INSTRUCTIONS FOR USE
Custom tCS/EEG device
POINT OF USE

Instructions for use

Models:
Custom tCS/EEG device REF 00600

Manufacurer

Bottneuro AG
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EU Authorised Representative:
Not applicable – the device is currently not authorised for sale in the EU

US Importer
Not applicable – the device is currently not authorised for sale in the US

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.

1. About this Instructions for Use

Version of this Manual: 1.4 **Effective from:** 2023/10/28 **Document ID:** IFU-0006

1.1 Following Instructions for Use are provided by Bottneuro AG

- Instructions for Use – Custom tCS/EEG device–Point of Use **Document ID: IFU - 0006**
- Instructions for Use – Miamind® Electrode and Gel Adapter **Document ID: IFU - 0005**

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 manufac turer or distributor.

This Instructions for Use is available in English language. The device may only be used by users and supervisors capable of understanding the language of all applicable user manual manuals

2 Change Record

Version 1.0 Intial version
Version 1.1 to 1.4: Minor revisions before the release of the device.

3. Table of Contents

4 Indications for Use

This Custom tCS/EEG device is a custom-made device capable of non-invasive neurostimulation and recording electroencephalogram (EEG).

The device conforms to the essential requirements (Part II of the UK MDR 2002, Annex I [as modified by Part II of Schedule 2A to the UK MDR 2002]).

The device conforms to the general safety and performance requirements set out in Annex I of MDR 2017/745.

4.1 Intended users and qualifications needed

This Custom tCS/EEG device is a custom made device manufactured to the specification provided by a prescribing neurologist.

4.2 Contraindications

⚠ The device shall not be used on persons with a know history of epileptic seizures

⚠ The following contradictions are known for neurostimulation:

- Metal skull implants
- Implanted hearing aids
- Deep brain stimulation leads for Parkinson's disease

5 Device Description

This Custom tCS/EEG device is a non-invasive brain stimulation and EEG device. The device has been specifically customised to an individual patient.

6 Safety Instructions and Safety Warnings

⚠ This device is specifically customised for an individual person. The device may not be used on any other person.

⚠ 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.

⚠ The device shall not be used for electro-cerebral inactivity (ECI) determination

⚠ The device must only be used AFTER the prescription of a stimulation protocol made by a specialized and qualified medical expert.

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

⚠ Do not connect the tablet to any power supply (such as mains supply adapters or power banks) or to USB-C hubs/splitters while the Neckpiece is connected to the tablet.

⚠ In the case of malfunction, immediately contact the manufacturer or the distributor.

⚠ The device must never be opened, manipulated, modified, or damaged. This may result in inaccurate EEG recordings, false stimulations, or electric shocks.

⚠ Do not touch the cap, wires, and electrodes during stimulation or while EEG monitoring. The cap, wires, and electrodes shall not contact other conductive parts including the earth.

⚠ Only use the electrodes provided or suggested by the manufacturer.

⚠ 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.

⚠ The device is not protected against the effects of de-fibrillation and may not be used with HF surgical equipment. The use of such equipment may cause burns, electrical shocks, or affect the stimulation and EEG results.

⚠ Do not use in emergency rooms or other environments where there are police, firefighters, or any personnel with radio transmitters.

⚠ Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.

⚠ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.

⚠ Keep the device away from children, pets or areas prone to pests.

7 Conditions of Use – Storage, Transport Durability

7.1 Conditions of use

- The device must be operated under the following conditions:
- Temperature Range: +5 to +30 °C
- Humidity (non-condensing): 15 – 93 %
- Atmospheric Pressure: 700 – 1'100 hPa
- Use the device in a clean and dry environment

7.2 Storage and Transport

The device must be stored inside the box between uses, under the following environmental conditions:

- Temperature Range: -20 to +50 °C
- Humidity: 15 – 93 %
- Atmospheric Pressure: 700 – 1'100 hPa
- After usage the Cap and Neckpiece need to be cleaned and stored securely in the transport box in a clean and dry environment.

7.3 Calibration, Maintenance and Service

The device may only be calibrated, maintained, repaired, or serviced by the manufacturer. No calibration or maintenance is required within the expected lifetime. In case of quality, accuracy, or performance concerns contact the manufacturer.

7.4 Lifetime

- The expected lifetime of the device is 1 year.
- After its lifetime the device can be disposed to electronic recycling according to local regulations.

