ELECTRODE SYSTEM

COGDAC/EL2 - Technical Manual

REBEL

Powered by AM Healthcare Group

1.0 Table of Contents

2.0 Introduction

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.

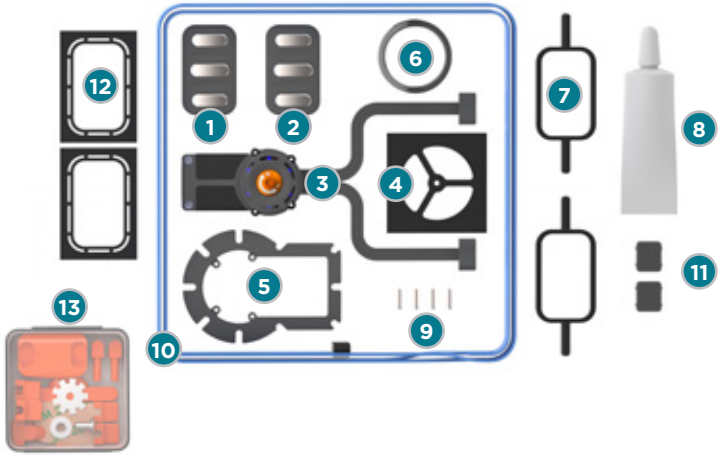
- Flexible upper electrode housing to conform to the inner socket wall for user comfort.
- The DAC has a Push and a 360 degree rotation input with a multicolour LED array.
- Manual and Auto gain adjustment.
- Boost mode which temporarily can give the user a 25% increase in output, to used when fatigued.
- 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.

3.0 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

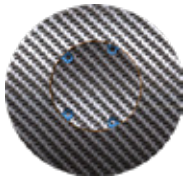
LAMINATION & VACUUM KIT		
14	**B13-0137**	KIT BOX
15	**B13-0088**	MOUNTING BRACKET BLANK
16	**B13-0082**	MONTING BRACKET
17	**B13-0083**	TOP PLATE BLANK
18	**B13-0087**	INNER SOCKET BLANK
19	**B13-0089**	SUS. LEG BLANK
20	**B13-0084**	CABLE ROUTE BLANK
21	**B13-0085**	EXTERIOR FRAME BLANK
22	**B13-0086**	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

4.0 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
T6 Torx driver	2.5mm Allen key	

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

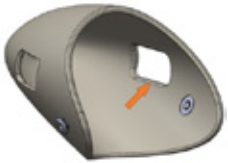
STEP 1	STEP 2
	
Apply the cutting template to the top side of the prosthetic socket.	Carefully cut along the red outline with a cutting disc. File down any sharp edges.

STEP 3	STEP 4
	
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.	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	**STEP 6**
	
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.	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.

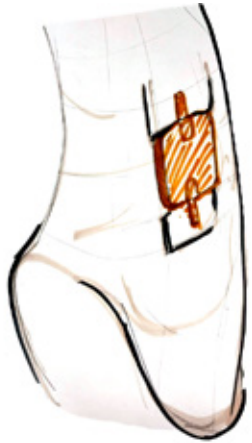
Failure to sufficiently enclose the battery will pose a serious threat to user safety due to the risk of water ingress.

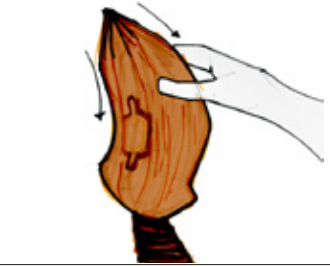
5.0 Electrode Fitting Instructions

5.1 Cutting Method

STEP 7	STEP 8
	
On the outer surface of the inner socket wall, place the electrode templates [B13-0077] in the desired position.	Cut the rounded rectangle from the centre of the template.
STEP 9	**STEP 10**
	
Add a small chamfer to the inside of both electrode apertures.	Add a small amount of silicone adhesive to the groove in the electrode, highlighted in orange. The push the electrode through the socket wall. Wipe any excess silicone adhesive as from the socket.

5.2 Lamination Method

STEP 1	STEP 2
	
Identify the position of the electrodes on the cast and check this area is completely flat to ensure a close fit of the inner socket lamination blank.	Apply a PVA sheet to the cast, with the gloss side in, ensuring there are no wrinkles within the socket area, and apply the vacuum. Attach the inner socket lamination blank using the attached double sided tape and feed 2 small pieces of dacron felt under the legs of the blank.

