Electrodes - ELEC50/60
Technical Information

steeper
Creating life's turning points, together

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Introduction

The electrode (ELEC60/ELEC50) is designed and manufactured by Steeper. It is the same size and shape as electrodes from other manufacturers and can be directly fitted into the cavities prepared for these electrodes. For all related products please refer to Steeper Upper Limb Prosthetic Components Catalogue.

ⓘ NOTE

Ensure the patient receives the User Guide included in the product packaging.

⚠ WARNING

Please read the information contained in this manual carefully before using the product.

Intended Use and Key Features

The electrode is to be used as the control input(s) for a myoelectric prosthesis. It is suitable for direct skin contact. Intended electrode use and key features include:

- This electrode will control prosthetic devices from most major manufacturers.
- Proportional output signals.
- Suitable for child or adult systems.
- High sensitivity (2000-100,000 fold) and range (90-450Hz).
- Able to function with threshold control using signals as low as 10μV.
- Interference protection from common power sources, depending on electrode type, and high frequency emitting devices.
- An Electrode Gain Control (EGC) is included to allow control of the myoelectric signal providing optimal control of the terminal device.
- Two fabrication options included in the kit.
- The contacts are coated with pure titanium, a bio-compatible material and an excellent conductor of signal.

Product Details

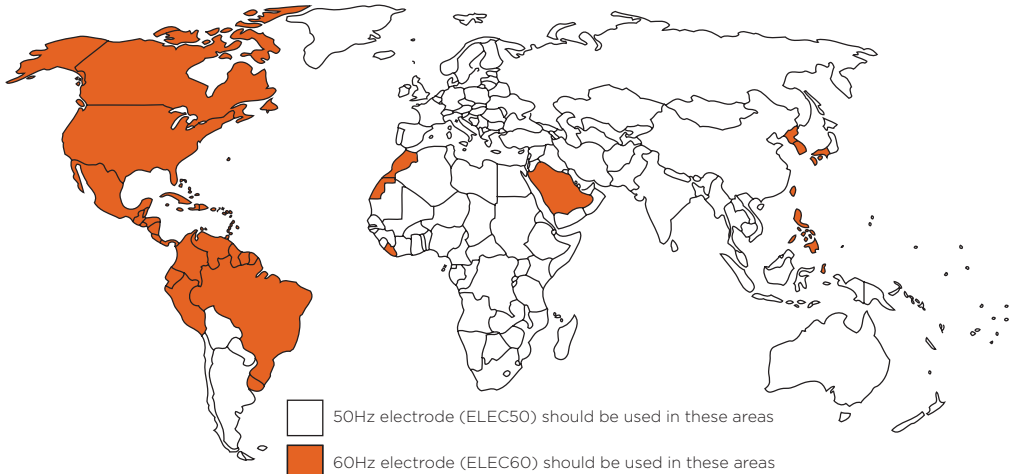
ELEC50
Light grey

- Provides interference protection in countries operating 50Hz mains power systems (see map opposite).
- Appropriate control device for prosthetic devices from most major manufacturers.
- Titanium contacts for optimum conductivity of signal and bio-compatibility.

ELEC60
Dark grey

- Provides interference protection in countries operating 60Hz mains power systems (see map opposite).
- Appropriate control device for prosthetic devices from most major manufacturers.
- Titanium contacts for optimum conductivity of signal and bio-compatibility.

