

electrode^{NE®}

Neuroelectrics[®] Electrodes

Instructions for Use



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About the Electrode User Manual

This Electrode Instructions for Use need to be read before using Enobio/Starstim devices. The PDF version of this document can be found under the User Manual section of Neuroelectronics webpage:

<https://www.neuroelectronics.com/resources/manuals>

List of abbreviations

EEG Electroencephalogram

tES Transcranial electrical stimulation

tDCS Transcranial direct current stimulation

Ag/AgCl Silver/Silver chloride

DC Direct Current

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1. Introduction

Electrodes are a family of medical devices designed and manufactured by Neuroelectrics. These electrodes are accessories intended to be used exclusively with Neuroelectrics devices, like Enobio (EEG system) and Starstim (tES-EEG or tES-only systems), and they are not compatible with any other commercial device.

The present instructions for use describe different types of electrodes manufactured and commercialized by Neuroelectrics: the standard EEG electrodes to be used with conductive gel, dry electrodes that require no contact liquid, and sponge stimulation electrodes to be used with saline solution. Pay special attention to the functionality of each type of electrode and always use it accordingly.

The electrodes family is composed of seven models that have different applications: EEG monitoring or brain stimulation. The only exception is our unique model named NG Pistim, which can be used for both techniques. Additionally, you will also find one type of electrode that can be used as the electrical reference for our devices.

Note: To access instructions for use of other electrodes supplied by Neuroelectrics but not certified (CE marked), please refer to our webpage: www.neuroelectrics.com/resources/manuals

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 on 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


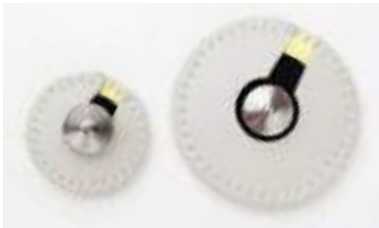

Safety warnings

- ⚠ 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	NG GELTRODE	FORETRODE	DRYTRODE
Electrode			
Code	NE021-P.08.MD:GV	NE032-P.08.MD:GV	NE023-P.08.MD:GV
Function	EEG	EEG	EEG
Description	Based on the next generation (NG) assembling system, the NG Geltrode is a EEG electrode that allows access to the scalp through the headcap. It requires the application of electrode gel; Signa Gel® is tested for compatibility.	The Foretrode is the ideal EEG electrode to be used on bare-skin scalp areas, like the forehead. The use of gel on the tip is optional.	The Drytrode is a dry EEG electrode. It does not require the application of any type of gel between the electrode and the scalp. It can be used in scalp areas with or without hair. The Drytrode was specially designed for fast applications out of the lab or requiring a gel-free experience. It is the perfect electrode when the mix of ease of use with acceptable signal quality is needed, like in BCI applications.
Composition	The NG Geltrode consists of two pieces: the fastener (top part) and the threaded washer (bottom part). The fastener is based on a Ag/AgCl sintered pellet with a 4 mm diameter. The contact area is approximately 1.6 cm ² .	The Foretrode is based on a Ag/AgCl sintered pellet with 4mm diameter. The contact area is approximately 0.1 cm ² .	The Drytrode is a Ag/AgCl coated electrode that provides a 10-point contact surface.