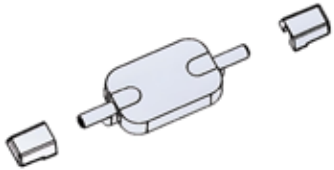
STEP 3	STEP 4
	
Fabricate the laminate socket in the usual manner.	Once the lamination procedure is complete, the outer surface over the blank is ground away to the level of the inner socket lamination blank.

STEP 5	
	On completion of the forearm fabrication, remove all the blanks. It is recommended that electrodes are inserted from the outside of the inner socket to prevent stress on the flexible legs.

5.3 Vacuum Method

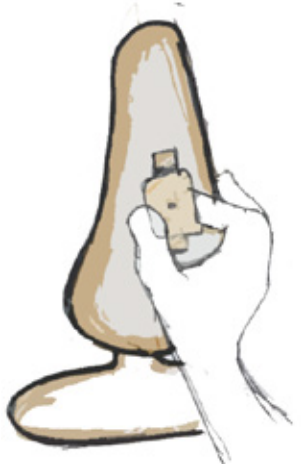
STEP 1	STEP 2
	
Ensure the electrode positions on the cast are identified and are suitably flat for a close fit with the blank. Place the cast into the drape station.	Apply nylon stockinette to the cast to act as a wick during the vacuum forming process.

STEP 3



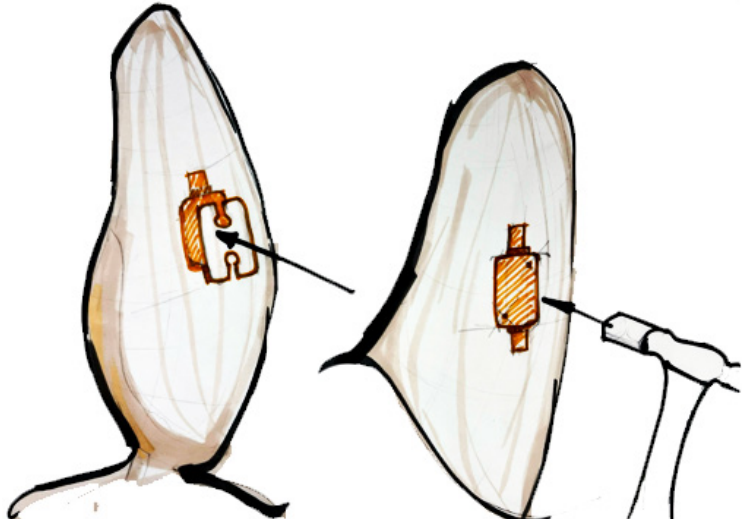
Select the inner socket lamination blank: [B13-0087], 2X [B13-0089] and attach two electrode mounting bracket blanks 2X [B13-0088]

STEP 4



Attach firmly to the stockinette using the attached double-sided tape [B13-0142].

STEP 5



Attach the inner socket vacuum blank [B13-0082] on top of the inner socket lamination blank and fix to the cast using round headed nails in opposite corners to prevent the blank rotating during the draping process.

STEP 6

Heat thermoplastic material in an oven as per manufacturer's guidelines and once ready drape the material over the cast taking care to ensure any wrinkles are pulled beyond the proximal trim.

STEP 7

Apply full vacuum once the material has draped fully over the cast. It may be necessary to use a wooden spatula to press the material into the corners of the blank to achieve a good fit.

STEP 8

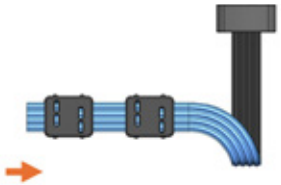
Once the material has cooled, the outer surface over the blank is ground away to the level of the electrode mounting bracket blanks. Remove the inner socket vacuum blank. Insert the cable route plate [B13-0084] with the tongue pointing towards the wrist and proceed to fabricate the forearm.

STEP 9

On completion of the forearm fabrication, remove all the blanks and fit the electrode mounting brackets (these are the slightly slimmer version to the blank). The electrodes can now be inserted to the inner socket and the arm fully assembled.

6.0 Connecting DAC to Electrode

STEP 1



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.

6.1 Check Orientation of Cable

PLEASE NOTE: Failure to orient the 4-way cable as shown will result in the DAC not identifying the electrodes.

STEP 2

PRESS FIRMLY the IDC connector to the electrode dagger pins.

