

REBEL HAND

Technical Manual - Model RBLM-W



REBEL

Powered by  AM Healthcare Group

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2.0 User Features

- Independently controlled digits delivering a powered compliant grip.
- Grip strength increase pattern allows the user to confidently increase their grip when required.
- Recommended for use with the REBEL COGPSU/3350 System - other 6-8.4V power systems are compatible.
- Grip configurations are programmed using via mobile application.
- Designed for people with uni/bilateral above wrist limb difference.
- Primary environment: Home Health Care

2.1 Essential Performance

The prosthetic hand is designed to comply with medical device requirements.

HAND - Essential Performance

The REBEL Bionics hand is designed to open and close in response to corresponding MYO signals, but the user is under no additional risk if this doesn't function, therefore it is deemed there is no ESSENTIAL PERFORMANCE.

3.0 Safety Precautions

Please read the following safety precautions prior to fitting the REBEL Bionics Hand.

- **WARNING:** To avoid risk of electric shock, this equipment must only be connected to a supply main with a protective earth.
- The Power Supply should only be fitted by a certified prosthetist; designed for people with uni/bilateral above wrist limb difference.
- Please make sure the Power Supply is OFF before connecting/disconnecting the prosthetic device to avoid damage to the device.
- All maintenance is to be performed by REBEL Bionics / trained service personnel. This product is not designed to be disassembled or serviced by the user/clinician.
- Rebel Bionics have the right to void the warranty of all products that have any type of modification or damage caused by any unauthorized or untrained personnel. Any damage caused by intentional harm or neglect will not be covered under the warranty.

3.0 Safety Precautions

- Do NOT attempt to use the prosthetic device. If functionality is impaired, seek immediate technical support with recommended technician.
- 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.
- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- WARNING: DO NOT USE IN AREAS OF HIGH EMC DISCHARGE
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally
- Any drop in performance, any component getting hot, making new and unusual noises is evident, please remove immediately.
- Clean with hot soapy water, Do NOT use any solvents or abrasives to clean the charge point as this might cause damage.
- Individuals who are exposed to hazardous environments that contain flammable liquid, or gas should NOT use this device when in those environments.
- Ensure access to wall plug to enable easy isolation if required.
- No known contraindications.
- The designed service life of the electrode is 5 years.
- This product uses semiconductors that can be damaged by electrostatic discharge (ESD).

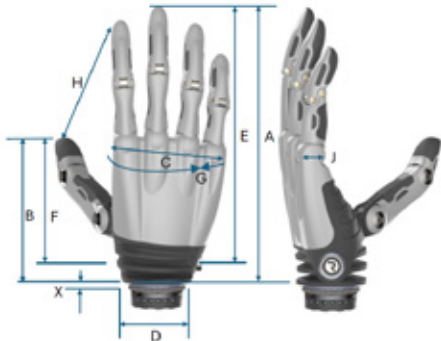
4.0 Environmental

OPERATIONAL AND STORAGE HUMIDITY	Maximum 80% humidity, non-condensing	
STORAGE AND USE TEMP RANGE	-20°C to +38.9°C	-4°F to +140°F
PRESSURE RANGE	700-1060 hpa	

Hand Voltage	7 to 8.4 V
Device Weight	450 Grams (Medium)
400 Grams (Small)	2.5mm ALLEN KEY
Maximum Hand Load Limit	90kg
Maximum Finger Load Limit	16kg
Maximum Current Consumption	5A
Full Open to Full Close Speed	0.7 Secs
Tripod Grip Speed	0.4 Secs
Tripod Grip Force	45N
Power Grip Force	70N
4 Key Grip Force	30N

4.0 Environmental




		Small	Medium
Dimension	Key	MM	MM
Middle fingertip to hand base	A	165	185
Thumb tip to hand base	B	124	124
Max chassis width	C	72	77
Diameter of chassis at wrist	D	47	47
Middle fingertip to flex axis	E	155	175
Thumb tip to flex axis	F	110	110
Palm circumference	H	180	190
Max opening width	I	105	110
Knuckle width	J	20	20
Thumb swing through angle	K	80	80
EQD only	X	3	3



5.0 Grips

Opposed	
	<ul style="list-style-type: none"> • Power Grip • Precision Open & Close • Trigger Grip • Tripod Grip • Rock Grip • Glove Grip • Column Grip

Unopposed	
	<ul style="list-style-type: none"> • Finger Point Grip • Tap Grip • Mouse Grip • Key/Card Grip • Relaxed Grip • Phone Grip

<p>RELAXED GRIP UNAPPOSED</p> 	<p>The Relaxed Hand position gives the REBEL hand a natural, lifelike look—perfect for everyday use. With the thumb angled slightly toward the palm and fingers gently bent, it transitions smoothly into a Hook Grip for carrying bowls or plates securely. The hand can also fully open for a flat palm when needed. Slim and practical, it's ideal for dressing tasks—especially when paired with the Column Grip.</p>
<p>PRECISION CLOSED OPPOSED</p> 	<p>The Precision Closed Grip offers a fast, reliable way to handle small items like coins or tissues. With the index finger and thumb working together while the other fingers close into the palm, it's ideal for tight spaces—like working at a desk—where extended fingers might get in the way. The grip activates in stages, giving users full control of the index finger for precise, confident handling.</p>
<p>PRECISION OPEN OPPOSED</p> 	<p>The Precision Open Grip delivers speed and accuracy for handling small objects. With the index finger opposing the thumb and the other fingers extended, users can easily perform tasks like unwrapping a candy bar or zipping a jacket. The thumb moves to a set midpoint, while the index finger remains fully under user control—making this grip ideal for precise, everyday actions.</p>



5.0 Grips

<p>HOOK GRIP UNOPPOSED</p> 	<p>Say goodbye to juggling bags and hello to effortless carrying with the Hook Grip!</p> <p>Designed for convenience and built for strength, the Hook Grip is your go-to solution for carrying everything—from sleek briefcases and stylish handbags to heavy shopping hauls. Its open grip design means you can swap bags on the fly without ever adjusting your fingers. Secure, versatile, and brilliantly simple—the Hook Grip makes carrying easier, smarter, and more comfortable.</p>
<p>ACTIVE INDEX/TRIGGER GRIP UNOPPOSED</p> 	<p>The Active Index (Trigger) Grip gives users precise control for operating tools and appliances with trigger mechanisms.</p> <p>Perfect for hairdryers, spray bottles, and power tools, this grip allows the hand to hold objects securely with the thumb and remaining fingers, while the index finger moves independently to activate the trigger. It's also ideal for typing, offering a natural, functional hand position for keyboard use.</p>
<p>COLUMN GRIP OPOSED</p> 	<p>The Column Grip delivers power and precision for pressing buttons and operating levers with ease.</p> <p>Whether you're driving, using appliances, or buttoning a jacket, this grip forms a secure fist—thumb tucked toward the palm, fingers closing over it—allowing users to push, press, and control larger switches confidently. Slim and practical, it's perfect for everyday tasks at home, work, or on the go.</p>

