

Personalized Electrical Stimulation for Home Use

Precision Medicine for Brain Health





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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Personalized Swiss Precision Medicine

The Miamind® Neurostimulator is personalized based on individual MRI data and manufactured using 3D printing. This customized technology enables precise stimulation of the desired brain region. Unlike standardized “one size fits all” approaches, Miamind® uses patient-specific computer models to optimize the electrode configuration and therapy plan. As a result, the electrical effectiveness in the target region is significantly enhanced.

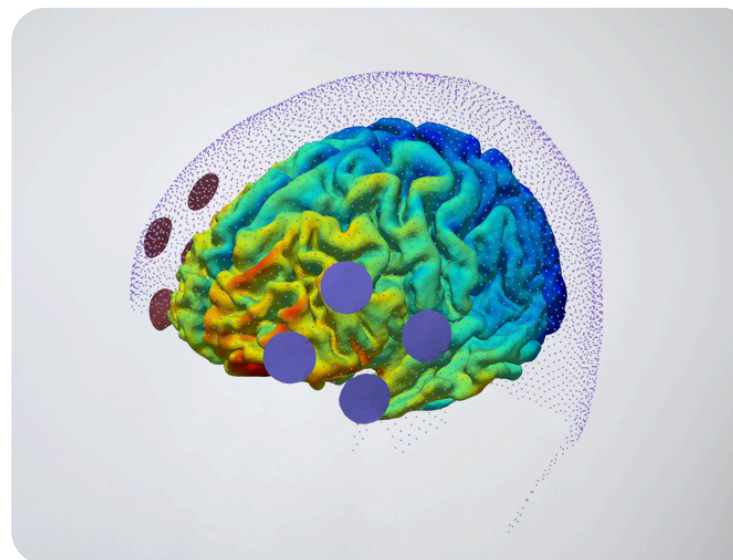


Comfortable Home Use

As an innovative brain stimulation device, the Miamind® Neurostimulator enables patients to carry out their therapy conveniently and safely at home. Patients benefit from the flexibility of home treatment, while the therapy is remotely monitored by the attending physician.

Diverse Applications

The wide range of possible stimulation parameters (tDCS and tACS), combined with a built-in EEG function, allows for the treatment of a variety of neurological conditions. Personalized neuro-stimulation shows particularly promising results in dementia therapy, as it specifically addresses the individual needs and anatomical characteristics of each patient.



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

Think of your brain as an electrical circuit made up of neurons that transmit signals to maintain bodily functions. Sometimes, these circuits work less efficiently, which can affect mood, memory, or cognitive abilities. tES (transcranial electrical stimulation) is like delivering a gentle electrical pulse to your brain. Special electrodes are placed on the head, through which a controlled electric current flows. The current used in this treatment is extremely weak and causes no pain or damage. The goal is to enhance neuronal communication. The electrical current can influence the activity of brain cells in the area where the electrodes are positioned.

Depending on the goal of the treatment, brain activity can be:

- *Increased to strengthen cognitive functions such as memory and attention*
- *Inhibited to calm overactive areas (e.g., epileptogenic zones)*
- *Adjusted to specific frequencies to normalize dysfunctional brain waves, as seen in Alzheimer's disease*

Different Types of tES

There are various forms of transcranial stimulation. The most commonly used methods are transcranial direct current stimulation (tDCS) and transcranial alternating current stimulation (tACS). Both aim to influence brain activity, but in different ways.

- **tDCS (transcranial direct current stimulation)** uses a constant, gentle electric current to modulate the activity of specific brain regions.
- **tACS (transcranial alternating current stimulation)** uses rhythmic electrical impulses to synchronize brain activity at a specific frequency.

Studies show that tDCS can be effective for depression, trauma, and stroke rehabilitation by promoting neuronal activity and neuroplasticity through weak direct currents. tACS specifically modulates brain oscillations to enhance frequency-specific neuronal activity, which can, for example, help reduce neuroinflammation and cognitive impairments in Alzheimer's disease.

The choice between tDCS and tACS depends on the treatment goals, as each method has different effects on brain activity. Stimulation protocols vary in frequency, number of pulses, duration, sessions, and type of stimulation.