To ensure the 4-Way is connected you will need to exert a firm amount of force. This will ensure the cable maintains a uniform connection and does not run the risk of falling out of the electrode during usage.

It is recommended to place the electrode under a peice of foam and press firmly the IDC connector into the electrode until it feels slightly sub-flush.

Ensure the cable orientation is as shown in the image.

Failure to connect the 4-way connector in the correct orientation will lead to the electrode system not functioning correctly.

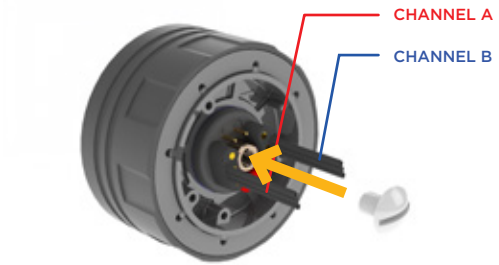
Multiple electrodes are designed to be fitted to a single cable. Position the four way curved connector close to where the DAC is mounted and wrap the cable around the socket. Trim the cable at the far side of the far electrode. Its not important whether the cable goes A to B or vise versa.

DO NOT trim the cable while the power is ON.

STEP 3

Connect 4-way to receiving end of DAC. Ensure the connection is secure before proceeding.

STEP 4



Each electrode is then connected to the coaxial core in the usual manner. Push the 3-way connector onto the receiving pins of the coaxial core.

Fasten the white retaining screw over the top of the connectors with a 3mm flat head screwdriver to ensure they are secure.

7.0 Safety Precautions

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

The Cogent 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. Cogent 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 Cogent Electrode System to an open flame.

Clean with hot soapy water, Do NOT use any solvents or abrasives to clean the DAC or electrodes as this might cause damage.

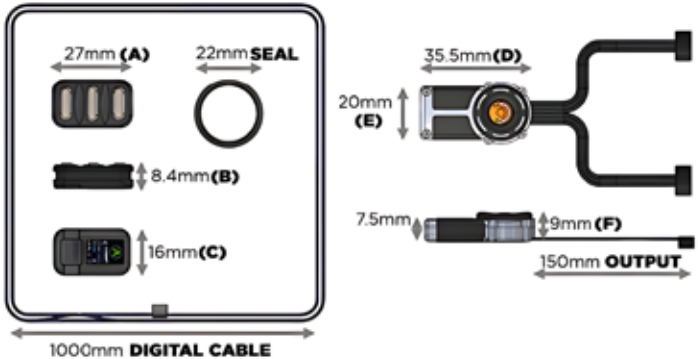
Individuals who are exposed to hazardous environments that contain flammable liquid or gas should NOT use this device when in those environments.

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 Cogent Electrode System (COGDAC/EL2) is 5 years.

8.0 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	

9.0 User Instructions

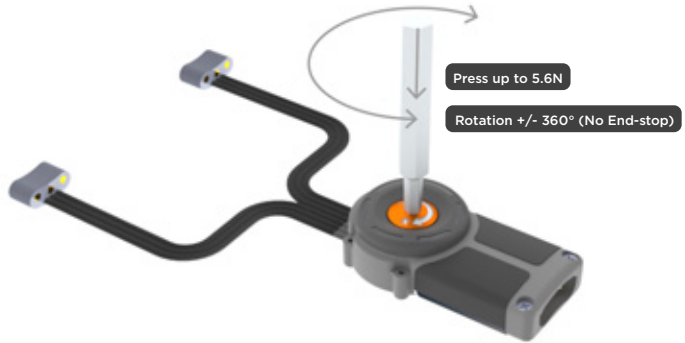
When using the DAC button, it is advised to use a 2.5mm Allen Key at all times, to avoid risk in damage and avoid improper use and disatisfaction of the device.

9.1 DAC Button Functions

You MUST **press firmly** whenever you press the DAC button. Ensure when you press the button it is straight and not twisted.

SINGLE PRESS (Up to 1.5 secs.) This makes a selection.

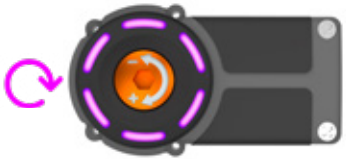
HOLD PRESS (3-5 secs.) This confirms a selection.



9.2 Turning the Limb Power On

When Power is sent to the system with both electrodes are identified, 6x purple will illuminate clockwise and then go blank.

Everytime the connection is reset or reconnected, the DAC will return an illumination.



9.3 Electrode Identification

If an electrode is not correctly identified during the intial connection. The DAC will return a single Red LED.