5.0 Grips

<p>FINGER POINT GRIP UNOPPOSED</p> 	<p>The Finger Point Grip offers precise control for pressing small buttons and using touchscreens.</p> <p>Ideal for tasks like ringing a doorbell or typing, this grip positions the thumb laterally while the other fingers fold into the palm—allowing the index finger to point and press with accuracy.</p>
<p>MOUSE GRIP UNOPPOSED</p> 	<p>The Mouse Grip is perfect for smooth, accurate computer control—whether at work or play.</p> <p>It allows the user to securely hold a mouse with the thumb and little finger, while the index finger clicks with precision. A simple close signal activates the click, and an open signal releases it—ideal for browsing, gaming, or office tasks.</p>
<p>KEY GRIP UNOPPOSED</p> 	<p>The Key Grip offers precise control for handling slim, flat objects like keys, cards, or plates.</p> <p>With the thumb in a lateral position and fingers partially closed, the thumb presses against the side of the index finger—allowing users to grip, reposition, or release objects with ease. Ideal for tasks like unlocking doors, folding towels, or carrying trays.</p>
<p>COMPLIANT POWER GRIP OPOSED</p> 	<p>The Compliant Power Grip delivers secure, adaptive control for everyday tasks.</p> <p>From shaking hands to using tools or eating fruit, this grip wraps around round or cylindrical objects with stability. All fingers close naturally, followed by a slight thumb delay—creating a strong, responsive hold that adjusts to the object's shape.</p>

5.0 Grips

<p>TRIPOD/PINCH GRIP OPPOSED</p> 	<p>The Tripod Grip offers precise, stable control for handling everyday objects.</p> <p>Ideal for picking up items like keys, coins, jar lids, or pens, this grip brings fingers 1 and 2 to meet the thumb, while the remaining fingers continue to close for added support. It's perfect for tasks like tying shoelaces or lifting lids with confidence and control.</p>
<p>ROCK GRIP OPPOSED</p> 	<p>With the REBEL Hand, you're just one grip away from full Rockstar mode.</p> <p>The Rockstar grip extends the index and little fingers while the middle and ring fingers fold into the palm, secured by the thumb—delivering that iconic rock 'n' roll sign with style and precision. Rock on with confidence and control!</p>

6.0 Grip Triggers

Grip Switch Triggers are inputs/signals from the user which allow the selection of the next grip. The Rebel Hand has numerous switching options to give you fast access to a multitude of grips.




- Open/open signal – This is an open signal when the hand is already open, commonly mapped to the next grip
- Long open hold signal – This is a continued open signal when the hand has reached its open position
- Co-contraction signal - this is both MYO signals, above a given threshold, within a given time. This is an advanced skill, normally used for switching between hands, wrist rotators and powered elbows.
- Dorsal button – push button on the back of the hand, simple for unilateral users, but can be challenging for bilateral users.
- Pronate/supinate thumb tap - Thumb tap in a direction of travel.



6.1 Control Strategy

The hand is controlled by 2x analogue inputs, traditionally coming from myoelectric electrodes. These output signals from 0.4v to 5v and react to the activity in the muscle it is placed on. These 2x signals are mapped to open and close, with the magnitude of the signal being mapped to the speed of the hand. The clinician can adjust the thresholds at which point the hand starts moving and when it moves at full speed.



6.2 Dorsal Button and Light Functions

	<p>Start up</p> <p>Stays blue for 60 seconds or as long as the Bluetooth connection is live.</p>
	<p>Fault Condition</p> <p>Fast flashing red.</p>
	<p>Low Power warning <7V</p> <p>Fast flashing amber.</p> <p>50% speed.</p>
	<p>Very low power warning <7V</p> <p>Solid amber.</p> <p>Quick buzz on vibration when it goes on.</p>
	<p>2 second hold of the dorsal button</p> <p>Stays green for 4 seconds to say it's in home grip.</p> <p>Quick buzz on vibration when it goes on.</p>

	<p>Active grip switch trigger</p> <p>Stays green for 2 seconds to say the hand has received a grip switch trigger.</p> <p>Quick buzz on vibration when it goes on.</p>
	<p>Double press dorsal button</p> <p>Standby mode, double press to reactivate Myo signals. Slow blue flash.</p> <p>Quick buzz on vibration when it goes on and off.</p>

6.3 Buzzer Configuration

The buzzer can be configured via the Rebel Bionics mobile application.

6.4 Grip Control

Starting from an open position, a close signal is applied and the digits in the specified grip pattern drive until either the close signal is removed or the motor stalls. If there is a stall and the close signal is still active, the power continues to be applied until there is a time out, about 0.5sec. Then after a 0.1 second gap the power is reapplied until there is a time out again and so on. In this way if the finger is jammed it can try to release itself.

When an open signal is applied, the digits move to the open limits and stop. The hand will remain static and will not open/C or back drive if no signal is applied or if a signal under the relevant threshold is received.

6.4.1 Grip Switchback Mode

Grip switchback when enabled, causes the hand to automatically load the first grip of the current table after a configured period of inactivity. (15s - 60s).

6.4.2 Grip Strength

Two modes are available:

- Proportional – Grip strength is proportional to input signal.
- Fixed – Grip strength is fixed at maximum configured value.

The maximum strength value can be configured between 20 and 100% of the available power. In “Proportional” mode this caps the delivered grip strength when the maximum input signal is applied, whereas in “Fixed” mode this grip strength is always used.

7.0 Thumb Tap

The product features an innovative “thumb tap” function, which activates a rocker switch at the base of the thumb when tapped laterally. Depending on the configuration, this triggers a specific action. By default, a pronated non-opposed thumb tap moves to the next table, while a supinated opposed thumb tap goes to the previous table. These actions can be customized in the app to perform any available function. This feature enables grip changes without relying on myoelectric inputs.

8.0 REBEL Bionics App

You can download the Reel Bionics App from Apple or Android stores. Only one app exists, but the experience differs for clinicians and users based on login credentials.

8.1 Downloading the App

Connecting the App to the Prosthetic Hand:

- Ensure Bluetooth is enabled on your phone and the Rebel Bionics hand is powered on.
- Connect using either:
 - A QR code scan.
 - The serial number of the hand.
- This connection only needs to be done once per user.
- Adding a User (Clinician App):
 - Avoid using full names for privacy (HIPAA compliance).
 - Use identifiers or customer numbers.
- After adding, you’ll see a list of all users linked to your account.

8.2 Setting up the Prosthetic Hand

- After selecting a user, you can:
 - Add another hand (for bilateral users).
 - Set permissions.
 - View usage statistics.
 - Hand Configuration Options
- Set:
 - Number of myosites.
 - Whether inputs are reversed.
 - Enable/disable notifications, vibration, and buzzer.
 - Configure triggers (e.g., hold open time, open/open time).

8.3 Diagnostic & Signal Setting

View diagnostics for:

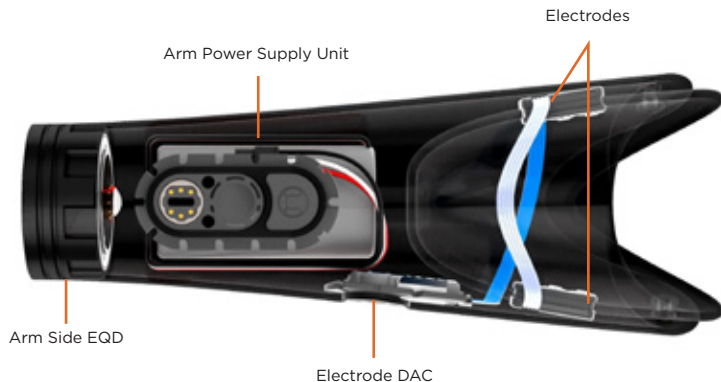
- Motors (e.g., thumb, index, middle flexors).
- Sensors (e.g., grip force).
- Adjust gain and threshold for muscle signals:
 - Red lines = Open signals.
 - Blue lines = Close signals.

8.4 User Feedback & Practice

Users can view their myograph to monitor performance.

Practice muscle triggers by observing if the correct signal activates the corresponding visual cue.

