortably achieve with a line on the graph. The bars are also displayed either side of the graph. The left bar represents Input A and the right bar represents Input B. Adjust the sliders to map the speed of the hand to the signals they can comfortably produce.

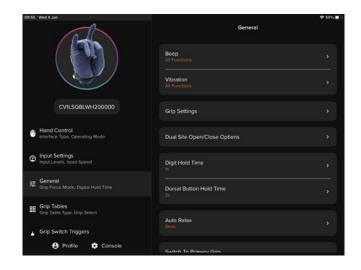
At the top of the Input Dials view there is a box titled 'Input Commands' which is designed as a training tool for the user to see they can successfully do the Open/Open, Long Hold Open, Co-contraction as well as other Grip Switch Triggers. As a signal is given a new bubble with the triggers name is added to the box. The furthest left bubble is the most recent trigger given. This is another way for you to determine if you need to adjust your patient's thresholds for easier control.

11.6 General

If you select the 'General' section inside of the Hand Overview, you will be taken to a range of configuration options for the COVVI Hand. If you are unsure of what a particular feature does, click on the section and the sub-options will be shown, as well as a description of what the function does.

Beep - The beep is an audible alert to notify the user of any activity. It can be assigned to all functions, only power on and standby, only power on or it can be turned off.

Vibration - There is also the option to be alerted of activity with a vibration. Like with the beep, it can be assigned to all functions, only power on and standby, only power on or it can be turned off.



Grip Settings:

Maximum Finger Strength - The Maximum Grip Strength is the strength at which the fingers grasp an object. It can be set between 20% and 100%. Click on the plus (+) or minus (-) symbol to adjust the percentage.

Maximum Thumb Strength - The Maximum Thumb Strength allows the grip strength to be controlled by one of two modes: fixed or proportional. In fixed mode the hand uses the same grip strength regardless of the user's input signal. It moves the maximum grip force down. In proportional mode, the grip strength is proportional to the user's input signal. Their signal not only controls the force applied to the object but the speed at which the hand moves. It offsets the maximum grip force from their input signal.

Auto Grip - Auto Grip works in power grip, tripod grip, precision open and precision closed. If the fingers sense an object is starting to slip, they reapply a small continuous force or pulse to gently grasp the object. It monitors the grip every half a second.

Auto Relax - After a certain period of inactivity, the hand moves into a relaxed position. The time parameter is user adjustable. If Auto Relax is off, it will say 0 min. Clicking on the plus (+) symbol will turn it on and set it to 1 minute, click on the plus (+) symbol to increase the time again to 2 minutes or click on the minus (-) symbol to decrease the time and turn Auto Relax off.

Switch to Primary Grip - After a certain period of inactivity, the current grip changes back into the primary grip in table A. The time parameter is user adjustable. If Switch to Primary Grip is off, it will say OFF. Clicking on the plus (+) symbol will turn it on and set it to 15 seconds. The time can be increased in 15 second intervals up to a minute. Click on the minus (-) symbol to decrease the time and turn Switch to Primary Grip off.

Digit Hold Time - This is the time you have to apply pressure on the FSR for the grip switch trigger to be activated. Click on the plus (+) or (-) symbol to increase or decrease the time.

Dorsal Button Hold Time - This is the time you have to hold the dorsal button down for the grip switch trigger to be activated. Click on the plus (+) or (-) symbol to increase or decrease the time.

Mode Specific Parameters

For Dual Site Open/Close the following parameters can be established:

Open/Open Time - This is the time in which a second open signal must be sent after the hand is fully opened or after the first open signal for the Open/Open grip switch trigger to work.

Long Hold Open Time - This is the time an open signal must be maintained once the hand is fully opened for the Long Hold Open grip switch trigger to work.

Co-Contraction Time - This is the time in which both inputs must pass the Co-contraction thresholds after the On threshold has been reached.

Input A and B Speed - The maximum speed of the fingers and thumb can be reduced. It can be set between 50% and 100%. If Input A is the open signal and Input B the close signal and you reduce the percentage for both inputs, the speed of opening and closing the hand will be reduced. If you just reduce the percentage for Input A, only the speed at which you open the hand will be reduced. This is a feature designed to aid new users who are still adapting to using a prosthetic device.

For Fast Open/Slow Close the following parameters can be established:

Fast Open / Slow Close Time - A signal sent within this time is interpreted as an open signal and a signal sent after this time is interpreted as a close signal.

Long Hold Open Time - This is the time an open signal must be maintained once the hand is fully opened for the Long Hold Open grip switch trigger to work.

