Intracranial Hemorrhage Model Project Design Specifications

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I. Physical and Operational Characteristics

A. Performance Requirements

The model must mimic the behavior of brain tissue undergoing acute cerebral damage, and specifically intracranial hemorrhage. The main requirement for imaging is to have a clear distinction between the brain material and the clot. In other words, imaging qualities of the clot and the brain material must not be similar. The client would also like the design frozen after each trial so that the model can be sliced for visual confirmation of clot extraction.

Model mimicking Brain under Intracranial Hemorrhage:

- As the clot is extracted, the brain-mimicking material must compress upon the clot as it is drained. No air void should be created inside the model when draining the clot.
- As in MR images of an actual hemorrhage, the model must exhibit clear contrast between the brain material and hemorrhage model.
- Membrane around clot should be created so that when rtPA is administered within the clot it does not leak into other areas of the model. No backflow is to occur.

B. Safety

The model will utilize either bovine or pig blood, which is considered a biohazard. Users of the model should be properly trained on handling bodily fluids. The university hospital has been contacted regarding policies and training for handling blood. Our final product will strictly adhere to all policies and standards in order to keep user health a priority. All stages of the model creation and usage are to be considered hazardous except the creation of the brain shell and brain material before the introduction of the clot.

C. Accuracy and Reliability

Because this model is being used to validate the treatment process for intracranial pressure, it must accurately represent the environment of the brain. The goal is to create a model which replicates the physiological properties of the intracranial environment. The clot model must prevent backflow in 95 percent of the trials. This will be shown in testing. Also, the model in MRI must collapse on the clot and under no situation can any air pocket form between the clot and the brain material upon shrinkage.

D. Life in Service

The brain shell produced should be capable of being reused for testing, at a minimum of 5 tests. The hyrdo(gel) within cannot be used due to the possibility of blood from the previous trial seeping in and creating a bio-hazardous situation. Between trials the brain-shell will be properly treated according to safety guidelines.

E. Shelf Life

The model will be created in a one-week span before testing trials. Models made far in advance are at a higher risk for incubating bacteria growth while in storage. After testing, the model must be frozen for later analysis.

F. Operating Environment

MRI suites will be the primary location of the use of the model, as the technology used to interact with the model is MR imaging.

G. Ergonomics

The adjustment of pressure, temperature, and other characteristics need to be simple to adjust so that the user may quickly make changes as required by different testing protocols. The model must sit on the MRI bed and remain stabilized during catheter insertion.

H. Size

The entirety of the brain model must fit within the bore of an MRI (60 cm). Because the first model will be a test of concept, the initial size will be around 350 cubic centimeters. The final brain mold will amount to a volume of 1400 cubic centimeters. The enclosure including the preliminary brain model will total 500 cubic centimeters, and the final model will be close to 1600 cubic centimeters. The extra space will represent space for cerebrospinal fluid, and will also allow for space for any future instrumentation to measure results of experiments.

The size of the hemorrhage void will represent the geometry of common hemorrhages.

***I.* Weight**

Since the model will be used for testing purposes, it should be portable to different testing sites; the design should weigh no more than 10 lbs.

J. Materials

Avoidance of ferromagnetic materials is a must so no interactions with the magnetic field occur. Biohazardous material must also be handled properly as discussed above. Any material that creates to high of a signature on the produced MR image must not be used.

K. Aesthetics, Appearance, and Finish

Aesthetics will be focused on last, giving most time and emphasis to replicating the conditions representing homeostatic processes in the brain.

Production Characteristics

L. Quantity

One brain and clot model must be produced by the end of the semester.

M. Target Product Cost

Estimated product cost is 100 dollars per model; the client believes this to be a competitive market price.