9.0 In Arm Requirements



The arm architecture includes:

1. EQD Please refer to section 6.0
2. Power Supply System please refer to Power Supply Technical Manual.
3. Electrode System please refer to Electrode Technical Manual.

10.0 Electronic Quick Disconnect

The REBEL Bionics Hand is equipped with the EQD (Electronic Quick Disconnect) or also known as (QWD - Quick Wrist Disconnect). This is the standard mechanical and electronic connection between a prosthetic hand and arm socket. This assembly is compatible with most prosthetic terminal devices.

10.1 Hand Side

The REBEL Bionics Hand is equipped with the EQD (Electronic Quick Disconnect) or also known as (QWD - Quick Wrist Disconnect). This is the standard mechanical and electronic connection between a prosthetic hand and arm socket. This assembly is compatible with most prosthetic terminal devices.



General Specification	
Maximum Recommended Axial Force	32kg
Maximum Recommended Lateral Force	32kg
Weight	150g
Current Rating	3.5A CONTINOUS, 6A PEAK (<0.2sec)
Total Height (Excluding Coaxial Core) [A]	22.70mm
Total Diameter [B]	48mm
Cable Length [C]	55mm standard (can be suited to your requirement)
Stack height [D]	14.80mm
Body Diameter (E)	35.86mm
Total Height (F)	21.05mm
Recommended PCB connectors	Molex 874370643 - Vertical
	Molex 874380643 - Horizontal

10.2 Arm Side

The arm-side EQD combines the timeless reliability of a traditional lamination ring with a cutting-edge, modernized locking interface—delivering a seamless blend of classic durability and next-generation adaptability. Designed with customization in mind, this innovative solution empowers you to tailor your setup to meet the exact demands of your application, ensuring both performance and precision every step of the way.



10.2 Arm Side

Technical Specification		
Weight (g)	100g	
Diameter [A]	45mm	50mm
Adapter Height [B]	48mm	
Adapter Height [C]	23mm	
Total Assembled Height [D]	31.75mm	
Coupling Height [E]	20mm	

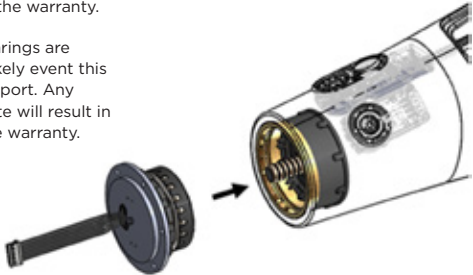
10.3 Connecting to the arm

The hand-side EQD will lock into the arm side by pressing along its central axis, as shown in below image. Expect a positive clicking sound to denote the lock has been successful. Ratchet the EQD around and pull axially to confirm securement of EQD.

10.3.1 Locking

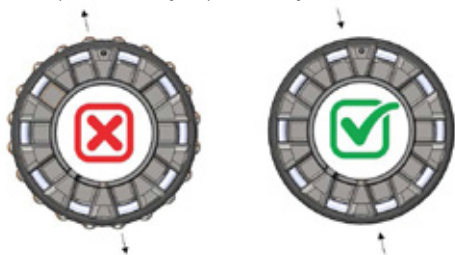
The EQD will not lock if the ball-bearings are radially locked outwards. In the unlikely event this occurs, please contact technical support. Any attempts to lock the EQD in this state will result in a damaged bearing and will void the warranty.

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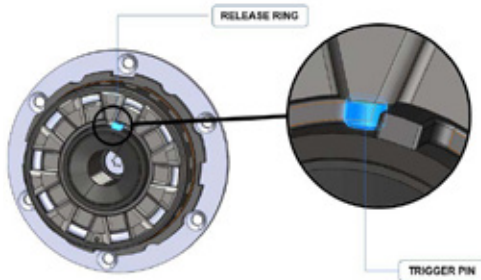


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The arm-side EQD combines the timeless reliability of a traditional lamination ring with a cutting-edge, modernized locking interface—delivering a seamless blend of classic durability and next-generation adaptability. Designed with customization in mind, this innovative solution empowers you to tailor your setup to meet the exact demands of your application, ensuring both performance and precision every step of the way.

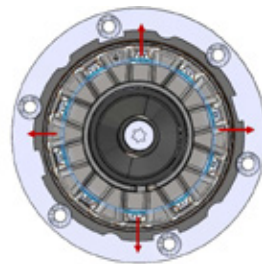


The EQD will not lock if the release ring is jammed against the trigger pin. If this case occurs, please rotate the toggle away from the trigger pin. This will free the release mechanism and enable the lock mechanism to work as intended. If the release ring cannot be rotated, please refer the EQD to technical support.



10.3.1 Locking

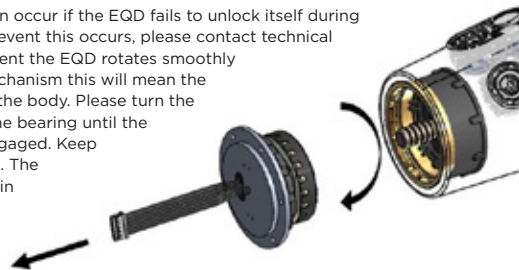
The EQD will not lock successfully if the bump ring becomes dislocated from the EQD body. In this case, the EQD may seat inside the lamination ring, but you will not hear any denotation of a lock sound. This case is only likely to occur due to tampering of the locking mechanism. If this occurs, please refer to technical support. A sign for confirming this case is inspecting the bottom-side of the EQD.



10.3.2 Ejection

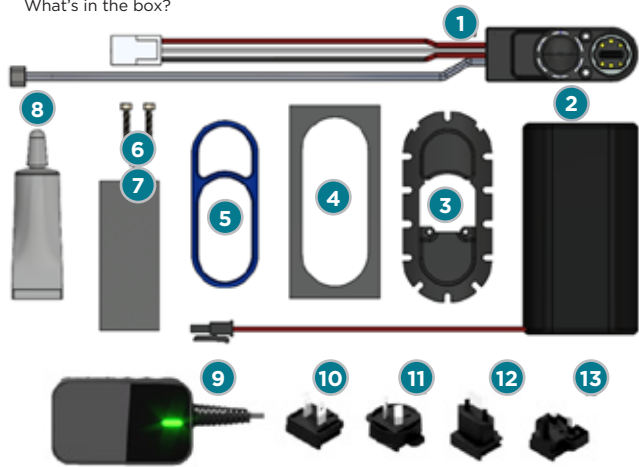
To eject the EQD, please rotate either side until the ratcheting mechanism results with the EQD ejecting. On some occasions, the ejection may require a higher force than what is required to turn the EQD on its ratcheting mechanism.

An unsuccessful ejection can occur if the EQD fails to unlock itself during the ejection. In the unlikely event this occurs, please contact technical support. If in the unlikely event the EQD rotates smoothly instead of its ratcheting mechanism this will mean the bearing has loosened from the body. Please turn the EQD clockwise to tighten the bearing until the ratcheting mechanism is engaged. Keep turning until the EQD ejects. The EQD will require tightening in this event and so technical support will be required.



11.0 Power Supply System

What's in the box?