Input A or B Speed - The maximum speed of the fingers and thumb can be reduced. It can be set between 50% and 100%. As the one input is used for both opening and closing the hand, if you reduce the percentage the speed of opening and closing the hand will be reduced. You cannot reduce the speed for just opening or just closing the hand. This is a feature designed to aid new users who are still adapting to using a prosthetic device.

For Single Site Alternating the following parameters can be defined:

Direction Change Time - A signal sent after this time will change the direction of the hand and a signal sent within this time will keep the direction of the hand the same.

Long Hold Open Time - This is the time an open signal must be maintained once the hand is fully opened for the Long Hold Open grip switch trigger to work.

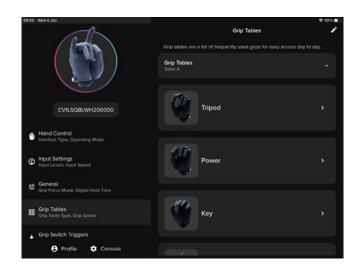
Input A or B Speed - The maximum speed of the fingers and thumb can be reduced. It can be set between 50% and 100%. As the one input is used for both opening and closing the hand, if you reduce the percentage the speed of opening and closing the hand will be reduced. You cannot reduce the speed for just opening or just closing the hand. This is a feature designed to aid new users who are still adapting to using a prosthetic device.

11.7 Grip Tables

To enter the Grip Tables section, click on the 'Grip Tables' option on the Hand Overview screen. You can populate up to four tables with up to six grips in each. Tables B, C and D can be empty, but Table A must contain at least one grip, so the hand always has a grip to go into. This grip is called the primary grip.

For new users, its recommended to start with one or two grips in either one or two tables. For advanced users, all the tables can be populated with grips for daily activities, for example one table for grips used at home, another for grips used when at work.

If the hand is to be used with a COAPT system, refer to the 'Default Config Setup' section, which will explain how to set up the hand for a COAPT system.



Default Grip Tables:

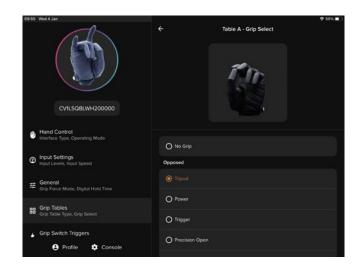
The default setup has two tables populated with the following grips. These are a mix of opposed and non-opposed grips. Tables C & D are empty and therefore disabled.

Α	В	С	D
Tripod	Key	Empty	Empty
Power	Column	Empty	Empty
Key	Tripod	Empty	Empty
Column	Power	Empty	Empty
Empty	Empty	Empty	Empty
Empty	Empty	Empty	Empty

Adding Grips:

Choose which table you would like to populate from the dropdown list at the top of the screen, whichever defaults to Table A. Below this you will see a list of the current grips in that table. If there is space in the grip table for more grips there will be a row with a '+' icon in a circle.

Click on the plus '+' row and a list of grips will appear divided into different groups. If you are unsure of what a particular grip does, select one to see a video showing the hand closing and opening with that grip. Choose the desired grip and click the back button at the top left. The grip will now appear in the next available position. Grips are added one-by-one.



Removing Grips:

To remove grips from a table, click on the pencil symbol in the top right of the screen. Clicking this will show a red trash icon at the right of each of the grips. Clicking the trash icon next to a particular grip will remove it from the table.

Changing Grips:

To change a grip in a specific table, click on one of the grips inside of a grip table. A list of all the available grips will now show with the current grip in that position selected. Clicking on one of the grips will allow you to change that selected grip.

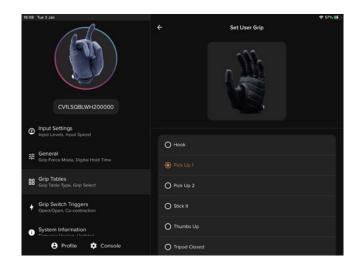
Press the back button to make the change. Selecting 'No Grip' at the top of this list will also remove the grip from the table.

11.8 User Defined Grips

In addition to the 14 standard grips available, your patient can request any custom grip they have in mind by contacting the COVVI Customer Service team. We can then incorporate it into our Grip Library so that it can then be downloaded from the cloud onto your patient's hand.

To install a User Defined Grip, the hand must have the firmware version 4.5.4 or higher. In the 'Add Grip Tables' screen, when the list of grips divided into different groups appears, scroll down to the last group which is called 'User Defined Grips'. You can store up to six User Defined Grips at once.

