



Smart Walker - BME 301
Product Design Specifications

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Section 302

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Function:

Patients with traumatic brain injury (TBI) frequently experience significant trauma followed by intensive rehabilitation aimed at restoring mobility and facilitating a return to daily activities. During rehabilitation, clinicians often face challenges in objectively measuring patient progress, limiting their ability to provide quantifiable feedback and to show insurance providers evidence of improvement, which complicates reimbursement for clinical services. The proposed smart walker accessories will objectively measure pressure applied, walking speed, and distance covered by patients during their daily evaluations. These data will be reported and displayed in real time to support clinicians in monitoring patient progress and enhancing patient motivation. Ultimately, the device is expected to streamline Medicare documentation requirements and provide objective indicators of patient readiness for discharge.

Client requirements:

- The device must measure pressure from 0-100kg, speed from 0-9.65 km/h, and track appropriate distances (limited constraint).
- The device must be suitable for both physical training sessions and everyday use.
- The device attachments must remain compatible with existing walkers without compromising their structural integrity.
- Each device attachment should be separable and usable both in tandem and individually.
- The device should be able to send real-time data to a mobile device and website, which will collect and display it.
- The device needs to be compact, user-friendly, accurate, and reliable within the project budget of approximately \$500.
- The device must be easily sanitized for daily use, including domestic personal purposes.

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements:

- i. The smart walker components should be easily detachable so that they can be connected to any walker.
- ii. The components, specifically the load sensor, should be able to withstand a load of 136kg, which is the standard load expected to be supported by a walker for patients undergoing rehabilitation with one-sided weakness, which is often the result of a stroke [1].
- iii. The electronic display should relay real-time information about the patient's walking pattern.
- iv. The electronic components and sensors should be able to measure weight-bearing, distance travelled, and speed travelled.

- v. All attachments to the walker should not impede its function or stability.
- b. *Safety:*
 - i. The structural integrity and stability of the walker should not be compromised
 - ii. The device must be able to withstand the weight of the patient.
 - iii. All electrical components should contain ESD (electrostatic discharge) prevention.
 - iv. All electrical components must comply with applicable ISO, IEC, and FDA requirements.
- c. *Accuracy and Reliability:*
 - i. The walker must measure distances, speeds of 0-9.65km/h, and pressures of 0-100kg within 10% of the absolute values.
 - ii. Metrics should be accurate over distances of at least 10m (standard 10-Meter Walk test)
- d. *Life in Service:*
 - i. The walker accessories should withstand up to 50 trials per day over 10 years before requiring serious maintenance (electrical component replacement).
- e. *Shelf Life:*
 - i. The walker is expected to last a standard shelf life of 3-5years as over time the rubber soles would wear out [2].
 - ii. The ultra-wideband sensor should last up to 7 years; it has a low frequency blink rate of 7Hz, but this low frequency would work for the application of this project [3].
 - iii. Load cells have a lifespan of 10 years. However, their lifespan is dependent on their fatigue life, specifically the number of cycles, so a load cell's lifespan is highly subject to its fatigue life [4].
 - iv. The HX711 amplifier board has a lifespan of between 5-10 years, although it is highly susceptible to damage due to environmental conditions, so it often doesn't reach its entire lifespan [5].
- f. *Operating Environment:*
 - i. Due to the number of electrical components associated with the attachments to the walker, the operating environment must be dry and indoors.
 - ii. The walker will be used at the client's neurorehabilitation center, which will be at a temperature of 16-26 °C.
 - iii. 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.
- 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[same as citation in other bullet points].
- h. *Size:*
 - i. The attachments should be small enough to avoid interference with the patient's movement and easy to transition between walkers.
 - ii. The components should not protrude from the existing walker by >10cm to ensure the walker still fits easily through doorways and can be stored effectively.
- i. *Weight:*
 - i. The attachments to the walker must be relatively light so they do not add significant weight to the preexisting walker.
 - ii. Clinical walkers weigh between 4.5 and 9 kg; therefore, the combined weight of the smart walker attachments and the walker should not exceed this range [7].
 - iii. Studies have found that the allowable attachment weight should be $\leq 5\%$ of the user's body weight to ensure stability and prevent slower gait patterns [8].
- j. *Materials:*
 - i. Walker structures are most commonly made from aluminum tubing and can include rubber or composite materials for mechanisms/grips, which all provide a stable base for the attachments [9].
 - ii. The end caps for load cells are 3D-printed from polylactic acid (PLA).
 - iii. The attachments will include electronic hardware such as wires, load cells, an ultra-wideband (UWB) sensor, an HX711 amplifier board, and batteries.
- k. *Appearance:*
 - i. Device attachments should be compact and integrated within the walker to maintain an unobtrusive appearance.
 - ii. Real-time data should be displayed through an intuitive UI on both the website and the attachment display to make it easier for clinicians and users to read.
 - iii. All electronic hardware should be concealed to extend the device's longevity and ensure patient safety.

