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COVVI
Partners in Prosthetics



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CV-000917-TC, Revision 5



THE COVVI HAND

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Instructions For Use

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1.0 FOREWORD

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If you are using the product with either the Natural Cosmetic Glove or the High-Definition Cosmetic Glove, after reading this Instructions for Use document, please then read the Instructions for Use: Cosmetic Glove document for information on how to use and care for the Cosmetic Hand correctly. Our Instructions For Use should be used as a starting point for new users of the COVVI Hand.

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

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



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2.0 SAFETY PRECAUTIONS

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2.1 Indications Of Use

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

2.2 Conditions Of Use

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

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

2.3 Contraindications

- The product should initially be fit by your Certified Clinician or Technician.
- Do **NOT** use the product without the integrated glove as it protects the product from water ingress and other foreign bodies, which could damage the internal components and cause the product to fail.
- Do **NOT** disassemble the product.
- Do **NOT** attempt to remove the glove from the product unless you have received training by a COVVI representative and received a certificate. NO other disassembly can be performed.
- Do **NOT** use any other glove from any other manufacturer. Only gloves sold by COVVI are compatible with the product.
- Do **NOT** attempt to use the product while the batteries are charging. When the batteries are charging, the power will automatically turn off. If for any reason the power does not turn off while charging, using the product can be potentially unsafe.
- Should the fingers and/or thumb move without an input, stop using the product immediately and contact your clinician.
- Do **NOT** use the product if a failure occurs, as it could cause damage to yourself or others.
- Individuals who are exposed to hazardous environments that contain flammable liquid or gas should **NOT** operate the product when in those environments.
- Do **NOT** subject the product to intentional excessive impacts.
- Do **NOT** submerge the product in water.
- Do **NOT** expose the product to an open flame.
- Do **NOT** use the product to operate a firearm.

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2.0 SAFETY PRECAUTIONS

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- Do **NOT** expose the product to chemicals such as solvents, acids, alkalis, corrosive substances, detergents, and similar chemicals as this could damage the components in the product.
- The product was designed and manufactured for everyday use and is **NOT** suitable for extreme activities or sports. These include, but are not limited to: operating a firearm, base jumping, sky diving, downhill/endurance mountain biking, motocross, rock climbing, abseiling, bouldering and power lifting. Any sport that would involve the product being submerged in a liquid must be avoided. These include, but are not limited to: diving, swimming, snorkelling, surfing, kayaking and canoeing.
- The product is **NOT** suitable to support body weight on crutches, we recommend the product is **NOT** used with crutches.
- Before operating a vehicle with the product, local regulations should be checked, and insurance company must be notified. We recommend that the product is fully charged. In the event of an accident occurring while operating a vehicle with any COVVI product; COVVI Ltd. and COVVI USA INC shall not be liable under any circumstances.
- Avoid remaining in the vicinity of visible strong magnetic or electrical interference, such as theft prevention systems.
- Maintain extra caution when handling sharp objects.

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.

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3.0 ENVIRONMENTAL CONDITIONS

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Maximum Temperature	104°F / 40°C
Minimum Temperature	-4°F / -20°C

4.0 CLEANING

- Switch off the product before cleaning.
- Clean the product with mild soap and a damp lint-free cloth. Abrasive cleaners and cleaning cloths will scratch the dorsal cover.
- Make sure no liquids get into the EQD.
- Dry the product with a lint-free cloth and then allow it to air dry fully.
- The product can be cleaned three times per day on average.

5.0 STORAGE

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

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6.0 USE

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

6.1 Connecting/Disconnecting The Product

- Make sure the Power Supply is **OFF** before connecting/disconnecting the product to and from the prosthesis.
- Only turn the power on once the product is properly connected to the prosthesis.

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



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

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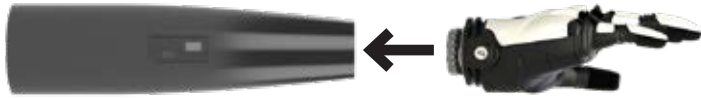
6.0 USE

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



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



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

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6.0 USE

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6.2 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.

COVVI



System Capacity



Firmware



Calibration



Charge Level



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



Press to show for
5 seconds

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6.3 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.

If there is a fault with the Power Supply, the screen will show the following warning icon. Turn off the power and contact your clinician.

