Design and Development of Biofeedback Stick Technology (BfT) to Improve the Quality of Life of Walking Stick Users

A thesis submitted to the Faculty of Health, Education and Life Sciences (HELS) in partial fulfilment for the degree of

Doctor of Philosophy

By

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March 2022

Declaration

By

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Dedication

I would like to dedicate this thesis to my dear parents, loving wife and siblings who have been a consistent source of inspiration and ray of guidance throughout my life

Acknowledgements

First and foremost, I would like to thank and praise Allah (God), the Almighty and the most merciful for the continuous blessing, strength, motivation, and ability to complete this amazing journey, and reach the final stage of this research.

Then I am eternally grateful to my supervisors, Dr. Vivek Indramohan, Dr. Bisola Mutingwende, Dr. Vijayalakshmi Ahanathapillai and Professor. Maxine Lintern, for their continuous support. They have dedicated a lot of time into my research, where they guided me and motivated me even under challenging periods.

I would also like to thank Birmingham City University for awarding me the scholarship to carry out my research at this University.

I would like to thank, Professor. Martin Levermore – who provided me with financial support, without which I would not have been able to continue my research.

I would like to thank, Ms. Sharon Atkinson – Finance Advisor, for supporting me morally throughout my journey.

I would like to thank, Associate Professor. Rehan Bhana – who has been my mentor for the past 8 years.

I would like to thank, Mr. Chen Yip Chai and Dr. Helen Gravestone – Biomedical Engineering and Life sciences, who helped me setup the equipment in the Biomechanics lab.

I would also like to thank my parents, Mr. and Mrs. Abdullah Jan, for their continuous support from a young age which have made me who I am today. Their unconditional love during certain difficult times has eased off a lot of pain from my shoulders and have made me mentally stable throughout my research. Without them, I would have never made this far so I am eternally thankful.

I would like to thank my wife. Thank you for being very patient with me throughout this journey. Your support has played a major role in the success of this research, and I truly believe that your kind words have motivated me more than ever.

Finally, I would like to thank my siblings; Shahid, Usman and Haider for always motivating me and making me laugh at times of difficulty to ease my stress.

Abstract

Biomedical engineering has seen a rapid growth in recent times, where the aim to facilitate and equip humans with the latest technology has become widespread globally. From high-tech equipment ranging from CT scanners, MRI equipment, and laser treatments, to the design, creation, and implementation of artificial body parts, the field of biomedical engineering has significantly contributed to mankind. Biomedical engineering has facilitated many of the latest developments surrounding human mobility, with advancement in mobility aids improving human movement for people with compromised mobility either caused by an injury or health condition. A review of the literature indicated that mobility aids, especially walking sticks, and appropriate training for their use, are generally prescribed by allied health professionals (AHP) to walking stick users for rehabilitation and activities of daily living (ADL). However, feedback from AHP is limited to the clinical environment, leaving walking stick users vulnerable to falls and injuries due to incorrect usage. Hence, to mitigate the risk of falls and injuries, and to facilitate a routine appraisal of individual patient's usage, a simple, portable, robust, and reliable tool was developed which provides the walking stick users with real-time feedback upon incorrect usage during their activities of daily living (ADL).

This thesis aimed to design and develop a smart walking stick technology: Biofeedback stick technology (BfT). The design incorporates the approach of patient and public involvement (PPI) in the development of BfT to ensure that BfT was developed as per the requirements of walking stick users and AHP recommendations. The newly developed system was tested quantitatively for; validity, reliability, and reproducibility against gold standard equipment such as the 3D motion capture system, force plates, optical measurement system for orientation, weight bearing, and step count. The system was also tested qualitatively for its usability by conducting semi-informal interviews with AHPs and walking stick users. The results of these studies showed that the newly developed system has good accuracy, reported above 95% with a maximum inaccuracy of 1°. The data reported indicates good reproducibility. The angles, weight, and steps recorded by the system during experiments are within the values published in the literature. From these studies, it was concluded that, BfT has the potential to improve the lives of walking stick users and that, with few additional improvements, appropriate approval from relevant regulatory bodies, and robust clinical testing, the technology has a huge potential to carve its way to a commercial market.

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Acronym Reference List

ADL	Activities of Daily Living
AHP	Allied Health Professionals
AI	Artificial Intelligence
BfT	Biofeedback Stick Technology
BOS	Base of support
CAD	Computer Aided Design
CAM	Computer Aided Manufacturing
CNS	Central Nervous System
COM	Centre of Mass
CVA	Cerebrovascular Accident
DOF	Degree of Freedom
EMG	Electromyography
ERM	Eccentric Rotating Mass
FSR	Force Sensing Resistors
GRF	Ground Reaction Force
GUI	Graphical User Interface
HRV	Heart Rate Variability
LEAD	Lower-Extremity Arterial Disease
LJMS	Limited Joint Mobility Syndrome
LRA	Linear Resonant Actuators
MEMS	Micro-Electrical-Mechanical System

ML	Machine Learning
MS	Multiple Sclerosis
NHS	National Health Service
OA	Osteoarthritis
PN	Peripheral Neuropathy
PNF	Proprioceptive Neuromuscular Facilitation
PPI	Patient and Public Involvement
QFD	Quality Functional Deployment
RTOS	Real Time Operating System
RTUS	Real-Time Ultrasound
WRMSD	Work-Related Musculoskeletal Disorder Statistics

Synopsis

Mobility, or the ability to move, is an inborne trait often taken for granted by those without need for accommodation. Once a person has learnt to walk, the ability to do so becomes innate provided the lower limbs function properly. However, mobility can become compromised through injury, medical complication, lifestyle habits, and age, leading to abnormal functionality which can hinder mobility and cause disruptions to quality of life and activities of daily living. Problems in the lower limbs affecting mobility are among the most reported physical impairments in the United Kingdom, drastically impacting the economy through medical bills and affected employees taking time off work.

A variety of walking aids have been developed to assist affected patients transition from out of total immobility. Perhaps the oldest and most well-known aid is the walking stick, which continues to be the walking aid commonly prescribed by allied health professionals (AHP). Although these walking aids have been utilised for centuries, adequate training is required to achieve proper use. As such, patients typically make recurring visits to health professionals throughout their rehabilitation progress to receive training and feedback. In the current geosocial climate, with global pandemics and an increasing need to stay at home, there is an urgency for augmenting walking aids with technology that can enable them to perform simple training and feedback tasks. Using the principle of biofeedback, a prototype of 'Biofeedback Stick Technology' (BfT) has been developed that assesses parameters from users and provides feedback in real-time. The aim of this thesis is to elucidate the conception and development of BfT and pave the way for its widespread use.

To begin with, it was important to gain an understanding of exactly where the relevant technology currently lies and what the needs are in terms of increasing mobility for patients. Chapter 1 provides an in-depth literature review which introduces conditions affecting mobility as well as current solutions and implications and discusses some of the biofeedback technology available that can be utilised for the BfT. It was also essential to involve stakeholders (walking stick users and AHPs) throughout the development of the BfT. Chapter 2 explains the methods used to involve the stakeholders and place their perspective at the centre of the design.

Several technologies were critically evaluated to determine the best possible components for the BfT. Chapter 3 details the design of the BfT, including the hardware and firmware involved in its development. Here, information pertaining to the use and functions of the BfT has been outlined. Chapter 4 outlines a series of quantitative pilot trials conducted to evaluate and validate various BfT functions. Once the prototype was developed and tested, it was important to seek feedback from the primary stakeholders on the usability of the finished product. Chapter 5 describes the methodology adopted to gather valuable feedback from primary stakeholders including walking stick users and allied health professionals. Chapter 6 concludes the thesis by bringing all this information together, discussing test results and comparisons between hardware and software, and paving the way for future studies and recommendations.

Chapter 1. Literature review

This chapter presents a critical review of the literature related to the research undertaken. Two important themes are discussed here: the first theme explores the 'significance of mobility' (sections 1.2 – 1.4), while the second theme explains the 'biofeedback' (sections 1.5 – 1.6).

1.1. Significance of mobility

"To move is to live. To live is to move." Medical science interprets this quote, which in its origin embodied a more abstract symbolism regarding human freedom. Mobility can be defined as the ability to independently perform basic daily activities of living (ADL). It is one of the key indicators of good health and quality of life, particularly in elderly people (Musich et al., 2018). The independence deriving from mobility, or the loss of it, also significantly impacts an individual's mental health, with mobility loss often associated with depression and anxiety (Harvard Medical School, 2017).

With age, the speed and agility of a person reduces, and, often, older people become less mobile. Besides aging, circumstances like illnesses, injuries, disorders, or accidents can also compromise mobility, which can have short-term or long-term impacts on the health of individuals. Reduced mobility has far-reaching negative effects on an individual's well-being, including on psychological and mental health (Bolton and Donohoe, 2019). The United Nations data predicts that by the year 2050, roughly one billion people will exceed the age of 60 years (Ergasheva et al., 2017). For people in this age group, mobility issues are a major concern as it limits the scope of their daily activities and makes them dependent on additional support such as mobility aids and caretakers (Cooper et al., 2012). While unhealthy lifestyles devoid of exercise and a good diet are a source of stiffness in bones, joint stiffness and reduced flexibility are particularly prevalent in older age people and can lead to unstable gait patterns. Walking becomes more of a challenge, and elderly adults with mobility concerns are more likely to have an injury due to the way ankle stiffness affects their posture (Kim and Lockhart, 2012). People with impaired mobility have restricted movement due to reduced muscle strength regardless of age so that they struggle to perform common daily tasks. Studies suggest that increasing daily physical activity, such as walking an extra mile each day, can improve heart rate, body mass index, lipid profiles, glucose levels, and reduce the risk of coronary heart disease, and cardiac diseases (Grimmer et al., 2019). Therefore, reduced mobility decreases the quality of life for an individual, and management of immobility is crucial for a healthy life.

1.2. Health conditions affecting mobility

Mobility restrictions create hindrance in activities of daily living (ADL) for an individual. Medical conditions of this nature can limit an individual's movement due to the inability to move a certain part of the body properly. Increasing evidence suggests that the presence of chronic diseases such as musculoskeletal disorder, cardiac arrest, or respiratory failure in individuals is accompanied by impaired mobility (Grimmer et al., 2019). Research has shown that strength and balance training can help increase joint mobility and lessen the likelihood of injury from tripping or falling (Kim and Lockhart, 2012). Lower limb problems can also occur due to genetic or environmental factors. Where some people are born with congenital limb diseases, others acquire limb problems due to accidents (Montesinos-Magraner et al., 2016). Movement impairments in the lower extremities can also be caused by the presence of other medical diseases such as a stroke, diabetes, or vertigo. Although it is impossible to cover every possible explanation, the following sections will look at the economic and social aspects that contribute to the occurrence of a few specific medical disorders.

A stroke is a cerebrovascular condition with a loss of supply of blood to the brain resulting in numbness or paralysis. Strokes are often accompanied by lower limb problems due to muscular weakness, abnormal motor control, and physiological changes in the muscle (Arene and Hidler, 2009). All of these are associated with joint stiffness, postural deformity, and reduced muscle force which affect the normal movement of the body. In the case of stroke affecting the limbs, the immediate after-effect is a reduced ability to walk or stand. Neurological improvements occur in the months following the attack. Studies suggest that even after a person regains the ability to walk, the issues of lower limb functions and difficulty in walking remain (Cooper et al., 2012; Arene and Hidler, 2009). People suffering from stroke also face the problem of knee hyperextension, wherein the knee is extended beyond the neutral anatomical position. This phenomenon helps in controlling the movement of an unstable limb which results in an injury of the ligaments or capsules in the knee leading to functional gait deformities (i.e., inability to walk) (Cooper et al., 2012).

Strokes are the third major reason for an untimely death as well as the main cause of disability among people in the UK (Naseer and Thomson, 2014). In 2016 alone, 57,000 new cases were reported of people suffering from a stroke in England (Impact Stroke, 2019). Stroke prevalence was found both to be greater in men than women and to rise with age.

Another health condition that increases the susceptibility of lower limbs is diabetes (Bell, 1991; Naidoo et al., 2015). According to one survey, about 50% of all nontraumatic amputations of the legs occur in patients who have diabetes mellitus, attesting to the seriousness and frequency of these infections (R. *Gleckman* et al., 2008). Diabetes mellitus is a chronic condition where the body suffers from an excess of glucose level, either due to insufficient production of insulin or inefficient use of insulin. This condition occurs in two types based on insulin dependency. Insulin-dependent (type I) diabetes occurs when the patient is not able to produce insulin, while non-insulin dependent (type II) diabetes occurs as a result of insulin resistance or insufficient production of insulin. Diabetes is typically accompanied with ischemia, a heart disease that restricts blood flow through the heart, and therefore increases the risk of complications such as gangrene and amputation in diabetic patients (Howangyin and Silvestre, 2014).

Studies suggest that the formation of ulcers in the limbs and improper healing due to ischemia result in gangrene, often requiring limb amputations (Bell et al., 1991). Thus, regular monitoring of patients is needed to prevent such deterioration. Early detection of abnormalities using radiology enables timely treatment and reduces the risk of limb impairments (Naidoo et al., 2015). Lower-extremity arterial disease (LEAD) is a serious disorder associated with poor cardiovascular health, lower limb impairments, and functional loss of limb motions and is more common in diabetic people (Nativel et al., 2018). Therefore, diabetes and its associated medical conditions increase the risk of lower limb disorders.

Within the UK, 3.8 million people were reported to suffer from type II diabetes in 2018. This is predicted to reach 5.5 million by 2030 *(Diabetes Prevalence 20*18 | Diabetes UK, 2018). The rise in the number of diabetic patients is due to an increasingly obese population in the United Kingdom (Donnelly, 2019). Diabetes has been identified as the leading cause of lower-limb amputations in the United Kingdom. A rise of 19.4% in lower-limb amputations was observed in the UK from years 2010 to 2017 (Diabetes UK, 2018).

Multiple sclerosis (MS) is an autoimmune disorder of the nervous system. Patients with MS generally suffer from reduced aerobic capacity, lower muscle strength, and poor balancing ability (Sandroff et al., 2013). This health condition is responsible for abnormalities in walking and gaits of patients (Sandroff et al., 2013).

In 2018, around 105,450 patients suffering from multiple sclerosis were reported in England, 5,600 in Wales, 4,830 in Northern Ireland, and 15,750 in Scotland. The number of cases per 100,000 people was highest in Scotland, followed by Northern Ireland, England, and Wales, respectively (Multiple Sclerosis Trust., 2020)

An increase in sedentary lifestyles and lack of exercise has given rise to balance disorders (Mraz et al., 2007). When afflicted with vertigo, a person experiences a false sense of motion in their surroundings even while stationary. Inner ear problems are the most common cause of this ailment because they alter the ear fluid, triggering movement irregularities. Likewise, musculoskeletal issues (i.e., abnormalities in skeletal muscles or joints of the body) have been linked to the development of the condition (Morinaka, 2009). The suggested solution to the problem includes exercise and physiotherapy for correcting the balance. Conditions such as migraine or stress may aggravate vertigo as well (Ludman, 2014). This condition increases the risk of falls for patients due to lower limb problems. The spinning sensation in the head of an individual makes the use of assistive devices popular amongst patients suffering from vertigo (Skymne et al., 2012). Research suggests that 1 in 10 people will face the problem of vertigo in a year (Robinson, 2016).

These statistics highlight the current trends in the prevalence of these health conditions and emphasize that a large proportion of the population in the UK suffers from ailments leading to lower limb disorders.

1.3. Consequences due to these health conditions

1.3.1. Impact on the lives of individuals

Health is one of the standard indicators for quality of life (QOL), with the prevalence of the health conditions mentioned in the previous section, QOL of those suffering from these health conditions is impacted (Gregory et al., 2009)

Since the occurrence of lower limb disorders is often attributed to diabetes,people with diabetes face an increased risk of disability and mobility issues (Bianchi and Volpato, 2016). Limited joint mobility syndrome (LJMS) and other musculoskeletal illnesses are connected with an increased risk of falls; this risk is exacerbated by diabetes, which can be triggered by serious nephropathic, neuropathic, and cardiovascular problems (Gerrits, 2015).

Patients with stroke struggle to regain correct posture and balance (Garland et al., 2003). Studies suggest that while some patients show improvement in movement after a few months post-stroke, others show deterioration. The factors responsible for capacities of improvement after a stroke vary between individuals, and it is crucial to identify patients who are susceptible to long-term deterioration for effective treatment and recovery (Van De Port et al., 2006). Patients suffering from MS face significant mobility issues (Sosnoff and Sung, 2015). Muscle weakness is associated with a decline in quality of life since it increases the risk of injury. The next step in treatment is a regimen of long-term pharmaceutical administration aimed at controlling the patient's condition (Snook and Motl, 2009).

Vertigo affects the daily functioning of the patient by causing constant dizziness and imbalance in walking. Vertigo also increases the risk of falls and physical injury in patients (Ludman, 2014).

1.3.2. Impact on the National Health Service (NHS) and economy

The National Health Service (NHS) is a government-funded medical care facility for residents of the UK, providing several freely available medical services. Each year, NHS funds are revised to expand the scope of benefits for residents (Allocations, 2021). This organization ensures medical benefits for all individuals. As an example, this subsection highlights some of the financial contributions of the NHS.

It has been reported that the National Health Service (NHS) was operating with a deficit of £5.9 billion for the year 2017/18. Additionally, in 2016/17, an emergency sustainable fund was created in order to provide an additional £1.8 billion to support the NHS; however, these funds are not permanent, and as a result, the deficit of the NHS is expected to increase in the coming years (Gainsbury et al., 2017). In addition to the growing financial strain, the National Health Service (NHS) has been experiencing a lack of personnel (medical professionals). This has led to an increase in the number of people on the waiting list, ultimately putting greater pressure on the NHS (NHS Workforce, 2022). Therefore, finding solutions that can contribute to the reduction of the fiscal deficit and staff shortage in the NHS is one of the UK government's priorities (Khan, 2022).

1.4. Treatment to improve mobility and balance

People emphasize treatment as a goal when the ability to walk or engage in various ADL are affected by illness or injury (Holliday et al., 2007). AHP helps patients through rehabilitation, therapies, and the use of conventional walking aids (Laufer et al., 2004). The treatments the AHP suggests enhancing mobility and balance are discussed in the sections below.

1.4.1. Rehabilitation therapies

Rehabilitation broadly refers to individualized therapy for people experiencing issues of a specific domain—physical or mental. This section focuses on rehabilitation in regaining the ability to stand and walk properly after any previously mentioned physical problems. Rehabilitation exercises enhance motor plasticity of the patient and improve recovery by minimizing functional defects (Diaz et al., 2011). People suffering from lower limb problems must undergo gait rehabilitation, exercise training, physiotherapy, or use walking aids to assist with mobility (Uger et al., 2018). Two types of therapies are mainly prescribed by AHP: (i) occupational therapy and (ii) physical therapy (Dorsey and Bradshaw, 2017). While occupational therapy focuses on the improvement of motor skills and muscles for performing daily activities, physical therapy enhances overall motor and muscle function (Castillo et al., 2008). Traditional methods are based on orthopedic exercises and neurophysiological approach (Bobath et al., 2018), Proprioceptive Neuromuscular Facilitation (PNF), and motor learning (Ezema et al., 2018). Patients must be largely inactive participants in neurophysiological procedures while actively engaging in motor learning techniques (Pollock et al., 2007). Below are some rehabilitation therapies which are used to improve the mobility of the patient.

1.4.1.1. Exercise training for posture and mobility

Exercise training is a series of physical activities performed at regular intervals structured typically for increasing the fitness of a person and assisting in overcoming mobility issues. Snook and Motl (2009) conducted a meta-analysis to understand the benefit of exercise training in enhancing the mobility of MS patients.

Tai Chi is a form of low-impact exercise that is known to improve the balance, gait, and muscle strength of a person. Orr et al (2006) evaluated the potential of Tai Chi in improving mobility among type II diabetes patients over 60 years of age. Their results showed that performing this exercise in older patients improved mobility. Other studies report the success of using a combination of physiotherapeutic techniques for effective improvement of lower limb functions (Pollock et al., 2007). Weight training was also evaluated for improving joint stiffness and limb stability (Kim and Lockhart, 2012). The results of this study showed that limb mobility issues can be reduced by following exercise training (Kim and Lockhart, 2012). It was also observed that ankle flexibility was better in the case of weight training.

1.4.1.2. Physical therapy

Physical therapy is an integral form of rehabilitation therapy that plays a crucial role in recovery on top of medical and surgical aids. Its execution consists of different types of interventions such as stretching and mobilization techniques, balance exercises, or neuromuscular facilitation, along with resistance and aerobic training sessions (Wiles et al. 2001). Disabling disorders, such as spinal cord damage and fracture, might have negative consequences that physical therapy can mitigate (Hogan et. al., 2009). In patients with MS, physical therapy helps in improving the functional status by creating new neural signals (neuroplasticity) and cortical reorganization (Morgen et al., 2004). Physical therapy acts as a catalyst to stimulate the brain by promoting neural adaptation in the central nervous system (CNS) (Iyigun et. al., 2010).

1.4.1.3. Gait training

The sole purpose of gait training is to ensure that a person walks properly with proper force on the feet and maintains sufficient balance during a walk. Through specific exercises, gait rehabilitation attempts to trigger motor plasticity for patients and increase their chances of recovery (Janice and Eng, 2011). Gait training is also a form of physical therapy that aids in improving the ability to stand and walk (Liu et al., 2018). It is recommended to patients with a history of injury or illness that affects their mobility. This is especially true for patients who suffer from stroke or neurological illnesses. Repetitive gait training exercises ensure strength improvements and sufficient balance (Eng and Tang, 2007). In several clinics, the process of gait training involves observing a patient's walk and analyzing the abnormalities in a particular gait (Therapist, 2016).

Gait training helps in gaining independence in mobility by strengthening muscles and joints, building endurance, and improving balance and posture. In the case of joint replacement, stroke, MS, amputation, sports injury, Parkinson's disease, brain injury, and osteoarthritis, gait training helps in retraining the lower limbs for repetitive motion. It facilitates the development of muscle memory and reduces the risk of falls by increasing stability and balance. Similarly, gait training is recommended to patients who have lost their mobility or have difficulties with walking. Gait training benefits patients with spastic gait (walking with Asymmetric foot-dragging), scissor gait (walking with bent knees), waddling gait (side-to-side torso movements), and propulsive gait (rigid posture with neck and head bent forward) (Ghosh et al., 2016). Specifically, the skill-strengthening activities included in gait training are meant to aid in the acquisition or relearning of walking. The training is based on increasing muscle strength and voluntary response in lower limb muscles along with improving coordination in lower limbs. Some of these exercises include walking on a treadmill, standing up, sitting down, stepping over objects, lifting legs, and completing muscle-strengthening activities (Mochizuki, et al., 2015). Although gait training has numerous advantages, limitations exist surrounding patient ability to manage weight support (Liu, 2018). Therefore, weight-bearing therapies are prescribed to aid in recovering weight-supporting abilities.

1.4.1.4. Weight-bearing therapy

Healing responses, such as those prompted by weight-bearing therapy, are credited with boosting metabolism and mobilising the body (Tkachenko et al., 2016). The action of mobility (i.e., walking) involves carrying the full body weight in each leg in an alternating rhythm (Skou and Roos, 2019). However, some mobility disorders (explained in the previous section) and\or injuries lead to a reduced ability to manage full weight on a single leg. Therefore, physical therapists and doctors recommend a partial weight bearing or non-weight bearing status to facilitate the healing of specific tissues. Kiran et al. (2019) stated that non-weight bearing status is based on the idea that different types of tissues can heal if provided enough time; however, the repair process is often slow. If the patient puts weight on the affected tissue too soon, it can slow or halt the healing process. Non-weight bearing involves physical therapy treatments that ensure no weight is placed on the affected leg. Assistive devices like crutches or walkers are used in this case. Alternatively, Rafiq et al. (2018) stated that the partial weight-bearing status is based on placing half of the weight on the affected leg. The injured leg is placed on a force plate to record the resulting force. Because the patient's centre of gravity is shifted to the walking aid, the patient is able to stand with less strain.

According to Braun et al. (2017), weight-bearing therapy is based on following the instructions, which can help in using crutches for walking and standing activities and involves balancing the weight according to these instructions. Along with repetition of prior-discussed stages, crutch positioning and management constitute the therapy. The weight must be carried while in a stationary or moving position. Mohamed et al. (2019) indicated that weight-bearing therapy and exercises are essential for the health of bones and muscles and help the body function against gravity. The therapy helps the bones build themselves while getting stronger as well as gain and maintain muscle strength—crucial steps for improving balance and coordination. Researchers have emphasised the need of weight-bearing therapy for individuals recovering from autoimmune disorders, surgeries, injuries, or fractures.

1.4.1.5. Robotics used to improve mobility

A more affordable approach towards rehabilitation has been proposed based on robotics (Díaz et al., 2011; Zhang et al., 2017). This method is automated and reduces physical efforts of therapists. This approach can also evaluate the level of recovery using quantitative measures of force and movement which are otherwise impractical for patients (Díaz et al., 2011; Zhang et al., 2017). Different types of gait trainers based on robotic lower-limb rehabilitation systems have been created. Depending on the type, these may use a treadmill, footplate, stationary and overground, or ankle rehabilitation device. The system may be stationary or active foot orthoses (Díaz et al., 2011). Some robotics systems integrating the feedback from the patient have been developed in different countries such as the HAL in Japan, NeXOS in England, and the Stewart platform based on a 6 Degree of Freedom (6-DOF) parallel robot in China (Zhou et al., 2013). Most lower-limb rehabilitation robots are either exoskeleton robots such as Lokomat (Swiss), BLEEX (Berkeley), and LOPES (Holland) or end-effector robots such as Rutgers Ankle, Haptic Walker (Zhang et al., 2017). While exoskeleton robots are either treadmill-based or leg orthoses-based, end-effector robots are footplate or platform-based. Exoskeleton-based robots are mostly fixed on the human body part and show poor adaptability in different patients while the end effector robots are easier for the patients to use without restricting movement (Zhang et al., 2017). Exoskeletons are the latest technical aids that assist in movements ranging from a single joint to a complete limb (Grimmer et al., 2019). These exoskeletons improve the specific movement as well as the ADL of the patient.

The robotic devices are a boon for patients with severe mobility impairments. However, there is still a lack of commercial exoskeletons available for improving mobility in daily life. Their effective use requires more research to understand the individual needs of any patient. Furthermore, these devices are not as popular as regular assisted devices such as walking sticks and crutches due to operational hindrances (i.e., the requirement to disconnect the device for the purpose of battery-charging) (Grimmer et al., 2019). Patients with issues in balancing and leg motions benefit from rehabilitation therapy, but these therapies necessitate regular doctor appointments. These approaches are costly and time-consuming for people with mobility difficulties. Therefore, using a conventional walking aid is a more affordable option for improving the mobility of an individual (Cost Charts, 2022).

1.4.2. Conventional Walking Aids

AHPs mostly favor the use of walking aids as the first line of assistive therapy for patients with limited mobility (Sokolowski et al., 2021). AHPs commonly recommend walking aids, which assist people with mobility issues and provide them with the freedom to perform their ADL, boosting their confidence and self-esteem (Gill et al., 2017). These walking aids are particularly popular among people with physical disabilities and adults over 65 years of age, as it helps to reduce the fear of falls among patients and improve their balance by providing support to maintain balance and mobility (Jeka, 1997; Maeda et al., 2001; Bateni and Maki, 2005; Culmer et al., 2014; Jeong et al., 2015; Gell et al., 2015; Costamagna et al., 2017; Gill et al., 2017). Studies on the use of walking aids by hemiparetic patients indicate that approximately 80% of patients use at least one of the aiding devices after the stroke incident (Laufer, 2003). In a nutshell, while walking aids enhance the quality of life of an individual (Bateni and Maki, 2005), the term ‘walking aid’ has been expressed in several different ways.

Terms often used are 'mobility aids', 'ambulatory devices', or 'assistive devices'. The term 'walking aid' will be used for the remainder of this thesis.

1.4.3. Type of walking aids

AHPs do not prefer a particular type of walking aid; rather, the prescription of particular walking aids depends on the patient's condition (Laufer, 2003; Ashton-Miller et al., 1996; Lu et al., 1997). Studies have shown that patients prefer to use walking aids which support their mobility and help them towards recovery, and patients recovering from an incident generally start to regain their normal gait at even faster speeds with the use of walking aids (Allet et. al., 2009). The subsections below will detail the different types of walking aids available.

1.4.3.1. Crutches

Crutches are amongst the most basic of key walking aids. They have been in use for decades and are available in approximately 5,000 different forms (Songs, Tian and Dai, 2016). Crutches are a mechanical structure used to support individuals who require full weight-bearing support, thereby facilitating them in standing and walking. Three of the more commonly used crutches are shown in Figures 1.1 – 1.3; auxiliary crutches, elbow crutches, and platform crutches.

The standard type of crutches are the traditional auxiliary crutches (Figure 1.1), which are readily available. The major advantage of using these crutches is that it simultaneously provides 100% weight-bearing ability when used in pairs (Bradley and Hernandez, 2011). However, they can also be used as a single crutch based on the type of mobility issues with a patient. Elbow crutches are designed without the bar (Figure 1.2). Unlike auxiliary crutches, they do not put pressure under the arms; instead, pressure is exerted from the hands and wrists. Platform crutches provide a horizontal platform for the forearms (Figure 1.3), which helps in managing weight. Platform crutches are used by patients with elbow contractures or when they have painful or injured hands or wrists. (Miski et al., 2016).

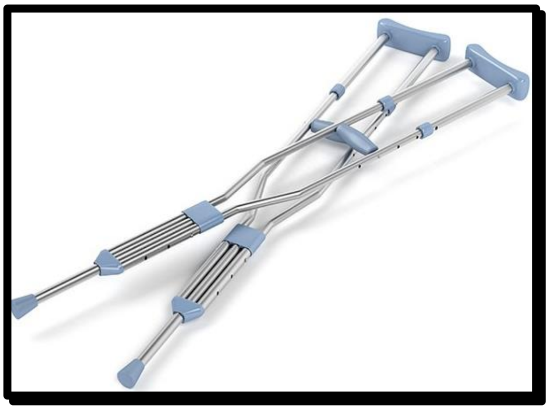

Figure 1.1: Auxiliary crutches

Figure 1.2: Elbow Crutches

Figure 1.3: Platform crutches (Source: Statewide Home, 2020)

1.4.3.2. Walkers:

Walkers help with improving the mobility of patients by providing them with weight support and balance (Bradley and Hernandez, 2011). Walkers are the second most popular walking aid after crutches, used by 2-5% of people above 75 years of age in both Europe and the US (Edwards and Jones, 1998). The use of walkers increases with age, as around 17% of users are reported to be above 85 years of age (Kaye et al., 2000). Ghosh et al. (2016) indicated that walkers provide a wide base of support to users who face walking limitations and disabilities. Two types of walkers, the standard walker and a rollator, are generally used (Figures 1.4-1.5). A standard walker is made up of foldable aluminum frame that adjusts according to the needs of its user. The standard walker can be available with or without wheels depending upon need. Walkers without wheels require lifting and movement by users while walking. In contrast, a rollator is a wheeled walker specifically designed to manage walking. It includes additional features (e.g., seat bench, handbrakes, and basket) and is often customized according to the demands of the users.

Liu et al. (2018) stated that walkers and rollators help users by providing stability when they walk. The wider base provides firm support and reduces the risk of falling. Miski et al. (2016) highlighted that a walker is recommended when the patient needs extra support for balance on both sides of the body. It is often used occasionally for moving small distances. Walkers assist in relearning to walk after injuries and surgeries. They provide support to the bones and muscles so they can heal. Further, walkers aid in the redevelopment and repairing of tissues.

Figure 1.4: Standard Walker (Source: New Leaf Medical, 2020)

Figure 1.5: Rollator Walker (Source: New Leaf Medical, 2020)

Back, shoulder, and wrist pain might come from improperly fitted walkers or rollators. Thus, therapy sessions are recommended for instruction in the correct application of such tools. An incorrectly adjusted walker can also affect the posture of the patient. Some of the limitations of walkers include the restriction of indoor usage and added care and precaution while using stairs (Bolton and Donohoe, 2019).

1.4.3.3. Wheelchairs:

Wheelchairs have existed for a long time to support mobility and are specifically designed to provide mobility from a seated position. Manual wheelchairs (Figure 1.6) are available in different types and forms; some wheelchairs can be traditionally folded. With time, advances in technology have helped in designing customized wheelchairs, including machine-operated (powered) wheelchairs (Figure 1.7), which reduce the energy required by the user to achieve movement.

Figure 1.6: Manual wheelchair (Source: Nanjing Foinoe, 2019)

Figure 1.7: Powered wheelchair (Source: Nanjing Foinoe, 2019)

Wheelchair users benefit from a combination of safety, efficiency, enhanced mobility (Braun et al., 2017). Wheelchairs lessen the potential for slips and falls, in turn lessening the likelihood of more injuries; further, many also fold up neatly and may be transported in almost any automobile. Patients who cannot bear their own weight on their legs and feet can benefit from using a wheelchair, which requires less upkeep. On the other hand, Miski et al. (2016) identified some limitations of using a wheelchair, including causing fatigue leading to pain in patients' arms and wrists. Further, moving the wheelchair on carpet, grass, and ramps requires more force, which can make accessibility difficult for patients.

Powered wheelchairs eliminate some of these issues by utilizing a motor instead of manual force. However, battery-powered wheelchairs come at a far steeper cost than their manual counterparts. Patients assisted by caretakers often prefer manual chairs overpowered wheelchairs for these financial reasons. Hence, it is important to choose a wheelchair after considering a combination of strengths, limitations, health conditions, and financial availability (Faruqui and Jaeblon, 2010).

1.4.3.4. Walking Sticks

Walking canes often referred to as 'walking sticks', are the most prescribed walking aid by health professionals globally (Gell et al., 2015). Over 4 million people use walking sticks in the USA alone (Bateni and Maki, 2005; Luz et al., 2017). In the UK, 17% of men and 25% of women who have mobility issues use walking sticks (Statistica, 2013). Gell et al. (2015) reported that about a quarter of patients use walking aids out of which 68% of the population with mild to intermediate mobility issues prefer walking sticks.

Nowadays, walking sticks are prescribed for a variety of rehabilitative applications including balance improvement, compensation for weak muscles, reduction of forces on injured joints, and improvement in ambulatory motion patterns and efficiency (Moran et al., 1995; Avelino et al., 2018). To overcome balance issues and achieve a state of equilibrium, the body's centre of mass (COM) needs to be aligned above the base of support (BOS) (Bateni and Maki, 2005). Walking sticks raise the user's base of support (BOS), enabling them to perform a wider variety of movements while imposing no additional net force on the body. Because it widens the base of support (BOS) and lessens the stress on the lower limbs, a walking stick is an essential piece of equipment for achieving biomechanical stability (Bateni and Maki, 2005; Au et al., 2008). A study revealed that stroke patients who use walking sticks often experience a reduction in centre of pressure displacement. This also reduces the load on an impaired limb and helps hip and spinal muscles (Lu et al. 1997). The use of a walking stick in peripheral neuropathy (PN) patients for improving stance and preventing falls was also reported by Ashton-miller et al. (1996). Of 20 stroke patients who used walking sticks, only 0.2% of their weight concentrated on the affected limb. Thus, the use of walking sticks substantially reduces the burden on the affected limb of the patients, helping relieve hip-joint pain (Lu et al. 1997). Patients who require partial weight-bearing therapy are also recommended to use walking sticks (Youdas et al., 2005). Proper use of a walking stick (i.e., as prescribed and advised by an AHP) ensures proper weight-bearing, as this approach is known to reduce knee pain and relieve knee osteoarthritis (OA) (Simic et al., 2011; Jones et al., 2012). Additionally, research has demonstrated that the usage of walking sticks in people diagnosed with knee osteoarthritis lowers the likelihood of knee adduction movement by 17% (Simic et al., 2011; Hart et al., 2019). Therefore, walking sticks have contributed to helping patients with mobility.

Various types of walking sticks are available: quadruped (Figure 1.8), tripod (Figure 1.9), offset (Figure 1.10), and standard single-pointed walking stick (Figure 1.11). These are all designed considering the separate needs of each patient to provide individualised support. Quadruped and tripod walking sticks consist of multiple legs and provide extra support for movement.

Contrastingly, offset walking sticks have bent shafts which help in weight distribution (Ghosh, et al., 2016)in a similar way as single-point walking sticks, sometimes referred to as standard walking sticks. Single-point walking sticks are utilised to improve an individual's balance by broadening the base of support for that person. They have adjustable lengths and foldable bodies (Inverarity, 2020). A drawback of using multi-legged walking sticks is that they must be used correctly by striking all legs on the ground simultaneously or the user can lose balance (Braun et al., 2017).

Figure 1.8: Quadruped walking stick (Source: Inverarity, 2020)

Figure 1.9: Tripod walking stick (Source: Inverarity, 2020)

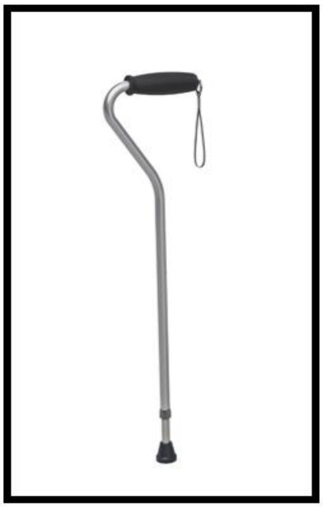

Figure 1.10: Offset walking stick (Source: Inverarity, 2020)

Figure 1.11: Single-pointed walking stick (Source: Inverarity, 2020)

While each of the four types of walking sticks has its advantages, single-point walking sticks are the most preferred as research indicates their ability to increase the walking distance of patients and allow easy change of direction while walking (Allet et al., 2009; Dogru et al., 2016; Jeong et al., 2015). One study reported that the use of single point walking allows hemiplegic patients to move with greater speed and balance (Jeong et al., 2015). Kirby et al. (1993) reported single point walking sticks to be beneficial in maintaining sway for hemiparesis patients. Single point walking sticks are particularly favorable for stroke survivors and are known to improve gait symmetry more than quadrupled walking sticks (Beauchamp et al., 2009; Perez and Fung, 2011). A walking stick with a single point is generally preferred because of its lightweight, cost-effective frame and convenience in use. As a result of the preference for and advantages provided by the single-pointed walking stick, this thesis will centre on the utilisation of the single-pointed walking stick.

1.4.4. Limitations of walking aids

Besides the many benefits of walking aids, certain limitations may hinder a patient's rehabilitation process. When a walking aid is prescribed to the patient, they are instructed about the correct usage of it. This usually involves one or more regular sessions with AHPs, where AHPs provide in-person, real-time, verbal feedback (Othrop et al., 2008). However, once a patient steps out of the clinical environment, there are no means to provide real-time objective feedback or assess the progress of the patient's rehabilitation. This is the case for all walking aids, including walking sticks, which are the focus of this thesis.

Liu et al., (2011) revealed that roughly 67% of walking stick users had not been given a prescription by medical professionals, while 82% had not been provided with adequate instructions on walking stick usage by the AHPs. In the absence of proper guidance from an AHP, problems associated with gait asymmetry and imbalance are likely to persist (Liu et al., 2011). Therefore, the correct usage of these aids is not only important for the rehabilitation process but also to prevent falls and injuries.

1.4.5. Selection of the walking aid

After reviewing the walking aids in detail, it can be concluded that each one of them has some benefits for its users; however, due to the time constraint, it was important to select a specific walking aid. Therefore, based on the most preferred and prescribed walking aid, the researcher selected a single-pointed walking stickfor this research. (Allet et al., 2009; Jeong et al., 2015; Gell et al., 2015; Dogru et al., 2016).

1.5. Biofeedback

Biofeedback refers to a therapeutic approach or procedure that can be used to learn for the purpose of acquiring greater awareness and control over one's own bodily functioning (Fong et al., 2019). Biofeedback therapy, in its broadest form, enables a patient to exert voluntary control over behaviors previously presumed automatic. This method is completely self-controlled but calls for some involvement from a qualified practitioner and high-tech equipment. The therapeutic procedure involves the use of various electronic sensors attached to different body parts for constant monitoring of the heart (blood volume pulse sensor) and breathing (respirator) rate, brainwaves waves (electroencephalography sensor), body temperature (thermistor), sweat (galvanic skin response sensor) and muscle tension or movements. Biofeedback helps patients assess their body activities and better control their physiological actions. Whether it's a flashing light, a beeping sound, a communicating AI assistant (audible), or changes shown on a sensor-connected monitor, the user receives feedback highlighting collected biological data. The user learns to regulate their responses and actions by receiving these feedback signals. This data is also shared with the trained practitioner which would assist the patient in understanding the feedback and using it to control their body function (Frank et al. 2010).

1.5.1. Working principle and types of biofeedback

The use of biofeedback has been crucial in sustaining balance (a more-or-less steady state of the body). This happens in four stages: stimulus, sensor, controller, and effector (shown in Fig. 1.12). When there is a need to control some variable, primarily as a result of significant deviation from its typical value, production of a stimulus is naturally prompted. The sensor's keep track of the variable's operating range and relay that information to the command post. Here, in the command hub, the data on the variables is checked against the expected range of values. In the event of an abnormality, the control station will alert the effector (organ, gland, muscle, etc.). The effector reacts to the command from the control center and takes corrective action to restore equilibrium. When a person's core temperature rises, for instance, nerve cells in the skin and the brain trigger an alarm. To cool down, the brain's temperature control center triggers perspiration (Alahakone and Senanayake, 2010).

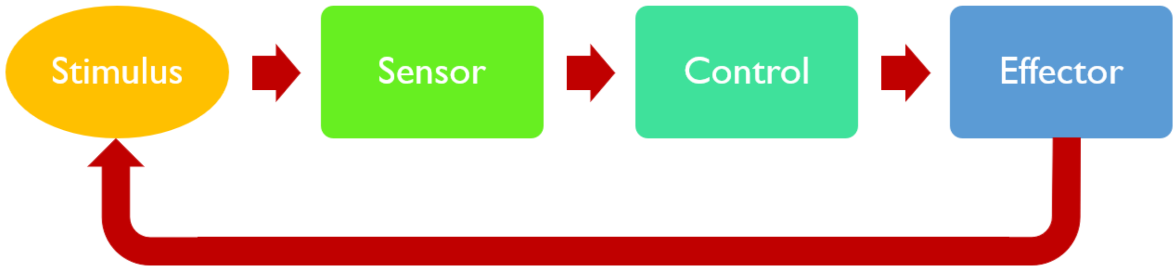

Fig. 1.12: Components of a biofeedback system for maintaining homeostasis (Alahakone and Senanayake, 2010)

Feedback, be it positive, negative, or neutral, can help the user regardless of the correctness of their response toward the stimuli. Feedback is mostly considered to be influencing learning. The use of negative feedback in the context of evaluating human performance is a widely accepted tactic used by counselors and educators alike. In one instance, negative feedback is described as, "When some functions of system output, any process/mechanism is provided back (fed back) in such a way that it reduces output fluctuations which can be caused by disturbances and input changes" (Fong et al., 2019).

Providing facts about one's shortcomings can enlighten users and patients towards greater gains and strive hard to attain better performance. The goal of delivering negative feedback about performance is to improve the user's or patient's cognitive learning behavior. By updating patients on their progress and any setbacks they may have experienced, therapists can spark a discontent response in their patients, which can then be used as a motivating inducer for increased precision in their efforts. Negative feedback helps patients to keep track of their behavior to attain recovery goals (Fong et al., 2019).

Negative feedback works the same way as sensors, which collect data and information about patients' activity, walking aid usage, and performance, and then send the gathered information to the processing unit. Subsequently, the processing unit provides feedback (sensory, auditory, or visual) to the user or therapist. The effectiveness of the feedback loop is determined by the clarity of the user's comprehension of the stimulus and the effectiveness of their response to that stimulus.

Biofeedback Signal Delivery

A feedback event occurs when the system's output is fed back into the system as an input, completing a feedback loop. Whereas biofeedback refers to a set of therapeutic treatments that use electrical or electromechanical devices to monitor and offer patient with information on their own physiological responses in the form of visual, aural, or tactile signals (Alahakone and Senanayake, 2010). The basic principle of gathering data or information from a biofeedback system is a bit complex and depends upon the context of usage to a greater extent.

For many years, observation and evaluation-based scoring systems were used to make assessments about falling risk in patients. While effective in clinical settings, tracking the timing and orientation of walking-stick insertion outside of sessions was difficult due to a lack of standardised instruments. Thus, it was of the utmost need to develop an embedded system in walking sticks capable of monitoring improper use of gait assistive devices. To determine if the user is employing the walking stick appropriately, feedback plays a significant part in the design of smart walking sticks. Feedback is important not only for users but to help therapists better grasp where the patient is struggling to use the walking stick and provide instructions accordingly (Boyles, 2015). Measurements of acceleration, angular velocity, and body mass could be gathered outside of clinical settings as part of an integrated biofeedback system. The therapist then could use this activity analysis to monitor the patient's healing (Sack, Schleu and Knarr, 2012).

Various factors are responsible for feedback success including:

- Accuracy and sensitivity of sensing components gathering biological information (body functioning, parameter, or activity of interest).
- Advanced software that can process the information precisely.
- Acquiring relevant feedback information with noise cancelation.
- Integrating appropriate feedback type.
- Sending feedback to appropriate modality.
- Translating feedback to an understandable format for the user/patient.
- Ensuring minimum cognitive load on the patient (Kos and Umek, 2018).

Mode, context, frequency, and timing are the four primary modules of a biofeedback signal transmission system, each with its own set of potential applications. By rearranging the order of these modules, clinicians can tailor the resulting biofeedback designs to meet the specific needs of their patients. The elaboration of the above components is as follows:

(i) Mode which can be visual, auditory, haptic (based on the sense of touch), ora combination of all (i.e., multimodal displaying two or more for the same variable simultaneously). By integrating these modes, biofeedback can be provided to the patients in direct ways such as a numerical direct measurement of range of movement, or it can be presented in more technical ways with graphical presentation.

(ii) Feedback context is the information surrouding the results of a patient's performance in the rehabilitation process. It may include specifics such as accuracy of body movement performance or how many times they completed a biofeedback therapy session. It gives a detailed account of mistakes and how best to rectify them.

(iii) Feedback frequency refers to the repetitions required for complete rehabilitation in the process of patient recovery. Frequency can remain constant and increase with each day or be applied in a decreasing manner depending upon the therapist's recommendation and patient needs.

(iv) Timing feedback can be provided once the practice or exercise session is over or concurrently and continuously during the session (Brennan, Zubiete, and Caulfield, 2020).

Physical therapy for post-injury or post-disabling rehabilitation demands patient cooperation and close observation. The user is the best source of information about the effectiveness of any assistive device. However, until the next scheduled session with the AHP, real-time monitoring and analysis of the patient's walking stick usage remain unreported. Therefore, without biofeedback, continuous monitoring of patient adherence to recommendations and proper usage of the walking stick is not possible. The use of biofeedback technology and methods in the rehabilitation process was first reported about three decades ago in the context of patients suffering from an injury (Tate and Milner, 2010). Hence, if the use of a walking stick in rehabilitation therapy is supplemented with biofeedback, it may enhance the patient’s ADL.

Researchers frequently employ haptic, visual, and aural feedback in their suggested systems.

1.5.1.1. Haptic feedback

Haptic feedback involves the use of advanced vibration patterns and waveforms to communicate information with the user. The typical way to demonstrate haptic feedback is by using vibration to convey important feedback messages. Haptic feedback is widely used in human rehabilitation, including gait analysis, motor learning, and gait retaining for the treatment of knee osteoarthritis (Rodrigues et al., 2019). Haptic feedback is preferable because it does not distort sounds coming from surrounding areas crucial for non-visual navigation. Further, touch is a natural channel for information about surrounding objects. Considering the proven benefits of using haptic feedback, it can potentially be integrated with a walking stick (Ahlmark et al., 2016). Haptic feedback is generally produced by using vibration actuators. There are two types of actuators generally used in haptic feedback: eccentric rotating mass (ERM) actuators,also known as unbalanced electric motors, and linear resonant actuators (LRAs), also known as mass-and-spring systems (Ahlmark et al., 2016).

The advantages of haptic feedback are:

- Haptic feedback can be used for individuals with auditory and visual disabilities. (Sorgini et al., 2017)
- It does not interfere with the audio from the surroundings (Ahlmark, 2016).
- Simple haptic feedback is intuitive (Lurie, 2011).

The disadvantages of haptic feedback are:

- Conveying detailed instructions through haptic feedback is very difficult, necessitating significantly more training for users (Ahlmark, 2016).
- Implementation of haptic feedback is costly (Rausch et al., 2012).

1.5.1.2. Visual Feedback

Visual feedback, also known as optical feedback, involves visual output from a device. Visual feedback is given to the patient as their centre of gravity, stability, and static balance are all measured by standing on a pressure plate. If the patient moves their body in front of a screen, they can view an image of their movements on the screen. Rehabilitation programs greatly employ visual feedback which proved to be very effective for rehabilitation. Stroke survivors managed to learn their symptoms with the use of this visual biofeedback by stimulating their proprioceptive information. Hence, companies are developing advanced biofeedback resources for physical training e.g., Nintendo® Wii Fit®, integrate play activities for balancing and active body movements and displays results on screens. Real activity-based VR technology encourages intense training, provides 3D feedback (visual, haptic, and auditory) via computer-generated scenarios, and trains patients for proper task executions (Barcala *et al.*, 2013).

Mirroring virtual feedback in therapeutic settings is said to hasten the functional recovery of patients who suffer from neurological illnesses (hemiparesis caused by stroke and brain injury or lesion (Ramachandran and Altschuler, 2009).

Virtual feedback design must incorporate some important factors

- Multiple low to high-intensity exercises
- Gamification-based feedback
- Performance evaluation scoring
- High-frequency real-time feedback

Further research in virtual augmented feedback is needed to attain the potential effects on patient recovery and motor rehabilitation function. Therefore, it is important to identify the various parts of the active intervention and learn the underlying physiological mechanisms that contribute to the positive clinical results observed after treatment. (Kearney *et al.*, 2019).

The advantages of visual feedback are:

- Rehabilitating stroke patients with the help of visual feedback has been proven to be more effective since it leads to improvements in postural sway (Walker et al., 2000).
- Visual feedback is helpful in real-time monitoring during rehabilitation (Coppus, 2011).

The disadvantages of visual feedback are:

- Visual feedback is often limited to the clinical environment, which is a non-living environment (Rayl and Fiedler, 2021).
- Incurs a high setup cost (Rayl and Fiedler, 2021).

1.5.1.3. Audio Feedback

Voice is utilized in the process of communicating with the user as part of audio feedback. It is the most common technique of feedback for communicating complicated facts and information and has a wide range of applications in rehabilitation (Ahlmark, 2016).

The advantages of audio feedback are:

- Audio feedback is helpful for both patient and instructor. Patients who received audio feedback followed the instruction more conveniently (Mercado et al., 2014).
- Masiero et al (2007) reported that audio feedback is useful in maintaining a high level of patient attention during rehabilitation.

The disadvantages of audio feedback are:

- Continuous auditory feedback can be very distracting and annoying for sensitive users (Ahlmark, 2016).
- Audio feedback is not useful in noisy environments (Fu et al., 2014).

1.5.2. Biofeedback in physical rehabilitation

Biofeedback has been used in physical rehabilitation for the past 30 years and facilitates restoring normal motion patterns after injury (Tate and Milner, 2010). It provides valuable, real-time information to the concerned patients. This information is divided into two types: augmented (extrinsic) feedback and sensory (intrinsic) feedback. Augmented feedback provides the user with added information via visual or auditory aid. By tapping into a device or data recorder that already contains biofeedback data, information can be gleaned for use in augmented biofeedback. However, sensory feedback conveys intrinsic data collected via various sensory receptors. Sensory feedback is internal feedback from the human body which utilizes visual and vestibular mechanisms (Giggins et al., 2013) and incorporates feedback that can be seen or heard, like visual displays or buzzing sounds.

Enabling access to biofeedback mechanisms for patients and clinicians during the rehabilitation process is likely to be a game-changer, making it easier for patients to manage the physical process of rehabilitation (Zhang et al., 2010). In addition to this, it will result in a more effective performance of functional tasks and an improved level of patient participation while simultaneously lowering the need for healthcare specialists to oversee and keep tabs on the implementation of rehabilitation programs (Giggins et al., 2013).

1.5.3. Categories of biofeedback

There are four categories of biofeedback: neurological, biochemical, biomechanical, and physiological biofeedback. These four feedback types are collected by various sensors. Physical rehabilitation prioritizes biomechanical and physiological feedback.

1.5.3.1. Biomechanical biofeedback

Biomechanical biofeedback requires the measurement of motion, postural control, and different body forces. Inertial and pressure sensors, electrogoniometer and force plates, etc. are employed in biomechanical feedback units to track posture, movements, and body forces (Giggins et al., 2013). When compared to other types of feedback, biomechanical sensors are significantly more complicated since they use a variety of sensors and feedback at the same time. Additionally, biomechanical sensors require specialized clinical conditions. For example, the pressure biofeedback sensing unit tracks muscle activity and delivers helpful biofeedback insights during therapy. Muscle activity is tracked with the help of an inflatable cushion linked with a pressure gauge. These output readings report muscle contraction and relaxation movements. Body force and postural control feedback are tracked by force plates. Joint kinetics, body functional movements, and associated tasks are measured by electrogoniometry which provides real-time feedback to patients as well as the therapist. Studies demonstrated that biomechanical feedback significantly reduced knee hyperextensions as compared to conventional physiotherapeutic approaches. Gait speed and posture improvements were also observed during biofeedback (Owen, 2013; Sardini et al., 2015). Biomechanical biofeedback plays a crucial role in physical rehabilitation (Malik and Dua, 2020). Furthermore, biomechanical feedback expedites the speed of motor skill learning during physical rehabilitation (Colborne et al., 1993). This thesis will focus on biomechanical feedback as it is the most appropriate type. This section further details various types of biomechanical biofeedback measurement devices.

1.5.3.2. *Inertial sensors*

Inertial measurement systems use accelerometers, gyroscopes, and/or magnetometers and are generally used to measure the orientation, linear motion, and rotational movements of the body in 3 dimensions (3D). Accelerometers, along with gyroscopes in these inertial sensors, obtain 3D kinematic data of the targeted body part, such as velocity and orientation. The function of the accelerometers is to calculate acceleration and gravitational force while gyroscopes are used for measuring angular velocity (Schepers, 2009). The parameters of inertial sensors act as input to the specific feedback system, providing audio and visual feedback to patients. Inertial sensors are useful for balance and motion due to their relatively small size (Giggins et al., 2013).

Various studies have shown positive results with inertial sensors based on biomechanical biofeedback in physical rehabilitation. Davis et al. (2010) reported that people of all ages (i.e., both young and elders) can significantly reduce their trunk sway (tilt of the body during a walk) through biomechanical biofeedback. Meanwhile, Doza et al. (2005) evaluated the benefits of using an audio biofeedback system involving accelerometer sensors to improve postural balance and recover bilateral vestibular damage. This study showed favorable results of using an audio biofeedback system as it improves the participants' balance significantly by minimizing postural sway (see Figure 1.12).

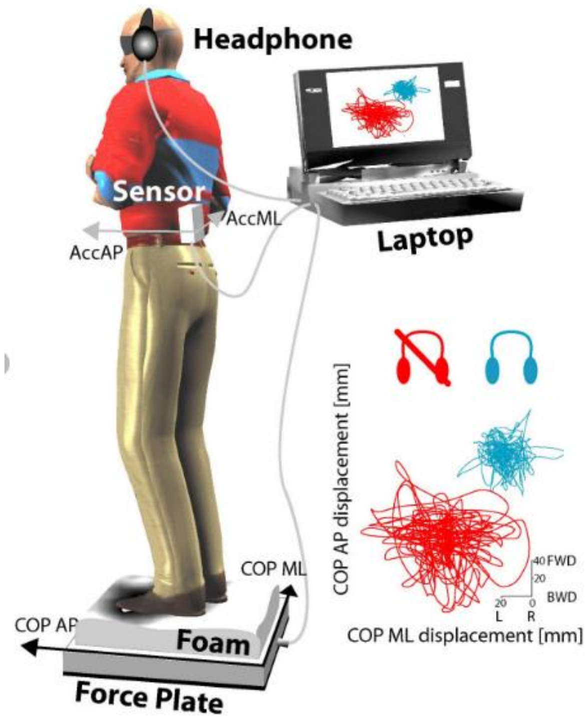

Figure 1.12: Audio biofeedback system (ABF) and protocol (Doza et al., 2005).

1.5.3.3. *Electrogoniometery and flexible electrogniometery*

Electrogoniometery helps in the evaluation of joint kinematics in two dimensions (2D) while performing functional tasks and various movements by providing real-time feedback to therapists and patients (Giggins et al., 2013).

Morris et al. (1992) compared the effectiveness of using the electrogoniometers biofeedback technique with traditional physiotherapy to deal with genu recurvatum in patients who suffered from a cerebrovascular accident (CVA). According to the findings of the research, patients treated with kinematic biofeedback exhibited a significant reduction in the number of knee hyperextensions over the course of treatment. On the other hand, the outcomes were not nearly as promising for patients who received traditional physiotherapy as their main form of treatment (Morris et al., 1992). With recent technological advances, reliable electrogoniometers and flexible modified systems are now available (e.g., computerized biofeedback knee goniometer; Figure 1.13) which are reported to reliable and accurate (Shamsi et al., 2019).

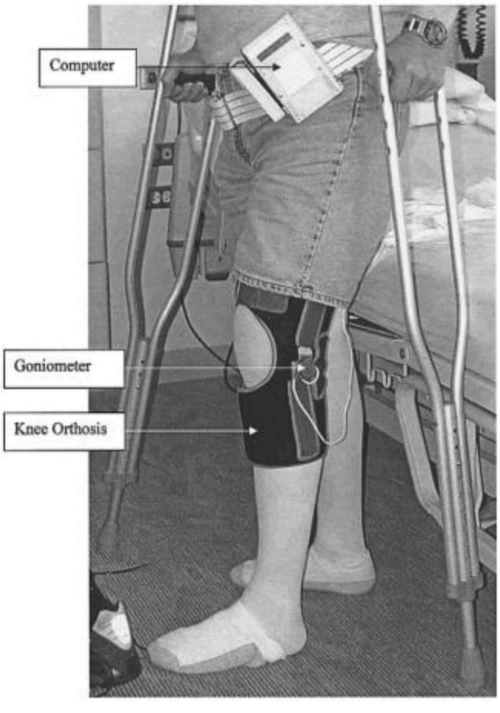

Figure 1.13: Computerised biofeedback knee goniometer (Pfeufer et al., 2019).