Click on one of the spaces. If it doesn't have a grip assigned you only need to click it once, if it does

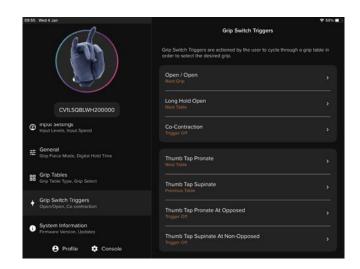


have a grip already assigned you will need to double click it. This will bring up a list of all the available User Defined Grips in our library. Choose the grip you would like to add to your configuration. If you have already assigned this grip, it will be faded in grey as you can only assign it once. All available grips are in white. If you are unsure of what a particular grip does, click on the grip to see a video showing the hand closing and opening in that grip. Click on the back button and the grip will now appear in the first list of grips under User Defined Grips. Click on the grip you would like to add into the table you are populating, click the back button again.

11.09 Grip Switch Triggers

Click 'Grip Switch Triggers' to set how your patient will switch between the grips and grip tables. All available triggers are shown in the list and all actions can be seen when you make a selection. The action assigned to a trigger can be seen in orange below its name.

Any trigger can be assigned to any action, you can only assign a grip switch trigger once, but you can assign the same action to multiple grip switch triggers. If you are unsure of what a particular trigger does, click on it and on the action selection screen you will see a description at the top of the screen.



The available Grip Switch Triggers are:

Open/Open - An Open/Open signal is an open signal to fully open the hand followed by another open signal. The second open signal must be sent before the Open/Open time.

Long Hold Open - A Long Hold Open signal is an open signal maintained. The hand can be closed, partially closed or fully open. The signal must be maintained for the Long Hold Open time once the hand is fully open.

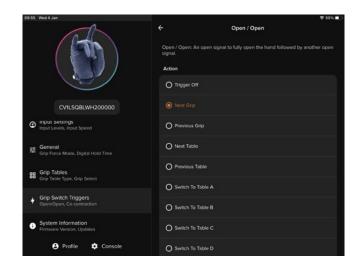
Co-Contraction - Co-contraction is when both inputs cross the Co-contraction thresholds within an amount of time from the On threshold being surpassed. The first input to cross the On threshold initiates the Co-contraction time (a timer customisable by the user) and if both inputs cross their Co-contraction thresholds before the Co-contraction time there will be a successful Co-contraction trigger.

In the Input Graph the Co-contraction thresholds must be higher than the On thresholds. Co-contraction only works when the hand is fully open. Co-contraction can be assigned to any action, however, we would recommend that it is mapped to switching between devices, for example, an elbow to a wrist.

Thumb Tap Pronate - The thumb is tapped inwards and will move into an opposed position, unless assigned to switch to a non-opposed grip where it will remain in a non-opposed position. The hand must be fully open.

Thumb Tap Supinate - The thumb is tapped outwards and will move into a non-opposed position, unless assigned to switch to an opposed grip where it will remain in an opposed position. The hand must be fully open.

Thumb Tap Pronate at Opposed - The thumb is tapped inwards but will remain in an opposed position. If this trigger is assigned to switch to a nonopposed grip, the thumb will move to a non-opposed position. The hand must be fully open.



Thumb Tap Supinate at Non-Opposed - The thumb is tapped outwards but will remain in a non-opposed position. If this trigger is assigned to switch to an opposed grip, the thumb will move to an opposed position. The hand must be fully open.

Index Hold - Pressure is applied to the force sensitive resistor in the index finger for two seconds. The hand must be fully open.

Thumb Hold - Pressure is applied to the force sensitive resistor in the thumb for two seconds. The hand must be fully open.

Four Finger Hold - Pressure is applied to the force sensitive resistors in the four fingers for two seconds. The hand must be fully open.

Dorsal Button Hold - Hold the dorsal button next to the E-Paper screen for two seconds. The hand must be fully open.

The available actions are:

Trigger Off - No action is assigned.

Next Grip - The next grip in the table is selected.

Previous Grip - The previous grip in the table is selected.

Next Table - The first grip in the next table is selected.

Previous Table - The first grip in the previous table is selected.

Switch to Table A / B / C / D - The first grip in Table A, B, C or D is selected.

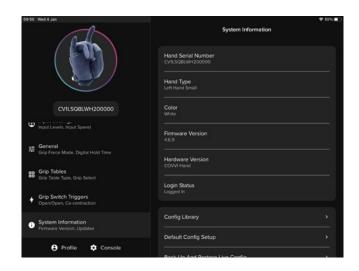
Map to Grip - This action allows you to assign the grip switch trigger to go into a specific grip. The grip does not need to be in the grip tables to be mapped.