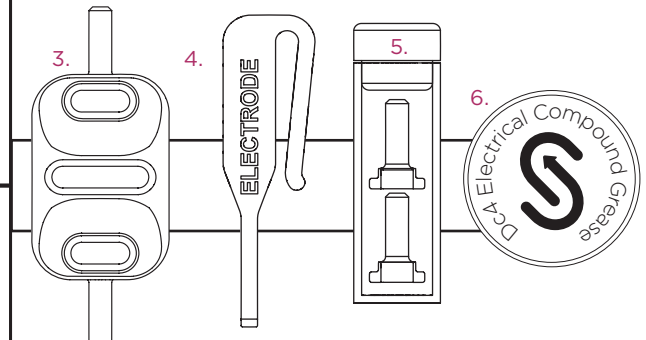
Mains Power System Map



Box Contents

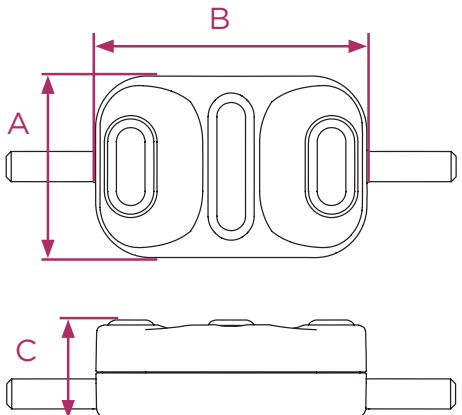
1. **E25591**
Vacuum kit

2. **E25590**
Lamination kit



1. Vacuum kit
2. Lamination kit
3. Electrode (ELEC50 or ELEC60)
4. Adjustment tool
5. Spare suspension legs
6. Dc4 Electrical Compound Grease
7. User Guide (RSLLIT328)
8. Technical Manual (RSLLIT327)

Principal Dimensions & Specifications



	Imperial	Metric
A - Electrode Width	11⁄16”	18mm
B - Electrode Length	1 1⁄16”	27mm
C - Electrode Height	3⁄8”	10mm
Weight	1⁄6 oz	4.4g
Power Supply	5V to 16V*	
Bandwidth	90-450Hz	

*We recommend that the Steeper electrodes are used alongside the Steeper batteries.

Electrodes: Important Information

- The electrodes (ELEC50/60) must only be prescribed and fitted by a qualified prosthetist in a suitable clinical environment.
- These electrodes are an accessory for a Medical Device and meets the general safety and performance requirements in MDR 2017/745 Annex I.
- Before use, check for any visible electrode damage, particularly the titanium contacts.
- The electrode should be placed against undamaged skin, avoiding scarred or unhealed areas.
- Do not disassemble the electrode.
- The electrode must only be used within the power range recommended in this technical literature.
- Do not immerse the electrode in water.
- Do not expose the electrode to a naked flame or excessive heat.
- Do not attempt to modify the product, seek specialist advice if required.

Electrodes: Important Information

- Please ensure the patient receives the User Guide included in the product packaging.
- Sensitive to EMC radiation.
- In case of an emergency remove forearm immediately. For internal batteries turn charge point switch to OFF position. For external batteries disconnect battery from housing.
- The Titanium contacts can be easily damaged and must be handled with care. The Titanium contacts must not be placed face down.
- If a serious incident occurs relating to the device, full details should be reported to the manufacturer and the component authority of the Member State in which the user and/or patient is established.
- Each time the cable block is removed from the electrode, a small amount of grease must be applied to the cable block recess. Any excess grease must be wiped clean.
- This product is intended for use by a single user during daily activities. See warranty for further information.

See www.steepergroup.com for the latest version of this technical manual.

Further Information

A guide for using the lamination kit and vacuum forming kit is available at:

www.steepergroup.com or
www.steeperusa.com

A printed copy is also available upon request, or contact customer services who will be happy to help.

Spares of the following parts can be ordered using the appropriate part number:

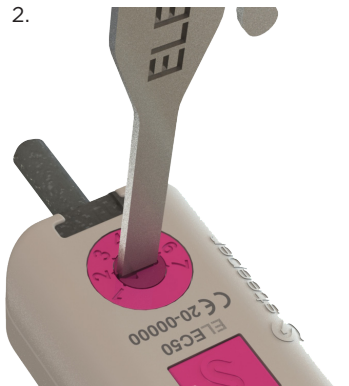
Part	Part Number
Cable Retaining Plug	B30819
• Lamination Kit • Vacuum Kit • Gain Level Adjustment Tool	ELECSP
Suspension Legs	B31032

Gain Level Adjustment

To adjust and balance the electrode, turn the dial on the back of the product using the tool provided. Number 1 is the lowest setting, number 7 is the highest setting.

1.

2.



3.

⚠ WARNING

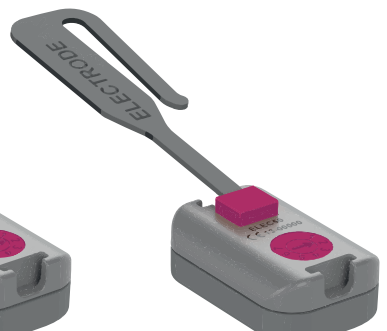
Do not force the dial beyond the end stops.

Connecting the Electrode

1.

2.

3.