1.5.3.4. *Force plates system*

Force plate systems calculate the ground reaction force (GRF) produced by the human body and are useful in providing feedback regarding balance, body motion, or gait (Lake et al., 2018). To obtain feedback, the GRF is used as an input to the specific visual display which varies as the force changes. Various experiments were conducted which provided that the force plate system is used to improve patient balance while standing (Ma et al., 2016). Patients undergoing CVA rehabilitation can benefit from the use of force plates which have been shown to be helpful in biomechanical biofeedback systems. This helps patients improve their balance and symmetry. Moreover, studies have shown that visual biofeedback exercises with the help of a force plate system is a productive way of achieving symmetrical posture following CVA (Ma et al., 2016). From seven arbitrary trials, Barclay et al. (2014) revealed that force platform biofeedback is effective in improving stance symmetry.

1.5.3.5. Pressure Biofeedback Unit

A Pressure Biofeedback Unit (PBU) is a useful biomechanical biofeedback tool used in retraining normal muscle functioning and provides necessary visual biofeedback during rehabilitation. It utilizes an expandable cushion attached to a pressure gauge to provide feedback on muscle activity. Advantages of PBUs include low cost and easy use in clinical settings (Giggins et al., 2013). PBUs are frequently used to find the exact contraction of the muscles present in transversus abdominis while performing the abdominal hollowing training. Cairns et al., (2000) evaluated abdominal muscular dysfunction in patients with lower back pain (LBP) and showed that use of PBU helped in lumbar spine stabilization, which increases gluteus medius and oblique activity. The information obtained from the PBU was essential in the patient's progression toward relief from lower back discomfort. Utilizing PBUs comes with several benefits, but it also has a number of drawbacks. Lima et al (2012) reported low accuracy of PBUs in measuring muscle activity while executing the voluntary contraction maneuver in patients suffering from nonspecific chronic low back pain.

Figure 1.14: A Pressure biofeedback unit (PBU) (Lima et al., 2012).

1.5.3.6. Physiological biofeedback

Physiological biofeedback involves monitoring the individual's physiological state and feeding information back to them (Peira et al., 2014). This section further details various types of physiological biofeedback techniques.

1.5.3.7. Neuromuscular biofeedback

Neuromuscular biofeedback is achieved by measuring either one or both neuromuscular systems: the nervous system and the musculoskeletal system. This helps patients increase activity in weak or paralyzed muscles. Furthermore, neuromuscular biofeedback has been reported to help patients retrain and rehabilitate the pelvic floor muscles (Giggins et al., 2013).

1.5.3.8. Cardiovascular biofeedback

Two types of cardiovascular measures are generally used to acquire real-time biofeedback: heart rate (HR) and heart rate variability (HRV). These methods have proven useful in controlling the blood pressure and treating asthma (Ahuja N, et al., 2004; Giggins et al., 2013).

1.5.3.9. Respiratory biofeedback

Respiratory biofeedback works by evaluating a patient's breathing using sensors connected to the abdomen. The breathing process is then translated into an audible signal through transducers. Respiratory biofeedback is reported to be useful for treating migraines (Kaushik et al., 2005).

1.5.4. Applications of biofeedback

Various disorders exist where biofeedback is used as a part of treatment. A few considerable applications of the biofeedback are cited below.

1.5.4.1. Rehabilitation of limb activities following stroke

Biofeedback is very useful in rehabilitation of limb activities particularly in people with a history of stroke. The use of biofeedback to augment feedback has been shown to be significantly more effective than the commonly used placebo therapy in enhancing lower limb movement and function following stroke (Stanton et al., 2011). The feedback mechanism helps patients use their limbs within certain boundaries prescribed and advised by AHPs. The patient can only ensure this based on the information delivered by feedback mechanisms.

1.5.4.2. Neuromuscular rehabilitation

Biofeedback therapy is used frequently in treating neuromuscular disorders by interpreting factors such as electrical brain activity (Figure 1.15). EMG biofeedback when used in conjunction with relaxation therapy has proven effective in treating spasmodic torticollis for years. In this technique, the individual undergoing rehabilitation is instructed to intentionally relax the muscle and increase the EMG action in the muscle group on the opposite side (i.e., opposite side to the spasm) (Sattar and Valdiya, 2017). This technique is also useful in the treatment of low backache and various other neuromuscular diseases like spinal cord injury, Parkinson's disorder, tremors, and cerebral palsy (Sattar and Valdiya, 2017).

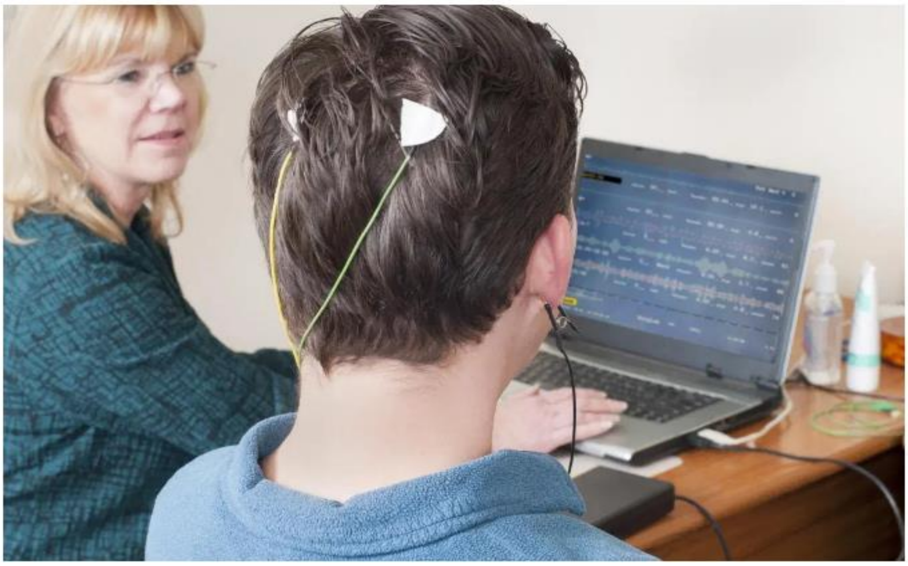

Figure 1.15: Biofeedback in Neuromuscular Rehabilitation (Nordqvist, 2018).

1.5.4.3. Headaches

After pharmacological treatment, biofeedback is the most popular treatment option to treat headaches. For more complex headaches, including migraines, the following options are recommended:

1. Thermal biofeedback
2. Biofeedback training to better manage the vasomotor activity
3. A combination of thermal biofeedback and autogenic training

The third option is considered as the most effective in treating migraines as the success ratio is as high as 70% (Strobel, 1985).

1.5.4.4. Gastrointestinal

The most widely used application of biofeedback is in the treatment of gastrointestinal disorders, particularly faecal incontinence. Faecal incontinence can be treated with biofeedback by showing the patient how rectal distension looks and then having them flex their outer sphincter in response. If the patient has successfully performed the action, they will receive feedback. Treatment continues until the patient can successfully contract the outer sphincter with a lower amount of stimulation. Another study has shown varying results; however, 72% of patients on average reported a decrease in the occurrence of faecal incontinence with biofeedback treatment (Sattar and Valdiya, 2017).

1.5.5. Benefits of biofeedback

There are various benefits to using biofeedback in physical rehabilitation. For example:

- Biofeedback therapy helps patients better control desired parts of the body to improve mental and physical health (Frank et al., 2010).
- Since biofeedback does not involve any medication, it has no medicinal side effects in physical rehabilitation (Frank et al., 2010).
- Biofeedback therapy helps improve patient gait (Ma Zheng et al., 2017).

1.6. Biofeedback Stick Technology

It has been established that walking sticks, which play a crucial role in offering support to people with mobility and balance issues, are the most prescribed and preferred walking aid by the AHP and mobility aid users. However, walking sticks still have certain limitations, notably that they do not alert the user upon incorrect usage (discussed in the section 1.5). This could potentially hamper the rehabilitation process and lead to injuries if left unaddressed. However, in the last two decades, biofeedback mechanisms have been widely used to enhance users' sense of agency and, by extension, their quality of life (Giggins et al., 2013). Considering the limitations of the current walking stick and the benefits of the biofeedback mechanism, this thesis presents a combination of the two (i.e., biofeedback mechanism and the walking stick), emphasizing current research on incorporating biofeedback technology into walking sticks. Researchers have been diligently working over the past decade to incorporate and improve the biofeedback mechanism that is already present in walking sticks by using a combination of different sensors. This has been done to make walking sticks more accessible to people with disabilities. These proposed sticks host a variety of sensors and self-contained feedback systems. (Citations listed in table 1.1). After conducting an in-depth literature review on biofeedback supported sticks, four critical fundamental qualities were identified and highlighted. These features served as the basis for comparing the various sticks. Weight-bearing, orientation, step count, and real-time feedback were some of the properties that were compared across a variety of sticks. These features, along with their references, can be found listed in table 1.1. As they are essential factors for comparative analysis of walking sticks, these features will be covered in the following parts.

Table 1.1: Investigations concerning the creation of a "Smart Walking Stick"

S. No	Researcher	Weight-Bearing	Orientation	Step Count	Feedback	Targeted User
1	Moran et al., 1995	✓	—	—	Audio	—
2	Wu et al., 2008	—	✓	—	Visual (GUI screen on the PDA)	Disabled and Elderly People
3	Culmer et al., 2014	✓	✓	—	Visual (GUI screen on the PDA)	—
4	Mercado et al., 2014	✓	✓	—	Audio	—
5	Vidal-Verdu et al., 2015	✓	✓	—	Audio	—
6	Wade et al., 2015	✓	✓	—	—	—
7	Laohapensaeng et al., 2015	✓	—	—	Audio	Stroke Patients
8	Rouston et al., 2016	✓	—	—	Haptic	Knee Osteoarthritis Patients
9	Gill et al., 2017	✓	✓	—	—	Elderly People
10	Val et al., 2017	—	✓	✓	Audio (via GUI)	Disabled and Elderly
11	Hall et al., 2018	✓	—	—	—	Knee Osteoarthritis Patients
12	Dang et al., 2018	—	—	✓	—	Elderly People
13	Wade et al., 2018	✓	✓	—	Haptic	Elderly People
14	Ballesteros et al., 2019	✓	—	—	—	Elderly People
15	Fernandez et al., 2020	✓	✓	—	—	Elderly People

The literature that is relevant to the foci of the study is outlined in Table 1.1, and a more in-depth explanation of the research's scope as well as its limitations will be provided in the following section. A method for measuring the axial walking stick forces during walking was devised by Moran et al. (1995). Ten people were given a walking stick with built-in acoustic feedback. Their research proposed a method whereby the user might exercise command using auditory cues. Walking stick load feedback was discovered to affect both peak walking stick forces and total duration of contracts. On the other hand, they found that the audio output did not affect mean cadence, speed, or stride length. However, there were power consumption issues with this system as the battery was only lasting 3 hours. Wu et al. (2008) further worked on building an intelligent walking stick system that uses commercially available microsensor, computing, and wireless technologies. The purpose of this research was to find ways to prevent potentially fatal falls among the elderly. In addition, they demonstrated how their system collects and makes use of data derived from patient interaction. The authors suggested centralised monitoring of this information by several authorities through merging this data with a telehealth system model. However, more people were needed to complete the study so that statistical models could be developed to advise users toward safe usage to improve stability and reduce falls. Culmer et al. (2014) developed the iWA (instrumented walking aid) system to assess the kinematic and kinetic properties of walking aid usage. The information gathered can subsequently be used to help users adjust their gait. Based on their findings, it was determined that measuring the weight of a person's walking aid is a reliable way to assess the phase when the primary axis of motion is the pitch. There was a need for larger user testing, hardware simplification, and higher performance scores to achieve these aims. Mercado et al. (2008) worked towards physical rehabilitation, particularly walking stick therapy. Like Moran et al., they developed an audio feedback walking stick system which corrects the patient if an incorrect load is applied on the walking stick. However, in their case, the system does include a graphical user interface to gather offline force measurement data for therapists. The system also had wireless capacity along with Bluetooth technology. The microprocessor, load sensor, three-axis accelerometer, and buzzer were all built inside the walking stick. The authors draw the conclusion that using auditory cues to guide movement helps people perform better under load. However, the design was too cumbersome, and more space should have been spent eliminating unnecessary wire components from the hardware. Vidal-Verdu et al. 2015 proposed a tactile sensor-based handle design for walking stick usage monitoring along with grip force tracking. The handling capacities of ten subjects using the walking stick were evaluated. Again, the data gathered can inform on walking stick usage and detect misuse. However, the design was wired, limiting the walking distance.

To develop a new-age walking stick, Wade et al. (2015) used a custom-made, low-power, highly modular microelectronics system embedded in the walking stick itself. Their design could not be distinguished from other regular walking sticks as they used rapid prototyped parts of the handle and the base. Data logging and consequent analysis could be done wirelessly to a PC application through their design. However, there were two major concerns in their proposed prototype. The concept was only evaluated for straightforward activities like walking. Secondly, no system to recognize falls or near-falls, which could drastically improve usage, was installed. Laohapensaeng et al. (2016) combined a gait analyser and the iWalking stick to develop a practice walking stick for stroke survivors. The former provided maximum force applicable on the walking stick while the latter offered audio feedback on excessive force. In addition, the feedback from two stroke patients who used the walking stick as part of their rehabilitation intervention, reported positively on their overall recovery and well-being. Regrettably, this study had fewer patients and lacked specificity in statement. Rouston et al. (2016) focussed on symptomatic knee osteoarthritis and suggested that 15% body weight force on the walking stick can reduce the progression of osteoarthritis. Vibrotactile biofeedback was integrated into their walking stick design to encourage walking stick loading. According to the findings, the smart walking stick was able to support about 18% more weight than a conventional walking stick guided by vocal commands. Nonetheless, no new information about falls or their prevention was supplied.

With the advent of better and more economical computing power, more smart walking sticks are being developed. Gill et al. (2017) designed a novel multi-sensor-based IoT-enabled assistive device. This design was clearly an improvement over all previous designs in terms of affordability and data monitoring. The walking stick also caught gait irregularities, pathologies, or modifications over time. The IoT technology made remote monitoring and intervention by caregivers possible. However, the weight of the developed assistive device was heavier than the previously developed systems, causing difficulties for the elderly users. Val et al. (2017) included accelerometers and magnetometers in their design and linked them locally via an application. Using an external application, their walking stick could calculate the distance travelled and visualize the real-time state. However, the walking stick did not have detection and prevention of any falls or irregularities. Hall et al. (2018) studied knee pain patients using a regular walking stick and a walking stick with an embedded lightweight uniaxial load cell and data logger. The application was economical and included no advanced wireless communication devices. It was shown that the walking stick off-loading increased immediately by 2.1% following a brief and straightforward training session with proper training. However, more prolonged and frequent training was not conducted under different gait conditions.

There are several studies assessing various aspects related to walking stick usage. Dang et al. (2018) attached inertial sensor units to multiple positions on the walking stick to estimate the walking distance and build an algorithm. The inaccuracy given by their algorithm for the benchmark walking stick was 1.27 percent. However, no out-of-the-ordinary circumstances were considered; therefore, the error rate may rapidly fluctuate under those conditions. Ballesteros et al. (2019) proposed a cheap alternative for load monitoring as a screening tool. Their design was simple and rugged enough to be installed on any regular walking stick without disturbing the design. The data generated (load analysis) by this system was used to correct gait, treatment interventions, and fall prevention in patients. The current Bluetooth setup operates with a larger pairing time and lesser battery backup. However, the sample size was less, and more tests are needed to be carried out under different operating conditions for evaluation. Wade et al. (2019) installed internal, force, and ultrasound sensors for the non-invasive data collection on a regular walking stick to examine the automatic characterization of functional mobility using an Instrumented Walking Stick System (ICS). Their module gathered patient information and identified those at low and high risk for falls. With a large data size, the system may be able to repeat and generalise their predictions and analyse the gait of older patients. Fernandez et al. (2020) developed a real-time fall-free feedback system using an inertial sensor-laded walking stick. The sensor collects inertial data and suggests contact phase and orientation to prevent patient falls. A convolutional neural network evaluates the contact phase in their design. The test subjects were young with no ailments. Hence, the results would be more reliable with older and unhealthy patients. The duration of the tests was also limited, leaving room for improvement in terms of their ability to foretell future gait patterns.

1.6.1. Weight-bearing

One of the methods to evaluate a patient’s health and recovery during rehabilitation is “weight-bearing”. It plays a vital role in convalescence of patients recovering after injury or surgery. After surgery, weight-bearing is used to fix fractures and restore ripped tendons (Anderson and Duong, 2019). Weight-bearing can be either full or partial, however, partial weight-bearing walking sticks are the most recommended (Youdas et al., 2005; Eickhoff et al., 2020). In partial weight-bearing, 10 – 40% of the bodyweight is allowed to be carried by the injured part of the body while the rest is supported by the walking stick (Pierson et al., 2002; Eickhoff et al., 2020).

The two most common methods to measure partial weight-bearing in clinical practices are bathroom scales and force plates (Figures 1.16 and 1.17; Graham et al., 2015). The bathroom scale is useful in measuring the weight-bearing during the static condition only while the accuracy is poor during mobility. On the other hand, the force plate scale is equally good in measuring weight-bearing in both static and mobile conditions of the patient. (Graham et al., 2015).

Figure 1.16: Bathroom scale

Figure 1.17: Force plate

In clinical practices, partial weight-bearing is also performed by using scales such as Tinetti Mobile tests (Ballesteros et al., 2019). In this scale, experts observe the patients to perform various balancing and gait tasks and take manual readings. However, this process is tedious for patients and therapists alike. To mitigate these drawbacks, wearable sensors, like force or pressure sensors, have been proposed (Ballesteros et al., 2019).

Partial weight-bearing is an important aspect of gait rehabilitation and generally considered focal during studies (Table 1.1). Among these, many studies have proposed using built-in force sensors such an FSR (force sensing resistor) or load cell, since the total load on a stick is a good way to measure partial weight-bearing (Ballesteros et al., 2019). It is calculated by evaluating the difference between the weight of the patient and the load on the stick (Ballesteros et al., 2019). This helps determine the load a patient can tolerate on the affected body part (i.e., the arm or leg).

1.6.1.1. Types of sensors used in weight-bearing

Two types of force sensors are mostly used by researchers to measure weight-bearing. These sensors are FSR and load cells where both types have distinctive applications and limitations.

1.6.1.2. FSR sensor

FSR sensors are devices that measure the force applied to their active surface (Figure 1.18). With no contact on the active surface, the resistance of this sensor remains high. The decrease in the resistance is exhibited with applied force on the active surface as it is then calibrated to give a meaningful value. (Ada, 2012; Sadun et al., 2016). Some of the advantages of using these FSR sensors include:

- Cost-effectiveness.
- Low power consumption.
- Flexible and thinner construction (easy to deploy) (Giovanelli and Farella, 2016).

Figure 1.18: An FSR sensor (Picture credit: Ada, 2012)

1.6.1.3. Load cells

A load cell functions by causing the strain gauges, arranged in a wheat stone bridge configuration, to distort under exertion of force. The strain gauge interprets the force applied as a change in electrical resistance and outputs a voltage proportional to this change. As the magnitude of stress that a load cell must face is lower than the material's limits, these electrical signals are amplified to utilize the data (Boyles, 2015).

A load cell consists of various components including the strain gauge and spring element (Figure 1.19). A strain gauge is a thin foil resistor that acts as the central sensing element in the load cell. The resistance in the strain gauge varies proportionally with the deformation in the spring element. Here, the strain is deformation in the material subjected to stress. Additionally, stress is the force acting on the material's per-unit-area basis. Changes in electrical resistance occur when stress is applied to conductors. The electrical resistance will vary more noticeably under greater stress (Muller et al., 2010).

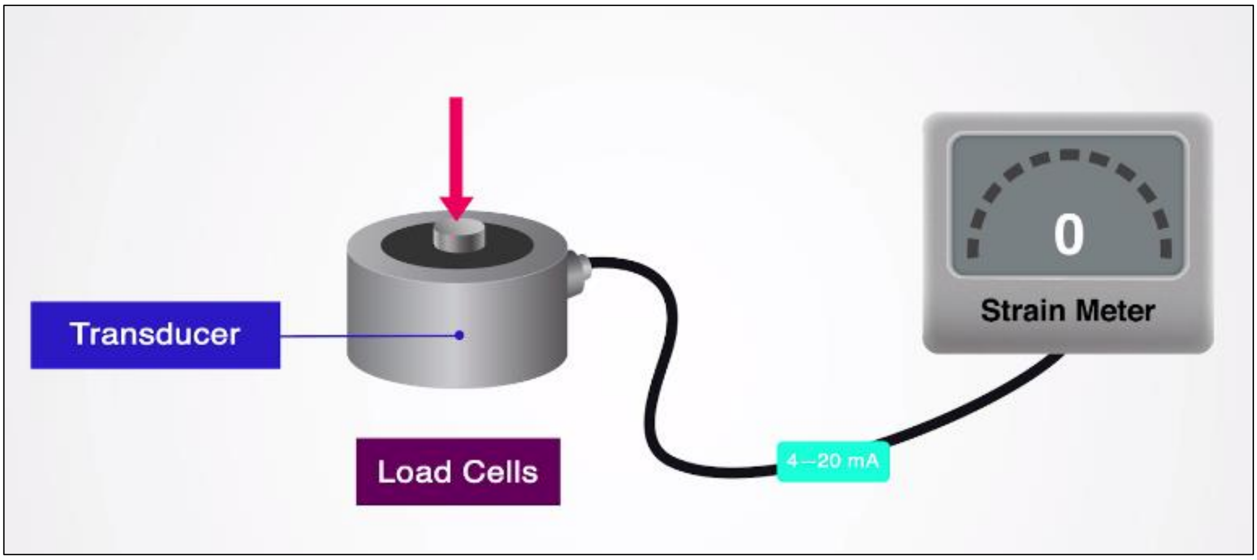

Figure 1.19: Load cell setup to measure force (Prielipp, 2019).

Due to higher accuracy, load cells are the most used sensors in the smart walking aids (Omega et al., 2020). Some of the advantages of load cells include:

- Accuracy and reliability
- Insensitivity to temperature variations (robust)
- Increased range to measure force (Muller et al., 2010; Msbte, 2019).

An overall comparison of the FSR and load cell sensors is provided in Table 1.2.

Table 1-2: The comparison of the FSR and Load cell sensors

Sensor	Applications	Limitations	Authors
FSR (Force Sensing Resistors)	Used for measuring the force applied for weight-bearing	Low precision Drifting, hysteresis and nonlinearity issues. Limited force measuring range.	Lawrence, et al., 2008; Leon, et al., 2015; Ballesteros et al., 2019; Routson, et al., 2020
Load Cell	Used for measuring the force applied for weight-bearing	Solid-body construction, thus less flexibility Only measure axial forces.	Moran, et al., 1995; Muller et al., 2010; Culmer et al., 2014; Wade, 2015; Sack et al., 2017.; Hart et al., 2018; Msbte, 2019

1.6.1.4. Position of the sensor

Choosing the right position of the sensor on the walking stick is equally important as selecting the right type of sensor. Three locations of the walking stick were commonly used by researchers in placing the force sensor: handgrip, upper shaft, or at the lower shaft & tip (Figure 1.20). All locations have individual advantages and disadvantages (Table 1.3).

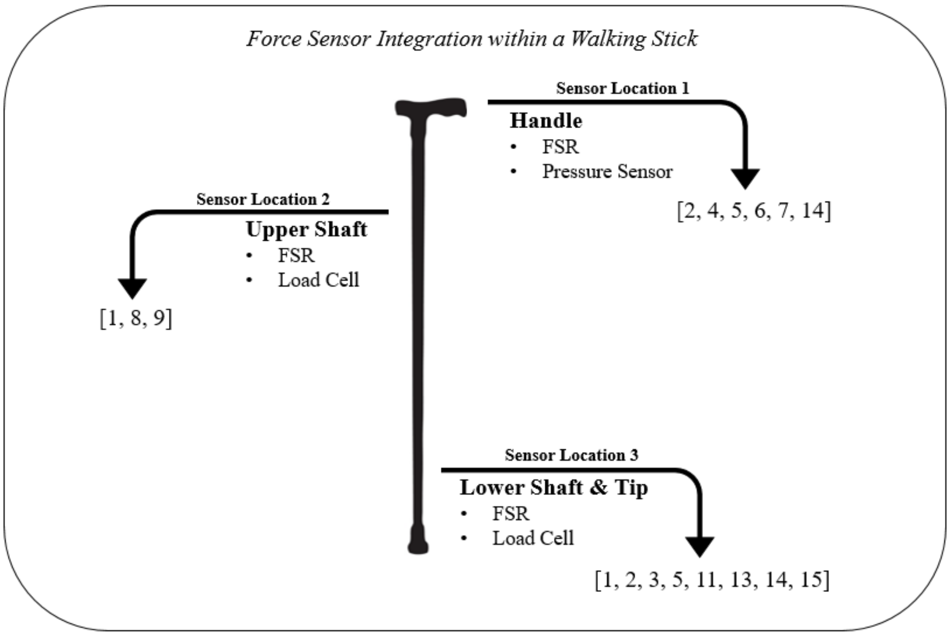

Figure 1.20: Location of the placement of force sensors. The numbers in the parentheses refer to the number of studies that have preferred to choose each placement of the sensor (see Table 1.1).

Table 1-3: The comparison of sensor locations with *advantages and limitations.*

Sensor location	Advantages	Disadvantage	Authors
Handgrip	Ability to measure dynamic forces	Requires appropriate ergonomics modifications. Have to place multiple force sensors to cover the area of the handgrip	Lawrence, et al., 2008; Laohapensaeng et al., 2015; Vidal-Verdu et al., 2015
Upper Shaft	Availability of greater space to place electronics	Require changes in the centre of the gravity of the stick	Moran, et al., 1995; Culmer, et al., 2014; Leon, et al., 2015; Hart et al., 2018
Lower shaft & Tip	Axial force on the walking stick could be measured more accurately	Excessive force could damage the sensor	Perez and Fung, 2011; Boyles et al., 2015; Ballesteros et al., 2019; Routson, et al., 2020; Fernandez, et al., 2020;

Placing the sensor in the lower shaft and tip of the walking stick is most preferred by researchers (Ballesteros et al., 2019; Routson, et al., 2020; Perez and Fung, 2011; Fernandez, et al., 2020; Boyles et al., 2015) as the weight of the shaft is calculated along with the weight-bearing at this location.

1.6.2. Walking stick orientation

Walking sticks play a crucial role in preventing falls and injuries. However, they can also contribute to falls and injuries if incorrectly used (Wu et al., 2008). Because of this, understanding how a walking stick should be oriented is highly crucial for the user.

In general terms, orientation is defined as the action of positioning an object relative to a specified location. In the case of walking sticks, orientation means being aware of where the walking stick should be located with respect to the body and ground (figure 1.21; Roiben et al., 2018).

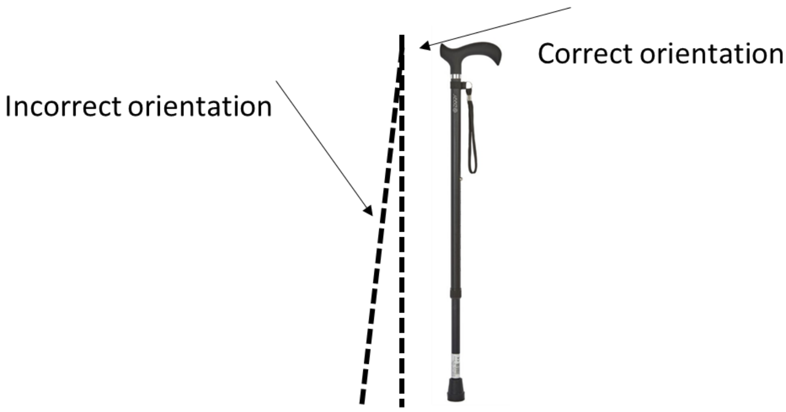

Figure 1.21: Correct orientation of stick and incorrect tilt angle

The knowledge of walking stick orientation involves kinetic and kinematic aspects of walking stick usage. Kinetic aspects revolve around evaluating the recommended range of walking stick load, while kinematic aspects involve knowledge of suitable orientation of the walking stick (Culmer et al., 2014).

1.6.2.1. Clinical ways to determine orientation of the walking stick

Determining the correct orientation of the walking stick plays a crucial role in training patients to help them avoid injuries and falls. The micro-electrical-mechanical systems (MEMS), 3D motion capture systems, and video cameras are the three most prevalent approaches used in clinical settings to assess the orientation of a walking stick (Culmer et al., 2014).

1.6.2.2. 3D motion capture system

The 3D motion capture systems (commonly referred to as mo-cap or mocap) are the most appropriate way to analyse kinematics as they can measure position and orientation with pinpoint accuracy (Topley et al., 2020). These 3D motion capture systems incorporate stereo photography methods. Therefore, it remodels the 3D position of the marker as it observes from more than one point of view (Anillao, 2018). Even though these 3D motion capture systems are incredibly accurate, there are still limitations to their obtainable measurements. These systems need a direct line of sight between the camera and patient under evaluation. Moreover, 3D motion capture systems also require light conditions and environment without reflective surfaces to enable clear detection of the sensors (García et al., 2020).

1.6.2.3. MEMS

MEMS-based sensors consist of a chip-based technology and are composed of a suspended mass between a pair of capacitive plates (Jewell, 2015). Due to their small size and chip-based technology, they are a preference for measuring precise orientation of the walking stick. MEMS can be mounted directly onto the body or the walking stick (Qiu et al., 2018).

1.6.2.4. Video cameras

Using video cameras to record rehabilitation sessions makes the learning process easy for patients using a walking stick. Video review of walking stick orientation helps in clinical assessments and facilitates the therapists in making the decision whether to continue or discontinue stick usage. However, the results from video camera footage are based on human observation, so are less accurate (Corbetta et al., 2015). The summary and comparison of the walking stick methods are provided in Table 1.4.

Table 1.4: The comparison of the walking stick methods

Method/Equipment	Advantages	Disadvantage	Authors
3D motion capture system	Higher accuracy	Costly Limited to clinical settings	Culmer, et al., 2014; Gill et al., 2017;
MEMS (Micro-Electrical-Mechanical System)	Easy to mount Low cost	Low accuracy	Culmer, et al., 2014; Leon, et al., 2015; Qiu et al. 2018.
Video Cameras	Real-time analysis	Doesn't provide technical numerical parameters	Laohapensaeng, et al., 2015.

1.6.2.5. Critical analysis regarding walking stick orientation

Center of mass and stability

A system's or an object's centre of mass is specified in relation to that system. The average position of a system is determined by adding up the masses of all its parts. The centroid is the mass centre of any simple rigid object with a constant density. Take a bottle as an example: most of its mass is concentrated towards its axis (Morasso, 2020).

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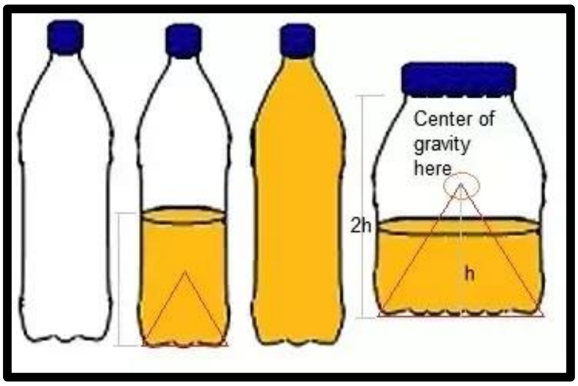

Figure 1.22: The bottle that serves as a symbol for the centre of gravity (Morasso, 2020)

Light fingertip contact on a ground-referenced item was investigated by Forero et al (2014), who ran an experiment to see how it affects balance while walking on a treadmill. Twenty young, healthy individuals participated in the study by walking on a treadmill at a speed of 3 kilometers per hour in two blocks of five different circumstances each. Both ocular opening (EO) and eye closing (EC) tests were administered to individuals in each condition (EC). Each block was given a random configuration consisting of four conditions: heavy

(H), light (L), no touch (N), and a force sensor positioned on the left or right-side rail being touched. For this study, a kinematic ultrasonic system was used to track the three-dimensional (3D) location of the COM and the midpoint of the posterior aspect of each leg, and a uniaxial linear accelerometer was used to track the acceleration of the COM in the anterior-posterior (AP) direction. Their results indicated that light touch was just as effective in reducing COM sway as vision and heavy touch. Both the COM sway and the AP acceleration were similar in both the open and closed eye circumstances when touch was used. In contrast, when participants lost the ability to see and feel their surroundings, they began to regress, and their coordinated stepping pattern was completely disrupted. Researchers came to the same conclusion as those using vision: somatosensory fingertip input from an external reference provides spatial orientation, which allows for the maintenance of body stability while walking on a treadmill (Forero et al., 2014).

On the other hand, stability is the resistance of an object to being tipped over by external forces. When compared to unstable objects, stable ones are much less likely to fall over. It is possible for the object to behave as though its mass were concentrated in its gravity centre. So, an object's stability depends on where its centre of gravity is located. One can observe from Figure 1.22 that; lower the center of gravity of an object, the more stable it is. When the line of action of the force of gravity moves outside of the base of a tilted item, the object will fall over. Consequently, the turning effect of forces is related to the location of an object's centre of mass. The width of the base and the height of the centre of mass are two aspects that must be measured to assess an object's stability. Knowing where the centre is can tell you if something will stay upright or fall over (Rajachandrakumar et al., 2018; Morasso, 2020).

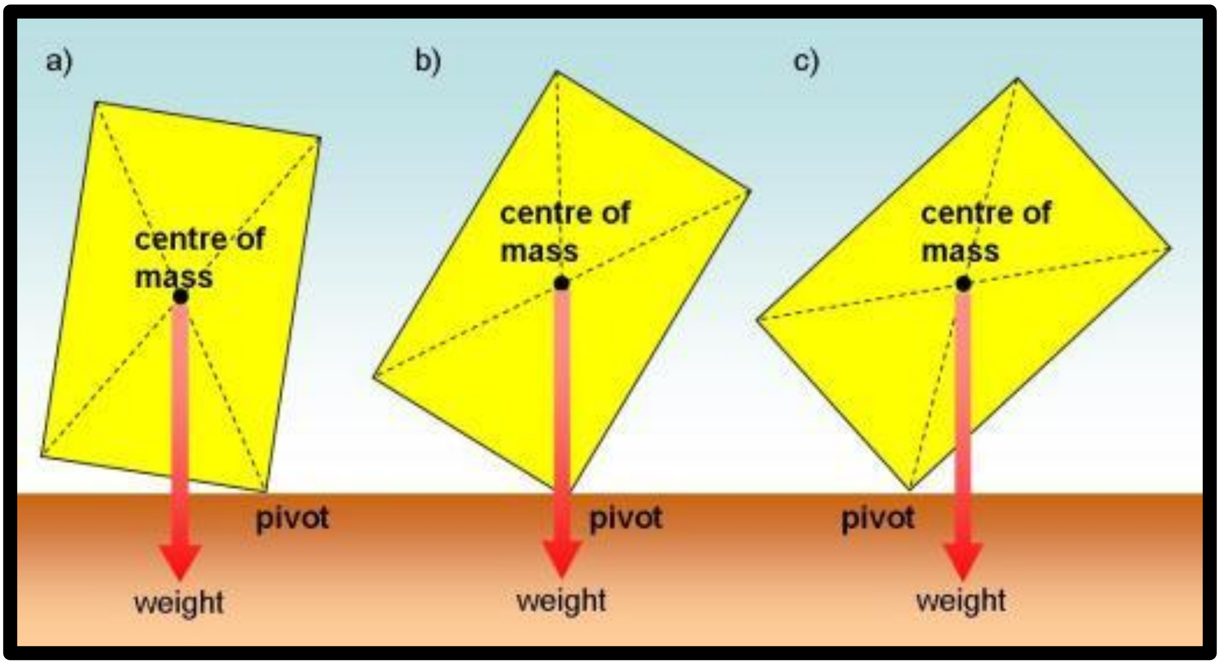

Figure 1.23: The graphic depicts the brick's tilt in three distinct phases (Rajachandrakumar et al., 2018)

Rajachandrakumar et al (2018) demonstrated the impact of orientation on the stability of an object, where it was concluded:

- That the weight of the brick as shown in figure 1.23 causes a twisting effect when tilted slightly (diagram a) and then release it, which causes the brick to right itself.
- The brick can be balanced on one edge by tilting it further in one direction (diagram b). Where the object's centre of gravity is perpendicular to the edge it is perched upon, as no turning force is applied.
- In diagram (c), the brick is shown at an even greater incline than in the previous diagram, and it immediately falls over when released. This occurs because the line of action of the weight is "outside the base" of the object

Human vision can also determine whether an object is physically stable. By making such assessments, observers can direct their motor activities in accordance with their expectations of how things will behave physically. The scientists investigated the connection between the viewer's perceived centre of gravity and physical stability of 3-D objects (as evidenced in stereoscopically observed rendered images) (COM). Experiment 1 had observers examine an object perched on the edge of a table and tilt it to the crucial angle, defined as the tilt angle at which the object was judged to have an equal chance of falling or righting itself. As in experiment 1, participants in experiment 2 used their eyes to determine the COM of the same group of objects. There was a comparison between observer condition and physical projection based on object geometry in both experiments. In-depth assessments of observers' critical-angle and COM settings indicated inconsistent preferences across the two tasks. Findings imply that users did not make physically sound COM estimations while making visual assessments of object stability (Steven et al., 2015).

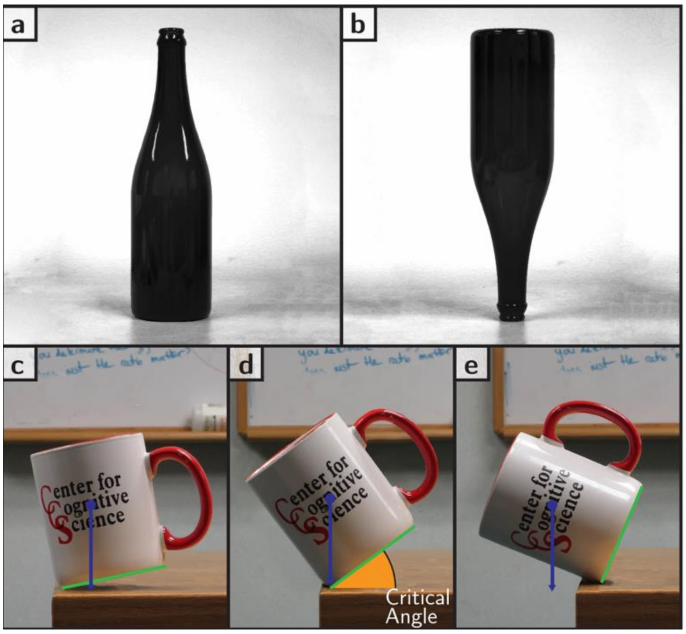

Figure 1.24: Real-world objects are more stable than these examples suggest. The top photos show a bottle on a table, in one configuration that is very perceptually stable (a) and another that is very perceptually unstable (b). In the images below, a coffee cup's centre of mass (shown by the blue circle and the blue line representing the gravity vector) is located vertically above the base (green; c), directly above the contact point when the object is at its critical angle (d), and outside the base (e), (Steven et al., 2015).

The same concept as discussed above can be applied to the stability of the walking stick. If the base area of the walking stick (ferrule) is more in contact with the ground, then the walking stick is said to be more stable, and as the contact between the ground and the base area of the walking stick reduces, the stability of the walking stick reduces. Hence, keeping check on the orientation of the walking stick is crucial for the stability of the walking stick and its user. Furthermore, few researchers have attempted to work on the orientation of a walking stick, which is summarised in the table below (Table 1.5).

Table 1.5: Comparison regarding the walking stick orientation

Author/Authors	Aim of the research	Limitation
Lawrence et al., 2008	To reduce the risk of falls by providing direct feedback to the users regarding the right orientation and use of the walking stick. For this purpose, a Smart Walking stick system is developed.	Research lacks the practical validation of the system.
Culmer et al., 2014	Gait improvement with the right usage of a smart walking stick. For this purpose, an instrumented walking aid system was designed.	The system validation for kinematic and kinetic measurements showed errors with testing on single test subject. The proposed system must be tested with increased number of iterations to validate its reliability and efficiency.
Leon et al., 2015	Gait rehabilitation with proper usage of a walking stick. A mounted sensor (MEMS) was used to monitor walking stick orientation.	The system uses wired data transmission which limits its usability.
Wade et al., 2015	Better gait assessment and rehabilitation with additional quantitative data availability and better observation of walking stick orientation. For this purpose, a clinical assessment tool is developed.	The power consumption of the proposed system was very high, resulting in low battery time.
Val et al., 2017	Real-time monitoring of the elderly and disabled people to avoid falls. For this purpose, their walking sticks are equipped with an accelerometer and magnetometer.	The proposed system showed satisfactory results for slow-walking phase, however, the accuracy was lower during the medium walk phase.

Culmer et al. (2014) and Leon et al. (2015) have both attempted to show the effectiveness of walking stick usage on gait improvement. On the other hand, Lawrence et al. (2008) and Wade et al. (2015) have attempted to show the effectiveness of using the walking stick orientation to minimize the chances of falls. However, the outcomes of this study, are inconclusive of any correlation between the orientation of the walking stick and falls (sideways or incorrect tilt).

1.6.2.6. Sensors used to determine walking stick orientation

From the literature search, it is evident that three types of sensor modules are commonly used by researchers to determine walking stick orientation. These sensors are independently available as accelerometers and gyroscopes, or in a consolidated form of an inertial measurement unit (IMU). IMU is not just the combination of the two, but it also might have some more sensors, such as magnetometers, temperature sensors, and air pressure sensors, the utility of which is outside the purview of this work. The following is a condensed explanation of these sensors for your reference:

1.6.2.7. Accelerometer:

An accelerometer is commonly used to measure the acceleration of an object. In human motion analysis, accelerometers can calculate different kinematic values including velocity and displacement of the user. This data can be integrated and used for finding several parameters, including step counts (Ravi et al., 2005).

1.6.2.8. Gyroscope:

In recent years, the gyroscope has become popular in various applications, including sports performance and gait analysis, along with other rehabilitation practices. There are two main kinds of gyroscopes: those that measure rate and those that integrate rate. Tilt angles are calculated by rate integrating gyroscopes whereas angular velocities are calculated by rate gyroscopes and integrated to calculate angles. These angles are useful in finding tilts and sways (Wantable and Hokari, 2006).

1.6.2.9. IMU:

IMU is the combination of accelerometer and gyroscope, which generally contains one tri-axial accelerometer and one tri-axial gyroscope. An inertial measurement unit can measure both the linear and angular motion in 3D space. Due to this versatile and compact form of gyroscopes and accelerometers, IMUs are being used widely in determining stick orientation and gait analysis (Gouwanda and Senanayake, 2008). A summary of the sensors used to determine the walking stick orientation are provided in Table 1.6.

Table 1.6: Comparison of the sensors used to determine the walking stick orientation

Sensor	Advantages	Disadvantage/Limitations	Authors
Accelerometer	• Low cost	• Data has more noise • Less sensitivity • Limited range	Wu et al., 2008; Wade, 2015; Lachar and Kachouri, 2017.
Gyroscope	• Extremely small and light in weight • Measures relative orientation on all the three axes	• More expensive • Can't measure linear motion • Less stability over temperature and humidity • Less reliable. • Value drifts with time.	Wu et al., 2008; Culmer, et al., 2014.
IMU	• Low power consumption • More accurate • More reliable	• More power consuming	Culmer, et al., 2014; Leon, et al., 2015; Gill et al., 2017; Fernandez et al., 2020.

Based on the data in Table 1.6, measuring acceleration and angular velocity with just a gyroscope and an accelerometer is not the most effective method. The IMU takes the place of the accelerometer and gyroscope, removing their shortcomings while providing highly accurate measurements of all three (Pao, 2018).

1.6.2.10. Filter utilisation for sensors in walking sticks

Raw data transmitting from the sensors is prone to noise. Although the data is digitised for processing, it still requires the use of filters and is important to minimize noise. While using the sensors mentioned above, researchers commonly used Kalman, Madgwick, and complementary filters for removal of noise and tracking (Ludwig and Burnham, 2018).

1.6.2.11. Kalman filter

Kalman filters consist of a set of numerical equations offering a systematic computational way to combine a range of sensor measurements to appropriately predict the state of a modelled system (Welch and Bishop, 2006). In the context of walking stick orientation, the Kalman filter offers an effective way to analyse and estimate walking stick orientation under dynamic human motion conditions with the help of IMU readings (Culmar et al., 2014). Advantages of Kalman filters include:

- It is a theoretically ideal filter to integrate the noisy sensors to extract clean and accurate estimates of walking stick orientation.
- It considers the required physical properties of a system like inertia and mass (Colton, 2007).

The disadvantages of Kalman filter includes

- Mathematical complexity.
- Increased processing time.
- High computation cost due to their complexity (Fernandez et al., 2020).

1.6.2.12. Madgwick filter

Madgwick filters have performance that is comparable to that of the Kalman filter but also feature a mathematically based orienting method. This method comprises of a normalised vector depicting the rotational motions of 6-degrees of freedom (6-DOF) and is mostly used in robotic systems such as robot arms and UAVs (Wondosen et al., 2021). Considering this, the mathematical modelling approach would enable the user to understand the system functionalities in more detail. This feature provides Madgwick filters with the same accuracy at a lower computational cost. This type of filter does faster calculations compared to the Kalman filter (Fernandez et al., 2020).

The advantages of this filter are:

- Higher accuracy.
- Lower computational cost compared to Kalman filter (Madgwick, 2010).

The disadvantages of this filter are:

- Its execution time is more than a complementary filter (Ludwiga, 2017)

1.6.2.13. Complementary filter

The complementary filter is a combination of fast-moving signals from a gyroscope and slow-moving signals from an accelerometer through synchronized integration of data. The experiments conducted on both the complementary filter and Kalman filter show that the complementary filter exceeds in performance compared to the Kalman filter by a great margin as it utilizes lower computational as well as processing power (Mahmood and Khan, 2016).

Advantages of this filter are:

- Use of less computational and processing power (Gui et al., 2015).
- Can assist in fixing noise along with the horizontal acceleration dependency.
- Estimates the angle faster and shows much less lag compared to other filters (Colton, 2007).

The disadvantages of this filter are:

- Less accurate than the Kalman filter (Tariqul, 2017).

1.6.3. Step Count

An interesting feature proposed by researchers Dang and Suh (2018) was the integration of the step count feature within the smart walking stick. Assessing acceleration and angular velocity of a walking stick has been emphasized to approximate the user's walked distance (Dang and Suh, 2018; Haddi, 2013). The subsequent sections discuss the various techniques and algorithms used to determine the step count.

1.6.3.1. Clinical methods and equipment used to measure step counts

There are many clinical tools available to determine the number of walking steps. Among them, the three most common are pedometers, optojumps, and video cameras.

1.6.3.2. Pedometers

A pedometer is a small device that keeps track of the number of steps the user has walked (Wood, 2008). Older versions of pedometers use spring systems to measure step counts while advanced pedometers use digital technology (Butler, 2020). Pedometers have limitations, as they are error prone at a rate which ranges from 13.95 % to 40.45 % (Hergenroeder et al., 2019).

1.6.3.3. Optojump

Optojump systems permit AHPs to analyse the gait of the patients. Optojumps contain two bars that receive and emit invisible LED light beams with a grid resolution of 1 cm. Every walking step interrupts the light communication and is counted at an accuracy of 1 ms. This makes optojump systems appropriate for measuring walking steps (Magrum et al., 2018).

1.6.3.4. Video Cameras

Video cameras have been used for quite some time in quantitative evaluation of human motion, with their ability to provide not only video information but also numerical parameters that can be overlaid on the video.

The primary limitations of video analysis for motion analysis are the associated costs, the lengthy setup, and the associated training challenges (Bridgman, 2015; Zhen et al., 2018).

1.6.3.5. Algorithms and approaches to measure or detect step counts

Determining step count is not a straightforward task. This requires the use of an algorithm to detect the ground contact and increment the step count. Three common methods used by the researchers for computing the step count are threshold, event, and machine learning-based methods.

1.6.3.6. Threshold-based methods

Threshold-based methods, when compared to other methods of estimating step count, come across far easier and quicker in execution. In this technique, bounds are set on the object's angular velocity and acceleration. This type of algorithm utilizes easy-to-understand threshold decisions and can be applied on the walking stick to estimate their location i.e., whether the walking stick is on ground or in the air. Thus, using these thresholds, the algorithm will increment the step count (Fernandez et al., 2020).

The advantages of this method are:

- Less complex (X. Kang et. al., 2018)
- Easy to use
- Low cost
- Good detection rate
- Suitable for real-time applications (Fernandez et al., 2020).

The disadvantages of this method are:

- Sensitive to noise (Fernandez et al., 2020).

1.6.3.7. Event-based methods

Event-based methods detect events of different gait patterns with the help of specific shapes of the received signal during ambulation. For example, in the case of a walking stick, the shape of the signal during the landing or ascent of the walking stick are preserved in the system, and the step count can be detected/measured based on the triggered events from the walking stick (Fernandez et al., 2020).

The advantages of this method are:

- High detection accuracy (Fernandez et al., 2020).

The disadvantages of this method are:

- Not suitable for real-time applications (Fernandez et al., 2020).

1.6.3.8. Machine learning methods

Machine learning methods use machine learning techniques to detect ground contact. As they can adapt to more than one gait condition, they enable improvement in estimation accuracy of step counting and provide higher accuracy of overall step count (Fernandez et al., 2020).

The advantages of this method are:

- Use in real-time applications
- Higher accuracy (Fernandez et al., 2020).

The disadvantages of this method are:

- Higher setup cost (X. Kang et. al., 2018)
- Complex system to use as more computation required (Fernandez et al., 2020).

Each of the mentioned methods has its own advantages and limitations; however, research shows that the threshold-based method is preferred by researchers due to its efficiency in real-time applications, lower complexity, and good detection rate (Ahlmark et al., 2016; Tahir and Rashid, 2020).

By tracking how often and for how long patients uses their walking aids, alternative health practitioners (AHPs) can get a sense of patients' overall health and recovery.

1.7. Summary

Although many researchers have attempted to mitigate the limitations of conventional walking sticks, much still needs to be done:

.

- User input and suggestions are crucial in medical device R&D. When users are not included in the design process, clinical outcomes suffer, and technology is more likely to malfunction (Mann et al., 1995; Reimer-Reiss, 1999; Ta et al., 2002; Grocott et al., 2007). However, user input is not commonly included in medical device design processes. To the author's knowledge, only Culmer et al. (2014) have incorporated limited user input into the prototype development of a smart walking aid. A strategy that includes stakeholders throughout the design and development of a medical device is required to develop a user-centered device that is on track for commercial success (Grocott et al., 2007).
- Solutions to issues surrounding traditional walking sticks have been presented by several researchers (Table 1.1); however, these alternatives have been designed more as clinical instruments than as practical devices to replace traditional walking sticks for daily use. What is needed is a tool that can collect data to be used by AHPs that also provides immediate feedback to the user even when they are in a free-living environment.
- Previous studies have primarily focused on a single illness or health problem, such as knee arthritis or a stroke. However, walking sticks are used by patients with a wide variety of conditions. There is a need for a device that can help those who have experienced various medical issues, such as a stroke, diabetes, knee arthritis, dizziness, multiple sclerosis, etc.
- In the past, visual feedback has played a role in improving the motor skills of patients suffering from mobility issues; recent research, however, has focused on incorporating haptic and auditory feedback (Kearney et al., 2019). Until now, visual feedback has only been available through additional hardware, such as portable digital assistants or mobile phones. Currently, no device incorporates visual feedback into the walking aid itself. While haptic and auditory feedback are effective, visual feedback is also essential for patients with hearing impairments and reduced sensory capabilities, for whom haptic and auditory feedback mechanisms may have limited utility (Sorgini et al., 2017).
- Using a walking stick incorrectly leads to an increased risk of falls and slows recovery. Providing walking stick orientation feedback to the user can lead to a higher rate of

proper use, reducing falls and improving outcomes (Culmer et al., 2014; Gill et al., 2017).

1.8. Conclusions

The following conclusions can be drawn about the need for biofeedback stick technology to support walking stick users.

- Good health is interlinked with the ability to move and perform activities of daily living.
- Mobility can be affected by different health conditions such as stroke, diabetes, MS, or vertigo.
- As a result of these medical issues, not only is the patient less mobile, but the patient also has a lower quality of life.
- The National Health Service (NHS) is under stress due to the widening budget gap and the accompanying scarcity of qualified medical professionals, prompting the government to seek ways to alleviate these problems. Therefore, it is essential to provide low-cost options to enhance mobility, which may have a beneficial effect on NHS resources.
- For the past three decades, biofeedback mechanisms have been used in various rehabilitation applications with results benefitting patients.
- Many researchers have proposed solutions to the problems that can arise from using walking aids. However, these approaches are limited to clinical environment. Hence, there is a need for a device that has the potential to support the walking stick users in their living environment.
- Despite the work of numerous researchers on the orientation of the walking sticks, no study has yet quantified the incorrect sideways tilt of the walking stick, an error that increases the statistical likelihood of falls and injuries. Therefore, there is a need for further investigation on the incorrect sideways tilt of walking sticks and resulting impact.
- There has been no significant advancement in the technology of biofeedback sticks, which have the potential to serve as an alternative to traditional walking sticks.

1.9. Aims and objectives

Aim: This research aims to improve the lives of people who use walking sticks, and the work of allied health professionals, by designing, developing, and evaluating biofeedback stick technology.

Objectives: The following objectives were set in relation to the aim:

1. The goal of this research is to design and develop a wireless biofeedback stick technology that can record, analyse, provide real-time feedback, and transmit information about a person's walking stick usage, such as the person's preferred orientation for using the stick and the stick's maximum weight capacity.
2. To incorporate the patient and public/stakeholder involvement model in the development of a walking stick.
3. To develop and test a user-friendly mobile application with a self-diagnosis home testing feature.
4. To develop and test a user-friendly graphical user interface for allied health professionals to assist with real-time monitoring of the walking stick usage and to set the desired parameters on the developed system.
5. Compare the constructed walking stick's accuracy, precision, and functionality across a variety of functional tasks related to activities of daily life and validate it against a gold standard system.

Chapter 2: Design Rationale

The process of designing and creating medical devices is both intricate and difficult, and it calls for a great deal of prudence (Harrison & Mort, 1998; Cayton, 2004). Designers and producers of medical devices must take several factors as highlighted below, into account during the design process if their products are to be both commercially successful and seen as useful by end users. According to studies (Tamsin & Bach, 2014; Privitera & Southee, 2017), there are four major difficulties associated with medical device design (MDD):

- Limited direct access to the users for the purpose of device development.
- Users have a lack of understanding of the impact their feedback has on the developmental process.
- Contract formalities limits communication between users and designers.
- The reciprocal logistics around establishing periodic communication and engagement amongst stakeholders / clinical users and medical device innovators.

In this section, the author presents a study strategy meant to encourage user engagement and participation in the medical device design process, which should help mitigate these four major problems.

There can be no room for error in the design or manufacture of a medical device since, as was stated in the preceding chapter, the outcome of any mistakes or inaccuracies could hold dire consequences for the patients who use them. Cafazzo & St-Cyr, (2012) confirmed this, stating that human error in operating a device can be a major cause of injury or death. This necessitates collaboration with end-users / stakeholders throughout the design process rather than at mandated intervals. As user-centered, collaborative design methods gain popularity, the user's traditional position in the design process is beginning to shift. As a result, members of public, patients, clinical users / stakeholders, are now seen as partners with designers in the development of innovative medical / healthcare technologies.

In order to improve patient safety and create devices / technologies aligned to the needs of end-users, researchers have advocated for MDD to integrate human factors engineering techniques in the design and development of such devices (Money et al., 2011). Limited research has examined the use of these techniques—which may include interviews, focus groups, and/or usability testing—during the entire design process (Dell'Era and Landoni, 2014). The limitations of previous research are mitigated by the current study's use of a design rationale that actively seeks and includes user input at every stage of the design and development process. For the purposes of this study, and in line with the literature, the term, "users" refers to either patient groups who have been prescribed with walking sticks, or specialist physicians, / health professionals, or care takers who enables the use of such devices with patients (Tamsin & Bach, 2014). In addition, the gap in the literature that serve to reaffirm the need for an intrinsic user-involved driven approach to the design, development, and assessment of a medical device in light of the limitations identified in the literature review are discussed in greater detail in the subsequent sections.

2.1 The value of user feedback in medical device design

When designing canes, sticks, and other walking aids, input from users is crucial to ensure a product's comfort and efficacy (Money et al., 2011). Human factors engineering (HFE) enhances the walking aid design process by considering users' distinct individual demands, work habits, and surroundings. Incorporating HFE into the design can increase patient safety, compliance, health outcomes, device utility, and happiness (Grocott et al., 2007). HFE methods also reduce device development time by identifying user difficulties earlier in the design process, allowing problems to be addressed immediately (Money et al., 2011; Riemer-Reiss, 1999). Involving users in the design and development process ensures a practical and result-assured device for quality health care. Involving users throughout an entire medical device development cycle—including in the supply chain and every other care pathway network that plays a role in getting the device to the ultimate user—is also beneficial (Grocott et al., 2007). Research has shown that medical devices developed in isolation are susceptible to failure (Ta et al., 2002), and incorporating HFE methods produces better outcomes for medical devices.

The importance of users' involvement in the development process is understated throughout the literature. For this reason, the focus of Chapters 2 and 3 is on user perspective framework derived from informal discussions with people who use walking sticks and AHPs to learn about their experiences and how those experiences can inform the beginning stages of the BfT's design and development process (Ta et al., 2002).

2.2 Ways of obtaining user perspectives

The user involvement strategy employed in the study was all inclusive based upon the recommendations by Esmail et al., (2015), who stated that the involvement of users should flow logically between all stages of development: (i) concept stage, (ii) design stage, (iii) prototype stage (iv) testing and trial Stage, and (v) deployment stage.

Understanding what the users desire and how their requirements may be satisfied through MDD collaboration is the same as incorporating user viewpoints and involvement. Several methods exist for eliciting feedback and input from end users. Many of these strategies are already used in real-world settings (Mathie et al., 2018). This is elaborated in the following sections.