#	PART NO.	DESCRIPTION
1	B10-A021	CHARGE PORT
2	B10-A006	3350mAh BATTERY
3	B10-0052	MOUNTING BRACKET
4	B10-0058	CUTTING GUIDE
5	B10-0069	ARM SEAL
6	SSCF-M2-10	M2 CAP HEAD

7	B10-0059	BATTERY VELCRO
8	B10-0060	SILICONE ADHESIVE
10	B10-0061	USB-C POWER SUPPLY
11	B10-0062	US ADAPTER
12	B10-0065	AUS/NZ ADAPTER
13	B10-0063	EU ADAPTER
14	B10-0064	UK ADAPTER

12.0 Fitting Instructions

TOOLS REQUIRED

DREMEL OR SIMILAR MULTITOOL	SMALL ROUND NEEDLE FILE	CARVING/ENGRAVING BIT
DREMEL CUTTING WHEEL	SMALL FLAT NEEDLE FILE	PLUseries® 60s Adhesive
T6 TORX DRIVER		



Personal protective equipment must be worn at all times during the fabrication process.



STEP 1.

STEP 2.



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.

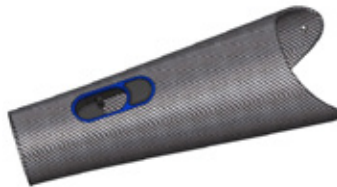
12.0 Fitting Instructions

STEP 3.



Offer the internal bracket to the inside of the aperture. Remove material from the wings if the housing is sitting too low in the arm.

STEP 4.



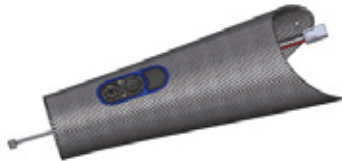
Use the seal to ensure the alignment is correct with the outer surface of the arm. Only bond the mounting bracket, not the seal at this stage. We would recommend bonding the lamination ring into the limb with +PLUseries® 60 Second Adhesive at this point and allow to cure.

STEP 5.



Offer the internal bracket to the inside of the aperture. Remove material from the wings if the housing is sitting too low in the arm.

STEP 6.



Secure the Charge port with the 2x cap head bolts screws using the T6 Torx driver (0.3Nm). Bond the seal in place with the silicone glue, taking care not to get glue on the outside surface of the charge point or the arm.



Failure to sufficiently enclose the battery will pose a serious threat to user safety due to the risk of water ingress.

13.0 Safety Precautions



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

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with a protective earth.

The Power Supply should only be fitted by a certified prosthetist, Designed to power MYO electric hands for people with uni/bilateral above wrist limb difference.

Please make sure the Power Supply is **OFF** before connecting/disconnecting the prosthetic device to avoid damage to the device.

This product is not designed to be disassembled or serviced. Cogent have the right to void the warranty of all products that have any type of modification or damage caused by any unauthorized or untrained personnel.

Any damage caused by intentional harm or neglect will not be covered under the warranty.

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 IN AREAS OF HIGH EMC DISCHARGE

Any drop in performance, any component getting hot, making new and unusual noises is evident, please remove immediately.

Clean with hot soapy water, **DO NOT** use any solvents or abrasives to clean the charge point as this might cause damage.

Individuals who are exposed to hazardous environments that contain flammable liquid or gas should **NOT** use this device when in those environments.

Ensure access to wall plug to enable easy isolation if required.

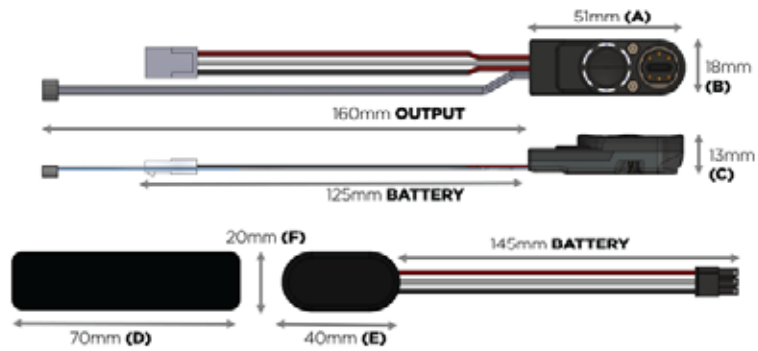
No known contraindications.

The designed service life of the Charge point is 5 years, Cells to be changed on an annual basis.

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

It is advised to disconnect the battery if the limb is unlikely to be used for some time or is being shipped, or stored.

14.0 System Specification



PART NUMBER	COGPSU/3350	
CAPACITY	3350mAh	
NOMINAL VOLTAGE	7.4V	
MAX. CURRENT DRAW	7A	
CHARGE PORT DIMENSIONS	51mm (A) x 18mm (B) x 13mm (C)	2" (A) x 0.7" (B) x 0.5" (C)
BATTERY DIMENSIONS	70mm (D) x 40mm (E) x 20mm (F)	2.7" (D) x 1.6" (E) x 0.8" (F)

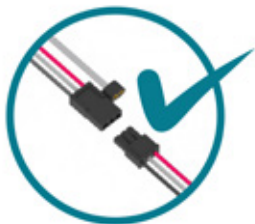
14.0 System Specification (continued)

SYSTEM WEIGHT	125grams	4.4oz
USB-C POWER SUPPLY	FRIWO Gerätebau GmbH - NEO006.0-I-X-05 P No.: 1960559	
Nominal Input Voltage	100-240V AC +/-10%	
Nominal Output Current:	1400mA	
Nominal Output Voltage:	5V DC +5% / -5%	
OPERATIONAL AND STORAGE HUMIDITY	Maximum 80% humidity, non-condensing	
CHARGE TEMP RANGE	-10°C to +45°C	14°F to 113°F
DISCHARGE TEMP RANGE	-20°C to +60°C	-4°F to +140°F
STORAGE TEMP RANGE	-20°C to +60°C	-4°F to +140°F
PRESSURE RANGE	700-1060 hPa	

15.0 User Instructions



Please ensure the battery is connected correctly to the Power Supply. There is only one orientation to connect the 3-way connector, all colours must line up and the square socket must line-up.



15.1 Turning the Limb Power On

Greater than 1 second hold turns on limb power.

6x purple will illuminate clockwise and then go blank.



15.2 Turning the Limb Power Off

Greater than 1 second hold turns off limb power.

6x purple will illuminate anticlockwise and then go blank.



15.3 Charging the Battery

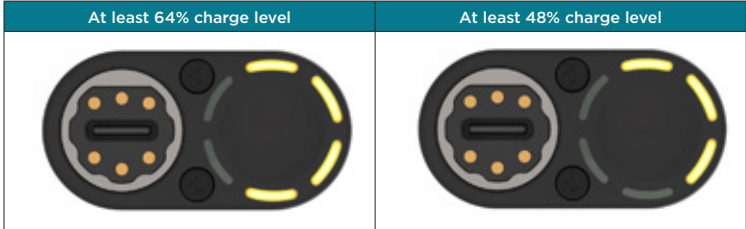
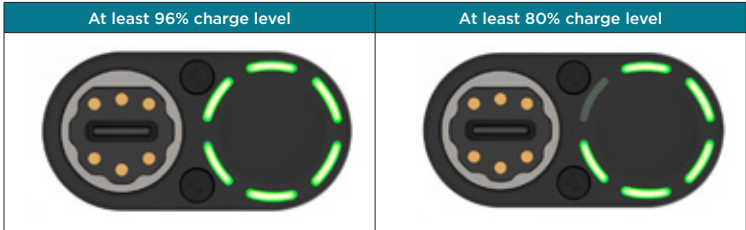
To charge the device connect the provided Mains AC USB-C connector or use the rightangle magnetic charger with a Mains AC USB-C power adapter.

If charging correctly, all 6x cyan will pulse slowly.

