301 - Tong - 45 - Smart Walker - Executive Summary

According to the National Institute of Neurological Disorders and Stroke in 2025, Traumatic brain injury (TBI) affects approximately 50 million people worldwide each year and contributes to over 500,000 permanent disabilities annually. TBI most commonly occurs amongst individuals above 65 years, and they frequently rely on walkers. Clinicians commonly use standardized tests, such as the 10-Meter Walk Test, to evaluate progress. However, current assessment methods are predominantly manual and subjective, relying on visual estimation of weight distribution, manual timing of walking trials, and approximation of distance traveled. This introduces challenges, including a lack of quantifiable evidence of rehabilitation progress, difficulty in demonstrating medical necessity to insurance providers, and reduced capacity to monitor subtle changes in gait stability.

Existing mobility aids are expensive, complex, or primarily designed for independent living and fall detection rather than clinical rehabilitation tracking. Most commercial mobility aids prioritize walking assistance and user safety over quantitative data for rehabilitation tracking. For example, the Bure Rise & Go Walker is designed for powered standing and transfer assistance but lacks gait measurement capability. Research prototypes incorporating FlexiForce™ sensors translate applied force and measurement units (IMUs) to estimate gait metrics, but aren't widely available for clinical use. Approximately 6.8 million adults in the United States use walking aids, highlighting a market for a system that tracks rehabilitation progress by integrating sensing and quantitative metrics.

The key innovation of the Smart Walker is its integration with any clinical walker while providing real-time data for all patients. Our design embeds dual load cells within custom end caps, a widely applicable and mass-producible design, and works in tandem with a mmWave radar to quantify weight-bearing and ambulation metrics, such as distance and speed. The mmWave radar overcomes the limitations of prior LiDAR-based approaches by providing higher occlusion tolerance and an extended sensing range of up to 45m. The modular, tool-free attachment of the system allows for easy fixation and removal, and is suitable for all walker models. This represents a novel approach to clinical-grade sensing not present in any current product. The combination of these sensing modalities within a compact, affordable, and universal platform constitutes a commercially viable and patentable system for rehabilitation monitoring.

Validation of the Smart Walker was conducted through a structured testing protocol that targets the three performance metric requirements: weight-bearing accuracy, distance and speed measurement, and wireless data transmission. Load cell accuracy evaluation compares measurements against a calibrated digital reference scale across incremental loads from 0 to 108kg (for each load cell) in 12-kg steps, with three trials per load cell. The system is designed to achieve a mean percent error within ±2% of the applied load, satisfying the client's accuracy requirements. The mmWave radar distance and speed measurements are validated against a tape-measured path using Tracker motion analysis software, targeting sub-5% error over a 45m distance. Wireless connectivity is tested across areas without EM noise and in a campus Wi-Fi environment to ensure data integrity. The design meets all primary client requirements: real-time display of weight-beard (0-100kg), speed (0-10km/h), and distance, and easy fastening. The device aligns with relevant standards, including: FDA 21 CFR Part 820, ISO 11199-1:2021 for walking frames, IEC 60601 series for electrical safety, and HIPAA for patient data confidentiality, demonstrating the Smart Walker as a clinically validated, commercially viable, and unique rehabilitation monitoring solution.