4. Electrodes' models

Name	NG PISTIM	SPONSTIM	EARCLIP
Electrode			
Code	NE021-P.08.MD:GV	Sponstim 8: NE026b-P.08.MD:GV Sponstim 25: NE026a-P.04.MD:GV	NE027-P.01.MD:GV
Function	EEG and Stimulation	Stimulation	Reference
Description	<p>Based on the next generation (NG) assembling system, the NG Pistim is the only hybrid electrode that provides a clear access to the scalp, allowing good control over the impedance values. The NG Pistim is a hybrid electrode that can be used for stimulation and for EEG monitoring. It requires the application of electrode gel, we recommend Signa Gel®.</p>	<p>The Sponstims are sponge electrodes for transcranial stimulation. They are available in two different circular sizes. The smallest model, with a contact area of 8 cm², is ideal for multifocal stimulation experiments. The circular model with 25 cm², on the other hand, is ideal for bipolar (anodal or cathodal) experiments.</p> <p>Sponstim electrodes work with saline solution, not with electrode gel.</p>	<p>The electrical reference Earclip is a dual electrode used to connect both CMS and DRL simultaneously to the same earlobe. The Earclip is a re-usable assembly that offers a quick assembling process. The use of gel on the tip is optional, but recommended.</p>
Composition	<p>The NG Pistim consists of two pieces: the fastener (top part) and the threaded washer (bottom part). It provides a cm² circular contact area. It is based on a sintered Ag/AgCl pellet of 12 mm diameter.</p>	<p>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: (a) circular shape with 25 cm², and (b) circular shape with 8 cm².</p>	<p>The Earclip consists of two opposed Ag/AgCl pellets of 8 mm diameter in a clip. Each one of the two pellets has a 0.5 cm² contact surface.</p>

5. Ag/AgCl-based electrode usage instructions

Precautions for handling the electrodes

The electrodes should not come into direct contact with metals as this may cause corrosion. Avoid touching or contaminating the bare electrode surface as dirt can increase the time necessary to achieve good connectivity. Use of corrosive chemicals will damage the electrodes.

Conditioning

To minimize DC offset and drift, place the electrodes in the working position 5 minutes before starting the recording. The electrodes need some time to achieve electrochemical equilibrium with the skin and with the electrolytes of the human body.

Use and durability

NG GELTRODE

Use Instructions

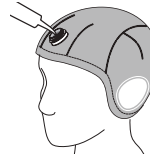
Durability



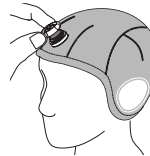
- 1 Unscrew the electrodes. Insert the bottom parts in the desired position of the neoprene cap.
- 2 Place the cap on the subject.



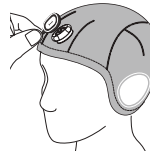
- 3 Ensure the syringe is filled with gel. For each electrode, use the syringe to part the hair and expose the scalp. Slowly dispense gel starting from the skin and gradually moving upwards until the electrode bottom is half full.



- 4 Screw together top and bottom parts of the electrode. Gel should now be touching both the skin and the screwed-on top part.



- 5 Connect the electrode cable connection to the top part of the electrode.



The NG Geltrode is a long-lasting electrode that can be reused many times. Its use is intended for 50 hours of EEG recording.

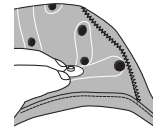
FORETRODE

Use Instructions

Durability



- 1 Insert the electrode in the desired position of the neoprene cap.

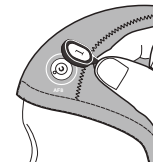


- 2 Inject a small portion of conductive gel in the contact surface of the electrode (optional).

- 3 Place the cap on the subject.



- 4 Connect the electrode cable connection to the electrodes inserted on the cap.



The foretrode is a long-lasting electrode that can be reused many times. Its use is intended for 50 hours of EEG recording.

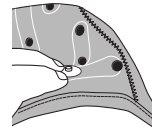
DRYTRODE

Use Instructions

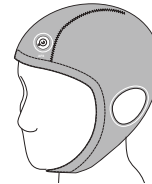
Durability



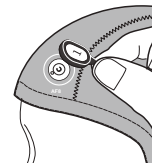
1 Insert the electrode in the desired position of the neoprene cap.



2 Place the cap on the subject.



3 Connect the electrode cable connection to the electrode inserted on the cap.



The Drytrode is a long-lasting electrode so it can be reused many times. Its use is intended for 50 hours of EEG recording.

Caution: Please make sure there is no excessive pressure or force on the head while using the Drytrode.

NG PISTIM

Use Instructions

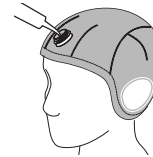
Durability



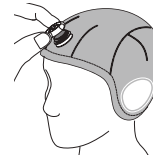
- 1 Unscrew the electrodes. Insert the bottom parts in the desired position of the neoprene cap.
- 2 Place the cap on the subject.