2.2.1 Quality function deployment

Quality function deployment (QFD), is a customer-centric framework for gathering user input, analyzing requirements, and setting priorities. However, it has been acknowledged that the user is not the only client and that the interest and requirements of other stakeholders should also be considered (Al-Bashir, et al., 2012). When QFD was initially developed in Japan in the 1960s, it was used as a planning technique for product development (Huang et al., 2021). While this use of QFD has remained pervasive throughout the years, the focus on customer or client satisfaction has become more pervasive (Liu, Shi, Li, & Duan, 2022). QFD identifies problem areas in the device's performance and develops strategies to address them, ultimately leading to increased satisfaction among the product end users (Al-Bashir, et al., 2012). Biggar & Yao (2016) and Liu et al., (2009) respectively used QFD to develop a robotic glove for hand rehabilitation and an instrument to assess the severity of symptoms of neck and shoulder pain to diagnose the origin of these symptoms. By utilizing an efficient QFD methodology, projects can avoid squandering time and money on the creation of features and functionalities that do not provide value.

2.2.1.1 Limitations of QFD

QFD is a helpful method for gaining insight into consumer preferences, however it has certain drawbacks, including its inapplicability and challenge of drawing a direct line between consumer needs and technical features (Jaiswal, 2012). In the medical sector, for instance, some devices are very specialized, so there are not as many potential customers or end-users. Furthermore, for a product of limited complexity with a small supplier base, the time and effort needed to conduct a comprehensive QFD analysis would need to be justified by the customer base, which has been reported to be a less common practice (Jaiswal, 2012).

- QFD is a complex process, where the analysis of the data is carried out in a subjective manner, leading to the inconsistencies of the outcome. The relationships between ‘WHATs’ and ‘HOWs’ are not accurately indicated. (Vinodh and Chintha, 2011)
- Effective QFD requires accurate data analysis that explores the correlative relationship between the users’ requirements and the device features.

- Establishing a link between consumer needs and technical specifications is challenging, and predominantly studies limit the implementation of this technique post the product planning phase (Bouchereau & Rowlands, 2000).
- The usage of customer language is leading to ambiguity and derivation of imprecise characteristics. These deficiencies result in questioning the effective outcome of QFD. (Andronikidis et al. 2009; Sener and Karsak 2011)
- For the QFD technique to be accurate, more data (at least 15 respondents) is needed than possible with the current study as a result of limited access to users (Wolniak, 2018).
- The Implementation of QFD has primarily focused on gaining user perceptions on the end product (Abdollah Shamshirsaz, 2015). There is a lack of clear guidance on how to properly implement QFD so that all stakeholder requirements are fully captured.

The researcher in this study investigated the concept of patient and public involvement as a means of overcoming the inherent characteristics of QFD, since the user needs are vital not only to the planning, but also to the process of design, production, and research underpinning the device.

2.2.2 Patient and public involvement

Patient and public involvement (PPI) research is well established in the United Kingdom (Mitchell et al., 2019). PPI can be defined as the process of taking informal input from stakeholders (i.e., patients and AHPs) to design, develop, or manage research, programs, or devices (Staniszewska., et al 2011). Patients and the AHPs should be consulted at every stage of product development (Carman et al., 2013) so that they can have input into every decision that is made (Jackson, et al., 2020). Staniszewska et al (2011), emphasised that the PPI focuses on research being designed and conducted for the interest of patients and the public through users' collaborative involvement, thereby aiding in the reduction of researcher bias. PPI works on the premise of user engagement, or the process of sharing information and knowledge about research, design, or plans with the public. This is crucial for demonstrating the importance of research to both the public and the individuals affected by a health condition, (i.e., raising awareness of research to the public). In contrast to the Quality Function Deployment (QFD) approach, the PPI method is centered around enabling end-users to learn and grow as experts in their own right (Jones, & Pietilä, 2020). Active involvement, on the other hand, is a step above simple participation or engagement and elevates into the domain of true teamwork. Patients, caregivers, members of the public, non-health professionals, community groups, patient support groups, and family members are just a few examples of the types of people whose actual involvement is included in the larger definition of PPI (Becker et al., 2010). The following section describes the process that was undertaken for this research.

2.2.2.1 The PPI process

The PPI process has clear procedures for engagement and involvement that were established by the Medicines and Healthcare products Regulatory Agency (MHRA) within their organization (MHRA, 2020). In the UK, many organisations such as Cancer research UK, Diabetes UK, Parkinsons UK and NIHR (National Institute for Health and Care Research) etc., have been campaigning for active involvement of PPI in research and there is no requirement for ethical approval when undertaking PPI work (INVOLVE, 2016; Mitchell, et al., 2019). This is as evidenced in a peer review study undertaken and published by Mitchell, et al., (2019), involving vulnerable children as the PPI group. As stated by Mitchell, et al., (2019, p.197), “Ethical approval and the use of consent or agreement forms for children, young people, or their parents is not necessary for PPI.” In this study the children presented their views and experiences relating to pediatric palliative care, which helped the researchers to design their investigation and resulted in the development of a framework that can minimize the risk of harm to children and young people.

The initial step in the PPI process was to define the outcomes expected from stakeholders, shown in Figure 2.1 (Skovlund, et al., 2020). The individuals invited to partake in the research were informed about the research and design process to ensure their ability to make informed decisions throughout the process. It was essential that the public and patients alike were present throughout the research and design process. Therefore, the use of digital means of communication was encouraged to enhance flexibility and maintain public and patient commitment to the research process (Liabo et al., 2018). The concerns of patients and the public, discussed in table 2.1 were crucial, all through the design phase of medical devices these requirements were catered for. Moreover, this procedure was established ensuring continuous review of the device during the design process and the in-depth involvement of both patients and the public.

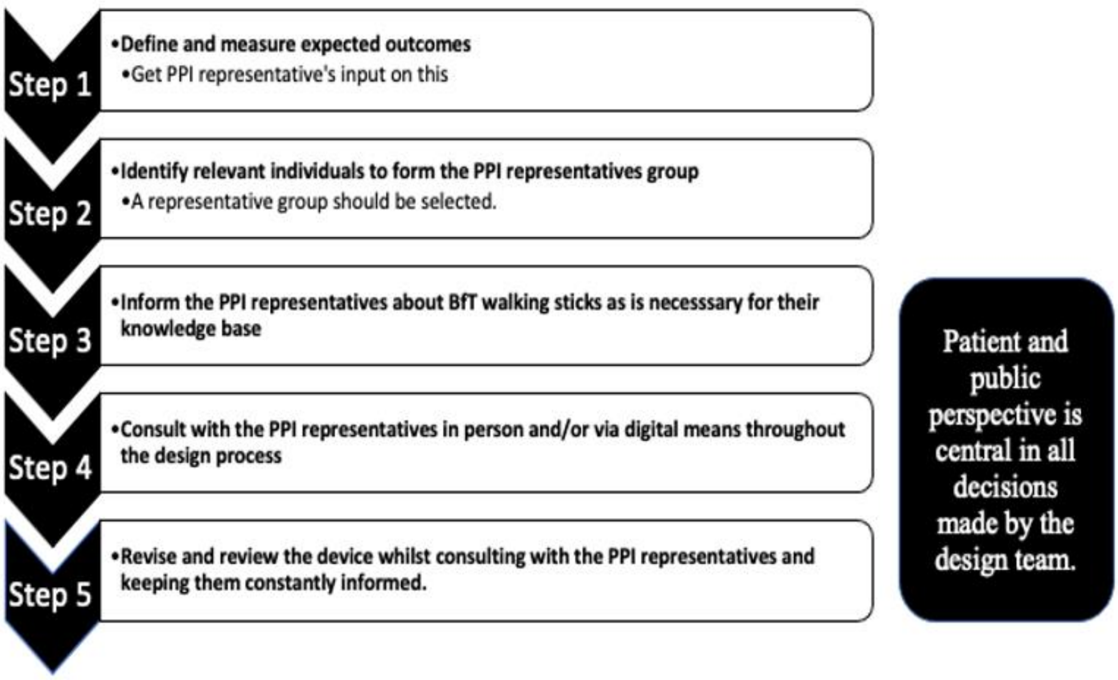

Figure 2.1: Diagrammatic representation of the PPI process (Skovlund, et al., 2020)

To better understand the depth of patient and public involvement in the PPI process, it is necessary to delineate the research process briefly and highlight their inclusion (Skovlund, et al., 2020). As a result of their insider knowledge and direct experience, PPI representatives can help understand what matters to the target population and refine the research question. Figure 2.2 shows how PPI representatives are generally included in the study process at every stage.

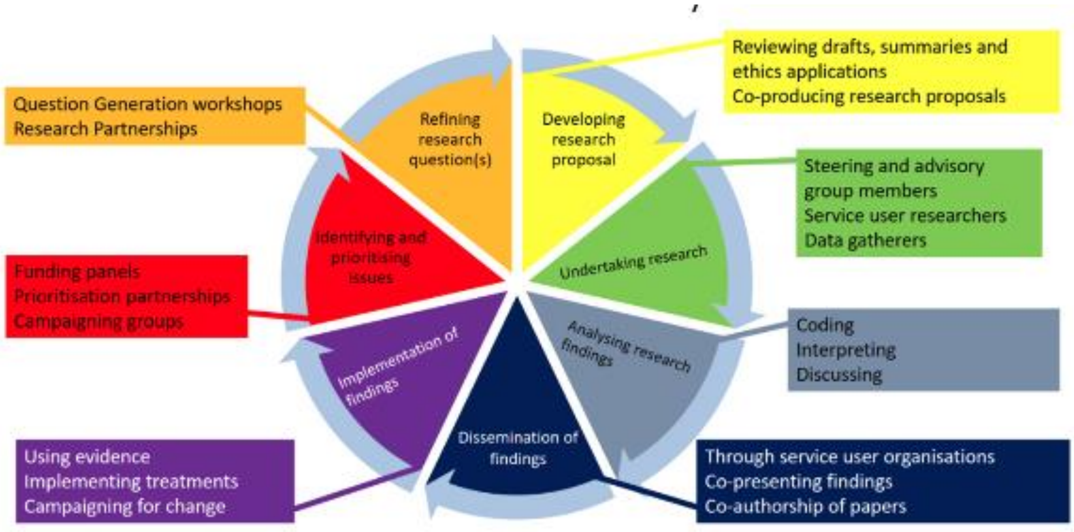

Figure 2.2: PPI involvement within the research cycle (Liabo et al., 2018)

2.1.2.2 *Benefits of incorporating PPI*

There is evidence to suggest that PPI can improve the process of making healthcare decisions (Fleurence et al., 2013, Jackson, et al., 2020). A significant benefit of PPI is that users are collaboratively involved during the entire process, meaning their input is integrated into the planning, design, and execution of the device. There is a drive throughout the UK to include the public in research, particularly that which alludes to health care. The National Institute for Health Research in England has made PPI central in its developmental plans for years 2021-2025 (MHRA, 2020). Human factors engineering has been found to improve medical device outcomes; therefore, it is imperative that both patient and public perspectives be considered (Liabo et al., 2018). Involving patients and the public also improves the research quality and relevance. Consulting with the end user prior to establishment of a new product is a novel shift even in the commercial arena.

With PPI, patients are kept at the centre of their own therapy and recovery (Greenhalgh, 2009), making it especially useful in the management of chronic conditions. As far as medical research is concerned, PPI receives praise as one of the most patient-centered and patient-led research processes available to find treatments, improve the quality of life of the patients and prevent illness (Fleurence et al., 2013, Jackson, et al., 2020).

Furthermore, the researcher and the user are seen as partners working towards a common goal.

This patient involvement strategy is not new. Over the past decade, Europe on the whole has experienced an overwhelming shift toward this research strategy for medical research. More recently, the MHRA published the guidelines and strategies for this approach with a projection of full implementation across healthcare research over the next 5 years. This further emphasizes the reason why this approach was chosen for the current research (MHRA, 2020).

In contrast to traditional stakeholder-involvement approaches and their focus on making the user a passive observer of the research process rather than an active collaborator and contributor, PPI encourages active engagement to get user perspective and collaboration. (Légaré et al., 2011).

2.3 Impact of PPI

Research (Mockford et al., 2012; Huang et al., 2021) showed benefits of PPI including giving patients power over their treatment strategies and/or the development of healthcare technologies informed by personal experience.

Brett et al. (2014a) conducted the first systematic review on PPI, reporting the importance of optimizing the context and process of involvement and creating potential for PPI to positively impact the research itself. In addition, Brett et al., (2014b) revealed the first international evidence on the extent of the impact of PPI in their mapping of the effects of PPI on social care and other areas, emphasising the necessity of a substantial improvement and expansion of the evidence database associated with the effects of PPI.

Several studies (Dimitri, et al., 2021; Huang et al., 2021) have reported the use of the PPI approach in the design and development of medical devices. Medical technology companies have recently discovered a method of treating recurrent ear infections in youth by inserting "ear tubes" into their ears. The PPI process informed the design of their clinical trial (Food and Drug Administration, 2020). Therefore, it can be ascertained that this approach has been substantiated and is a viable method to use for the present study and its PPI representative involvement. Since biofeedback research necessitates technical expertise, one might wonder if it is truly worthwhile to involve individuals in such research. However, Russo et al. (2020) discovered a high degree of interest in biofeedback training despite a lack of familiarity with the technology. In addition, there are few biofeedback medical devices developed with user input, so this strategy would improve people's outlook toward these tools and foster a stronger belief in their own ability to manage their health (Russo et al., 2020).

2.4 Method

Exploring the literature discussed in section 2.2 and attending workshops organized by FACE, a university department dedicated to providing healthcare education, led to the creation of protocols defined in the following steps (FACE, 2022):

2.4.1 *Step 1: Define expected outcomes*

The outcomes of this study's PPI process were first defined. In this research endeavor, the three most important outcomes were identified. The first anticipated outcome of the research study was that the PPI representative would be aware of and provide improvement suggestions regarding the mechanisms available to monitor and capture the correct or incorrect usage of the walking stick outside of the clinical environment as well as how the data can be stored in user-friendly application. The second outcome was to incorporate the PPI representatives' aesthetic, ergonomic, and/or functional preferences into the design of the BfT walking stick. The third outcome was to determine how much weight should be placed on the stick and how to lessen the negative effects of improper use—such as a ferrule breaking.

2.4.2 *Step 2 and 3: Identify relevant individuals to be PPI representatives and inform the representatives about the BfT walking sticks to better equip their knowledge base*

The study participants submitted request forms to health societies (see appendix D) relating to Diabetes, Stroke, etc. The purpose of the study, participant roles, and the expected timeline were all outlined in the form. All potential PPI representatives were advised about the nature of the PPI process and given background information on BfT walking sticks to better equip them for their involvement in the research process. Interested individuals contacted the researcher, and all informal discussion sessions were organised based on the availability of PPI representatives. Prior to each discussion, verbal consent for participation was gathered from participants.

2.4.3 *Step 4: Consultation with the PPI representatives*

A total of 13 participants, aged 40 to 65, joined as PPI members. Some PPI participants favored in-person meetings while others preferred discussions through a landline phone. Furthermore, a few patients urged their carers or next of kin to liaise with the researcher to engage in such informal discussions on their behalf. Representatives from the PPI were contacted in the manner they preferred.

The researcher facilitated informal discussions with the walking stick users, asking asked about past experiences with walking stick usage, any issues encountered, and the most desirable potential aspects for a smart walking stick. The discussions with the AHPs were focused on the reasons to prescribe a walking stick and follow-up methodologies for rehabilitation of patients. They were asked about the data most useful for health professionals to better track patient recovery and the usage of the stick. AHPs were also consulted about the possibility of inclusion of specific technical features that health professionals would like to incorporate into the walking aid to improve efficacy of training and instruction to patients.

The PPI representatives' key recommendations are displayed in Table 2.1.

2.5 Results

Based on the informal discussions with the PPI participants, some common solutions, suggestions, and guidelines were obtained. The key concepts were compiled in a way to allow the BfT to better serve the requirements of its end users.

Step 1’s first and third outcomes were achieved as the PPI representatives provided suggestions regarding the mechanisms available to monitor and capture the correct or incorrect usage of the walking stick outside the clinical environment and how the data could be stored in a user-friendly application. Recurring themes were that cautions and reminders from the walking stick application should be in real time to acquaint users with its correct usage, thereby reducing the likelihood of the ferrule of the walking stick tearing off quickly due to incorrect usage. Another common thread was the idea that the stick must have data recording capabilities to keep track of the user's daily usage patterns along with specialized feedback features and functions related to weight bearing. To address the second outcome, PPI participants recommended designing the body and handle of the walking stick more ergonomic with options for varying colors to enhance aesthetic value. Beyond the initial established outcomes, the PPI participants also mentioned that a significant issue is the market price of existing smart walking sticks.

Table 2.1: Concerns of PPI participants and the demonstrable impact

Concern of PPI participants	Demonstrable impact
Real-time feedback on incorrect usage of the walking stick is only limited to clinical settings.	The proposed system could have a mechanism to detect the orientation of the walking stick. Where a functionality may be provided to alert the user upon the incorrect stick sway.
No mechanism available to monitor and capture daily usage of the walking stick outside the clinical environment and preferred the data to be stored in a user-friendly application	The proposed system would allow the user to log when and how often they used their walking stick in the course of their regular routine (ADL). Using the walking stick is made more enjoyable by the addition of a milestone configuration option. To alleviate the burden of monitoring the clinical database, allied health workers will instead have their patients' information saved on a more accessible app.
The correct amount of weight-bearing on the walking stick	Important feedback functions to be included in the proposed solution: Vibration and Audio feedback for weight-bearing.
PPI led to the recommendation to have an ergonomic handle.	Handle of the proposed solution to have an ergonomic design.
PPI led to the recommendation that the stick should be available in different colors.	The body of the proposed solution to have color options.
The ferrule of the walking stick tearing off quickly due to incorrect walking stick usage	Investigate the cause for the tearing of the ferrule and the best material to use.
An alarm to prompt incorrect stick use and an LCD to display progress during use were both suggested based on user feedback gathered through PPI.	Alarm function and an LCD to be included in the proposed solution.
Given the high cost of existing solutions, PPI suggested aiming for a price point of less than £100 for the proposed smart walking stick.	Low product cost to be considered during the selection of the components.

2.6 Discussion

Although human factors engineering processes are popular in the literature, the implementation of the PPI process in Biofeedback MDD is a newer approach that researchers have identified as beneficial for the end-user (Food and Drug Administration, 2020). Patient and public involvement (PPI) is often viewed to help reconstruct the health policy for an establishment of a patient centred health care system (Bret, 2014). Strong theoretical evidence suggests PPI has potential benefits in optimising health-care decision making but it still comes with some risks that are concerning (Skovlund, 2020).

PPI centred studies have been increasing (Benz, 2020), this growing focus leads to the question; why PPI is needed to be included in medical research? Firstly, fairness in health care decision making, as all health care funds (taxes, insurance, government funds) are generated for and from the people, their participation has direct effect on NHS governance and legitimacy (Baumann, 2021). Secondly, the feel-good effect; since the participants feel like they are giving something back to the people as seen in the answers recorded by PPI members in cancer research (Pii, 2021).

Despite having a general positive view, PPI comes with concerning problems. Senior scientist Burton proposes, the consideration that more participation could lead to better results is a huge mistake as this can give rise to overenthusiasm, where people's expectations are not always met (Pizzo, 2015). Secondly, PPI can be used as a justification for not conducting robust studies, this could lead to poor conduction which can be expensive, time consuming and ultimately unreliable (Pizzo, 2015). Most PPI participation is voluntary, this can create an unjust approach where participants are required to do something for free, for which experts are always paid for, challenging the equity and fairness objectives of PPI (Baumann,2021). Although PPI is thought to provide a wide range of benefits, most of these arguments are theoretical and still require extensive research to assess their credibility (Benz, 2020).

In terms of establishing biofeedback stick technology through the incorporation of a PPI process, the benefits to the end users encompass understanding the biomedical engineering landscape as a user and as a designer, having their previously unmet needs attended to, and being an active participant in narrowing the discrepancies between user and health professionals' requirements.

The PPI representatives in this study established that there are three main issues with available walking sticks that need to be addressed, namely:

- The lack of mechanisms available to monitor and capture the correct or incorrect usage of the walking stick outside the clinical environment
- Smart walking sticks on the market are very expensive
- The design of smart walking sticks available on the market are not ergonomic or aesthetically pleasing.

As the PPI was consulted for general information only, no ethical consideration was required, as per BCU policy. Subsequently, only informal information from the PPI discussions was used to inform the project direction, aims and objectives. Nevertheless, the design aspects were in line with the initial recommendations of the stakeholders which obviously is subjected to improvisation as part of the product evaluation cycle as this perhaps is the nature of the medical devices design and development cycle.

2.7 Conclusion

PPI in the design and development of a medical device such as the walking stick helps to place the perspective of the user or patient and AHP at the forefront of the design. This preliminary PPI process has highlighted the importance of making the smart walking stick (i.e., the BfT) as innovative and intuitive as possible within a pre-determined budget. Alongside other proposed solutions, it may serve as a significant technological development to aid health care sectors like the NHS and enhance rehabilitation efforts. The gaps identified in the literature review as well as the input from the PPI representatives provided the basis to form the rationale for the design of the BfT walking stick.

Chapter 3: Design and Development of BfT

3.1. Design and development methodology

In the previous chapters, a thorough review has been conducted, providing a foundation for the development of the BfT system. The review has elucidated the gaps in related literature and the systems available to date. In Chapter 1, a detailed literature review is presented, which demonstrates the need for BfT, which may truly benefit walking stick users. Different walking aids are compared considering both biomedical research and the recommendations from PPI members. This identified the limitations of the existing systems, as explained in Chapters 1 and 2. This study was constructed in a multi-dimensional manner as it focuses on mechanical design, choice of material, suitable electronics, and real-life requirements as endorsed by various stakeholders. In previous research and developments, either the solutions listed in the literature were impractical and unable to be used in the products or they concentrated on a single mechanical or electronic aspect only (as shown in Table 1.1). This thesis encompasses all aspects, from mechanical design to state of the art electronics deployed in the development of BfT, from the design proposal to the completion of the prototype.

The methodology for implementation is presented in this chapter, highlighting the approach towards the design and development of the proposed BfT. The chapter has been sub-divided into four parts: (i) Implementation strategy, starting from the concept of the BfT design, considering the choice of electronics hardware and other mechanical aspects; (ii) firmware design methodology ensuring the BfT is complete according to requirements; (iii) firmware for the embedded system deployed within the BfT; and (iv) a summary of the key features of the developed prototype.

3.2. Implementation framework

A framework was developed (F) to define the building blocks of BfT, which relies on recommendations from walking stick users and AHPs (Figure 3.1).

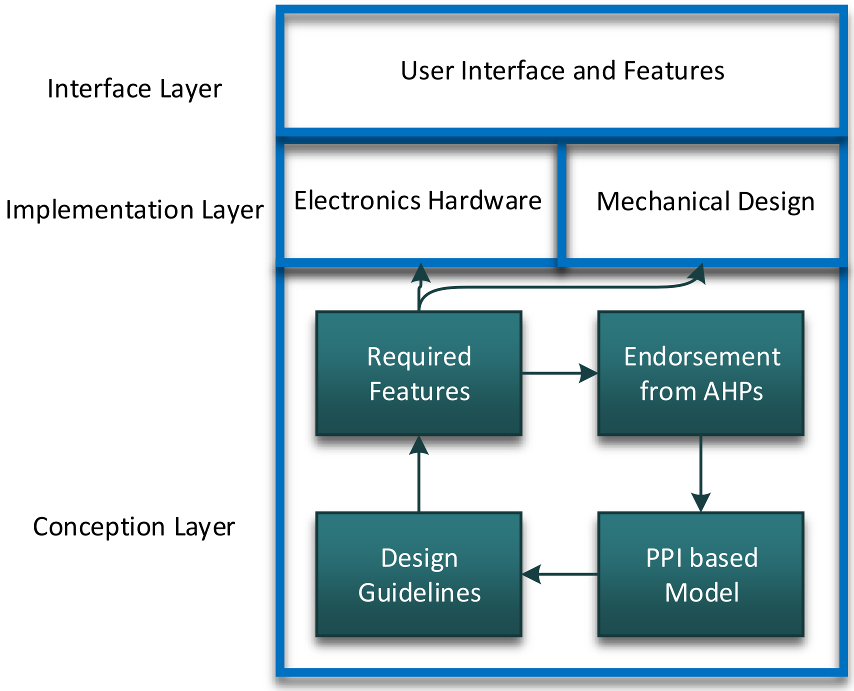

Figure 3.1: Methodology for BfT Implementation Planning and Design

A layered approach was adopted for the implementation of the BfT. This is a three-layer design from conception to implementation covering all aspects described in the previous chapters. These layers are briefly described in this section and covered in detail in rest of the chapter.

3.2.1. Conception layer

The conception layer entails the thought process, collection of data, literature review, analysis of commercially available/existing products, and finalisation of requirements to create a state-of-the-art smart walking stick that accommodates the design and development aspects required by the stakeholders for convenient daily use. This approach clearly elaborates the refined requirements for the development of BfT. The inputs from this layer are not restricted to the hypothetical design; rather, they define the final requirements for the product. The design objectives of the BfT are stated as follows:

- It should be able to provide real-time feedback to walking stick users through the choice of output modules as per their convenience
- It should immediately alert the walking stick user for any anomaly in usage and placement of stick
- It should be capable of data recording and logging for data to be analysed at later stage

- It should be able to wirelessly transmit data to both walking stick user and health professionals via Bluetooth
- It should be facilitated with a smart GUI with the aid of the mobile and PC application.

3.2.2. Implementation layer

Based on the design guidelines finalised from the conception layer, details and findings were taken to the implementation layer. This involves the implementation both in terms of electronics and mechanical design. The electronics aspects provide details about the requirements of the electronics to acquire important information about the position of the BfT and the amount of force being exerted on the BfT, whereby processing all this information using an intelligent processing core of microcontroller. Thus, creating meaningful information to be used by AHPs and walking stick users. The electronic hardware implemented at this layer is then installed in the mechanical housing which provides the mechanical platform for the embedded solution to function.

The mechanical aspects presented in this layer mainly discuss the choice of material required for the BfT. The strength of the material was passed through comparative analysis and multiple materials were shortlisted based on weight and strength. Mechanical assembly of the BfT is ensured to house the necessary electronics without changing the overall aesthetics of the walking stick. The ferrule of the BfT during usage should be placed firmly on the ground ensuring the correct posture of the walking stick user. The mechanical assembly powered with necessary and sufficient electronics comprising both sensors and processing module defines the hardware or implementation layer. This layer, together with essential computations, is expected to enable the BfT to acquire and process higher layer physiological data to provide meaningful user-friendly information for various stakeholders.

3.2.3. User interface layer

As PPI approach was incorporated into the proposed design, to ensure utilisation of proposed hardware highlighted by smart electronics. The user interface is equally ensured to justify the requirements of both walking stick users and AHPs. This was done without neglecting the design requirements from the conception layer. This includes guaranteeing data availability without any loss of information during the capture, processing, and displaying. This interface uses Bluetooth from the physical layer of the hardware and connects it with the outside world using the implementation layer. In the proposed interface layer, there are certain real-time facilitations incorporated for the walking stick users, which include OLED (Organic Light-Emitting Diode) display, buzzers, vibration notification, and

GUIs. For clinicians, technical information is of essence, but data recording in the data logger device is adjustable and time-stamped in the proposed design. A mobile application was developed, connecting to the electronics via Bluetooth and offering walking stick users the chance to view and store data while practicing the use of their BfT. In contrast, for AHPs, a GUI application is developed which not only provides the walking stick user's BfT usage information but also allows AHPs to set up the threshold parameters of the BfT'sforce and angle. Hence, the output is multi-modal and ensures outputs in the following ways:

1. Vibrations for instant feedback to walking stick user
2. Buzzer for audio intimation
3. OLED display
4. Data logging on SD card
5. Mobile application with interactive GUI via Bluetooth

With the proposed technical framework, the BfT was developed from inception to a complete prototype. In the subsequent sections, embedded electronics were discussed followed by mechanical design and eventually the interface layer due to the implementation requirements.

3.3. Electronics design and development

Electronics design was considered first, as the implementation was not constrained with the mechanical limitations, (figure 3.2). Once the requirements were met in the electronics, they were then housed and integrated in the mechanical assembly.

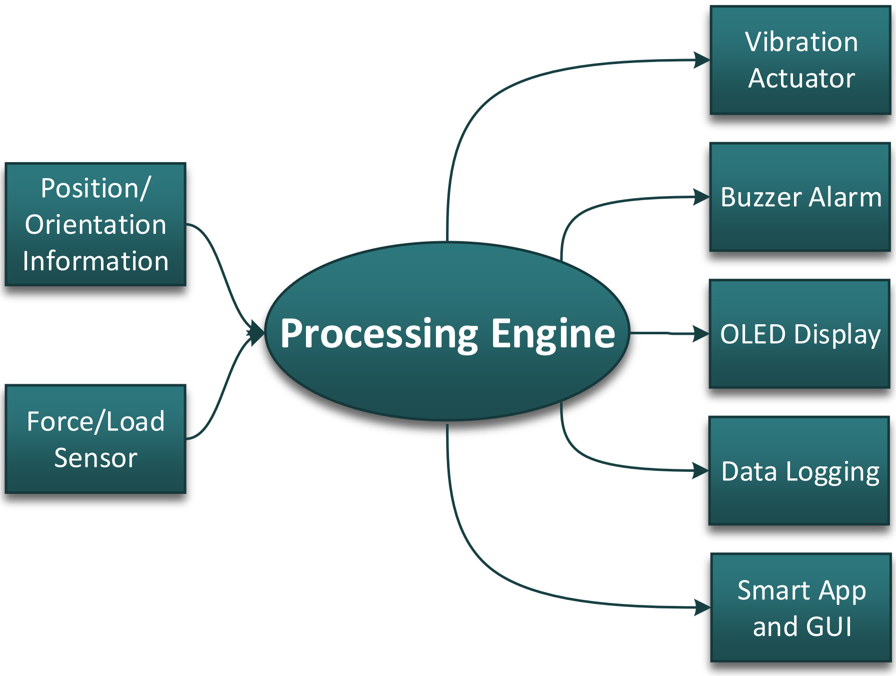

Figure 3.2: Electronics design layout for BfT

Standing in a correct position and recovering the gait with correct posture are basic requirements for walking stick users. Therefore, orientation and force sensors are key prerequisites as they are the main input parameters required from the sensors to achieve the goal. Orientation sensors are required to acquire the orientation of the BfT while force sensors are required to obtain the amount of force exerted upon the BfT. These raw inputs from the sensor are then passed on to the processing module (i.e., either microcontroller or a DSP processor) which will compute the accurate position and orientation of the BfT and any further auxiliary information, if required. The orientation is computed using a suitable algorithm, and processed information is passed on to the microcontroller connected for interfacing. The on-screen display, buzzer-based alarm, and haptic feedback via vibration motors are available for immediate alerts to the walking stick user. This process is initiated when any out of bound operations are done by the walking stick user (i.e., inappropriate application of force and wrong orientation of BfT). Data logging capability is provided for recording data for post processing and analysis. Finally, the design of mobile and GUI applications was interfaced with the computing engine using Bluetooth interface. These requirements are considered thoroughly, and state of the art module devices are chosen to fulfill all such demands while considering the cost aspects as well (as shown in Table 3.1).

Table 3.1: Selection of hardware modules and their requirements

Functional Requirements	Module Type	Part Number
A processing module capable of receiving inputs of different diverse interfaces, good computation power, RTOS support, Internet of things (IoT) support	Microcontroller	FireBeetle ESP32
A sensing module that can precisely measure the stick's orientation, location, linear acceleration, and rotations in order to gain a 3D perspective of its use.	IMU Sensor	Adafruit BNO055
Stick force measurement module that sends amplified signal and digital data to the controller's algorithm for processing	Force Sensor and ADC	Load Cell SEN13332 with ADC HX-711
External module for time stamping for analysis and usage of stick	External RTC Module	Adafruit DS3231
Real time vibration feedback module	Vibration Motor	Speed Studio 316040001
OLED display to visualize the parameters	OLED	SSD1306
Data recording for post processing and analysis	SD card	Kingston 32GB microSD
A real time operating system for embedded software development of proposed algorithm for BfT.	RTOS	FreeRTOS

3.3.1. Processing engine (microcontroller)

The key processing module is the microcontroller device, a master module to manage all inputs and outputs via a processing algorithm. The choice for this processing engine is the FireBeetle ESP32 IoT microcontroller due to its technical advantages over other counterparts available in the market (Kadir et. al 2021). It is the main hub for sensor data fusion, data processing, and essential wireless telemetries. Since the microcontroller is the key device, it is important to understand the selection criteria.

3.3.1.1. Selection criteria

The DFRobot FireBeetle series is a low-power consumption microcontroller specifically designed for Internet of Things (IoT) applications (Almeida, et. al 2007; Prasetyo et. al. 2019; Kadir et. al 2021). The FireBeetle Board-ESP32 includes a Dual-Core ESP-WROOM-32 module that enables MCU and Bluetooth connectivity. In profound sleep mode, the electric current is as low as 10μA. In addition, the FireBeetle technology makes it possible for designers and engineers to construct devices without the use of breadboards or soldering, which is very useful for applications that need to be worn or carried around. Consequently, the FireBeetle ESP-32 was chosen for the proposed BfT since it is superior to other boards in terms of price, size, support for Li-Ion batteries, Wi-Fi, Bluetooth, a variety of peripherals, GPIO, and Real Time Operating System (RTOS) support (Prasetyo et al., 2019). Since the size of the electronics dictates the size of the housing in the BfT, the board should fit inside the casing of the BfT. In this configuration, the version with a dual-core processor was selected to enable multitasking needed for the sensor fusion in the microprocessor. The parameters of the selected controller are compared to other viable competitors (Table 3.2). It can be seen in the Table 3.2 that, from dimensional size to cost and performance to availability with diverse interfaces, FireBeetle ESP32 is the most suitable choice for the BfT.

Table 3.2: Comparison of FireBeetle ESP32 with other competitive microcontrollers (See Appendix A)

Parameter	Arduino Uno	Beetle ESP32	Espressif ESP8266	FireBeetle ESP32
Power supply interface	USB / DC 2.1	USB / DC 2.1	USB / 3.7V Li-Po	USB or 3.7V Li-Po
Operating Voltage	5V	5V	3.3V	3.3V
CPU Frequency (MHz)	16	16	160	240
Flash (M)	0.032	0.256	16	16
SRAM (KB)	2	8	50	520
Analog Pins	6	16	1	5
Digital Pins	14	54	10	10
Wi-Fi Protocol	-	-	802.11 b/g/n	802.11 b/g/n
Bluetooth Protocol	-	-	-	Bluetooth / BLE
UART, I2C, SPI	1	2	1	2
Li-ion Charger Support	No	No	No	Yes
Dimensions (mm)	75x54	102x53	58x29	58x29
Price (£)	21.88	10.90	8.71	13.83
FreeRTOS Support	Yes	Yes	No	Yes

3.3.1.2. Architecture of FireBeetle ESP32

The FireBeetle ESP32 was developed by Espressif Systems (Shanghai, China) and includes a built-in power amplifier, low-noise transceiver, antenna switches, power-management modules, and filters. It has a dual-core processor (Tensilica Xtensa LX7) and diverse interface support (Atif et al., 2020). The architecture of FireBeetle ESP32 can be understood in terms of five functional blocks (figure 3.2).

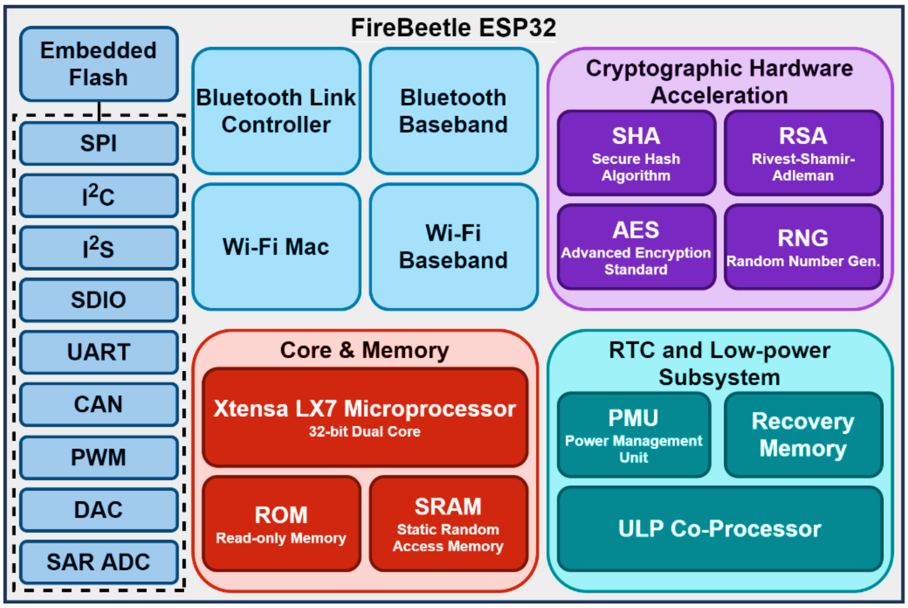

Figure 3.2: FireBeetle ESP32-S3 functional architecture (Atif et al., 2020)

3.3.1.3. CPU and core processing block

The Tensilica Xtensa LX7 is based on 32-bit real-time architecture with a mature C/C++ compiler support making it feasible to implement algorithms for BfT. Multiple cores in the processor enable it to support multi-threaded tasks and improve execution times by parallelization. For this prototype, an IoT-oriented digital signal processing (DSP) "Fusion F1" was selected due to the sensor-based application. The microcontroller device Fusion F1 is generally used for implementation of low-power IoT and wearable applications, low-end IEEE 802.11ah, narrowband IoT, and Bluetooth communication functions. This is a dual core processing system where the first processing core is fully capable of handling complex tasks with ease. This is further powered by the presence of second core available for utilisation if needed. Inbuilt ROM as program storage memory is available which houses the final code while Static Random-Access Memory (SRAM) memory for code execution is also available on-chip. This provides sufficient storage to store the programs for BfT implementations. ESP32 accesses the external Queued Serial Peripheral Interface (QSPI) flash and SRAM through high-speed caches. CPU code space is memory-mapped with support of 16 MB of external flash and CPU data space is memory-mapped with 520 KB of SRAM. Internal ROM of ESP32 contains the bootloader to start the code from external ROM. The core processing capabilities with all the necessary on chip support makes ESP32 a fine choice for the implementation of BfT algorithms (Atif et al., 2020).

3.3.1.4. Wireless communication block

The BfT is intended to provide wireless data over user interfaces developed for walking stick users and AHPs, which necessitates the requirement of a wireless communication module. FireBeetle ESP32 provides support for both Bluetooth and 802.11 b/g/n Wi-Fi for wireless data transmission. The communication block support baseband physical layer implementations make it convenient to incorporate dual mode communications without concern of the underlying waveform implementation. Waveform in physical layer of the communication means end to end protocol for data transmission. Bluetooth Low Energy (BLE) baseband processing is the main source of communication between the ESP32 and the mobile application developed for walking stick users and AHPs, thereby providing wireless data interfacing.

3.3.1.5. RTC and low power block

The battery included in the BfT is its only source of power, making energy management critical. Keeping the ESP32 alive for performance requires careful power budgeting to ensure that BfT can run for as long as possible. The on-chip real-time clock (RTC) modules and an external RTC module are responsible for this. The low-power subsystem of ESP32 is responsible for managing power, and it does so by configuring one of five different power efficiency levels based on the system's needs:

1. Active Mode
2. Modem Sleep Mode
3. Light Sleep Mode
4. Deep Sleep Mode
5. Hibernation Mode

Whenever the ESP32 enters any of the sleep modes, power is disengaged from the specific section depending upon the mode. Only random-access memory (RAM) has enough power to keep the currently running program data intact. An ultra-low-power (ULP) co-processor aids in power management by doing fundamental operations such as sensor monitoring and measurement collection when the primary processor is idle. ESP32 works in different modes according to the operation done by the BfT (Table 3.3).

Mode	State of BfT	Active on-chip Modules	Current usage
Active	Connected to mobile app	Core block, wireless communication block, I/O peripherals, ULP, RTC	160 ~ 260 mA
Modem sleep	Normal operations	Core block, ULP, RTC	3~20 mA
Light/Deep sleep	Critical battery condition	ULP, RTC	0.01~0.8 mA
Hibernation	Hyper critical	RTC	0.002 mA

Table 3.3: Power modes of operation available for RTC and low power block (See Appendix A)

Monitored data needs to be strictly time-stamped to properly understand the walking patterns of the user at any given time. This is provided using Real-time Clock (RTC) which provides the time tick based on internal elements that are periodically signaled. External RTC modules are also used to track date and time in real-time (Hadi et al., 2018).

3.3.1.6. I/O interfacing block

The FireBeetle ESP32 has various interfaces available for both serial and parallel communications. It is powered by on-chip Universal Asynchronous Receiver Transmitter (UART), Pulse Width Modulation (PWM), Analog to Digital Converter (ADC) and Digital to Analog Converter (DAC). It is also supported by industry standard Controller Area Network (CAN) bus ready to communicate without any excessive wiring hassles. It has Inter Integrated Circuit (I^2C) support for fast serial communication. The external RTC module is interfaced via I^2C communication protocol, and it keeps track of timestamps of the monitored data in the BfT. Such diverse peripheral availability in small package is one key reason to choose this microcontroller for the BfT.

3.3.1.7. Cryptographic hardware acceleration block

Wireless communication is an important area as it interfaces the data telemetry to the GUI using a smart phone application. Encryption functionality can be obtained, if necessary, through the FireBeetle's built-in encryption hardware acceleration blocks. The widely used Advanced Encryption Standard (AES) is computationally intensive and taxing on a device's core, which is already busy with the primary processing of the BfT algorithm. Rather than the core encrypting and decrypting data on its own, which would incur a greater computational cost, the hardware accelerators on the chip can accomplish this work far more quickly and with little impact on the core's efficiency. This enables walking stick users to keep their wirelessly transmitted data encrypted and avoid unauthorized access.

3.3.2. Orientation sensor (IMU)

The choice of FireBeetle ESP32 provides a strong development platform for the foundation of the embedded solution of the BfT. However, the main input upon which the entire processing relies is the orientation sensor. Separately, gyroscopes provide angular movements in deg/h or rotation angles in degrees, while accelerometers which can provide acceleration in specific directions. The orientation of any freely moving body in 3D space can be tracked using the four basic movement parameters: pitch, roll, yaw, and acceleration in three axes; this is called 6 degrees of freedom (6-DOF) (Baglietto et al., 2011).

3.3.2.1. Selection Criteria

The Adafruit BNO055 MEMS Inertial Measurement Unit (Figure 3.3) is equipped with three-axis gyroscopes, three-axis accelerometers, and three-axis magnetometers respectively. Because of this, it is a full 6-DOF solution provider for any navigation system. In robotic terms, it is a 9-DOF solution provider. However, magnetometers were not used in this system as they are sensitive to magnetic fields, and this could compromise the measurements (Culmer et al., 2014). Adafruit BNO055 has a very small footprint and can easily be integrated in the BfT due to reduced dimensions.

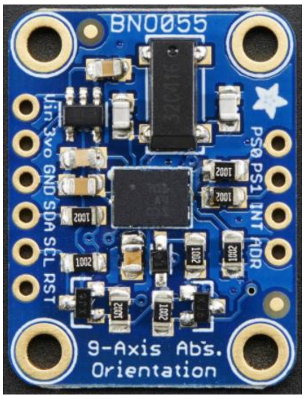

Figure 3.3: Adafruit BNO055 MEMS IMU

Apart from size, cost and performance, another reason to use this sensor was the choice of algorithm planned for the BfT (i.e., use of Euler angles). Sensor fusion algorithms are the gateway solution that merges accelerometer, magnetometer, and gyroscope data into a stable three-axis orientation output. The chosen IMU is compared against the competitive sensors and was found to be the right choice for implementation on low-cost real-time systems without compromising on the performance (Table 3.4).

Table 3.4*:* Comparison of different MEMS based IMU sensors (Source: Adafruit 2021)

	L3GD20	FXAS21002C	LSM9DS0	LSM9DS1	MPU-9250	BNO055
Sensor Type	3 Axis MEMS Gyroscope	3 Axis MEMS Gyroscope	9 Axis* MEMS Sensor (Accel + Mag + Gyro)	9 Axis* MEMES Sensor (Accel + Mag + Gyro)	9 Axis* MEMS Sensor (Accel + Mag + Gyro)	6 Axis MEMS Sensor (Accel + Gyro)
Gyro Sensitivity	±250°/s, ±500°/s, or ±2000°/s	(±250/±500/±1000/±2000°/s)	±245/±500/±2000 °/s	±245/±500/±2000 °/s	±250, ±500, ±1000, ±2000°/s	± 125, ±250, ±500 ± 1000, ±2000 °/s
Accelerometer Sensitivity	Not available	Not available	±2/±4/±6/±8/±16 g	±2/±4/±8/±16 g	±2g, ±4g, ±8g and ±16g	± 2 g, ± 4 g, ± 8 g, ± 16 g
Magnetometer Sensitivity	Not available	Not available	±2/±4/±8/±12 gauss	±2/±4/±8/±12 gauss	±2/±4/±8/±12 gauss	Not available
Resolution	16-bit	16-bit	16-bit	16-bit	14-bit	16-bit

BNO055 has very low noise measurements of angular rates and acceleration compared to the other sensors. With the proposed microcontroller, the devised electronics solution is fully capable of digesting all the sensor data and abstract the sensor fusion in real-time per the intended focus of this thesis. The data that is generated by this IMU can be used in a variety of different algorithms, ranging from those that solve quaternions to those that calculate Euler angles or rotation vectors. In this thesis, the method chosen for determining the position of the BfT was to make use of Euler's angles, which are covered in greater detail in the following section of this chapter.

3.3.2.2. IMU data processing

The BfT being under motion could experience noise as the reliability of the IMU degrades with time due to accumulation of error. Previous researchers have used different filters to remove the noise and ensure the data reliability and precision. The most commonly used filter to remove the noise from the IMU is the low-pass filter (Lajimi, et al., 2017). Low-pass filters have shown promising results in noise cancellation (Dang et al., 2018).

The Simulink platform provided by MATLAB was used to design and implement a noise mitigation filter for the data extracted from the IMU. The Simulink platform assists researchers in numerous fields to simulate systems in real-time. It provides the necessary modules to run, analyse behavior of different systems, and provide robust solutions to complex systems. The user interface allows the researcher to insert blocks of design or mathematical expressions from MATLAB workspace, running the simulation and providing accurate results regarding system response. The output can be visualised and analsyed by using the scopes and 3D image projection blocks available in the Simulink environment (Xue, 2022).

In the context of the present investigation, the data obtained from the IMU sensors were input into the Simulink block, where noise cancellation was performed. The Simulink platform was utilised for the development of the Simulink model that can be seen in Figure 3.4.

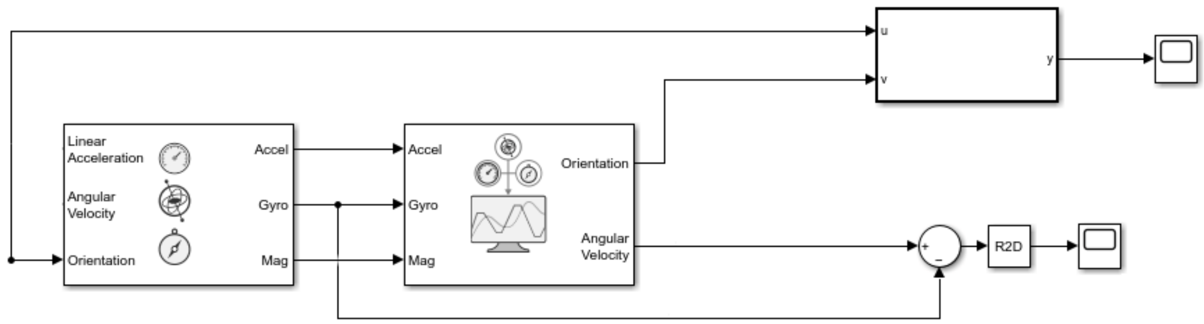

Figure 3.4: Simulink model for noise filtering

The in-built IMU block included with MATLAB is depicted as the first block in Figure 3.4. As a result, there is a path leading to the dataset gathered and provided to this block to receive the signals and continue processing them. The subsequent block is known as the processing block, and its job is to process the data and transform the numeric values into radian form.

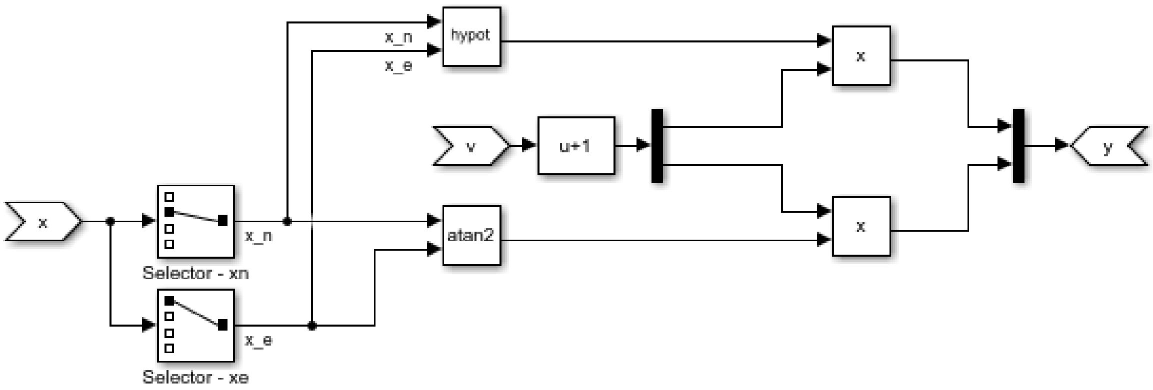

Figure 3.5: Explored view of the processing block

The examined perspective of this block can be shown in Figure 3.5. X is the data set collected from the IMU sensor containing the noise as can be seen in Figure 3.6. After the conversion of the data from the radian to the numeric value, the data is delivered to the filtering block where the noise is removed from the acquired data. Figure 3.7 shows the filtered data.

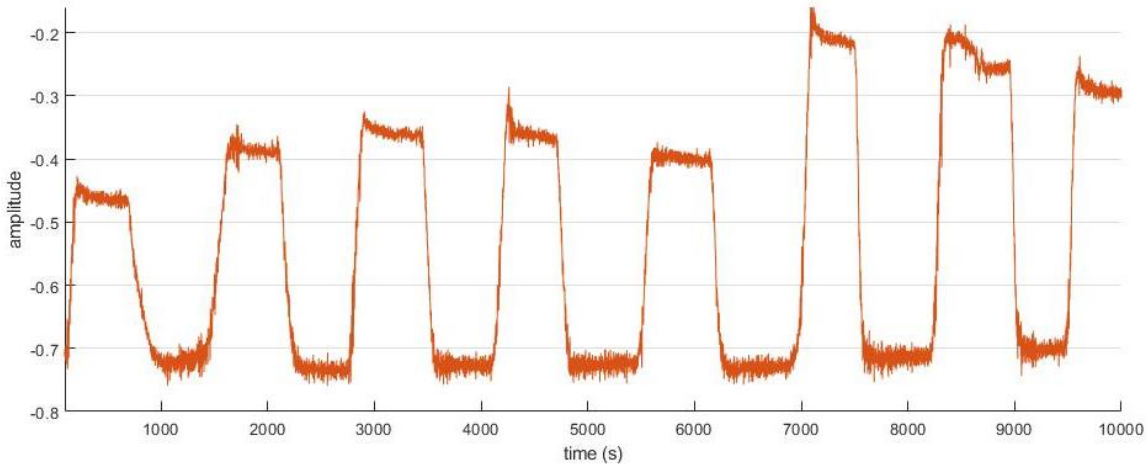

Figure 3.6: IMU data with noise

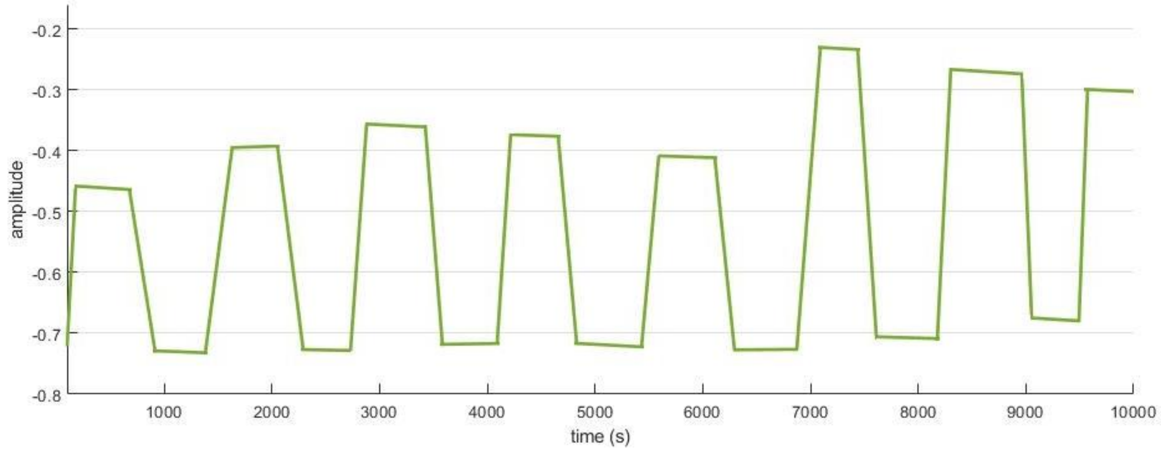

Figure 3.7: IMU data after filtration of noise

Hence, with this noise filtration system implemented within the BfT system, the noise was removed from the sensors.

3.3.2.3. *Technical specifications*

The Adafruit BNO055 has 16-bit resolution the technical specifications including a brief description and its bespoke purpose within the research listed below (Table 3.5).

Table 3.5: Technical specifications of Adafruit BNO055 (See Appendix A)

Parameters	Frequency (Hz)	Description	Purpose
Absolute Orientation	Euler Vector, 100	Three-axis orientation data based on a 360° sphere	Provides orientation angles
Absolute Orientation	Quaternion, 100	Four-point quaternion output for more accurate data manipulation	Useful for quaternion-based approach
Angular Velocity Vector	100	Three-axis of 'rotational speed' in rad/s	Used for computing angles
Acceleration Vector	100	Three-axis of acceleration (gravity + linear motion) in m/s^2	Useful for step counts
Linear Acceleration Vector	100	Three-axis of linear acceleration data (acceleration minus gravity) in m/s^2	Provides correction for accelerations
Gravity Vector	100	Three-axis of gravitational acceleration (minus any movement) in m/s^2	Useful for calibration correction parameter
Temperature	1	Ambient temperature in degrees Celsius	For temperature corrections

3.3.2.4. *Working principle and algorithm*

It is not easy to express, calculate, and keep tabs on an individual’s spatial orientation. Several algorithms, including the Runge-Kutta technique, Heun's approach, and Euler's method, have been developed to deduce an object's orientation from IMU data. Euler's method is the most often used approach (David, I. et.al. 2018).

The Euler method is a first-order numerical strategy for solving ordinary differential equations (ODEs) with a given starting value in mathematics and computing science (David, I. et.al. 2018). It is the most fundamentally explicit approach to the numerical integration of ordinary differential equations. The Runge-Kutta method, which finds approximations to the solutions of any non-linear equation, is based on Euler's method. Despite this, it is computationally costly and complicated (Tracogna. al., 2010; Mai et al., 2021). In contrast, Heun's methodology takes a more geometrical method in its pursuit of a solution, and as a result is typically used in investigations that include keeping tabs on geometrical preferences (Tracogna et al., 2010). Heun's technique builds on Euler's by using the estimated solution from Euler's method as a starting point to construct tangent lines and approximate solutions (Hussain et al., 2016; Lajimi et al., 2017).

When comparing these approaches to solving a differential equation, the Euler method is superior to the other two methods, especially when the dataset is more than 100 numeric values. If the dataset is less than 100 in numeric value, then the Runge-Kutta method and Heun's method is preferred over the Euler method for higher-order equations. However, since the data collected from the IMU sensor exceeds 100 numeric values, many researchers have implemented Euler's method for orientation calculation (Olinski et al., 2016; Jouybari et al., 2019). Therefore, for this study Euler's angle approach was chosen.

Euler's rotation theorem states that in 3D space, every displacement of a rigid body corresponds to a single rotation around an axis that passes through the fixed point so that it remains fixed to the rigid body (Janota, Vojtech, et al. 2015). A rotation of this nature can be defined by three independent parameters: two for describing the axis and one for the rotation angle.

Positions are often transformed from one Cartesian (3D) reference frame (F) to another (3D) reference frame (F') using a 3D rotation matrix. The orientation of F' relative to F can be represented by this 3x3 matrix. Orientation cannot be defined concisely using this representation (Janota, Vojtech et. al. 2015).

The use of quaternions allows for a more concise description of orientation. The encoding for these four scalars is a normalised vector. It is more convenient than the rotation matrix in robot controllers because it is both smaller and less prone to approximation errors. However, due to its lack of intuitiveness, the quaternion is rarely employed as a medium of communication between a user and the robotic controllers (Janota, Vojtech et. al. 2015).

3.3.2.5. Solution using Euler angles

Euler angles consist of three numbers that each describe a rotation around one axis. Various Euler angle notations are used globally, depending on the order of rotations. Euler angles are not unique, but their order is important. Euler angles are typically denoted as α, β, γ, ψ, θ, or φ. Different sets of rotation axes are used to define Euler angles, but generally they are a set or sequence of three angles denoted by roll, pitch, and yaw (Janota, Vojtech et. al. 2015). Euler angles are best understood by considering two 3D cartesian frames of references: one rigid and the other moving. At initial conditions, both frames coincide at the same origin. Rotations about the fixed frame are called extrinsic while those about the moving frame are intrinsic rotations (figure 3.4).

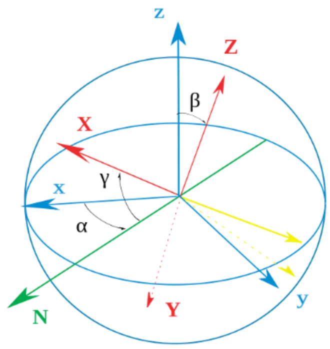

Figure 3.8: Rigid and moving frames and Euler angles (Janota, Vojtech et. Al. 2015)

The axes of the original frame are denoted as x, y, z, while the axes of the rotated frame are denoted as X, Y, Z. The definition in terms of geometry starts by defining the line of nodes (N) as the intersection of the planes xy and XY. With this configuration of frames, the three Euler angles can be expressed as:

1. 'α' is the signed angle between the x axis and the N axis
2. 'β' is the angle between the z axis and the Z axis.
3. 'γ' is the signed angle between the N axis and the X axis.