8 Technical Specifications and Performance Characteristics

8.1 EEG functionality

- Compliant to IEC 80601-2-26
- Number of channels: up to 32
- Sampling rate: 500 SPS
- Bandwidth: -1 mV ... 1 mV
- Resolution: 1 µV
- Measurement noise: <1µV RMS
- EEG recording is exported in the European Data Format (EDF+ https://www.edfplus.info/specs/edfplus.html)

- Accuracy of signal reproduction: ±20% or ±10µV, whichever is greater
- Input dynamic range and offset voltage: Within ±10% at a DC offset voltage range ±150 mV and differential input signal voltage of ±0.5 mV.
- Frequency range and bandwidth: 0.5 Hz ... 80Hz
- Common mode rejection: ≤ 100 µV peak-to-valley (over a period of ≥ 10s)

8.2 Stimulation functionality

- Number of channels: up to 32 (from 8 current sources)
- Frequency range: 20 ... 80 Hz
- Sampling rate: 2 kHz
- Stimulation types: Transcranial Alternating Current Stimulation (tACS)
- Maximum current per channel: 2 mA
- Current resolution: 1µA
- Current accuracy: +/- 10µA
- Maximum amplitude voltage (channel to device ground): ± 15 V
- Maximum potential voltage (channel to channel): 30 V

8.3 Safety features

- Maximum input current per channel: 2 mA
- Maximum total injected current: 8 mA
- Stimulation session needs to be programmed beforehand
- Abort functionality possible at any instant
- Safety and essential performance tested according to IEC 60601-1:2005+A1:2012+A2:2020

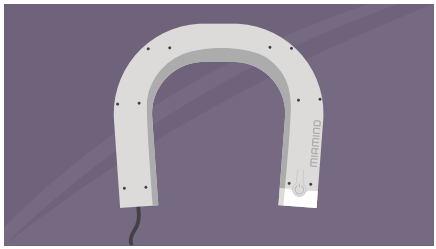
8.4 Other Technical Specifications

- The inner side of the cap and the bottom of the neckpiece are type BF applied parts according to IEC 60601-1.
- All-pole and simultaneous disconnection from the supply network is done by unplugging the USB-C connector from the tablet
- Typical operating time: 2.5 hours (combined EEG/Stimulation use)

9 Components of the Device

9.1 Neckpiece

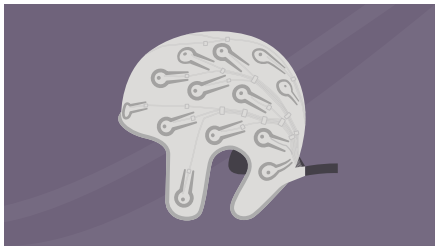
The Neckpiece is the core of the control unit of the device. The Neckpiece connects the electrodes on the cap to the tablet. The Neckpiece is made from biocompatible nylon material.



Neckpiece

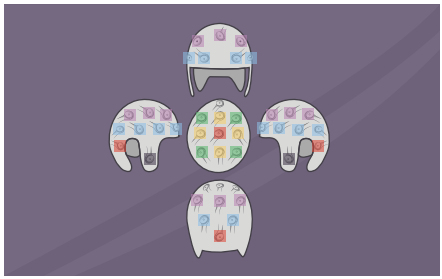
9.2 Cap

The Cap provides up to 34 electrode connectors for inserting electrodes. Out of these 34 electrode connectors, 32 channels are for stimulation and EEG functionality. Additionally, there are two channels for Common Mode Sense (CMS) and the Driven Right Leg (DRL). These connections are preinstalled permanently and not user removable. The Cap is made from biocompatible nylon material.



Cap

Electrode mapping displayed in the App

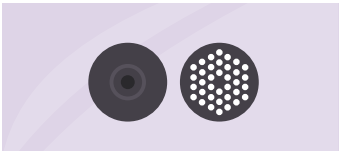


Electrode Names and Positioning

9.3 Miamind® Electrodes

Miamind® Electrodes are Ag/AgCI coated EPDM-rubber brush electrodes. The Electrodes can only be used in combination with the electrode connector (REF 00550) and electrode gel adapter (REF 00500) developed by Bottneuro. Do not use the product on patients with silver allergy.

Please refer to the document Instructions for Use – Miamind® Neurostimulator Electrodes – Document ID: IFU-0005



Miamind® Electrode

9.4 Tablet and App

The Tablet and App are solely responsible for the transfer of the EEG data from the custom tCS EEG device to the Webserver and to provide USB power to the custom tCS EEG device. Disconnecting the Neckpiece from the Tablet will pause an ongoing treatment.

