



MIAMIND®

Custom made, personalized tES and EEG caps



www.bottneuro.com



Miamind® Neurostimulator

The Miamind® Neurostimulator is a modern non-invasive brain stimulator and EEG device which allows for precise and multifocal brain stimulation on up to 32 electrode channels. The custom made medical device applies defined currents, in specific frequencies for defined amounts of time. The device is specifically customized to an individual patient. To address individual skull anatomy and ensure perfect fit for repeated optimal electrode positioning, the device is 3D printed based on a patient's anatomy derived from MRI scans. Treatment progress can be monitored by measuring brain EEG before and after each session.

Components of the device:

- Miamind® Neurostimulator Cap – 3D printed and customized to participants anatomy.
 - Miamind® Neurostimulator Neckpiece – main control unit of Miamind® Neurostimulator.
 - Miamind® Neurostimulator Tablet App – it is used for therapy monitoring and data transfer.
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What is tES?

Transcranial Electrical Stimulation (tES) is a non-invasive technique that employs low electrical currents to modulate nerve cells in the brain, potentially alleviating symptoms of various conditions. Unlike invasive procedures that require surgery or incisions, tES is performed without any need for such interventions.

How it works

tES works by using a very low electrical current to influence the activity of the brain.

Think of your brain as a big electrical circuit. It has wires (neurons) that carry electricity to make your body work. Sometimes, our brain circuits don't work as well as they should, and that can affect mood, thinking, or memory. tES is like giving a tiny impulse of electricity to your brain. It's done using a special device with small pads or electrodes placed on your head. A very mild and controlled electrical current is sent through the electrodes and into your brain. It's important to know that the current used in this treatment is extremely weak and doesn't cause any pain or harm. The idea is to help your brain's neurons to communicate better. The electrical current can change the activity of the brain cells in the area where the electrodes are placed. It can make these parts of your brain more or less active, depending on your healthcare professional's prescription. It's like giving your brain a little nudge to work better. But it's essential to remember that this is a medical procedure, and you should only do it under the guidance of a trained healthcare professional. They will make sure it's safe and suitable for you.

There are several types of transcranial stimulation techniques, the most frequently used ones are called **Transcranial Direct Current Stimulation (tDCS)** and **Transcranial Alternating Current Stimulation (tACS)**. Both methods aim to influence brain activity, but they do it in different ways. Doctors choose between these techniques based on the specific goals of treatment or research.

Think of tDCS as a steady, continuous flow of very gentle electrical current. tDCS is often used to either boost or reduce the activity of specific brain areas, depending on the direction of the current. tACS, on the other hand, is like a rhythmic, back-and-forth pattern of electrical current. tACS is used to synchronize brain activity with the frequency of the alternating current. By this, brain activity patterns which are disturbed by a disease can be restored and a healthy brain state can be reinduced.

Studies show that tDCS is effective in treating depression, trauma, and stroke recovery, altering neural activity and encouraging neuroplasticity by channelling low intensity direct currents for mood stabilization, trauma healing, and rehabilitation.

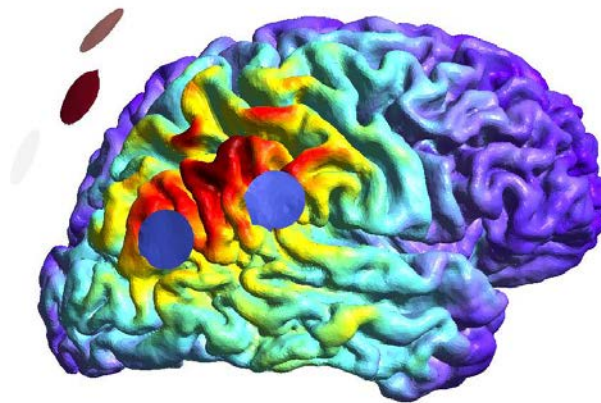
tACS modulates brain oscillations, therefore enhances neural oscillations in the targeted brain areas frequency specific. For example, in Alzheimer's Disease, disrupted brain oscillations and detrimentally activated microglia contribute to neuroinflammation and cognitive decline.

It's important to remember that the choice between tDCS and tACS depends on what the doctor aims to achieve in their treatment, as each method has its own unique effects on brain activity. The specific characteristics of stimulation protocols can vary widely, encompassing parameters like stimulation frequency, the number of pulses, duration of stimulation, the number of sessions, the presence and duration of follow-up periods, the choice of stimulation targets (single or multiple), and the presence or absence of concurrent cognitive training.