3.3.2.6. *Conventions of intrinsic rotations*

Intrinsic rotations take place about the axes of a coordinate system XYZ, attached to a moving body. Their orientation changes after each elemental rotation. The XYZ system rotates, whereas xyz is fixed. For initial conditions where XYZ overlaps xyz, a composition of three intrinsic rotations is required to reach any target orientation for XYZ. Euler angles defined by intrinsic rotations can be represented by successive orientations (Giulia Piovan, Francesco Bullo, 2012), denoted as:

- x-y-z, or x_0-y_0-z_0 (initial)
- x′-y′-z′, or x_1-y_1-z_1 (after first rotation)
- x″-y″-z″, or x_2-y_2-z_2 (after second rotation)

- X-Y-Z, or x_3-y_3-z_3 (final)

The first rotation of an element (X) in this series defines the orientation of the line of nodes (N). To simplify things, we can write N as x′. Third elemental rotation overlaps z″ and shifts orientation around Z. (Bojanczyk and Lutoborski, 2005). The Euler angles can then be defined more simply as:

- α represents a rotation around the z axis,
- β represents a rotation around the x′ axis,
- γ represents a rotation around the z″ axis.

3.3.2.7. Conventions of extrinsic rotations

Elemental rotations about the fixed axis xyz are called extrinsic rotations. Starting with XYZ coinciding with xyz, a sequence of three extrinsic rotations can be used to reach any desired orientation for XYZ. The Euler α, β, and γ are the amplitudes of these elemental rotations. These rotations are understood as:

- The XYZ system rotates by γ about the z axis,
- The system rotates by β about the x axis,
- The third rotation of XYZ system by angle α about the z axis.

A total of three rotations occurs about z, x, and z, denoted as z-x-z (or 3-1-3).

3.3.2.8. Proper Euler angles

The problem comes with calculating the Euler angles to find the orientation of the BfT. The fastest way to calculate this is by comparing the three given vectors in the form of a matrix with its theoretical counterpart. To understand the mechanism of Euler angles, the most used conventions of ZXZ were considered with the help of a projection diagram (figure 3.5). Other conventions can be obtained by renaming the axes (Janota, Vojtech et. al. 2015).

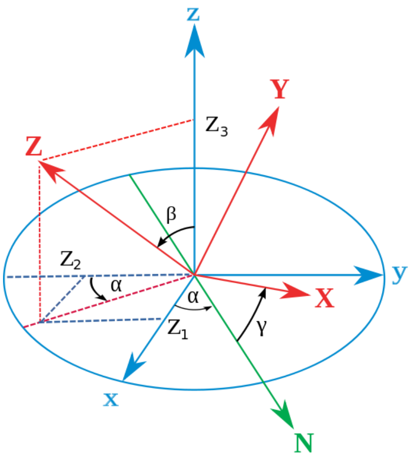

Figure 3.9 Euler angles projection (Janota, Vojtech et. al. 2015)

The coarse alignment technique is used to enumerate the initial Euler angles, offering estimates of the pitch and roll angles. The three rotation angles that comprise the direction cosine matrix (DCM), which transfers inertial readings from Body Frame b (BF) to NED frame n, are pitch, roll, and yaw angles. These may be derived using the coarse alignment equation as follows.

Consider the generic frames a and b. As a direct consequence of this, the transformation from the b-frame to the a-frame is represented by a rotation vector, quaternion, and rotation matrix DCM. To define the transition from the navigation frame NED to the body frame BF, the matrix equation that follows combines three rotation matrices that are specified by Euler angles as follows:

$$\boldsymbol{C}_n^b = \begin{bmatrix} 1 & 0 & 0 \\ 0 & \cos(\rho) & \sin(\rho) \\ 0 & -\sin(\rho) & \cos(\rho) \end{bmatrix} \begin{bmatrix} \cos(\theta) & 0 & -\sin(\theta) \\ 0 & 1 & 0 \\ \sin(\theta) & 0 & \cos(\theta) \end{bmatrix} \begin{bmatrix} \cos(\psi) & \sin(\psi) & 0 \\ -\sin(\psi) & \cos(\psi) & 0 \\ 0 & 0 & 1 \end{bmatrix} \quad \text{(i)}$$

Where ρ is the roll angle, θ is the pitch and ψ is the yaw angle.

$$\boldsymbol{C}_b^n = \begin{bmatrix} \frac{-\tan(\varphi)}{g} & \frac{1}{\omega_e \cos(\varphi)} & 0 \\ 0 & 0 & \frac{-1}{g\omega_e \cos(\varphi)} \\ \frac{-1}{g} & 0 & 0 \end{bmatrix} \begin{bmatrix} (\boldsymbol{a}^b)^T \\ (\boldsymbol{\omega}_{ib}^b)^T \\ (\boldsymbol{a}^b \times \boldsymbol{\omega}_{ib}^b)^T \end{bmatrix} \quad \text{(ii)}$$

Where $\boldsymbol{a}^b = [a_x\ a_y\ a_z]^T$ is the accelerometer measurements, $\boldsymbol{\omega}_{ib}^b$ is the angular rates measurement vector, g is the gravity, ω_e is the earth rate, and φ is the latitude. The Earth rotation rate expressed in NED coordinate system is evaluated as (Shin et al., 2005).

$$\boldsymbol{\omega}_{ie}^n = [\omega_e \cos\varphi, 0, -\omega_e \sin\varphi]^T \quad \text{(iii)}$$

Corresponding quaternion in NED is as follows (Shin et al., 2005)

$$\mathbf{q}_{n(k-1)}^{n(k)} = \begin{bmatrix} \cos\|0.5\zeta_N\| \\ -\frac{\sin\|0.5\zeta_N\|}{\|0.5\zeta_N\|} 0.5\zeta_N \end{bmatrix} \quad \text{(iv)}$$

Where $\zeta_N = \boldsymbol{\omega}_{ie}^{n} \, T_s$ and T_s is sampling period of the inertial data.

It is important to note that the assessment of the rotation vector may be made more easily if the change in the latitude of the body frame can be disregarded. The orientation is determined through a series of calculations:

First, the feedback *b* is examined, but only the roll and pitch angles are considered since poor alignment cannot produce a consistent yaw angle.

$$\boldsymbol{b}_k = \begin{bmatrix} \cos\Theta_{a,k-1} & 0 & 0 \\ 0 & 1 & 0 \\ \sin\Theta_{a,k-1} & 0 & 0 \end{bmatrix} \left(\begin{bmatrix} \Phi_{a,k-1} \\ \Theta_{a,k-1} \\ 0 \end{bmatrix} - \begin{bmatrix} \Phi_{\omega,k-1} \\ \Theta_{\omega.k-1} \\ 0 \end{bmatrix} \right) \quad \text{(v)}$$

Here, a and b are the pitch and roll angles supplied by the coarse alignment and are the equivalent angles provided by the angular rate integration. The transformation from NED to BF is carried out in equation (iv).

The corresponding quaternion $\mathbf{q}_{b(k)}^{b(k-1)}$ to the difference $\boldsymbol{b}_k$ is then calculated as;

$$\mathbf{q}_{b(k)}^{b(k-1)} = \begin{bmatrix} \cos\|0.5\zeta_N\| \\ \frac{\sin\|0.5\zeta_N\|}{\|0.5\zeta_N\|} 0.5\zeta_N \end{bmatrix} \quad \text{(vi)}$$

Knowing quaternions $\mathbf{q}_{n(k-1)}^{n(k)}$ and $\mathbf{q}_{b(k)}^{b(k-1)}$ we can compute Euler angles represented by $\mathbf{q}_{b(k)}^{n(k)}$ using the chain rule

$$\mathbf{q}_{b(k)}^{n(k)} = \mathbf{q}_{n(k-1)}^{n(k)} * \left(\mathbf{q}_{b(k-1)}^{n(k-1)} * \mathbf{q}_{b(k)}^{b(k-1)} \right) \quad \text{(vii)}$$

Hence, the Euler angles are then extracted from $\mathbf{q}_{b(k)}^{n(k)}$

A simple example below illustrates this fact: assume that the actual orientation of then sensor is given by

$$R_{actual} = R\,(\theta_z = 45^\circ, \theta_y = 75^\circ, \theta_x = 20^\circ) = \begin{pmatrix} 0.183 & 0.431 & 0.884 \\ 0.183 & 0.898 & 0.4 \\ 0.966 & 0.089 & 0.243 \end{pmatrix}$$

where the yaw, pitch roll convention has been assumed. Further assume that the orientation reported by the measurement system is “tilted” by 1º about the global *x*-axis:

$$R_{estimate} = R\,(0^{o}, 0^{o}, 1^{o})\,R_{actual} = \begin{pmatrix} 0.183 & 0.431 & 0.884 \\ 0.200 & 0.896 & 0.396 \\ -0.963 & 0.104 & 0.250 \end{pmatrix}$$

Calculating the heading (θ_z), pitch (θ_y) and roll (θ_x) angles in the *zyx* order for $R_{estimate}$ yields

$\theta_z = 45^{o}$

$\theta_y = 75^{o}$

$\theta_x = 20^{o}$

.

3.3.3. Force sensor with ADC (load cell)

The ferrule is an important component in all types of walking sticks (G-Ortego et al., 2014). Placement of the ferrule should be firm and smooth so that the entire base lands on the ground with maximum horizontal contact. The orientation is handled by the IMU; however, the next critical aspect of BfT was to determine the amount of load or pressure being exerted by an individual on the BfT. This generates the requirement of load cells for measurement of the force on the BfT. The following load cells were considered:

1. Hydraulic load cells
2. Pneumatic load cells
3. Strain-gauge load cell

Although various types of force sensors have been developed over the last few decades, strain gauge force sensors have become widely used for force measurement due to their practicality and reliability (Kumar et al., 2017). Considering the dimensions of the walking stick, the strain-gauge load cell was the best available option to select. The other two load cells (Hydraulic and Pneumatic) were available in dimensions that would not fit in the walking stick.

Strain-gauge type load cell works on the principle of Wheatstone bridge (Muller et al., 2010). These sensors generate a potential difference whenever the load is applied and balanced bridge is disturbed. The load cell transducer measures the instantaneous value of the force applied as it converts forces such as tension, compression, pressure, or torque into a measurable electrical signal. The load cell disc (TAS606) (SEN-13332) is selected for the proposed stick which works on the principle of strain gauge (figure 3.6. The load cell typically outputs a millivolt-level signal, which is insufficient for the ADC to measure directly and necessitates amplification. An HX711 ADC chip with a preamplifier has been included into the circuit of the load cell utilised in this application. The chip was developed for specific use in weighing systems (Load Cells, 2021).

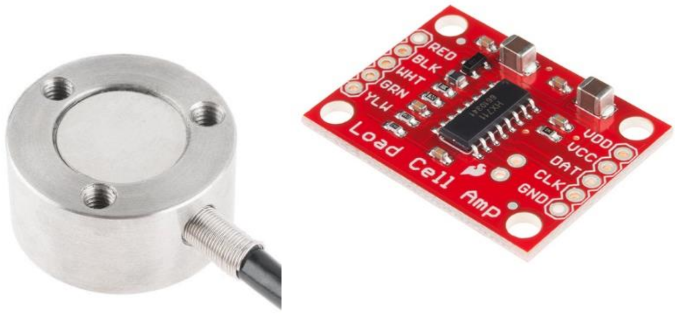

Figure 3.10: Load cell TAS606 with ADC HX711 (Load Cells, 2021)

3.3.3.1. Selection criteria

Load cell is based on the principle of a strain gauge which works via electrical conductance and the geometry of the conductor. Whenever a conductor is stretched within the limits of its elasticity, it does not break but gets narrower and longer. This increases its resistance and disturbs the electrical equilibrium of balanced bridge—the working principle of the strain gauges. This change in resistance is reflected by the change in voltage, which is measured directly proportional to the amount of force being exerted on the cell (Lee et al., 2012).

HX711 is based on Avia Semiconductor's patented technology and equipped with a very high resolution 24-bit ADC designed especially for weight measurement technology. It is excessively used in weighing scales and industrial control applications given its ease in interfacing directly with a bridge sensor. It is the most widely accepted load cell ADC in the industry, as other ADCs for load cell are not configurable in gain. HX711 not only has two channels but provides a choice of selectable gain as well (Load Cells, 2021).

3.3.3.2. Technical specifications

As precision and accuracy were critical, ADC HX711 was chosen as it is powered with selectable gains with 24-bit dual-channel ADCs, allowing precise amplification of the signal from the load cell. It uses a two-wire interface (data and clock) for communication. Wiring up the module with the microcontroller ESP32 allows reading the changes in the resistance of the load cell. Specifications for ADC are listed in table 3.6.

Table 3.6: Specifications of Load Cell Amplifier (HX-711) (See Appendix A)

Parameter	Description
Input Voltage	40 mV
ADC Resolution	24 bits (24 bits A/D)
Gain	Selectable 32, 64, or 128
Operating Voltage	2.6 ~ 5.5 V
Operating Current	< 10 mA

3.3.3.3. Working principle

As weight is the most important variable of force applied to the BfT, the load cell assembly produces standard digital values used by the microcontroller to generate results. Force applied to the BfT is measured by a load cell so that walking patterns can be analysed. Using the algorithm's predetermined logic, the BfT's gathered weight data is used to provide real-time feedback to the user.

To provide weight measurements, the load cell feeds the low-noise programmable gain amplifier (PGA) with a differential input from the input multiplexer with two channels. Channel A is programmed to set the gain, which corresponds to a full-scale input. A configuration circuit for use of HX711 ADC with the load cell is shown in figure 3.7.

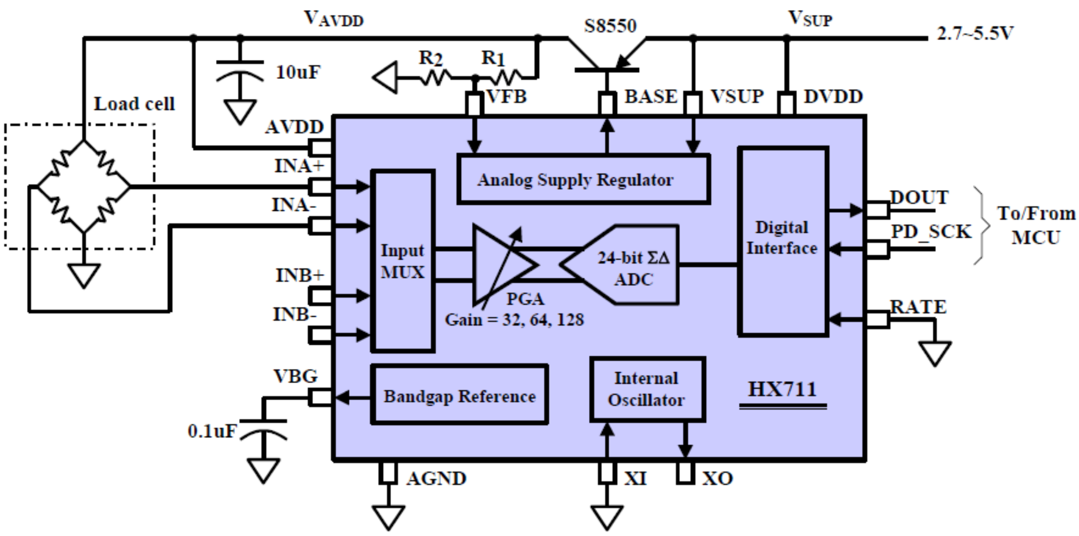

Figure 3.11: Load cell connected with HX711 (Al-Mutlaq et al., 2016)

HX711 ADC produces differential voltage in the range of 0 to ±40mV based on force applied to the load cell. Channel B has a fixed gain of 32. The need for an external supply regulator to provide analogue power for the sensor and ADC is eliminated due to the on-board power supply regulator. The clock input is flexible as it is provided from an external clock source with a crystal or the on-chip oscillator which does not require any further component. On-board power-on-reset circuitry eases the digital interface initialization. The digital output from HX711 ADC is used by the microcontroller ESP32 to calculate the weight exerted on the BfT (Al-Mutlaq et al., 2016).

3.3.4. Real-time clock (external RTC module)

To have a time stamp for every sample of data being processed, it is imperative to contain an RTC module. Since BfT usage patterns are to be analysed over certain time periods through the GUI applications, the RTC module was added as a separate time measuring unit to the electronic system. This not only provides the accuracy but also adds to the reliability (Mahajan and Markande, 2016). This also reduces the vulnerability to power loss, whereby the loss of timestamps on the monitored data could hamper monitoring the BfT user's progress. The external RTC module selected for the proposed design is Adafruit DS3231, which is used to enable date and time tracking for time stamps obtained from external sensors, removing the power constraints as Adafruit DS3231 can run for around 2 years on a coin cell (CR2032). Thus, it is a low-cost, long endurance, and accurate module with I^2C communication protocol and extremely low power consumption.

3.3.4.1. Selection criteria

Table three compares some common parameters between the Adafruit DS3231 and other modules.

Table 3.7: Comparison of DS3231 with other competitors

Parameters	Adafruit DS3231	SF BOB-12708	Adafruit PCF8523
Dimensions (mm)	23 x 17.6 x 7.2	20 x 20 x 12	25.8 x 21.8 x 5
Battery Life (Years)	2	1	> 3
Power Consumption	500	510	230
Accuracy	99.99	95.99	90.99
Cost (£)	10.26	11.74	3.64

All RTC modules available on the market suffer from time-drift, particularly with variations in temperature and pressure (Jiming Zhong et. al. 2018). These modules usually drift the clock so much that it is inaccurate by around five minutes per month. This is the key reason why DS3231 has been chosen for this specific application. It is considerably more accurate, as it comes with an internal temperature compensated crystal oscillator (TCXO), making it independent of temperature.

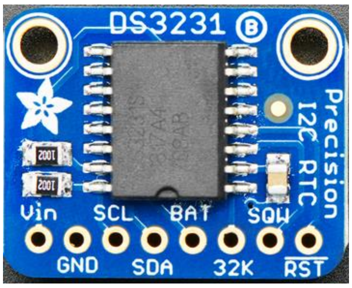

Figure 3.12: RTC Module of DS3231 (See Appendix A)

3.3.4.2. Technical specifications

The Adafruit DS3231 is a high-precision Real-Time Clock (RTC) module that features a 32Kb EEPROM and a 10-bit temperature sensor. The device has a battery input, so the time stamp will still be accurate even if the main power goes off. The integration of the crystal resonator enhances long-term accuracy of the module. The DS3231 is available commercially, and industrial temperature ranges, offered in a 16-pin, 300-mil SO package. Table 3.8 lists the specifications of the Adafruit DS3231.

Table 3.8: Technical specifications of RTC module (See Appendix A)

Parameter	Description
Operating Voltage Module	2.3V – 5.5V
Current Consumption (on Battery)	500nA
Max Signal Voltage for SDA and SCL	V_{cc} + 0.3V
Operating Temperature	-45 to +80
Battery Cell Type	CR2032

3.3.4.3. Working principle

An oscillator is circuitry that generates a continuous, repetitive, alternating waveform in the absence of input (Song, 2003). Oscillators transform linear current flow from a DC source into an AC cycle with the frequency determined by their circuit components. To obtain oscillations of constant amplitude, the energy delivered must be correctly regulated and equal to the energy lost. Practically, oscillators are nothing more than amplifier circuits with positive or regenerative feedback, in which a portion of the output signal returns to the input as can be seen in Figure 3.13.

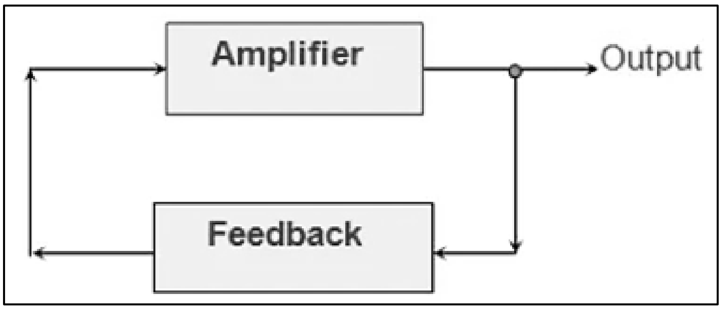

Figure 3.13: Block representation of Oscillator

The amplifier comprises of an amplifying active element, which can be a transistor or an Op-Amp. The feedback signal is held accountable for sustaining the oscillations by compensating for circuit losses (Song, 2003; Brain, 2009; Do. 2020). Due to the electrical noise in the system, oscillations begin to appear by turning on the system. This noise signal moves around the loop, amplifies, and soon corresponds to a single-frequency sine wave. The closed-loop gain of the oscillator depicted in Figure 3.13 is illustrated as.

$$G = \frac{A}{1 + A\beta}$$

Where A is the amplifier's voltage gain, and β is the feedback network's gain.

Parameters like the feedback system and the shape of the output waveform are used to categorise oscillators. The circuitry in an oscillator, which is used to represent time, works by first amplifying noise at the crystal frequency (typically quartz) (Chirikov, 1979; Osram, 2012). The output of a crystal oscillator is converted into pulses that can be used in digital electronics. These dampen the crystal's frequency and convert it into the right shape for the screen.

An RTC module maintains the time and clock by using the cycles of an oscillator: usually an external 32.768 kHz crystal oscillator circuit, an internal capacitor-based oscillator, or the embedded quartz crystal. This RTC operates on the principle of a phase-locked loop (PLL), shifting its internal clock reference to ‘lock’ it onto the external signal. This enables the ticks to be integrated to form hours, minutes, and seconds as per user requirement (Kabir et al., 2019)

3.3.5. External interface modules

The following section discusses the output interfaces which displays or logs the data for both walking stick users and AHPs.

3.3.5.1. OLED display module

Visual feedback information for walking stick users was through an OLED display placed on top of the handle, maximising its visibility to the user. OLED screens are gaining popularity due to advances in screen technologies. OLED is the organic-LED with a concept of self-illuminating pixels, unlike traditional LEDs which provide brighter displays with higher contrast.

The 0.96-inch diagonal OLED module (SSD1306) was chosen due to its monochrome display. It is powered with 128 x 32 pixels, and the power consumption of OLED is relatively lower when compared to the power consumption of other displays since its pixels only require energy when they are powered on.

Figure 3.14: OLED display SSD 1306 (Goyal et al., 2020)

The monochrome display is available in blue and white pixels and can display 2-3 text lines based on font size selection. This module also has support for the I^2C communication protocol. Table 3.9 lists the specifications of the SSD1306.

Table 3.9: Technical specifications of the OLED display (See Appendix A)

Parameter	Description
Display size	0.96”
Resolution	128 x 32
Communication Protocol	I^2C Interface
Display Color	White
Operating Voltage	3.3V – 5V
Dimensions (mm)	36 x 12.5
Viewing angle	>160°

3.3.5.2. *Haptic and Audio feedback*

To augment the OLED display, feedback via vibration and/or audio to the user as an alert is critically important. The alert signal was to be initiated for incorrect usage of BfT so that the walking stick user may rectify themselves. This may help in understanding the severity of the underlying health condition if the incorrect usage pattern is of high frequency. Ultimately, this may help AHPs and walking stick users in regulating the BfT usage via active feedback, which may considerably speed up the rehabilitation process.

The functionality was governed by the installation of a small vibration motor and a buzzer in the handle of the BfT. This provides haptic and aural feedback to the user, alerting them if they are placing more weight on the BfT than what is required or positioning the BfT at inappropriate angles. The AHPs have the capability of deciding and pre-setting the threshold value of the triggering weight and orientation of the BfT. It is necessary that the vibration motor and buzzer utilised for this function be shrunk much like the rest of the electronics in order to keep the same level of powerful vibrational and loud aural feedback. The vibration motor model 316040001 and piezo buzzer was selected for the designed model (figure 3.10). Vibration motor has a vibration amplitude of 2mm operates on 2.5-3.5V range (some specifications listed in Table 3.10).

Figure 3.15: Vibration motor model 316040001 (Left) & Piezo Buzzer (Right)

Table 3.10*:* Technical specifications of the vibration motor (See Appendix A)

Parameter	Description
Type	DC motor
Function	Vibration
Rated Voltage	3V
Terminal Style	Wire leads
Operating Temperature	-20 ~ 70 ^{O}C

3.3.5.3. *Data logging (SD Card)*

Today, machine learning is all about collecting and storing data. For long-term study and a comprehensive knowledge of an individual's progress or reversal in health, this data will display the consumption pattern with temporal distributions. The processing engine employed an SD card to save the information. Today's SD cards can be broken down into several distinct categories, each based on factors like data transfer rate and storage capacity. When sorting data for embedded applications like smartphone storage, many prioritise data type over transfer rate (Hadi et al., 2018). The following are some illustrations:

- C2 (Class 2): minimum write speed of 2MB/s
- C4 (Class 4): minimum write speed of 4MB/s
- C6 (Class 6): minimum write speed of 6MB/s
- C10 (Class 10): minimum write speed of 10MB/s

Cards varying in storage capacity are classified as follows:

- SD: up to 2GB
- SDHC: 2GB to 32GB
- SDXC: 32GB to 2TB
- SDUC: 2TB to 128TB

For the intended research and prototype development, a 32 GB SD card was used. The following equation was used to find the days for data storage:

$$Number\ of\ storage\ days = \frac{size\ of\ SD\ card}{Packet\ size * sampling\ rate * active\ hours\ per\ day}$$

Assuming a packet rate of 40 bytes per 10 milliseconds, a 32 GB SD card should last up to 200 days. The sampling rate and data size can be adjusted accordingly by selecting the parameters to be monitored (Hadi et al., 2018).

3.3.5.4. *Mobile application display*

With the rapidly emerging technology, it is more important to consider user empowerment when developing or adapting the technology. Therefore, to further facilitate the BfT users, a mobile application (app) was developed. This mobile app uses the BLE variant of Bluetooth. This comes in the category of interface layer. This enables the stakeholders to:

- Monitor data in real-time from the sensors
- Analyse and visualise the data through graphical support
- Select the parameters for data logging
- Adjust the sampling rates of the data logged

The BFT's electronic components are depicted in their entirety together with their interconnections at the block level in Figure 3.11. To keep the BfT's overall efficacy and accuracy, all modules were chosen based on cost and energy usage.

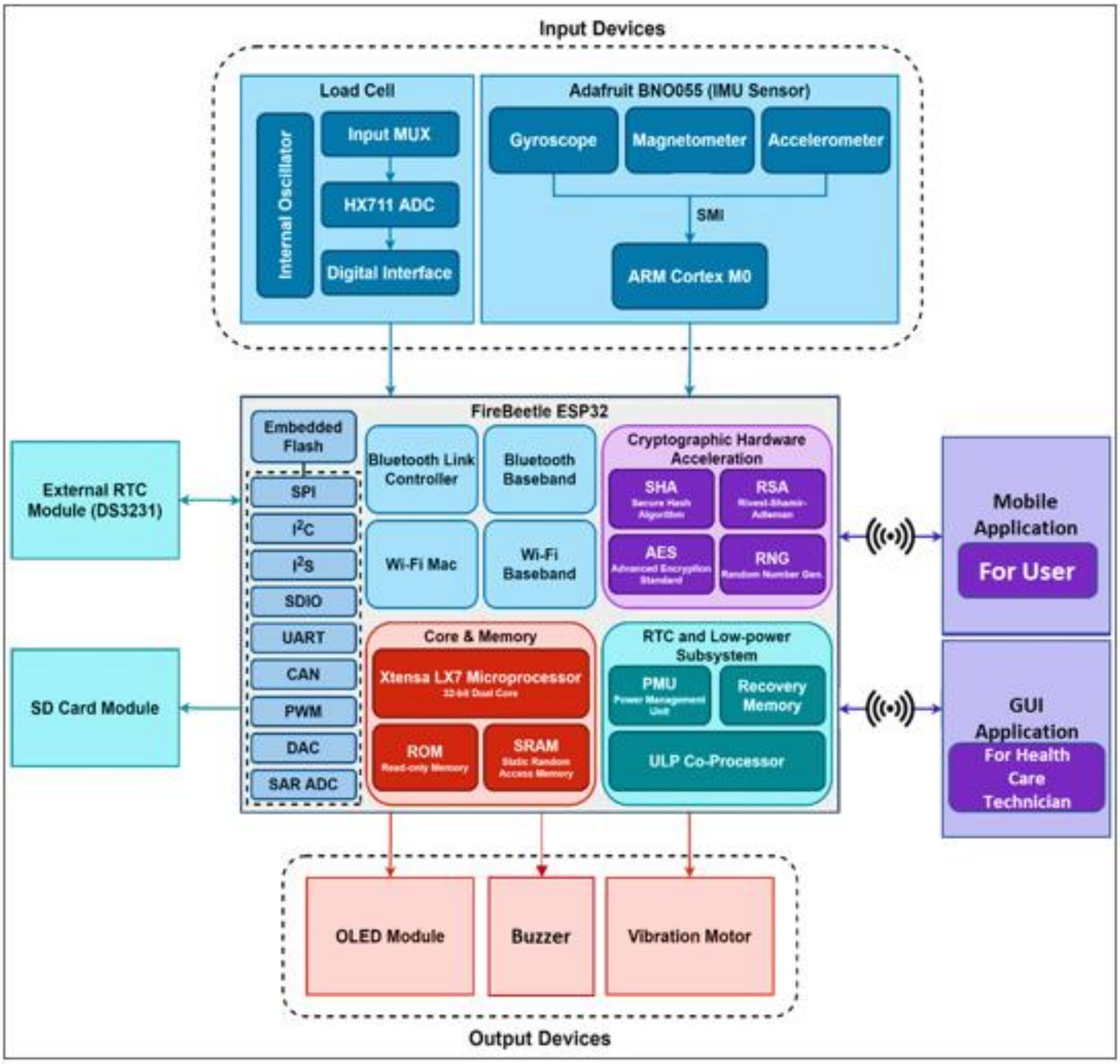

Figure 3.16: Over all electronics connectivity functional block diagram

3.3.6. Powering the prototype battery

With the entire electrical load in view of the proposed electronics, it is easier to power up the system. As such, the choice of battery is critical. The BfT keeps the ESP32 in modem sleep mode to save power, only entering active mode to transfer data to the mobile application (Ayala et al., 2019; Figueiredo et al., 2021). While in modem sleep mode, power to the Bluetooth module is limited, meaning the module draws only 3 mA to 20 mA of current. For this reason, Li-ion is a suitable choice for the BfT, especially when considering the dimensions of the stick. Li-ion is available in a cylindrical shape, which can easily fit into the BfT and is easily replaceable. The overall consumption details of the stated electronics are listed below (Table 3.11).

Table 3.11: Load calculations for electronics of the BfT

Device	Working Mode	Consumption	Units
ESP32 Beetle	Normal	80	mA
BNO055	Normal	12.3	mA
Load Cell Sensor (10kg)	Operating Current	<1.7	mA
	Shutdown Current	<0.001	mA
SD Card Reader	Typical	80	mA
	MAX	200	mA
	MIN	0.2	mA
RTC	Typical (3.3V)	0.02	mA
OLED 128x32	Display off	0.004	mA
	Display on **(Black Screen)**	0.004	mA
	Contrast 31, **50% pixels lit**	16.2	mA
	Contrast 127, **50% pixels lit**	19.7	mA
	Contrast 255, **50% pixels lit**	21.7	mA
	Contrast 31, **100% pixels lit**	27.5	mA
	Contrast 127, **100% pixels lit**	33.8	mA
	Contrast 255, **100% pixels lit**	36.0	mA
Total Consumption	**Typical**	**249.8208**	**mA**

The capacity of the Li-ion battery used is rated with 6000mAh and the typical current rating of the device is computed at about 249mA to 250mA. The total operating time of the BfT is computed as:

$$Working\ time\ of\ BfT = \frac{6000}{249} = 24.09\ hrs$$

Hence, the BfT would work for approximately 24 hours in the normal mode.

3.3.6.1. PCB design and schematics

PCB was designed with the help of Proteus Software Version 8.0, available at the University. In Intelligent Schematic Input System (ISIS) section, headers were appropriately picked for the selected sensors from the respective component libraries. All the sensor pins related to their respective pins on an ESP unit (figure 3.17).

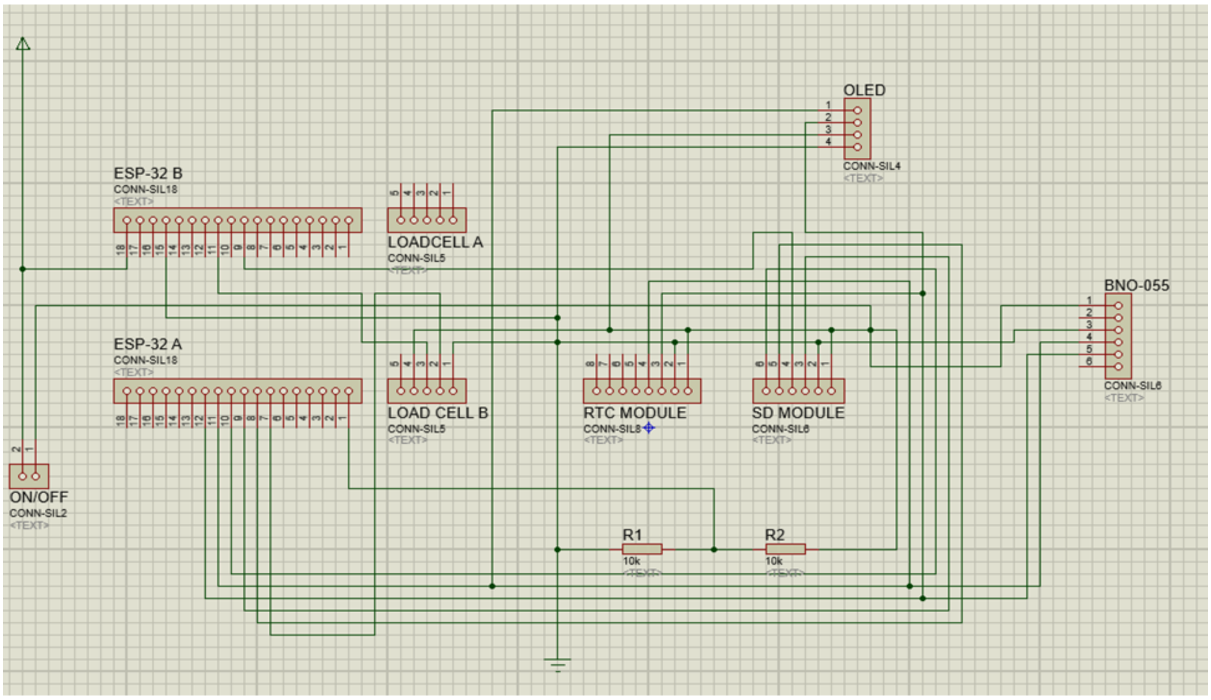

Figure 3.17: PCB Design of electronics of BfT

3.3.6.2. Power On/Off Circuit

ESP processing engine was attached with a power supply in the form of a battery, push button (V_{cc} pin) and through V_{adc} from the output of a voltage divider circuit (figure 3.18). The change in the position of the push button from off to on enabled the user to power all the sensors, including the ESP Unit. ESP constantly monitors the value from V_{adc}. If ever V_{adc} fails to provide value to ESP Unit, ESP will go in deep sleep mode to preserve energy.

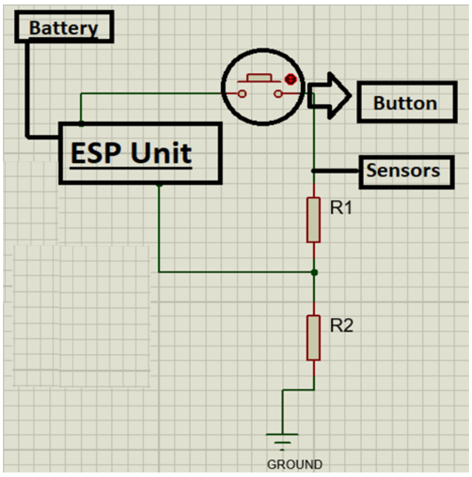

Figure 3.18: On-Off circuit for on board electronics

Subsequently, the layout (figure 3.19) for the PCB was drawn for the silk-screen with the help of Advanced Routing and Editing Software (ARES) section. The silk screen was the input file used for PCB manufacturing. During the silk screen preparation, it was ensured that all components were placed within the boundary wall of the PCB board along with all the sensors.

3.3.6.3. PCB Substrate

Substrate material selection influences the performance of the circuit. Making the appropriate decision is crucial to the PCB design. PCBs are made up of two main components: printed wires and a substrate (the board) (the copper traces). Substrates that distinguish the different layers are necessary for multi-layer boards.

Printed wires and circuit components are held in place physically by the substrate, which also acts as electrical insulation between conductive components. Knowing the Coefficient of Thermal Expansion (CTE) of substrate materials, for example, becomes critical because difficulties might arise if two substrate materials (or even just the substrate and components) along the same printed circuit board have a CTE mismatch. Substrates with discordant CTEs may have flaws induced by the rate of expansion or because the substrates' dielectric constant becomes unstable (Sabunin, 2009; Xu Xiangmin et al., 2011; Gridnev, 2016). While silicon memory chips may have a low CTE, fiberglass laminates have a high CTE. The mismatch in expansion rates might cause solder junctions to break or components to be damaged.

A similar approach is required when choosing a PCB for substrates. Different factors can alter circuit impedance, especially when the circuits run at high frequencies ranging up to 100 GHz (Lau et al., 2019). Moisture absorption and heat conductivity, for example, can have an impact on the dielectric constant. PCBs containing moisture-absorbing substances or high-temperature elements have a higher dielectric constant, impairing high-frequency circuit performance. Consequently, careful consideration of material and design interactions is essential when opting for flexible PCB substrates in electronics circuit design (Zheltova, et al., 2021).

There are four different kinds of substrates, each with a distinct set of properties for a particular application.

FR-2: This less expensive substrate is constructed of impregnated paper, often known as phenolic, which is simple when used over a substrate made of fiberglass. Flame Resistant is the phrase that the "FR" stands for. Usually, less priced consumer gadgets use this kind of substrate (Xu Xiangmin et al., 2011).

FR-4: Woven fibreglass is treated with a flame-retardant material to make fibreglass substrates. Drilling, cutting, and milling are all possible with this tough material. However due to the abrasive nature of fibreglass, tungsten carbide tools are recommended. FR-4 substrates are typically utilised in more expensive electronics due to their increased durability and resistance to breakage and cracking as compared to FR-2 substrates. To handle high power radio frequency applications, printed circuit boards frequently use RF substrates, which are low dielectric polymers. An excellent electrical performance can be expected from this substrate (Xu Xiangmin et al., 2011).

FLEX: Rigid core materials are not used in all circuit boards. Flex circuits are those that are made to be exceedingly just minimally flexible. As substrates, thin, flexible polymers and/or films are used. Although the manufacturing process is more challenging than using rigid substrates, it has advantages over using rigid substrates, such as the ability to save space by bending the circuit board to suit a specific place or when repeated movement necessitates a flexible layer (Zheltova, et al., 2021).

METAL: A substrate with low thermal resistance is necessary for power electronics. Larger copper tracks and the high electrical currents utilized with these kinds of circuit boards may be handled with the help of a ceramic core or metal core substrate (Zheltova, et al., 2021).

This research work has employed glass-fiber reinforced epoxy resin (FR4-PCB) and Lead-free aluminium. The completed PCB's withstand voltage, insulation resistance, dielectric constant, dielectric loss, and electrical characteristics including heat resistance, moisture absorption, and environmental protection (Zheltova, et al., 2021).

This was the final stage for the electronics design. It was followed by electronics integration and basic testing.

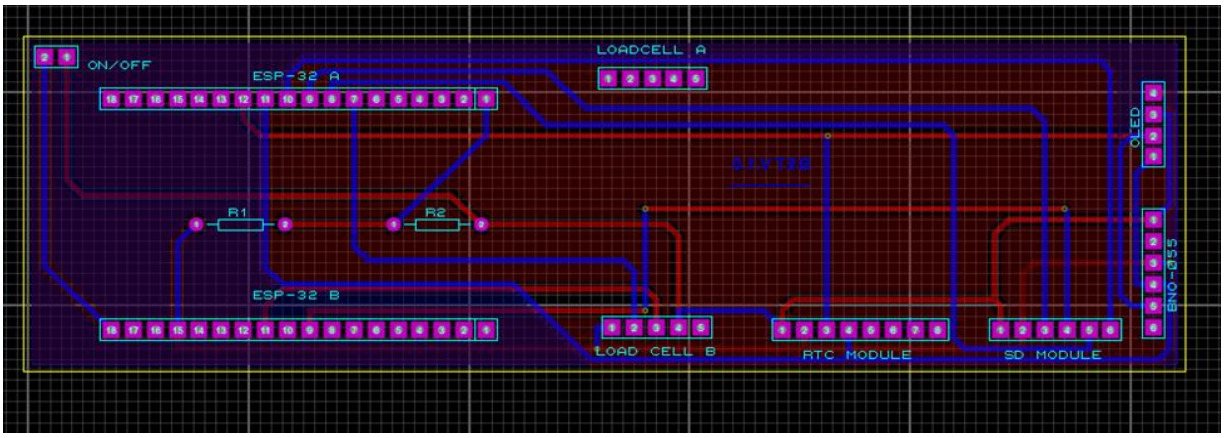

Figure 3.19: PCB layout of the electronics for the BfT

3.4. Mechanical design and development

This phase involves mechanical development of the BfT using the state-of-the-art 3D printing and placement of the above-mentioned electronics modules electronics within the walking stick. A detailed comparison of the existing mechanical designs was illustrated in section 1.6.1.4, which lead to the design of the BfT. Hence, the handle of the BfT was custom designed to accommodate the electronics being designed. Furthermore, material considerations for 3D printing of the stick are highlighted, with a focus on comparisons of the materials available to date.

3.4.1. Assembly of BfT

Various mechanical parts of a standard walking stick are shown in figure 3.15. Given the requirements of the smart BfT, electronics were positioned in various locations of the walking stick. However, to overcome any issues pertaining to the physical compatibility of existing walking sticks to accommodate many electronics modules, the BFT was re-designed to accommodate the components required for this research.

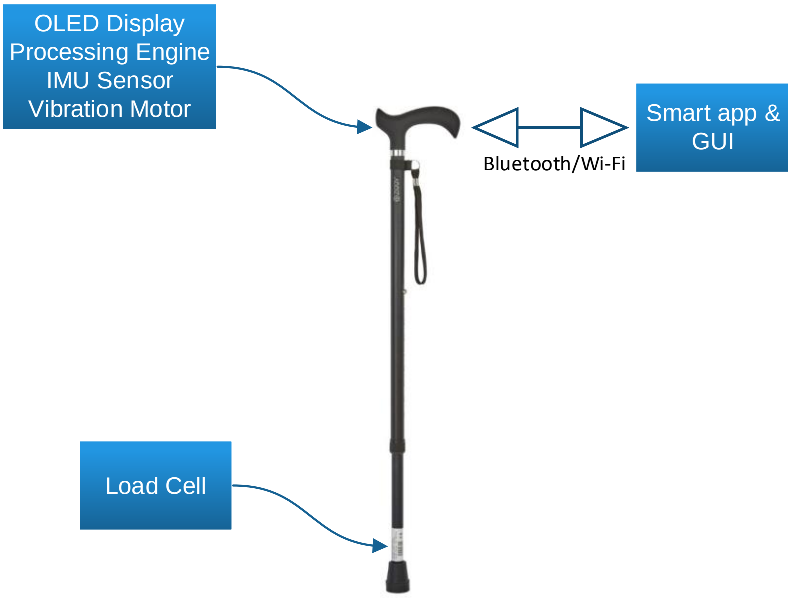

Figure 3.20: Standard walking stick with intended area of placement for electronics

The handle of the stick is the key place to carefully position and embed the sensor electronics and processing engine in-situ. It is the hub with maximum space where most modules can be placed, although this then necessitated the redesign of the handle. After much consideration, all modules were placed in the stick in alignment with the Informal PPI discussions, alongside other technical consideration such as the size of the handle.

3.4.2. Placement of electronics

The key locations of the walking stick to be housed with various electronics modules are described in Table 3.12.

Table 3.12: Placement of electronic modules and reasoning

S.No.	Module in BfT	Placement Position	Rationale
1.	Vibration and audio	Handle	Walking stick user may feel the haptic feedback immediately and/or listen to the audio alert for correcting the posture. The warning is either due to the inappropriate placement of ferrule on the ground causing an incorrect orientation or due to excessive application of force on the BfT
2.	Handle	Redesigned and at the top of the stick	Support for the housing of the core electronics
3.	IMU	In the handle	Best space for electronics to stay in-situ and to retain the perfect IMU alignment once balanced and calibrated
4.	OLED display	Edge of the handle	Being the sensitive component prone to damage due to mishandling or inappropriate pressure. However, the OLED is also required to be vertically upward so that walking stick user may have a clear view of the information being displayed. This is managed by placing OLED at the edge of the handle.
5.	Load Cell	Near the ferrule	Provides the actual measure of the force on the BfT with the best of precision and usefulness.

3.4.3. 3D-printing of mechanical assembly

Conventional walking sticks are available in different materials, providing structural varieties for users. 3D-printing techniques have provided an additional option to the designer, enabling one to develop a bespoke walking stick with their choice of material. The decision to go for 3D printed parts over pre-available was made in a heuristic manner. A predesigned and pre-available aluminium body iwas used so that aluminium's strength may be utilised without redesigning the entire stick. At this stage of study, a handle containing the electronics was 3D printed. Thus, the aluminum stick and custom 3D printed handle resulted in a cost-effective BfT.

The key advantages of the 3D printing are as follows.

1. Low cost due to selection of material as per requirement
2. Availability of 3D materials with different tensile strengths to evaluate several models
3. Easier redesign and provision to customise characteristics as per demand

Based on these main parameters, the BfT was designed in the Solidworks software, which has several state-of-the-art features that enables making multiple changes in the design as per requirement (Lombard, 2013).

3.4.3.1. Solidworks for 3D design

SolidWorks is a solid modelling computer-aided design (CAD) and computer-aided engineering (CAE) program developed by Dassault Systèmes. It is an application used globally to help imaginative designers create 3D patterns. 3D geometry can be created from a set of 2D sketches with various implementable features such as lines, rectangles, circles, arcs, and splines. Shape of sketches can also be changed using features such as rounding, trimming, mirroring, rotating, and stretching (Onwubolu, 2012). When the sketch is ready, the design engineer transforms the sketch into a 3D model using other features provided by SolidWorks, such as extrusion, rotation, fillets, and hole cutting, to create a complete 3D model of a particular component (Lombard, 2013).

3.4.3.2. *Handle design*

One of the requirements proposed during the PPI sessions was an ergonomic handle for the BfT to reduce strain on the wrist. The handle was designed with aesthetics and ergonomics in mind, resulting in the current design (figure 3.21). To ensure that the proposed design can support the force being applied to the stick, the metal bar (B) was kept horizontal, and the plastic casing of the metal bar was replaced with the 3D printed casing. The design proposes the compartment “C” to house the IMU sensor “G”. This IMU sensor was integrated with the circuit through wires that pass through the aluminium tube. System feedback messages to the user were displayed on the OLED screen represented by “H” which was connected to the ESP32 in compartment “D” through wires running through the aluminium vessel. The OLED display was placed where it wouldn't interfere with the user's hold on the stick handle while also providing easy access to the displayed data. The PCB of the prototype was built, so the dimensions of compartment "D" were kept at 215mm x 215mm x 300mm. As a result, the length of the handle was shortened so that it could be more easily manufactured.

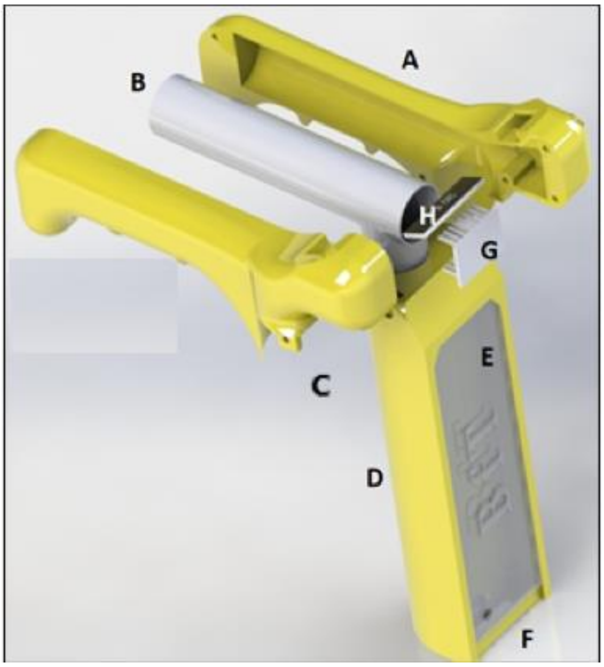

Figure 3.21: 3D Model of the handle assembly

The design and development of the handle was planned in 2 cross-cut halves to maintain the original aluminium structure. Consequently, it was essential to design ‘through holes’ to connect the two cross-cut parts by screws. The mechanical diagrams represent the exact dimensions and relative position of each part of the handle assembly. The final design of the handle is shown in figure 3.22.

Figure 3.22: Final 3D Model of the handle

3.4.3.3. Design of load cell assembly

The load cell was positioned at the base of the BfT near the ferrule to measure the total weight exerted by the user. This necessitated the redesign of the base tip with an accessible compartment for the load cell and its associated peripherals. The complete design of the load cell assembly and the base tip of the BfT are shown in figure 3.23.

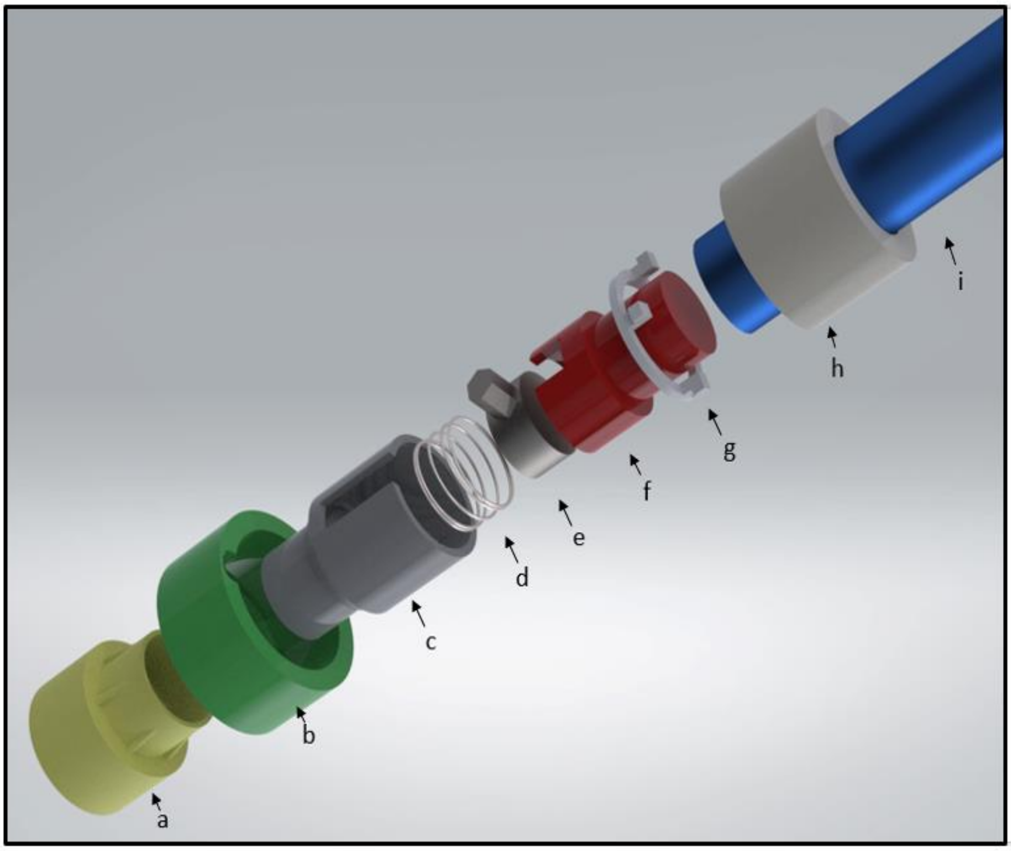

Figure 3.23: Base of the stick and load cell coupling assembly

The ferrule, shown in figure 3.18 as “a”, prevents the BfT from slipping on the floor. It also distributes the force exerted on “c”, which contains a protrusion that contacts the sensor regardless of the inclination of the pole (shown in figures 3.23 and 3.24). Part “d” is a spring separating part “c” and the sensor “e”, preventing the sensor from responding to any pseudo-stimulus associated with the weight of the walking stick. Part “c” also contains a slot to allow the free movement of cables. To facilitate the linear motion of component "e," part "c" is equipped on its inner surface with three shallow grooves. Part "f" provides the coupling between the aluminium rod and the sensor that is necessary to maintain proper alignment of the sensor. The "g" component is a binding ring that secures the "c" and "h" components together and keeps them from dislodging when the BfT is lifted. Part "h" is the one that holds the ring "g" and ensures the linear movement of the sensor. Part "b" prevents the sensor cables from any accidental blow that may compromise the reading.

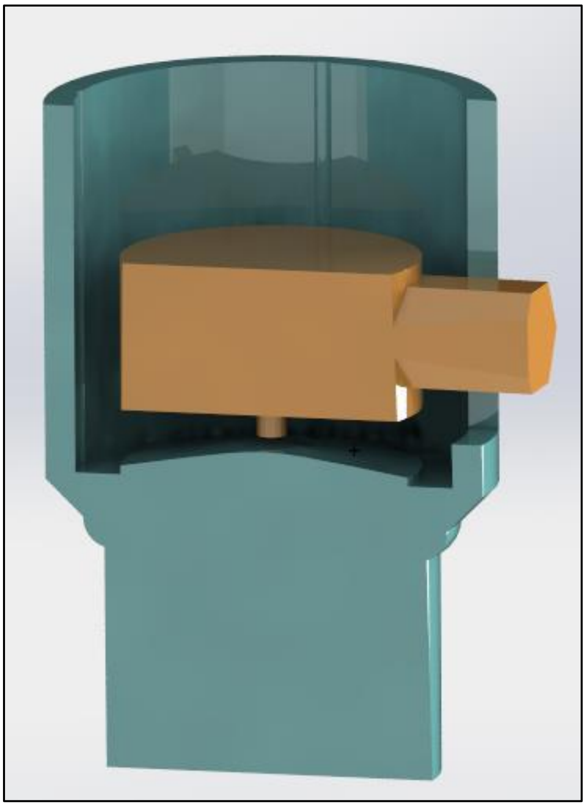

Figure 3.24: Cross sectional view of chassis load cell assembly

3.4.3.4. Design of spring for load cell assembly

A spring enables the pressure to be maintained when the BfT is placed on the ground and ensures that no force is being applied while it is being raised. Part “b” protects parts “c” and “e” from the contact establishment for the very same purpose. This guarantees a certain amount of force is applied to the load cell placed inside and that it takes the reading precisely without any error at zero load conditions. The design has been tweaked to prevent the load cell's operation from being damaged in the absence of a spring, which could have a negative impact on the BfT's overall usefulness. Below is the evaluation of the properties of various spring to enable the selection of the appropriate one for the BFT.

3.4.3.5. Elastic device (spring)

A compression spring is an elastic device common in machinery and that stores mechanical energy. The change in force per unit length change is known as spring rate or spring constant, defined as the ratio between the change in force and change in deflection. This is line with Hooke’s Law. The primary purpose of the coil spring, as adopted in this design, was to utilise the spring force to return the force sensor to its initial state once the BfT was lifted from the ground, as well as when no force was applied (Mohan et. al. 2010).

3.4.3.6. *Spring design heuristics*

Figure 3.25 shows a cross-sectional view of the sensor and the coil spring. The design intent of the spring is such that the spring force can overcome the weight of the sensor and the frictional force. The weight of the sensor was 50 g, which is 0.49 Newton. The conservative estimation of the friction coefficient for steel (the spring) on PLA (Polylactic Acid) 3D (the casing) is 0.2, so the friction force was calculated to be 0.1 Newton using equation 3.1 (Mohan et. al. 2010).

$$f_s = \mu_s N \tag{3.1}$$

where,

f_s: Frictional force, N

μ_s: Frictional coefficient, dimensionless

N: Normal force, N

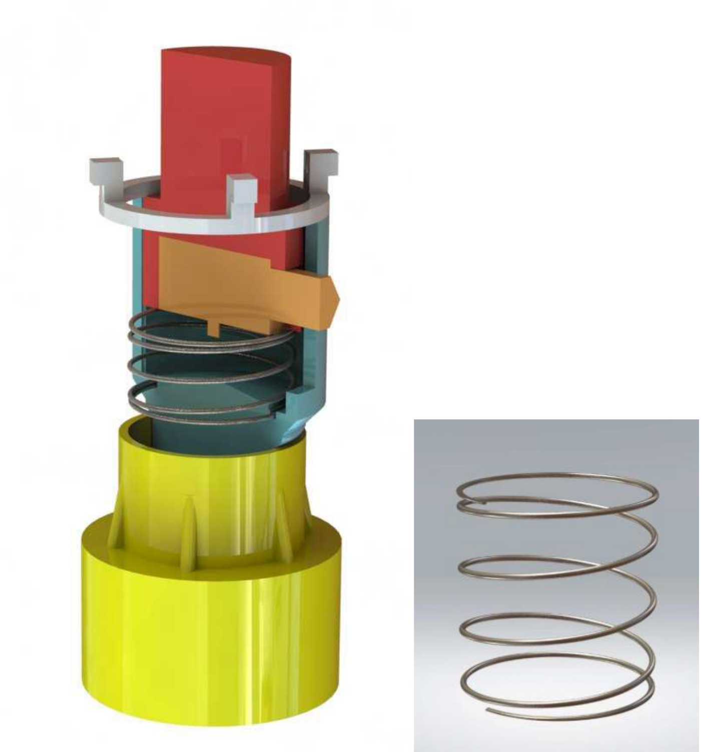

Figure 3.25: Cut-out view of force sensor and coil spring

The force sensor has a 20-millimeter diameter and an 11-millimeter height. The assembled load for the spring was planned to be 0.9 Newton with an outer diameter of 21.6 mm to resist the force of the force sensor (0.59 Newton) and the surrounding space (21.6 mm 0.9 N).