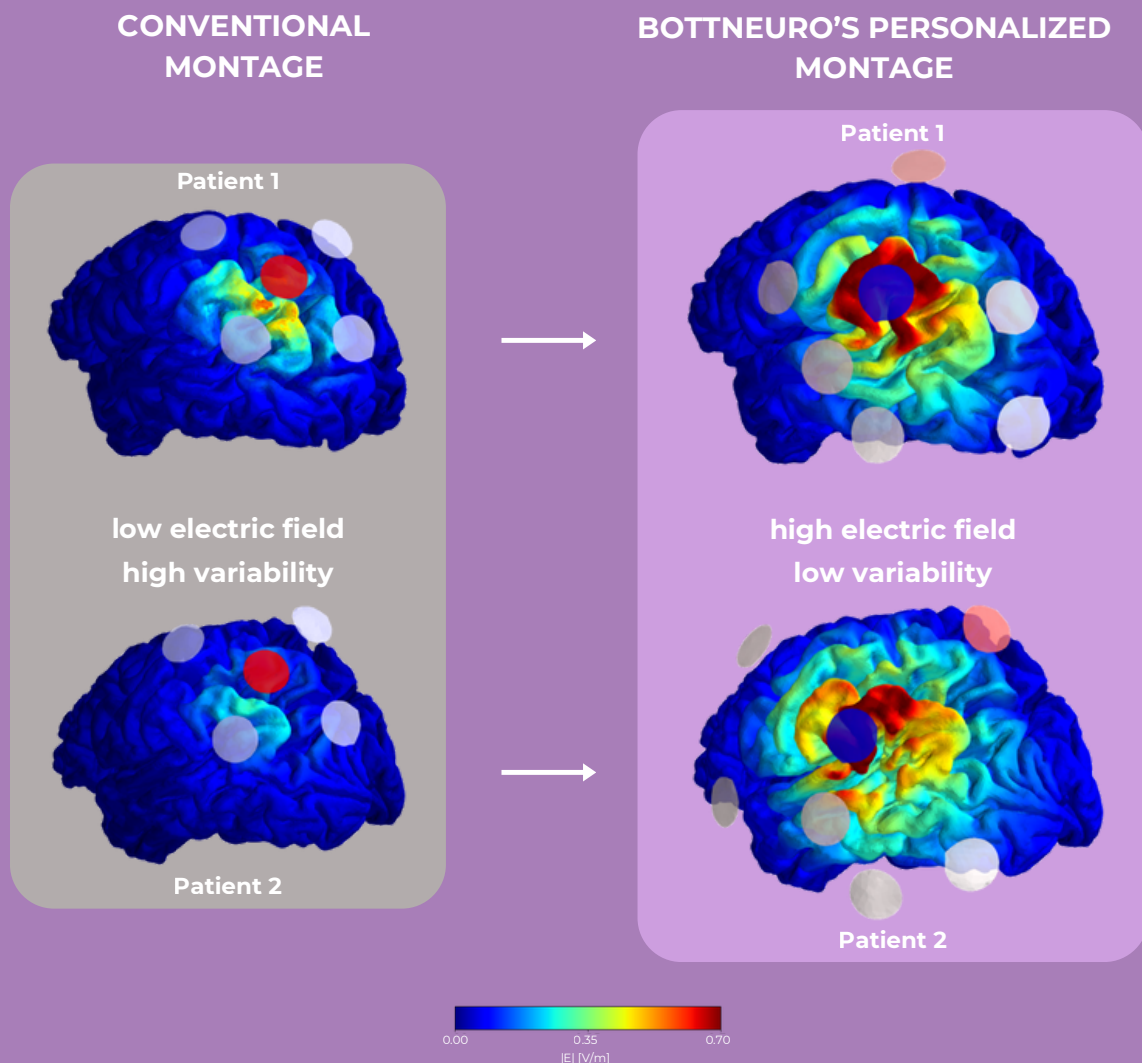
Custom-Made tES with Miamind

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 the same settings are used for everyone, differences in people's anatomy can affect the treatment.

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 eight electrodes and a combination of tACS and tDCS.





