REBEL HAND

Technical Manual - Model RBRM-B

REBEL

Powered by AM Healthcare Group

1.0 Table of Contents

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).

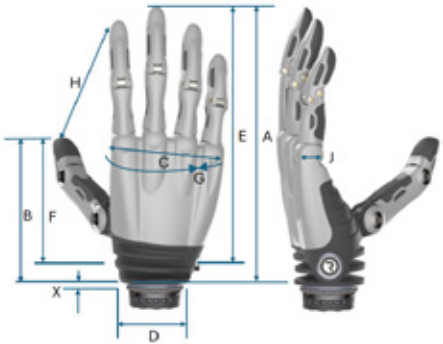
4.0 Environmental

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	• Power Grip • Precision Open & Close • Trigger Grip • Tripod Grip • Rock Grip • Glove Grip • Column Grip

Unopposed	• Finger Point Grip • Tap Grip • Mouse Grip • Key/Card Grip • Relaxed Grip • Phone Grip

RELAXED GRIP UNAPPOSED 	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.
PRECISION CLOSED OPPOSED 	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.
PRECISION OPEN OPPOSED 	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.

5.0 Grips

HOOK GRIP UNOPPOSED 	Say goodbye to juggling bags and hello to effortless carrying with the Hook Grip! 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.
ACTIVE INDEX/TRIGGER GRIP UNOPPOSED 	The Active Index (Trigger) Grip gives users precise control for operating tools and appliances with trigger mechanisms. 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.
COLUMN GRIP OPPOSED 	The Column Grip delivers power and precision for pressing buttons and operating levers with ease. 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.

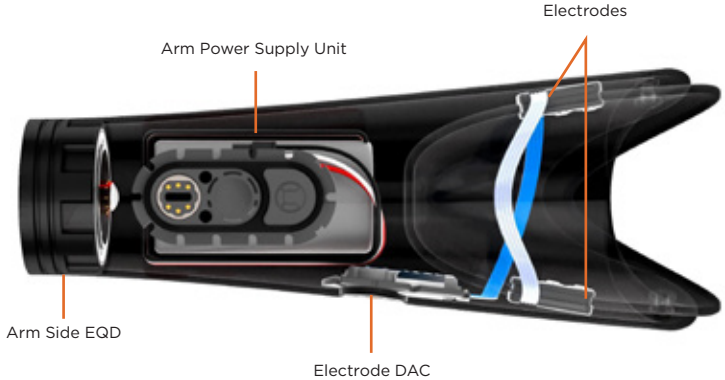
5.0 Grips

FINGER POINT GRIP UNOPPOSED 	The Finger Point Grip offers precise control for pressing small buttons and using touchscreens. 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.
MOUSE GRIP UNOPPOSED 	The Mouse Grip is perfect for smooth, accurate computer control—whether at work or play. 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.
KEY GRIP UNOPPOSED 	The Key Grip offers precise control for handling slim, flat objects like keys, cards, or plates. 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.
COMPLIANT POWER GRIP OPPOSED 	The Compliant Power Grip delivers secure, adaptive control for everyday tasks. 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.

5.0 Grips

TRIPOD/PINCH GRIP OPPOSED 	The Tripod Grip offers precise, stable control for handling everyday objects. 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.
ROCK GRIP OPPOSED 	With the REBEL Hand, you're just one grip away from full Rockstar mode. 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!

6.0 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.

7.0 EQD

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.

7.1 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

7.2 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.

7.2 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	

7.3 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.