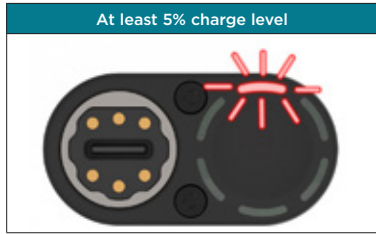
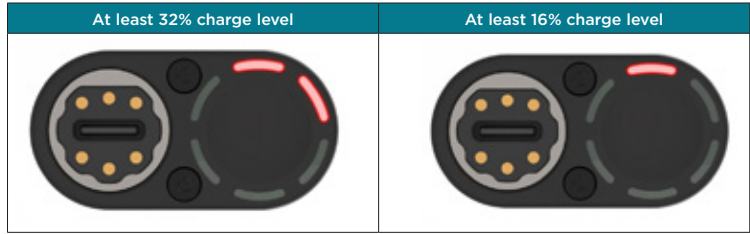


15.4 Charge Indication

QUICK PRESS (for less than 1.5 seconds) to view battery charge level for 2.5 secs, then will go out.



15.4 Charge Indication (continued)

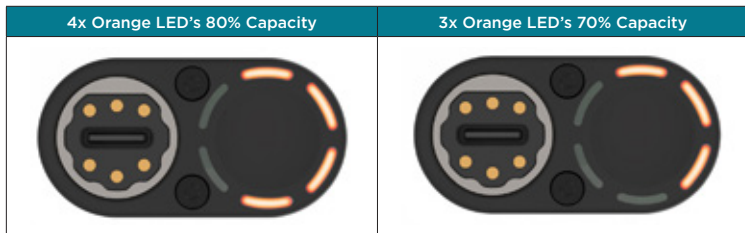
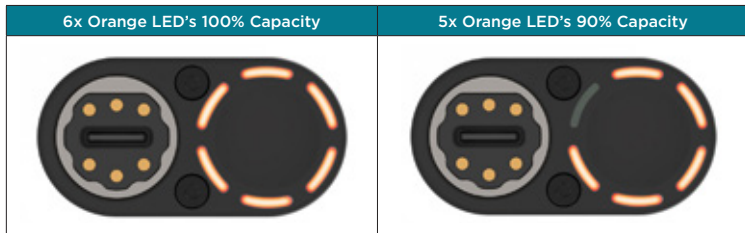


Lower LED will flash red when the battery is lower than 5%. This doesn't require a button press.

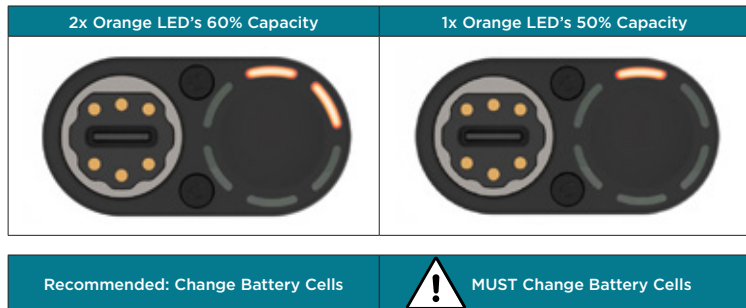
15.5 Battery Health Indication

2x QUICK PRESS (first within 1.5s and the second within 1.5s) enters the battery health indication display. This will appear for 2.5 secs, then will go out.

The following displays what to expect the battery level indication to be at various states.



15.5 Battery Health Indication (continued)



15.6 Full System Reset

To enable Full System Reset, you will need the Limb Power OFF and not charging.

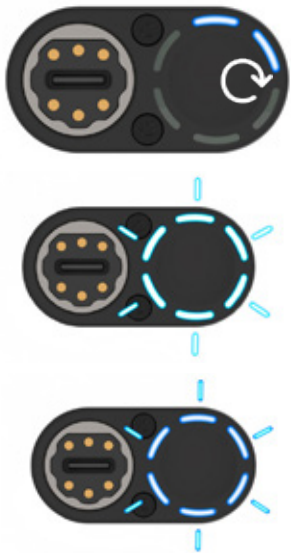
2x QUICK PRESS within a 1.5 second succession will skip through to the Full System Reset Indication.

6x Further presses within a 1.5 second succession illuminates the LED's in a clockwise direction one by one.

Final press it will flash aqua marine and flash blue twice. This confirms the system is complete reset.



A FULL RESET WILL BE REQUIRED IF THE BATTERY IS SWAPPED.



16.0 Battery Replacement

The Cogent 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 the Cogent Power Supply and we recommended the cells are swapped every 12 months.

16.1 Replacement Instructions

1. Completely deplete the old batteries until flat and the limb no longer moves.
2. Disassemble the limb and replace the cells - Only Use Cogent 3350 mAh Battery, Part Number **B10- A006**.
3. Reassemble the limb, connect the batteries to the USB-C charger, follow the instructions as provided on Section 4.0
4. Fully reset the system (instructions on page 9)
5. Allow system to fully charge.
6. If this initial charge or the full reset is not conducted properly it will negatively affect how the system calculates the remaining charge.
7. Check your local waste regulations to safely dispose of your old batteries.

17.0 Disposal

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

18.0 Declaration of Conformity

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices. The undersigned declares, under their sole responsibility, 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	REBEL Bionics Power Supply
Legal Manufacturer	REBEL Bionics, Unit 5A, Balm Road Industrial estate, Beza Street, Hunslet, Leeds, LS10 1BG, United Kingdom
Manufacturers SRN	Not Yet Available
Basic UDI-DI	5065015353AAA003G2
Variants	As per Appendix II (This document) - Product Listing/Schedule
Intended Purpose	Supply power to upper limb prosthesis
MDR Classification	Class 1 (Rule 13)
Notified Body	Not applicable
CE Certificate	N/A
EC Authorised Representative	ADVENA LTD. Tower Business Centre, 2nd Flr. Tower Street, Swatar, BKR 4013 Malta
EC Authorised SRN	MT-AR-000000234
Medical Device Regulation Assessment Route	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745. In accordance with Article 19 of the Medical Device Regulation.

Ted Varley,
Managing Director
2nd April 2024

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.

19.0 Electrodes

This is the all-new digital Electrode system which uses a digital sensing approach, with multiple electrodes on a single bus wire. The system includes a compact controller (DAC), which allows remote gain adjustment for the clinician and a boost function for the user. The System contains two analogue outputs and is fully compatible with all Myo-electric systems. The electrodes are smaller than analogue electrodes from other manufacturers and can be directly fitted into the cavities with the suspension leg adapters.

This Electrode is compatible with most Myo-electric prosthetic devices.

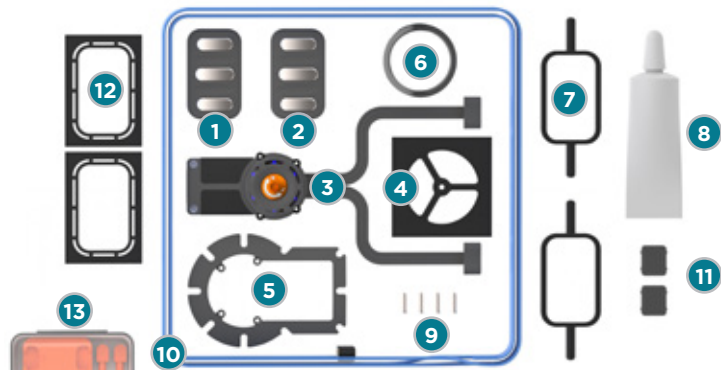
- Flexible upper electrode housing to conform to the inner socket wall for user comfort.
- The DAC has a Push and a 360 degree rotation input with a multicolour LED array.
- Manual and Auto gain adjustment.
- Boost mode which temporarily can give the user a 25% increase in output, to used when fatigued.
- Global dual frequency filtering, both 50Hz and 60Hz as standard.
- Highly proportional signal processing.
- Compact design suitable for child or adult systems.
- High sensitivity (2000-100,000 fold) and range (90-450Hz).
- Digital Interference protection, no unshielded analogue cables.
- Both sealing and suspension leg adapters included in the kit.
- The contacts are coated with pure biocompatible titanium.
- No known contraindications.

