Product Design Specifications

Project: A Phantom for use in an MR imager

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Background:

Millions of people suffer from back pain due to degenerative intervertebral disks of their spine. The spine consists of many vertebra and cushioning disks between to act as shock absorbers. As people grow older the stress on their back begins to add up, resulting in deterioration of the intervertebral disks. This deterioration can cause vertebrae to shift, leading to possible pinched nerves and muscle spasms. Researchers know that intervertebral disks degenerate as a result of diminished blood supply and water content, part of the aging process. Researchers would like to better assess the degree of damage or disk integrity using disk water content and magnetic resonance imaging (MRI).

Function:

The phantom is meant to assess the accuracy of an MR scanner by comparing known T2 values to that which the MR scanner measures. Measurements made with the phantom will help assess which variables affect the accuracy of the MR scanner, such as the distance between the spinal coil and the patient's spine, the size of the patient, and the sensitivity of the MR scanner to very similar solutions. The phantom will also hold artificial samples which have a composition of water, collagen, and proteoglycans and a T2 value comparable to that of lumbar intervertebral disk tissue. Research will be done using the phantom examining the relationship between disk water content, T2 value, and collagen/proteoglycan content in order to better assess the integrity of intervertebral disk tissue using MRI technology.

Client Requirements:

- Phantom able to have different distances between disks and spinal coil (typically 10 cm)

- Phantom able to hold different water volumes (imitate large and small patient volumes)
- Phantom able to hold different solutions of close relaxation values (T_2=50 to 100 ms) to assess sensitivity of scanner
- Phantom able to hold artificial lumbar intervertebral disk tissue (made up of water, collagen, proteoglycans) with varying water percentages
- Phantom should sit securely atop spinal coil of the MR scanner
- Phantom should be easy to handle by hospital staff

Design Requirements:

1. Physical and Operational Characteristics
    a. *Performance requirements:* This phantom will be used less than once per week to help hospital personnel calibrate the MR scanner for lab experiments as well as periodically recalibrate the machine. It will need to be loaded onto the spine coil that is placed on the MR table. Therefore, it will need to be loaded onto a nearly flat surface.
    b. *Safety:* Since this phantom will be used in a MR scanner, no metallic materials should be used in its construction. Nickel chloride hexahydrate is commonly used inside phantoms to obtain different relaxation times. It is classified as a hazardous waste product. We will need to include a safety warning label and beware of leakage if this material is used.
    c. *Accuracy and Reliability:* Since the phantom itself is being used to assess accuracy of a MR scanner, the T2 of the solutions in the phantom must be made with great accuracy in order to have valid data. These T2 values also must be stable and not change during the life of the phantom.
    d. *Life in Service:* This product will have to be durable and have a long life of service. Ideally its service life should be multiple years with usage on a less than weekly basis.
    e. *Shelf Life:* This product will be stored at room temperature. The containers holding any hazardous liquid must be able to maintain a tight seal to prevent leakage.

f. *Operating Environment:* This device will be used in the MR scanner, and an operator will be lifting it onto the scanner table. We will need to ensure that it is easy to handle, a reasonable weight, and leak-proof.

g. *Ergonomics*: Product must be relatively easy to hold and transport from one laboratory to another. There is no need for human interaction other than for set up and transport of the product, therefore the product must first and foremost fulfill design requirements and perform task.

h. *Size:* Size of product may ultimately be no bigger than the dimensions of the bore of the MR scanner (40 cm diameter?). However, the product must be easy to lift and move and for that reason must not be too big. The product must be as close to spinal coil as a patient's spine, approximately 10 cm.

i. *Weight:* The current phantom model weighs 11 lbs. No restrictions were set by the client other that the product must be easy to move and transport (not physically laborious).

j. *Materials:* No ferrous materials (metals) may be used due to the interference with the MR machine. Current models utilize all plastic materials such as nylon screws and Plexiglass containers.

k. *Aesthetics, Appearance, and Finish:* No restrictions on aesthetics. Current models are transparent or translucent. (For many phantom examples visit http://www.cirsinc.com/index2.html)

2. Production Characteristics

   a. *Quantity:* One product needed for laboratory calibration.

   b. *Target Product Cost:* Within reason. (http://www.cirsinc.com/index2.html)

3. Miscellaneous

   a. *Standards and Specifications:* The client did not inform us about any standards that the final product has to meet.

   b. *Customer:* Our client prefers straightforward designs that are capable of making accurate measurements for MRI.

   c. *Patient-related concerns:* Since phantoms are used for quantitative imaging experiment, there are no patient-related issues. However, for

safety concerns of the researchers using it, it is important to securely contain the chemical solutions within the phantom.

d. *Competition:* Various types of resolution phantoms are available from companies like GE and USA Instruments. Some designs are much more complicated than others. For example, our client showed us a phantom that has a transparent, cylindrical body. There are various slits and openings within the phantom. On the other hand, a plastic bottle containing chemical solutions can also be used as a phantom. Although these phantoms are unique in shapes and dimensions, they all contain similar chemicals, including nickel chloride, hexahydrate, and copper chloride.