BMEDesign: Product Design Specification

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Team project: Smart Walker

Lab section: 400

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Function

In the rehabilitation process of acute strokes or similar conditions, it is necessary for the patient to be able to walk well enough before returning home to ensure their safety. The client, Mr. Dan Kutschera, is a physical therapist that evaluates patients that come from an acute stroke clinic. He requests a device that will improve his evaluation process of the patients and is able to work in conjunction with a standard clinical walker. In order for the physical therapist to evaluate the patients' ability to walk, they must obtain various forms of data; such as the speed the patient goes, the distance they are able to travel, and the pressure applied to the walker from the patient. All of these sensors will be housed and powered on the walker, and after the metrics are taken, they will be displayed to a screen on the walker. The Smart Walker would enhance the ability of our client to evaluate the rehabilitation process of his patients.

Client requirements

- The device will be designed to enhance a standard physical therapy walker so it can be used in a clinical setting for the client
- The Smart Walker must be durable enough to withstand daily usage, year round with minimal maintenance.
- The device must be manufactured within the budget of $300, what will be purchased with this budget is a walker, electrical components, and other housing components.
- A display module attached to the walker will display measured data from the enhancements to the walker. Such data will be the pressure applied to the walker, the speed of the walker, and the distance traveled.
- An initiation and termination button for the walker will be implemented so the device is only measured during the trial period.
- All measurements will be in customary units so the patients have a better understanding of their performance.

Design requirements

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

The Smart Walker would be required to perform within distances of 10 meters and for time periods within 30 minutes. The Smart Walker would be an enhanced clinical walker and it will retain its standard functions of supporting the weight of the user, no more than 140 kg [1], whilst the user walks across the room. The enhanced performance of the walker will allow it to measure and display the pressure applied to the walker, the speed of the walker, and the distance traveled. The added enhancements of the walker should not make using it more difficult, such as not impeding the walking motion of the user nor adding additional weight to the walker.

    b. **Safety**

Safety is a high priority concern for the Smart Walker, given that it is going to be used by patients who are in rehabilitation after an acute stroke, or acute stroke adjacent event. The Smart Walker should follow standard OSHA guidelines regarding clinical services in physical therapy. The Smart Walker should not be used near water and must have both the equipment and electrical components maintained properly to avoid mechanical failure or electrical exposure [2]. The physical therapist should also be properly trained to both handle the device and guide a patient through the use of it.

    c. **Accuracy and Reliability**

The Smart Walker would need to measure values within an accuracy of 10% the true value. It would also need to be very reliable and vary from its measured value within 5%. These metrics of accuracy and reliability will need to be true for distances within 10 meters and for time periods within 30 minutes.

    d. **Life in Service**

The Smart Walker will be required to be used every day in the lab for no more than 10 patients a day and for no more than 5 trials per patient. Each trial will take no longer than 30 minutes at a time. The Smart Walker should operate for 10 years without maintenance.

    e. **Shelf Life**

In storage the Smart Walker should be kept in dry, room temperature conditions (16-26 deg C). The device should be folded while in storage to minimize the space it occupies and reduce the risk of unexpected forces. When lifted while in a folded state the walker should not unexpectedly unfold [3] . The alkaline batteries used for the Smart Walker have a shelf life of approximately 10 years while the Arduino should last much longer [4]. Given the shelf life of the individual parts the device should last about 10 years in storage before requiring replacement parts.

f. **Operating Environment**

The walker will be used in a neurorehabilitation center with a 16-26 °C ambient temperature and relatively flat surfaces. It should not be used outdoors and therefore should not be exposed to unexpected environmental conditions or loading conditions. The walker will need to be sanitized between users and therefore should be able to withstand repeated exposure to alkaline cleaning products. The Smart Walker will often be subjected to uneven force distribution and should be able to maintain stability despite up to 10 kgs pressure difference. The walker should also hold up to 140 kgs pressure for periods of up to 30 minutes [1]. Finally when engaged, the brakes on the walker should be able to withstand pushing forces of up to 6 kgs and pulling forces up to 4 kgs [3].

g. **Ergonomics**

The walker should have an adjustable height of 0.8 m to 1.1 m to accommodate a wide range of user heights. The width should be within 0.64 m and 0.74 m to accommodate users while still allowing room within doorways and hallways. The walker should withstand braking forces of 4-6 kgs and an applied weight of 140 kgs [3]. The Smart Walker display should only show speed and pressure measurements after recorded trials to avoid distracting users interacting with the device.