The Performance characteristics are:

- To control the endoprosthesis correctly.
- The predominant risk to health and safety of the user or other persons is:
- If the functions stop working, this will not cause a risk to the user or other persons

As these characteristics are covered by Basic Safety, there is no essential performance.

20.0 What's In The Box?



#	PART NO.	DESCRIPTION
1	B13-A004 (A)	ELECTRODE CH. A
2	B13-A004 (B)	ELECTRODE CH. B
3	B13-A006	DAC ASSEMBLY
4	B13-0076	DAC CUTTING GUIDE
5	B13-0063	DAC MOUNTING BRACKET
6	B13-0067	DAC ARM SEAL

7	B13-0062	SUS. LEG ADAPTER
8	B10-0060	SILICONE ADHESIVE
9	SCS-M1.4-6	M1.4X6 CSK SCREW
10	B13-A005	4 WAY DIGITAL CABLE
11	B13-A008	IDC CONNECTOR
12	B13-0077	ELECTRODE TEMPLATE
13	B13-A028	LAMINATION & VAC. KIT



LAMINATION & VACUUM KIT		
14	B13-0137	KIT BOX
15	B13-0088	MOUNTING BRACKET BLANK
16	B13-0082	MONTING BRACKET
17	B13-0083	TOP PLATE BLANK
18	B13-0087	INNER SOCKET BLANK
19	B13-0089	SUS. LEG BLANK
20	B13-0084	CABLE ROUTE BLANK
21	B13-0085	EXTERIOR FRAME BLANK
22	B13-0086	EXTERIOR BLANK INSERTS
23	B13-0142	ELECTRODE BLANK DECAL
24	B13-0002	LAMINATE DUMMY WASHER
25	B13-0001	M4 INSERT
26	B13-0003	M4 LOW HEAD BOLT



21.0 DAC Fitting Instructions

TOOLS REQUIRED

Dremel or similar multitool	Small round needle file	Carving/engraving bit
Dremel cutting wheel	Small flat needle file	PLUseries® 60s adhesive
⚙️ 6 Torx driver	2.5mm Allen key	



Personal protective equipment must be worn at all times during the fabrication process.

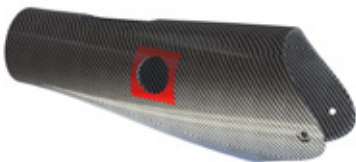


STEP 1



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

STEP 2



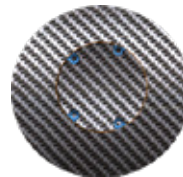
Carefully cut along the red outline with a cutting disc. File down any sharp edges.

STEP 3



Offer the internal bracket to the inside of the aperture. Remove material from the wings if the housing is sitting too low in the arm.

STEP 4



Use the seal to ensure the alignment is correct with the outer surface of the arm. Only bond the mounting bracket, not the seal at this stage. We would recommend bonding the lamination ring into the limb with +PLUseries® adhesive at this point and allow to cure.

STEP 5



Once cured, offer the DAC to the aperture from the inside of the socket and retain with the 4x M1.4 x 6 CSK Bolts. Ensure the body of the DAC aligns with the mounting bracket.

STEP 6


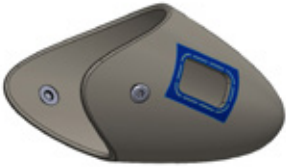




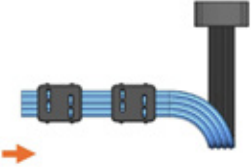

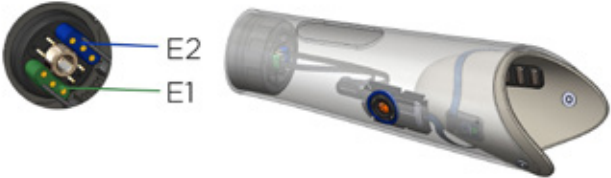
Bond the seal in place with the silicone glue, taking care not to get glue on the outside surface of the DAC or the arm.



Failure to sufficiently enclose the battery will pose a serious threat to user safety due to the risk of water ingress.

22.0 Electrode Fitting Instructions

STEP 7	STEP 8
	
<p>On the outer surface of the inner socket wall, place the electrode templates [B13-0077] in the desired position.</p>	<p>Cut the rounded rectangle from the centre of the template.</p>
STEP 9	STEP 10
	
<p>Add a small chamfer to the inside of both electrode apertures.</p>	<p>Add a small amount of silicone adhesive to the groove in the electrode, highlighted in orange. Then push the electrode through the socket wall. Wipe any excess silicone adhesive as from the socket. Fit the A electrode on the inside of the arm and the B electrode on the outside of the arm.</p>

STEP 11	STEP 12
	
<p>Take the digital cable and slide the two IDC connectors onto the cable. Ensure the side with the four holes faces the blue side of the cable. PLEASE NOTE: Ensure blue side of cable is facing the correct way or the electrode system will not work.</p>	<p>Multiple electrodes are designed to be fitted to a single cable. Position the four-way curved connector close to where the DAC is mounted and wrap the cable around the socket. Trim the cable at the far side of the far electrode. It's not important whether the cable goes A to B or visa versa, but the the grey side of the cable must face the electrodes, blue faces outwards.</p>
STEP 13	
	
<p>Connect the 4-way cable to the DAC and re-assemble the arm. Connect the two connectors to the coaxial core. Green connector to E1 and the Blue connector to E2.</p>	

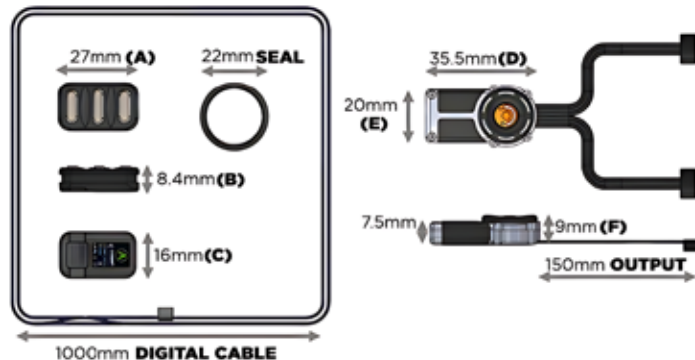
23.0 Safety Precautions



Please read the following safety precautions prior to fitting the REBEL Bionics Electrode System.

- The REBEL Electrode System should only be fitted by a certified prosthetist.
- Please make sure the Power Supply is OFF before shortening the 4-way digital cable.
- This product is not designed to be disassembled or serviced. Rebel 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.
- Do NOT expose the REBEL Electrode System to an open flame.
- Do NOT use any solvents or abrasives to clean the DAC or electrodes as this might cause damage.
- Individuals who are exposed to hazardous environments that contain flammable liquid, or gas should NOT use this device 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).
- The designed service life of the electrode is 5 years.