Custom made tES

Our custom made approach for tES features personalized therapy plans and electrode positioning for precise tES targeting specific brain regions.

To enhance the precision and effectiveness of tES treatments a personalized approach is essential. The distribution of electrical fields in the brain is influenced by both electrode positions and individual anatomy. Even with identical electrode montages and stimulation parameters, anatomical differences between patients alter induced fields, impacting the effects of tES treatments. This means, even if we use the same setup and settings for everyone, differences in people's anatomy can affect how well the treatment works.



By leveraging MRI images of your brain, we simulate how the electrical fields spread based on where we place the electrodes and the settings we choose. These personalized simulations aid in selecting an optimal electrode montage and stimulation parameters, ensuring the desired electrical field reaches the target region while minimizing off-target stimulation. This optimization process accounts for each patient's unique anatomy, treatment protocol, and the specific brain area or network being targeted.

Our non-invasive device features a custom-fit 3D printed cap with up to 32 electrode channels for reliable treatment. It offers both tACS ranging from 20 to 80 Hz and tDCS, allowing customization of stimulation parameters like frequency, duration, and session count. The therapy plan can involve multiple steps, utilizing EEG or stimulation patterns with the flexibility to select up to 8 electrodes and a combination of tACS and tDCS.



Risk and side effects

tES is a non-invasive method of stimulating the brain. Unlike procedures such as deep brain stimulation, tES doesn't involve surgery or the need for implanted electrodes. Moreover, unlike electroconvulsive therapy (ECT), tES doesn't induce seizures or lead to memory loss. It also eliminates the need for anaesthesia, sparing individuals from entering a sleep-like state.

tES has been extensively studied, with no reports of serious or severe adverse effects. Typically, tES is regarded as safe and generally well-tolerated.

Common side effects

Side effects are typically mild to moderate and tend to improve shortly after a session. These sensations can sometimes persist for the entire duration and for a brief period after stimulation is complete, but usually disappear shortly after stimulation begins. The most common side effects associated with tDCS and tACS are:

- *Slight tingling, itching and burning sensation and discomfort under the electrode*
- *Visual sensation when turning stimulation on and off*
- *Moderate fatigue, skin redness, headache, difficulty concentrating during and after the stimulation*

Uncommon side effects

These side effects can occur but are very rare:

- *Nausea*
- *Nervousness*
- *Ringling in the ear*
- *Acute mood swings*
- *Temporary visual impairment*

If you experience side effects during or after tES, immediately inform your healthcare provider, describe the side effects, follow their advice, keep records, monitor changes, and ask questions for guidance. Your healthcare provider is there to help you.



What is Electroencephalography (EEG)?

EEG is a non-invasive neuroimaging technique that records and measures the electrical activity generated by the neurons.

How it works

It involves small electrodes located on the scalp to detect the fluctuations in electrical potential that occur as a result of neuronal communication.