Home Use

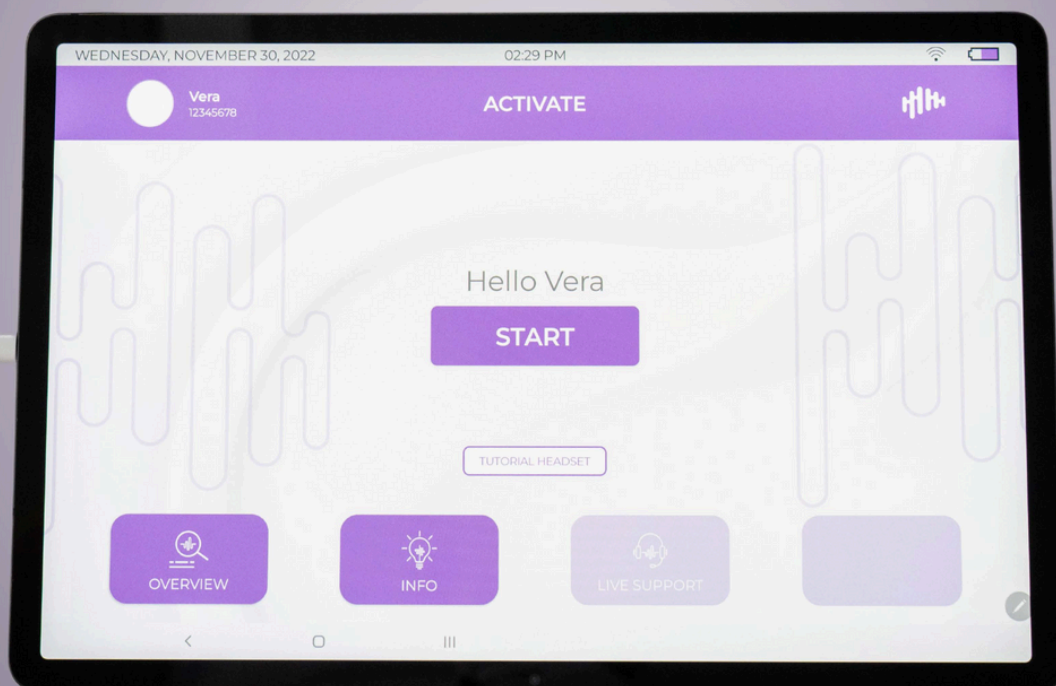
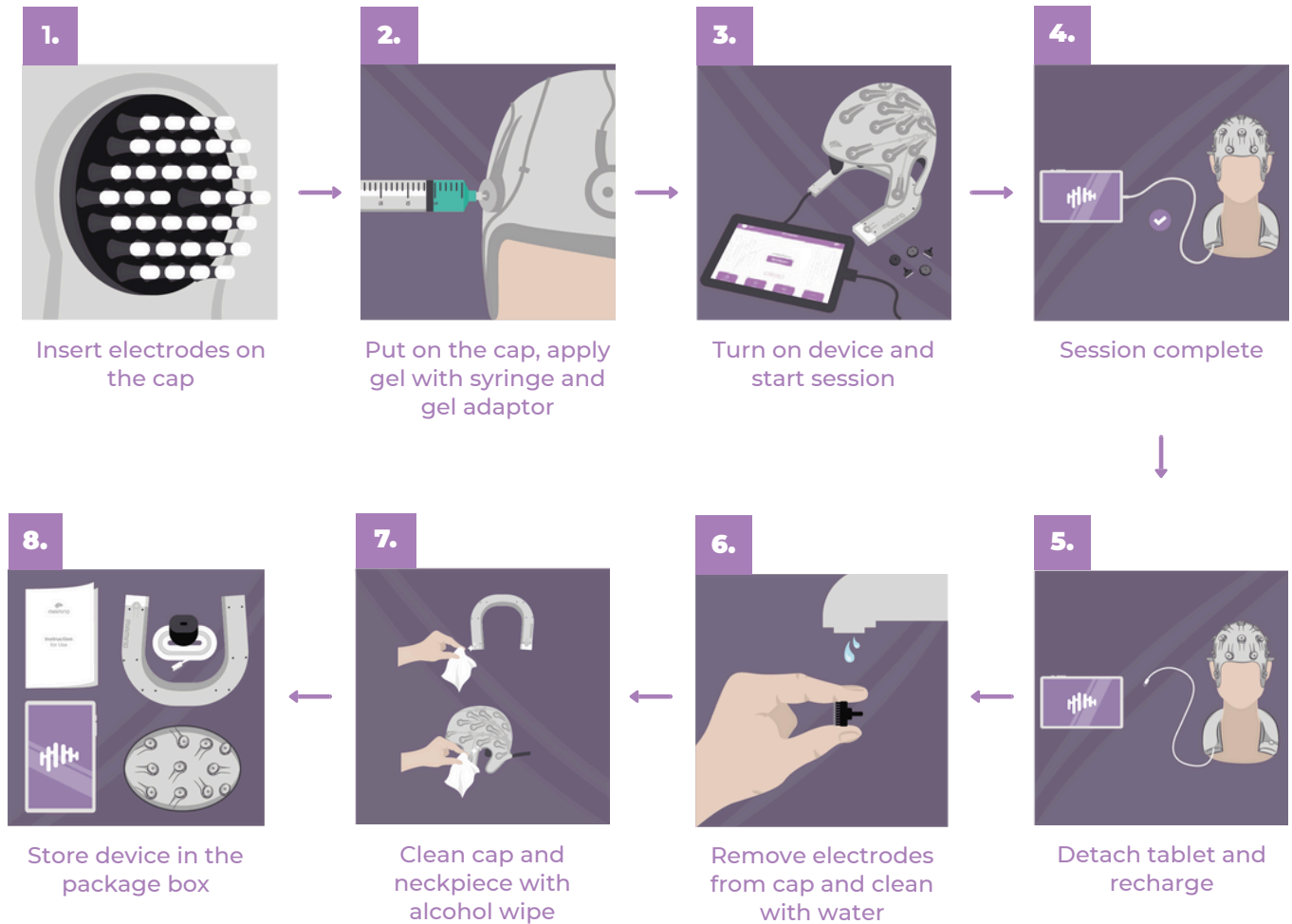
The MiamiMind® Neurostimulator can be used by patients in the comfort of their homes. After wearing the device on the head to start the treatment, the tablet's user-friendly app guides users through each session. This simplicity not only enhances the overall user experience but also encourages regular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