24.0 System Specification



PART NUMBER	COGDAC/EL2	
WORKING VOLTAGE	6V-8.4V	
MAX. CURRENT DRAW	<200mA	
ELECTRODE DIMENSIONS	27mm (A) x 8.4mm (B) x 16mm (C)	2" (A) x 0.7" (B) x 0.5" (C)
DAC DIMENSIONS	35.5mm (D) x 20mm (E) x 9mm (F)	2.7" (D) x 1.6" (E) x 0.8" (F)
SYSTEM WEIGHT	*grams	*oz
STORAGE & OPERATIONAL HUMIDITY	Maximum 80% humidity, non-condensing	
STORAGE & OPERATIONAL TEMPERATURE RANGE	-20°C to +60°C	-4°F to +140°F
PRESSURE RANGE	700-1060 hPA	

25.0 User Instructions

TURNING THE LIMB POWER ON



Upon correctly identifying both electrodes and during power up of the limb, the DAC LEDs will illuminate clockwise and then return blank.

NOTE:

If 1 electrode is not read, the DAC will return a single Red LED to show there's 1 electrode not connected and a single Green LED to show there's 1 electrode connected. Please ensure the electrode connections are correct and try again.

ELECTRODE MODES

Quick press (less than 1.5s) will show the electrode mode.

STANDARD MODE



This mode allows the clinician to manually adjust the gain levels and is shown by a single green LED

AUTO GAIN MODE



This mode allows automatic gain adjustment and is shown by two amber LEDs.

This can only be done by a clinician.

BOOST MODE



This mode is selectable by the user and gives a +25% boost to the manually selected levels. This is to aid with user fatigue.

ACTIVATE BOOST MODE - PRESS AND HOLD BUTTON FOR 2 SECONDS UNTIL THE 3 LEDS FLASH BLUE, THEN RELEASE. When in this mode the 3x BLUE LEDS remain illuminated.

De-activate boost mode - press and hold button for 2 seconds until the 3 leds go out, then release.

You are now in standard mode; in this mode there is no illumination. If the limb power is turned off the boost mode will be cancelled and return to standard mode.

25.0 User Instructions

CLINICAL ADJUSTMENT MODE SELECTION

A long press for greater than 3 seconds enters the CLINICAL SET UP MODE. You will be presented by a flashing green light; this is to select MANUAL MODE.

A quick press of less than 1.5 seconds will allow you cycle between each of the modes. Press and hold for 3 seconds will select that mode.

ENTERING MANUAL GAIN ADJUSTMENT MODE



A single green light will now be flashing. Press and hold for 3 seconds will select that mode.

ENTERING AUTOMATIC ADJUSTMENT MODE



From the single flashing green light of the manual gain mode, press the button for less than 1.5 second. There should be now 2x LEDS flashing amber. Press and hold for 3 seconds will select that mode.

ADJUSTING THE GAIN MANUALLY



The 2x colours equate to the 2x electrodes:

- Green LED is for Electrode 1
- Blue LED is for Electrode 2



Quick Press (less 1.5s) swaps between the two electrodes.



To adjust the electrode, use the 2.5mm Allen Key and rotate the central orange segment of the switch.

Clockwise increases the gain, anticlockwise reduces the gain.

There is no physical end stop. There are six segments and four levels per Segment:

Blank (0%),
Slow flash (33%)
Fast Flash (66%),

Solid (100%) so there are 24 gain levels.






Once the preferred gain level is selected for both electrode sites, Press the button for 3 seconds.




The DAC will display six purple rings to signify the process is complete.

25.0 User Instructions

USING THE AUTOMATIC GAIN ADJUSTMENT

This is a method to simplify the gain setting process. The user is asked to provide a resting, weak signal followed by a maximum, strong signal. The signals the users can achieve will set the gain levels.

	<p>The user must now provide a resting signal for 1 second. Once satisfied with the resting signal, Press the button (less than 1.5s) to move to the next step.</p> <p>The aim is to ensure the DAC LED indication is as low as possible.</p>
	<p>The user must now hold a strong signal.</p> <p>Once satisfied with the strong signal, Press the button (less than 1.5s) to move to the next step.</p> <p>The aim is to ensure the DAC LED rings are fully indicated at this signal.</p> <p>Hold the button for greater than 3 seconds to confirm E1 settings.</p>
	<p>The user must now provide a resting signal for 1 second. Once satisfied with the resting signal, Press the button (less than 1.5s) to move to the next step.</p> <p>The aim is to ensure the DAC LED indication is as low as possible.</p>

	<p>The user must now hold a strong signal.</p> <p>Once satisfied with the strong signal, Press the button (less than 1.5s) to move to the next step.</p> <p>The aim is to ensure the DAC LED rings are fully indicated at this signal.</p> <p>Hold the button for greater than 3 seconds to confirm E2 settings.</p>
	<p>The user can now view each electrode channel signal via the LED indication.</p> <p>If the user is satisfied with the selected signals for E1 and E2, they can confirm the settings by pressing the button for greater than 3 seconds.</p> <p>If the user is not satisfied with the selected signals for E1 and E2, they can press the button for less than 1.5 seconds which will return to the beginning of the automatic gain adjustment.</p>
	<p>The user must now provide a resting signal for 1 second. Once satisfied with the resting signal, Press the button (less than 1.5s) to move to the next step.</p> <p>The aim is to ensure the DAC LED indication is as low as possible.</p>

26.0 Disposal

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

27.0 Declaration of Conformity

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices. The undersigned declares, under their sole responsibility, 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	REBEL Bionics Power Supply
Legal Manufacturer	Rebel Bionics, Unit 5A, Balm Road Industrial estate, Beza Street, Hunslet, Leeds, LS10 1BG, United Kingdom
Manufacturers SRN	Not Yet Available
Basic UDI-DI	5065015353AAA002FY
Variants	As per Appendix II (This document) - Product Listing/Schedule
Intended Purpose	Acquisition of signals for a prosthetic hand
MDR Classification	Class 1 (Rule 13)
Notified Body	Not applicable
CE Certificate	N/A
EC Authorised Representative	ADVENA LTD. Tower Business Centre, 2nd Flr. Tower Street, Swatar, BKR 4013 Malta
EC Authorised SRN	MT-AR-000000234
Medical Device Regulation Assessment Route	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745. In accordance with Article 19 of the Medical Device Regulation.

Ted Varley,
Managing Director
2nd April 2024

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.

28.0 Compatibility

Brand	Type	Model/Code	Available
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	
Steeper	Seal-in Electrode	ELSK50	Yes
Steeper	Seal-in Electrode	ELSK60	Yes
Ossur	Compact Electrode Kit, 50Hz	PL091050 (300mm Cable)	Yes
Ossur	Compact Electrode Kit, 50Hz	PL091127 (600mm Cable)	Yes
Ossur	Compact Electrode Kit, 60Hz	PL091060 (300mm Cable)	Yes
Ossur	Compact Electrode Kit, 60Hz	PL091128 (600mm Cable)	IBT Glide TBC
Batteries			
Ottobock	MyoEnergy Integral	757B35=5	Yes
Steeper	S-Charge System	SCBP2200	Yes
Touch Bionics	Replaceable Battery Assembly Kit	PL238149	Yes

28.0 Compatibility

Brand	Type	Model/Code	Available
Touch Bionics	Replaceable Battery Assembly Kit w/ switch block	PL238163	Yes
Ossur	1300mAh battery	PL000336	No
Ossur	2000mAh battery	PL000335	Yes
IBT	FlexCell	1027201 / 1027202 / 1027203 / 1027204	Yes
Vincent	Vincentaccu Flex	flex1290	Yes
Elbow			
Ottobock	MyoEnergy Integral	757B35=5	Yes
Steeper	S-Charge System	SCBP2200	Yes
Touch Bionics	Replaceable Battery Assembly Kit	PL238149	Yes
Fillauer	Utah Arm 3 Base	5010110 / 5010111 / 5010112	Yes
Fillauer	Utah Arm 3	5010035 / 5010036 / 5010038	Yes
Fillauer	Utah Arm 3+	5010039 / 5010040 / 5010041	Yes
Fillauer	Utah Hybrid Arm	5010042 / 5010043 / 5010044	Yes
Steeper	Espire Pro Elbow	EEP	Yes

