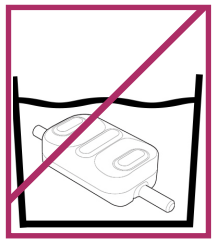
Electrodes
User Guide

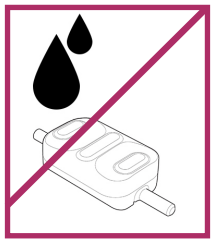
steeper
Creating life's turning points, together

steeper USA
Creating life's turning points, together

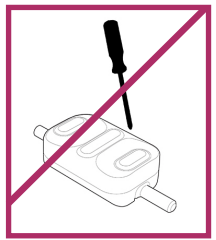
Electrodes: Important Information



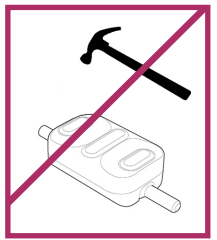
Do not immerse the electrode in water.



Do not expose the electrode to dirt, dust or oil.



Do not attempt to disassemble the electrode.



Do not expose the electrode to shock or vibration.

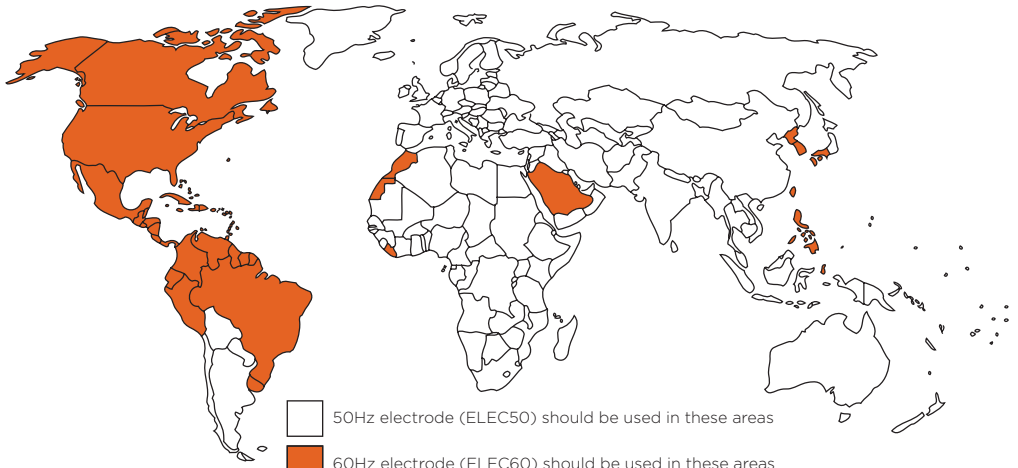
- The electrodes (ELEC50/60) must only be fitted by a qualified prosthetist in a suitable clinical environment.

Warning: Do not modify this equipment.

Electrodes: Important Information

- These electrodes are an accessory for a Medical Device and meets the general safety and performance requirements in MDR 2017/745 Annex I.
- Ensure the electrode contacts are regularly cleaned. Clean with a cloth, lightly moistened with soapy water.
- Never clean the electrode with a solvent based cleanser.
- If your prosthesis stops working contact your prosthetist.
- If your prosthesis becomes uncomfortable or the control becomes unpredictable contact your prosthetist.
- 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.
- The electrode must only be used within the power range recommended in the technical manual
- Sensitive to EMC radiation.
- If a serious incident occurs relating to the electrodes, full details should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Mains Power System Map



Disposal

These electrodes are an electrical device and should not be mixed with general household waste. For proper treatment, recover and recycling, please take this product(s) to the clinic where it was prescribed or fitted for appropriate local advice.

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

If items are to be returned for any reason, please contact your prosthetist.

Warranty Terms

The warranty for the electrode is 12 months. Warranty covers design and manufacturing issues only. The service life of the electrode is 5 years.

Where a claim is made under warranty by your provider on your behalf, this claim must be supported by appropriate documentation. You may be asked by your provider to take photographs of any failed products if applicable.

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.

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.

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, and meets requirements ISO14791: 2019.

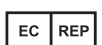
This electrode is an Accessory for Class I Medical Devices which meets the general safety and performance requirements in MDR 2017/745 Annex I.

This device 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 device 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 user guide, 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

MD	Indicates the item is a medical device.	ISO/DIS 15223-1 2020 Reference no: 5.7.7
LOT	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)
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)
	Single Patient - Multiple Use Symbol	ISO/DIS 15223- 1:2020(E) Reference no. 5.4.12. (ISO 7000-3706)

	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)
	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

Steeper Group
Unit 3, Stourton Link
Intermezzo Drive
Leeds
LS10 1DF
United Kingdom

+44 (0) 113 270 4841
customerservices@steepergroup.com

www.steepergroup.com

SteeperUSA
8666 Huebner Road
Suite 112
San Antonio
TX 78240
USA

(+1) 210 481 4126
sales@steeperusa.com

www.steeperusa.com

RSLLIT328 Issue 4 March 2021

EC REP EMERGO EUROPE
Prinsessegracht 20, 2514 AP The Hague, Netherlands