electrode NE®

Neuroelectrics® Investigational Use Electrodes

Instructions for Use

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List of abbreviations

EEG	Electroencephalogram
tES	Transcranial electrical stimulation
tDCS	Transcranial direct current stimulation
Ag/AgCl	Silver/Silver chloride

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1. Introduction

The present instructions for use describe different types of electrodes commercialized by Neuroelectrics: 6 manufactured by Neuroelectrics and 1 manufactured by another company. The electrodes designed and manufactured by Neuroelectrics are intended to be used exclusively with Neuroelectrics Starstim systems (tES-EEG or tES-only), and they are not compatible with any other commercial device.

Herein described you may find the corresponding use instructions and the guidelines on how to properly clean and store each type of electrode. You will also find a description of the sponge electrodes used for brain stimulation.

Additionally, because you might want to combine brain stimulation with magnetic resonance imaging (MRI), we also provide MRI compatible stimulation and reference electrodes.

All the electrodes are compatible with the easy-insert system of the Neuroelectrics neoprene headcap and headband. All of them are compatible with the electrode cables included in the packages, except the MRI compatible electrodes which require special cables, which are included in our multi-channel MRI kit.

Pay special attention to the functionality of each type of electrode and always use it accordingly.

2. Use of electrodes

Intended purpose and indications

Electrodes are intended to connect the cables from the Enobio or Starstim devices to the human head tissues allowing the flow of electrical and ionic currents between the human brain and those devices so they can achieve their purpose.

The electrodes are intended to be used by those patients who will go through sessions with the Enobio and Starstim devices.

The electrodes have been designed for use in a clinical environment, hospital, research center or home healthcare environment, by healthcare professionals and people specifically trained to use devices for transcranial electric stimulation or EEG monitoring, during sessions with Enobio and Starstim.

3. Electrode safety information

Safety warnings

⚠ Do not continue to use electrodes beyond the usage durability ratings described in this document.

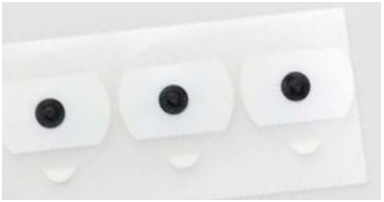
⚠ The Neuroelectrics electrodes should be used only with Neuroelectrics devices.

⚠ Before using, confirm the condition of the electrodes and check if they are clean.

⚠ Electrodes should only be used with the conductive solutions specified in this manual. Do not use other solutions but those recommended in the Instructions for Use.

⚠ Perform a careful inspection of the skin under the stimulation site before and after the stimulation session. Observed adverse effects include: skin itching, tingling, headache, burning sensation, and discomfort. In rare cases, skin lesions have been observed. If any of the mentioned effects is observed, the stimulation must be suspended immediately, and the equipment must be checked for defects.

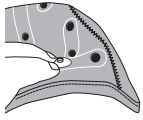
4. Electrodes' models

Name	**SPONSTIM**	**MRI SPONSTIM**	**Disp. radiotranslucent electrode**
Electrode			
Code	**Sponstim Pi**: NE026d-P.08.RU:GV **Sponstim 5x7:** NE026c-P.02.RU:GV	**MRI Sponstim 25**: NE026MRIa-P.04.RU:GV **MRI Sponstim 8**: NE026MRIb-P.08.RU:GV **MRI Sponstim 5x7**: NE026MRIc-P.02.RU:GV **MRI Sponstim Pi**: NE026MRId-P.08.RU:GV	NE025MRI-P
Manufacturer	Neuroelectrics	Neuroelectrics	BIOPAC Systems
Function	Stimulation	Stimulation (MRI compatible)	Reference
Description	The Sponstims are sponge electrodes for transcranial stimulation. They are available in two different sizes and shapes. The smallest circular model, with a contact area of π cm^2, is ideal for multifocal stimulation experiments. The rectangular model with 35 cm^2, on the other hand, is ideal for bipolar (anodal or cathodal) experiments. Sponstim electrodes work with saline solution.	The MRI Sponstim's correspond to the MRI compatible version of the Sponstim's. The four distinct models can be used to perform brain stimulation in a subject undergoing an MRI experiment. Similarly to the Sponstim, the MRI Sponstim electrodes require the application of saline solution.	The disp. radiotranslucent electrode is a recommended is disposable and radiotranslucent pregelled electrode, proven to be compatible with our Starstim devices. It has the advantage of being compatible with MRI (up to 7T, with any scanning sequence). Therefore, it is the reference electrode that should be used for stimulation sessions performed simultaneously with MRI. The code of the model is PKEL508.
Composition	The Sponstim consists of a sponge cover, a carbon rubber core and a metallic pin made of nickel plated brass. The contact surface differs among the two models: (c) rectangular shape with 35 cm^2 (5 cm x 7 cm), and (d) circular shape with π cm^2.	The MRI Sponstim consists of a sponge cover and a carbon rubber core, both radiotranslucid materials. The contact surface differs among the four models: (a) circular shape with 25 cm^2, (b) circular shape with 8 cm^2, (c) rectangular shape with 35 cm^2 (5 cm x 7 cm), and (d) circular shape with π cm^2.	The disp. radiotranslucent electrode is a pre-gelled electrode with a circular latex-free contact surface with 41 mm diameter. It contains a Ag /AgCl laminated core with a carbon composition contact with a 11 mm diameter.

