



Human Subjects

Office of Research

UNIVERSITY OF GEORGIA

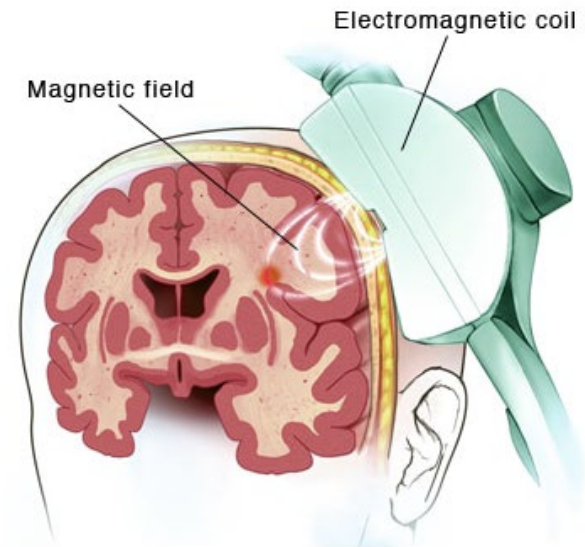
Transcranial Magnetic Stimulation (TMS) Safety Protocol

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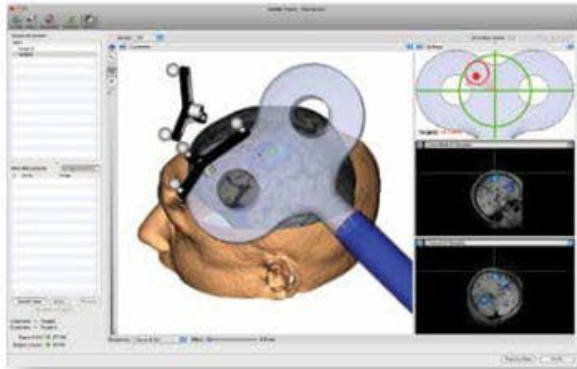
What is Transcranial Magnetic Stimulation (TMS)?

- TMS is a noninvasive procedure used to stimulate small regions of the brain
- TMS can either be used as:
 - Measurement Tool – to assess cortical excitability or indirect estimates of neurochemical concentration
 - An intervention to increase or decrease the activity within a given region (e.g., to treat depression)



An electromagnetic coil placed against the scalp creates a magnetic field that stimulates certain areas of the brain



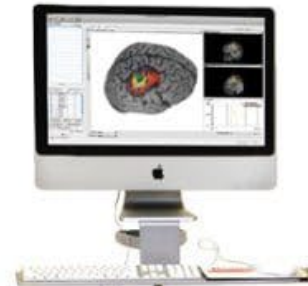


Brainsight® for TMS

- Works with any coil from any manufacturer
- Flexible, easy coil calibration
- Define target based on anatomy, MNI or Talairach coordinates, MRI overlay, previous TMS session
- Links to TMS device via TTL trigger and serial port
- Integrated 2-channel EMG for mapping studies
- Simpler coil calibrations
- New subject-Image registration refinement step
- At each TMS pulse, Brainsight™ can record:
 - coil position and orientation
 - coil status (on supported TMS models)
 - intended target
 - positioning error
 - distance to target
 - EMG response
 - EEG response (when using NEUROPRAX EEG)
 - NIRS optode locations

New Subject Chair

- Smaller Footprint
- Reclined and Upright
- Improved Coil Arm
- Less Intrusive
- Preserves field of view



Side Effects

Common

- Headache
- Scalp discomfort at the site of stimulation
- Tingling, spasm or twitching of facial muscles
- Lightheadedness

Uncommon

- Seizures
- Mania (i.e., bipolar disorder)
- Hearing loss (if there's inadequate protection during treatment)



TMS Technical Safety

- Refers to hazards to the subject or operator other than those related to the effects of the E-field induced in a body when the intended magnetic field is generated around the TMS coil
- For example, technical aspects relevant to TMS safety include:
 - Electrical insulation of high voltages
 - Heating, vibration, fractures
 - Acoustic clicking
 - Biocompatibility and weight of the coil
 - Reliability of generating the intended magnetic field
 - Electromagnetic interference with other devices
 - Neck pain due to head posture
 - Headache or neck pain due to pressure on the scalp
 - Human factors (e.g., incorrect use or access by unqualified personnel)

Stimulation Dose Safety

- Refers to the effects of the TMS magnetic field with the intended dose induced in the body of anyone exposed to the field (i.e., subject, operator, bystander, or fetus)
- TMS Dose - all device parameters that influence the generated magnetic field and the resultant induced E-field in the body
 - TMS accessories (i.e., coil arms, neuronavigation, software) can affect the dose selection and delivery
 - The stimulation risks can be subject-dependent. A dose that is safe for one subject may not be safe for another (e.g., a different [seizure threshold](#) or interaction with different drugs).
 - Safe doses may depend on the cortical region that is targeted by stimulation and may differ depending on the precise shape of the E-field that is generated by a specific coil.

Seizures Caused by TMS

- While seizures caused by TMS have greatly reduced overtime, they continue to occur even in individuals without identifiable risk factors and with stimulation within the “safe” parameter space
- Over 62% of seizures occurred on the first exposure to TMS, and 75% occurred within the first three exposures.
- Precautions should be higher for early TMS exposures than for later sessions



Risks Analysis of the Stimulation Dose

- Risks to be evaluated include effects on:
 1. The brain
 - e.g., seizures or thought processing
 2. Implanted objects
 - e.g., [cardiac pacemakers](#), [brain implants](#), hearing aids, surgical clips
 3. A fetus
 4. Operator



User Responsibilities

1. Consider the origin of any TMS device or accessory
 - Did the maker implement adequate risk management and quality assurance?
2. Operate according to TMS device instructions
3. Safety monitoring during the conduct of research
 - Be prepared to deal with a seizure that might arise
4. The presence of operators in proximity (i.e., less than 40 cm) of the magnetic coil during prolonged stimulation sessions should be minimized. The use of ear plugs or earmuffs is mandatory for operators.



User Responsibilities (cont.)

6. Hearing safety concerns for subjects should be addressed:

- Use of well-fitted and approved hearing protection (earplugs or earmuffs) by patients, subjects, & operators
- Referral for auditory evaluation of any individual complaining of hearing loss, tinnitus, or aural fullness following TMS
- Individuals with pre-existing noise-induced hearing loss or concurrent treatment with ototoxic medications (aminoglycosides, cisplatin) should undergo TMS only after careful consideration of risk/benefit ratio.

7. Report adverse event at once to the IRB



Helpful Links/Resources:

- [Safety and Recommendations for TMS use in healthy subjects and patient populations](#)
- [Transcranial Magnetic Stimulation](#)
- [Seizure Threshold](#)
- [Reviewing Studies with Medical Device](#)
- [Welcome Centre Integrative Neuroimaging - TMS](#)

Thank you!



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