The App illustrates the status of the session, but it deos not control the custom tCS EEG device . Sessions can only be started from the Neckpiece. The App does not display or modify measurement data recevied from the custom tCS EEGdevice.

Do not connect the tablet to any power supply (such as mains supply adapters or power banks) while the Neckpiece is connected to the tablet

Do not use inductive/wireless charging for the tablet.

The Tablet App requires the following Hardware and Operating System:

- Samsung Galaxy Tab S8+ 5G
- Processor: Octa-Core 2.99GHz, 2.4GHz, 1.7GHz
- Display: Touchscreen, 12.4" (315.0mm), 2800 x 1752
- RAM: 8 GB
- Memory: 101.1 GB
- Connectivity: WIFI, 5G
- Android V12
- Knox pre-installed Software (by Bottneuro AG)

9.5 Accessories

- Miamind® Electrode set, REF 00400, 00410, 00420, 00430, Bottneuro AG
- Miamind® Electrode Gel Adapter, REF 00500, Bottneuro AG
- Signa Gel, 250ml, REF 15-25 Parker Laboratories, Inc.
- Syringe with Luer-Lok connection

10 Using the Device

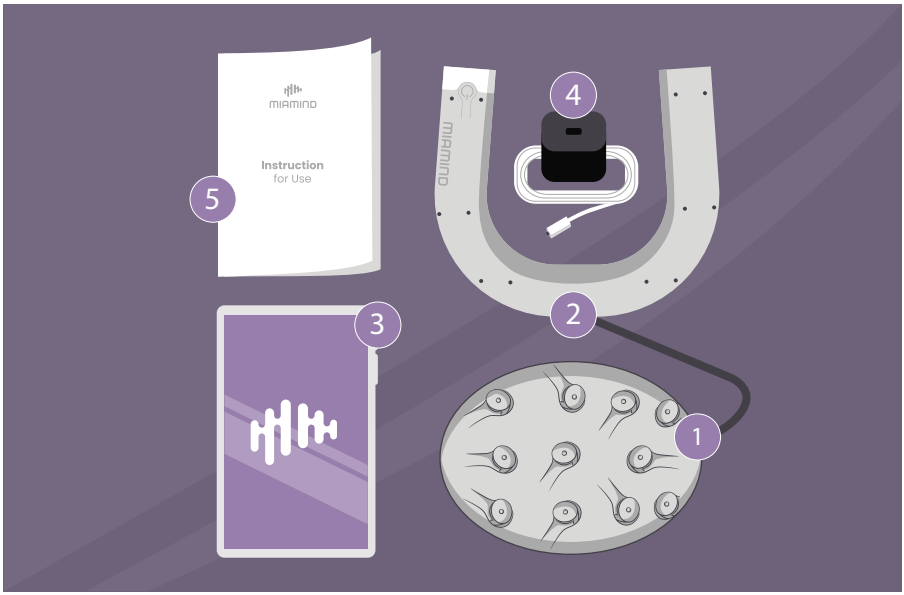
The device has been designed exclusively for an individual patient by an expert. The device shall not be used on any other person than the indicated patient.

10.1 Preparing the Device

10.1.1 Remove contents from the storage box

Box Contents

1. Cap
2. Neckpiece
3. Tablet
4. Charger and cord for Tablet
5. Instruction for Use

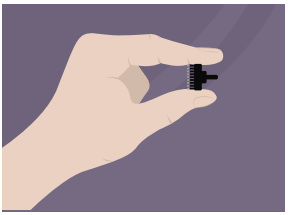


After each use put the device and other parts back in the box.

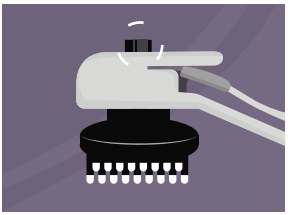
10.1.2 Installing the Electrodes

Install all 34 Electrodes in the Cap. To install the Electrodes into the electrode connector, gently support the cantilever structure by holding the socket back-end. Grab an Electrode by its side and push the Electrode into the socket front-end until you see the tip of the Electrode protruding from the backend.