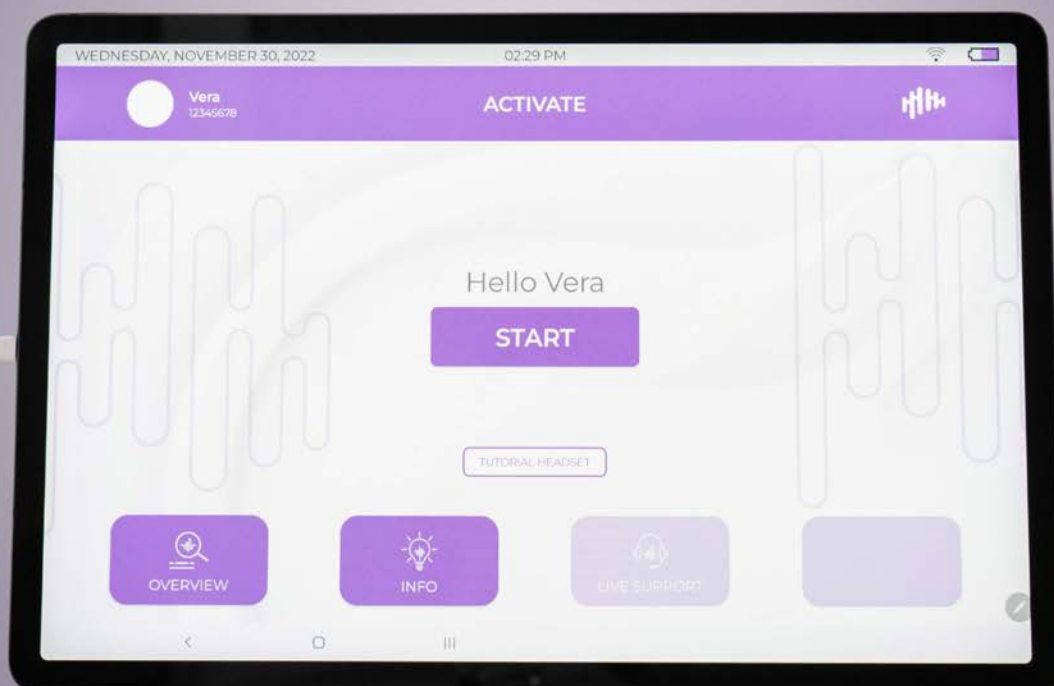
These electrodes pick up signals from different regions of the brain, allowing for the creation of an EEG recording. This recording provides valuable information about the brain's activity patterns, such as the presence of certain rhythms or abnormalities. Compared to other neuroimaging techniques, EEG offers great temporal resolution able to detect even small alterations in brain activity.

EEG is widely used in clinical settings and research to assess brain function, diagnose neurological disorders, and monitor changes in brain activity during various tasks or conditions. It's a non-invasive and valuable tool for understanding the dynamic electrical activity occurring within the brain.

Custom made EEG

Our 3D printed EEG technology enables easy monitoring of brain activity patterns with up to 32 electrodes and an additional reference electrode.

It facilitates repetitive clinical assessments, offering insights into conditions like Alzheimer's disease. By combining precise head anatomy data, it converts EEG signals into neuroimaging results. This clinical-grade EEG device, integrated into a personalized 3D printed cap, allows continuous, long-term remote tracking for various neurological conditions, aiding in their understanding, diagnosis, and treatment.

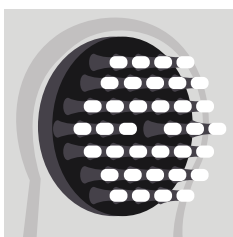




Home Use

The MiamiMind® Neurostimulator can be used by patients in the comfort of their homes. After wearing the device on the head to start the treatment, the tablet's user-friendly app guides users through each session. This simplicity not only enhances the overall user experience but also encourages regular and effective use, making neurostimulation therapy more convenient.

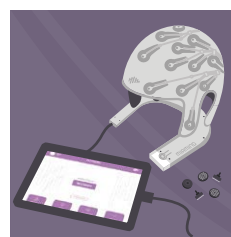
Steps for each treatment session at home



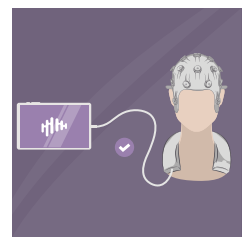
1. Insert electrodes on the cap



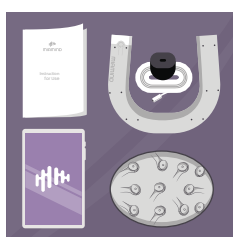
2. Put on the cap, apply gel with syringe and gel adaptor



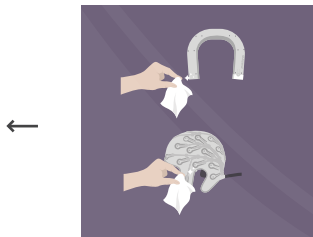
3. Turn on device and start session



4. Session complete



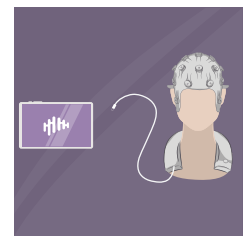
8. Store device in the package box



7. Clean cap and neckpiece with alcohol wipe



6. Remove electrodes from cap and clean with water



5. Detach tablet and recharge

Patient Journey

Before the Treatment:

Consultation: The journey starts when you first notice symptoms that concern you. You'll have an initial consultation with your family doctor to better understand the nature of these symptoms.

