



MIAMIND®

MIAMIND® Electrode and Gel Adapter

Instruction for use

(Addressed to users, supervisors and experts)

Models:

Miamind® electrode REF 00400, 00410, 00420, 00430

Electrode gel adapter REF 00500

Electrode connector REF 00550

Manufacturer

Bottneuro AG

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Please contact the Manufacturer Bottneuro AG for questions, complaints, or feedback

Any serious incident that occurs concerning the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

About this instructions for use

Version of this Manual: 1.1 **Effective from:** 2023/05/31 **Document ID:** IFU-0005

This Instructions for Use is provided by Bottneuro to patients, supervisors, and experts.



Read and follow all applicable instructions for safe and proper use before the first use of the device. Store these instructions for future reference. In case of technical assistance or feedback, contact the manufacturer or distributor.



This Instructions for Use are available in English. The device may only be used by users, supervisors, and experts capable to understand the language.

Safety Instructions and Safety Warnings



The device must not be used if any medical, clinical, or other indications are against its intended use.



The device must only be used for the described intended use and as described herein.



Before using, please check that the device is not damaged, and the packaging has not been affected by transport or storage.



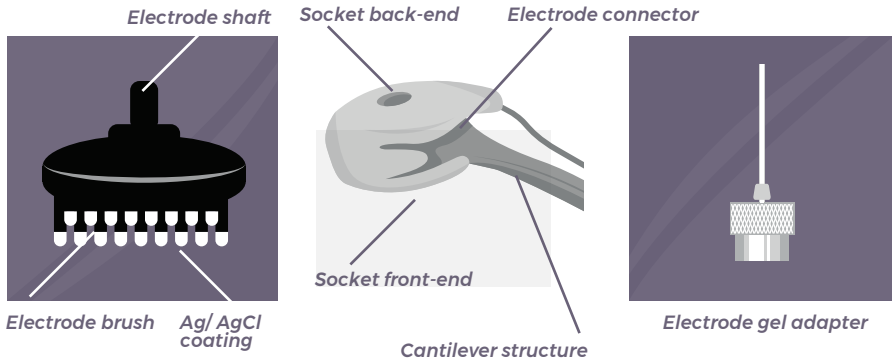
The device can only be used on healthy skin without wounds. The device is not provided sterile and should not be sterilized.



The device is not MR Safe. The device should not be used in an MRI room or close to CT, diathermy, RFID, and electromagnetic security systems such as metal detectors.

Device description

The Miamind® Electrodes are Ag/AgCl coated EPDM-rubber brush electrodes for dry or conductive gel usage. The Miamind® Electrodes can only be used in combination with the electrode connector (REF 00550) and electrode gel adapter (REF 00500) developed by Bottneuro.



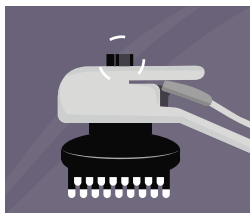
Intended use

The electrodes are intended to be used on the head as an accessory to:

- a tCS (transcranial current brain stimulation) device, or
- an EEG (electroencephalograph)

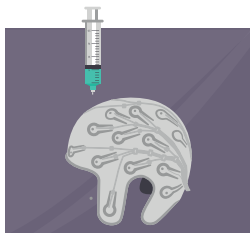
The electrode gel adapter is used to apply gel through the electrode shaft.

Use Instructions



1. Installation of the electrode

To install the electrodes into the electrode connector, gently support the cantilever structure by holding the socket back-end. Grab an electrode by the side and push the electrode into the socket front-end until you visually see the tip of the electrode protruding from the back-end.



2. Applying gel onto the electrode

Fill a Luer-Lok syringe with conductive gel and then screw on an electrode gel adapter (REF 00500). Insert the gel adapter into the electrode shaft and apply gel to the electrode. The amount of gel should be adjusted to the amount of hair a patient has (typically 0.8 – 1 ml).



Excessive conductive gel may cause a short circuit. Use a syringe to control the amount of gel applied.



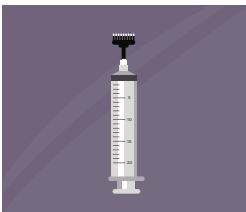
Only use dedicated electrodes gel adapter provided by Bottneuro. No sharp tip or needle shall be used to inject gel through the electrode shaft.



3. Remove an electrode

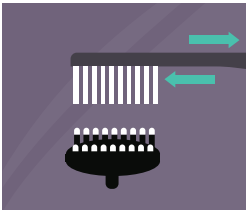
Gently grab the socket back-end. Grab the electrode by the side and pull it out of the socket. Take special care to not bend the cantilever structure on the cap while doing so, to ensure its lifetime. Not supporting the cantilever structure can lead to it breaking, rendering the device unfunctional.

Cleaning the electrodes



1. Cleaning between sessions

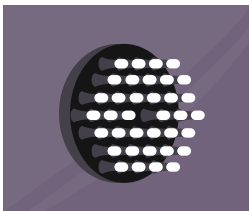
Remove all electrodes from the cap. Use a syringe filled with water to gently rinse through the electrode shaft. Remove all gel in between the electrode brushes by slightly tilting the electrode and rinse with the syringe water jet. Rinse each electrode thoroughly until all gel is removed. Avoid drying out the conductive gel on the electrode. In case the gel dries out, soak the electrode in water for 1 hour before resuming cleaning.



2. Deep cleaning

If gel cannot be removed with water only, deeper cleaning is required for the electrodes. A soft brush under running tap water can be used. Although this method is more effective; it is also more aggressive on the Ag/AgCl coating layer. Extra precautions need to be taken while deep cleaning. (i) Use only a soft brush;* (ii) do not bend the brushes of the electrodes during the cleaning process.

** The cleaning procedure has been validated with Merido® EXTRA GENTLE toothbrush supplied by GABA Schweiz AG.*



3. Inspection and Drying

Visually inspect the electrodes. A clean electrode does not have leftovers of conductive gel in between the brushes and inside the shaft. Inspect if the Ag/AgCl coating and electrode body are intact.

Spray the electrode with Isopropyl Alcohol 70%*. Dry the electrodes thoroughly with a paper wipe and let the electrodes air dry fully.

** The cleaning procedure has been validated with: Klercide 70/30 IPA, Article: 116179E supplied by Ecolab*

Cleaning the electrode gel adapter



Clean the electrode gel adapter by pressing water through it 3 times using a syringe. Rinse off the outside of the adapter with tap water to remove any leftover gel. Dry the gel adapter thoroughly with a paper wipe afterwards and allow it to air dry fully.

Durability

The Miamind® electrodes can be used multiple times without significant loss of performance if both the main body and the coating remain fully intact. If any portion of the main elastic body or the conductive coating is damaged as shown in the picture, functionality can no longer be guaranteed, and the electrode needs replacement. The electrodes should be replaced after a maximal use of 30 sessions.



Example of damaged coating on the Miamind® electrode.

Storage

Store the MiamiMind® electrodes in a dark and dry location before and after application to optimize the lifetime of the component. Avoid direct contact with metal during storage. The product shelf life in an intact, originally sealed packaging is expected to be 24 months.

Explanation of symbols used



Manufacturer of the device



Temperature Limitation



Date of Manufacturing



Consult instructions for use



Keep away from sunlight



Caution



Reference number



The device is not MR safe



Lot number



This device is a medical device



European Authorised Representative - not applicable



Unique Device Identifier