Brand	Type	Model/Code	Available
Elbow (continued from page 25)			
Steeper	Espire Hybrid Elbow	EEH	Yes
Steeper	Espire Classic Elbow	TBC	No
Steeper	Espire Classic Plus Elbow	EEC-P	Yes
Steeper	Espire Basic Elbow	TBC	Yes
Motion Control	Motion Arm EL	50-10142 / 50-10144 / 50-10143	Yes
Motion Control	Motion Arm ML	50-10139 / 50-10141 / 50-10140	Yes
Ottobock	ErgoArm Hybrid Plus	12K44 (All Sizes)	Contact us for options
Ottobock	ErgoArm Electronic Plus	12K50 (All Sizes)	Contact us for options
Ottobock	DynamicArm Elbow	12K100N (All Sizes)	Yes
Ottobock	DynamicArm Plus Elbow	12K110N (All Sizes)	Yes
Ottobock	Analog Adapter	13E100	Yes
Glaze	Whizzlink	—	Yes

28.0 Compatibility

Brand	Type	Model/Code	Available
Connection Cable			
Ottobock	Electrode Cable	13E129 (All Sizes)	Yes
Ossur	3-way Cable 300mm	PL091029	Yes
Ossur	3-way Cable 600mm	PL091030	Yes
Wrist			
Ottobock	MyoRotronic	13E205	Yes
Ottobock	Electric Wrist Rotator	10S17	Yes
Fillauer	MC Standard Wrist Rotator	5010045	Yes
Fillauer	MC ProWrist Rotator	5010056	Yes
Fillauer	MC Powered Flexion Wrist	3010993	No
Pattern Recognition			
COAPT	COAPT	G2SC	Yes
Ottobock	MyoPlus TR	13E520	No
Lamination Rings			
Ottobock	Lamination Ring	10S1 (All Sizes)	Yes
Steeper	Lamination Ring	QDALR-40/45/50	Yes
Ossur	Lamination Ring	089003/091037	Yes

Brand	Type	Model/Code	Available
Coaxial Plug			
Steeper	Espire Hybrid Elbow	EEH	Yes
Steeper	Espire Classic Elbow	TBC	No
Steeper	Espire Classic Plus Elbow	EEC-P	Yes
Coupling Piece			
Ottobock	Coupling Piece	10S4	Yes
Steeper	Coupling Piece Kit	QDACP	Yes
Ossur	Coupling Piece	PL091032	Yes

29.0 Maintenance

To ensure optimal performance and longevity, it is recommended that the Rebel Bionics Hand undergoes a full service annually.

If your patient experiences any issues with their REBEL Bionics Hand, please reach out to Rebel Bionics Customer Services. Our teams at Rebel Bionics Ltd. are available to carry out servicing and provide support with any maintenance concerns.

Regular servicing may include firmware updates, component replacements, and internal checks to maintain device integrity. While annual servicing is encouraged, declining a service will not void the product's warranty.

30.0 Warranty

REBEL Bionics provides a 24-month standard warranty for its products, covering manufacturing defects from the date of activation (for the REBEL Bionics Hand) or invoice (for ancillary products). An extended warranty for the REBEL Bionics hand (3, 4, or 5 years) is available if purchased within the original warranty period. Products are subject to be evaluated for warranty.

REBEL Bionics 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. Rebel 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 REBEL 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 REBEL, to refund the purchase price of a full refund, partial refund, or no refund, depending on the condition of the return.

Our commitment 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.







REBEL has the right to void the warranty on all products that have any type of modifications or damage caused by any unauthorized 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 REBEL products will null and void all warranties.

31.0 Liability




To the fullest extent permitted by law REBEL Bionics 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 Rebel, irrespective of whether the Clinician or User has been advised or otherwise might have anticipated the possibility of such loss or damage.






REBEL Bionics 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 Rebel which may result in direct, indirect, incidental, special, punitive, or consequential losses or damage.

32.0 Symbols Used









Symbol	Title	Description	Standard	Ref. No. of symbol
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1	5.5.1
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1	5.4.3
	Keep Dry	Indicates medical device kept away from moisture	ISO 15223-1	5.3.4
	Temperature Limit	Indicates temperature the medical device can be exposed	ISO 15223-1	5.3.7
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 15223-1	5.3.8
	Type BF applied part	Indicates an electrical medical device that complies as Type B	IEC 60601-1 IEC 60601-1 IEC 60878 ISO 9687:2015	5334

32.0 Symbols Used

Symbol	Title	Description	Standard	Ref. No. of symbol
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	Device is prescription use only by a designated healthcare professional	None; this is symbol generated by the company	21 CFR
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1	5.4.4
		This product contains electrical and electronic components that may contain materials which, if disposed of with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or recycling instructions for this product. Residents outside of the European Union must dispose of or recycle this product in accordance with local laws or regulations that apply.	IS EN 50419	Fig. 1
	Bluetooth [®]	Bluetooth [®] wireless or enabled technology	Trademarks of Bluetooth Special Interest Group (SIG)	N/A

Symbol	Title	Description	Standard	Ref. No. of symbol
	Follow instructions for use	Refer to instruction manual/ booklet	IEC TR 60878	N/A
IP 22	Ingress Protection Level	Protection against solid foreign objects of 12.5 mm diameter and greater, and protection against vertically falling water drops when tilted up to 15 degrees.	IEC 60601-1	Table D.3, Symbol 2
	FCC Part 15	Electromagnetic interference from the device is under limits approved by the Federal Communications Commission.	Federal Communications Commission	N/A
	Complies with Australian Radio communications requirements.	Complies with Australian Radio communications requirements.	AS/NZS 4417.1	N/A
	CE Mark	For European Compliance	93/42/EEC Medical Devices Directive	Annex XXII
	Recycling	Battery is recyclable - follow local recycling & reclaiming procedures	ISO 7000	1135

32.0 Symbols Used

Symbol	Title	Description	Standard	Ref. No. of symbol
	China RoHS Mark	China RoHS Mark I logo. Product does not contain toxic and hazardous substances or elements above the clip level in any material or application including those exempt from the requirements of the EU RoHS Directive.	SJ/T11364-2006	N/A
	Recycling under the Waste Disposal Act	Subject to recycling under the Waste Disposal Act.	Environmental Protection Administration, R.O.C. (Taiwan)	N/A
	Serial Number	Indicates a unique identifier used for identification and traceability purposes	ISO 7000 / IEC 60417	N/A
	Medical Device	Indicates the product is a medical device	ISO 15223-1	N/A
	Unique Device Identifier	A unique numeric code that identifies the labeler and the specific version of the device.	ISO 15223-1:2021	N/A
	European Union Representative	Indicates the authorized representative in the European Community/ European Union.	ISO 15223-1:2016 Reference no 5.1.2	N/A
	Non Sterile	Indicates a medical device that has not been subjected to a sterilization process.	ISO 15223- 1:2016 Reference no. 5.2.7. (ISO 7000-2609)	N/A
	Single Patient - Multiple use	To indicate that the medical device may be used multiple times (multiple procedures) on a single patient	ISO/DIS 15223-1:2020(E) Ref no. 5.4.12. (ISO 7000-3706)	N/A

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.

REBEL

Powered by  AM Healthcare Group



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