Modern brain electrotherapy has the potential to enhance cognitive functions, alleviate neurological symptoms, and improve quality of life. With a brain stimulation device for home use, you benefit from:

- *Convenient use in the comfort of your own home, without clinic visits*
- *Remote monitoring by your treating physician*
- *High flexibility regarding therapy times and session frequency*
- *Reduced travel costs and time commitment*

MiamiMind makes these benefits accessible by integrating the latest research into a user-friendly home device.

Steps for each treatment session at home



Using Miamind

Prescribed by a physician, MRI-based, individually customized. From the first consultation to your personalized therapy - your journey is clearly structured and supported by experienced professionals.

Consultation & Referral

It all begins with an open discussion with your physician. If needed, a referral is made to a specialized clinic, where experts provide an accurate diagnosis and plan your treatment with Miamind.

Analysis & Planning

Your health status is carefully assessed. Using advanced imaging techniques (MRI, EEG), the brain region to be stimulated is identified - tailored specifically to your needs.

Personalization & Manufacturing

Based on your MRI data and stimulation protocol, Bottneuro develops your custom Miamind® Neurostimulator.

Training & Start of Therapy

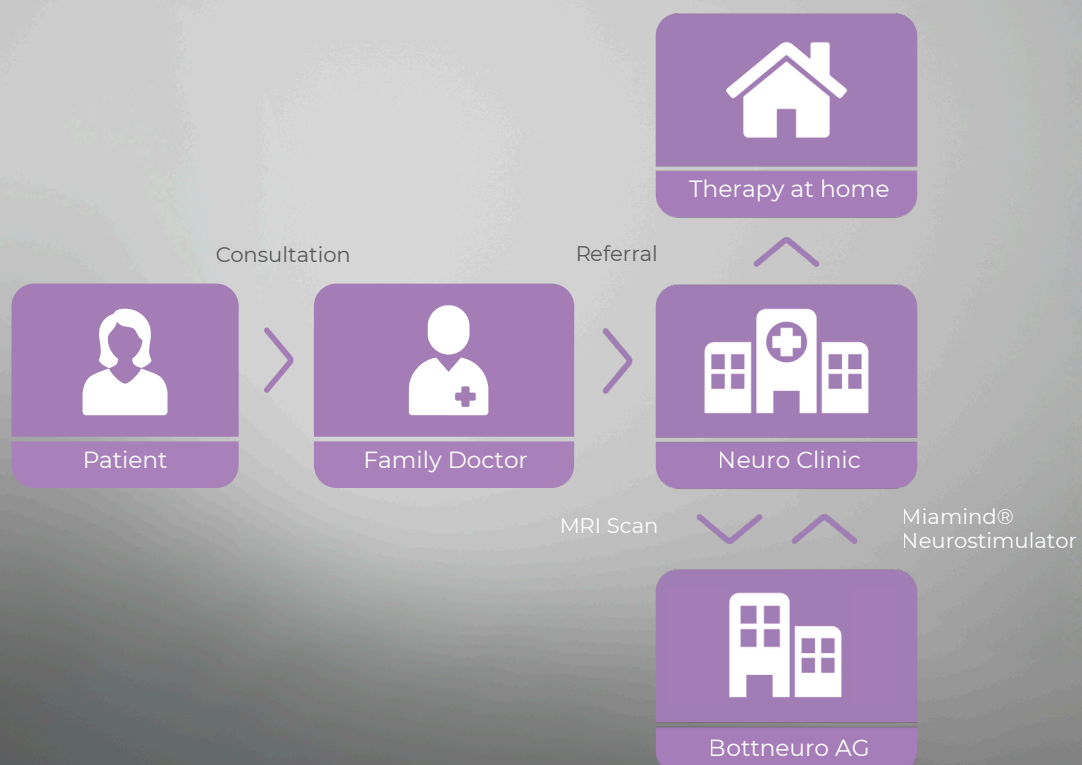
At the clinic, you receive instruction on how to use the Miamind® Neurostimulator. Sessions can then be conducted conveniently at home or under supervision at the clinic.