Referral to Clinic: For specialized diagnosis and treatment planning, you will be referred to a dedicated clinic for precise assessments and targeted intervention strategies. The specialists will discuss your specific condition and explain the goals of the treatment with the Miamind® Neurostimulator.

Health Assessment: Your healthcare provider assesses your overall health and any pre-existing medical conditions to ensure the procedure is safe for you. In addition, contraindications for neurostimulation like electric implants (e.g. Deep Brain Stimulator, Vagus nerve stimulator, implanted hearing aids, cardiac pacemaker etc.) should be identified.

Identifying the region of interest: To locate the brain area which should be stimulated, various methods are used, including neuroimaging (MRI, fMRI), brain mapping (EEG, MEG), clinical assessments, predefined research targets, and individualized approaches tailored to the patient's unique needs. Your healthcare provider determines the appropriate method based on the specific goals and available resources.

Order Placement with Bottneuro: The clinic interfaces with Bottneuro through the Miamind Portal. Bottneuro crafts a tailored therapy plan best suited for you and manufactures your personalized Miamind® Neurostimulator. In the clinic, you will receive training on how to use the device.

During each Treatment:

tES sessions with the Miamind® Neurostimulator can be done either at home or in a dedicated clinic. Generally, multiple sessions per week are carried out.

Setup: For the stimulation session, you'll be seated comfortably, and the Miamind® Neurostimulator will be placed on your head, the Miamind® Neckpiece is placed around your neck. This process is painless. After starting the treatment, it is possible that you will feel a gentle tingling or itching sensation on your scalp.

Duration: The treatment session typically lasts from 20 minutes to an hour, depending on the specific protocol chosen by your healthcare provider.

Monitoring: The clinic receives data and monitors you during the procedure to ensure your safety and comfort. If you experience any discomfort, you should let them know immediately.

Cooperation: It's essential to follow the healthcare provider's instructions and engage in activities recommended by your healthcare provider.

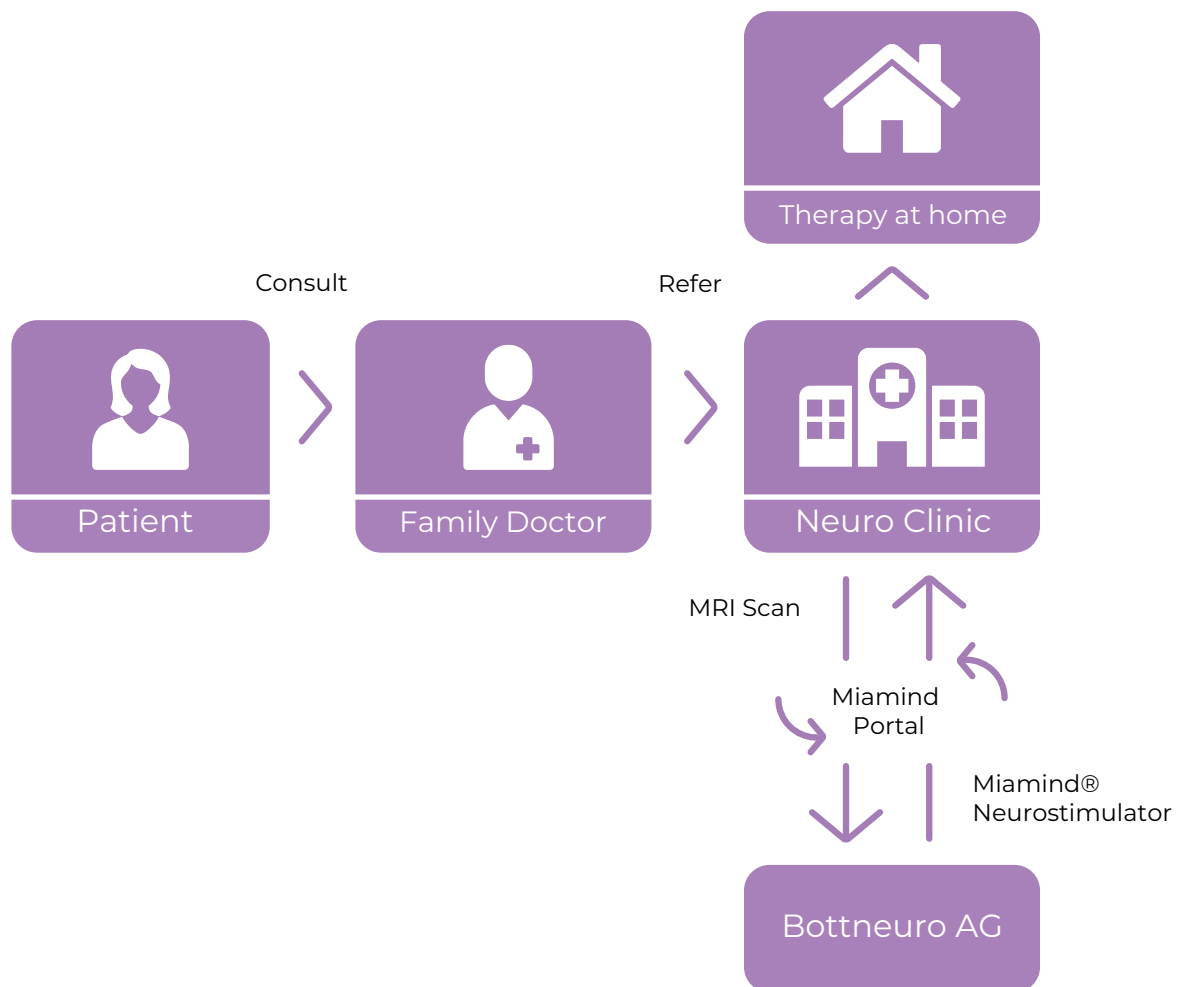
After the Treatment:

Immediate Effects: You can return to your normal daily activities after your treatment. You might not notice significant changes right after your first session. Some people report feeling more alert, while others feel a bit tired. The effects can vary from person to person.

Follow-Up: Your healthcare provider will discuss a treatment plan with you. Depending on your condition, you may need multiple sessions over a period of days or weeks to see the desired results.

Long-Term Benefits: The true benefits of tES might become noticeable after a series of treatments. Your healthcare provider will monitor your progress and adjust the treatment plan as needed.

Communication: It's crucial to maintain open communication with your healthcare provider throughout the process. If you experience any unexpected changes or side effects, inform them promptly.



How it impacts your daily life

In general, you can return to your normal daily activities after your treatment. However, the frequency and duration of tES sessions can affect your daily routine.

Some treatment protocols involve daily sessions, while others may be less frequent. Longer sessions may require more of your time. If you need to travel to a medical facility for tES sessions, it may involve time and transportation considerations, potentially affecting your daily schedule.

tES may cause mild side effects, like a headache or skin irritation, which could temporarily impact your comfort and daily activities. These effects usually subside shortly after a session.

Regular follow-up appointments and monitoring with healthcare professionals may be necessary to track progress and adjust the treatment plan, which requires time and effort.



FAQ

Is the Miamind® Neurostimulator certified?

This Custom tES/EEG device is a custom-made device capable of non-invasive neurostimulation and recording EEG.

This custom made tES/EEG device is registered with Swissmedic and UK MHRA as a custom-made medical device. The device conforms to the general safety and performance requirements set out in Annex I of MDR 2017/745.

This device is tested and developed according to the following standard:

- *ISO 13485, ISO 14971, ISO 10993*
- *IEC 60601, IEC 62304, IEC 81001, IEC 80601*

What are the conditions while using the Miamind® Neurostimulator?

The device must be operated under the following conditions:

- Temperature Range: +5 to +30 °C
- Humidity (non-condensing): 15 – 93 %
- Atmospheric Pressure: 700 – 1100 hPa
- Use the device in a clean and dry environment

Where should I store the Miamind® Neurostimulator?

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 – 1100 hPa
- After usage the Cap and Neckpiece need to be cleaned and stored securely in the transport box in a clean and dry environment.

How long does a tES session take?

The duration of a transcranial electrical stimulation (tES) session can vary based on the specific treatment protocol and the condition being addressed. Generally, sessions can range from 20 minutes to an hour. It's important to consult with your healthcare provider or follow the recommended guidelines for your particular tES treatment plan to ensure optimal results.

Please contact Bottneuro AG for further information.



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Miamind[®] is a product by Bottneuro

If you have any questions that have not been answered, please contact us via e-mail. This brochure and the information contained herein is provided for informational purposes only and is not intended to replace a discussion with a healthcare provider. All decisions regarding patients must be made with a healthcare provider and consider the unique characteristics of each patient.

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