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



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



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

6.0 USE

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6.5 Integrated Flex Wrist

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

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



-30° Extension



0° Neutral



30° Flexion

6.6 Dorsal Button

The dorsal button has 3 functions:

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



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6.0 USE SUPERSEDED

6.7 Thumb Tap Make sure to check the newest version

The product has a novel feature called the thumb tap whereby you laterally tap the thumb which activates the rocker switch in the base of the thumb and depending on the configuration, a certain action will happen. The default setup has the thumb tap pronate non-opposed and thumb tap supinate opposed mapped to 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.

A practical example of using the thumb tap would be:

Table A: Tripod, Power, Key, Finger Point

Table B: Key, Finger Point, Tripod, Power

Table C: Phone

Table D: Trigger, Mouse, Glove, Column

Thumb Tap Pronate Non-Opposed: Next Table

Thumb Tap Supinate Opposed: Previous Table

Thumb Tap Pronate Opposed Next Grip

Thumb Tap Supinate Non-Opposed: Next Grip

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

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

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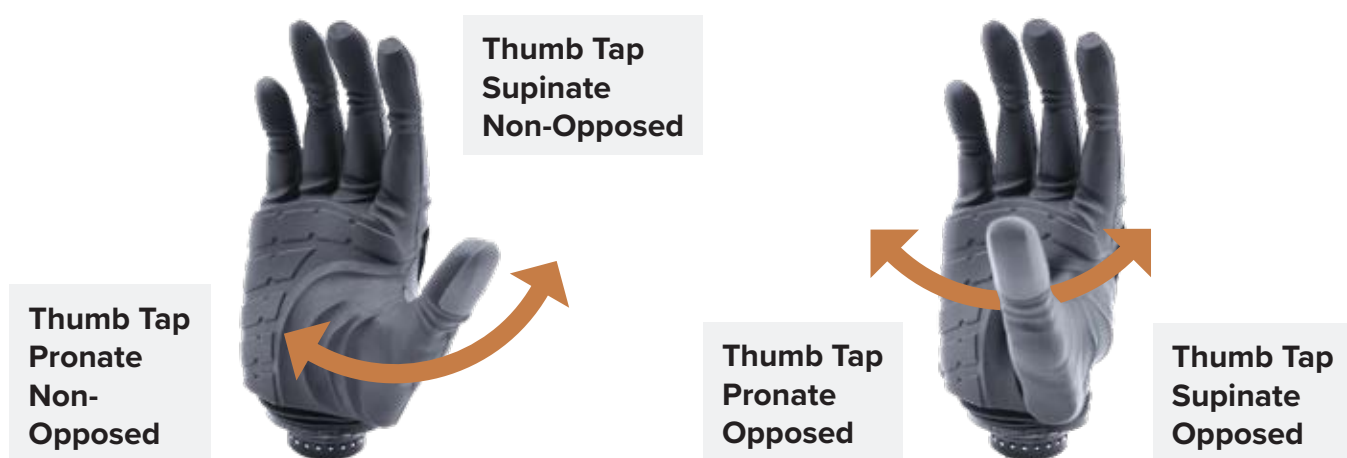
6.0 USE

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- The product is initially in an opposed position (Tripod).
- Tapping the thumb outwards (Thumb Tap Supinate Opposed) will change to the previous table, selecting the first grip in Table D (Trigger). The thumb will not rotate as Trigger is also an opposed grip.
- Tapping the thumb inwards (Thumb Tap Pronate Opposed) will cycle the grip, selecting the next grip in Table D (Mouse). The thumb will rotate as Mouse is a non-opposed grip.
- Tapping the thumb outwards (Thumb Tap Supinate Non-Opposed) will cycle the grip, selecting the next grip in Table D (Glove). The thumb will rotate as Glove is an opposed grip.
- Tapping the thumb outwards (Thumb Tap Supinate Opposed) will change to the previous table, selecting the first grip in Table C (Phone). The thumb will rotate as Phone is a non-opposed grip.