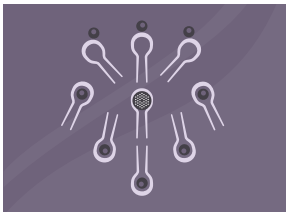
To remove Electrodes, gently hold the socket back-end. Grab the sides of the Electrode and pull it out of the socket. Take special care not to bend the cantilever on the cap. Not supporting the cantilever can lead to damage.



How to hold the Miamind® Electrode



Miamind® Electrode connected to the socket (side view)



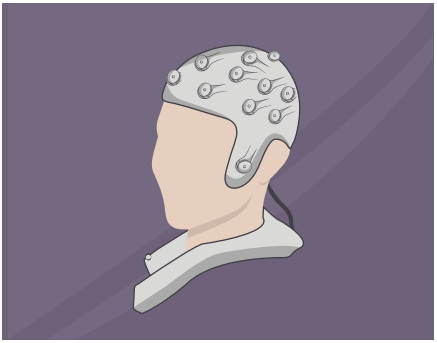
Miamind® Electrode connected to the cap (inside view)

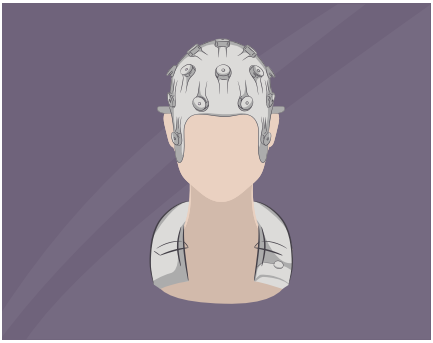
10.1.3 Wearing the Neckpiece

Ensure the forehead is free from make-up and any hair products before you start. Place the Neckpiece on the neck of the patient from behind with the open end facing forward. Make sure no cables are tangled.

10.1.4 Wearing the Cap

With all 34 Electrodes inserted, place the cap on the head of the patient before the session starts. The Cap is worn correctly when the cables, that connect to the Neckpiece appear on the backside of the head. The patient wears the Cap during active sessions.

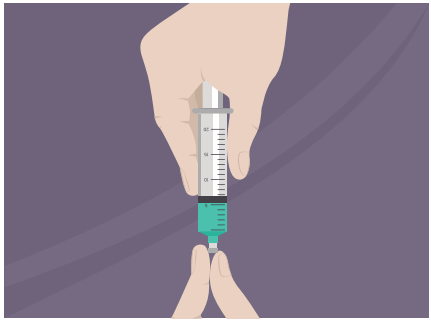




10.2 Applying conductive gel

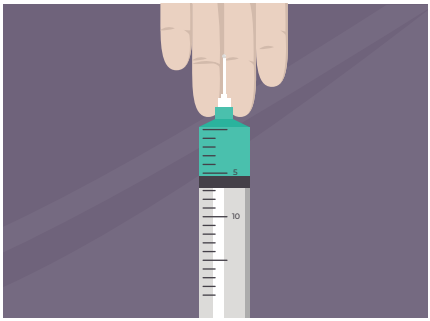
Before a session is started a sufficient low impedance needs to be ensured. Therefore, conductive gel needs to be applied through the Electrodes.

Load the syringe with the conductive gel provided in the consumables package. Press the syringe hub on the gel tube and gently pull the plumger up with your thumb.

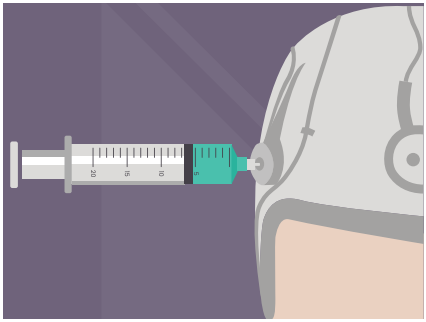


Screw on the Electrode Gel Adapter to the Luer-Lok syringe.

Note: Only use the Electrode Gel Adapter (REF 00500) provided by Bottneuro. Using non compatible adapters, may risk puncturing the skin on the patient's head.



Press the plunger down to remove air from the syringe barrel until some gel drips from the gel adapter



Insert the Electrode Gel Adapter all the way into the Electrode shaft and apply gel. The amount of gel may be adjusted to the amount of hair a patient has (usually 0.8 – 1ml).

To avoid missing an Electrode position, keep track of the sequence when applying gel to the Electrodes.

After applying gel, wait at least 5 minutes before starting the therapy session.

⚠ Excessive conductive gel may cause a short circuit between electrodes.