Auto Grip - Auto Grip will be turned on and off.

11.10 System Information

The final section in the Hand Overview is the 'System' Information' section. You will be able to find key information on the hand here, as well as the login status on the app.

There are some additional sections inside of here which you will be able use. These are Config Library (formerly Config History), Default Config Setup, Backup and Restore Live Config and Software Update. Each of these features will be covered specifically in the following sections.



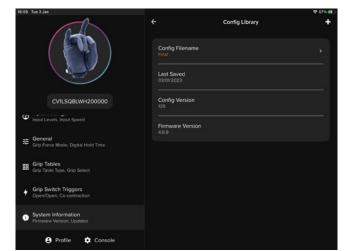
11.11 Config Library

The Config Library is a backup option which allows the user to save their configuration and revert to it later.

Click on 'Config Library' option in the System Information section. This will bring up a list of all the configurations saved to your hand, with the names and dates that they were last saved. If you want to add a new configuration, click on the (+) symbol in the top right of the screen. Provide a name for the new config and then click 'Save' to add it to the Config Library. You must be connected to the internet to save a new config.

If you want to view a configuration, then click the name of the config. You will be navigated to a screen which will show a breakdown of the entire configuration.

If you want to delete the configuration, click on trash icon at the top right of the screen. If you want to restore the configuration, click on 'Restore' at the bottom of the screen, which will send that configuration to the hand.

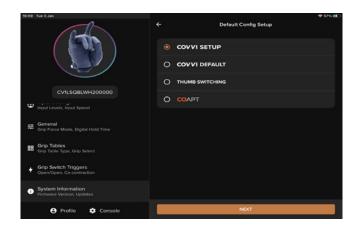


11.12 Default Config Setup

We have made it easier than ever to quickly setup the COVVI Hand. Inside of the 'Default Config Setup' section, which can be found inside of System Information, you will find four options. These are:

COVVI Setup - This takes you through the Setup Wizard. It would be useful to use this when you first setup a new hand as it takes you through all the configuration options and changes are made in real time.

COVVI Default - This allows you to reset a hand back to the default configuration, just as it came out of the box.



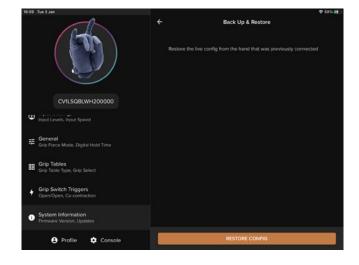
Thumb Switching - This is a configuration which makes use of two grip tables. In one of the grip tables you will have opposed grips and the other will have non-opposed grips. Switch between the tables by using the thumb rocker.

COAPT - This is a configuration setup which we recommend for COAPT systems.

11.13 Backup and Restore Live Config

In case you ever want to copy a configuration from one hand to another, we have created 'Backup and Restore Live Config' section, which is found within the System Information screen. When you first go into here, you will see the 'Backup Data' option at the bottom of the screen. Clicking this will store the configuration for the hand locally onto your device.

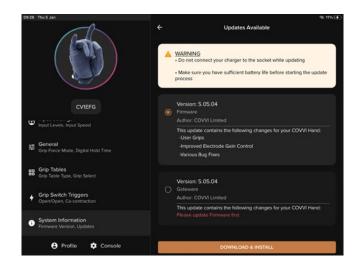
If you reconnect with a new device and navigate back to here, you will instead see the option to 'Restore Config'. Clicking this will write the configuration from the original hand to the newly connected one.



11.14 Software Update

To continuously improve the COVVI Hand, an integrated update feature runs on the device firmware. These updates include improvements, new features, bug fixes, etc. These updates do not require the user to send their hand into a COVVI repair centre to be updated, they can be downloaded to the hand remotely from the cloud.

Click the 'Check For Updates' option in the System Information screen to check if an update is available; if no update is available, you will be notified. If an update is available, you will be shown the option to select one or more updates. Please complete the Firmware update first, then carry out the Gateware update.



