Patient Transfer Aid

Product Design Specification

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Problem Statement / Function: Patient transfer and positioning limitations onto and within medical imaging devices, which may include the initial patient transfer and/or maintaining static positioning during data acquisition and measurement, have rendered many individuals with disabilities unable to reap the benefits of imaging technologies. To date, foam wedges and/or wrap-around "coils" are used for static positioning within CT and MRI scanning systems. However, more versatile and effective means are required to meet the wide range of disabilities and imaging systems that are encountered by medical physicians and technicians on a daily basis.

Client Requirements:

- Versatile to fit the form and function of several imaging technologies
- Compatible with different imaging materials (e.g., CT, MRI, x-ray)
- Adaptable to sustain a variety of body segments and patient positions
- Structurally able to support a 500-pound individual
- Adjustable for storage and maintenance
- Intuitively designed for use by a wide-range of medical personnel
- Ergonomically developed for operators with limited strength and flexibility
- Low cost to counterbalance the downward trends in medical budgets

Design Requirements:

1. Physical and Operational Characteristics

A. *Performance Requirements:* The device would be used multiple times each day based on the number of disabled patients requiring medical imaging attention. The maximum loading experienced by the positioning device would be during patient transfer. Depending on the severity of the disorder, transfer time can be approximated to no longer than 15 minutes. Once on the imaging platform, the device, in some cases, would be required to keep the patient static for anywhere from a few seconds to 60 minutes depending on the imaging technique being used.

B. *Safety:* As the device will be in direct contact with the patient, it should not have any sharp edges or abrasive ends. Materials used for the device must be compatible with each of the imaging technologies, so as not to cause injury to the patient. As a medical device, it must be regulated and approved by the Food and Drug Administration (FDA) according to the Code of Federal Regulations, Title 21, Volume 8, Subpart G (general hospital and personal use, miscellaneous devices). The system would likely be classified as a Class II device with its non-

invasiveness and special use functionality. A warning label with abbreviated instructional directions to ensure proper user control would additionally aid in preventing unnecessary injury.

C. *Accuracy and Reliability:* Obtaining a usable image through the aid of CT, MRI, and/or x-ray technologies is inherently dependent on properly positioning the patient within the gantry of the system. If the patient positioning process is inaccurately completed, the results will be, at best, oblique and difficult to interpret. In addition to patient positioning, material section is a design priority that will ultimately affect the system's overall accuracy. Materials selected for the design must not cause attenuation or distortion of measurements throughout a given imaging session. Such difficulties may render the patient's examination useless, wasting both the time of the medical physician and, more importantly, the patient. Therefore, the accuracy and reliability of this patient positioning device serves as a primary concern through the systems entire lifespan.

D. *Life in Service:* The final device will be expected to have a 15 year lifespan. This lifespan will match and/or beat the longevity of the typical medical machinery the positioning system will come in contact with (e.g., CT, MRI, X-ray).

E. *Shelf Life:* The device will be stored at standard laboratory conditions at room temperature, and normal humidity and pressure. These storage conditions should allow for the components to last for the intended life in service.

F. *Operating Environment:* During operation, the device will be placed in a relatively sterile medical environment. Depending on the system the design is working in conjunction with, the operating environment may be subject to a magnetic field on the order of 3 Tesla or higher. Therefore, ferromagnetic characteristics must be taken into account when designing the system. The average temperature range will be from 60º to 90º F under normal atmospheric pressure and humidity.

G. *Ergonomics:* A medical technician will be directly handling this device, so it must be user-friendly and designed for the medical population. The user-interface and technology behind the positioning aid should be easily understood by typical medical staff personnel (e.g., doctors, physicians, technicians, nurses, biomedical engineers). The system should be relatively easy to move and transfer for maintenance and positioning purposes by medical personnel who may or may not have limited strength and flexibility.

H. *Size:* The device itself must be structured to properly position patients ranging from small children to adults. At its maximum weight bearing, the positioning aid must be able to transport and position a patient segment belonging to a 500-pound individual. These weight requirements must be met while maintaining a small and compact size, allowing for proper operation within the bore of a multitude of

imaging devices. The positioning system must also allow for compact storage during testing and maintenance.

I. *Weight:* The device must be massive enough to properly position a body segment belonging to a 500-pound individual. At the same time, the positioning aid must be lightweight, allowing for ease of adjustment by healthcare workers with limited strength and flexibility.

J. *Materials:* The materials used in the construction of the prototype must not interfere with the intricate measurement techniques of various medical imaging technologies. The device must be comprised of non-ferrous materials so as to function in the ferromagnetic environment of an MRI chamber.

K. *Aesthetics, Appearance, and Finish:* The device's shape should be similar to the beds of current imagers and body scanners. The device must be aesthetically appropriate for a typical hospital environment to maintain a user-friendly appeal to the operator while keeping the patient calm and relaxed.

2. Production Characteristics

A. *Quantity:* One functional prototype is required by the client. If the prototype is pursued as a meaning of patient positioning in medical imaging devices in the future, mass production will be a concern with the ultimate goal of equipping all medical imaging machinery with the patient positioning device.

B. *Target Product Cost:* The lowest possible cost to produce the prototype is desired. Such a target cost would simplify mass production and marketing concerns and develop a content customer base. The maximum allowable cost has been set at $2,000.00.

3. Miscellaneous

A. *Standards and Specifications:* According to the FDA, this is Class II medical device. Controls for this device may include labeling requirements, mandatory and voluntary performance standards and post-market surveillance. This device will be subject to pre-market notification as well as the Quality System regulation.

B. *Customer:* The device must be easily adjustable for medical professionals who have limited strength or flexibility. The positioning system must be user-friendly and understandable by a variety of medical professionals, including but not limited to doctors, physicians, technicians, nurses, and biomedical engineers.

C. *Patient-Related Concerns:* The client requests a device that will be able to hold the weight of an individual as large as 500 pounds. The device should be able to transport, support, and stabilize patients with a variety of disabilities. Furthermore, the device should be aesthetically concurrent with the other hospital beds as to not startle the patient or affect his or her demeanor. This is particularly

important in cases of neurological scans such as fMRI or metabolical examinations such as PET scans.

D. *Competition:* Currently, there are several body positioning devices on the market. However, none of these devices suit the client's needs. One device, patented by Mabel Marshall, was created to work with CT, MRI, X-ray and ultrasound. Mabel Marshall's device is comprised of an inclined surface with a concave recess to support the patient's torso at the low end segment, and the feet at the high end. This device allows for better imaging of the spinal column and head. Pillows and cushions are used to support and immobilize the patient. While this device is compatible with several imaging technologies, it does not suit the disabled and overweight individuals the client is considering.

A second device, created by Lunar Corporation, supports and holds the patient in the lateral decubitus position for imaging using a densitometer. This device was created to be used with radiation imaging machines as well as radiation therapy machines. This positioning creates less pain than lying in the supine position for patients with spinal injuries. While this device is ideal for disabled patients with its restraining characteristics, it is not compatible with a variety of different imaging technologies.

Additional positioning aids are available on the market and used to support different parts of the body. However, many of these aids are created to suit only a specific part of the body; they are not created to support a variety of body segments and positions as requested by the client.