An MRI-compatible leg exercise device for assessing cerebral blood flow responses to exercise (Leg Exercise)

Project Design Specifications
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Function:

Traditionally, transcranial Doppler ultrasound can be used to measure human cerebral blood flow in response to environmental stress or exercise. Exercise-induced increased cerebral blood flow can then be analyzed to determine if cerebral blood flow patterns differ in patients suffering from obesity or pre-diabetes. Transcranial Doppler ultrasound is limited in that it only measures middle cerebral artery velocity. Magnetic Resonance Imaging (MRI) can be used to also study global cerebral blood flow patterns and blood vessel diameter, but any exercise device used in an MRI must be non-ferromagnetic. We aspire to design and test a durable, non-ferrous exercise device that utilizes dynamic exercise and that is able to raise the average patient's heart rate to 120-130bpm for a minimum of five minutes.

Client Requirements:

- Must be non-ferromagnetic and fit on a standard MRI bed
- Must increase heart rate to 120-130bpm for a minimum of five minutes
- Must minimize head and chest movement
- Be comfortable to use by patients of varying fitness levels
- Operable by patients of heights 5'4"-6'4"
- Maximum width of 24" to fit MRI bed
- Must be portable and easily removed from MRI bed and suite

1. Physical and Operational Characteristics

A. **Performance requirements**: The product must increase the heart rate of the user to 120-130bpm for a minimum of five minutes and also restrict any significant movement along the anteroposterior axis.
B. **Safety**: The product must be non-ferromagnetic, stable, and safe to use in an MRI machine. The product cannot cause muscle injury in patients.
C. **Accuracy and Reliability**: The product must allow researchers to take precise and accurate images of blood vessel diameter and measure middle cerebral artererial velocity.
D. **Life in Service**: The product must be usable for three years while undergoing frequent use.

E. **Operating Environment**: As the device is to be used while an MRI is in progress, no ferromagnetic materials may be used in construction.
F. **Ergonomics**: As this device will be used by a range of patients at varying heights and fitness levels, ergonomics is extremely important. The final product must allow patients to exercise using a "natural-feeling" motion. The product must also adjust to fit male and female patients of average heights, from 5'4" to 6'4". The device must also have minimal set-up and be portable and simple for technicians and patients to operate.
G. **Size**: The product must be small enough to fit onto the standard MRI bed and should be positioned to ensure that a patient's movement during exercise is not restricted by the MRI bore.
H. **Weight**: The product should be as lightweight as possible without impeding functionality or usability as it is to be positioned on the MRI bed with the patient. A heavy product may limit the weight of potential research subjects or be difficult to transport and set up.
I. **Materials**: No ferrous materials can be used in the final product, as this device is to be used within 30 ft of a MRI. The materials that contact patients must be easily sterilized with alcohol to ensure cleanliness and allow the device to be used by multiple subjects.
J. **Aesthetics, Appearance, and Finish**: The product should be simple for both patients and researchers to use. The device should look professional and if possible, match the appearance of the MRI.

2. Production Characteristics

A. **Quantity**: One device should be constructed.
B. **Target Product Cost:** A similar prototype cost $275.50 so a new device should be under a budget of $1,000.

3. Miscellaneous

A. **Standards and Specifications:** If marketed, the final product will require the approval of the Food and Drug Administration.
B. **Customer:** The intended user is an exercise research study patient and will vary in fitness level and height. Thus, the product must be compatible with many different body types, be simple to operate, comfortable for the user and provide researchers with a way to adjust the resistance and applied workload. The product should also ensure head and neck stability in order to minimize any artifact in images captured by the MRI. Each of these requirements must be considered in designing a final product.
C. **Patient-related Concerns:** In order to be useful to researchers, the product must meet the terms of all and any Food and Drug Administration provisions relating to its design and use. It must not be harmful to the user in any way and it must allow a patient to exercise in a 'natural' motion. As multiple users are to exercise with the same device, it should be easily disinfected to prevent cross-contamination.
D. **Competition:** Similar products currently on the market do not allow a patient to exercise while being scanned and can cost upwards of $50,000, making these

products ill-suited for many researchers. This device will allow researchers to observe cerebral blood flow during exercise and thus could become a competitor to these other products.