Treatment & Care

During stimulation, you may feel a slight tingling - a sign that the gentle stimulation is taking effect.

Progress & Adjustment

Results often appear gradually. Your progress is medically monitored throughout the sessions. For medical questions, your healthcare provider is available, and for technical support, Bottneuro is always ready to assist.



Risk and side effects

Unlike procedures such as deep brain stimulation, tES doesn't involve surgery. No electrodes need to be implanted, and anesthesia is not required. tES has been extensively studied, with no reports of serious or severe adverse effects. Typically, tES is considered 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*
- *Ringing in the ear*
- *Acute mood swings*
- *Temporary visual impairment*

If you experience side effects during or after tES, immediately inform your healthcare provider.



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 for tES may involve daily sessions, while others are scheduled less frequently, depending on your specific therapy plan. Longer sessions can require more of your time, and if the treatment is conducted at a medical facility rather than at home, travel and transportation must also be considered, which could affect your daily routine and schedule.

tES is generally well tolerated, but it may occasionally cause mild side effects, such as a headache, tingling, or skin irritation at the site of electrode placement. These effects are usually temporary and subside shortly after a session, but they may briefly impact your comfort or daily activities.

In addition, regular follow-up appointments with healthcare professionals are often necessary to monitor your progress and make adjustments to the treatment plan. These visits require additional time and effort, but they play an important role in ensuring the therapy remains safe, effective, and tailored to your individual needs.



FAQ

Is the Miamind® Neurostimulator certified?

The Miamind® Neurostimulator is a custom-made device registered with Swissmedic in accordance with ANNEX XIII of the EU MDR and with the UK MHRA under MepV Art. 10 for custom-made devices. The device complies with the general safety and performance requirements outlined in Annex I of MDR 2017/745 and has been developed and tested according to the following standard:

•ISO 13485, ISO 14971, ISO 10993

•IEC 60601, IEC 62304, IEC 81001, IEC 80601

Where can I get Miamind?

Within Switzerland and other European countries, Miamind is considered a custom-made device and can be prescribed by a specialist physician. You can contact your treating doctor, who may refer you to a specialist if necessary. More information is available on our website.

www.miamind.com

Do I need to make any special preparations before therapy?

Miamind is used on an outpatient basis, allowing you to undergo therapy comfortably in your own home or familiar environment, so there is no need for hospital visits. At the start of treatment, you and your caregivers will be trained in using Miamind. A Miamind therapy session lasts about one hour, including preparation and follow-up. During this time, you should be able to sit comfortably. You can also read, listen to music, or watch TV during the session.

How long does treatment with Miamind last?

The success of treatment depends on the regularity and consistency of its use. Therefore, Miamind should be used several times per week. Typically, therapy sessions are scheduled 3–5 days per week, each lasting approximately 30 to 60 minutes. It is important to consult with your healthcare provider and follow the recommended guidelines for your specific treatment plan to achieve the best possible results.

Why do I need an MRI before using Miamind?

The personalization of Miamind is based on an MRI scan. This ensures that the device is perfectly tailored to your individual situation, taking into account your unique brain anatomy and medical condition.

Does health insurance cover the cost of Miamind?

Currently, Miamind is not covered by health insurance.

Please contact Bottneuro AG for more information.

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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