MRI Compatible Motion Platform - BME 400

Product Design Specifications
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Function

MRI phantoms are often static models of the human body that are used to test and calibrate MRI's. Natural process' such as respiration and digestion create constant motion within the human body. Static phantoms used to calibrate MRI's do not properly represent this motion. This demonstrates a need for an MR compatible device that holds a phantom and is capable of simulating the movements found within the human body.

Client requirements:

- MR Compatible
- Moves back and forth
- Minimize the use of electronics inside the room
- Potentially incorporate materials currently available from the client
- Create a prototype with a budget of $1000
- Utilize commercially available parts
- Avoid complex fabrication methods

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The product will be a magnetic resonance compatible platform that provides a periodic waveform motion. The waveform motion will have a frequency of 4-20 cycles/min and amplitude of 1-6 cm to represent physiological breathing patterns. The motion will be consistent for 15 minutes and is allotted a standard deviation of 5% from the desired waveform. The product must withstand the size and weight of a phantom liver for testing purposes.

b. *Safety*: The device will be entirely made of MR compatible material and will pose no safety risk within the MR environment. The device's magnetically induced displacement and torque forces will be tested to assure these forces are below their gravitational equivalents. The device will also be evaluated for RF heating, eddy currents, gradient induced vibrations, and gradient induced extrinsic electrical potential risks, as also recommended by the FDA [1]. As this device will utilize electronics, it is classified as an active medical device and will follow FDA 21 CFR part 801 and ASTM F2503 labeling requirements.

c. *Accuracy and Reliability*: The device must be able to produce repeatable patterns of movements within 2mm. The components of the device must not decrease the signal to noise ratio of the calibration phantom being tested. The device must be able to reliably repeat MR scans with minimal decrease in image quality between scans.

d. *Life in Service*: The device must operate for up to 60 minutes at a time as that is the time an MRI may take to produce an image of a medium-sized area [2]. A non-magnetic motor should last 20,000 hours under normal operating conditions [3]. Overall the device should last as long as an MRI scanner, which is approximately 10 years [4].

e. *Shelf Life*: Based on the motor components it should be stored in -40 to 70 °C temperatures with humidity 0 to 80% non condensing [2].

f. *Operating Environment*: The device must be able to withstand upwards of 3 tesla for 1 hour [5]. The device must be able to withstand potential RF heating, eddy currents, gradient induced vibrations, and gradient induced extrinsic electrical potential risks associated with devices within strong magnetic fields [1].

g. *Ergonomics*: The platform should have a height that is comfortable and safe for people to interact with when placed in the MRI. No force should be applied by a person to the motor or any moving parts during operation. An emergency stop feature should be implemented to allow users to immediately stop the motion platform in case of any issues or safety concerns.

h. *Size*: The platform will be no smaller than 25cm x 35cm in order to hold a range of phantom liver samples [6]. The platform will be rectangular shaped.

i. *Weight*: In order for the user to install and uninstall the platform during each segment of testing, the weight should not exceed 10kg. The platform must be able to withstand 4kg [7].

j. *Materials*: The product will be composed of MRI compatible materials. Ferrous and magnetic metals will not be used; other metals, such as brass and aluminum, will be limited to minimize the possibility of induced currents. A nonmagnetic ultrasonic piezoelectric motor will be used to provide platform motion. Nonmetalic sliding rails and bearings will be used to guide the platform through the MRI machine.

k. *Aesthetics*, *Appearance, and Finish*: Color, shape, form, texture of finish should be specified where possible (get opinions from as many sources as possible).

2. Production Characteristics

a. *Quantity*: Produce one motion controlled platform.

b. *Target Product Cost*: The budget for this project is $1000 with many of the components already provided including some motors, rails, software, and hardware. Existing MRI compatible designs cost around $9700 excluding the cost of the phantom used [7].

3. Miscellaneous

a. *Standards and Specifications*: MRI systems and accessories must follow the multiple sets of standards designed by the organizations like the FDA involving forms of testing the functionality of the machine including any additional accessories. Accessory parts should allow appropriate function in testing MRI displacement force ASTM F2052, torque ASTM F2213, RF heating ASTM F2182, and image artifact ASTM F2119 [8].

b. *Customer*: Preferences on stability and levelness will assist users in creating more genuine images. Reducing additional noise from both the platform and machine would be beneficial to more optimal usage.

c. *Patient-related concerns*: The device would need to be appropriately cleaned and disinfected for each use as instructed with the associated manufacturer. Appropriate dimensions levelness of the platform will need to be monitored to help with specimen/subject safety. Additionally cleanliness of the machine is an important consideration as the device should not leak motor oil or other fluids on the MRI bed.

d. Competition:

- Vital Biomedical Technologies MRI Compatible Multi-Modality Motion Stage is a programmable linear motion stage. This product is used in the bore of the MRI scanner and follows user-defined trajectories. The programmed trajectories are loaded onto the control system through a micro SD card. This product has a patent pending and there are a suite of other similar motion stages by this same company to address different anatomical motions [9].

- For a study done by the Department of Radiology at University of Texas Southwestern Medical Center researchers developed a one-dimensional MRI compatible motion platform. They used this in combination with an abdominal phantom to assess how movement during imaging affected the quality of images and the accuracy of quantitative metrics. This design consisted of a motorized linear stage residing inside the MRI machine and driving electronics outside the MRI room. The motorized stage followed sinusoidal, harmonic, random or user-defined trajectories. The device was used for the study and is not on the market for outside use [7].
- The Quasar MRI Motion Phantom is a completely MR safe programmable phantom. In this device the motion capable components are incorporated directly with the phantom. This design uses piezoelectric motors to create desired motions. It is intended to be used to test Deep Inspiration Breath Hold protocols. It is unclear how useful this product would be in protocols that require normal respiratory movement rather than breath holding [10].

References

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