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



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7.0 GRIP PATTERNS

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7.1 Opposed Grips

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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

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7.0 GRIP PATTERNS

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7.2 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

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8.0 APP SETUP

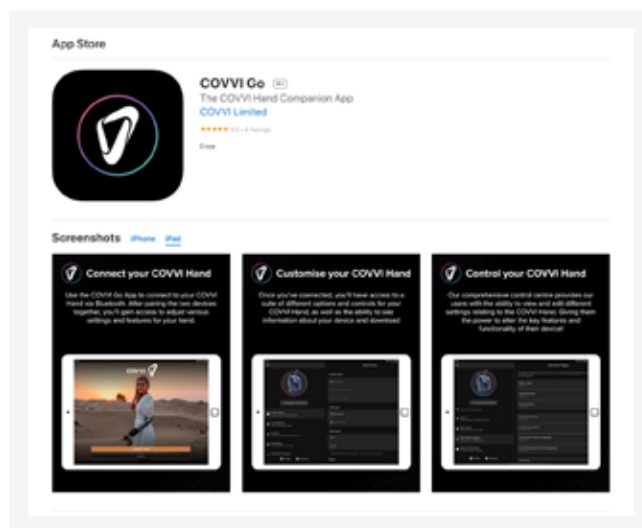
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8.1 Registration

Register Your Interest for a COVVI Go Account by filling out the form on the COVVI website, www.covvi.com. Your clinician or a COVVI Representative is responsible for adding your account, whereby you will receive a link to reset your password in the COVVI Portal. Once you have successfully registered, you can download the App onto your smart device from the Apple Store or Google Play Store. There is another way to Register Your Interest for an account, in the App, by clicking on Get Started and then Sign Up.

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



8.2 Connection

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

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

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

If you experience Bluetooth connectivity issues, please first reset the product using the dorsal button. If the connectivity issues persist, please ensure the product doesn't have low battery and that you don't have Bluetooth interference.

8.3 Configuration

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

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8.0 APP SETUP

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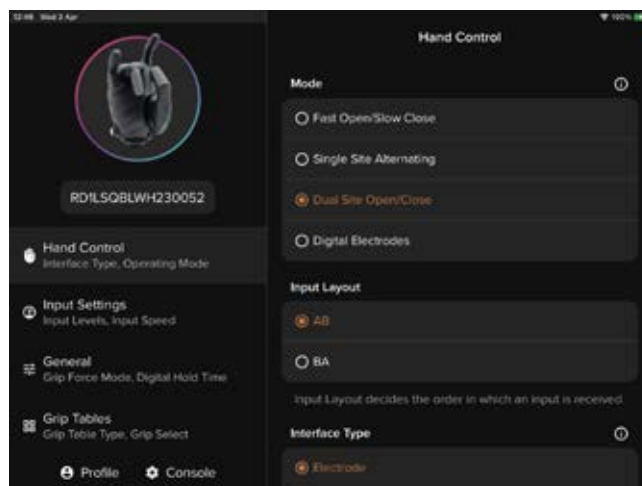
8.4 Hand Control

This section should only need programming once and may not even need any changes at all.

The available options are:

1. Operating Mode: One available for dual site, two available for single site, or multiple digital electrodes for use with a pattern recognition system.
2. Input Layout: To order the open and close signals.
3. Interface Type: To choose what control interface you are using.

*If your product was purchased before April 2024, you may see a different layout.

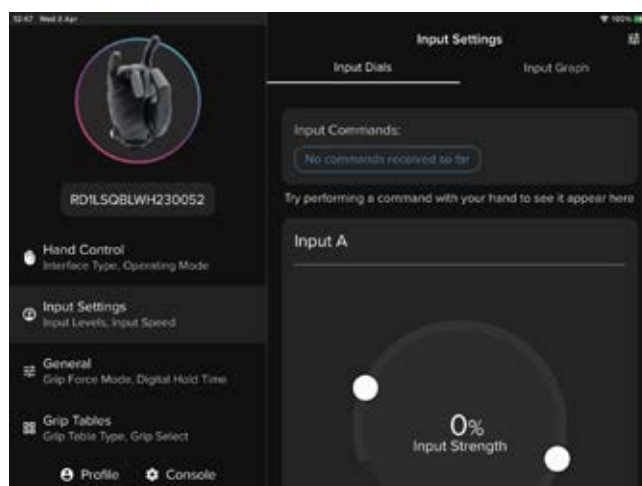


8.5 Input Settings

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

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

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



You can view these thresholds on either dials or a graph. Please note if you map co-contraction, an additional threshold will appear for adjustment.