10.3 Turing on the device

10.3.1 Tablet Power On/Off

- Power on: Long press side key to turn on the tablet. The App will automatically open.
- Power off: Long press side key and volume down key together to access menu. Choose between power off or restart.

10.3.2 Connecting the Neckpiece to the Tablet

Connect the Neckpiece via USB-C cable to the Tablet charging port. Make sure the plug is all the way in the USB-C port. The Neckpiece automatically turns on when the USB-C cable is connected to the power source (Tablet) and the Tablet is turned on. A message will indicate that connection is successful.

10.4 Starting a Therapy Session

10.4.1 Tablet App Homepage

Each patient is assigned a unique patient ID. The App receives the patient ID information from the Neckpiece and displays on the upper left of the homepage. Verify the patient ID matches the patient's name in your clinical record.

Note: When the patient ID does not match the patient's name, the Tablet App and Neckpiece are not paired correctly. In this case, the device must be returned to the manufacturer for resetting the pairing.

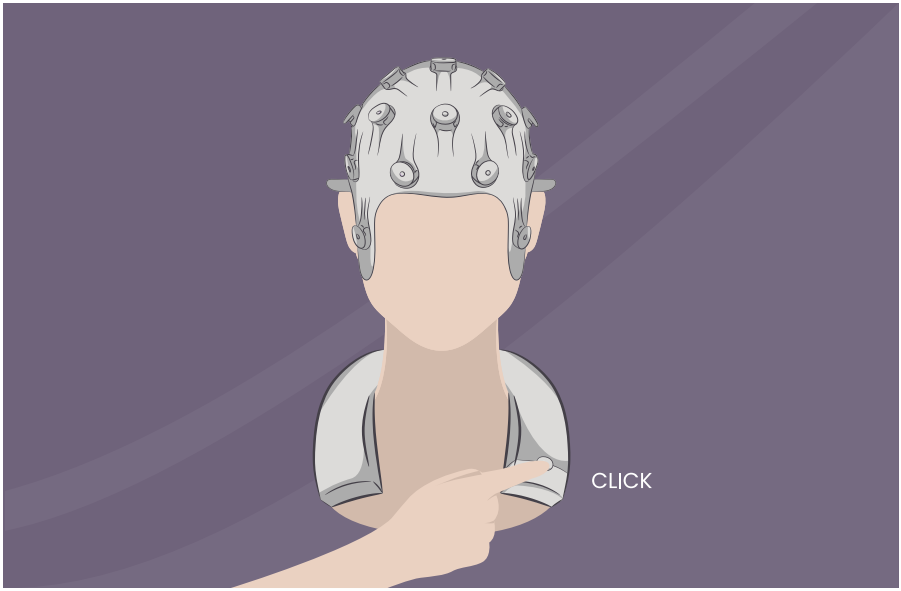
10.4.2 Starting a session on the Neckpiece

The session has been designed by an expert specifically for a patient and is preloaded on the Neckpiece. A session can comprise of stimulations and/or EEG measurements. A typical sequence is: EEG -> Stimulation session -> EEG.

The Neckpiece has a LED indicator light that shows the status of the device.

- White light: Session paused. Press Push-Button to resume.
- Blue light: Waiting for user input. Follow the App instructions.
- Purple light: EEG session running.
- Pulsating purple light: Stimulation session running.
- Green light: Session complete.
- Red light: Device error. Refer to error message.

After clicking the START button on the App, follow the App instructions and press the Push-Button on the Neckpiece to start a session.



The device will then perform an automatic check if

- the battery level on the tablet is high enough to complete the session.
- there is sufficiently low impedance on all required electrodes.

After the automatic check, the device will proceed with the session and the indicator light will turn purple.

If the impedance is not sufficiently low the indicator light will turn blue. Follow the steps below to ensure sufficiently low impedance.

10.4.3 Ensuring sufficiently low impedance

The device performs an impedance check before each EEG and continuously during the stimulation. The device automatically pauses if the impendence of an Electrode is too high. In this case, the indicator light will turn blue, and a message will appear on the App asking the user for help.

The App message will show the area of electrodes which do not have sufficiently low impedance. Tapping on the App message will also show specific Electrode positions. Gently press and wiggle these Electrodes positions, so that the Electrode brushes can contact the skin surface and lower the impedance.

If impedance cannot be lowered by pressing, check that conductive gel has been applied correctly to these Electrode positions. More conductive gel can be added, but the total amount of gel applied in an Electrode should not exceed 1.2 ml.