To perform the update, click on it and a select 'Download and Install'. The update first downloads from the app onto the hand, then the update will be installed to the hand. This process can take upto 30 minutes, so we recommend keeping the hand close to the device to ensure a strong Bluetooth connection is maintained and download speeds are optimal. The E-Paper screen will change to indicate an update is taking place. The hand will also need to remain connected to a power source until the update is complete. If it is disconnected from power, it will stop the update, which means it will need to start again. It cannot be connected to a charger during the update because this will turn the hand off. Once the update is complete the hand will reboot. If you also have a Gateware update available, navigate back to the Software Update section and select the 'Gateware' option, which follows the same process.

Note: You will not be able to update Gateware if there is an outstanding Firmware update at the same time.

12.0 Maintenance



Do NOT use the COVVI Hand if the glove is punctured.

It is recommended to service the COVVI Hand every year. If the user notices any problems with their COVVI Hand, please contact COVVI Customer Services so COVVI Ltd. and COVVI USA INC can perform a service and assist with any maintenance issues.

13.0 Warranty

Please read these Warranty Terms and Conditions carefully before using all COVVI products and services. We may modify these Terms, for any reason at any time, by posting a new version on our website; these changes do not affect rights and obligations that were defined prior to such changes. There are various limited warranties that apply to manufactured products and goods purchased from COVVI.

13.1 24-Month Manufacturer's Warranty

The COVVI Hand has a 24-month manufacturer's warranty included with the purchases of the hand which takes effect from the date of fitting. Products are subject to be evaluated 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.

Limitation in those instances where changes, alterations or modifications are made in materials at the request or instruction of the customer, the customer agrees not to claim or commence suit against COVVI based on any such disclaimed warranties.

Our obligation is limited only to the repair or replacement of defective parts within the warranty period or, at the sole discretion of COVVI, to refund the purchase price of a full refund, partial refund, or no refund, depending on the condition of the return. The possible refund will be given subject to our Quality Department.

Our obligation is limited only to the repair or replacement of defective parts within the warranty period. The original warranty period resumes when the defective part is replaced.

13.2 Optional Extended Warranty of up to 36 Additional Months

The COVVI Hand has the option of an extended warranty for up to 36 months. The extended warranty can be purchased with the hand or at any time within the first 12 months of the 24-month Manufacturer's Warranty period.

Products are subject to be evaluated 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.

Limitation in those instances where changes, alterations or modifications are made in materials at the request or instruction of the customer, the customer agrees not to claim or commence suit against COVVI based on any such disclaimed warranties. Our obligation is limited only to the repair or replacement of defective parts within the warranty period or, at the sole discretion of COVVI, to refund the purchase price of a full refund, partial refund, or no refund, depending on the condition of the return. The possible refund will be given subject to our Quality Department.

Our obligation is limited only to the repair or replacement of defective parts within the warranty period. The original warranty period resumes when the defective part is replaced.

14.0 Warranty Service and Repairs

Only the COVVI Hand is serviceable, all COVVI supporting products are designed to be maintenance free. When any COVVI product is sent in for repairs or to be evaluated for faults, it must be returned to COVVI completely assembled and not tampered with. COVVI has the right to void the warranty of all products that have any type of modifications or damage caused by any unauthorised or untrained personnel. Any form of abuse, neglect, and excessive damage that is caused by usage outside the intended design and technical specifications, and/or any modifications made towards COVVI products will null and void all warranties. All products received will go through COVVI's Quality Department to assess the condition of the product sent in. The products are evaluated in the order that they are received.

Should the product be under warranty and have any manufacturing and/or workmanship defects, the part(s) will be replaced at no charge. The warranty holder will be informed of any and all defects that are covered and not covered under warranty. Any product out of warranty that is sent in to COVVI will be evaluated by our Quality Department and quoted with repair parts and labour as required. Once the repair estimate is sent to the customer, they will have a 60-day approval period. Once the 60-day approval period expires, COVVI has the right to ship the device back to the customer.

14.1 Limited Liability

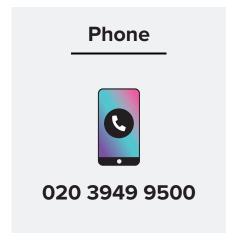
To the fullest extent permitted by law COVVI Ltd. and its affiliates, directors, officers, employees, partners, contractors, or agents will not be liable for any losses or damages whether direct, indirect, incidental, special, punitive, or consequential resulting from the use of the COVVI Hand and associated products, irrespective of whether the Clinician or User has been advised or otherwise might have anticipated the possibility of such loss or damage.

COVVI Ltd. and its affiliates, directors, officers, employees, partners, contractors, or agents shall not be responsible for strikes, labour slowdowns, war, terrorism, riots, severe weather conditions, natural disasters, acts of God or any other forces beyond the reasonable control of COVVI which may result in direct, indirect, incidental, special, punitive, or consequential losses or damage.