Bottom LED: **Channel A**
Next LED: **Channel B**

If an electrode is identified during the initialisation, the DAC will return a corresponding Green LED.

Please check your connections, ensuring the pin-outs are aligned.

9.4 Electrode Modes

Standard Mode	Automatic Mode
	
This mode allows the clinician to manually adjust the gain levels and is shown by a single green LED.	This mode allows automatic gain adjustment and is shown by two amber LED's. 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. TO ACTIVATE BOOST MODE: Press and hold button for 2 seconds until the 3 LED's 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 LED's 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.

9.5 Clinical Adjustment Mode

A long press for greater than 3 seconds enters the clinical set up mode. You wil be presented by a flashing green light, this is to select manual mode.

Entering Manual Mode

A single green light will now be flashing, Press and hold up to 5 seconds will confirm that mode.

Entering Automatic Mode

From the single flashing green light of the manual gain mode, press the button for less then 1.5 second. There should be now 2x LED's flashing amber.

Press and hold up to 5 seconds will confirm that mode.

9.5.1 Manual Adjustment

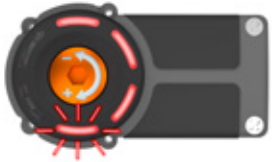
The 2x colours equate to the 2x electrodes:

Red LED is for Electrode 1 (CHANNEL A)

Blue LED is for Electrode 2 (CHANNEL B)

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

9.5.1 Manual Adjustment



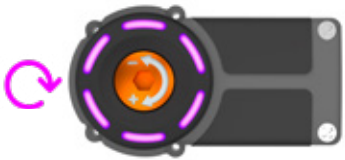
To adjust the electrode, use a 2.5mm Allen Key and rotate the central orange segment of the switch.

Clockwise increases the gain, Anti-clockwise 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 and Hold the button for up to 5 seconds.

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

9.5.2 Automatic 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 is able to achieve will set the gain levels.

The user must now provide a weak, resting signal for 1 second. While satisfied with the resting signal, Press the button (less than 1.5s) to move to the next step.

The aim is to ensure the DAC LED indication is as low as possible.

The user must hold a strong signal.

While satisfied with the strong signal, Press the button (less than 1.5s) to move to the next step.

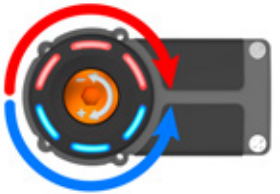
The aim is to ensure the DAC LED rings are fully indicated at this signal.

Hold the button for greater than 3 seconds to confirm E1 settings.

9.5.2 Automatic Adjustment

	The user must now provide a weak, resting signal for 1 second. While satisfied with the resting signal, Press the button (less than 1.5s) to move to the next step. The aim is to ensure the DAC LED indication is as low as possible.
	The user must hold a strong signal. While satisfied with the strong signal, Press the button (less than 1.5s) to move to the next step. The aim is to ensure the DAC LED rings are fully indicated at this signal. <u>Hold the button for greater than 3 seconds</u> to confirm E2 settings.

9.5.2 Automatic Adjustment

 Co-contraction 	The user can now view each electrode channel signal via the LED indication. A purple LED signifies Co-contraction and direction shows whether it is towards E1 or E2. 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. 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.
	Once the preferred gain level is selected for both electrode sites, <u>Press and Hold the button for up to 5 seconds.</u> The DAC will display six purple rings to signify the process is complete.

10.0 Warranty

All Cogent products are covered by a 24-month manufacturer's warranty included which takes effect from the date of fitting. Products are subject to be evaluated for warranty. Cogent 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. Cogent 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 Cogent 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 Cogent, 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. Cogent has the right to void the warranty of all products that have any type of modifications or damage caused by any unauthorised or untrained personnel. Any form of abuse, neglect, and excessive damage that is caused by usage outside the intended design and technical specifications, and/or any modifications made towards Cogent products will null and void all warranties.

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

Cogent Mechatronic 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 Cogent which may result in direct, indirect, incidental, special, punitive, or consequential losses or damage.

11.0 Disposal

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

12.0 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

Symbol	Title	Description	Standard	Ref. No. of symbol
	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
	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 801
	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

Symbol	Title	Description	Standard	Ref. No. of symbol
	Bluetooth®	Bluetooth® wireless or enabled technology	Trademarks of Bluetooth Special Interest Group (SIG)	N/A
	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
1	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.

13.0 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

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