

Intracranial EEG Phantom

Product Design Specifications

Lab: 308

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Function

A brain phantom is a model of a human brain designed to mimic the physical properties of the brain for the sake of testing. This brain phantom will be used to test the simultaneous use of transcranial magnetic stimulation (TMS) and intracranial electroencephalography (iEEG) in pediatric subjects for the study of TMS's effect on epilepsy. This means the phantom must exhibit expected responses from a normal, pediatric brain and skull when subjected to TMS and iEEG experiments individually. TMS works by sending a magnetic field into the brain, changing excitability of certain regions, while iEEG directly reads the electrical potential of the brain [1].

Client requirements

- The phantom must be separated into 3 unique materials: the skull, the white matter, and the gray matter
- The budget for this phantom is \$1000
- The phantom must be an accurate anatomical representation of any pediatric brain
- The phantom must be able to withstand iEEG and TMS separate of each other

Design requirements

1. Physical and Operational Characteristics

a. Performance requirements

The brain phantom will undergo transcranial magnetic stimulation (TMS) and intracranial electroencephalography (iEEG) in order to simulate the use of these two simultaneously in pediatric patients with epilepsy. The phantom must withstand a magnetic field with a frequency of 1 Hz or less, for 20-30 minutes, with an intensity set at or slightly above the resting motor threshold (RMT) to show it is strong enough to withstand TMS operations commonly used to treat epilepsy [2]. The brain phantom must be able to have electrodes inserted into it and should not sustain any significant damage when doing so.

b. Safety

The brain phantom must not be made out of an easily flammable material, as TMS testing with iEEG always runs the risk of creating a very large current [1]. This large current dissipates a lot of power as thermal energy, meaning the brain phantom could catch fire if made of a flammable material.

c. Accuracy and Reliability

The phantom must accurately display the electromagnetic and some physical properties of real, pediatric white matter, gray matter, and skull tissue to ensure accurate testing. Conductance in particular can be modeled after adult samples due to it being a property that does not change with age [3]. Conductance for white matter should be roughly 0.22 S/m for white matter, 0.47 S/m for gray matter, and 0.02 S/m for the skull [4]. The shear modulus must also be taken into account to ensure any movement of the electrodes during testing is accurate to what would happen in human samples. The shear modulus of pediatric patients, who have had some brain development and stiffening, is roughly the same shear modulus as adults [5]. Adult samples are roughly around 1 kPa, meaning the model should have a shear modulus of around 1 kPa [5].

d. **Life in Service**

The lifetime of the phantom must last the entire duration of testing to validate simultaneous TMS and iEEG safety protocols. The phantom must be able to withstand repeated stimulation of TMS application without degradation of the phantom materials.

e. **Shelf Life**

The shelf life for the phantom must last the entire duration of testing. Gelatin based phantoms should be stored in a dark humid refrigerated environment to prevent degradation of bacterial growth and drying out and extend shelf life to around 50+ days. The addition of many different additives like 4% chlorhexidine gluconate can also extend shelf life of gelatin phantom. The shelf lives of the iEEG and skull material is negligible and should outlast testing.

f. **Operating Environment**

The phantom will be used in a sterile environment and room temperature and humidity at around 22-24 C and 40-60%. The phantom will be used in conjunction with TMS and iEEG technology which requires non metallic sensors as to not affect signals and reactions.

g. **Size & Weight**

The Brain Phantom will be a 1:1 replica of a pediatric brain, including the skull, white matter, and grey matter. The volume and weight of each replicated material must be comparable to what is found in a pediatric brain. The volume of a pediatric brain is dependent heavily on the age of the subject in question. For example, the volume of the brain was found to grow by 25% between early childhood (19-33 months) and mean adolescence (12-15 years) [6]. For this project, brain specifications for 6-8-year-olds will be used to develop a comparable brain phantom to an adolescent brain before it reaches its developmental maximum.

h. **Materials**

The Brain Phantom must use three distinct materials to represent the skull, gray matter, and white matter. The gray and white matter should be made from nonmetallic tissue-mimicking materials whose electrical conductivity can be adjusted by changing the concentration of additives. The materials should target conductivities of ~ 0.47 S/m for gray matter and ~ 0.22 S/m for white matter. The skull should be made from a rigid, nonmetallic material with a conductivity of ~ 0.02 S/m. Previous head phantom research has shown that synthetic materials can be modified to reach a threshold that simulates the electrical properties of a skull [9]. All materials must withstand repeated TMS and iEEG testing while remaining under the \$1000 budget.

i. **Aesthetics, Appearance, and Finish**

The phantom should accurately represent the general anatomy of a pediatric brain and skull so that TMS coils and iEEG electrodes can be positioned realistically. The skull, gray matter, and white matter should be distinguishable by some metric. The exterior should be smooth with no noticeable defects, and contain identifiable anatomical features to allow consistent placement of equipment between tests.

2. Production Characteristics

a. Quantity

One pediatric brain phantom with a pediatric-representative skull and brain that can accommodate implanted iEEG electrodes for TMS testing and allow measurement of TMS-induced electrical current, temperature changes, and electrode displacement.

b. Target Product Cost

Total cost should remain within the project budget of \$1,000, using existing department equipment and available iEEG electrodes when possible. We are targeting a cost-optimized approach to keep the prototype within budget.

3. Miscellaneous

a. Standards and Specifications

The phantom will meet the requirements for an FDA Class I medical device based on its low-risk research application and non-patient use [7].

The phantom will follow applicable requirements under 21 CFR Part 882 for neurological devices related to intracranial EEG and TMS.

Electrical components and measurement equipment will follow applicable IEC 60601-1 safety requirements.

b. Customer

The primary customer will be the physician or researcher conducting iEEG studies. There is a need for a reliable phantom that functions as a controlled alternative to the patient, replicating the different sections of the brain for the most accurate results.

c. Patient-related concerns

Patient-related concerns during TMS and iEEG treatments include electrode displacement, electrode heating, and induced current from the electrodes. The phantom must mimic conditions where iEEG electrodes are located in the brain with a TMS coil positioned above it, so the treatment can be safely conducted on pediatric patients.

d. Competition

A similar phantom was recently designed at the University of Iowa to replicate the conditions of the brain during TMS and iEEG studies. This design was developed using polyacrylic acid (PAA) saline gel inside a 3/16 in. polymethyl methacrylate (PMMA) container. The gel was designed to simulate the brain tissue, while the PMMA container represented the skull. The phantom also used platinum electrodes embedded in a silicone-based material to replicate the electrode setup for iEEG testing [8]. This design provides a useful starting point for iEEG phantom development; however, the existing phantom was designed for general use and does not account for the anatomical and safety considerations associated with pediatric patients.

4. Citations

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