- 3 Ensure the syringe is filled with gel. For each electrode, use the syringe to part the hair and expose the scalp. Slowly dispense gel starting from the skin and gradually moving upwards until the electrode bottom is half full.



- 4 Screw together top and bottom parts of the electrode. Gel should now be touching both the skin and the screwed-on top part.



- 5 Connect the electrode cable connection to the top part of the electrode



Each electrode should be replaced after 10 hours of stimulation because the Ag / AgCl is expected to be consumed. Nevertheless, the time of the Ag / AgCl consumption depends on the type and intensity of the stimulation current.

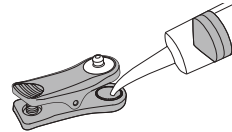
EARCLIP

Use Instructions

Durability

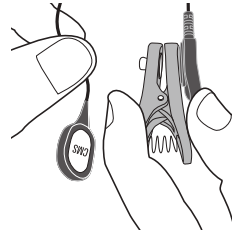


- 1 Apply some electrode gel to the sensors (recommended).

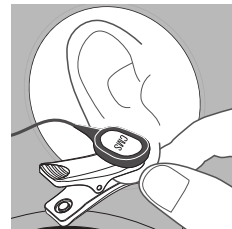


The Earclip is a long-lasting electrode so it can be reused many times. Its use is intended for 50 hours of EEG recording.

- 2 Connect the CMS and DRL cable connections to the Earclip.



- 3 Clip it to the right or left earlobe.



Maintenance instructions

Follow these instructions for all Ag/AgCl sintered electrodes.

Cleaning

The Ag/AgCl electrodes are porous and therefore behave like sponges: they absorb water and electrode gel. The deeper these liquids penetrate the electrode, the longer it takes for them to evaporate. Corrosion will take place as a consequence and, in the long term, it will make the electrodes noisier and decrease the signal quality. Therefore, it is highly recommended to clean and let the electrodes dry immediately after each use. In order to avoid undesired contacts of the pellet with other metals, you may clean them one by one.

To clean this type of electrodes, use tap water to gently rinse the gel from the electrodes. Warm water will dissolve the gel more quickly. Use of paper towels or cloths is not recommended for washing as they may leave residues or dust on the electrode surface. Electrodes should be left to air dry on a paper towel

or cloth away from sunlight before moving them to long-term storage in the packaging. The top half of the electrode should be dried pellet side up (pin side down). Ensure that they are completely dry before storing. Placing wet electrodes in packaging may cause premature degradation. Never allow electrolyte fluid or gel to dry in or on the electrode, wash immediately after use. When the electrodes dry while covered with gel, salt or minerals, the cleaning process becomes more difficult and the electrode may degrade prematurely.

After most electrode applications, rinsing with tap water suffices.

Disinfection

When disinfection is required, only standard isopropanol or ethanol formulations should be used. The electrodes and cable insulation can not withstand steam. The electrodes must not be sterilized, including via autoclave.

Darkening

When not in use, avoid direct sunlight exposure. Silver chloride is light-sensitive. Exposure to light may darken the electrode surface. Electrode darkening does not affect electrode performance.

Storage

The electrodes should be handled with care. They must not be stored in contact with metals including the metallic fasteners on the top of some electrode assemblies. Substances that could affect their electrochemical characteristics should also be avoided. Bare electrodes should be stored in a clean, dry and dark container (plastic or glass). NG Geltrode, NG Pistim and Foretrode electrodes should be stored back in the electrode holder always ensuring that no surfaces or materials are in contact with the Ag/AgCl pellets.

Malfunction

If an electrode is not operating as specified and/or you experience noise in an EEG, notice a degradation of the electrode surface, or experience difficulty achieving low enough impedances to perform stimulation consistently with a single electrode, then please follow the directions below concerning noisy electrodes.

Noisy electrodes

A continuously noisy electrode generally means that it has reached its end of life and should be replaced with a new one.