7.3.1 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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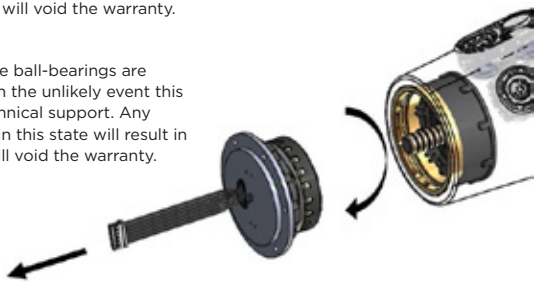

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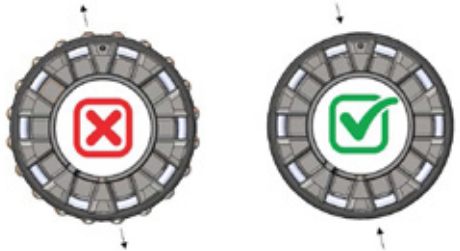
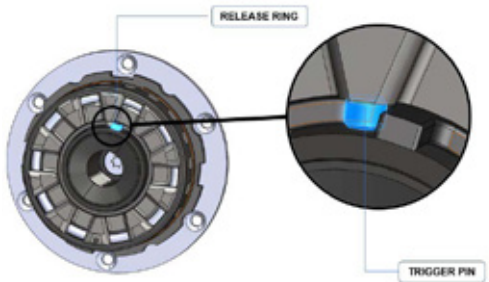
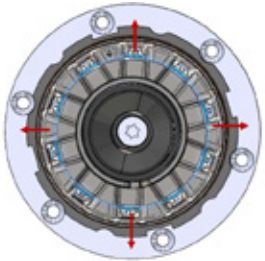


The EQD will not lock if the release ring is jammed against the trigger pin. If this case occurs, please rotate the toggle away from the trigger pin. This will free the release mechanism and enable the lock mechanism to work as intended. If the release ring cannot be rotated, please refer the EQD to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



7.3.1 Locking

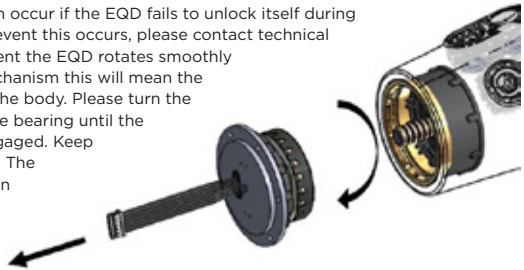
The EQD will not lock successfully if the bump ring becomes dislocated from the EQD body. In this case, the EQD may seat inside the lamination ring, but you will not hear any denotation of a lock sound. This case is only likely to occur due to tampering of the locking mechanism. If this occurs, please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



7.3.2 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.



8.0 Grip Triggers

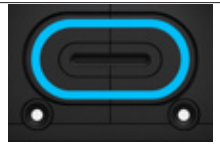
Grip Switch Triggers are inputs/signals from the user which allow the selection of the next grip. The Rebel Hand has numerous switching options to give you fast access to a multitude of grips.

- 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.

8.1 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.

8.2 Dorsal Button and Light Functions

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

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

8.3 Buzzer Configuration

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

8.4 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.

8.4.1 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).

8.4.2 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.

9.0 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.

10.0 Rebel Bionics App

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

10.1 Downloading 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.

10.2 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).

10.3 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.

10.4 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.

11.0 Disposal

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

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12.0 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.

13.0 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 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.

14.0 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.

15.0 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

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

15.0 Compatibility

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

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

15.0 Compatibility

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

16.0 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

16.0 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

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
SN	Serial Number	Indicates a unique identifier used for identification and traceability purposes	ISO 7000 / IEC 60417	N/A
MD	Medical Device	Indicates the product is a medical device	ISO 15223-1	N/A
UDI	Unique Device Identifier	A unique numeric code that identifies the labeler and the specific version of the device.	ISO 15223-1:2021	N/A
EU REP	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	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.

17.0 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 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	COGDAC/EL2
Legal Manufacturer	COGENT MECHATRONIC LTD. Unit 5a, Balm Road Industrial Estate, Beza Street, Hunslet, Leeds, LS10 2BG
Manufacturers SRN	Not Yet Available
Basic UDI-DI	TBA
GMDN Code	63118
Variants	As per Appendix II (Available upon Request)
Intended Purpose	To be used exclusively for providing exoprosthetic fittings of the upper limbs.
MDR Classification	Class IIB [Rule 9]
Notified Body	N/A
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	In conformity with Annexes II and III and have drawn up the DoC 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.

Version 1.0

July 2025

REBEL

Powered by AM Healthcare Group

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