BMEDesign: Product Design Specification

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Project title: Smart Walker

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Function/Problem Statement:

Patients with TBI often undergo traumatic events followed by intense rehabilitation to help them walk and return to everyday life as soon as possible. During rehabilitation, doctors struggle to measure progress as patients are gaining strength, making it hard for physicians to give patients tangible data of their improvement. The insurance companies also often do not feel that there is enough evidence of improvement, making it harder for the clinic to be paid for the services they provide. The smart walker will measure the pressure applied, speed, and distance walked of patients with neuro-rehabilitation needs. This data will be reported and displayed in real-time to help clinicians monitor progress and motivate patients. Ultimately, the device will reduce the time required to meet Medicare's documentation needs and increase objective markers of patient readiness for discharge.

Client requirements:

The device must provide real-time data on user pressure, speed, and distance. It must be compatible with the walkers currently being used without compromising the structural integrity of the walker. Data provided by the smart walker should be presented in a metrics report that is comprehensible to insurance companies. Furthermore, the client requested a compact design that is easy to use, accurate, and reliable. The budget for this project is ~$500.

Design requirements

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

i. The smart walker attachments will modify an existing clinical walker, which can support a patient weighing up to 140 kg.
ii. The added attachments should not impede the function of the original walker.
iii. The metrics provided by the walker attachments will include distance, speed, and pressure, and should be recorded and displayed to both the user and clinician.

b. *Safety*
   i. The structural integrity of the existing walker must not be compromised
   ii. The device must follow all of the neuro-rehabilitation facility's safety standards and regulations
   iii. ISO requirements must be followed for all electronic and battery components[4].
   iv. Clear instructions should be given on how to use our walker attachments

c. *Accuracy and Reliability*
   i. The walker attachment should accurately measure the values of distance, speed, and pressure within 10% of absolute values.
   ii. The measurements should also not vary more than 5% from their measured values.
   iii. These metrics need to be accurate over distances of 10 m and over time periods of 30 minutes.

d. *Life in Service*
   i. The walker should withstand up to 10 patients for up to 5 trials a day over a period of 10 years before requiring maintenance.

e. *Shelf Life*
   i. The walker attachment should last 10 years before needing repair or part replacements.

f. *Operating Environment*
   i. The walker will be used at the client's neurorehabilitation center, which will be at a temperature of 16-26 °C. It is designed for indoor use and should not be taken outside to prevent damage from outdoor conditions.
   ii. The walker will be used by multiple people, which will require sanitation between each use. The walker should be able to withstand continuous use of alcoholic disinfectants.
   iii. The walker should hold 140 kgs (~300lbs) of pressure for up to 20 minutes at a time. The attached pressure devices should be able to withstand this pressure and read a pressure this large[5].
   iv. The attachments to the walker should be able to be moved to different walkers.

g. *Ergonomics*

i. The height of the walker should be adjustable to heights of 80-100 centimeters[6].
ii. The width of the walker should be 60 centimeters. This will not be adjustable; however, the attachments designed can be switched between walkers if needed[6].

h. Size

i. The size of the smart walker attachments should not impact the usability of the existing walker.
ii. The components should not protrude from the existing walker by more than 10 cm to ensure that the walker can still easily fit through doorways and can be stored effectively.

i. Weight

i. The walker attachments should not add significant weight to the preexisting walker.
ii. Clinical walkers typically weigh between 4.5 and 9 kg; therefore, the combined weight of the smart walker attachments and the walker they are on should not exceed this range[7].

j. Materials

i. Walkers are typically made of Aluminum with vinyl handles, serving as the base for smart walker attachments.
ii. The attachments will include various electrical components and a display.

k. Aesthetics, Appearance, and Finish

i. The smart walker attachments should be as noninvasive as possible to ensure the look is as close as possible to a regular walker. This will ensure that it is easy to use for patients and clinicians.
ii. All wires should be contained to protect the lifespan of the device and improve patient usability.
iii. All data should be displayed in a way that is accessible to both patients and clinicians, and provide real-time updates to motivate improvement.

2. Production Characteristics
    a. Quantity
        i. There will be attachments for one walker, which include four pressure sensors, a device to measure speed and distance, and a display. All attachments should be removable and switchable between walkers.
    b. Target Product Cost
        i. The Budget for this project is $500
3. Miscellaneous
    a. Standards and Specifications
        i. FDA 21 CFR Part 820 (Quality System Regulation / QMSR):

1. Specifies quality system requirements for medical devices, including design control, production processes, and corrective actions. FDA's new QMSR aligns this regulation with ISO 13485:2016, which will govern the design and manufacturing of Class II medical devices such as the Smart Walker.

ii. IEC 60601-1-2:2014 – Electromagnetic Compatibility (EMC):
    1. Specifies requirements to ensure the Smart Walker's sensors and circuits are immune to electromagnetic disturbances and do not emit interference that could affect other devices in home or clinical environments.

iii. ISO 11199-2:2005 – Assistive products for walking, Part 2: Rollators:
    1. Specifies performance and safety requirements for walkers with wheels, including stability, braking systems, strength, fatigue resistance, and labeling. Ensures the device meets international expectations for durability and safety.

iv. ISO 11199-1:2021: Assistive products for walking — Walking frames — Requirements and test methods
    1. This standard highlights the performance, safety, and durability requirements for walking frames, such as our Smart Walker. This includes the load, fatigue, and stability testing. This is intended to ensure that walkers and any add-ons do not compromise user safety or functionality.

v. ISO 14971:2019: Medical devices — Application of risk management to medical devices
    1. This standard defines a structured process for identifying hazards, estimating and evaluating risks, implementing control measures, and monitoring effectiveness. This standard is essential for documenting and managing risks for many components of our Smart Walker, such as structural failure, inaccurate weight data, or electrical hazards associated with the add-on.

b. Customer

i. The metrics should be displayed live to motivate users and aid in recovery as efficiently as possible.

ii. The smart walker attachments need to attach to a 2-wheeled walker, as most patients are already familiar with the operation of a 2-wheeled walker.

iii. A display should be located near the handles, allowing patients to see it while using the device.

iv. Since the users of this device reside in the U.S., all units need to be reported in empirical units to make it easier for patients to understand

v. All wiring and battery components need to be enclosed to protect user safety.

c. *Patient-related concerns*
   i. The requirements need to be removable and sanitizable since a variety of patients will use them.
   ii. The user interface must be accessible to all ages, given the high incidence of elderly stroke patients.

d. *Competition*
   i. Few walkers on the market have similar features to what Mr. Kutschera is looking for in this walker. Some designs record speed, but there is nothing on the market that effectively records the pressure exerted by the patient on the walker.
   ii. All known walkers are also extremely expensive and unreasonable for what Mr. Kutschera is using them for.
   iii. One device called the Camino uses multiple sensors to detect the gait of the walker and the changes in gait. It can also detect changes in terrain to help prevent falls in patients. Although this device has many good features, it does way more than Mr. Kutschera needs and is way too expensive. It also does not track the pressure the patient puts on the walker[1].

References

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