3.4.3.7. *Spring design parameters*

The key design parameters of the coil spring derived from Mohan et. al. (2010), include:

- Total number of coils: 5
- Wire diameter: 0.7 mm
- Mean diameter of spring: 21.6 mm
- Spring rate: 0.075 N/mm
- Weight: 1.03 g
- Material: carbon steel
- Shear modulus: 77000 MPa
- Spring free length: 23 mm
- Assembled height: 11 mm
- Assembled load: 0.9 N
- Shear stress at assembled state: 144 MPa
- Height at fully loaded: 5 mm
- Load at fully loaded: 1.35 N
- Shear stress at fully loaded: 216 MPa

3.4.3.8. *Spring design equations*

The equations used for designing elastic spring as adapted from Paul Peter (2012) and Michel (1986) are shown below in equations 3.2 to 3.3.

$$K = \frac{Gd^4}{8D^3 n_u} \tag{3.2}$$

$$K = \frac{(77000)(0.7)^4}{8(21.6)^3(5)} =$$

$$\tau = \frac{8FD}{\pi d^3} \tag{3.3}$$

$$\tau = \frac{(8)(1.35)(21.6)}{\pi(0.7)^3} = 216 \text{ MPa}$$

where:

- *K*: Spring rate, N/mm
- *F*: Load applied on spring, N
- F_0: Assembled load on spring, N
- τ: Shear stress, MPa
- *G*: shear modulus, MPa
- *d*: wear diameter, mm
- *D*: Spring mean diameter, mm
- *x*: Spring deflection, mm
- n_u: Total number of coils

Maximum stress on the spring coil occurs at 216 MPa when the spring is fully loaded and 144 MPa when the spring is at its assembled load. Spring has a tensile strength of at least 1000 MPa (ASTM A228) at its utmost stretch (Jeanne, 2007). A Goodman fatigue factor was employed to determine whether the stress on the spring coil was tolerable (Mohan et. al. 2010). Goodman is the premier design for compromise between converseness and tensile strength. This design of spring experiences pressures that result in a Goodman fatigue factor of 8.17 (John Portiero, 2010), which is far higher than the 2.0 threshold typically used for acceptance. This design was used for the BfT spring. How the Goodman fatigue factor was determined is detailed in equations 3.4–3.8. (John Portiero 2010).

$$USS = \frac{2}{3} UTS \tag{3.4}$$

$$USS = \frac{2}{3}(1000) = 667 \text{ MPa}$$

$$\sigma_s = \frac{1}{2} USS \tag{3.5}$$

$$\sigma_s = \frac{1}{2}(667) = 333\ MPa$$

$$\sigma_a = \frac{1}{2}(\sigma_2 - \sigma_1) \tag{3.6}$$

$$\sigma_a = \frac{1}{2}(144 - 76) = 34\ MPa$$

(3.7)

$$\sigma_m = \frac{1}{2(144+76)} = 110\ MPa$$

(3.8)

$$FF = \frac{333\left(1 - \frac{110}{667}\right)}{34} = 8.17$$

where:

USS: Ultimate Shear Strength, MPa

UTS: Ultimate Tensile Strength, MPa

σ_s: Shear endurance limit, MPa

σ_a: Alternate Stress, MPa

σ_m: Mean Stress, MPa

σ_1: Spring Stress at Assemble

σ_2: Spring Stress at Fully Loaded

FF: Goodman Fatigue Factor

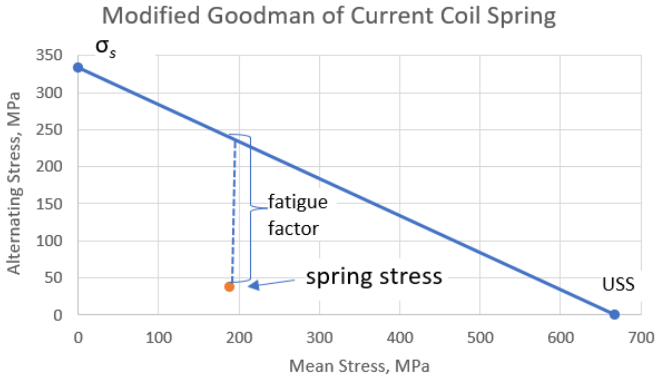

Figure 3.26: Modified Goodman Diagram of the Coil Spring Design

3.4.3.9. Spring fatigue considerations

The shear stress has been used to calculate the fatigue factors of the spring, as the spring is coiled, resulting in an acute angle between the wire and the axial direction of the force (Animesh et. al. 2015). As a result, when the spring is loaded, the wire undertakes a twist or torsional motion. The twist motion on the coil results in a shear stress state for the coil. This is critical as the spring in the BfT is placed near the ferrule and may face some torsion. The most dominant failure modes are fracture and fatigue, along with the outer diameter proving the maximum shear stress to be a major cause of failure. Figure 3.27 illustrates a typical failure mode of coil spring (Animesh et. al. 2015).

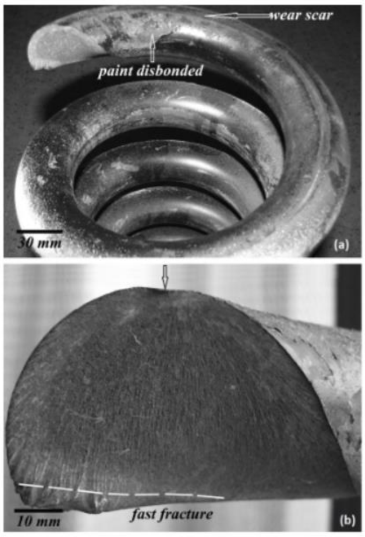

Figure 3.27: Typical failure mode of a coil spring outer diameter (Animesh et. al. 2015).

3.4.3.10. Spring acceptance criterion

The acceptance criterion is largely based on industrial common practices and is equally applicable to the choice of spring in the BfT. A better understanding towards the real application compares the fatigue strength during testing, recommending that a lower fatigue factor can be used (Animesh et. al. 2015).

3.4.3.11. Spring materials

The selection of spring material is based on cost effectiveness and strength requirements. A list of spring materials is as follows:

- High-carbon steel (ASTM A228)
- Beryllium copper alloy (ASTM B197)
- Monel K500
- Chrome silicon alloy steel (ASTM A401)
- Stainless steel (AISI 304)
- Inconel 600
- Nickel alloy (ASTM A286)

While springs are manufactured from a variety of materials, carbon steel is the most used material (Feyzioğlu, A., 2005).

3.4.3.12. Spring selection

In this design, a common carbon steel is selected due to its relative low stress fatigue and cost effectiveness. Carbon steel is widely used as for its efficient tensile strength and shear endurance. While small springs are coiled from pre-hardened stock, larger springs are made from annealed steel and hardened after fabrication (Feyzioğlu, A., 2005).

3.4.3.13. Ultimaker 3D printer

The Ultimaker 3 was utilised to 3D print the Solidwork-designed components. The Ultimaker 3 is more flexible than ever thanks to its cutting-edge dual extrusion capabilities and new connectivity choices. The following are a few of the main benefits of this printer that were outlined by Jo and Song (2021):

- Dual extrusion, which allows to print using more than one material.
- Hot-swappable print cores
- Wi-Fi connectivity

3.4.3.14. Material selection criteria

Based on the diversity of the required features, comparison of the appropriate material for 3D printing was done. (Table 3.13) (Pandian et. al., 2016).

Table 3.13: Comparison of several 3D printing materials (Pandian et. al., 2016)

Properties	**ABS (Acrylonitrile Butadiene Styrene)**	**Flexible**	**PLA (Polylactic Acid)**
Ultimate strength	40 MPa	26~43 MPa	65 MPa
Stiffness	5/10	1/10	7.5/10
Durability	8/10	9/10	4/10
Max service temperature	98 °C	60~74 °C	52 °C
Coefficient of thermal expansion	90 µm/m-°C	157 µm/m-°C	68 µm/m-°C
Price per kg	7.4~30 £	22~52 £	7.4~30 £
Printability	8/10	6/10	9/10
Extruder temperature	220~250 °C	225~245 °C	190~220 °C
Heated bed	Required	Optional	Optional
Bed temperature	95~110 °C	45~60 °C	45~60 °C
Recommended build surfaces	Kapton Tape	PEI, Painter's tape	Painter's tape, Glue stick, Glass plate, PEI
Other hardware requirements	Heated bed and enclosure	Part cooling fan	Part cooling fan
Soft	No	Yes	No

Evidence suggests that PLA is the most appropriate material for 3D printing products in the available low-cost bracket as it is durable and can resist high temperatures (Nazan et. al., 2017). As PLA is printed at a reasonably low temperature, heat beds are not mandatory, and the risk of warping is low.

3.5. Firmware design and development

The following two approaches were analysed for the integration of the firmware algorithm; thereby enabling the users to determine the orientation and force with desired telemetries of data to the interfaces, including OLED and data logging on the SD card (Shahzad et al., 2021):

1. Bare metal approach
2. Real-time operating system (RTOS) approach

In the bare metal approach, drivers are implemented according to the selected hardware. This requires serious micromanagement at the register level of the microcontroller for proper integration of the hardware modules connected to the processing engine. For example, drivers for OLED, force sensors, and IMU were required to be written at the base level. This approach is time-consuming and takes the concentration away from the implementation of the actual functionality. In contrast, RTOS provides an encapsulated control over the hardware without micromanagement of the processing device and managing register-level information for the hardware. The general architecture of any RTOS is given in figure 3.28.

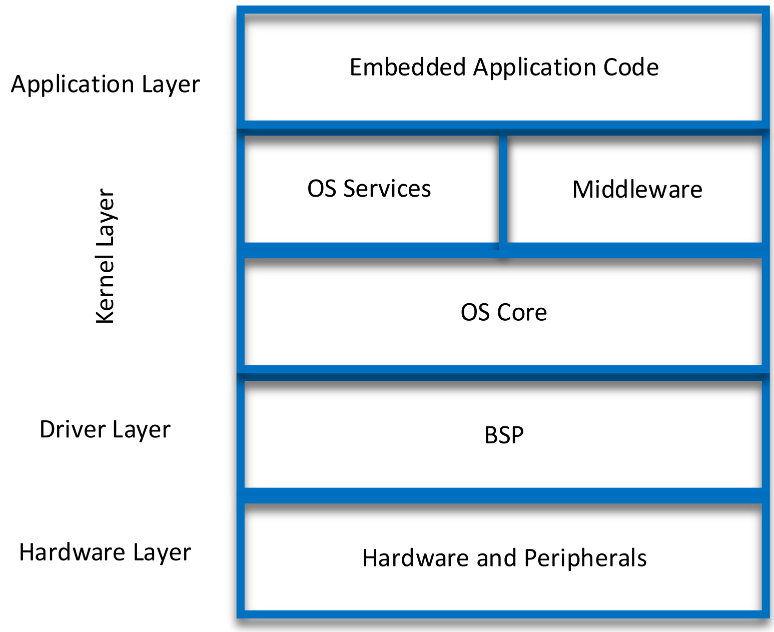

Figure 3.28: RTOS Architecture for hardware implementation (Micrium RTOS)

The requirements of RTOS are dependent on the services it offers. In the case of the BfT, ESP32 microcontrollers (Hardware Layer) were interfaced with the selected sensors and actuators. The board support package (BSP) Driver Layer contains the drivers of the hardware modules for microcontroller implementation. These are pre-available libraries that require specific configuration and provides necessary debug information to be used at higher layers. After the BSP, the Kernel Layer comprises of two parts:

1. OS kernel core layer
2. OS kernel service layer

OS (operating system) core is hardware-dependent and non-relocatable code that needs to be integrated with the processing device of choice. Specifically, this entails configuring the on-chip available timers in accordance with the hardware provision and then integrating the scheduling services into one of those timers. This fundamental component of the OS must be modified before it can be relocated or adapted to work with different hardware.

Traditional operating system features like semaphores, mutexes, mailboxes, and queues are all supported by the services section of the kernel. At the same layer, middleware is provided to facilitate the use of external devices such as USB and other interface modules. The functional code is stored in the Application Layer per the software development model. Data from sensors, algorithm processing, and transmission to telemetries were all handled at this level of the proposed architecture. This is considered the main code of the embedded solution, providing all technical functionality, processing the numbers at CPU core, and enhancing usefulness for the end user. The user's facilitation features are all incorporated at the interface layer of the GUI where the data is to be used by AHPs mainly regarding gait patterns and orientation information during usage. The following section provides an insight about the RTOS selected for the proposed scheme.

3.5.1. FreeRTOS

There are several choices for selection of the RTOS for the implementation of the proposed algorithm. The following requirements are important while selecting the OS (Micrium RTOS):

1. Small footprint
2. Reliable scheduler
3. No hidden code
4. Available source code
5. Efficient scheduler

FreeRTOS and Micrium's µC-OS/II were the two contenders for implementation of the scheme on the hardware. Both had a small footprint, meaning the size of code when programmed into flash memory for the embedded application, and offered the smart scheduler with pre-emptive interrupt driven system. However, µC-OS/II, had a larger footprint in comparison to the FreeRTOS which had all the necessary features of the OS services with about 9,000 lines of code. While it is true that an RTOS provides all the capabilities necessary for a straightforward real-time implementation, this does not rule out the possibility that the size of the binary file to be programmed will surpass the amount of the memory, rendering the programming impossible. Only about 6 percent of the ESP32's RAM is used by FreeRTOS. As a result, the BfT functionality-carrying embedded application still has plenty of free memory. Therefore, a smaller footprint size on memory with final code and availability of source code, which can be integrated with application firmware, are the key characteristics that aided selection of FreeRTOS. The kernel code can be divided into two submodules in terms of functionality: tasks and communications, both with small binary code. The discussion is generalised and applicable to all embedded systems deploying RTOS, including the BfT.

3.5.1.1. Tasks

FreeRTOS is a pre-emptive kernel, meaning that its software modules can be assigned different priorities. A functional module is called a 'task', which comprises of one or more function(s) integrated into a common functionality. Hence, tasks perform a functionality with some assigned priority. Tasks are executed turn by turn in the order of the priority (Desai et al., 2018). The hierarchy of tasks is shown in figure 3.29.

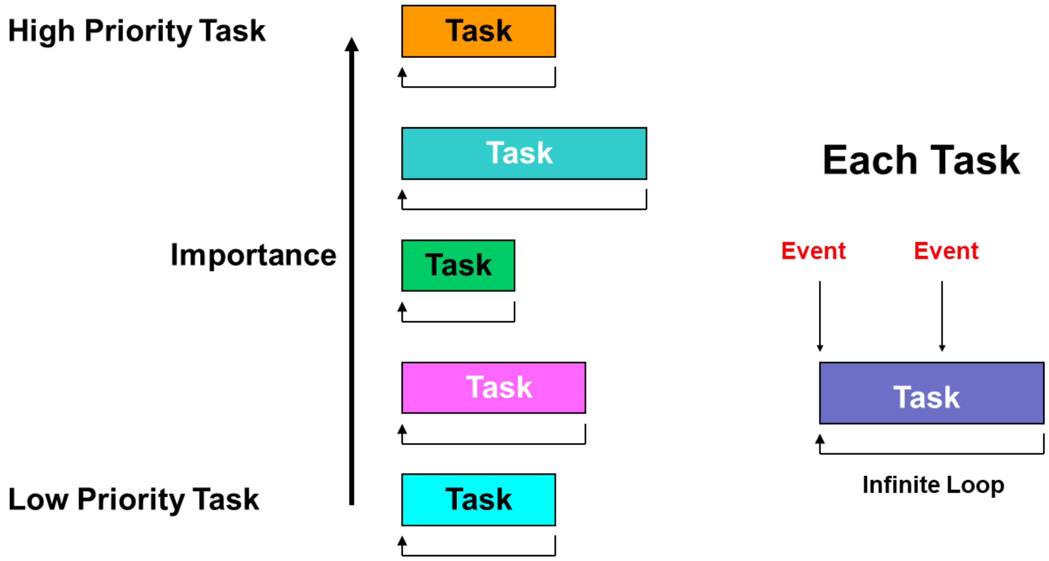

Figure 3.29: Preemptive tasks on FreeRTOS (Desai et al., 2018)

These tasks are maintained by a scheduler, which is the core of the RTOS. Its main purpose is scheduling and maintaining tasks. BfT deploys the RTOS, and several designated tasks are created for the implementation of the algorithm for the BfT.

3.5.1.2. Communication

The control over the location where functionality is being implemented is provided by tasks. Services are essential for communication within jobs as well as with the outside world. The service layer of the kernel is responsible for providing these services. Because of this layer, the operating system can transmit information. Within the framework of the method and plan that we suggested, the computation of force was carried out in a separate task from the implementation of orientation information. This information was forwarded on to the primary module so that it can be utilised to its full potential. Some of the most important aspects of the FreeRTOS, which are responsible for providing the services necessary to communicate information between jobs, are as follows:

- Semaphores
- Mutexes
- Mailboxes
- Queues

The middleware uses this support from the OS to implement any kind of functionality. A major portion of FreeRTOS code deals with such communication (Desai et al., 2018).

3.5.2. Algorithm design

With all electronics in view and selection of RTOS, the next step was actual implementation of the algorithm, which was modular. Code functionality is explained in the subsequent sections. At the application layer, the modular functions were implemented as tasks. The algorithm acquires the data from the IMU sensor and performs Euler angle computations (as described in section 3.3.2) to determine the pitch and roll of BfT. The force and load cell readings were acquired from the ADC, and the amount of force being exerted was computed as load in a separate task. The resource management of execution is managed at the kernel in scheduler. The rest of the tasks use these computations and deliver this information to the OLED display. Another task dispatches the data after assessing threshold levels and initiates the buzzer and vibration motor. Meanwhile, the RTC task acquires signals and computes time for data logging. A task dispatches the processed information on the wireless interface where a mobile application receives data and displays the information. This task also acquires the data from the wireless interface for any selection of parameters. Figure 3.30 outlines a flow chart for the execution of the code.

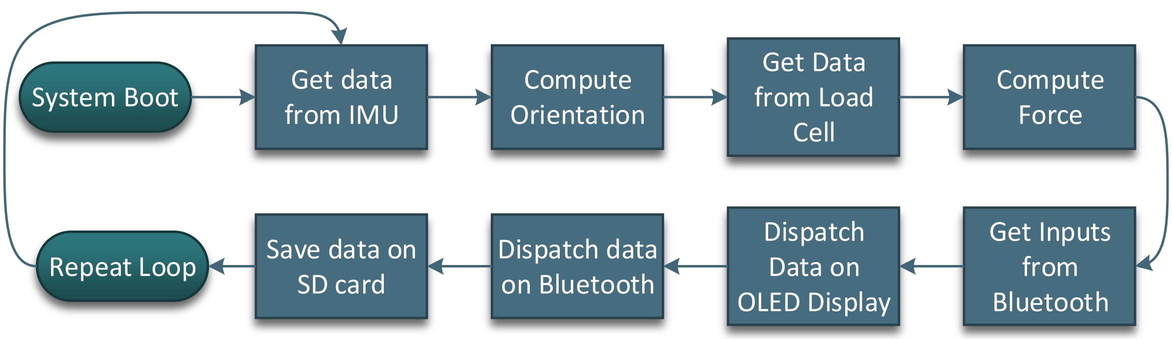

Figure 3.30: The functional flow chart for the embedded firmware

The specified tasks are distributed and computed in the source code and its modular explanation is discussed in the following sections.

3.5.3. Firmware implementation

The code was written in the form of a single file which contains all modes of implementation. The library support is available in the form of header (*.h or h) files (figure 3.31), which were included at the start of the code.

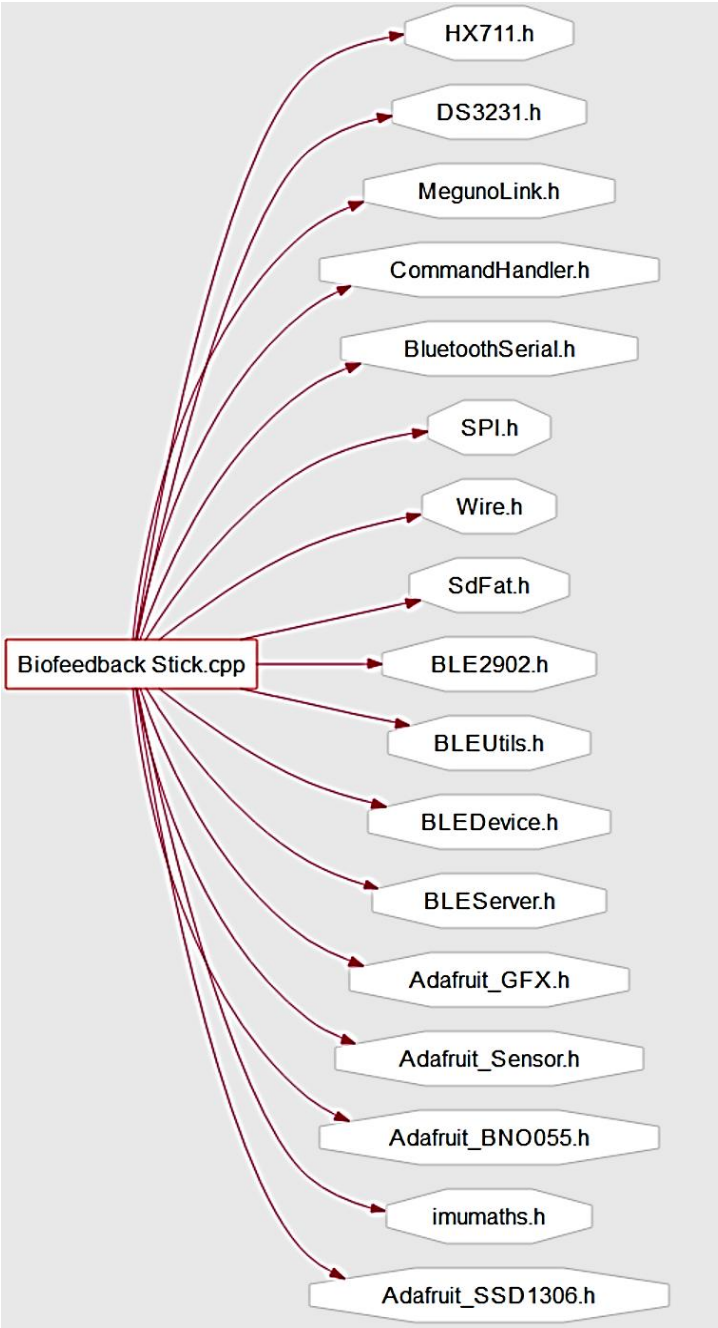

Figure 3.31: The header (.h) files call structure for the master module

Header files contain the drivers of the specific hardware modules clearly distinguished by the part numbers used in the file names; for example, BLE files are Bluetooth support files. The internal call structure of the overall code is shown in figure 3.32.

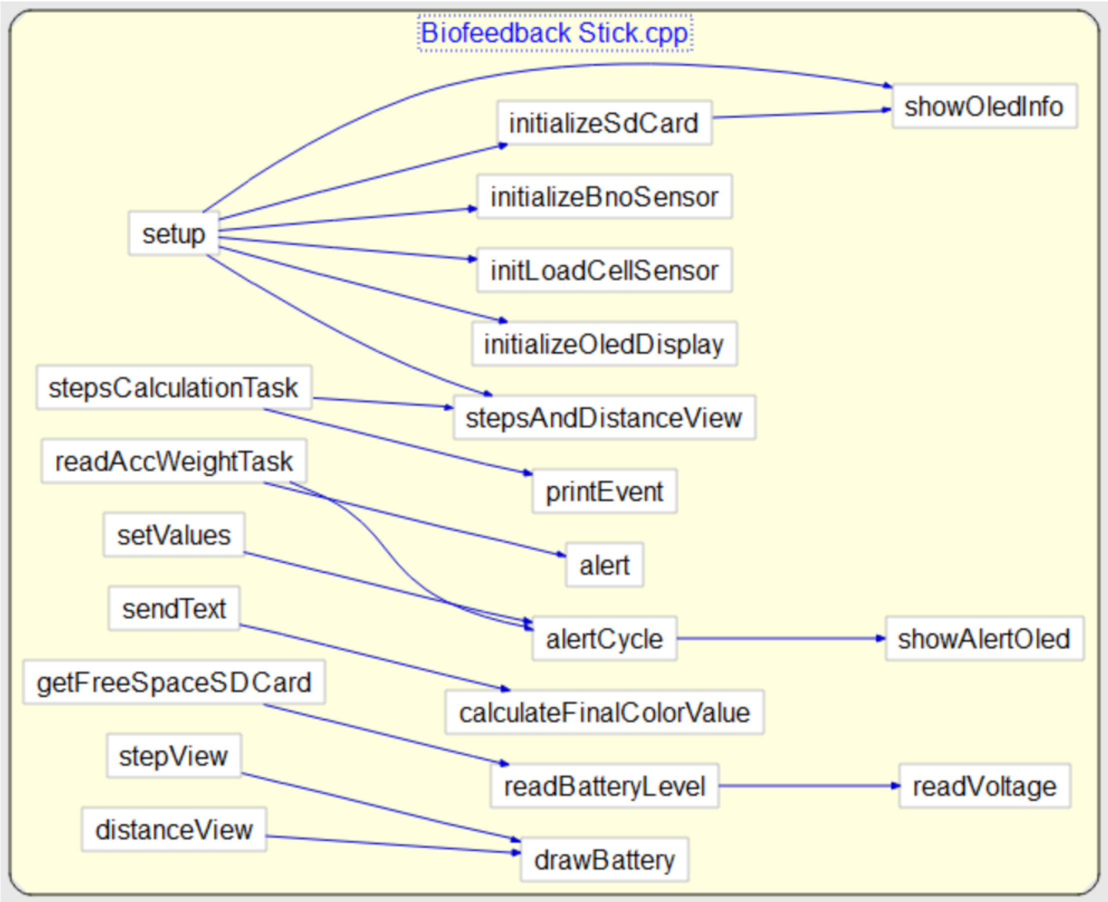

Figure 3.32: Internal call structure of embedded application firmware

3.5.3.1. Initialization and setup

The setup function initializes all hardware modules, including the SD card, IMU sensor, load cell and OLED display. These hardware modules are initialized to purge any garbage values at startup, allowing data to be obtained in a clean way. The Bluetooth module (BLE) is initialized and setup using classes. This entire setup process is shown in figure 3.33.

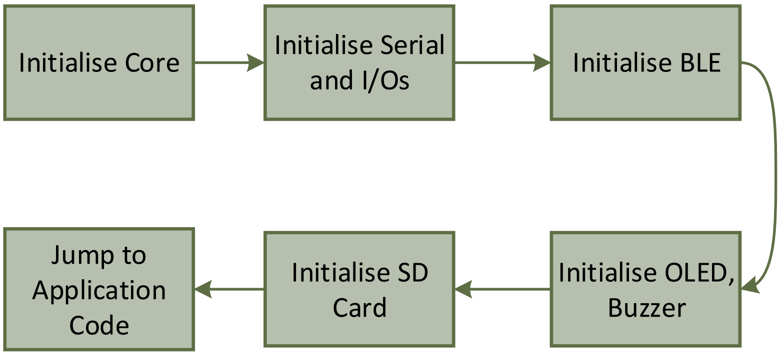

Figure 3.33: Initialisation at boot time

3.5.3.2. IMU orientation task

The ‘stepCalculationTask’ block shown in figure 3.34 is the function which computes the orientation angles from the BNO055 IMU sensor. This is called by the OS Task ‘stepCalculationTask’, which not only computes the Euler angles but also computes the number of the steps taken by the walking stick user using the BfT. If the number of steps taken is less than required, the information is displayed using the ‘printEvent’ function, which is further shown on the output modules. Tasks executed in this module are shown in figure 3.34.

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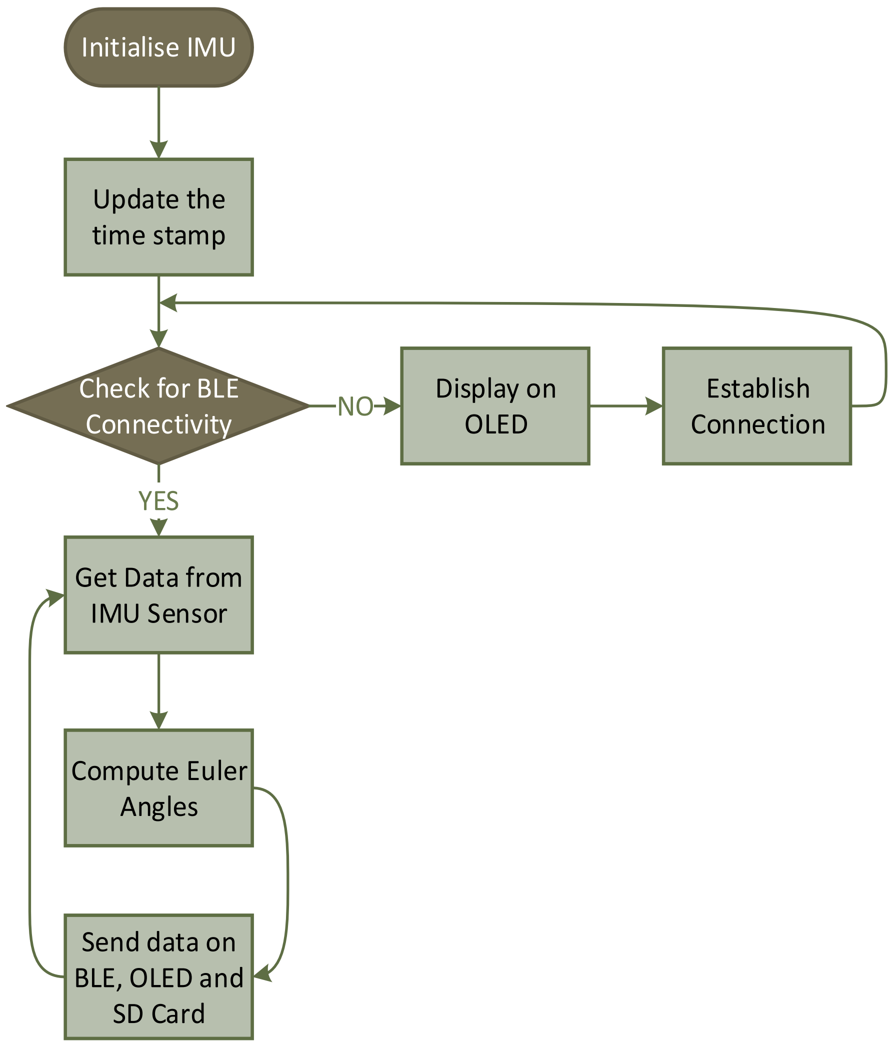


Figure 3.34: Computation of Orientation

3.5.3.3. Force computation task

'readAccWeightTask' is the block which computes the force being exerted on the BfT, which acquires values from the load cell sensor via HX711 ADC. It also compares the values against the threshold being selected and adjusted for the walking stick user via buzzer, OLED, and/or vibration motor. A flow chart outlining the force computation is shown in figure 3.35.

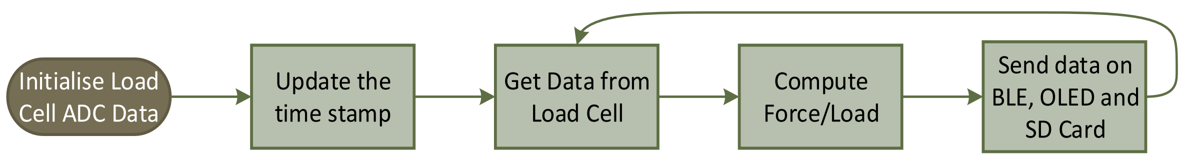


Figure 3.35: Computation of Force

3.5.3.4. *OLED Display Task*

Computation of orientation and force takes place through the functions 'stepCalculationTask' and 'readAccWeightTask'. When force is exerted on the BfT, it not only computes the required angles, but also checks if a certain threshold is exceeded by comparing the values with the limits set for a certain BfT user. Once such threshold limits are exceeded, a notification is immediately sent on the OLED using the 'alert' and 'alertCycle' functions. The overall flow for the module is shown in figure 3.36.

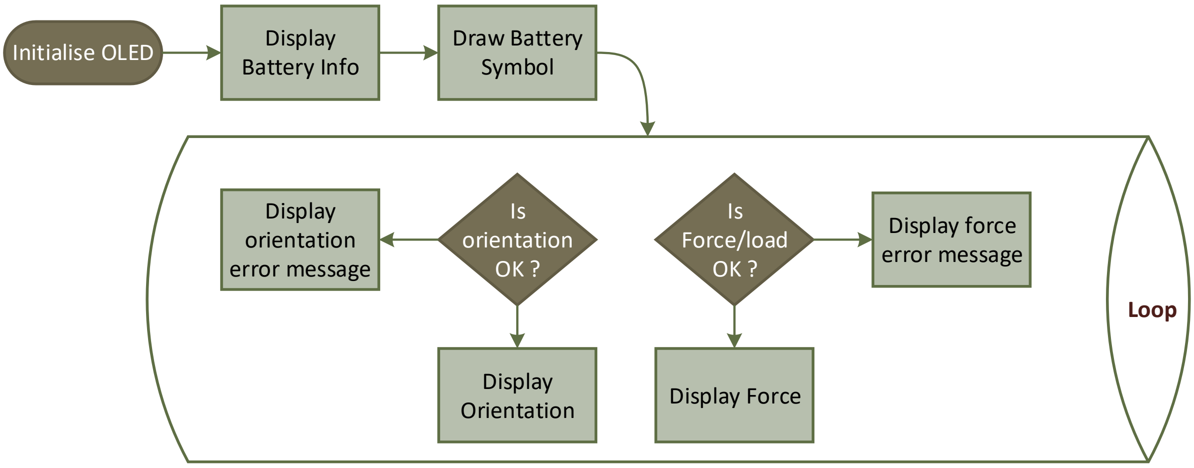


Figure 3.36: OLED Display information flow

3.5.3.5. *Vibration and buzzer feedback task*

The inappropriate orientation and force are immediately signaled to the user based on the implementation in 'stepCalculationTask' and 'readAccWeightTask'. The 'alert' module triggers the vibration and buzzer so the user may correct their posture and applied force. The triggers will stop once the posture and force go back to their limits. Figure 3.37 outlines the order of steps in the execution of the buzzer and vibration.

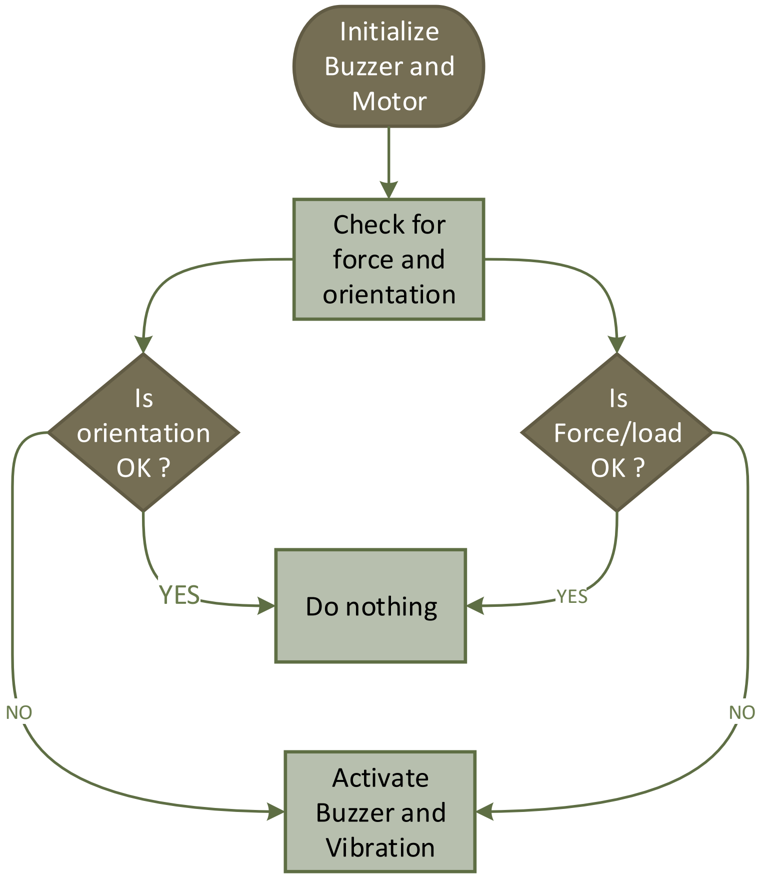


Figure 3.37: Flowchart for working of buzzer and haptic feedback

3.5.3.6. Bluetooth low energy (BLE) functionality

Bluetooth interface is a critical part of the design implementation as all the processed data is to be dispatched via BLE for the usage and evaluation. The Bluetooth communication uses two interfaces: the GUI, which clinicians can use for analyzing data, and the mobile app developed for walking stick users.

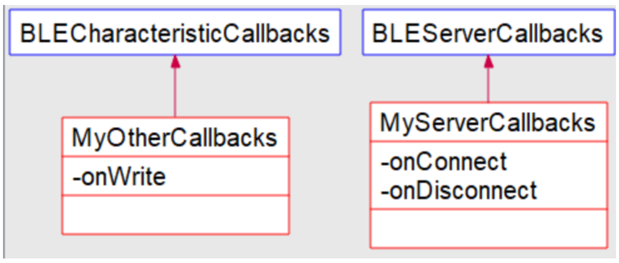


Figure 3.38: Bluetooth BLE implementation stack

Two services (Figure 3.38) pertaining to the Bluetooth module were integrated within the firmware: characteristic call backs and server call-backs. Server call-backs are active when BLE is initiated, or a Bluetooth device is connected or disconnected. The rest of the communication is handled by BLE characteristic call-backs, which perform the handling of commands for the selection of parameters and dispatch of the telemetry data and informatics on the developed GUIs.

3.5.3.7. Battery information feedback

The 'drawbattery' module in the code displays the symbol of battery on the OLED panel. The battery levels are read and displayed on the panel and the mobile application. This software module implementation reads the value of the battery power available for further usage. This informs the user regarding the time duration for which the BfT can be used without any charging or battery replacement.

3.5.3.8. SD card storage

The data is logged on the SD card and the system also calculates the space remaining on the storage device. This is performed by the function 'GetFreeSpaceSDCard' and is also depicted in the internal call hierarchy in figure 3.39.

Figure 3.39: SD card storage flow

3.6. User application design and GUI

The data prepared in the processing engine from sensors was set to be viewed, analysed, and utilized. Data packets are available in the air over the Bluetooth interface, which are then viewed via one of the two platforms:

1. Mobile application for mobile devices
2. PC-based GUI

Mobile applications have become an integrated and universal part of our modern-day lives. The proposed BfT for data aiding was powered by smart phone application, enabling the completion of the proposed design as intended. The application has all the features and displays all information in real-time. Data stream is available in the form of numbers and real-time graphs. A similar PC GUI application was also developed for the AHPs which facilitates real-time monitoring of the walking stick users.

3.6.1. Mobile application development using flutter

The Android-based application is made in Flutter, an open-source software. Flutter provides the data analysis and visualization utility without compromising the real-time nature of the data in a convenient way. Flutter is widely used and has the following key features (Kuzmin et al., 2020):

- Rapid prototype development
- Expressive and flexible UI
- Interactive controls

Flutter's user interface does not require any platform-specific components to be rendered. It provides a canvas to draw on (Ozgoren, M. K. 2019). The Flutter rendering method distinguishes the framework from the other mobile application developing platform, reducing concerns about UI consistency between platforms. In short, sharing the UI and business logic, which is possible with Flutter, saves the time and effort of the developer without negatively impacting the end performance (Ozgoren, M. K. 2019). It provides reduced code development time with its hot reload function. It has a simple platform-specific logic implementation, which is best for datasets from IMUs and GPS. The most notable benefits of the framework are (Wu, W. 2018):

- Faster code development
- Separate rendering engine
- No reliance on platform-specific UI components

3.6.2. Mobile application interface

The interface of the mobile app is made simple for walking stick users to conveniently use and communicate with the BfT. The steps and layout of the operative screen are shown in the following sequence (figure 3.40). As the firmware dispatches the information over the Bluetooth interface, the app, powered by Android, establishes the connection using the BLE server implemented in the firmware.

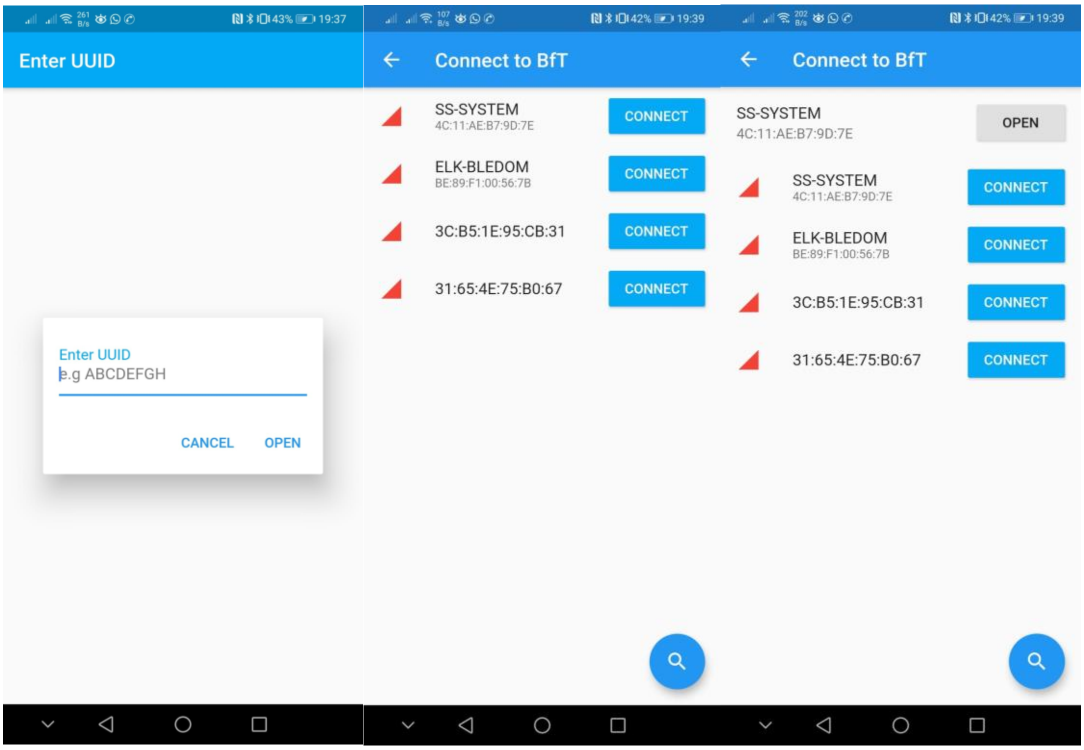


Figure 3.40: Application interface of the app for BfT

Each user has a unique ID which acts as the key for logging into the mobile app. It displays the list of available Bluetooth connections around and enables the user to pair with their intended device.

3.6.3. Mobile application modes

The usage of the mobile application can be classified into the following two categories:

1. Normal usage mode
2. Self-test and diagnostic mode

In normal usage mode, the data available in the air over the Bluetooth link are used and analysed for real-time analytics—just like a normal interface, where every bit of information is available. This can be viewed, and the walking stick user can readjust their posture, based on feedback, but self-test and diagnostic mode is one of the novel options added after careful evaluation based on the input from PPI discussions. These are explained as follows while the boot sequence execution flow is shown in figure 3.41.

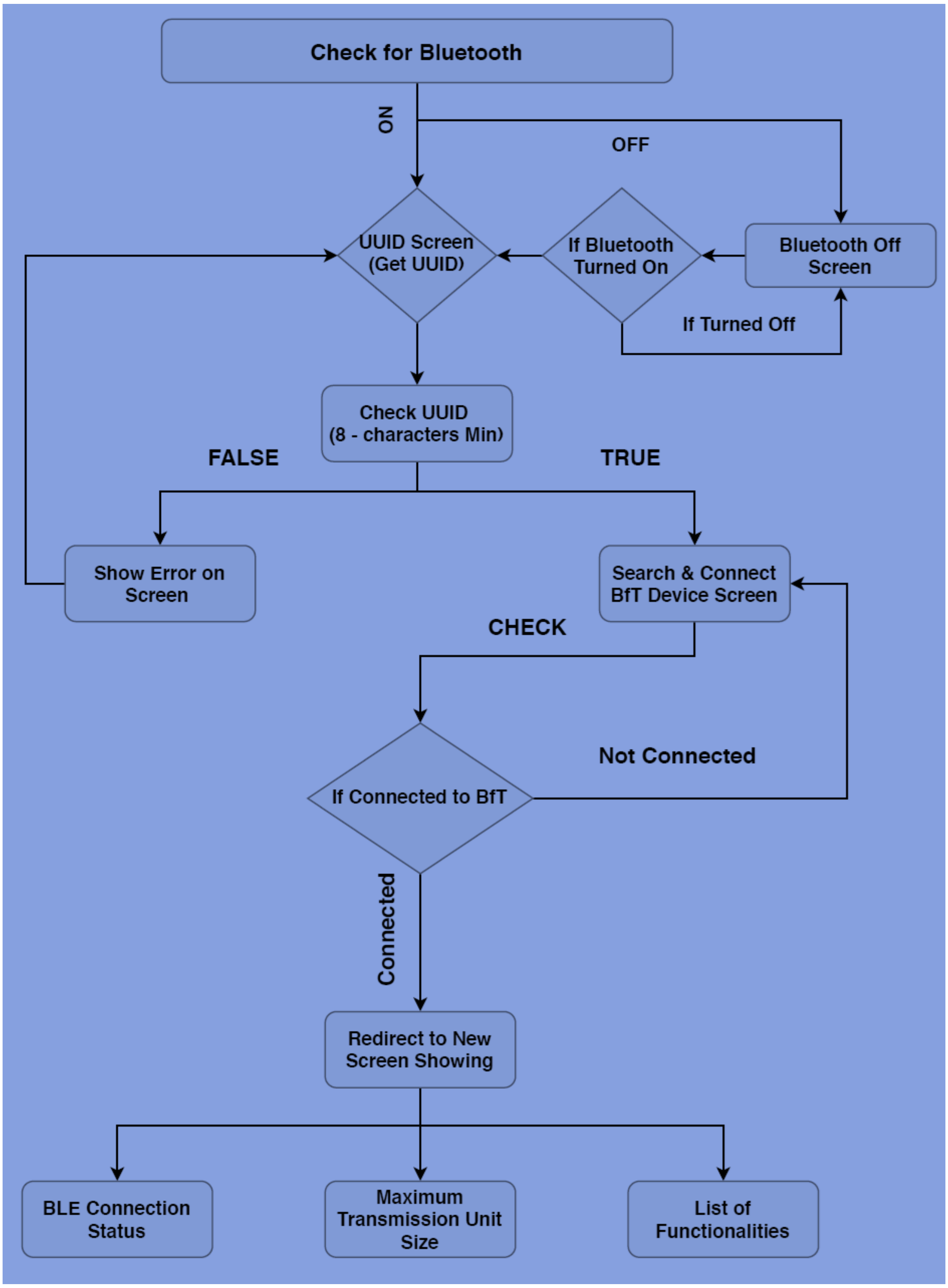


Figure 3.41: Flow of app boot process

3.6.3.1. *Normal operation mode*

Once a connection is established via Bluetooth, the user can access information such as orientation or force. The opening screen is shown in Figure 3.42, and Figure 3.43 shows the list of functionalities, including the mode of operation, available for users. Serial data provides all the information in the textual manner.

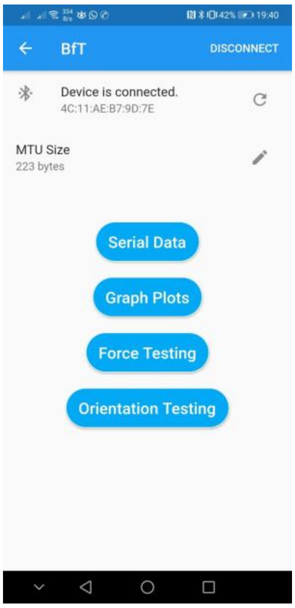


Figure 3.42: Opening screen of the app after BLE connectivity

Selecting the serial data will open the information panel with all details relating to orientation and applied force. The text-based information is shown in Figure 3.44 where the information is displayed in real time. IMU section displays the orientation angles and the acceleration in the three dimensions. It also displays the step count, battery, and SD card usage.

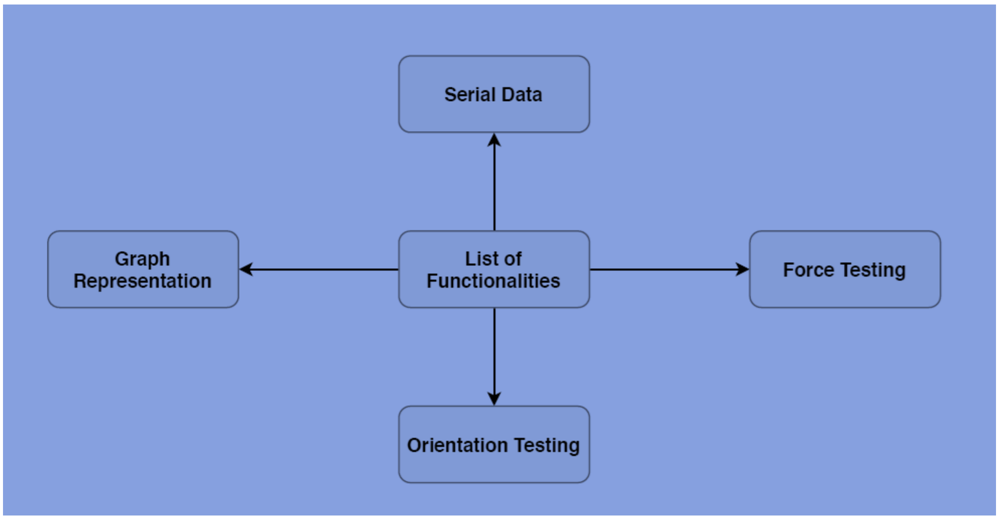


Figure 3.43: Opening screen flow

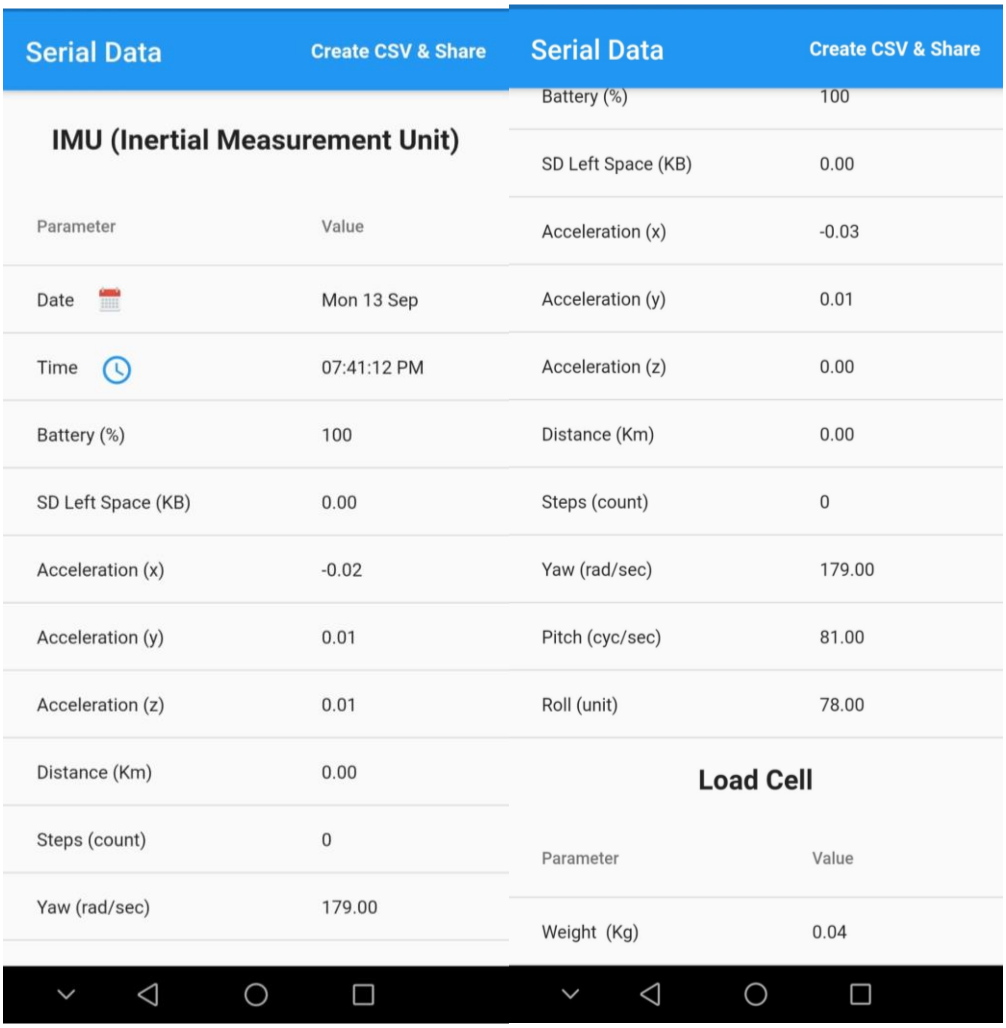


Figure 3.44: Normal mode serial data display

3.6.3.2. Self-test and diagnostic mode

Traditionally, for training and feedback on the progression of walking stick usage, walking stick users make frequent visits to AHPs, who first observe walking stick usage and then provide feedback (Nascimento et al., 2016). Rather than making frequent visits to an AHP, a self-test and diagnostic mode feature was developed in the mobile application with the aim to help the user self-test and monitor their usage of the BfT within their living environment alongside AHPs. This may not only reduce the number of visits the BfT user makes to an AHP, but also aims to contribute to a reduction of carbon footprint and workload on the AHPs (Matalenas et al., 2016).

In this mode, the user is provided with 2 options, where they can choose either 'force testing' to observe the weight being applied on the BfT, or 'orientation testing' to observe the orientation of the BfT during their gait. Once a testing mode is selected, a graphical display of 10 empty bar graph appears, where each bar represents a step (figure 3.45). As per literature, for testing patient's gait with assistive device, the distance has ranged from 3 meters to 20 meters (Soubra et al., 2019). Therefore, 10 steps (~ 7.63m) was chosen with the hypothesis that this may be feasible for the BfT users to perform in their living environment. Thus, to complete the self-test BfT user must walk 10 steps.

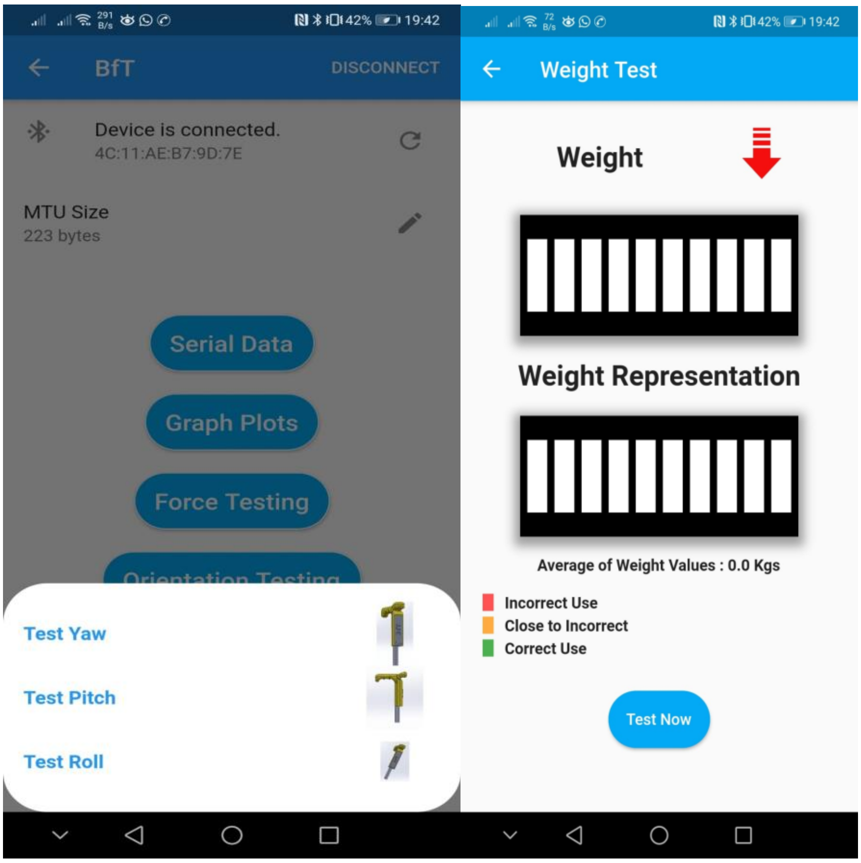


Figure 3.45: Test mode screen for calibration

Like the traffic light system, red, amber, and green were selected as reference colors, informing users about the accuracy of BfT usage. If a user initiates number of steps in line with the threshold limits of force or orientation, the bar turns green. If the bar shows amber, it means that user has reached close to the threshold value but has not yet breached it (Figure 3.46). This is more of a caution and warning for user to swiftly amend their weight being applied on the BfT or correct the orientation of the BfT.

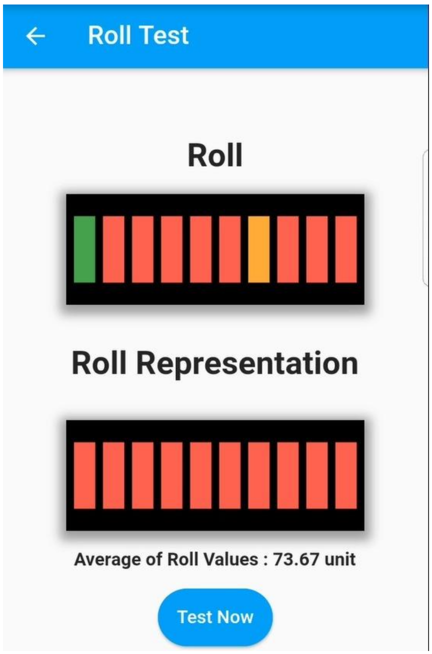


Figure 3.46: Usage indication in test and calibration mode

Figure 3.46 depicts the result of the orientation test, where the user took one correct step with eight incorrect steps and one step closer to the threshold limit. In this way, a user can practice their gait with the BfT and independently monitor their usage, avoiding any unnecessary visits to the AHP (Matalenas et al., 2016). The graphical flow for orientation and force testing is shown in figures 3.47 -3.49.