2. Production Characteristics

- a. *Quantity:*
 - i. There will be 1 final smart walker with three separate attachments: four pressure sensors with end caps to measure force, an ultra-wideband sensor to measure speed and distance, and a live reader display.
 - ii. All attachments should be removable within 5-10 secs and be compatible with other walkers.
- b. *Target Product Cost:*

- i. The budget for the design is approximately \$500. Load cells cost around \$100 each, and UWB sensors cost range from \$50 to \$100 [10]. All other costs will be kept to a minimum.

3. Miscellaneous

a. *Standards and Specifications:*

- i. The Smart Walker accessory device is for clinical rehabilitation environments and must comply with standards relevant to medical devices, assistive mobility, electrical safety, and patient data privacy.
- ii. Medical device standards: FDA 21 CFR Part 820 Quality System Regulation[11], with the newest amendment effective on February 2, 2026, incorporates ISO 13485:2016 Medical Device Quality Management Systems, serve as comprehensive guidelines and requirements for consistent medical design, development, production and servicing. ISO 14971:2019 Risk Management for Medical Devices [12] requires systematic identification, evaluation, and mitigation of risks of Smart Walker including device instability, inaccurate measurements, electrical hazards, and user misuse.
- iii. Assistive mobility standards: ISO 11199-1:2021 Walking Frames [13] and ISO 11199-2:2021 Rollators [14], together specify strength, stability, fatigue resistance, and safety testing requirements of Smart Walker to ensure the attachments added to the walking frame do not compromise walker safety or performance.
- iv. Electrical safety standards: IEC 60601-1-12:2014 Medical Electrical Equipment Safety [15] applies to electrical components, including pressure and distance sensors in the Smart Walker, used in clinical environments, covering protection against shock, overheating, and electrical hazards.
- v. Patient data privacy requirements: The Smart Walker system might store, export, or transmit patient data including walking speed, distance, and applied pressure to floor, it may become part of a system handling Protected Health Information (PHI) and therefore must align with the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules [16].

b. *Customer:*

- i. Primary customers are rehabilitation clinicians and therapy facilities treating TBI and mobility-impaired patients, while secondary customers include hospital administrators and insurance providers.
- ii. Customer needs including:
 - 1. Objective and repeatable metrics for patient rehabilitation progress documentation
 - 2. Real-time display of walking performance, in the format of both a display on the handles and a remote monitor at a distance.
 - 3. Durable and low-maintenance hardware for daily clinical use

4. Intuitive interface usable by therapists and patients
5. Enclosed electronics to ensure safety
6. Potential capability with electronic medical recording systems

c. *Patient-related concerns:*

- i. Patients using the device often have neurological impairments and mobility limitations caused by TBI, therefore the design should not impair the basic functions of a 2-wheeled walker by not increasing the walker's instability or the user's risk of falling. The device's weight and size must not significantly increase the walker's effort. Displays must be readable without forcing unsafe posture changes by the patients. Components must avoid sharp edges.
- ii. In practical applications, Smart Walker must maintain fundamental durability and ease of use for patients. Materials used can tolerate routine cleaning and sanitization between patients. The system must operate reliably without requiring technical knowledge from patients.

d. *Competition:*

- i. Existing products mainly focus on assisting patient movement instead of a clinical rehabilitation monitoring tool as Smart Walker. Therefore, those solutions fall into the following categories:
 1. Standard walkers and rollators: Conventional walkers only provide mobility assistance but do not record rehabilitation progress. Therapists need to rely on either subjective observation or manual timing and distance measurements during therapy sessions
 2. Smart mobility aids [17]: Some advanced walkers measure gait parameters or walking speed, like a competitive product by Camino Mobility [18]. But these systems are often designed for long-term monitoring and are extremely expensive (\$2999 RSVP for Camino), complex, and impractical for routine clinical sessions.
 3. Fall prevention mobility devices: Certain smart walkers incorporate terrain sensing to support independent living of people with walking disabilities, but those designs are often in format of home safety installations, wearable alert and monitoring systems, footwear, and mobility support furniture [19], which do not meet the Smart Walker customer needs.
- ii. Thus, the purpose of Smart Walker differentiates itself from those competitive designs by serving as a clinical monitoring and documentation tool rather than a mobility aid. It provides objective metrics such as pressure support, walking speed, and distance to quantify rehabilitation progress.

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