15.0 Returns

If the user notices any problems with their COVVI Hand, please contact COVVI Customer Services so COVVI Ltd. and COVVI USA INC can perform a service and assist with any maintenance issues.

Clinicians will need to fill out a Repair Form and obtain a COVVI Repair Number. Get in touch with us via:







16.0 Disposal





Please check your local regulations prior to disposing any items to avoid having a detrimental impact on health and the environment.

17.0 Symbols Used



















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

United States/FCC ID: A8TBM71S2

Canada IC: 12246A-BM71S2

Europe/CE

China/SRRC: CMIIT ID: 2016DJ5890



R 005-101150



MSIP-CRM-mcp-BM71BLES1FC2



注意!

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

公司、商號或使用者均不得擅自變更頻率、加大 功率或變更原設計

之特性及功能。

四條 低功率射頻電機之使用不得影響飛航安 全及干擾合法通信;

經發現有干擾現象時,應立即停用,並改善至無 干擾時方得繼續使用。

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

18.0 CE Declaration of Conformity

Declaration of Conformity for:

The COVVI Wrist Kit

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices.

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	COVVI Wrist Kit
Legal Manufacturer: (Name on Label)	COVVI Ltd., Unit 4 (Direct House), Quayside Business Park, George Mann Road, Leeds, LS10 1DJ, United Kingdom
Manufacturers SRN:	N/A (Not Yet Available)
Basic UDI-DI:	506072613GMN003WY
GMDN Code	41086
Variants:	As per Appendix II (Available on Request) - Product Listing/Schedule
Intended Purpose:	To mechanically and electrically connect the patients hand endoprosthesis to their socket, batteries system and electrodes (or other input devices).
MDR Classification:	Class 1 [Rule 13]
Notified Body:	N/A
EC Certificate:	N/A
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor., Tower Street, Swatar, BKR 4013, Malta
EU Authorised Representative SRN:	MT-AR-00000234
Medical Device Regulation Assessment Route:	In conformity with Annexes II and III and have drawn up the DoC in accordance with Article 19 of the Medical Device Regulation.

Simon Pollard, CEO - November 12th 2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.



18.0 CE Declaration of Conformity

Declaration of Conformity for:

The COVVI Power Supply

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices.

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	COVVI Power Supply
Legal Manufacturer:	COVVI Ltd., Unit 4 (Direct House), Quayside Business Park, George Mann Road, Leeds, LS10 1DJ, United Kingdom
(Name on Label)	N/A (Not Yet Available)
Manufacturers SRN:	506072613GMN004X2
Basic UDI-DI:	36534
GMDN Code	As per Appendix II (Available on Request) - Product Listing/Schedule
Variants:	The COVVI Hand is to be used exclusively for exoprosthetic fittings of the upper limbs
Intended Purpose:	Class 1 [Rule 13]
MDR Classification:	N/A
Notified Body:	N/A
EC Certificate:	Advena Limited. Tower Business Centre, 2nd Floor.,
EU Authorised Representative:	Tower Street, Swatar, BKR 4013, Malta
EU Authorised Representative SRN:	MT-AR-00000234
Medical Device Regulation Assessment Route:	In conformity with Annexes II and III and have drawn up the DoC in accordance with Article 19 of the Medical Device Regulation.

Simon Pollard, CEO - November 12th 2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.



18.0 CE Declaration of Conformity

Declaration of Conformity for:

The COVVI Hand

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices.

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	COVVI Hand
Legal Manufacturer: (Name on Label)	COVVI Ltd., Unit 4 (Direct House), Quayside Business Park, George Mann Road, Leeds, LS10 1DJ, United Kingdom
Manufacturers SRN:	N/A (Not Yet Available)
Basic UDI-DI:	506072613GMN001WU
GMDN Code	41497
Variants:	As per Appendix II (Available on Request) - Product Listing/Schedule
Intended Purpose:	The COVVI Hand is to be used exclusively for exoprosthetic fittings of the upper limbs.
MDR Classification:	Class 1 [Rule 13]
Notified Body:	N/A
EC Certificate:	N/A
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor., Tower Street, Swatar, BKR 4013, Malta
EU Authorised Representative SRN:	MT-AR-00000234
Medical Device Regulation Assessment Route:	In conformity with Annexes II and III and have drawn up the DoC in accordance with Article 19 of the Medical Device Regulation.

Simon Pollard, CEO - November 12th 2021

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