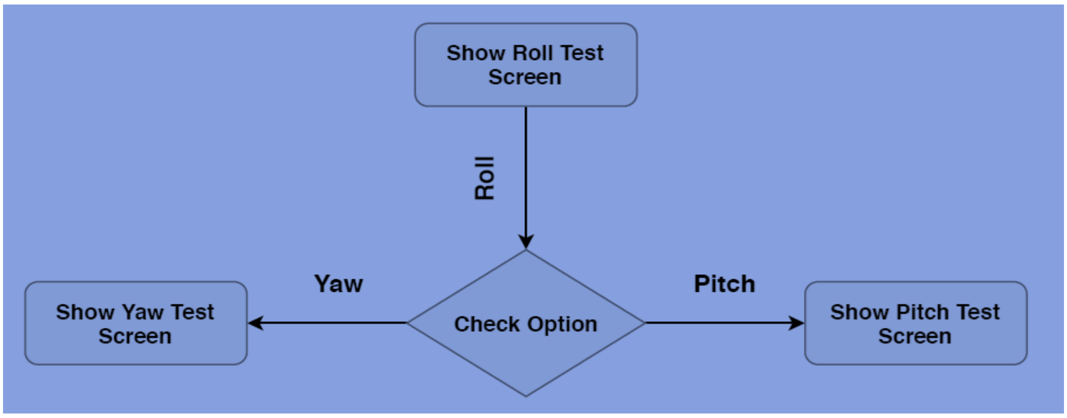


Figure 3.47: Selection flow for testing mode if orientation is selected

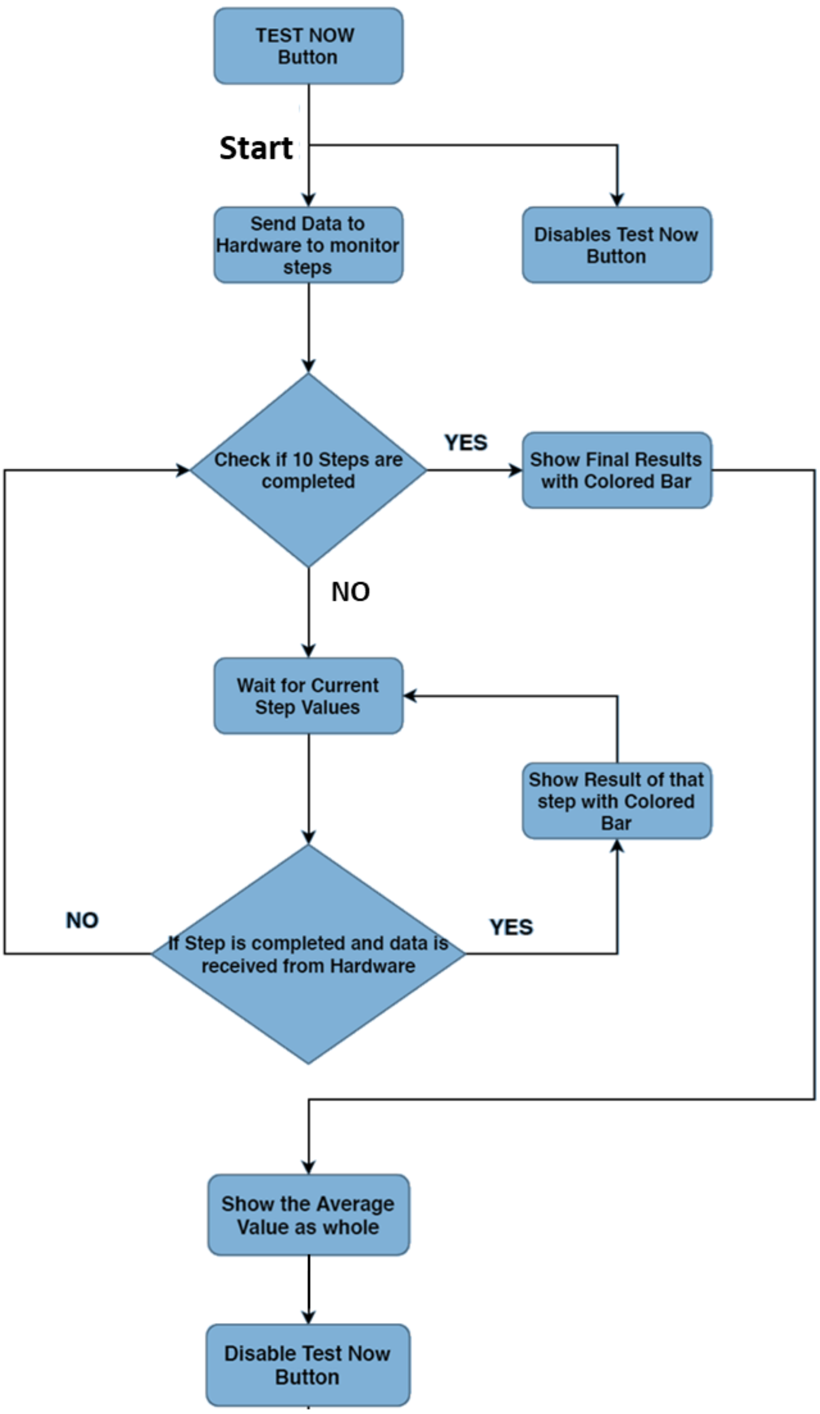


Figure 3.48: Flow chart for orientation testing

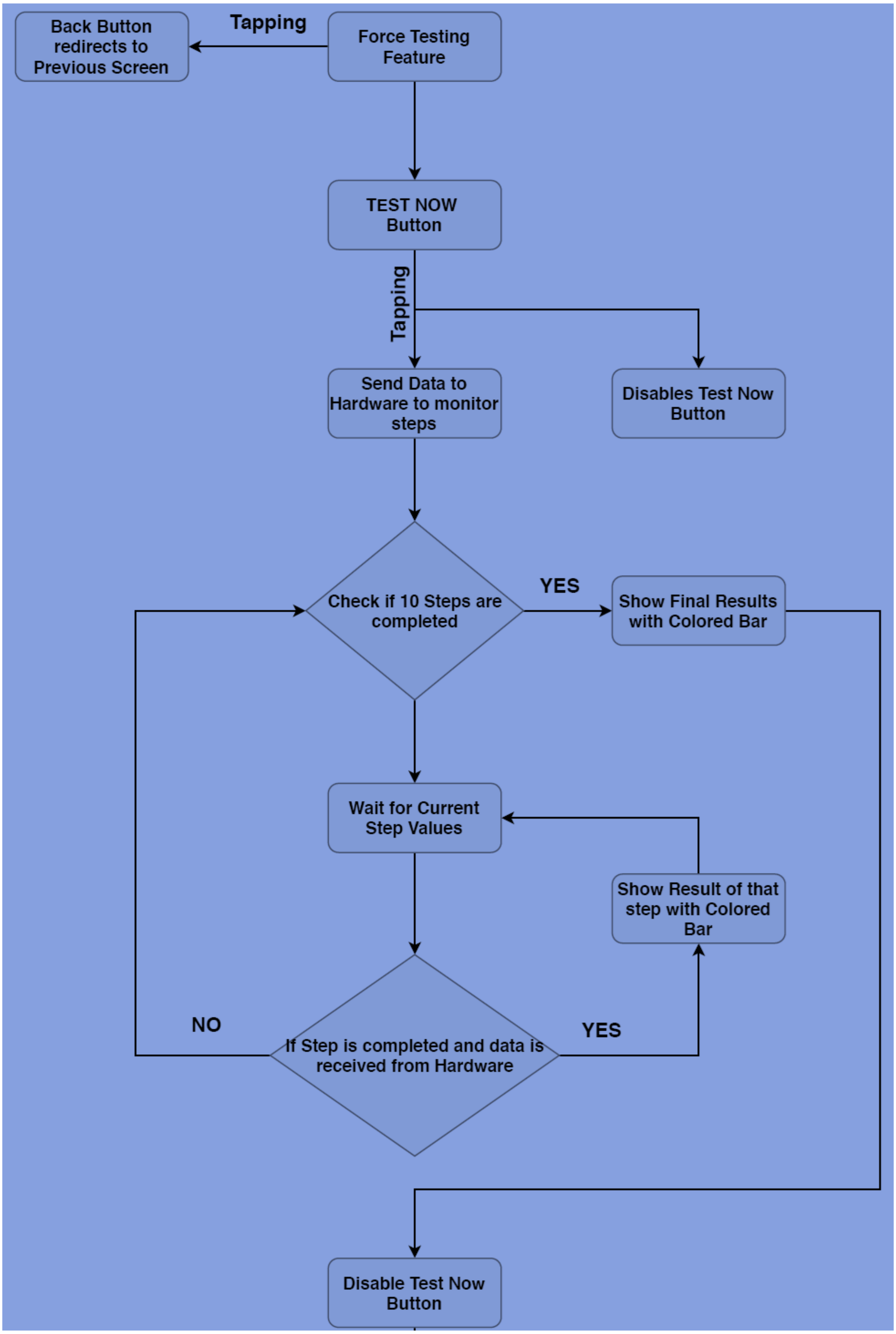


Figure 3.49: Flow chart for force testing

3.6.3.3. *Graphical mode*

Aesthetics and relevant information can be provided by graphical representation of data accumulated over time. The selection page is simple (figure 3.50) and provides the user with access to four different real-time graphs from which they can make their option.

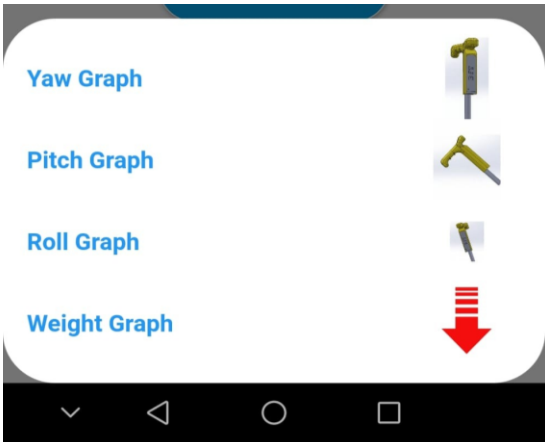


Figure 3.50: Selection menu for graphical mode

If the roll or weight graph is selected, the real-time continuous curve is displayed with sample points (figure 3.51).

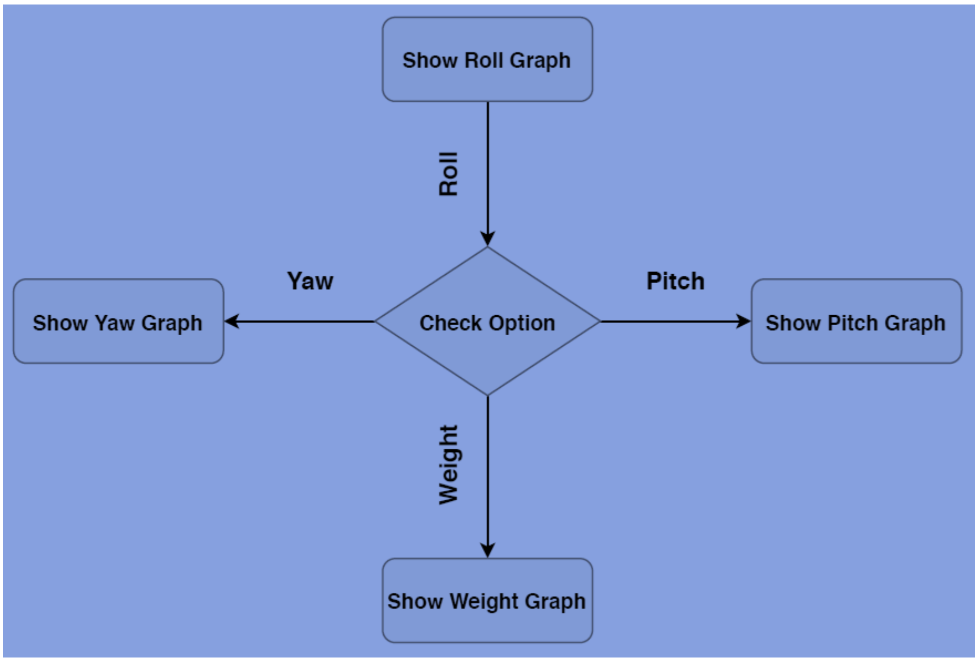


Figure 3.51: Flowchart for selecting graph mode

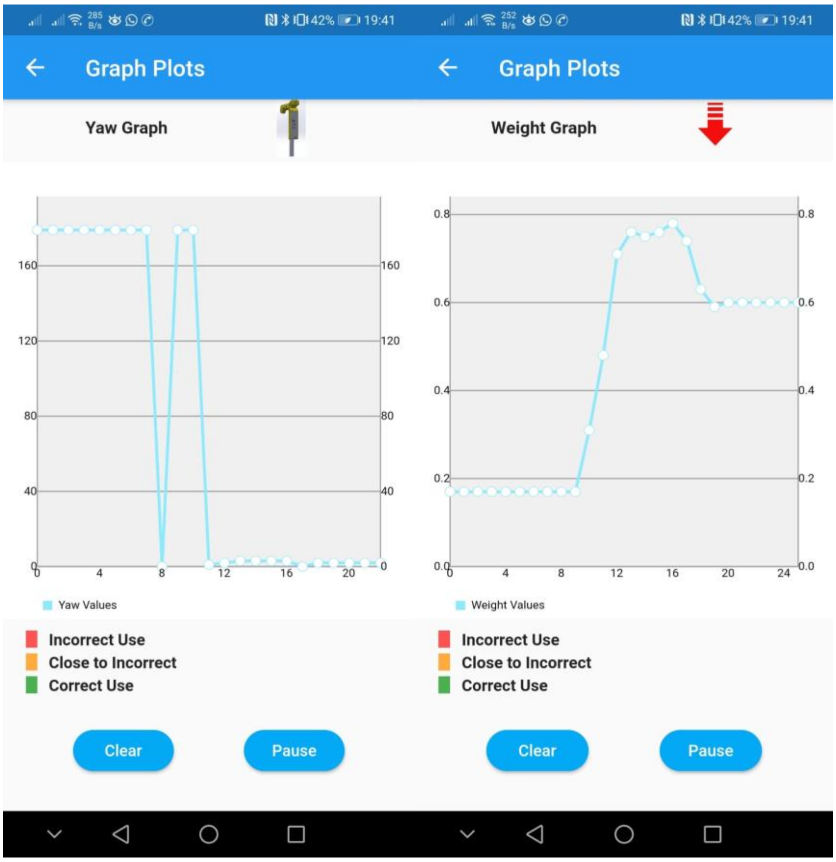


Figure 3.52: Roll and Weight graphs

3.6.4. GUI development using Meguno

In addition to the data from the available mobile application, a GUI consideration dedicatedly for AHPs was also developed. The mobile application is fully featured but primarily developed for the walking stick users. There is a dedicated GUI developed in Meguno, an open-source software, which provides all the data visualisation in the PC-based program. The added feature is the control of parameters and bulk amount of data visualization. This GUI also uses the Bluetooth link, and the key features of the GUI are:

- Programmable parameters to set bounds for user operation
- Graphical display of real-time data
- Bulk data visualisation in less time

Figure 3.53 is an example of a snapshot from the graphical user interface, displaying a grouping of data organised in an agronomic fashion. The text-based fields are on the left side of the user interface while the base section shows the parameter selection and adjustment panel. The detail of the panels is shown in the subsequent sections.

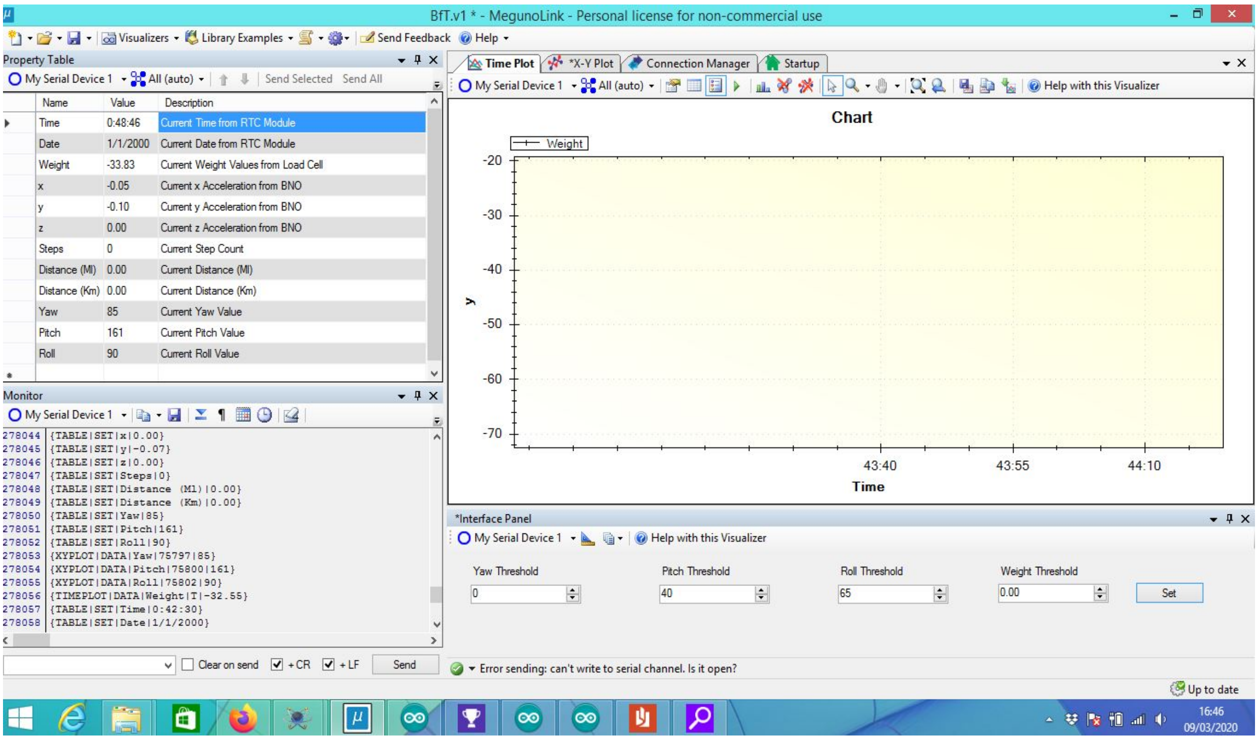
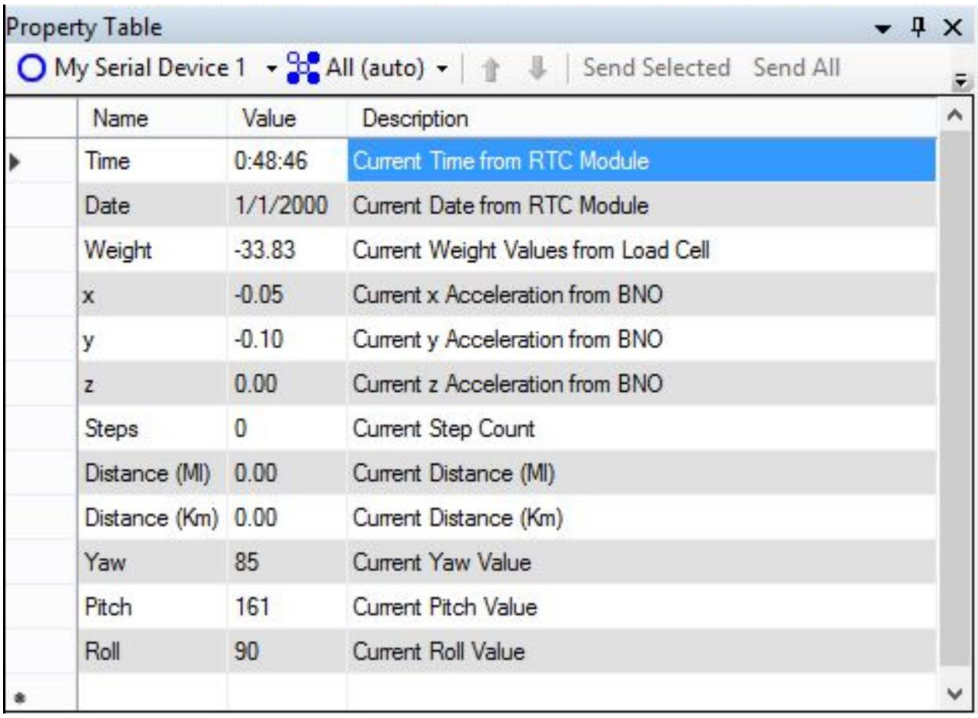


Figure 3.53: The GUI display of the application

3.6.4.1. *Property panel*

The textual view provided by the property panel is comparable to that provided by the mobile application and offers information on the sensory values (figure 3.54).



Property Table

My Serial Device 1 | All (auto) | Send Selected | Send All

Name	Value	Description
Time	0:48:46	Current Time from RTC Module
Date	1/1/2000	Current Date from RTC Module
Weight	-33.83	Current Weight Values from Load Cell
x	-0.05	Current x Acceleration from BNO
y	-0.10	Current y Acceleration from BNO
z	0.00	Current z Acceleration from BNO
Steps	0	Current Step Count
Distance (MI)	0.00	Current Distance (MI)
Distance (Km)	0.00	Current Distance (Km)
Yaw	85	Current Yaw Value
Pitch	161	Current Pitch Value
Roll	90	Current Roll Value

Figure 3.54: Property Panel of the GUI

3.6.4.2. *Log monitor data panel*

The log monitor data panel displays raw information of the functions BfT is performing and is an instant-command feedback information provider. This panel provides a quick view of the diagnostic information of sensor electronics. The log monitor displays functions performed with the BfT in real-time. This is diagnostic information and may be helpful to analyse any issues with the BfT (figure 3.55). The letters x, y, and z correspond to pitch, roll and yaw of the BfT.

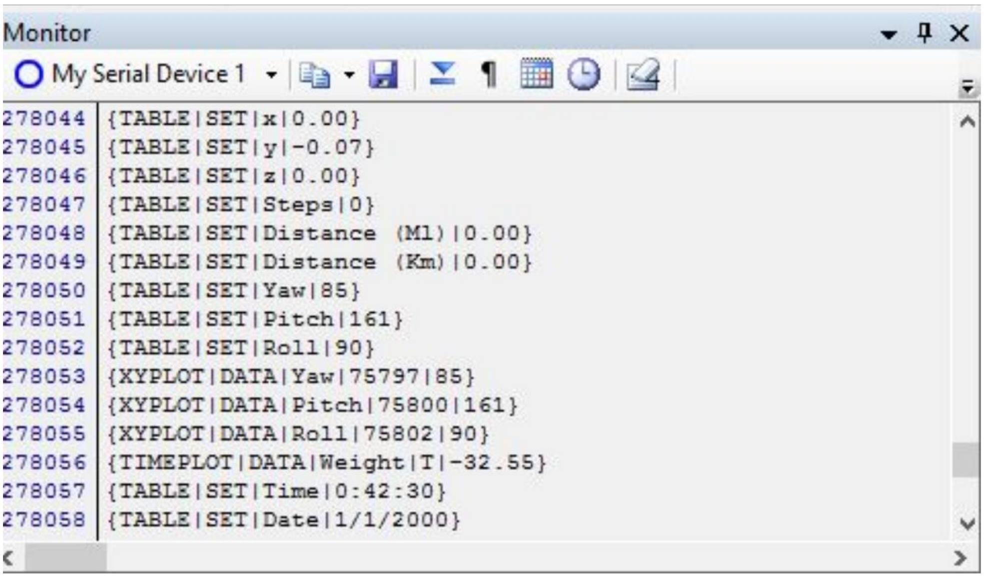


Figure 3.55: Real-time monitor panel

3.6.4.3. *Graphical view section*

As shown in Figure 3.56, this panel provides real-time graphs of BfT usage, enabling AHPs to have a profile-oriented view of the walking stick. This is useful because it provides recent information in an integrated view and has been incorporated based on advice and recommendations of PPI’s.

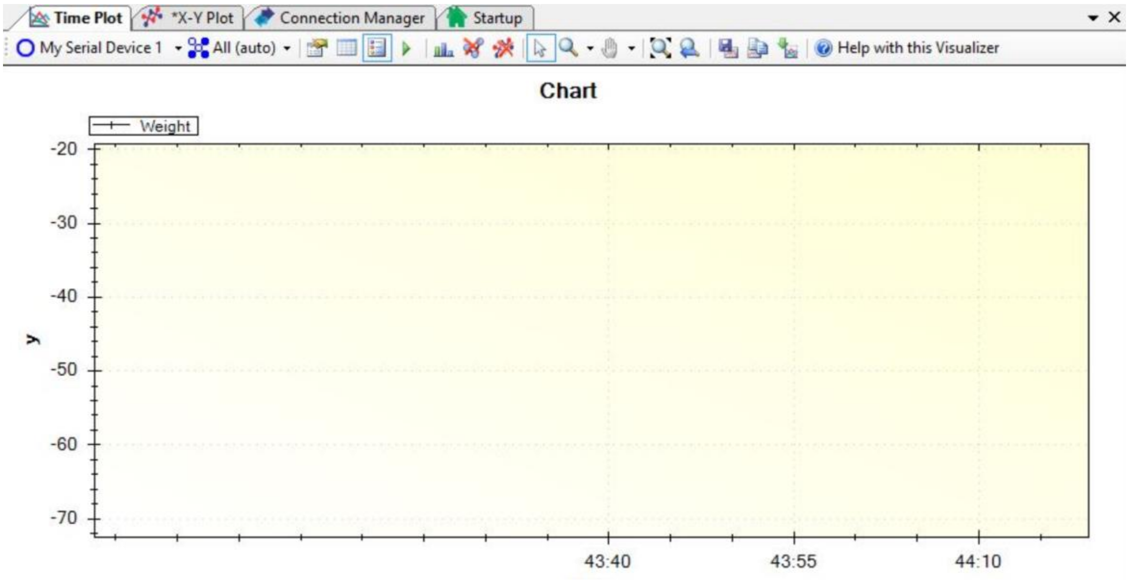


Figure 3.56: Graphical view section

3.6.4.4. Programmable parameters panel

The programmable parameters panel enables AHPs to program certain parameters for users. It is a simple panel as can be seen in figure 3.57, to ensure simplicity for AHPs to set threshold limits of the BfT.

Figure 3.57: Interface panel for parameters adjustment

3.7. Summary

In this chapter, a detailed design methodology for the design and development of the BfT is provided. This initiated with the development of a foundation framework, providing a complete design cycle. It starts with the acquisition of design parameters, considering the input from walking stick users and AHPs through PPI discussions. This is followed by a detailed analysis and study of the electronics and the resulting selection of supporting peripheries for the embedded system. The mechanical design is discussed using state of the art design methodology: 3D-printing techniques for developing the BfT. The design of the handle for housing the electronics modules has been considered thoroughly. A special spring assembly has been devised for correct usage of the BfT. Embedded software development has been accomplished with support of real time kernel of FreeRTOS. Meguno based GUI has been established for the AHP while a Flutter-based mobile application has been developed for the walking stick users. The last section details the firmware used to program the parameters. The section also elaborates on GUI usage, whereby an AHP can set the parameters of the BfT by simply accessing the pop-up menus in the GUI. In this way, a complete modern biofeedback stick is designed and developed, from conception to a fully functioning prototype.

Chapter 4: Evaluation of BfT

Validation and testing of all components are necessary before incorporating them into the biofeedback technology walking stick. No piece of equipment can be relied upon off the shelf, without testing, regardless of how adaptable its technical specifications may be. Its performance must be measured against benchmarks or with approved tools (Bitkina et al., 2020). This section contains the results of the BfT evaluation, and, after providing a high-level overview of the testing methodology and plan layout, this chapter dives further into the testing apparatus and the data acquired.

4.1. Testing and Evaluation Methodology

The BfT's convenience comes from its roots—having been borne of the straightforward idea that walking stick users deserve instant feedback if deviation from established medical parameters occurs. BfT logs the usage information and provides the health care professionals with an interactive platform that, through better evaluation, may reduce the recovery time and risk of serious injury for walking stick users (Patterson et al., 2016). The BfT collects a large amount of data, the most important of which are the angles at which the BfT is being held and the magnitude of the force exerted on it. So, the calculated values in terms of angles and applied load are crucial to the entire process. Since this data determines the credibility of the BfT, it is imperative that the computed angles and load values are accurate and reproducible. Acquiring and delivering these values to the terminal mobile and GUI programs were discussed in the previous chapter, and then their accuracy was evaluated. However, due to MHRA (Medical Healthcare Regulatory Authority) regulatory concerns (discussed in Chapter 6), the planned test to validate the BfT by enrolling healthy subjects from within the University was not feasible. Therefore, a proactive approach was adopted by the researcher to demonstrate the developed product (BfT) was fit for purpose. As in prior studies, a literature search and concurrent validity techniques were taken to evaluate and validate the BfT against the performance of gold standard equipment based on the validation criteria (Patterson et al., 2016; Anwary et al., 2021). This is described in the following sections.

4.2. Bench testing results

The BfT is equipped with two main sensors i.e., IMU and force sensor, which are detailed in chapter 3. Before being deployed into the BfT, these sensors were qualified at the bench.

4.2.1. Force sensor bench testing

Initial load sensor calibration was carried out using the usual weight method (Xiong et al., 2018; Song and Fu, 2019). A known force was applied to the load sensor and the results were measured. Forces of 10 N, 20 N, 30 N, 100 N, 120 N and 150 N were applied to the load sensor using masses of 1 kg, 2 kg, and 10 kg. The first trial was performed using the 1 kg weight (i.e., using a force of 10 N) as the input (Figure 4.1a). The output was 10.02 N, thus there was a zero error of 0.2 N. The steady state conditions are depicted in Figure 4.1. The transient phase is not shown because it is irrelevant to sensor accuracy, which is the primary and sole purpose of the bench qualification. The problem that occurred with 0.2 N has been rectified, and the patch has been incorporated into the embedded code. This was validated by applying forces of 20, 30, 100, 120, and 150 Newtons each. The outcomes obtained by applying constant forces of 20, 30, 100, 120 and 150 N are displayed in Figures 4.1b-f respectively. After applying the zero-error correction factor, the measurements of 20 N, 30 N, 100 N, 120 N, and 150 N all indicated 'Nil' as the appropriate value for their offset error.

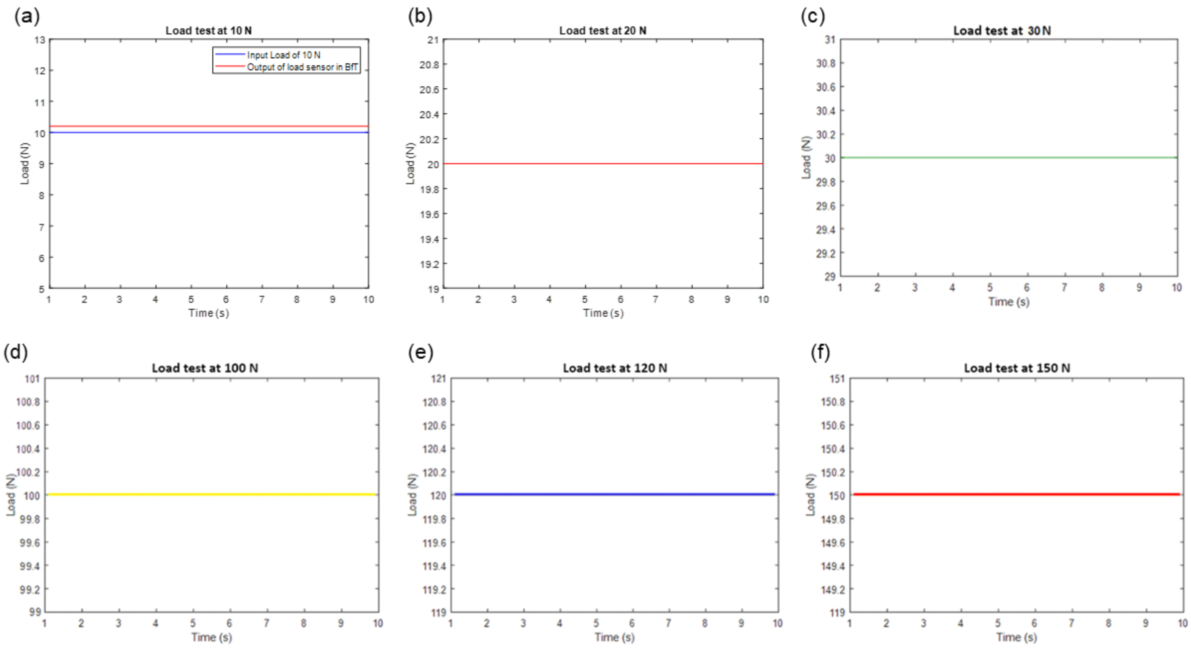


Figure 4.1: Bench test of load sensor at a. 10 N load, b. 20 N load, c. 30 N load, d. 100 N load, e. 120 N load, and f. 150 N load. x-axis shows time and y-axis shows load (N).

4.2.2. IMU gyroscopes bench testing

Calibrating IMU is a time-consuming process, which requires expensive equipment (Skog and Handel 2006; Nieminen et al., 2010). It was for this reason that the pre-calibrated IMU 'BMI055' was chosen. However, the gyroscope and accelerometer of the IMU were bench verified to ensure their accuracy. For the bench testing of the gyroscope of the IMU, the sensor was attached to a walking stick (Figure 4.2).

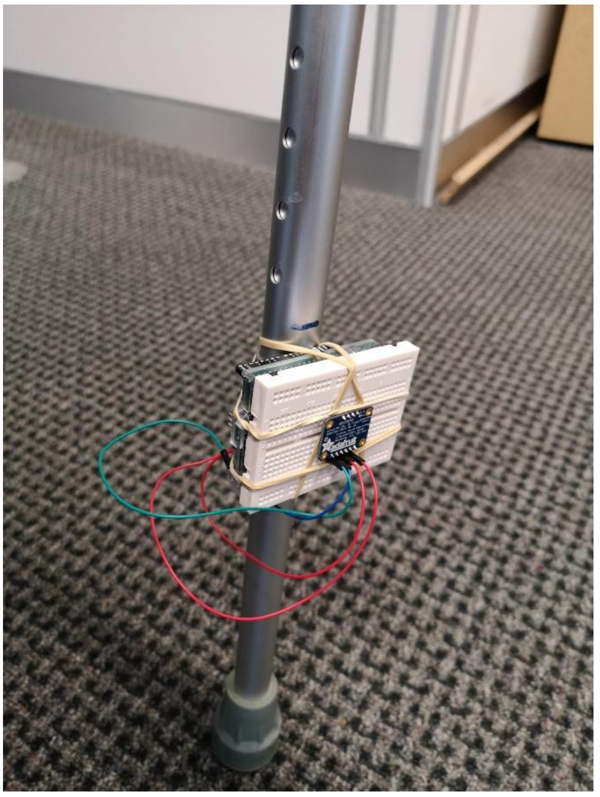


Figure 4.2: Bench test of IMU sensor connected to stick

The walking stick was laid on the ground and raised smoothly upright and vertical with the ferrule flat on the ground. The angles were measured from 0° to 90° and then the stick was taken back to the initial position on the ground. If the stick's movement is visualized, it forms a quarter sine wave with input angles of 0° to 90° and then back to 0° (Figure 4.3a). The pitch angle was likewise adjusted in this way, although this time the stick was slanted forward rather than side to side. It was set down on the ground, lifted until the stick was perpendicular to the ground at a ninety-degree angle, then set back down (Figure 4.3b).

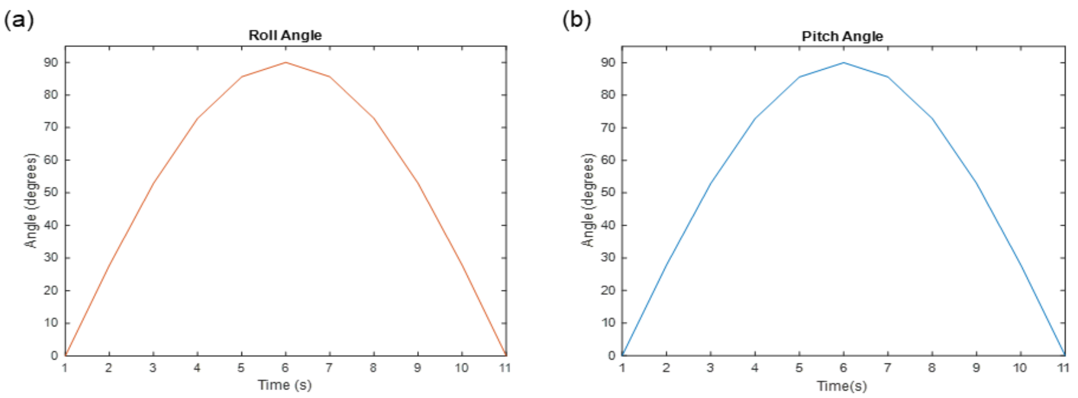


Figure 4.3: An IMU being tested on a bench, with the horizontal axis representing time in seconds and the vertical axis representing the two tested angles, roll and pitch, respectively (degrees)

4.2.3. IMU accelerometer bench testing

To test the acceleration of the accelerometer, the IMU was put in three distinct axes perpendicular to one another, as illustrated in Figure 4.4. In one of these axes, the module would read a value of 10, due to gravity, consecutively over the course of three separate tests. In each test one axis read 0 and the other read 1 g as 10 since its sensitive axis pointed in the direction of gravity's acceleration. This was done for each of the three possible IMU orientations, yielding A_x, A_y, and A_z values of 1 g (or 10) in each case (where x, y, and z correspond to the axes of the Cartesian coordinate system). Acceleration readings on the x-axis registered at 10, whereas readings on the y- and z-axes registered at 0. (Figure 4.4).

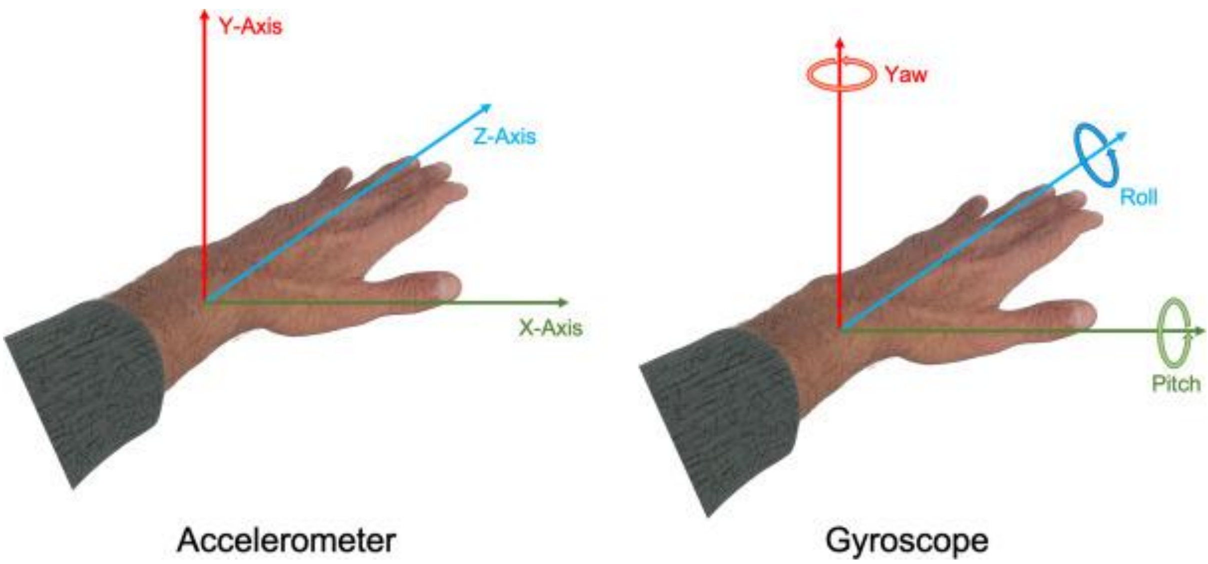


Figure 4.4: Three perpendicular axis (Ghislieri et al., 2019)

The module of the IMU was tilted 90°to enhance the sensitivity of the y axis, enabling it to measure acceleration due to gravity. The x and z axes were measured zero (Figure 4.5). Both axes have shown correct measurement of accelerometers, and the same test was repeated for the z-axis (Figure 4.5c). The completion of bench testing showed the strong calibration of modules for force and orientation sensors. Therefore, the sensors were mounted on the BfT and taken to the validation process.

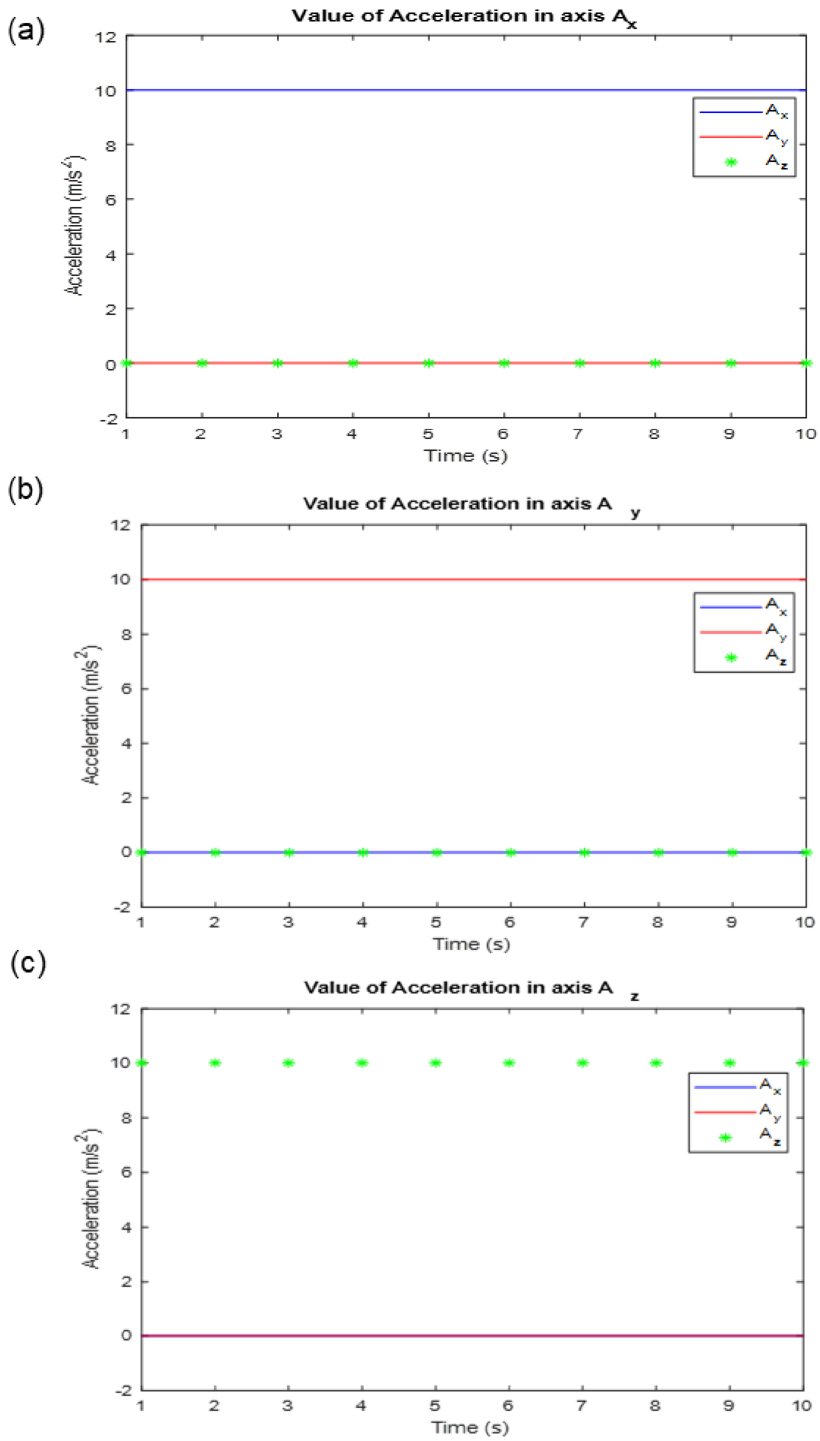


Figure 4.5: Bench test of IMU for acceleration in a. x-axis, b. y-axis, and c. z-axis. Horizontal axis shows time (s) and vertical axis shows acceleration (m s^{-2}), blue line shows A_x, red line shows A_y, and green dots represents A_z

4.3. Validation through calibration approach

The validation process can be divided into following three steps:

1. Acquire measurements from standard equipment that has established accuracy.
2. Acquire measurements from the BfT.
3. Compare the values of BfT against the values of gold standard equipment.

The model for validation is illustrated in Figure 4.6, where there is a common input to both systems (i.e. BfT and the standard equipment). The values were compared for accuracy and reliability with each other. All sensors were initially tested at a test-bench for their formal values before being placed into the BfT. The BfT embedded solution was aligned with the chassis and installed. The BfT was assessed using this methodology by taking readings from both the BfT and the gold standard at the same time.

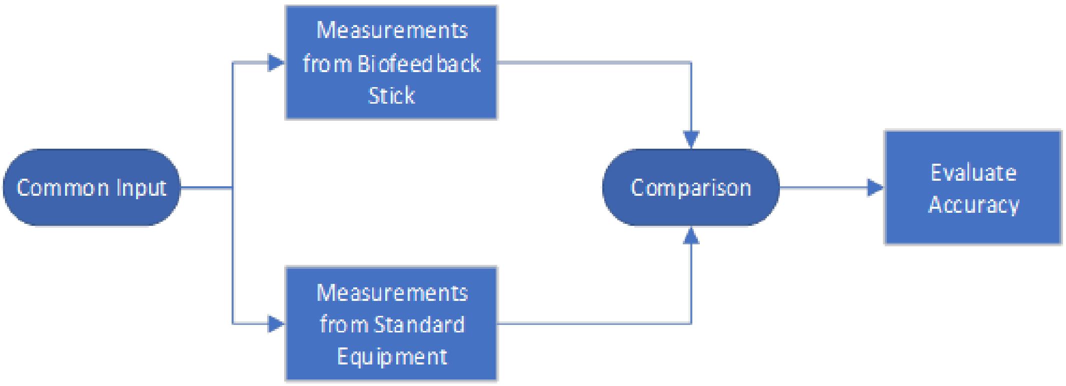


Figure 4.6: Validation of the model via comparison to the standard apparatus

The output from the BfT can be considered as accurate if the values scale linearly with the output from the standard equipment. Ideally the scaling factor (β) should be 1, i.e., no scaling is required. Equation 4.1 shows the relationship between the output from the two systems, where m is the measurement of the BfT, m_c is the measurement of the standard equipment, and β is the scaling factor (Fong, 2008).

$$m = \beta m_c \qquad \text{(E 4.1)}$$

4.4. Validation procedure

Two key measurements are force and angle of the BfT. The marginal errors in force and angle should not only be measured but must also be accurately displayed. The measured force and angles from the BfT were compared against the following equipment:

1. Force against force plates (force sensor)
2. Angles against Qualisys System (IMU)
3. Angles against CodaMotion System (IMU)
4. Step count against OptoJump (IMU)

The rationale of all performed experiments can be found in Chapter 6. The Pearson correlation coefficient was carried out to determine the degree of association existing between the prototype (BfT) and the gold standard system. This statistical analysis reveals the linear connection between the two variables and determines the effect that a shift in one variable has on the other. Further, it determines how strongly two variables are linked to one another. In table 4.0 it can be seen that It ranges from -1 to +1, with values closer to -1 indicating a strong negative association and those closer to +1 a strong positive one (Chok, 2010).

Table 4.0: Interpretation of Pearson correlation coefficient value (r)

Correlation Coefficient Value (r)	Direction and Strength of Correlation
-1	Perfectly negative
-0.8	Strongly negative
-0.5	Moderately negative
-0.2	Weakly negative
0	No association
0.2	Weakly positive
0.5	Moderately positive
0.8	Strongly positive
1	Perfectly positive

Figure 4.7: Practical testing of BfT

4.4.1. Force testing and validation using force plates

The force sensor computations from the BfT were compared against force plates to establish the measure of accuracy and end to end comparison of the development hardware and firmware embedded within the BfT against the force plates. Force plates provide a mechanism by which the amount of force exerted on the plate can be calculated. To make things consistent, the force applied on the force plates is through the BfT.

4.4.1.1. Force plates

Force plates are ‘mechanical sensing systems designed to measure the ground reaction forces (GRFs) and moments involved in human movements. Force plates are regularly used in research and clinical studies for evaluation of balance, gait, and sports performance. Figure 4.8 shows the force that is measured as a subject comes into contact with the platform (Popovic, 2019).

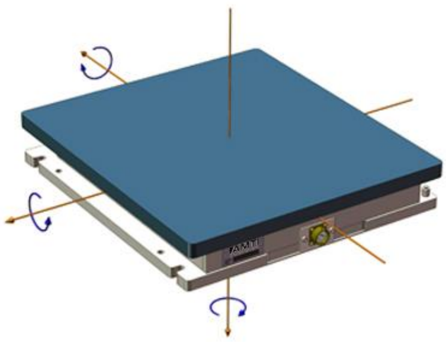


Figure 4.8: The 3-axis force plates (Popovic, 2019).

4.4.1.2. System overview of force plates

Force plates can be used individually Force plates can be used individually or arranged in a walkway format to collect multiple footfalls. A complete force plate system consists of the force plate, an amplifier, a computer, or data acquisition system, mounting hardware, interconnecting cables, and data acquisition software. The force plates are available in single axis and multi axis support. The dimensional diversity facilitates various activities. Force plates are generally selected for one of the following three types of applications (Christina Seimetz et. al. 2013; Steven and Peter, 2009):

- Gait
- Balance
- Sports

4.4.1.3. Experimental setup

The subject walked along a 5-metre walkway, in the middle of which was embedded a force-plate (60 × 40 cm, IDS, Leicestershire, UK). The force plate captured the ground reaction force at a sampling frequency of 1000 Hz, and the BfT's force sensor (load cell) was temporally synchronised at a sampling frequency of 50 Hz, which has been recommended by various researchers (Laohapensaeng et al., 2015; van Lieshout et al., 2016; Routson et al., 2016; Ballesteros et al., 2019; Wade et al., 2019; Fernandez et al., 2020; Caderby et al., 2022). Figure 4.9 illustrates the setup of the force plates and grey force plates on which the force was applied through the BfT. The plate had been calibrated beforehand, and it returned readings of zero while it was not in use. When the calibrated load was applied, the force values remained consistent with one another. The force was applied to the BfT while the ferrule is intended to be placed on the force plate. The readings were obtained for both the BfT and the force plates available in the test setup.

Figure 4.9: Experimental setup and validation process in laboratory.

4.4.1.4. Results and Analysis

Once the setup was established, several tests were conducted through performing activities to evaluate the data received from the BfT (Table 4.1). Three trials each were performed for basic static push, load during gait and the real-time force feedback test. This was done to evaluate the accuracy, measure the load and test the real-time force feedback feature of the firmware (Cloete and Scheffer, 2008).

Table 4.1: Experimentation details for load calculations

Activity	Iterations
Static Push	3
Load applied during gait	3
Threshold Alert Test	3

4.4.1.5. Static push trials

The data for the static push trials obtained from the BfT and force plates is shown in Figure 4.10. It is the comparison of the force produced by the force plate and the force sensor as a function of time. In addition, the information for the trial tests of the static push (first, second, and third) can be found in Table 4.2. The three static push trials showed good correlation between the force measured by the BfT and the force plate. The time for which the force was applied was taken at random to ensure that there was no periodic behaviour of the sensors and was time invariant. The force Vs time curves in trial 1 revealed two idle regions with load applied in the middle region from 2 seconds to 7 seconds (Figure 4.10a). The idle region between 0 to 2 seconds has been marked with a red dotted oval, which shows zero error in the BfT. In trial 2 the same trend was observed, with correlation between the resultant forces (Figure 4.10b). Gradual increasing force was applied from 0 to 2 seconds, followed by partial steady force from 2 seconds to 7.5 seconds. Finally, after 7.5 seconds the red dotted region revealed the gradual lift-off of the BfT from the force plate, causing the value of force to change from a given value of 150 N to zero (Figure 4.10b).

All the trials exhibited sufficient acquisition time, and consistency between the values taken from both systems (Figure 4.10). In general, the BfT and the force plate showed a slight discrepancy of 14N to 15N. This discrepancy arose due because the force plate recorded the user's input along with the complete weight of the BfT (1.4 kg, 14 N), whereas the BfT recorded only the user's input after the assembly weight of the BfT was subtracted out during calibration. For example, in trial 1, at 3 seconds the force plate showed 100N and the BfT indicated 86N. Therefore, the difference between them was of 14N. In trial 2, at 3 seconds the force plate showed 98N and the BfT indicated 86N. The difference between them was 14N. Trial 3, showed 130N at 3 seconds and the BfT showed 116N. These differences were applicable throughout the force plate vs force sensor tests (Figure 4.10).

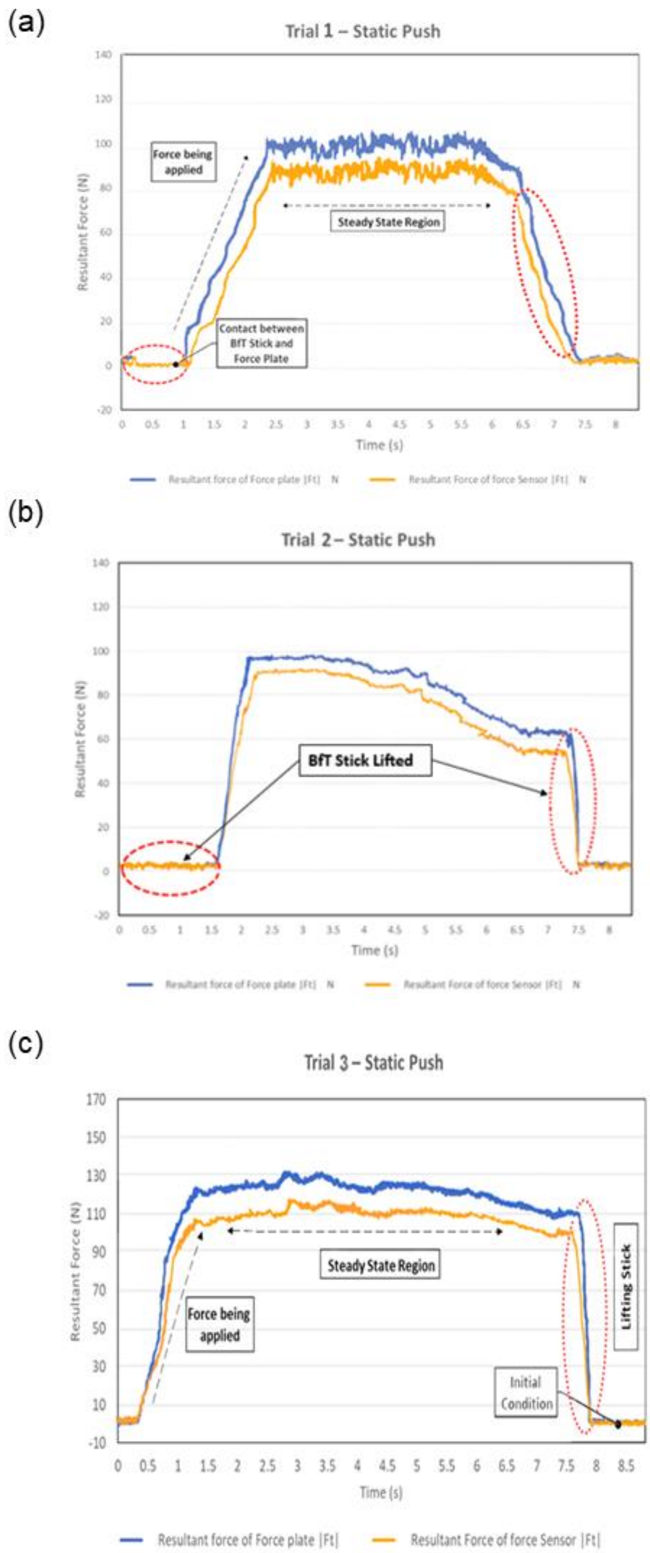


Figure 4.10: a. In trial 1, the red dashed line indicates where the BfT stick contacted with the force plate, the black arrow indicates when force was applied, and the horizontal arrow indicates the steady state region, b. In trial 2, the red dashed line indicates where the BfT stick contacted with the force plate. Trial 2, oval red dashed line represents when BfT stick was lifted c. Trial 3, oval red dashed line represents when BfT stick was lifted of static push,

inclined dashed arrow represents when force was applied, horizontal dashed arrow represents the steady state region, blue line shows resultant force of force plate and yellow color depicts resultant force of force sensor.

Table 4.2: Trial tests (1st, 2nd, and 3rd, of static push for balance)

1st test of static push for balance			
Time (s)	Resultant Force of Force Plate |N|	Resultant Force of Force Sensor |N|	Absolute Error (Range) (N)
0 – 1	0	0	0
1 – 2	0 – 54	0 – 40	0-14
2 – 3	54 – 105	40 – 91	14
3 – 4	105 – 108	91 – 93	14-15
4 – 5	108 – 105	93 – 91	15-14
5 – 6	105 – 95	91 – 81	14
6 – 7	95 – 35	81 – 20	14-15
7 – 8	35 – 14	21 – 0	14
2nd test of static push for balance			
Time (s)	Resultant Force of Force Plate |N|	Resultant Force of Force Sensor |N|	Absolute Error (Range) (N)
0 – 1	0	0	0
1 – 2	0 – 90	0 – 75	0-15
2 – 3	90 – 98	75 – 84	15-14
3 – 4	98 – 95	84 – 81	14
4 – 5	95 – 90	81 – 76	14
5 – 6	90 – 70	76 – 55	14-15
6 – 7	70 – 63	55 – 49	15-14
3rd test of static push for balance			
Time (s)	Resultant Force of Force Plate |N|	Resultant Force of Force Sensor |N|	Absolute Error (Range) (N)
0 – 1	0 – 100	0 – 86	0-14
1 – 2	100 – 125	86 – 110	14-15
2 – 3	125 – 128	110 – 114	15-14
3 – 4	128 – 120	114 – 106	14
4 – 5	120 – 125	106 – 111	14
5 – 6	125 – 120	111 – 105	14-15

6 – 7	120 – 110	105 – 96	15-14
7 – 8	110 – 0	96 – 0	14-0

The linear correlation between the force plate and the BfT stick was calculated using Pearson correlation. A significant positive relationship was found between the force plate and BfT stick results (Figure 4.11). In each of the three experiments, the value of the correlation coefficient, r, was found to be 0.98, and the p-value was less than 0.001, indicating a highly significant correlation (Table 4.3).