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8.0 APP SETUP

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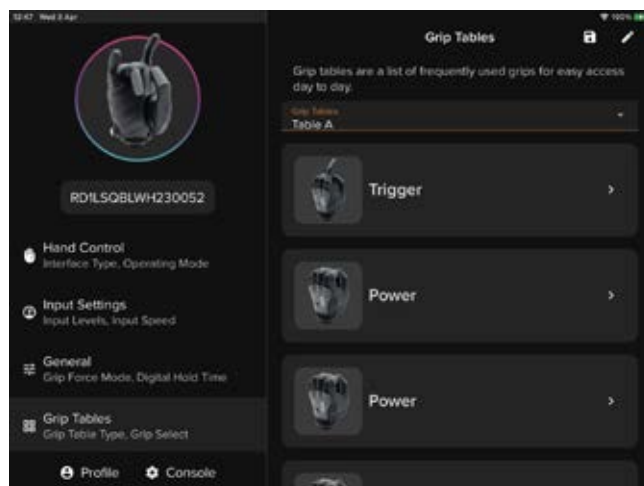
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8.6 Grip Tables

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

To add a grip, select the table you would like to populate and click on the + sign. Choose the desired grip from the list and then click back. The grip will now appear in the next available position. Grips are added one-by-one. If you are unsure of what a particular grip does, select one to see a video showing the product closing and opening with that grip.

To remove a grip, click on the pencil symbol in the top right of the screen then on the trash icon. The grip will no longer appear in the table. There is the option for you to save these changes to any config saved in the config library, or by adding a new config, by clicking on the save icon at the top of the screen.



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8.0 APP SETUP

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8.7 Grip Switch Triggers

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

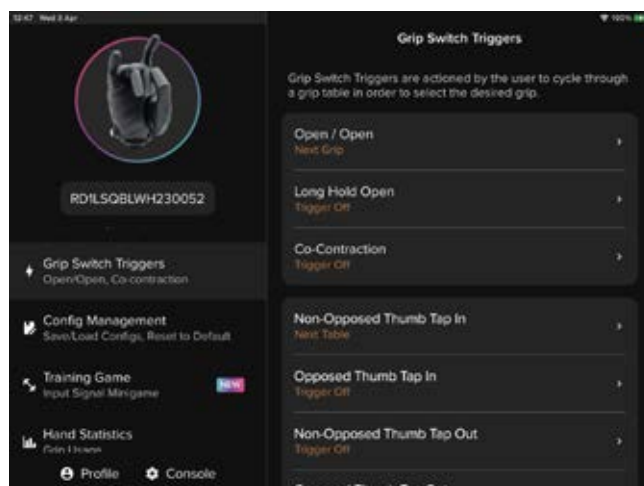
The available grip switch triggers with myo-inputs are:

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

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

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

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



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8.0 APP SETUP

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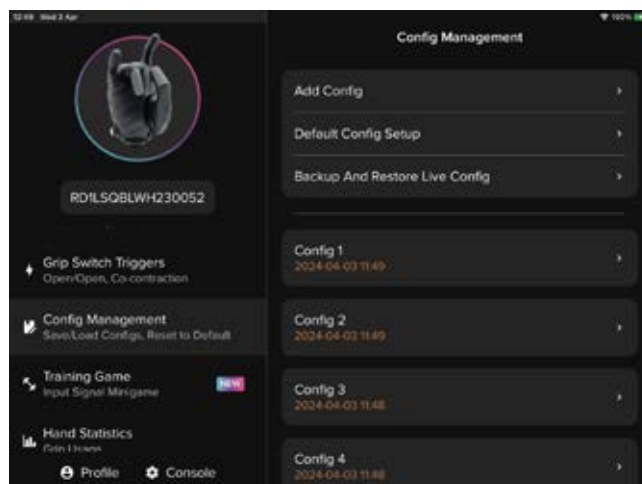
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8.8 Config Management

In Config Management you have 3 options:

1. Add Config: This allows you to save a new configuration to the cloud, so you always have a backup.
2. Default Config Setup lets you choose COAPT for if you are using a COAPT system with your prosthesis.
3. Backup and Restore Live Config is to transfer configurations between devices.

