Computer-Assisted Transcranial Magnetic Stimulation

(SAINT™ Treatment)

A new functional MRI (fMRI) connectivity targeted, accelerated intermittent theta burst stimulation (iTBS) treatment for Major Depressive Disorder

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Computer-Assisted Transcranial Magnetic Stimulation

Background and Clinical Data

- **Magnus Medical, Inc.**
  Founded in 2020 to advance the development of fMRI connectivity targeted, accelerated neuromodulation treatment for major depressive disorder
- **Breakthrough Device Designation**
  The Magnus Neuromodulation System with SAINT Technology was awarded FDA Breakthrough Device Designation in 2021

  FDA Breakthrough Designation indication: *Treatment of major depressive disorder (MDD) in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode*
- **Technology Development**
  fMRI connectivity targeted, accelerated iTBS procedure originally developed at Stanford University

  Three Stanford clinical trials in treatment-resistant depression demonstrated safety and rapid effectiveness (79% to 90% remission rate with 5 days of treatment)

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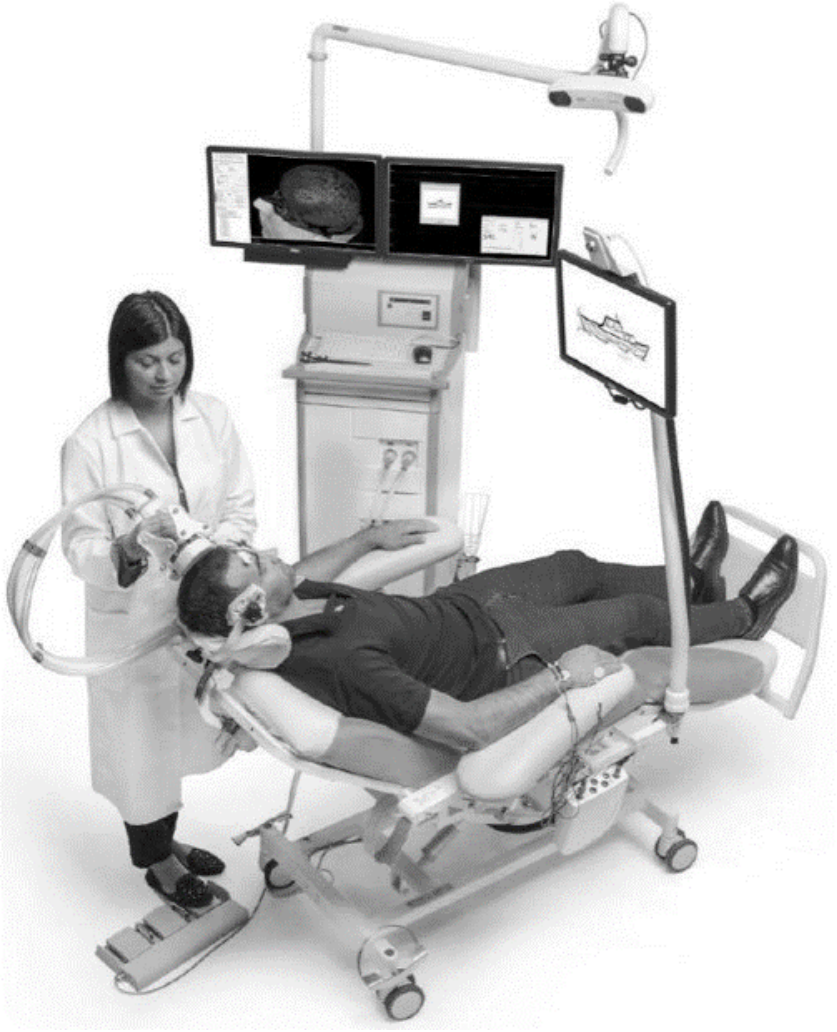
Indication: Treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior medication in the current episode

Overview:
(1) fMRI scan is analyzed to determine individualized, optimal target in dorsolateral prefrontal cortex (DLPFC)
(2) Non-invasive magnetic stimulation is targeted to this individualized location in DLPFC
(3) Optimized stimulation patterns are delivered 10 times per day over 5 days

Safety: No serious adverse events over 3 trials and a 4th ongoing
Typical mild side effects (*e.g.* mild headache, fatigue)

Setting: Inpatient and outpatient due to rapid effect, non-invasive procedure

EMR: Found under ‘procedures’ in the medical record or under ‘progress notes’



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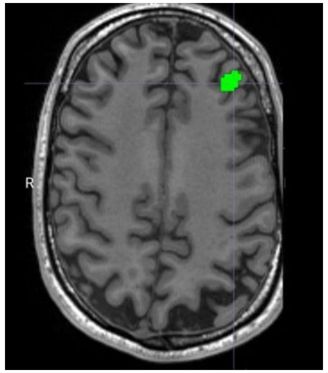
Three key novel aspects of the procedure



1. **Target Identification**
   Individual fMRI data are analyzed to identify the specific area of the brain where treatment is needed

2. **Dose**
   18,000 pulses per day delivered over five days
   Intensity is 90% of resting motor threshold amplitude, calculated with anatomical depth correction

3. **Stimulation Procedure**
   Five consecutive days
   Ten ten-minute sessions are delivered per day
   Breaks between sessions (“inter-session intervals”) are 50 minutes

Note: fMRI connectivity targeted, accelerated iTBS treatment requires all three aspects shown above.

Day 1	Day 2	Day 3	Day 4	Day 5
iTBS1800	iTBS1800	iTBS1800	iTBS1800	iTBS1800
50 min ISI	50 min ISI	50 min ISI	50 min ISI	50 min ISI
iTBS1800	iTBS1800	iTBS1800	iTBS1800	iTBS1800
50 min ISI	50 min ISI	50 min ISI	50 min ISI	50 min ISI
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iTBS1800	iTBS1800	iTBS1800	iTBS1800	iTBS1800
50 min ISI	50 min ISI	50 min ISI	50 min ISI	50 min ISI
iTBS1800	iTBS1800	iTBS1800	iTBS1800	iTBS1800

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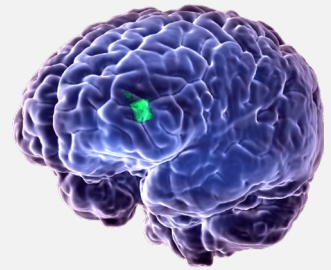
Steps of the procedure

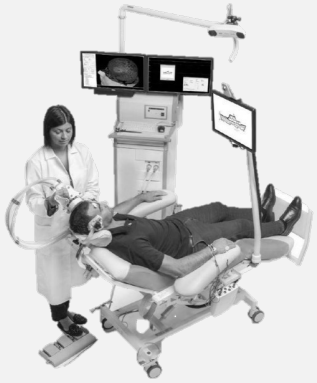
1. Patient has head MRI scan (functional and structural)

2. MRI data are processed to extract functional connectivity data and determine the optimal, individualized target of neurostimulation for MDD



3. Physician maps head shape and registers MRI data to patient

   Physician measures brain excitability, performs depth correction, and adjusts pulse intensity



4. Targeted TMS treatment is delivered to the optimal location in prefrontal cortex

   Treatments occur 10 times per day for 5 consecutive days

   (50 minute interval between sessions within a day)

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Note: All steps shown are required

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Tradename

SAINT™

Generic name

Functional MRI (fMRI) connectivity targeted, accelerated intermittent theta burst stimulation (iTBS) treatment for Major Depressive Disorder

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