

## **Appendix D: Product Design Specifications**

### **Product Design Specification for BME 400-Group 12: MRI-Compatible Lower Leg Exerciser**

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#### ***Problem Statement:***

The goal of this project is to design and construct a lower leg exerciser that is compatible with MR imaging and Doppler Ultrasound to be used during cardiopulmonary research studies on pulmonary hypertension patients and healthy volunteers. The device must have repeatable loads that can be measured and relayed to the patient via biofeedback.

#### ***Client Requirements:***

##### **1. Design Requirements**

The device must meet all of the client requirements.

- a. *Performance requirements:* To exercise the patient with a device supplying variable loads to reach maximum workload and a specified percentage of that, usually 40%, and also raise pulmonary systolic blood pressure by 7-8 mmHg. Device must accommodate different patient sizes and capabilities and provide suitable biofeedback for them to continue exercise at the desired level. Device must not damage the scanner bed in any way.
- b. *Safety:* The exercise device must cause no harm to the patient while in use or during scanning. The biofeedback must not damage any patient senses (visual or audio). All materials must be MRI-compatible for the safety of the magnet and medical personnel.
- c. *Accuracy and Reliability:* Maintain consistent loading from patient to patient. Biofeedback must accurately display measurement within 5% of actual value.
- d. *Life in Service:* 5 years
- e. *Shelf Life:* 5 years
- f. *Operating Environment:* Hospital and research lab in presence of EKG leads, MRI scanner and ultrasound devices.
- g. *Ergonomics:* Device must be comfortable for the patient while exercising and during scanning, while lying in the MRI tube for up to two hours.
- h. *Size:* Must be compatible with dimensions of scanner bore: 11.83" radius, 21.875" table width, 4.50" height from table to center of bore, and 18.79" scanner bed width.
- i. *Weight:* Less than 30 lbs; able to be transported by hand.

j. *Materials*: All materials must be non-ferrous and durable.

k. *Aesthetics, Appearance, and Finish*: Device shouldn't squeak excessively during use or contain sharp corners or edges.

## **2. Product Characteristics**

a. *Quantity*: One working prototype with goal of creating more devices to be used in other research studies.

b. *Target Product Cost*: \$150

## **3. Miscellaneous**

a. *Standards and Specifications*: IRB approved for use on human test subjects.

b. *Customer*: Researchers in cardiovascular physiology medicine

c. *Patient Related Concerns*: Comfort and multiple options for biofeedback to notify patients with possible disabilities.

d. *Competition*: Other labs and design groups with similar interest from competing universities, and commercially, Lode Ergometry.