Note: The Data Sheet on the Dc4 Electrical Compound Grease can be viewed and downloaded from www.steepergroup.com

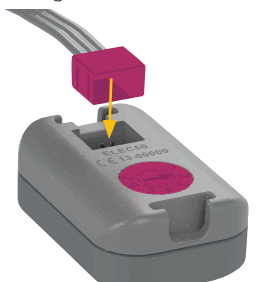
4.

⚠ WARNING

Ensure blue side of electrode cable (ECA=300, 600 or 1000) is facing towards the electrode.

5. Using the Electrode tool, apply a small amount of grease in the Cable block recess prior to inserting the cable block.*

6. Insert fully until the cable block is flush with the electrode casing.



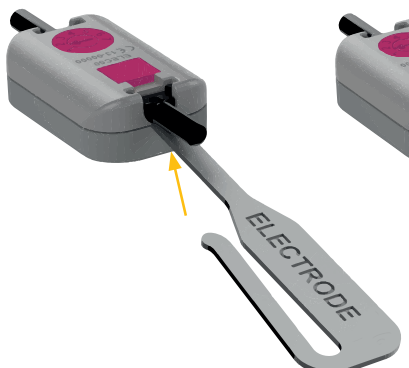
7. Remove any excess grease from electrode casing after connection.

*Ensure that each time the cable block is removed from the Electrode a small amount of grease is applied.

Electrode Suspension Leg Removal

If the electrode suspension legs become worn over time, they may need replacing. There are two replacements included. Firstly remove them as shown and then replace as shown.

1.



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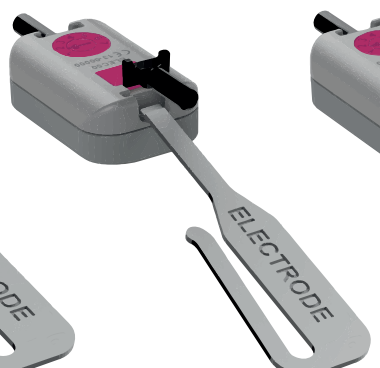
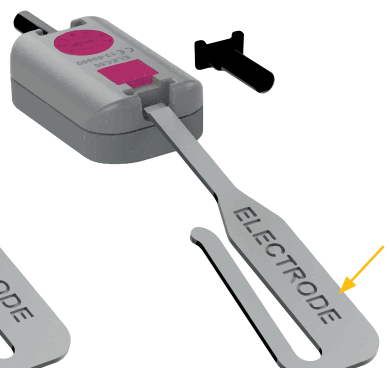


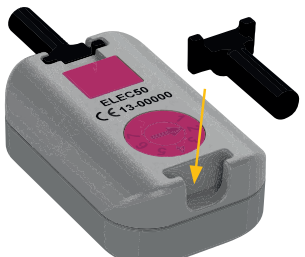
3.



Electrode Suspension Leg Reattachment

1. Apply a small amount of NAD0107 glue to the underside of the electrode suspension leg in the area shown.

2. Insert the suspension leg into the cavity.



3. Remove any excess adhesive after insertion.

Environment and Operational Conditions

Please note the following environmental operational conditions for the Steeper electrodes.

Storage, transport and operation	-20°C (-4°F) to +60°C (+140°F)
Operational	-15°C (+5°F) to +60°C (+140°F)
Pressure range	700-1060 hPA
Maximum 95% relative humidity, above non-condensing	
Do not expose to EM emissions above 8kV contact, 15kV air	

If the electrodes have been in storage or have been transported, place the electrodes in ambient temperature (20˚C) two hours prior to use.

Disposal

These electrodes are an electrical device and should not be mixed with general household waste. For proper treatment, recovery and recycling, please take this product(s) to designated collection points. Alternatively, in some countries, you may be able to return your products to your local retailer upon the purchase of an equivalent new product.

Disposing of this product correctly will help save valuable resources and prevent any potential negative effects on human health and the environment, which could otherwise arise from inappropriate waste handling.

Please contact your local authority for further details of your nearest designated collection point. Penalties may be applicable for incorrect disposal of this waste, in accordance with your national legislation.

Returns

Prior to return of any device, the customer must contact Customer Services for an RA (Returns Authorisation Number), and complete a 8.2.1 FRM 028 Product Concern Report in full, and submit with product return.

Warranty Terms

The warranty for the electrode is 12 months. Warranty covers design and manufacturing issues only.