h. **Size**

The smart walker should have a maximum height of 1.1 m that can be lowered to 0.8 m depending on the user. It’s maximum width should be 0.74 m to avoid taking up too much space within hallways and to allow it to easily pass through doorways. Finally for portability, the walker should fold and weigh between 2-4 kgs.

i. **Weight**

The smart walker should be roughly between 4.5 and 9 kilograms. This is so that it is easy to move and the attachments added do not add an unreasonably heavy weight to the walker. This way when used in trials, the walker is realistic. This smart walker should be able to support no more than a 140 kg patient which is what a normal walker will be able to do [1].

j. **Materials**

A typical walker is made of aluminum and the handles of vinyl. These are this way to be anti-perspirant and can withstand the pressures a patient exerts. There are certain materials that should not be used on the walker for health reasons and safety reasons. These include wood, cloth, leather, and other materials that can bring along more sanitization, maintenance, or safety issues. These do not want to be a worry for our client in a clinical setting.

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

The smart walker should look almost identical to a regular walker. This is so that it is not intimidating for the patient and they feel as though they are working with a walker that is not what they are used to seeing. The handles on the walker should be resistant to perspiration so that proper grip can be used at all times without a worry about the patient’s grip being limited. Lastly, wires should be tucked away on the smart walker so that there are no wires dangling that the patient could get caught up on mentally or physically.

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

There should only be one Walker designed. The client has asked that there is only one walker to start and use in the clinical setting.

b. **Target Product Cost**

The target cost is between $250-$350 dollars for one of the walkers. There are competing designs that are roughly $2500 at times which the client does not want to spend.

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

While the Food & Drug Administration (FDA) allows custom medical devices to be exempt from pre-market approval and other such requirements [5], the Smart Walker, because it is intended to be used with multiple different patients as opposed to one particular person, will still be subject to regular FDA standards. Similar electronic mobility devices have been classified as a Class II medical device, meaning that this device will most likely also be classified as such, thus requiring compliance with the FDA's quality system regulation, basic and medical performance standards [6], and also a 510(k) premarket notification. Most generally, hazards associated with device use must be identified and controlled as per ISO 14971 [x3], and while the Smart Walker won't be particularly harmful to the user, nor will it be a life-sustaining device, it remains important to understand any possible faults that could cause bodily harm, especially in regards to the batteries/power-supply. These safety concerns are expounded upon by IEC standards numbered 60601-1 and 62366-1, who deal specifically with medical instrumentation [7][8].

b. **Customer -> change to User?**

Mr. Kutschera outlined a few important preferences that he had for the Smart Walker that fit his vision for the most effective version of the device. First of all, he envisioned the device being implemented into/onto an existing 2-wheel walker because most of his patients use something similar. He also believes that having live feedback given to the patient during their walking test with the walker will help boost enthusiasm for the therapy session; as such, some sort of screen is required near the handles of the walker to display metrics about speed, distance, and force to the patient as they are using the device. That being said, he also explicitly stated that these values must be in imperial units because metric units don't mean much to people outside of STEM careers. Finally, any batteries or wires must be fully encased within the walker or their own housing parts, as loose wiring could make the device unwieldy and/or dangerous in some cases.

c. **Patient-related concerns**

Because the Smart Walker is meant to be used by a variety of patients throughout the day, proper sanitization measurements must be taken between uses of this device by different patients. Furthermore, the differing users of this device give rise to concern about its stability, adjustability, and weight outlined in the *ergonomics* and *size* sections (1g & 1h). Finally, the UI for the Smart Walker must be accessible to (usually elderly) acute stroke patients, meaning that tactile buttons would be preferred over a touchscreen interface, as there has been a similar robotic walker by Frontiers in Neurorobotics that experienced difficulty with such a UI [9].

d. **Competition**

There are a few similar devices to the Smart Walker that are either on the market or used for research, but none of them have the exact use-case that Mr. Kutschera desires, plus most of them are egregiously expensive. One such device is called the Camino, which integrates multiple sensors in the walker to detect changes in terrain and drive a motor accordingly to make walking easier for the user. Similar to the Smart Walker, it is also able to track its user's gait, but the Camino incorporates AI to filter through the input data in order to do so [10]. The aforementioned walker by Frontiers in Neurorobotics, while mostly used to prevent the elderly from falling, has a spongy handle that senses changes in air pressure when being compressed [11]. Patents for other proof-of-concept devices also exist online, as seen in patents US20220211568A1 and US7826983B2 that each outline some application of sensors on a walking device, but these devices most likely never made it to fruition [12][13]. That being said, there really doesn't exist a device that works perfectly for Mr. Kutschera's needs, but there are such devices that can help guide the Smart Walker in the right direction.

Citations

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