Life expectancy and disposal instructions

Ag/AgCl sintered electrodes have a limited life span. This is caused by several processes such as corrosion, the dissolving of the chloride in the pellets and the wearing of the pellet during the cleaning process. Eventually, the color of the pellets will change from grey/brown (AgCl) to silver (Ag) due to the loss of the

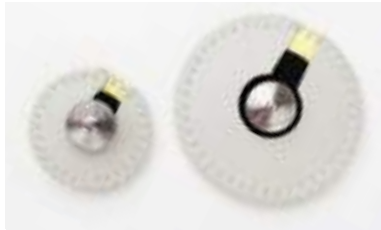
chloride. The AgCl slowly dissolves in gel and water during the cleaning, which leaves only Ag behind. The resulting pure silver electrode has much higher drift and noise characteristics than the original Ag/AgCl electrode and may not support stimulation ion transfer processes. At this point, replacement of the electrode is required.

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

Shelf-life

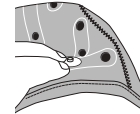
Ag/AgCl sintered electrodes have a shelf-life of two years.

6. Sponstim

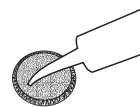


Use Instructions

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

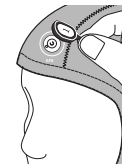


- 2 Using the syringe, slowly inject the saline solution on the yellow external surface of each of your sponge electrodes, so they become wet but not soaking. Make sure not to soak the headcap.



- 3 Place the cap on the subject.

- 4 Connect the electrode cable connection to the electrode inserted on the cap.



- 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 of Sponstims

After each use, wash the sponges and rubber separately with tap water and let them dry before storage. The cleaner Sponstim is kept, the longer it lasts. 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. Electrodes may be disposed of through standard waste disposal methods without the need for special measures.

Shelf-life




Sponstim electrodes have a shelf-life of two years.






7. Summary table





	Use	Cleaning	Maintenance	Durability	Material
NG Geltrode	EEG	After each use, use tap water to completely remove the gel from the NG Geltrode.	Ensure correct drying before storage. Avoid direct sunlight exposure and contact with metals when the electrode is not being used.	The NG Geltrode is a long-lasting electrode that can be reused many times. Its use is intended for 50 hours of EEG recording.	Ag/AgCl
Foretrode	EEG	After each use, use tap water to completely remove the gel from the Foretrode.	Ensure correct drying before storage. Avoid direct sunlight exposure and contact with metals when the electrode is not being used.	The Foretrode is a long-lasting electrode so it can be reused many times. Its use is intended for 50 hours of EEG recording.	Ag/AgCl
Drytrode	EEG	After each use, you may use water to complete the cleaning of the Drytrode	Ensure correct drying before storage. Avoid direct sunlight exposure and contact with metals when the electrode is not being used.	The Drytrode is a long-lasting electrode so it can be reused many times. Its use is intended for 50 hours of EEG recording.	Ag/AgCl

	Use	Cleaning	Maintenance	Durability	Material
NG Pistim	EEG / Stimulation	After each use, use tap water to completely remove the gel from the NG Pistim.	Ensure correct drying before storage. Avoid direct sunlight exposure and contact with metals when the electrode is not being used.	Each electrode should be replaced after 10 hours of stimulation because the Ag / AgCl is expected to be consumed. Nevertheless, the time of the Ag / AgCl consumption depends on the type and intensity of the stimulation current.	Ag/AgCl
Earclip	Reference	After each use, use tap water to completely remove the gel from the Earclip.	Ensure correct drying before storage. Avoid direct sunlight exposure and contact with metals when the electrode is not being used.	The Earclip is a long-lasting electrode so it can be reused many times. Its use is intended for 50 hours of EEG recording.	Ag/AgCl
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

8. Symbols

Symbol	Description
	CE marking without the intervention of a Notified Body, as a Medical Device classified as Class I according to EU Regulation 2017/745 on Medical Devices.
	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.

Symbol	Description
	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.
	The symbol indicates the item is a medical device according to the ISO 15223-1:2021.
	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.

Symbol	Description
	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.
	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 electrodes please contact the manufacturer.

Notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and to the authority having jurisdiction in your locale.

10. Regulatory statements

The electrodes described in this manual are certified (CE marked) class I medical devices under Regulation (EU) 2017/747 on medical devices.

The electrodes described in this manual are investigational devices in US: “CAUTION Investigational devices. Limited by Federal (or United States) law to investigational Use”.