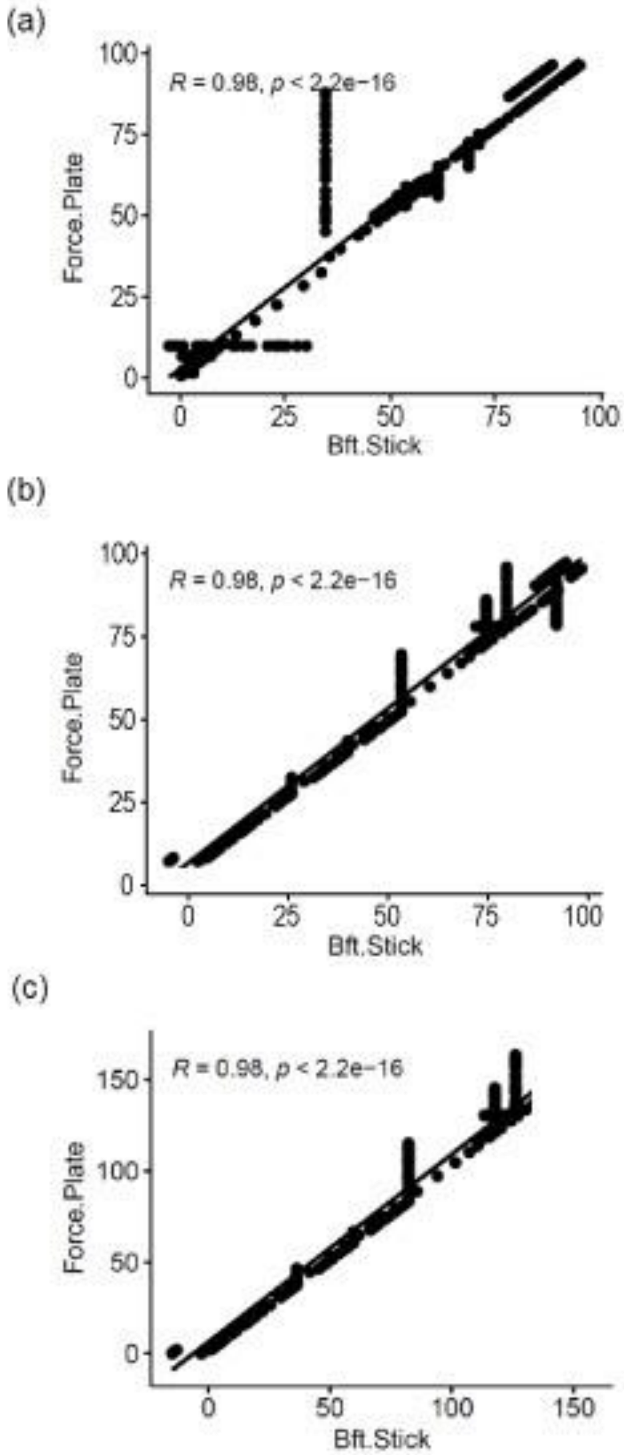


Figure 4.11: Pearson correlation coefficient of a. trial 1, b. trial 2, and c. trial 3, x-axis shows BfT stick, y-axis shows force plate, R represents correlation coefficient value.

Table 4.3: Pearson correlation of trial tests between force plate and BfT stick

Trial Number	Corr\r	p-value	Mean Y	Mean X	SD Y	SD X
1	0.98	0.000002	108	93	50	48
2	0.98	0.000002	109	95	49	47
3	0.98	0.000002	140	127	47	42

4.4.1.6. Gait trials

Dynamic trials were performed on data collected through statistical trials (BfT). The purpose of the gait trials was to assess the BfT's built-in force sensor in relation to the force plates while the user was in motion. The BfT's performance was measured over the course of three separate walking tests. The data gathered from the gait tests is shown in Figure 4.12. The gait trials lasted between 4 and 5 seconds, and recommended in the available literature, the BfT user walked at a normal gait speed of 1.04 m s^{-1} (Kamiya et al., 2017). Gait evaluation sample test results are displayed in Table 4.4.

All the gait trials showed strong correlation ($r > 0.98$, $p < 0.001$) between the data acquired from the BfT and the data from the force plates. In trial 4, the subject started the gait test movement between 0 and 1 seconds, where the BfT was in the air. The BfT was on the ground from 1 to 2 seconds, landing on the outside of the force plate. Therefore, the force plate shows zero force, while the BfT shows the force pattern (Figure 4.12a) and a difference of more than 100N can be seen between the BfT and the force plate. It was necessary to do this to ensure that the BfT was accurately measuring the force. Figure 4.12a shows the moment the stick was raised into the air, with the BfT and plate reading zero, as a red dotted area lasting from 2 to 3 seconds. At 3.6 seconds into trial 4, the BfT stick contacted with the force plate, registering a reading of 155N Figure 4.12a). In trial 5, the force plate reading at 3.8 seconds was 154N, whereas the BfT stick reading was 140N, a discrepancy of 14N. (Figure 4.12b). Trial 6 took place at 3.3 seconds, with the force plate registering 250N and the BfT stick registering 236N, a discrepancy of 14N. (Figure 4.12c). These distinctions were observed in all comparisons between force plates and force sensors (Figure 4.12).

In trial 5 and 6, the same protocols were followed and the BfT was grounded outside the force plate before landing the BfT on the force plate, hence a difference of more than 100N can be seen between the BfT and the force plate. In Figures 4.12b and 4.12c, the regions from 0.7 to 1.7 s and 1.0 to 1.8 s, show the BfT being placed on the ground, hence no measurement was recorded by the force plate. The red oval dotted region in figure is the duration in which the BfT was raised in the air. Both the force plate and the BfT showed zero force value. From 2.75

to 3.7 s (Figure 4.12a) and 3.0 to 3.8 s (Figure 4.12b), the BfT was placed on the force plate and a high curve representing the force was produced.

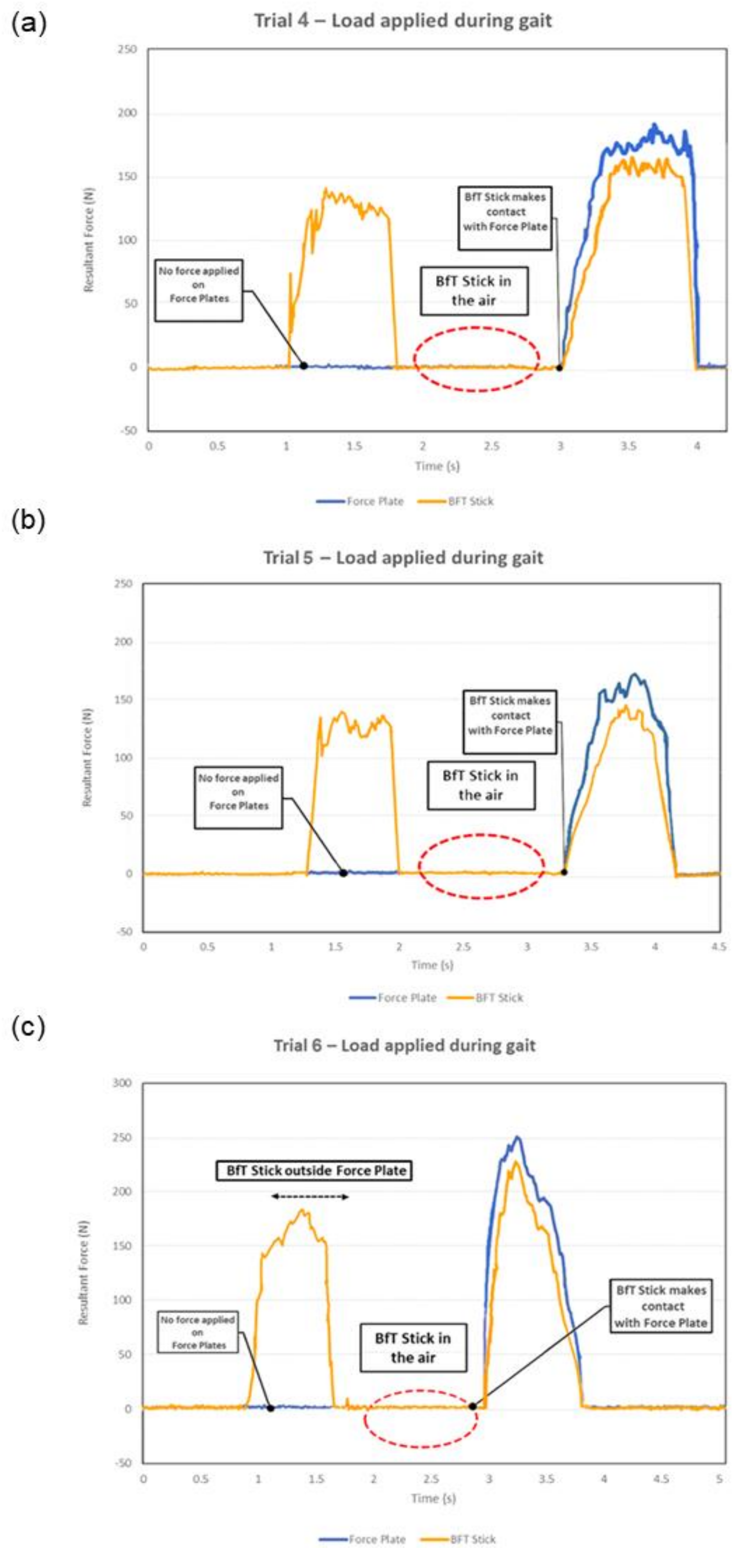


Figure 4.12: Force curves for load applied during gait a. trial 4 (1st iteration of gait testing), b. Trial 5 (2nd iteration of gait testing), c. Trial 6 (3rd attempt of gait testing), horizontal blue line represents the time when no force was applied on force plate, oval red dashed line shows

the time when the BfT stick was in air, diagonal blue and yellow line shows the time when the BfT stick contacted the force plate, blue line shows force plate, yellow line represents BfT stick, horizontal dashed arrow shows the time when the BfT stick was outside force plate.

Table 4.4: Trial tests 4 (1st test of gait evaluation), trial 5 (2nd attempt of gait testing), and trial 6 (3rd attempt of gait testing)

1st test of gait evaluation			
Time (s)	Resultant Force of Force Plate |N|	Resultant Force of Force Sensor |N|	Absolute Error (Range) (N)
0 – 1	0	0	0
1 – 2	0	0 – 135	0-135
2 – 3	0	0	0
3 – 4	0 – 150	0 – 134	0-14
2nd test of gait evaluation			
Time (s)	Resultant Force of Force Plate |N|	Resultant Force of Force Sensor |N|	Absolute Error (Range) (N)
0 – 1	0	0	0
1 – 2	0	0 – 130	0-130
2 – 3	0	0	0
3 – 4	0 – 135	0 – 121	0-14
3rd test of gait evaluation			
Time (s)	Resultant Force of Force Plate |N|	Resultant Force of Force Sensor |N|	Absolute Error (Range) (N)
0 – 1	0	0 – 86	0
1 – 2	0	0 – 130	0-130
2 – 3	0	0	0
3 – 4	0 – 100	0 – 86	0-14

For trials 4, 5, and 6, the Pearson correlation analysis revealed a significant and positive relationship between the force plate and the BfT stick (Figure 4.13). In trials 4 and 5, the coefficient value, r, was 0.98, while in trial 6, the value was 0.99, and the p-value was less than 0.001, indicating that there was a highly significant association (Table 4.5).

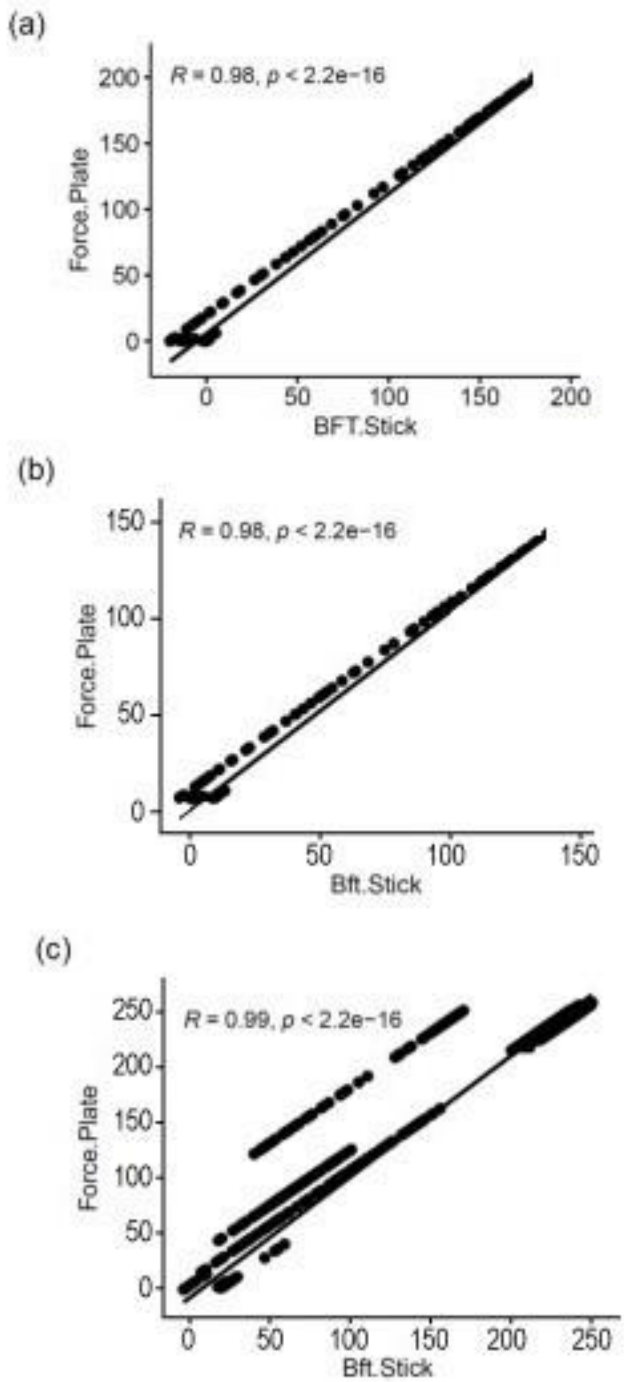


Figure 4.13: Pearson correlation coefficient of a. trial 4, b. trial 5, and c. trial 6, x-axis shows BfT stick, y-axis shows force plate, r represents correlation coefficient value.

Table 4.5: Pearson correlation of trial tests between force plate and BfT stick

Trial Number	Corr\r	p-value	Mean Y	Mean X	SD Y	SD X
4	0.98	0.000002	100	85	39	32
5	0.98	0.000002	120	106	39	36
6	0.99	0.000002	109	94	23	21

4.4.1.7. Weight and threshold alert trials

The static weight and dynamic force tests have validated the accuracy and repeatability of BfT's force measuring ability. In this final set of force testing trials, the BfT was put to test for the weight and threshold trials so that the real-time weight alert feature of the BfT is also evaluated.

The method of computing 12% of the weight value was simple, where the weight of the test subject was measured using the weight scale and then 12% of that weight was computed. If x percentage is to be computed from the total weight, then the generalised formula is as follows:

$$x\%weight = \frac{x}{100} \times totalweight$$

Upon lifting the BfT, both the plate and BfT showed zero error, as shown between 0 and 0.75 seconds (Figure 4.14). At the point of impact, there was a glitch showing a negative value, such glitches can have two causes. Firstly, due to incorrect calibration or secondly, due to manufacturing defects of the force sensor (Indramohan, 2010). If the glitch was solely due to calibration, the glitch exhibited in trial 7 should also have been exhibited in trials 1 to 6. Since it was not the case, the second explanation is more likely the cause of the glitch in this case. Thereby, the force applied to the BfT was not allowed to be negative and the error was automatically filtered out. Specifically, the force was saved as an unsigned integer, with a lower and upper limit of values specified. The real-time alert feature functioned correctly as an alert was generated at 3.75 seconds (Figure 4.14) when 12% of body weight was being applied to the stick, indicating the BfT user had reached the threshold limit. The data for trial 7 (12% bodyweight alert testing) is provided in Table 4.6.

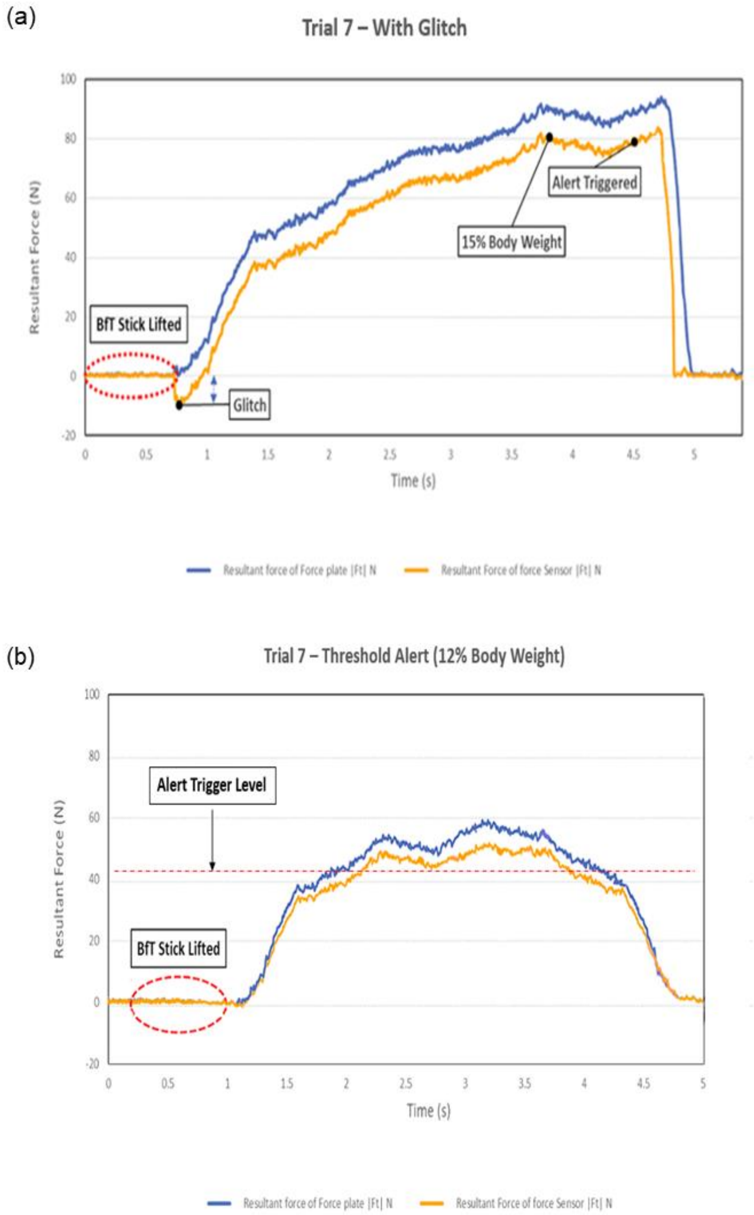


Figure 4.14: Force curves for trial 7 a. with glitch, black horizontal line shows glitch b. threshold alert (12% bodyweight), red horizontal dashed line represents alert trigger level. The oval red dashed line shows the time when the BfT stick was lifted, and the blue line shows resultant force of force plate and yellow line depicts resultant force of force sensor

Table 4.6: Trial 7 (12% bodyweight alert testing)

Time (s)	Resultant Force of Force Plate |N|	Resultant Force of Force Sensor |N|	Absolute Error (Range) (N)
0 – 1	0	0	14
1 – 2	0 – 45	0 – 31	0-14
2 – 3	45 – 55	31 – 40	14-15
3 – 4	55 – 46	40 – 32	15-14
4 – 5	46 – 0	32 – 0	14-0

Threshold alerts was tested again in trials 8 and 9, during which the weight was applied at a consistent level, and it was checked to ensure that an alarm was triggered along with the values of the force plate (Figures 4.15). In trial 8, there was no exertion of force between 0 and 3.5 s (dotted red oval). Nonetheless, the stick made contact with the ground, and the force reached a critical magnitude between 3.5 and 12.5 seconds later. At 4 seconds, an alarm went on and did not go away until the stick was raised, at which point the warning was silenced. The entire steady state region between 4.25 and 11.5 seconds showed good correlation between the two forces (Figure 4.15a).

Trial 9 showed that the alert was continuously generated when the force was constantly applied (Figure 4.15b). The moment the load was taken off, the readings of the BfT followed the readings of the force plates, ensuring no drift in values during the continuous usage of the BfT. Zero reading was being measured by both the BfT and the plate between 0 and 4.5 seconds, and the two systems (BfT and force plate) showed good correlation even when the force was applied at a maximum level and retained at its peak. Maximum force was reached at about 7.5 seconds and the alert was generated. The experiments for the static and dynamic force tests demonstrated the repeatability of the BfT's force sensor. The data for trial 8 and trial 9 is given in Table 4.7.

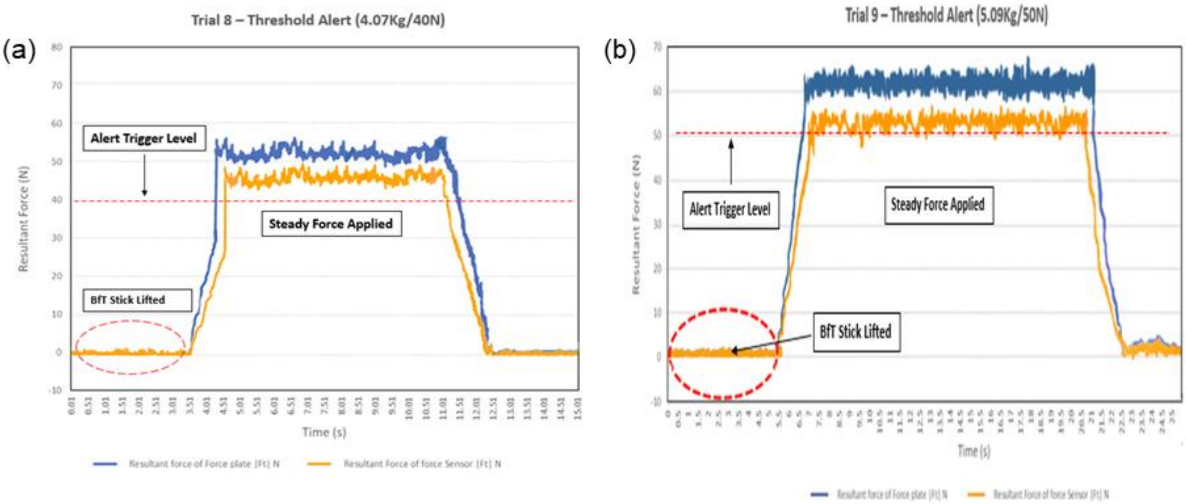


Figure 4.15: Force curves for a. trial 8 (4.07 kg / 40 N threshold testing), b. trial 9 (5.09 kg / 50 N threshold testing), with the red horizontal dashed line representing alert trigger level and the oval red dashed line showing the time when BfT stick was lifted.

Table 4.7: Trial 8 (4.07 kg / 40 N threshold alert testing) and trial 9 (5.09 kg / 50 N bodyweight alert testing)

Trial 8 (4.07 kg / 40 N threshold alert testing)			
Time (s)	Resultant force of Force plate |N|	Resultant Force of Force Sensor |N|	Absolute Error (Range) (N)
0 – 3	0	0	0
3 – 6	0 – 55	0 – 41	0-14
6 – 9	55 – 53	41 – 38	14-15
9 – 12	53 – 20	38 – 6	15-14
12 – 15	20 – 0	6 – 0	14-0
Trial 9 (5.09 kg / 50 N bodyweight alert testing)			
Time (s)	Resultant Force of Force Plate |N|	Resultant Force of Force Sensor |N|	Absolute Error (Range) (N)
0 – 4	0	0	0
4 – 8	0 – 20	0 – 6	0-14
8 – 12	20 – 60	6 – 45	14-15
12 – 16	60 – 62	45 – 48	15-14
16 – 20	62 – 65	48 – 51	14
20 – 24	65 – 62	51 – 47	14-15

The findings of the correlation showed that the force plate had a coefficient value of r=0.97 with the BfT stick in trial 7 and r=0.95 in trial 8, with a p-value that was less than 0.001 in both cases (Figure 4.16). It demonstrated that there is a significant positive association between the two tests (Table 4.8).

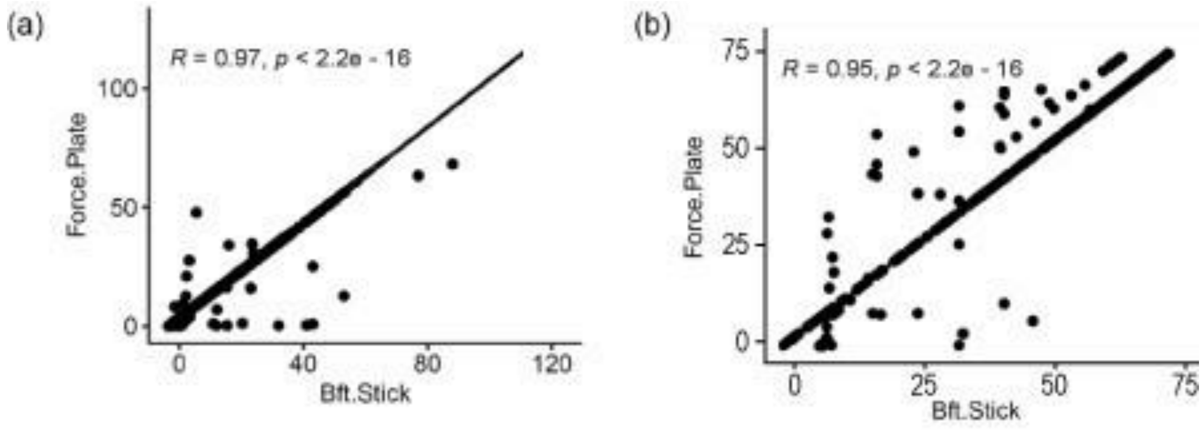


Figure 4.16: Pearson correlation coefficient of a. trial 7, b. trial 8, x-axis shows the BfT stick, y-axis shows the force plate and r is the correlation coefficient value.

Table 4.8: Pearson correlation of trial tests between force plate and BfT stick.

Trial Number	Corr\r	p-value	Mean Y	Mean X	SD Y	SD X
7	0.97	0.000002	103	87	30	29
8	0.95	0.000002	102	96	32	30

4.4.2. Orientation testing and validation using Qualisys system

One of the key features of the BfT is the inclusion of real-time feedback on incorrect orientation. However, in a real-world scenario, the two angles of pitch and roll are of key importance. They are depicted by the forward and backward tilting and sideways tilt respectively. Yaw in this case is the pivotal motion and is not applicable in this study. Testing of the position or orientation of BfT was validated with the help of two 3D motion capture systems (Mocap). One was the Qualisys system and the other was the CodaMotion system. 3D motion capture systems have been used by various researchers to study the kinematics of the human body. (Malý and Lopot, 2013; Vilas-Boas et al., 2019; Yeo and Park, 2020).

4.4.2.1. Qualisys system

The Qualisys system included twelve infrared cameras and thirty-six retroreflective markers placed on the subject's body according to the marker settings used by Rocha et al. (2018). The cameras emitted infrared light, which was then reflected by retroreflective markings that had been placed on the person. The mesh of cameras in the network were able to pick up on the reflected light, and this information was then sent to the program. The Qualisys software reconstructed 3D information of the test subject, based on received coordinate information of markers from the cameras.

Initially the Qualisys system was calibrated to determine the axes being set up for the defined test area and varying test volumes. This was completed using static and dynamic calibration techniques. In the case of static calibration, a fixed L-shaped bar with markers in a predetermined position was used. This L-shaped bar was then utilised to calibrate the test area and positioned on either side of the force plate to cover the area where gait analysis was performed. This arrangement enabled the Qualisys software to compute the axes setup for the testing area in the lab. On the other hand, a wand was used in the dynamic calibration procedure to adjust for the different test volumes. The wand's two marks were spaced at a particular distance apart. The wand was moved through the test area for about 60 seconds to allow the Qualisys system to record the marker positions and determine the twelve cameras (Vilas-Boas et al., 2019). The position was acquired deterministically using all the twelve cameras. The configuration of Qualisys marker and sensors is illustrated in Figure 4.17.

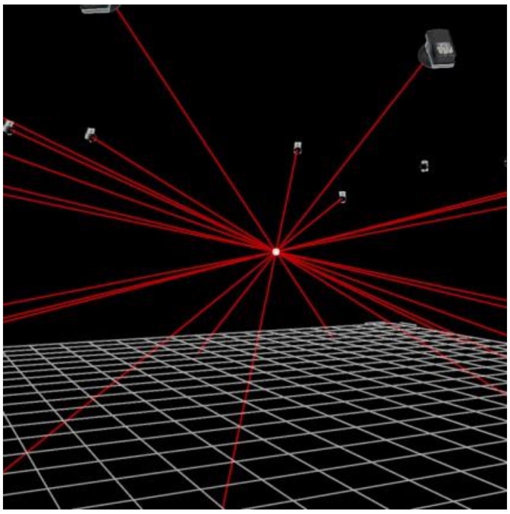


Figure 4.17: Qualisys marker and sensors configuration.

4.4.2.2. System overview

The method of using the Qualisys requires the markers to be applied not only on the test subject but also the BfT. This provides dual information (i.e., the movement of the BfT user and the tilt angles of the BfT during usage). Raw information captured by the sensors was passed through the Qualisys software to process and retrieve the information of the angles. The process of rendering information from Qualisys was cumbersome, as the data obtained has to be passed through several post-processing applications to extract the information. The special markers and camera arrangement creates an accurate environment to measure the angles generated for the BfT displacements.

4.4.2.3. Experimental setup

In the setup of the experiment, the IMU and the Qualisys system were set at 100 Hz sampling frequency (Zhou et al., 2020). The markers were installed on the test subject and the BfT (Figure 4.18). The placement of markers comprehensively covered almost the whole body. Two markers were placed on both the sides of temporal lines, followed by one at the seventh cervical vertebra, and two on the acromion-process position. These five markers provide the information of tilt and bend of head and shoulders while using the BfT (Laribi and Zeghloul, 2020). Two markers were positioned on the medial edge of each scapula to keep track of the whole arm length required to hold the BfT. One on each vertebra, two on either side of the sacrum, one on the space between the acromion process and the olecranon, one on the lateral epicondyle of the humerus, and one on the styloid process of the ulna. To capture the movement of the lower part of the body, four markers were placed about the medial epicondyle of femur, two on both legs around the curve of tibia, two on the medial malleolus on each foot, and one on calcaneus on both feet (Cloete and Scheffer, 2008; Laribi and Zeghloul, 2020). On the BfT, one marker was installed on the handle, one in the middle, and one at the bottom near the ferrule. Cameras captured the motion of the BfT and the subject, which was then post-processed after rendering through designated software.

Figure 4.18: Arrangement of the experimental components, including the attachment of markers to the subject and the use of BfT in the lab.

4.4.2.4. Results and Analysis

By using the BfT and with the help of rendering software '3D visual', post-processing data was extracted to obtain bespoke information (summarised in Table 4.9). The collected data was filtered using a 4th order low pass Butterworth filter with a 6 Hz cut-off frequency to eliminate the noise present in the data (Costamagna et al., 2017; Zhang et al., 2020).

The forward and backward tilts were referred as pitch movements, while tilting sideways was considered a roll movement. Three different angles were picked in order to test the roll and pitch of the BfT and to observe the stability of the BfT; the specifics of these tests and observations will be covered in Chapter 6. Three trials were performed for each activity (roll, pitch, correct posture and incorrect posture walk) (Cloete and Scheffer, 2008).

Table 4.9: Details of experimentation for orientation.

Activity	No. of Iterations
Hold BfT steady at 90º Roll	1
Hold BfT steady at 65º Roll	1
Hold BfT steady at 105º Roll	1
Hold BfT steady at 90º Pitch	1
Hold BfT steady at 72º Pitch	1
Hold BfT steady at 110º Pitch	1
Correct Posture Walk	3
Incorrect Posture Walk	3

4.4.2.5. Roll trials

The Qualisys view for experimental trials (1, 2, and 3) with roll at different degrees (90°, 65°, and 105°) is shown in Figure 4.19. The results regarding holding the BfT stick steady at different degrees is shown in Figure 4.20. The details of experimentation for orientation using Qualisys for roll at different degrees (90°, 65° and 105°) is presented in Table 4.10.

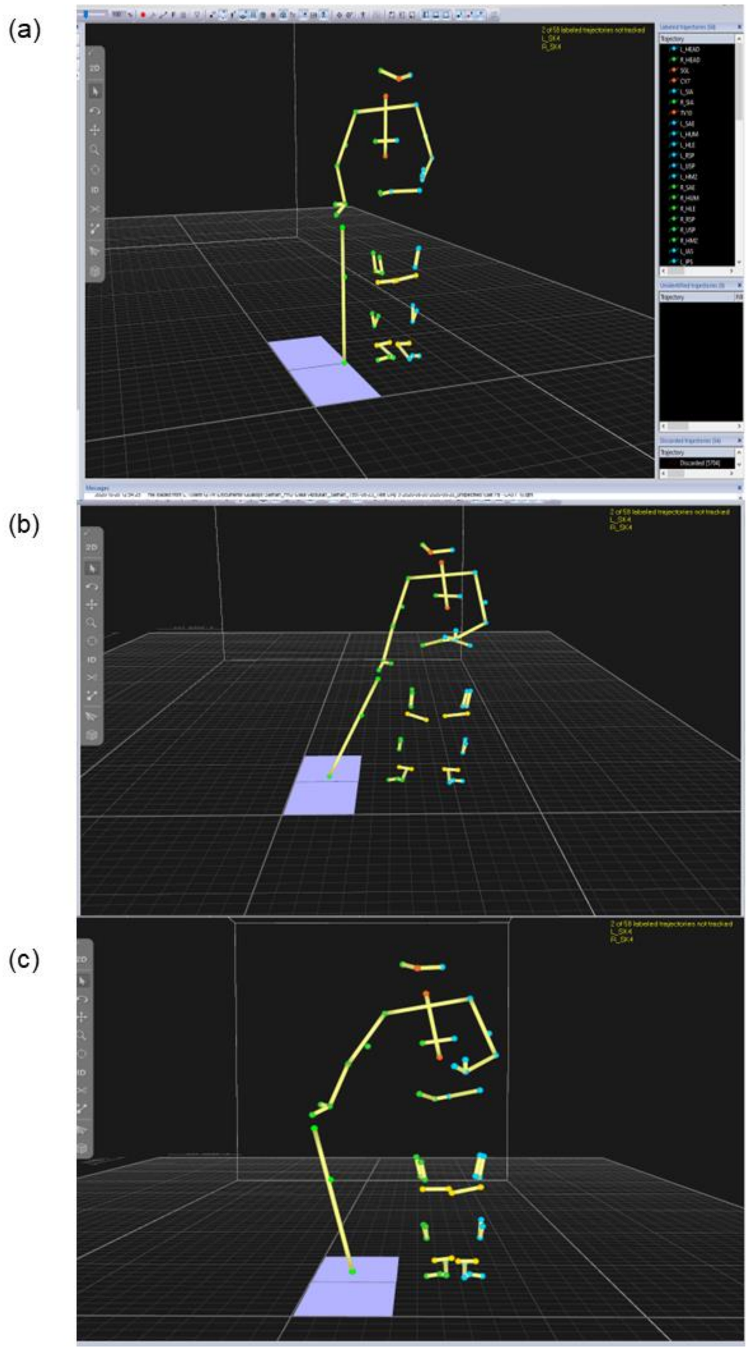


Figure 4.19: Qualisys view for experimental a. Trial 1 with roll at 90°, b. Trial 2 with roll at 65°, c. Trial 3 with roll at 105°.

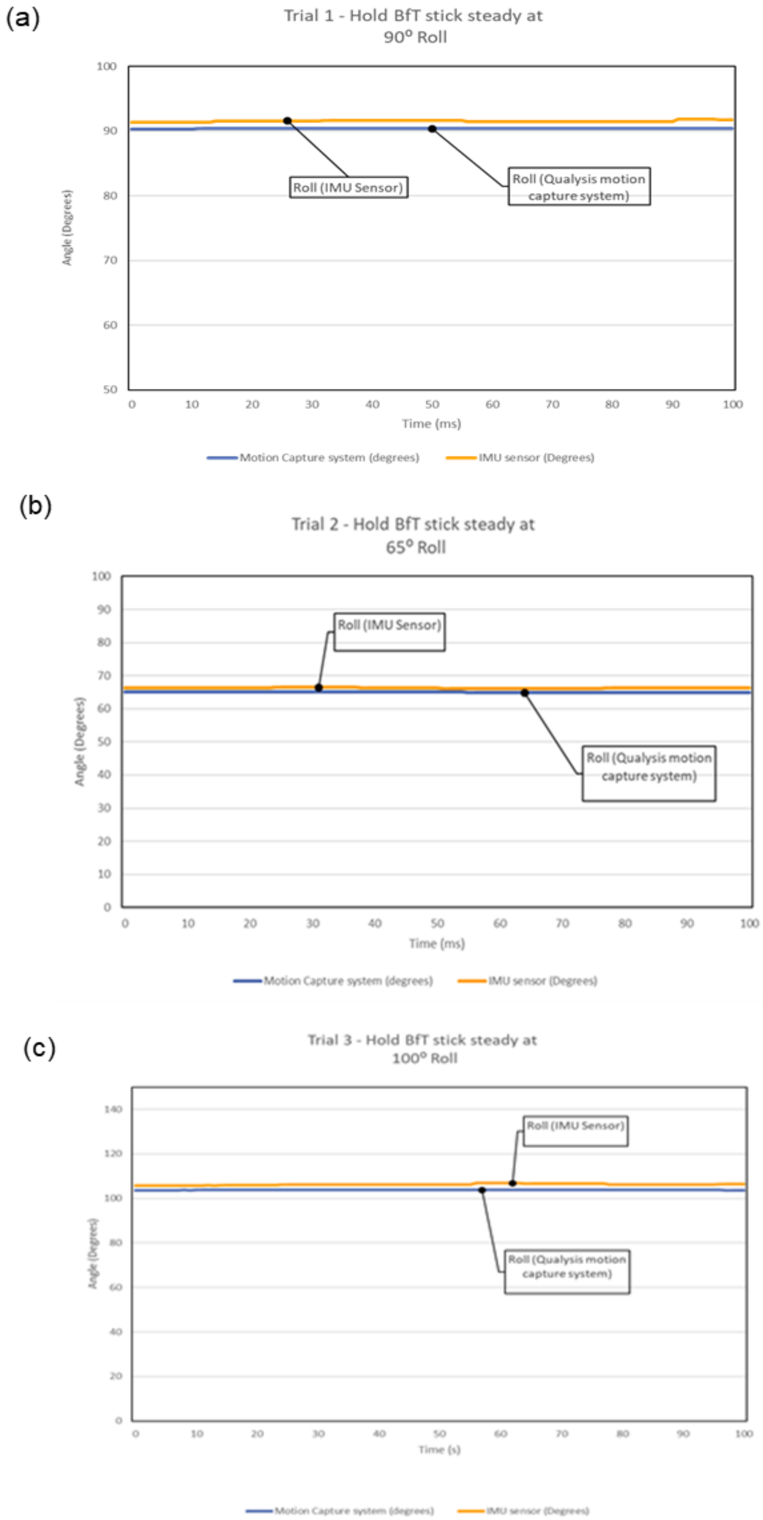


Figure 4.20: Experimental a. Trial 1 with roll at 90°, b. Trial 2 with roll at 65°, and c. Trial 3 with roll at 105°, blue line represents motion capture system (degrees), yellow line represents IMU sensors (degrees).

Table 4.10: Details of experimentation for orientation using Qualisys for roll at different degrees (90°, 65° and 105°)

Orientation using Qualisys for roll at 90°			
TIME (ms)	Qualisys System (degrees)	BfT IMU Sensor (degrees)	Absolute error (degrees)
0 – 20	90	91	1
20 – 40	90	91	1
40 – 60	90	91	1
60 – 80	90	91	1
80 – 100	90	91	1
Orientation using Qualisys for roll at 65°			
TIME (ms)	Qualisys System (degrees)	BfT IMU Sensor (degrees)	Absolute error (degrees)
0 – 20	65	66	1
20 – 40	65	65	0
40 – 60	65	66	1
60 – 80	65	65	0
80 – 100	65	66	1
Orientation using Qualisys for roll at 105°			
TIME (ms)	Qualisys System (degrees)	BfT IMU Sensor (degrees)	Absolute error (degrees)
0 – 20	105	105	0
20 – 40	104	105	1
40 – 60	105	106	1
60 – 80	106	106	0
80 – 100	106	107	1
0 - 20	105	105	0

Pearson correlation exhibited strong positive correlations between Qualisys system and BfT stick in roll trials 1, 2, and 3 (Figure 4.21). The coefficient value was r = 0.96 in trial 1, r = 0.97 in trial 2, and r = 0.98 in trial 3 with a p-value <0.001, which suggested a highly significant association (Table 4.11).

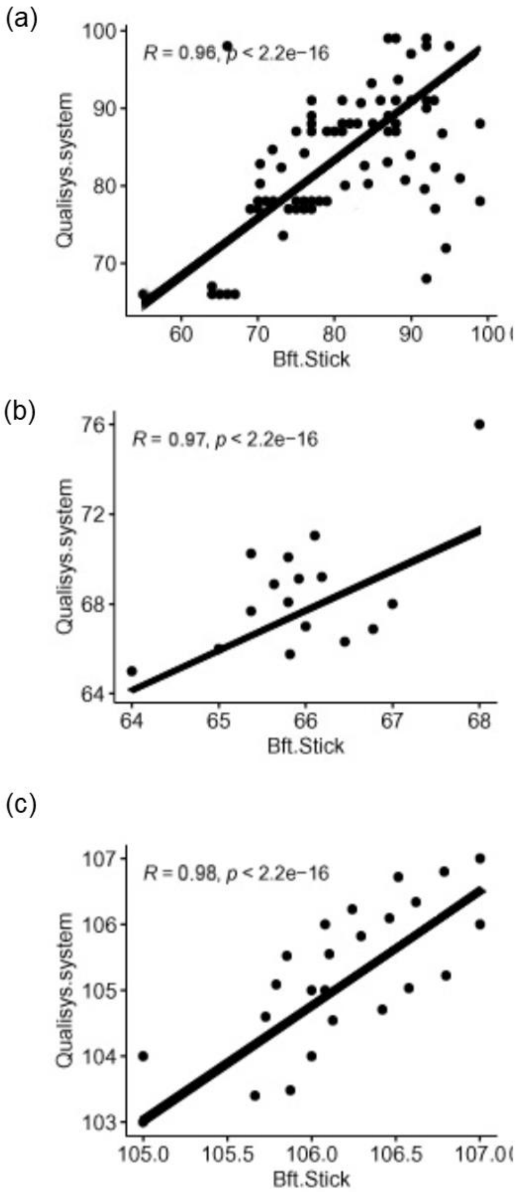


Figure 4.21: Pearson correlation coefficient of roll trials a. Trial 1, b. Trial 2, c. Trial 3, x-axis shows BfT stick, y-axis shows Qualisys system, r represents correlation coefficient value.

Table 4.11: Pearson correlation of trial tests between Qualisys system and BfT stick

Trial Number	Corr\r	p-value	Mean Y	Mean X	SD Y	SD X
1	0.96	0.00022	84	83	9	9
2	0.97	0.00022	65	66	0.12	0.11
3	0.98	0.00022	104	105	0.12	0.04

4.4.2.6. Pitch trials (forward and backward movements of stick)

The Qualisys view for experimental trials (1, 2, and 3), with pitch at different degrees (90°, 72°, and 110°), is shown in Figure 4.22. The data for holding BfT stick steady at different angles of pitch is depicted in Figure 4.23. Table 4.12 contains the results of experiments conducted with Qualisys to investigate the effects of roll angles of 90°, 65°, and 105°, respectively.

(a)

(b)

(c)

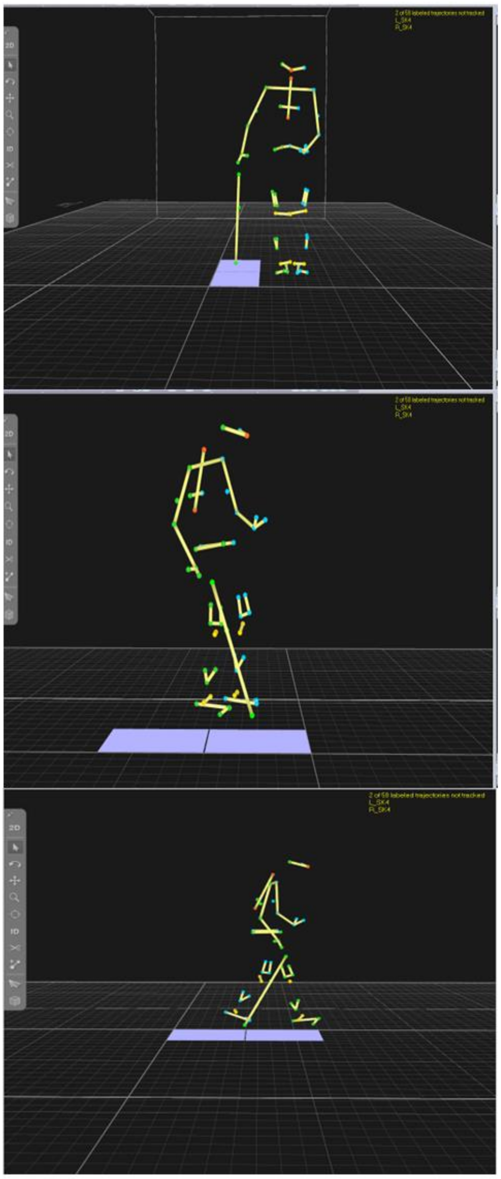


Figure 4.22: Qualisys view for experimental a. Trial 3 with pitch at 90°, b. Trial 5 with pitch at 72°, c. Trial 6 with pitch at 110°.

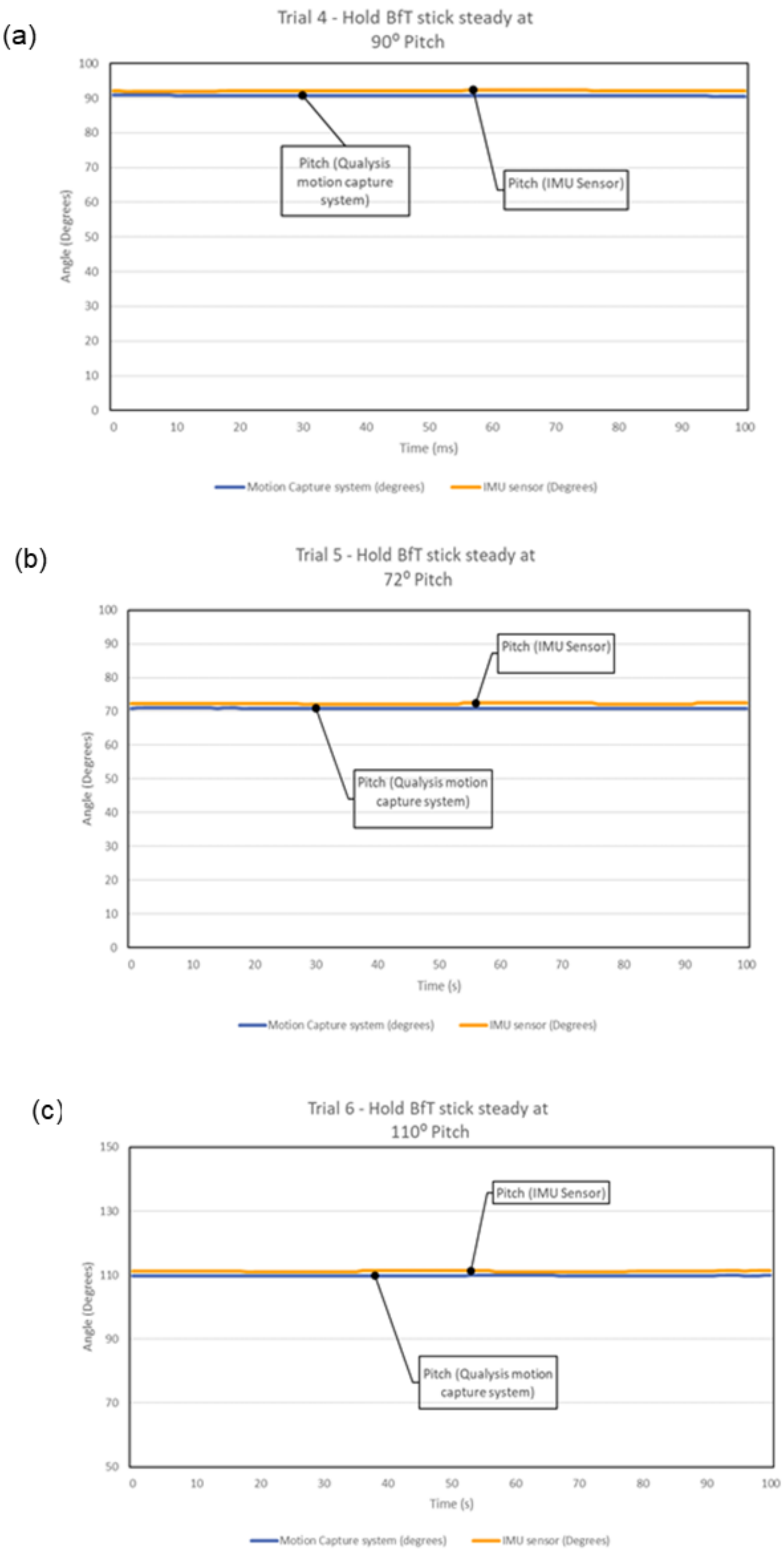


Figure 4.23: Experiment a. Trial 4 with pitch at 90°, b. Trial 5 with pitch at 72, c. trial 6 with pitch at 110°, blue line represents motion capture system (degrees), yellow line represents IMU sensors (degrees).

Table 4.12: Details of experimentation for orientation using Qualisys for roll at different degrees (90°, 72° and 110°).

Orientation using Qualisys for pitch at 90°			
TIME (ms)	Qualisys System (degrees)	BfT IMU Sensor (degrees)	Absolute error (degrees)
0 – 20	90	90	0
20 – 40	90	91	1
40 – 60	91	91	0
60 – 80	91	92	1
80 – 100	92	92	0
Orientation using Qualisys for pitch at 72°			
TIME (ms)	Qualisys System (degrees)	BfT IMU Sensor (degrees)	Absolute error (degrees)
0 – 20	72	73	1
20 – 40	72	73	1
40 – 60	72	72	0
60 – 80	72	73	1
80 – 100	72	73	1
Orientation using Qualisys for pitch at 110°			
TIME (ms)	Qualisys System (degrees)	BfT IMU Sensor (degrees)	Absolute error (degrees)
0 – 20	109	110	1
20 – 40	110	110	0
40 – 60	110	111	1
60 – 80	111	111	0
80 – 100	112	113	1

Pearson correlation exhibited strong positive correlation between the Qualisys system and BfT stick in pitch trials 4, 5, and 6 (Figure 4.24). The coefficient value was $r = 0.90$ in trial 4, $r = 0.92$ in trial 5, and $r = 0.98$ in trial 6 with a p-value <0.001, which suggested a highly significant association (Table 4.13).

(a)

(b)

(c)

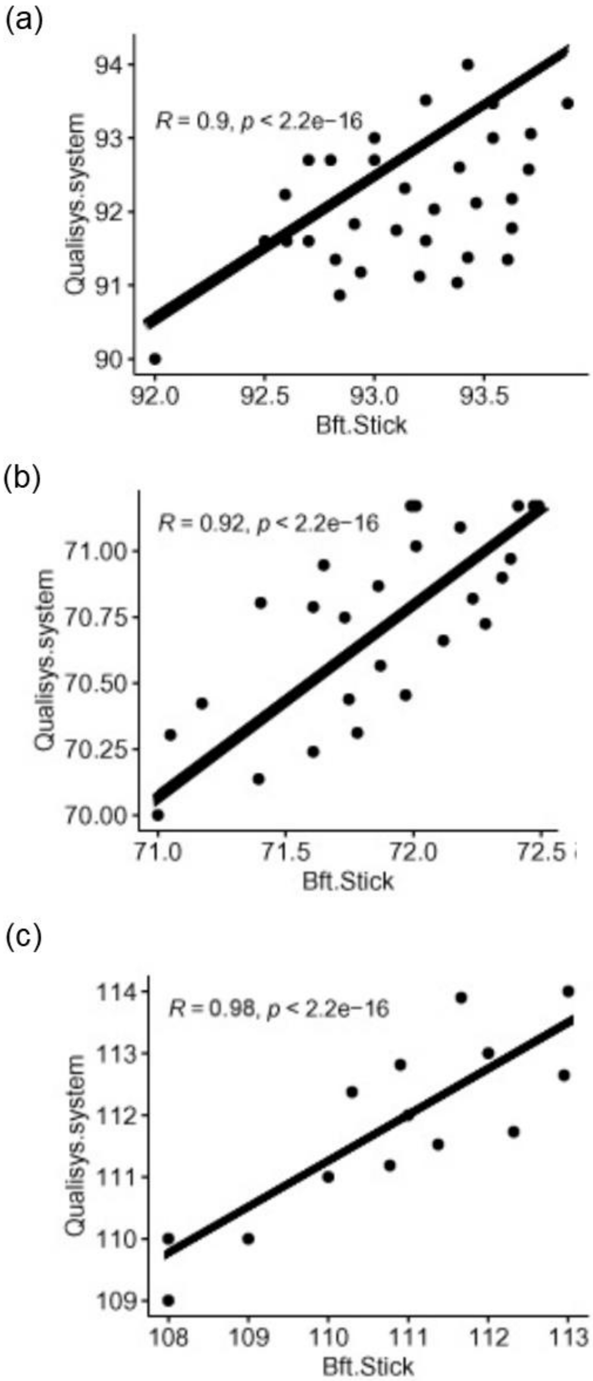


Figure 4.24: Pearson correlation coefficient of pitch trials a. trial 4, b. trial 5, c. trial 6, x-axis shows BfT stick, y-axis shows Qualisys system, r represents correlation coefficient value.

Table 4.13: Pearson correlation of trial tests between Qualisys system and BfT stick

Trial Number	Corr\r	p-value	Mean Y	Mean X	SD Y	SD X
4	0.90	0.00022	90	91	0.17	0.09
5	0.92	0.00022	70	71	0.16	0.04
6	0.98	0.00022	109	110	0.16	0.012

The roll and pitch trials were conducted to validate the tilting of the BfT. When an AHP demands good ferrule landing, they expect the walking stick to be held perfectly upright with no tilt whatsoever. This is defined as the correct posture, and anything else is termed incorrect posture. Alignment is described in terms of orientation of the stick being perpendicular to the ground, making an angle of 90° between the ground and the BfT; this is called the 'desired mean position'. In this position, the ferrule was perfectly placed on the ground which means that both the pitch and the roll are to be measured at 90°.

To validate this, first a trial of IMU was performed with a roll angle of 90°, where the BfT was held perpendicular to the ground. For the second experiment, the BfT was rolled to the side with the handle leaning toward the user, simulating the improper sideways tilt angle of the walking stick. The roll angle of the BfT was measured to be 65° when it was tipped so that much of the ferrule was in the air and only the edge touched the ground. From this, researchers deduced that any angle close to or below 65° could allow the BfT to skid, contributing to potential falls or injury. Figure 4.19b shows a posture attained while the subject attempts to land the BfT on the ground, showing the BfT being held at 65°. The angle was less than 90º and quite drifted from the vertical position. While the angle was measured as 67° by the Qualisys system, the BfT reads it as 66°. In the third roll trial, the BfT was tilted in the other sideways direction (i.e., an angle of 105°) to ensure the BfT can measure angles in the other direction, to check that it can also be used by left-handed users (Figure 4.19b). The angle measured by the Qualisys was 104°, while the BfT measured 105°, an observable difference of one degree.

The same concept was applied to the pitch trials. Three trials were performed on the BfT at 90°, 72° and 110° for the measurement of pitch angles. The roll of pitch at 90° is important, as it ensures the perfect resting position of the BfT. To determine the extreme forward and backward tilt of the walking stick, the BfT was tilted forward (72°) (Figure 4.22b) and backward (110°) (Figure 4.22c), until most of the ferrule was in the air, with only the edge in contact with the ground. The roll and pitch trials showed good correlation between angles of the BfT and the Qualisys system with $r \geq 0.90$ and $p < 0.001$.

4.4.2.7. Correct posture trial

The optimal walking stance is depicted in three dimensions in Figure 4.25, and the results to identify the optimal orientation for correct walk postures 1, 2, and 3 are shown in Table 4.14 and in Figure 4.26.

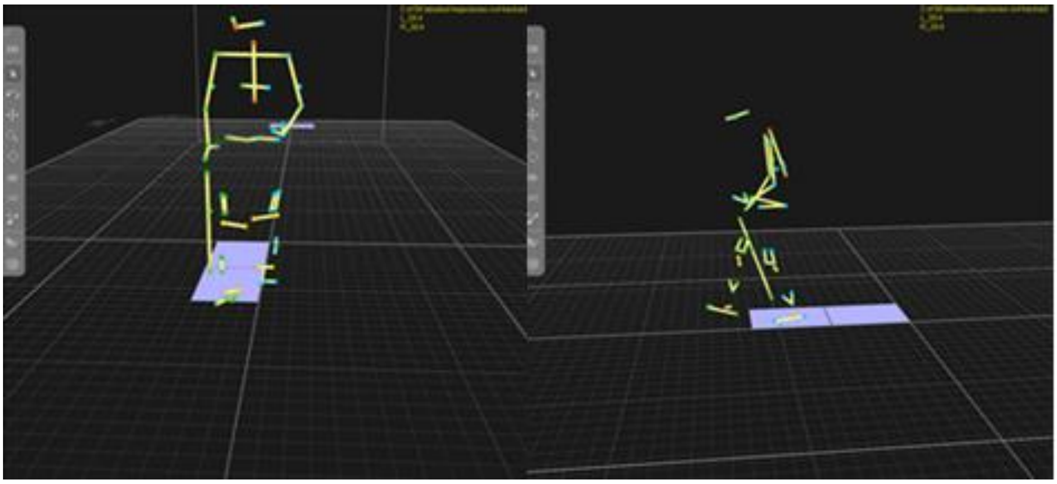


Figure 4.25: 3D view of correct posture walk.