The designed service life of the electrode is 5 years.

The electrode is a solid state, maintenance free device created using ABS plastic and titanium plated contacts. Store in a cool dry place.

Where a claim is made under warranty, this claim must be supported by appropriate documentation. Photographs of any failed products must be provided in lieu of the product itself.

The warranty will be void on all system components if any components have been subject to abuse, modification, neglect, deliberate damage, loads beyond those for which the product was designed, or repair or maintenance by an uncertified person.

The design and manufacture of Steeper equipment and components are subject to a policy of continuous reappraisal. The company therefore reserves the right to introduce changes and withdraw products without notice.

Quality Assurance

Steeper/SteeperUSA operate a UKAS approved quality management system and fully complies with the requirements of BS EN ISO 9001:2015. This certifies that Steeper/SteeperUSA meet the appropriate international quality standards for design, manufacture and supply of prosthetic products.

Steeper is registered with both the Medicines and Healthcare Regulatory Authority in the UK, and the Food and Drugs Administration of the United States Government for the manufacture and supply of prosthetic and orthotic products.
MHRA Registration N°: 0000006617
FDA Registration N°: 9612243
Model N°: STP-RP605

Continued compliance with the standard is monitored by a program of internal and external audits. Applied Standards:
ISO 9001:2015 (QMS)
Directive RoHS 2015/863/EU
IEC 60601-1-2: 2007
IEC 60601-1:2005, AMD:2012
Meets requirements ISO14791: 2019

Quality Assurance cont.

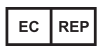
The electrode is an Accessory for Class I Medical Devices which meets the general safety and performance requirements in MDR 2017/745 Annex I.

The electrode is CE marked which indicates that the device meets EU safety, health and environmental requirements. It also indicates device's compliance with EU legislation and free movement within the European market.

This electrode is UKCA marked which indicates that the device meets safety, health and environmental requirements. It also indicates device's compliance with the legislation of Great Britain (England, Wales, Scotland) and free movement within the market of Great Britain.

The design and manufacture of Steeper equipment and components are subject to a policy of continuous reappraisal. The company therefore reserves the right to introduce changes and withdraw products without notice. For the most recent issue of this technical manual, please visit: **www.steepergroup.com**.

Symbols Used on Product & Packaging

Symbol	Definition	Source
	Indicates the medical device manufacturer.	ISO 15223- 1:2016 Reference no. 5.1.1. (ISO 7000-3082)
	Indicates the authorised representative in the European Community/European Union.	ISO 15223-1:2016 Reference no 5.1.2
	Indicates a carrier that contains Unique Device Identifier information.	MDR 2017/745 23.2(h) ISO 15223-1:2016
	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223- 1:2016 Reference no. 5.1.5. (ISO 7000-2492)
	Indicates the item is a medical device.	ISO/DIS 15223-1 2020 Reference no: 5.7.7

UK CA	Certification mark that indicates conformity with the applicable requirements for products sold within Great Britain (England, Wales, Scotland).	https://www.gov.uk/guidance/using-the-ukca-marking
CE	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Regulations.	765/2008/EC, 768/2008/EC MDR 2017/745 (Articles 2, 13, 14, 20, 21, 22, 74 and Annex V)
1	Single Patient - Multiple use Symbol.	ISO/DIS 15223-1:2020(E) DRAFT Reference no. 5.4.12. (ISO 7000-3706)
NON STERILE	Indicates a medical device that has not been subjected to a sterilisation process.	ISO 15223- 1:2016 Reference no. 5.2.7. (ISO 7000-2609)

	This product contains electrical and electronic components that may contain materials which, if disposed 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 the European Union must dispose or recycle this product in accordance with local laws or regulations that apply.	IS EN 50419:2006 Reference no. Fig. 1
	Type BF Applied Part. Type BF (body floating) is used for applied parts that have conductive contact with the patient, or have medium or long term contact with the patient.	IEC 60601-1
	To indicate that the marked item or its material is part of a recovery or recycling process.	ISO 704, ISO/IEC 13251, ISO 10987-1, ISO 9687 (Reference no. ISO 7000 -1135)
FSC	Packaging is covered by Forest Stewardship Council assurance that it is made with, or contains, forest-based materials from FSC- certified forests or reclaimed sources.	FSC Certification

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RSLLIT327 Issue 5 March 2021

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FSC NON STERILE