Note: Do not attempt to entirely remove and wear again the cap on the head, as this might cause the conductive gel applied to smear and cause short circuit between electrodes.

After resolving the impedance problem, the session will continue automatically.

10.5 Running a Therapy Session

The device will execute the session as defined in the therapy plan.
The remaining time of an active EEG or stimulation session is displayed on the tablet. During a running session, the indication light will shine purple (constant purple for an ongoing EEG measurement and pulsating purple for stimulation).

The following controls are possible:

10.5.1 Pause the session (Stimulation currents will be halted immediately)

By pressing the Push-Button the session will be paused. The indication light will turn white and a message will appear in the App.

The following actions will also pause a session:

- Removing the USB-Cable
- Switching off the Tablet
- Power loss off from the Tablet

The session can be resumed by pressing the Push-Button again. The session will be resumed from the point before the session has been interrupted.

10.5.2 Abort a session

The user can stop and abort the session at any time by pressing the power button on the Neckpiece. The session will pause with a short press, and a continued pressing for more than 5 seconds will abort the session.

10.5.3 Interruption by the device

The device carries out an impedance check before each EEG and continuously during stimulation. The device automatically pauses if the impendence of an Electrode is too high. In this case, the indicator light turns blue. Resolve the impedance problem as described in chapter " 10.4.3 Ensure sufficiently low impedance".

10.5.4 Device failure

If the indicator light shines red, the device has a failure, and an error message will appear. Remove the device and long press (>5 seconds) the Push-Button to turn off the device. Return the device for servicing.

10.6 Completed session

The session will stop automatically when completed. A green indication light indicates a completed session.

After a session is completed, the patient must give feedback to the session on the Tablet App. The device can then be removed from the patient for cleaning.

11 Disassembling and Cleaning the Device
11.1 Disassemble

- Remove the USB-C Cable from the Tablet. Recharge the Tablet with the supplied charger.
- Remove the Cap and Neckpiece from the patient.
- Remove all Electrodes from the socket in the Cap.
- Transfer the Cap, Neckpiece and Electrodes to the cleaning area.

Note: Do not disassemble the cable between the Cap and Neckpiece.
Note: Do not disassemble the electrode connector in the Cap.

11.2 Cleaning the Cap and Neckpiece

- Use running tap water and a cleaning brush **on the Cap only** to remove visible contaminations from the cap.
- Clean the Cap and Neckpiece system with a lint-free wipe soaked in 70% isopropyl alcohol.
- Spray the Cap only with 70% isopropyl alcohol until the whole Cap is wet.
- If there are still visual signs of contamination, repeat the steps above as necessary.
- Let the Cap and Neckpiece dry in an upright position on a flat surface, ensure no compression on the electrode socket cantilever structure. Allow the device to dry completely.
- Put the device back in the storage box and store in an environment described in chapter 7.

Cleaning validation was performed with a nylon instrument cleaning brush (REF 3FRIN550116, Vereinigte Papierwarenfabrik GmbH) and 70% isopropyl alcohol (Klercide™, REF 3078430, Ecolab).

11.3 Cleaning the Electrodes, Electrode Gel Adapter

Refer to the Instructions for Use for Miamind® Electrodes and Gel Adapter- Document ID: 0005 .

The electrodes should be replaced after a maximal use of 30 sessions.

12 Error Messages

Error	Code	Generated by	Description	Resolution
Sum Of Currents Not Zero	100	Core	The sum of all applied currents does not equal zero.	1. If an error occurred during the first use of a new treatment session: Correct the therapy plan. 2. If an error occurred in a previously successfully used treatment session: restart the session after consulting with a medical professional, contact manufacturer if the problem occurs frequently.
Potential Correction Current Too High	101	Core	The current through the DRL channel exceeded the limit of 2mA.	
Stimulation Current Too High	102	Core	The applied current is greater than 2mA.	
High Impedance	103	Core	A too high impedance has been detected, so the requested current cannot be applied.	Adjust the contacts of the electrodes by following the instructions described in chapter 10.4.3.
Invalid Therapy Plan	200	Firmware	Therapy plan validation failed, or no therapy plan loaded at all. Checked during startup.	Generate a therapy plan according to the specification, contact a manufacturer service expert if the problem occurs frequently.
Low Battery At Therapy Start	201	Firmware	Therapy cannot be started because the battery level of the Tablet is too low. Checked at therapy start (button press)	Disconnect the Tablet from the Neckpiece and connect it to the charger. Wait until battery is fully charged.
Firmware crash	202	Firmware	Firmware crashed, external watchdog triggers.	Disconnect the Tablet from the Neckpiece and reconnect it. If the problem persists, contact manufacturer.
I2C Bus Failed (EEPROM)	203	Firmware	I2C bus communication with EEPROM failed. (Cannot read serial number)	
I2C Bus Failed (Status LED)	204	Firmware	I2C bus communication with Status LED failed.	
SPI Bus Failed (ADC)	205	Firmware	SPI bus communication failed.	
SPI Bus Failed (ADC)	206	Firmware	SPI bus communication failed.	