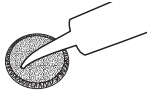
5. Sponstim and MRI Sponstim usage instructions

Use Instructions

1 Insert your sponge electrodes in the desired position of the neoprene cap.

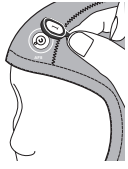


2 Using the syringe, slowly inject the saline solution on the yellow external surface of each of your sponge electrodes, so they become wet but not soaking. Make sure not to soak the headcap.



3 Place the cap on the subject.

4 Connect the electrode cable connection to the electrode inserted on the cap. For MRI Sponstim, MRI compatible electrode cables required come included with the MRI compatible kit for stimulation prepared by Neuroelectrics. More detailed instructions on how to assemble the MRI compatible kits can be found in the MRI Kit Manual at: http://www.neuroelectrics.com/documentation



5 If the impedance check of an electrode fails, insert the syringe through a hole of the cap near that electrode. Ensure the syringe ending touches the bottom of the sponge and add a bit more of saline solution on the sponge surface.

Maintenance, durability, and disposal instructions

After each use, wash the sponges and rubber separately with tap water and let them dry before storage. The cleaner the electrode is kept, the longer it lasts. When stored, make sure the metallic pins (for Sponstim) do not come into contact with the sponges, so they do not become rusty.

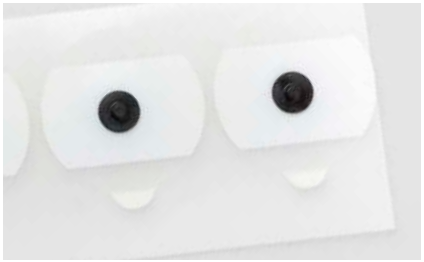
After 100 hours of stimulation, the rubber core loses its conductive properties, and the electrode should be replaced.

Electrodes may be disposed of through standard waste disposal methods without the need for special measures.

Shelf-life

Sponstim and MRI Sponstim electrodes have a shelf-life of two years.

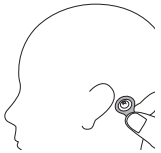
6. Disp. radiotranslucent electrode



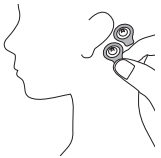
Recommended Use Instructions

1 Remove the adhesive cover.

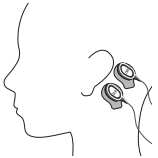
2 Place the first electrode (CMS) on the mastoid and ensure there is no hair underneath. Place the cap on the subject.



3 Place the second electrode (DRL) inferiorly to the CMS electrode.



4 Connect the CMS and DRL electrodes to the MRI-compatible electrode cables. The Disp. radiotranslucent electrode and the MRI electrode cables are included in the MRI compatible kits for stimulation prepared by Neuroelectrics. More detailed instructions on how to assemble the MRI compatible kits can be found in the MRI Kit Manual at: http://www.neuroelectrics.com/documentation



Maintenance, durability, and disposal instructions

The disp. radiotranslucent electrode should be stored at 10 - 30ºC temperature and used only once. After use, electrodes may be disposed of through standard waste disposal methods without the need for special measures.

Shelf-life

When properly stored, the shelf life of the electrode is approximately 2 years.

7. Summary table

	Use	Cleaning	Maintenance	Durability	Material
Sponstim and MRI Sponstim	Stimulation	After each use, wash the sponges and rubber separately with tap water and let them dry before storage.	Ensure correct drying before storage. When stored, make sure the metallic pins do not come into contact with the sponges, so they do not become rusty.	After 100 hours of stimulation, the rubber core loses its conductive properties, and the electrode should be replaced.	Sponge and conductive rubber
Disp. radiotranslucent electrode	Reference	N/A	N/A	It should be used only once.	Ag/AgCl laminated core with a carbon composition

8. Symbols

Symbol	Description
	ISO 7000-3082 Device manufacturer symbol according to EN ISO 15223-1:2021.
	ISO 7000-0626 Transport package shall be kept away from rain and in dry conditions according to EN ISO 15223-1:2021.
	ISO 7000-0632 Transport and storage temperature conditions according to EN ISO 15223-1:2021.
	ISO 7000-2620 Transport and storage humidity conditions according to EN ISO 15223-1:2021.
	ISO 7000-0624 Transport package shall not be exposed to sunlight according to EN ISO 15223-1:2021.

Symbol	Description
	ISO 7000-2493 Catalogue number, to identify the manufacturer's catalogue number of the medical device according to EN ISO 15223-1:2021.
	ISO 7000-2492 The symbol indicates the manufacturer's batch code according to the ISO 15223-1:2021.
	ISO 7000-2607 The symbol indicates the date after which the medical device is not to be used according to the ISO 15223-1:2021.
	ISO 7000-0434A Caution symbol according to EN ISO 15223-1:2021.

Symbol	Description
	ISO 7000-1641 Read Instructions for use symbol according to EN ISO 15223-1:2021. The symbol is accompanied by the link to have access to the electronic instructions for use.
	IEC 60417-5333 BF type applicable part according to EN 60601-1:2006/A12:2014.

9. Notice to the user

For assistance in setting up, using or maintaining the investigational use electrodes or to report any serious incident that has occurred in relation to the device, please contact the manufacturer.

10. Regulatory statements

The electrodes described in this manual are investigational devices in US:. “CAUTION Investigational devices. Limited by Federal (or United States) law to investigational Use” and in the EU : “exclusively for clinical investigations”.