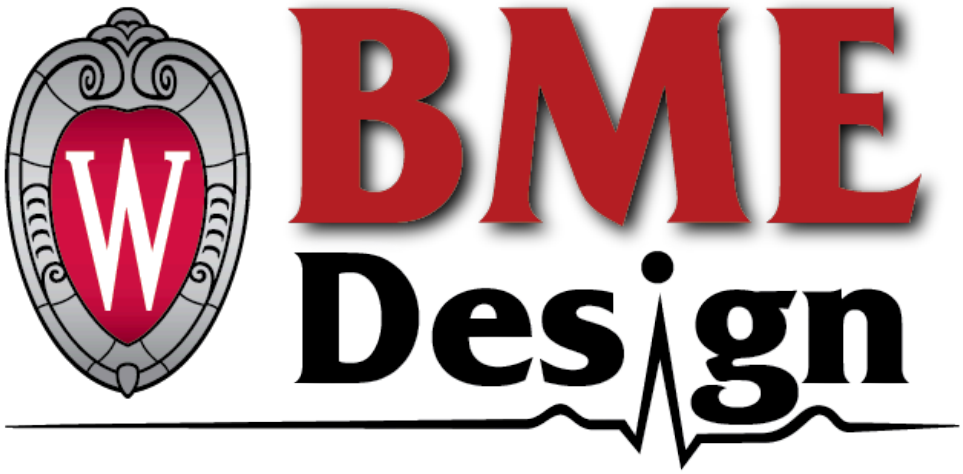

Dynamic Balance Device

Product Design Specifications

BME 301

Lab 304

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Function:

An estimated 30% of patients who have suffered from stroke experience Spatial Neglect Syndrome or lose vestibular sense, leading to falls that set back their recoveries [1]. Therefore, it is important that clinicians have devices that help patients practice balance and retrain neural networks so they can complete daily activities such as walking independently. However, existing devices don't allow the clinician to easily assist the patient because they are too heavy, or are not complex enough to effectively improve balance. The goal of this project is to design a lightweight device that allows the patient to practice scanning and complete a functional reaching test using an electronic component. As opposed to the previous design of an aluminum pipe with an LED, this device will be multifunctional and durable for convenient use.

Client requirements:

- The design is significantly lighter than the previous prototype
- The prototype is durable and well constructed, especially where the electronic components attach
- Feedback elements, including auditory feedback
- At least a 7.5 cm diameter display so that it is visible for patients with limited eyesight
- Varying colors and target shapes on the display
- A ruler integrated into the device so that a functional reaching test can be performed
- A reusable device that can be easily sanitized with a wipe

Design requirements:

1. **Physical and Operational Characteristics**
    a. **Performance requirements**:

        The final design must assist the physical therapist in improving visual scanning and postural balance for post-stroke patients suffering from spatial neglect syndrome. It must have a display at the end of the shaft that has the ability to present a variety of colors. The final design must be able to withstand frequent use, every weekday for up to 8 hours. The shaft must be a fixed length and durable while being a lightweight material that resists bending and deformation due to the load at the end of the shaft from the display.

    b. **Safety**:

        The final design must be a strong and durable material to ensure the device is stable and prevent failure while in use. This material must also be lightweight to prevent strain for the therapist and allow attention to be focused on patient care while using the device. The electronic elements must be safely enclosed to reduce risk of injury or hazards associated with exposed circuitry. The final design must also not include any sharp edges that could potentially harm the therapist while using the device.

c. **Accuracy and Reliability**:

The final design must accurately display the correct color when prompted by the therapist. The shaft of the device must have an accurate measurement system to ensure the provider collects reliable data when performing the functional reach test [2]. The final prototype must also reliably provide auditory feedback when the patient accurately completes the task.

d. **Life in Service**:

The final prototype must last at least one year with minimal servicing. The device will be used frequently for up to eight hours a day and five days a week. The handle and shaft of the prototype must be durable in order to avoid service within the first year. The electronics and circuitry may need quick maintenance, such as changing batteries, but these replacements must be simple and quick to perform.

e. **Shelf Life**:

The final device will be used exclusively indoors. The prototype must withstand frequent sterilization, as it must be wiped down between patients.

f. **Operating Environmen**t:

This device will be used in indoor environments for physical therapy. The device will be non-porous, as it will be cleaned and sterilized frequently. The device should be resistant to common deterioration and fluid corrosion. As the device will be used very frequently, it is important that it remains sturdy and can withstand normal forces from impacting the floor of the physical therapy spaces. Patients will be interacting with the device, so for preventative measures in case the patients hit the device against something, it may need additional force resisting properties along the base of the rod.

g. **Ergonomics**:

This device will be used by a physical therapist to assist in the rehabilitation process with a patient who has experienced a stroke. The device must be able to be held in one hand, easily held, and easily maintained for long periods of time, allowing the user to aid the patient if necessary. The colored target portion of the device should be easy to adjust and to have a control panel near the device's main interface near the handle.

h. **Size**:

The size of the rod should be a maximum of 1 meter in length. The display needs to be a target with at least a 7.5 cm diameter.

i. **Weight**:

The device needs to be under 2 kg with the majority of the weight located in the handle of the device to prevent fatigue for the patient while they are holding it up. The patient's perception of the weight is especially important, due to the higher torque load that comes with more weight allocated to the opposing end of the device.

j. **Materials**:

The materials for this device will need to be sterilized frequently, meaning they will need to be non-porous and able to undergo minimal maintenance without issue. The materials for the screen will need to be lightweight, waterproof, and have the ability to portray the main three primary colors, as per the interactive portion.

k. **Aesthetics, Appearance, and Finish**:

The device will have a professional and quality appearance. The device must be easy to clean and sterilized. The light up portion of the device must display various bright colors. The design will also include measurement markings up to 1 meter, so the user and patient can both easily determine how far the patient can reach in any given condition.

2. **Production Characteristics**
   a. **Quantity**:

There will be a total of one unit constructed for this project. More prototypes and development may be made in the future, but are outside the scope of this project.

b. **Target Product Cost**:

The target product cost will be within $500.

3. **Miscellaneous**
   a. **Standards and Specifications**:

The final prototype must adhere to the regulations for a Class I medical device under FDA 21 C.F.R. Part 890 [3]. This device is classified as low-risk and therefore does not require any premarket approval by the FDA. The final prototype will contain electronic components and may be subject to IEC code 62353:2014 [4].

b. **Customer**:

The client is a doctor who specializes in neurological rehabilitation and physical therapy. The client intends to use the device daily, therefore, durability must be a priority. The previous prototype felt too heavy so lightweight material choices will be important. Additionally, the client will be using the device daily, for up to 8 hours per day, so it must be comfortable to hold for long periods of time. The device should appear more sleek and professional than the client's current set-up. The device must be intuitive to use and not have a steep learning curve.

c. **Patient-related concerns**:

The device does not need to be sterile but should be able to be easily cleaned with a wipe when necessary. The device must also be able to be used with one hand, allowing the physician to support the patient with the other, maximizing patient safety.

d. **Competition**:

Competition for this device includes the client's current solution, a 1 meter long PVC tube with a bright-colored laminated dot affixed to the end. This product is very rudimentary and was not intended to be a long-term solution. Additionally, a device currently on the market is the Bioness Integrated Therapy System [5]. This solution provides a variety of assessments for the patient as well as testing balance, reach, and their Romberg score. The client currently has this system in their clinic, however, this device is static and does not allow the patient to move while using it, limiting its efficacy in helping patients get back to performing daily tasks with ease and regaining full-body awareness.

References

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[2] “The Functional Reach Test: Strategies, performance and the influence of age,” Annals of Physical and Rehabilitation Medicine, vol. 57, no. 6–7, pp. 452–464, Aug. 2014, doi: https://doi.org/10.1016/j.rehab.2014.03.003.

[3] C. for D. and R. Health, “Code of Federal Regulations (CFR),” FDA, Aug. 2023, Accessed: Feb. 01, 2026. [Online]. Available: https://www.fda.gov/medical-devices/overview-device-regulation/code-federal-regulations-cfr

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