Error	Code	Generated by	Description	Resolution
Power Supply Out of Range	207: U5V_LOW 208: U5V_HIGH 209: U3V3_LOW 210: U3V3_HIGH 211: U3V3_BU_LOW 212: U3V3_BU_HIGH 213: U15V_LOW 214: U15V_HIGH 215: U15Vn_LOW 216: U15Vn_HIGH 217: U3V3_AN_LOW 218: U3V3_AN_HIGH 219: U5V_AN_LOW 220: U5V_AN_HIGH 221: U2V5_LOW 222: U2V5_HIGH	Firmware	Any power supply failed (out of range)	
Self-check Failed	223	Firmware	The self-check of the device failed	Disconnect the Tablet from the Neckpiece and reconnect it. If problem persists, contact manufacturer.
Wrong Patient ID	300	Mobile App	Wrong headset was connected to the Tablet (Patient ID does not match).	Check if the Neckpiece is paired with the correct tablet. If not, send the device to manufacturer to reset pairing.
No impedance data received	301	Mobile App	Impedance check is running, but no impedance data is being received from the Firmware.	Disconnect the Tablet from the headset and reconnect it. If the problem persists, contact manufacturer.
No eeg data received	302	Mobile App	EEG measurement is running, but no eeg data is being received from the Firmware.	

Error	Code	Generated by	Description	Resolution
Creation of history file failed	310	Mobile App	History file could not be created.	Restart the Tablet. If the problem persists, contact manufacturer.
Creation of EEG file failed	311	Mobile App	EEG (edf) file could not be created.	
Upload of history file failed	312	Mobile App	History file could not be uploaded to the file server.	Check internet connection. Tablet will upload the data as soon as connection is established again. If the problem persists, contact manufacturer.
Upload of EEG file failed	313	Mobile App	EEG (edf) file could not be uploaded to the file server.	
Download of PDF files failed	314	Mobile App	PDF files to be shown in the info menu could not be downloaded.	1. Check internet connection. 2. Restart the Tablet. Tablet will download the PDF as soon as connection is established. If the problem persists, contact manufacturer.
Therapy Not Initialized	320	Mobile App	Could not read therapy info from the headset.	Disconnect the Tablet from the headset and reconnect it. If the problem persists, contact manufacturer.
Server connection not configured	321	Mobile App	Could not connect to the file server, since the connection is not configured.	Restart the Tablet. If the problem persists, contact manufacturer.
History check failed	322	Mobile App	Failed to check, if a history file is available on the file server.	
History download failed	323	Mobile App	Failed to download history file from the file server.	
History download invalid	324	Mobile App	Failed to decode the downloaded history file.	

13 Explanation of Symbols used


Manufacturer of the device


Date of Manufacturing

European Authorised Representative – not applicable


Keep away from Sunlight


Keep Dry

Reference Number

Serial Number


Temperature Limitation


Consult instructions for use


Atmospheric pressure


Caution

The device is not MR safe

This device is a medical device

Unique Device Identifier


Humidity

14 Electromagnetic Compatibility (EMC) Information

Concerning electromagnetic disturbances, the device complies with the emission and immunity requirements of EN 60601-1-2:2014 + A1:2020 and (IEC 60601-1-2:20 14+AMD1:2020)

Phenomenon	Home healthcare environment	Compliance
RF emission	CISPR 11	Class B Groupe 1

Table 1: EMC emission summary

Phenomenon	EMC standard	Home healthcare environment
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Electrical fast transients / bursts	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency
Surges (Line-to-ground)	IEC 61000-4-5	± 2 kV
Immunity to proximity magnetic fields	IEC 61000-4-39	9 kHz - 13.56 MHz

Table 2: EMC immunity test levels