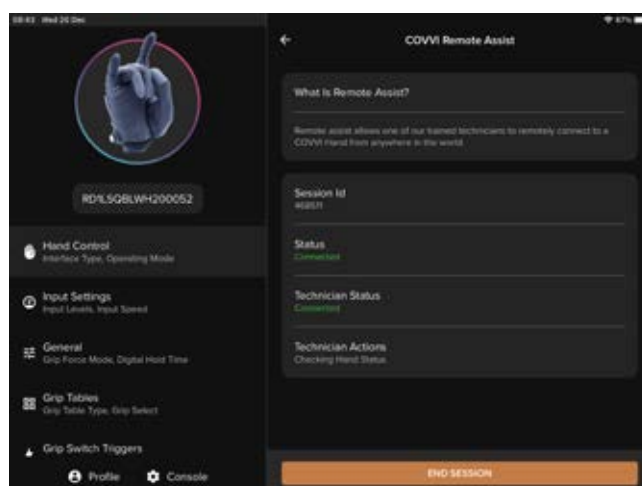
Underneath these options there is the Config Library, where you can see all configurations that you have saved to the product. To restore a configuration, click on the desired one and then on Restore.



8.9 Remote Assist

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

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



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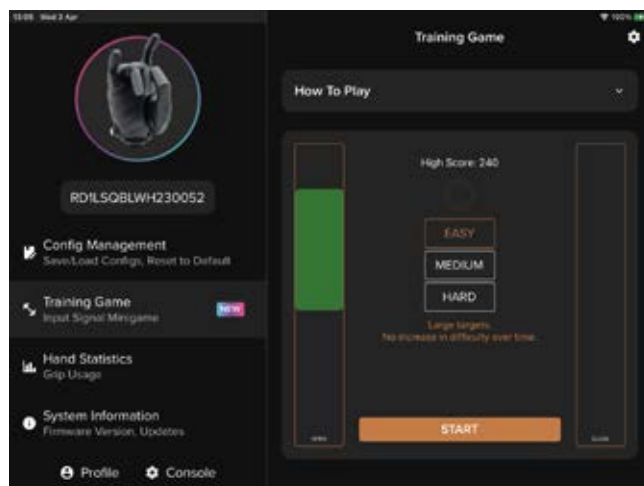
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8.0 APP SETUP

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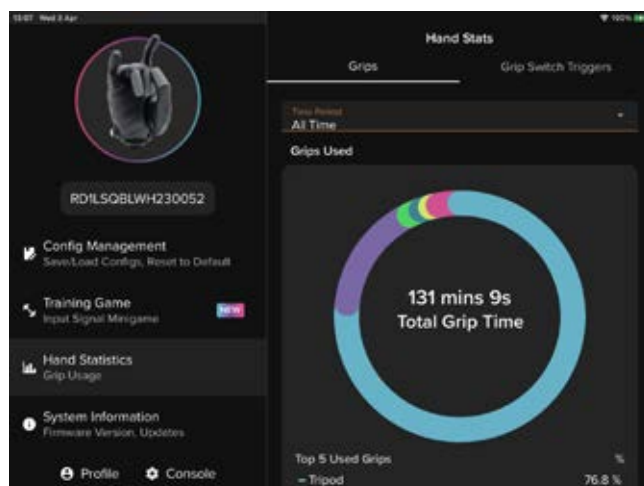
8.10 Training Game

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



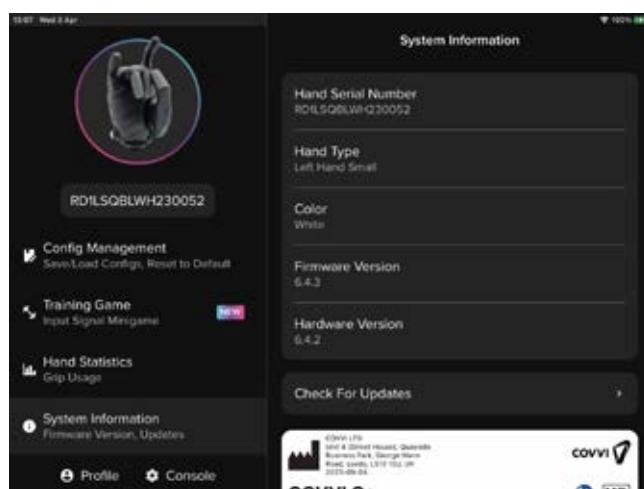
8.11 Hand Statistics

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



8.12 System Information

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



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9.0 SYMBOLS USED

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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



CCAN16LP0011T7

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。

第十四條 低功率射頻電機之使用不得影響飛航安
全及干擾合法通信；

經發現有干擾現象時，應立即停用，並改善至無
干擾時方得繼續使用。

前項合法通信，指依電信規定作業之無線電信。

低功率射頻電機須忍受合法通信或工業、科學及
醫療用電波輻射性

電機設備之干擾。

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