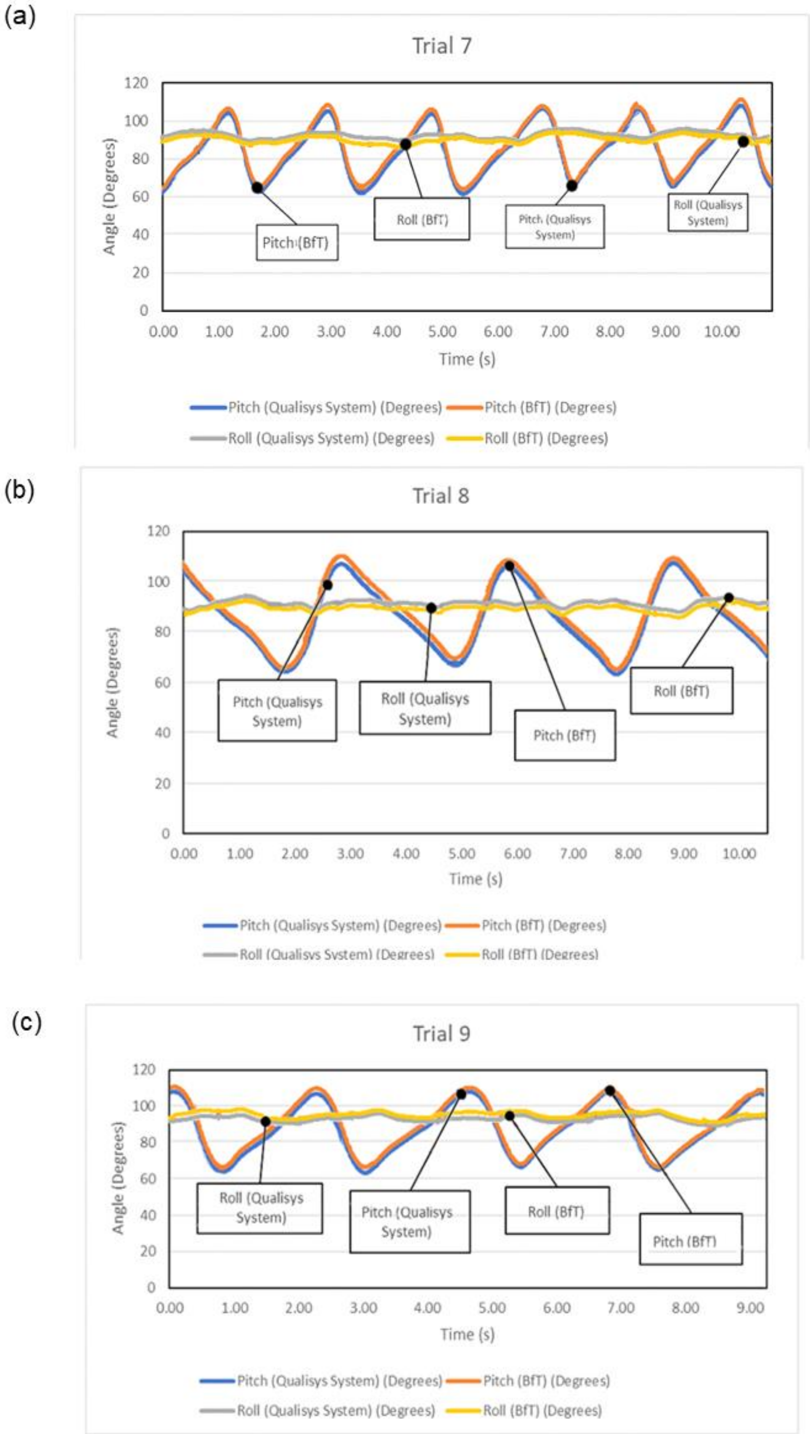


Figure 4.26: Experimental a. Trial 7 with correct posture trial walk 1, b. Trial 8 with correct posture trial walk 2, c. Trial 9 with correct posture trial walk 3, blue line represents pitch (Qualisys system), orange line represents pitch (BfT), grey line represents roll (Qualisys system), and yellow line represents roll (BfT).

Table 4.14: Experimentation for orientation using Qualisys for correct posture of walk

Orientation using Qualisys for correct posture walk 1						
TIME (s)	Qualisys System (Roll – X axis) (degrees)	BfT IMU Sensor X (degrees)	Qualisys System (Pitch – Y axis) (degrees)	BfT IMU Sensor Y (degrees)	Abs Error (Roll) (degrees)	Abs Error (Pitch) (degrees)
0 – 2	90 – 88	89 – 87	60 – 63	61 – 64	1	1
2 – 4	88 – 88	87 – 88	63 – 66	64 – 66	1-0	1-0
4 – 6	88 – 90	88 – 89	66 – 80	66 – 81	0-1	0-1
6 – 8	90 – 91	89 – 90	80 – 83	81 – 84	1	1
8 – 10	91 – 90	90 – 90	83 – 89	84 – 90	1-0	1
Orientation using Qualisys for correct posture walk 2						
TIME (s)	Qualisys System (Pitch – X axis) (degrees)	BfT IMU Sensor X (degrees)	Qualisys System (Roll – Y axis) (degrees)	BfT IMU Sensor Y (degrees)	Abs Error (Pitch) (degrees)	Abs Error (Roll) (degrees)
0 – 2	85 – 89	85 – 89	103 – 65	104 – 66	0	1
2 – 4	89 – 90	89 – 91	65 – 85	66 – 86	0-1	1
4 – 6	90 – 91	91 – 92	85 – 105	86 – 105	1	1-0
6 – 8	91 – 92	92 – 93	105 – 62	105 – 63	1	0-1
8 – 10	92 – 93	93 – 94	62 – 80	63 – 80	1	1-0
Orientation using Qualisys for correct posture walk 3						
TIME (s)	Qualisys System (Roll – X axis) (degrees)	BfT IMU Sensor X (degrees)	Qualisys System (Pitch – Y axis) (degrees)	BfT IMU Sensor Y (degrees)	Abs Error (Roll) (degrees)	Abs Error (Pitch) (degrees)
0 – 2	90 – 91	90 – 91	105 – 98	106 – 99	0	1
2 – 4	91 – 92	91 – 93	98 – 85	99 – 86	0-1	1
4 – 6	92 – 90	93 – 91	85 – 83	86 – 83	1	1-0
6 – 8	90 – 87	91 – 88	83 – 70	83 – 71	1	0-1
8 – 10	87 – 92	88 – 93	70 – 100	71 – 101	1	1

There was a significant positive correlation between the Qualisys system and BfT during trials where the subject was holding the BfT in the correct position (Figure 4.27). In trial 7, the coefficient value was r=0.98, in trial 8, it was r=0.96 and in trial 9, it was r=0.94, with all p-value less than 0.001. Hence, strong correlations were observed between the variables (Table 4.15).

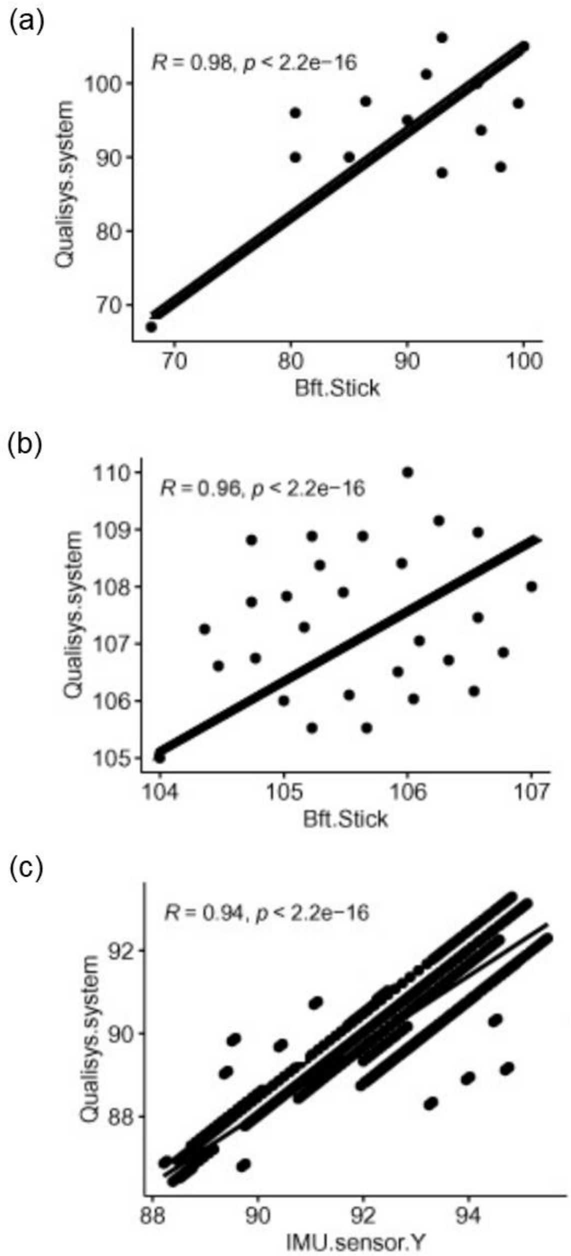


Figure 4.27: Pearson correlation coefficient of a. Trial 7, b. Trial 8 and c. Trial 9 x-axis shows BfT stick, IMU sensor, y-axis shows Qualisys system, r represents correlation coefficient value.

Table 4.15: Pearson correlation of trial tests between Qualisys system and BfT stick

Trial Number	Corr\r	p-value	Mean Y	Mean X	SD Y	SD X
7	0.98	0.00003	84	85	13	13
8	0.96	0.00003	90	91	1	1
9	0.94	0.00003	85	84	8	8

4.4.2.8. Incorrect posture trials

The 3D view of the incorrect walk posture is shown in Figure 4.28. The experimentation for orientation using Qualisys for incorrect walk posture 1, 2 and 3 is given in Table 4.16. The results of experimental trials 10, 11, and 12 with incorrect posture are shown in Figure 4.29.

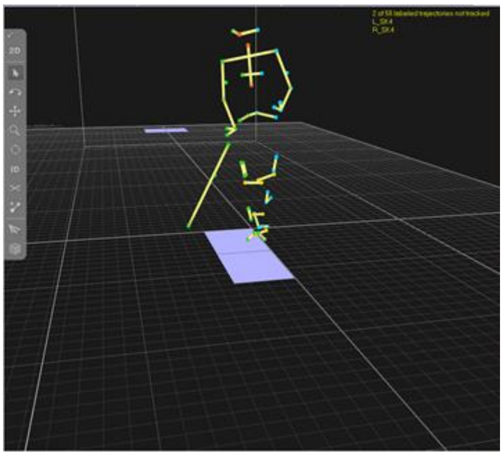


Figure 4.28: 3D view of incorrect posture walk.

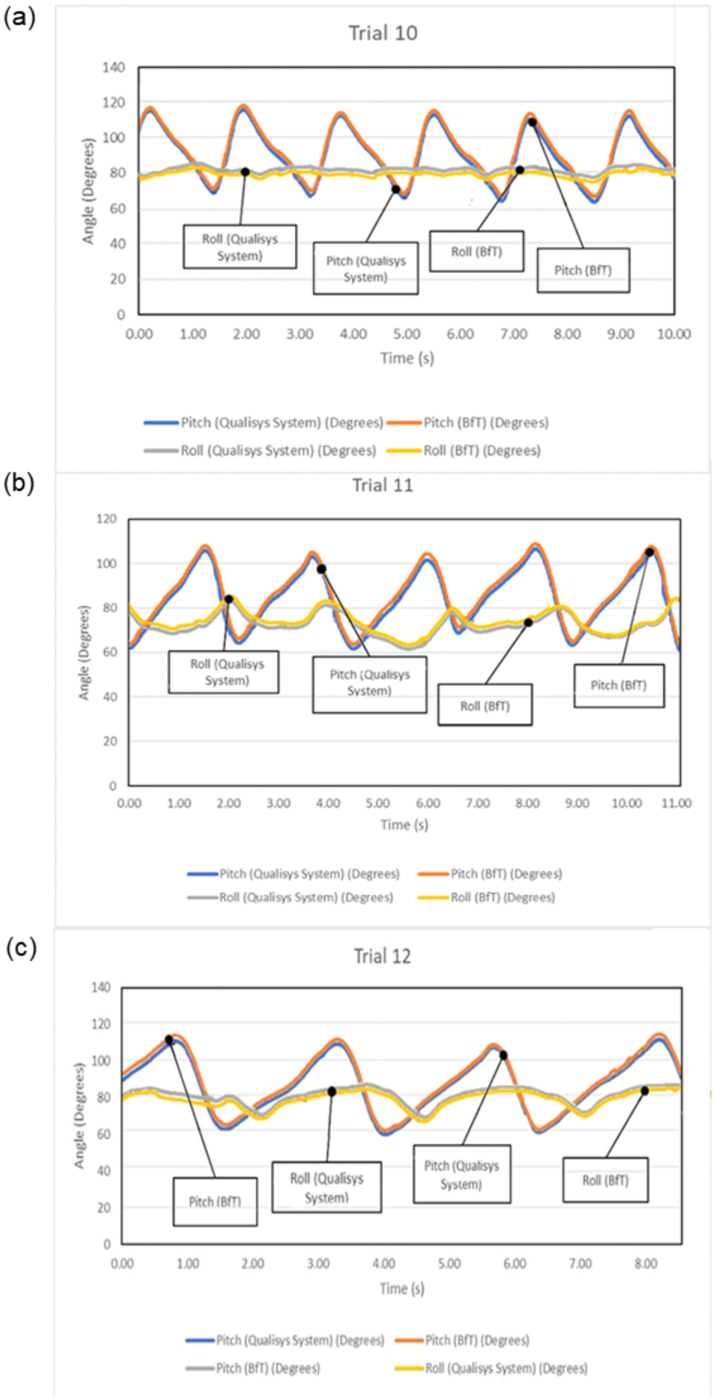


Figure 4.29: Blue line represents pitch (Qualisys system), orange line represents pitch (BfT), grey line represents roll (Qualisys system), and yellow line represents roll (BfT) in the following experimental trials: a. Trial 10 with incorrect posture trial walk 1, b. Trial 11 with incorrect posture trial walk 2, and c. Trial 12 with incorrect posture trial walk 3.

Table 4.16: Experimentation for orientation using Qualisys for incorrect posture of walk

Orientation using Qualisys for incorrect posture walk 1						
TIME (s)	Qualisys System (Pitch – X axis) (degrees)	BfT IMU Sensor X (degrees)	Qualisys System (Roll – Y axis) (degrees)	BfT IMU Sensor Y (degrees)	Abs Error (Roll) (degrees)	Abs Error (Pitch) (degrees)
0 – 2	100 – 110	101 – 111	79 – 80	80 – 81	1	1
2 – 4	110 – 105	111 – 105	80 – 81	81 – 82	1	1-0
4 – 6	105 – 96	105 – 97	81 – 79	81 – 79	0	0-1
6 – 8	96 – 84	97 – 85	79 – 80	79 – 81	0-1	1
8 – 10	84 – 80	85 – 81	80 – 80	81 – 81	1	1
Orientation using Qualisys for incorrect posture walk 2						
TIME (s)	Qualisys System (Roll – X axis) (degrees)	BfT IMU Sensor X (degrees)	Qualisys System (Pitch – Y axis) (degrees)	BfT IMU Sensor Y (degrees)	Abs Error (Roll) (degrees)	Abs Error (Pitch) (degrees)
0 – 2	80 – 79	80 – 79	62 – 70	63 – 71	0	1
2 – 4	79 – 82	79 – 83	70 – 80	71 – 81	0-1	1
4 – 6	82 – 63	83 – 63	80 – 98	81 – 99	1-0	1
6 – 8	63 – 74	63 – 75	98 – 100	99 – 100	0-1	1-0
8 – 10	74 – 70	75 – 71	100 – 84	100 – 85	1.	0-1
Orientation using Qualisys for incorrect posture walk 1						
TIME (s)	Qualisys System (Roll – X axis) (degrees)	BfT IMU Sensor X (degrees)	Qualisys System (Pitch – Y axis) (degrees)	BfT IMU Sensor Y (degrees)	Abs Error (Roll) (degrees)	Abs Error (Pitch) (degrees)
0 – 2	80 – 77	81 – 78	90 – 64	91 – 65	1	1
2 – 4	77 – 81	78 – 81	64 – 60	65 – 61	1-0	1
4 – 6	81 – 82	81 – 83	60 – 80	61 – 80	0-1	1-0
6 – 8	82 – 80	83 – 81	80 – 103	80 – 103	1	0
8 – 10	80 – 78	81 – 79	103 – 82	103 – 83	1	0-1

Pearson correlation also showed a strong positive correlation between Qualisys system and BfT in the incorrect posture trials (Figure 4.30). The coefficient value was r = 0.99 in all trials with a p-value <0.001. It showed highly significant association between the measured variables (Table 4.17).

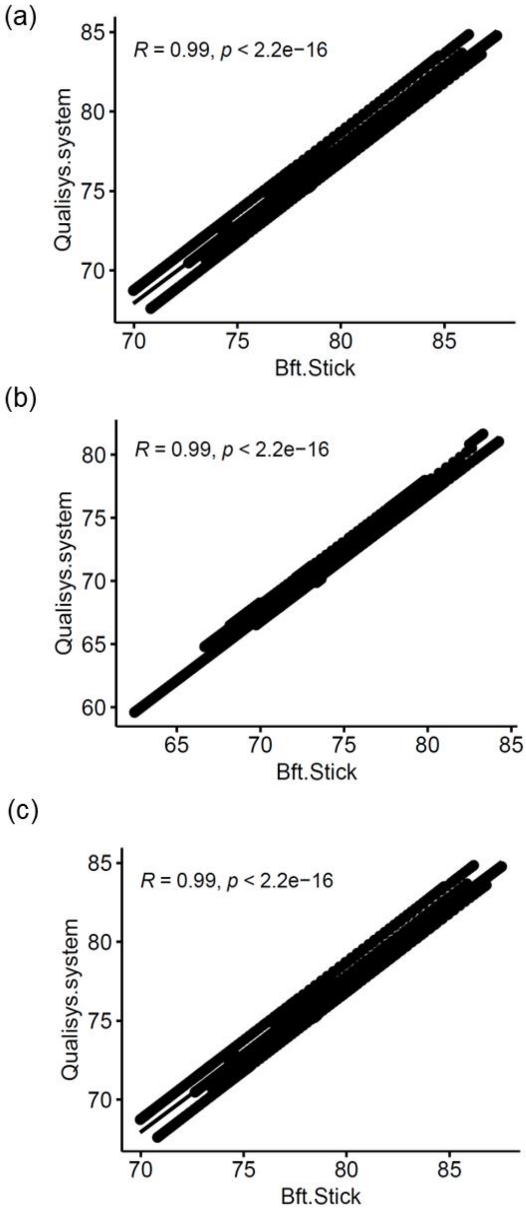


Figure 4.30: Pearson correlation coefficient of a. trial 10, b. trial 11 c. trial 12 of BfT stick and Qualisys system, x-axis shows BfT stick, y-axis shows Qualisys system, r represents correlation coefficient value.

Table 4.17: Pearson correlation of trial tests between Qualisys system and BfT stick.

Trial Number	Corr\r	p-value	Mean Y	Mean X	SD Y	SD X
10	0.99	0.00003	89	90	14	14
11	0.99	0.00003	70	71	4	4
12	0.99	0.00003	84	85	12	13

The BfT static trials using stationary postures with fixed angles showed good accuracy of the BfT. Therefore, the BfT was tested under dynamic conditions, where the subject mimicked the correct and incorrect use of the BfT during gait. Three trials each were conducted for the correct and incorrect trials, where in each trial the subject walked from one side of the platform to the other at a normal gait speed. The length of the platform was 10m. For the correct posture trials, the subject held the BfT perpendicular to the ground, with 20° to 30° flexion in the elbow as per the guideline of physiotherapist (Lam, 2007). Graphs of trial 7,8 and 9 illustrates the roll and pitch angles of the BfT, it can be seen that the roll angle of the BfT averaged at a range around 90° and the pitch angle of the BfT ranged between 60° to 110°.

A key feature of the BfT is that it informs the user about inappropriate use, therefore, the BfT was also used with an incorrect posture-oriented gait. For the incorrect posture trials, no information was found in the literature regarding the incorrect angle of holding the walking stick. Therefore, the researcher mimicked walking with incorrect BfT angle, whilst landing the BfT on the ground in such a way that only the edge of the ferrule was touching. The BfT's roll angle was roughly 65°, whereas the BfT's pitch angle ranged between 60° and 110°, as shown in the graphs of trials 13, 14, and 15. As can be seen in Figure 4.31, the BfT also provided alerts for improper use by means of a buzzer, vibration, and text displayed on the OLED.

Figure 4.31: Alert for Incorrect Posture

Overall, the tests and trials have shown high consistency in different postures of static and dynamic environments. There was good correlation between the angles of the BfT and the Qualisys system, thus validating the accuracy and repeatability of the BfT's orientation measuring capability.

4.4.3. Orientation testing and validation using CodaMotion

The results from the validation of the BfT's IMU against the Qualisys system showed good agreement of the BfT with the gold standard. To further validate the BfT, it was tested again with another 3D motion capture system, CodaMotion. The aim of this test was to test the intra-rater reliability of the BfT.

4.4.3.1. CodaMotion System

The CodaMotion indoor optical 3D motion capture system, with its capture system and movement analysis products, is built on a strong foundation of research stretching back to the 1970s. This system uses passive corner-cube retro-reflecting prisms as markers. This system was termed 'CODA 3', acronym for 'Cartesian Optical Dynamic Anthropometer (3 dimensional)'; and later termed 'CodaMotion'.

4.4.3.2. System overview

Although Qualisys is a highly rated system in terms of accuracy, it does have complexities such as setup formation which is time-consuming and tedious, as well as having a complicated rendering process. It involves the extraction of raw data from the system, thus requiring further processing in specific software to retrieve useful and meaningful information. Conversely, CodaMotion is a lightweight and portable system with shorter setup times, comprised of the following hardware modules:

1. CX1 CODA sensor unit
2. Markers
3. Drive boxes

The CX1 CODA sensor unit is the main part of every CodaMotion 3D system, particularly for indoor applications (Figure 4.32a). By incorporating three separate motion sensor arrays into a single housing, the CX1 can provide a full 3D measurement when used alone. Markers help track the motion and orientation of test subjects (Figure 4.32b) and are compatible with the entire family of CodaMotion marker drive boxes. They are identified by their marker ID from the marker drive box (Figure 4.32c).

Figure 4.32: CX1 CODA sensor unit (a), markers for CODA System (b), drive Box for Markers of CODA System (c).

CodaMotion's 4-marker drive box is, at half the size of a matchbox and weighing in at a mass of <22g, smaller in size. Users can now activate a group of markers on a test subject's body at the desired location. Up to four active markers can be powered by a single drive box, which can be charged and programmed using a standard USB cable.
The key advantages of the CodaMotion system are:

- Easy implementation
- Short setup times
- Portable and deployable
- No data-filtering required through post-processing software

4.4.3.3. Experimental setup

The experimental setup at the University's biomedical engineering laboratory comprises of the CX1 CODA sensor unit mounted on a tripod stand (Figure 4.33). The IMU and the CodaMotion system were set at 100 Hz sampling frequency (Lubetzky et al., 2019; Zhou et al., 2020). The configuration called for the employment of two drive boxes: one was installed on the stick, and the other was placed on the ground in such a way that it formed a line perpendicular to the base of the BfT. The BfT installed with drive box 1 had two markers attached, one near the handle and one near the ferrule of the BfT. Both markers should ideally be in a straight line to form a 90° angle. However, they were offset slightly due to the shape of the walking stick and placement difficulty. Nonetheless, placement of the markers on the BfT was as close as possible to maintain a straight line along the length of the BfT. The second drive box was used with one sensor only, placed on the ground to be perpendicular to the BfT. The tripod stand supported the prism-oriented motion capture module, which uses sensors to detect motion and location. We were able to detect and record relative motions in the form of textual data, and we also derived real-time graphs from the information.

Figure 4.33: Experimental setup using CodaMotion.

Real-time readings on the mobile app correspond to motion-gesture data plots displayed on background monitors (Figure 4.33). The BfT under this setup was subjected to various tilts and motions, ranging from 0° to 180° and the data were recorded for each of the iterations performed. If the BfT was moved forwards or backwards, this tilt was taken and recorded as pitch. If the BfT was moved towards or away from the sensor placed at the side, it was recorded as roll.

4.4.3.4. Results and Analysis

The stationary tests conducted with the Qualisys were promising. Using the CodaMotion system setup, tests were performed by giving BfT tilt from 90° to 0° and 90° to 180 °. This not only provides the measure of the angles in the fixed position, but also in the dynamic environment where the position is held. Three iterations were performed for each activity and the data were simultaneously recorded for both systems (BfT and the CodaMotion) (Table 4.18) (Cloete and Scheffer, 2008).

Table 4.18: Detail of experimentation with multiple iterations of pitch and roll.

Activity	No. of Iterations
Tilting BfT 90º to 0º - Roll	3
Tilting BfT 90º to 180º - Roll	3
Tilting BfT 90º to 0º - Pitch	3
Tilting BfT 90º to 180º - Pitch	3

4.4.3.5. Roll Trials

The roll transition of 90º to 0º was observed by using CodaMotion software as shown in Figure 4.34 and data is shown in Table 4.19. The results of tilting the BfT stick are presented in Figure 4.35.

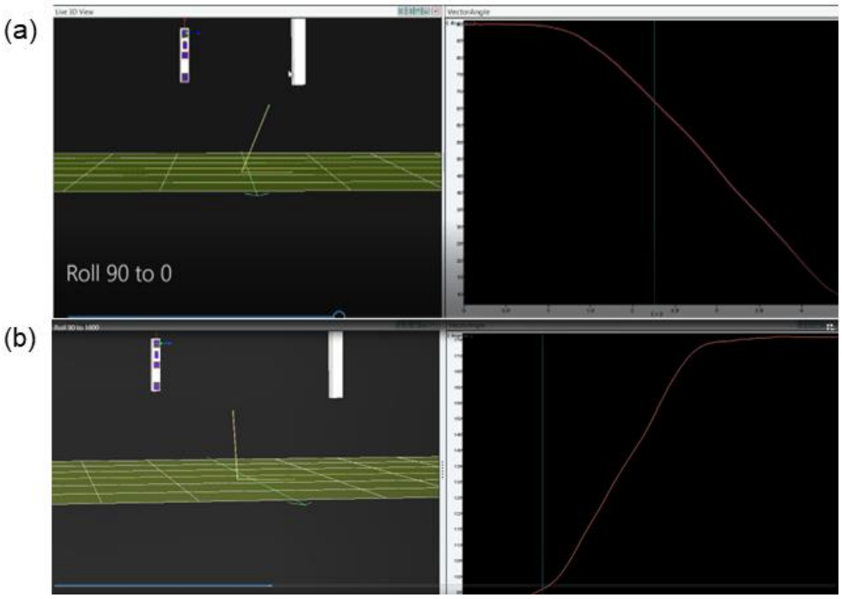


Figure 4.34: CodaMotion software view a. roll transition 90º to 0º, b. roll transition 90º to 180º

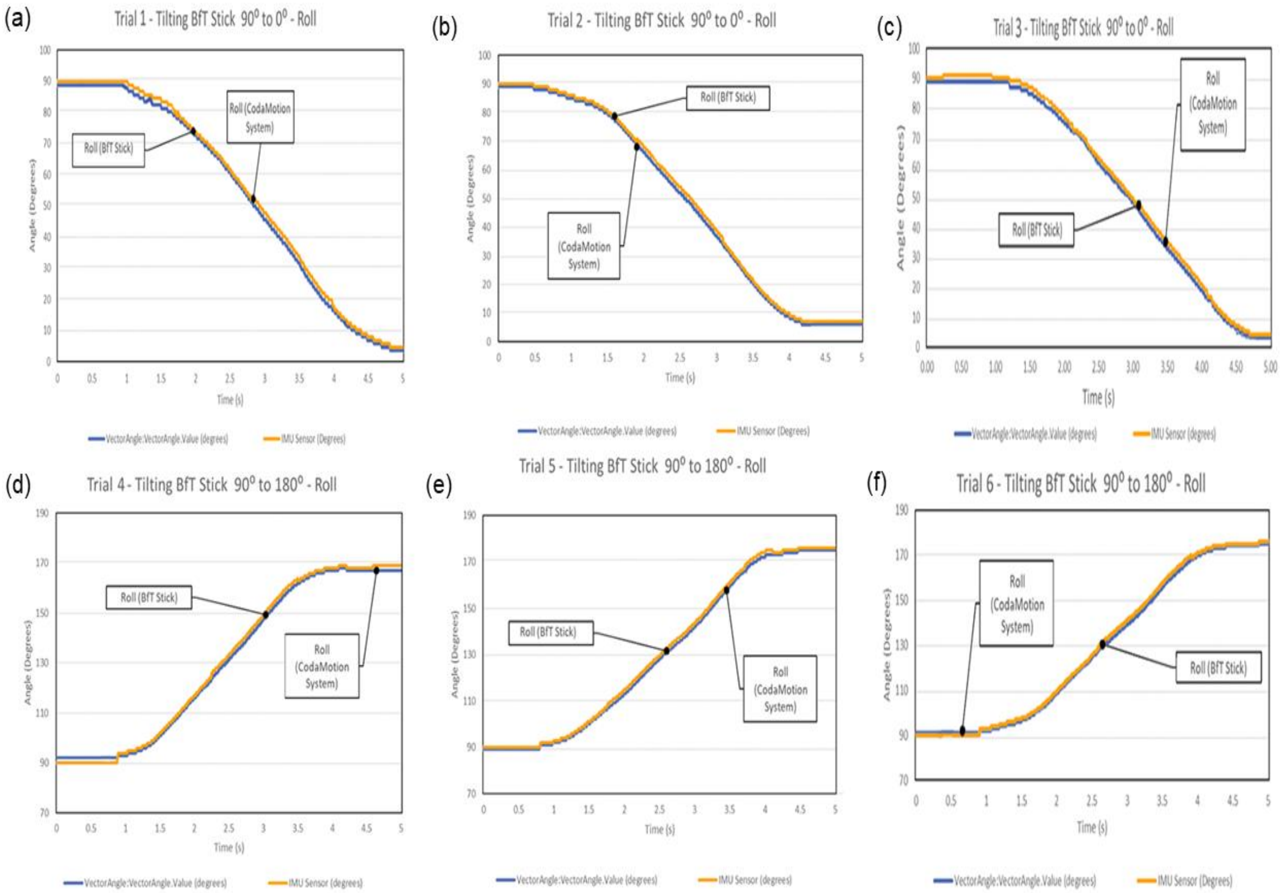


Figure 4.35: a. Trial 1 using CodaMotion with roll 90º to 0º, b. Trial 2 using CodaMotion with roll 90º to 0º, c. Trial 3 using CodaMotion with roll 90º to 0º, d. Trial 4 using CodaMotion with roll 90º to 180º, e. Trial 5 using c with roll 90º to 180º, f. Trial 6 using CodaMotion with roll 90º to 180º, blue line shows CodaMotion, and yellow line shows IMU sensor

Table 4.19: Trials using CodaMotion with roll

Trial 1 using CodaMotion with roll 90º to 0º			
Time (s)	CodaMotion System (Degrees)	BfT IMU Sensor (Degrees)	Absolute error
0 – 1	89 – 88	90 – 89	1
1 – 2	88 – 73	89 – 74	1
2 – 3	73 – 47	74 – 48	1
3 – 4	47 – 19	48 – 19	1-0
4 – 5	19 – 7	19 – 8	0-1
Trial 2 using CodaMotion with roll 90º to 0º			
Time (s)	CodaMotion System (Degrees)	BfT IMU Sensor (Degrees)	Absolute error
0 – 1	89 – 87	90 – 88	1
1 – 2	87 – 69	88 – 69	1-0
2 – 3	69 – 39	69 – 40	0-1
3 – 4	39 – 10	40 – 11	1
4 – 5	10 – 9	11 – 9	1-0
Trial 3 using CodaMotion with roll 90º to 0º			
Time (s)	CodaMotion System (Degrees)	BfT IMU Sensor (Degrees)	Absolute error
0 – 1	89 – 86	89 – 86	0
1 – 2	86 – 67	86 – 68	0-1
2 – 3	67 – 50	68 – 51	1
3 – 4	50 – 20	51 – 21	1
4 – 5	20 – 5	21 – 6	1
Trial 4 using CodaMotion with roll 90º to 180º			
Time (s)	CodaMotion System (Degrees)	BfT IMU Sensor (Degrees)	Absolute error
0 – 1	91 – 95	90 – 96	1
1 – 2	95 – 115	96 – 116	1
2 – 3	115 – 150	116 – 151	1
3 – 4	150 – 168	151 – 168	1-0
4 – 5	168 – 169	168 – 169	0-1
Trial 5 using CodaMotion with roll 90º to 180º			
Time (s)	CodaMotion System (Degrees)	BfT IMU Sensor (Degrees)	Absolute error

0 – 1	90 – 92	91 – 92	1
1 – 2	92 – 110	92 – 111	0-1
2 – 3	110 – 140	111 – 141	1
3 – 4	140 – 170	141 – 170	1-0
4 – 5	170 – 175	170 – 176	0-1
Trial 6 using CodaMotion with roll 90º to 180º			
Time (s)	CodaMotion System (Degrees)	BfT IMU Sensor (Degrees)	Absolute error
0 – 1	90 – 92	91 – 92	1
1 – 2	92 – 110	92 – 111	0-1
2 – 3	110 – 140	111 – 141	1
3 – 4	140 – 170	141 – 170	1-0
4 – 5	170 – 175	170 – 176	0-1

Pearson correlation results between the CodaMotion system and BfT stick showed a strong correlation in all trials, with correlation coefficient values greater than $r = 0.95$ (Figure 4.36) and p-values < 0.001 (Table 4.20).

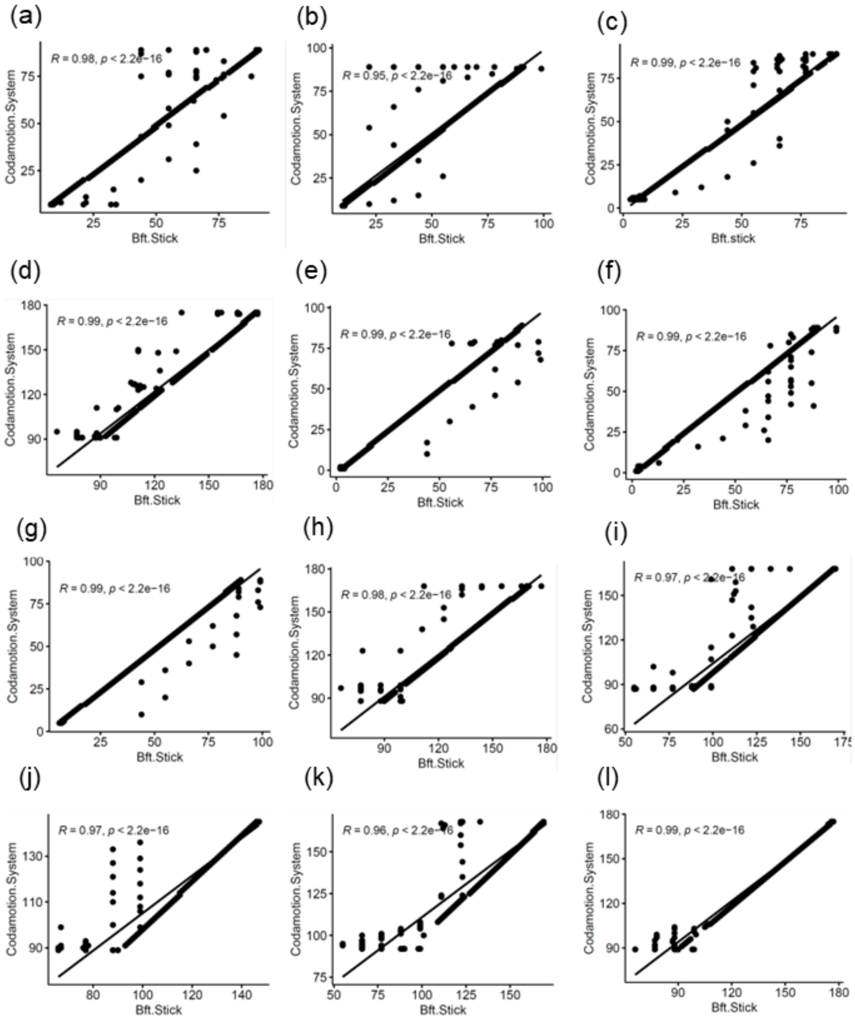


Figure 4.36: Pearson correlation coefficient of roll trials of CodaMotion with BfT stick, x-axis shows BfT stick, y-axis shows CodaMotion system, r represents correlation coefficient value.

Table 4.20: Pearson correlation of trial tests between CodaMotion and BfT stick

Trial Number	Corr\r	p-value	Mean Y	Mean X	SD Y	SD X
1	0.98	0.00001	54	55	30	29
2	0.95	0.00001	58	57	29	29
3	0.99	0.00001	47	48	33	32
4	0.99	0.00001	139	138	34	36
5	0.99	0.00001	39	40	35	35
6	0.99	0.00001	40	41	32	32
7	0.99	0.00001	40	41	33	33
8	0.98	0.00001	134	135	32	32
9	0.97	0.00001	134	135	33	34
10	0.97	0.00001	122	121	21	22
11	0.96	0.00001	136	137	31	31
12	0.99	0.00001	128	127	35	34

4.4.3.6. Pitch Trials

CodaMotion software was utilized to examine the transition in pitch from 90º to 0º, and the results are depicted in Figure 4.37 and Table 4.21 respectively. Figure 4.38 depicts the outcomes that occurred as a result of tilting the BfT stick.

(a)

(b)

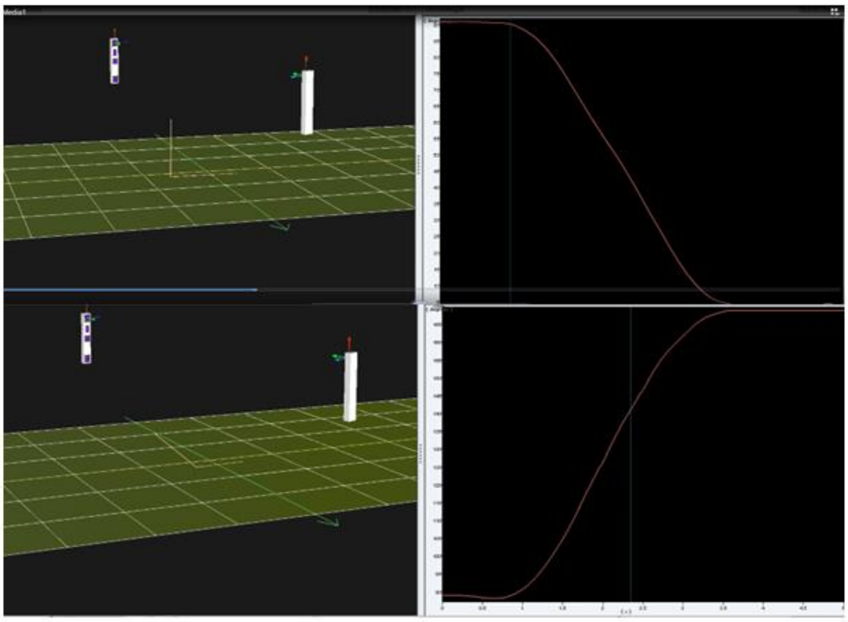


Figure 4.37: CodaMotion software view a. pitch transition 90º to 0º, b. pitch transition 90º to 180º

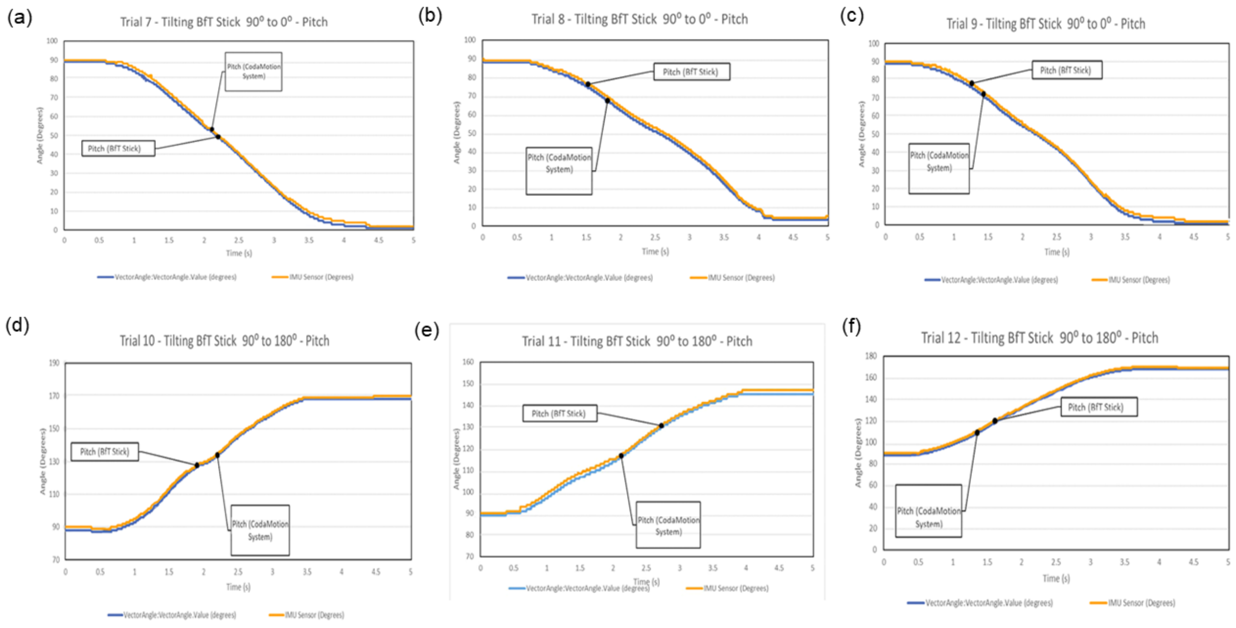


Figure 4.38: a. Trial 7 using CodaMotion with pitch 90º to 0º, b. Trial 8 using CodaMotion with pitch 90º to 0º, c. Trial 9 using CodaMotion with pitch 90º to 0º, d. Trial 10 using CodaMotion with pitch 90º to 180º, e. Trial 11 using CodaMotion with pitch 90º to 180º, f. Trial 12 using CodaMotion with roll 90º to 180º, blue line shows CodaMotion, and yellow line shows IMU sensor

Table 4.21: Trials using CodaMotion with pitch.

Trial 7 using CodaMotion with pitch 90º to 0º			
Time (s)	CodaMotion System (Degrees)	BfT IMU Sensor (Degrees)	Absolute error
0 – 1	89 – 85	89 – 85	0
1 – 2	85 – 54	85 – 55	0-1
2 – 3	54 – 20	55 – 21	1
3 – 4	20 – 5	21 – 6	1
4 – 5	5 – 1	6 – 2	1
Trial 8 using CodaMotion with pitch 0º to 90º			
Time (s)	CodaMotion System (Degrees)	BfT IMU Sensor (Degrees)	Absolute error
0 – 1	89 – 87	90 – 88	1
1 – 2	87 – 62	88 – 63	1
2 – 3	62 – 40	63 – 40	1-0
3 – 4	40 – 8	40 – 9	0-1
4 – 5	8 – 4	9 – 4	1-0

Trial 9 using CodaMotion with pitch 90º to 0º			
Time (s)	CodaMotion System (Degrees)	BfT IMU Sensor (Degrees)	Absolute error
0 – 1	89 – 82	90 – 83	1
1 – 2	82 – 52	83 – 52	1-0
2 – 3	52 – 20	52 – 20	0
3 – 4	20 – 4	20 – 5	0-1
4 – 5	4 – 0	5 – 1	1
Trial 10 using CodaMotion with pitch 90º to 180º			
Time (s)	CodaMotion System (Degrees)	BfT IMU Sensor (Degrees)	Absolute error
0 – 1	88 – 90	89 – 91	1
1 – 2	90 – 126	91 – 127	1
2 – 3	126 – 161	127 – 161	1-0
3 – 4	161 – 168	161 – 169	1
4 – 5	168 – 170	169 – 171	1
Trial 11 using CodaMotion with pitch 90º to 180º			
Time (s)	CodaMotion System (Degrees)	BfT IMU Sensor (Degrees)	Absolute error
0 – 1	88 – 99	88 – 99	0
1 – 2	99 – 115	99 – 116	0-1
2 – 3	115 – 135	116 – 136	1
3 – 4	135 – 148	136 – 149	1
4 – 5	148 – 149	149 – 150	1
Trial 12 using CodaMotion with pitch 90º to 180º			
Time (s)	CodaMotion System (Degrees)	BfT IMU Sensor (Degrees)	Absolute error
0 – 1	89 – 99	90 – 100	1
1 – 2	99 – 125	100 – 125	1-0
2 – 3	125 – 160	125 – 161	0-1
3 – 4	160 – 170	161 – 170	1-0
4 – 5	170	171 – 171	1

To test the inter-rater reliability of the BfT, the BfT was testing against another gold standard 3D motion capture system known as Codamotion. Markers on the BfT were placed and the BfT was held perpendicular in respect to the ground. During the trials, the roll and pitch of the

BfT was tested, where the BfT was tilted from 90° to 0° and 90° to 180°. Thus, for the trials as far as the reliability of the system is concerned, there was good consistency and agreement in terms of the changing angle curves recorded by both the system, which showed good repeatability and reproducibility in the data recorded by the BfT.

4.4.4. Step-count testing and validation using OptoJump

In addition to the force sensor and IMU, the other feature being offered by the BfT was the number of steps taken (distance). While many people use smart watches and fitness bands for this purpose, the BfT has also been upgraded to have this capability, thanks to the incorporation of IMU sensor.

4.4.4.1. OptoJump System

OptoJump is an optical measurement system consisting of a transmitting and receiving bar, each containing 96 light emitting diodes (LEDs). The LEDs on the transmitting bar communicate continuously with those on the receiving bar. The system detects any interruptions in communication between the bars and calculates their duration. This makes it possible to measure flight and contact times during the performance of a series of jumps with an accuracy in the order of milliseconds. With this fundamental basic data and the dedicated software, it is possible to obtain a series of parameters connected to the subject's performance with the maximum accuracy in real-time (Glatthorn et al., 2011; Falbo et al., 2016).

4.4.4.2. System overview

The absence of moving mechanical parts ensures accuracy and great reliability. OptoJump can measure quick steps and jumps of agile athletes, so measuring the slow steps of users during rehabilitation was a simple task (Falbo et al., 2016; Song et al., 2018). The system can measure the interruption between the transmitting and receiving bars further processed by the system under usage (Figure 4.39).

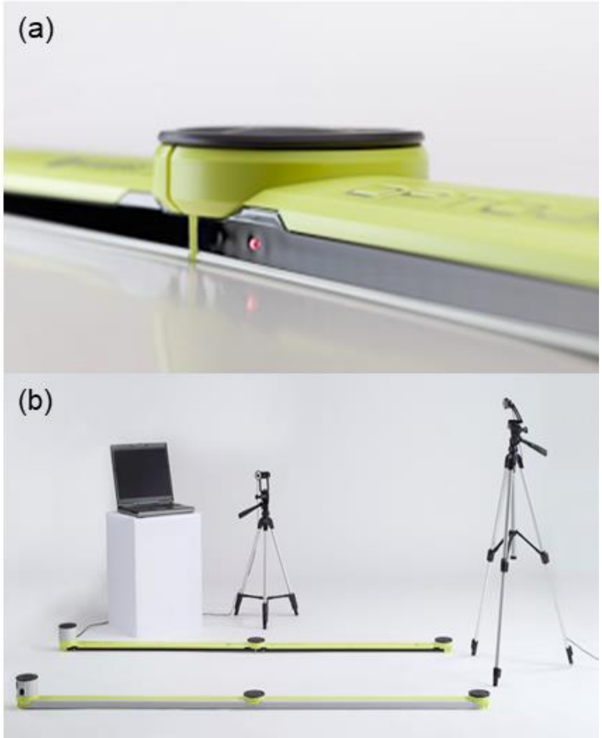


Figure 4.39: a. OptoJump rail closeup, b. system overview of the OptoJump system (OptoJump Next, 2022)

4.4.4.3. Experimental setup and results

To test the BfT's step count function, ten separate trials were conducted, each with a different combination of step length and gait speed (Table 4.22).

Table 4.22: List of trial of step count using OptoJump system

Trial number	OptoJump count	BfT count	Absolute error
1	8	8	0
2	8	8	0
3	4	4	0
4	4	4	0
5	13	14	-1
6	10	12	-2
7	8	8	0
8	8	8	0
9	10	12	-2
10	8	12	-4

OptoJump and BfT sampling frequencies were set at 1000 Hz and 100 Hz, respectively (Falbo et al., 2016; Song et al., 2018). The ten trials were classified into the following five categories as shown in Figure 4.40.

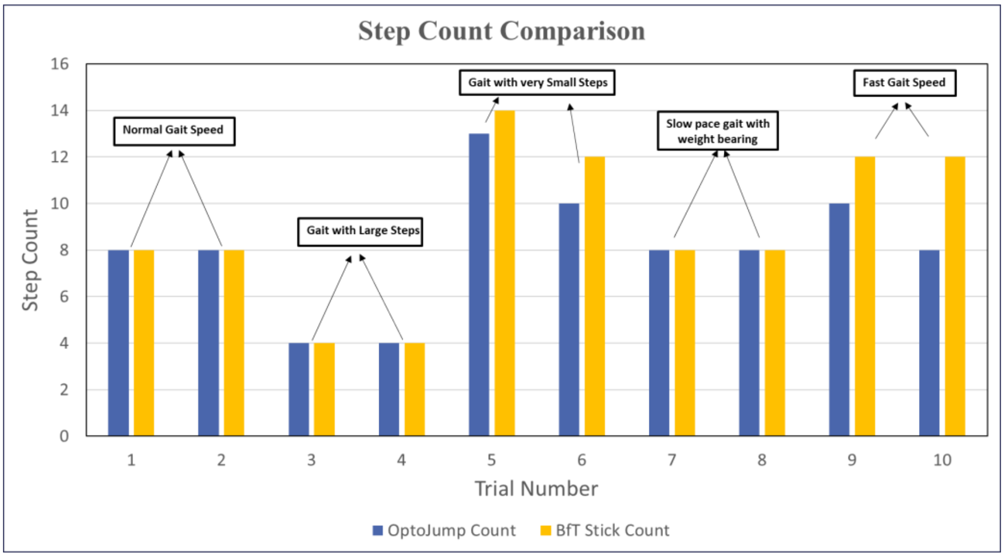


Figure 4.40: Comparison bar graph of step count between BfT and OptoJump system, blue bars represent OptoJump count, and yellow bars shows BfT stick count.

The subject performed the gait between the two parallel fluorescent lime green-colored bars or stripes, which are the transmitter and receiver (Figure 4.41). The step count measured by the OptoJump was compared against the step count of the BfT.

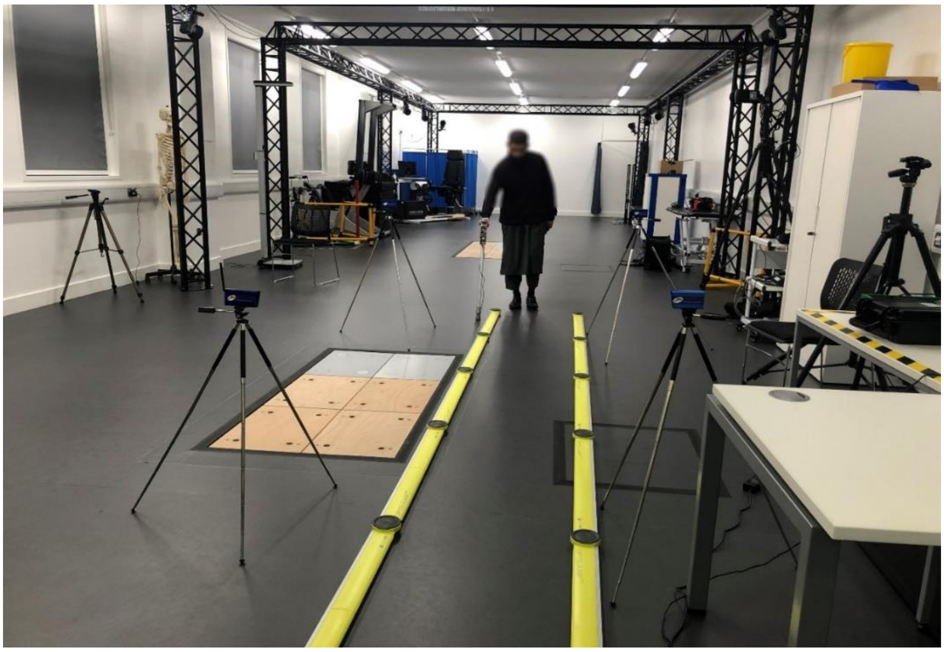


Figure 4.41: Experimental setup for step count of BfT using OptoJump (OptoJump Next, 2022).

Pearson correlation results between OptoJump and BfT stick showed perfect correlation (r = 1.0) in most of the trials except trials 5, 6, 9, and 10 (Figure 4.42). Trials 5, 6, 9, and 10 exhibited strong positive association (r>0.94) with a p-value < 0.001 (Table 4.23).

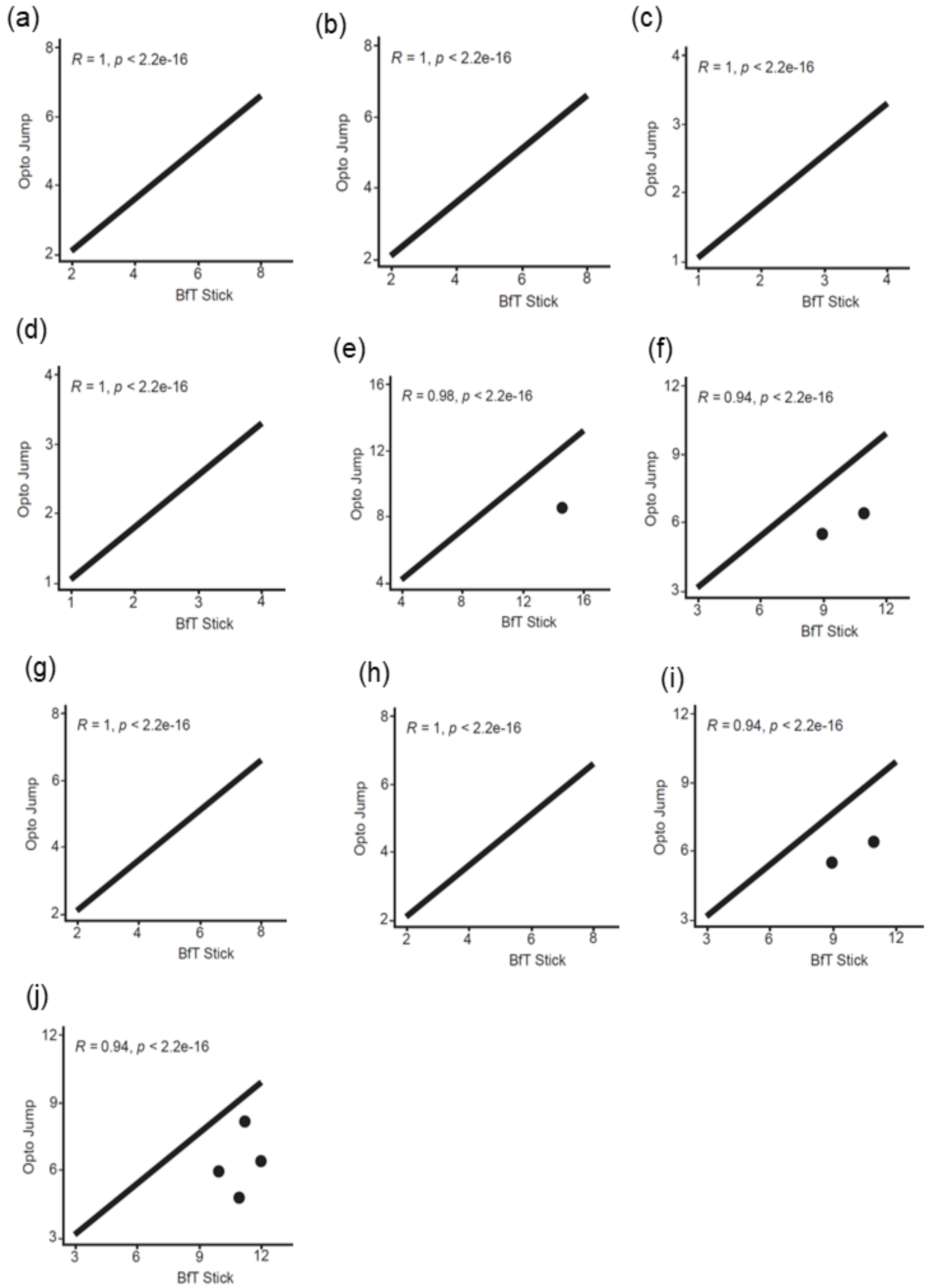


Figure 4.42: Pearson correlation coefficient of OptoJump with BfT stick, x-axis shows BfT stick, y-axis shows OptoJump, r represents correlation coefficient value.

Table 4.23: Pearson correlation of trial tests between OptoJump and BfT stick

Trial Number	Corr\r	p-value
1	1	0.000002
2	1	0.000002
3	1	0.000002
4	1	0.000002
5	0.98	0.000002
6	0.94	0.000002
7	1	0.000002
8	1	0.000002
9	0.94	0.000002
10	0.94	0.000002

4.4.4.4. Normal gait speed

Normal gait speed of 1.04 m/s was tested for people who can have simple support to maintain correct posture (Delahunt Monaghan, 2007; Kamiya et al., 2017). This method was used for both trials 1 and 2. Both the BfT and the OptoJump system agree that eight steps were taken during trials 1 and 2.

4.4.4.5. Gait with large steps

The third and fourth trials had the subject's gait being characterised by large steps. For rigorously evaluating the BfT, however, a gait with large steps (105 ± 6 cm) was undertaken (Latt et al., 2007). Four large strides were taken in this test due to the length limitation of the OptoJump System. The BfT showed no deviation from the readings of the OptoJump system.

4.4.4.6. Gait with very small steps

Walking stick users, particularly those who are struggling with the rehabilitation process, are likely to take small steps (16 ± 2 cm). To simulate this situation, small steps were also taken. For this trial, the BfT computed more steps than the OptoJump system. There was a marginal difference that cannot be categorised as error as the BfT appears to be more sensitive to small steps than the OptoJump system (Figure 4.41). According to health professionals, counting too few steps is more of a problem than counting too many steps (Latt et al., 2007; B. O'Neill et. al. 2017)

4.4.4.7. Slow gait with weight bearing

The BfT is most likely to be used by those who are elderly or who are in the process of recovering from an accident and require a slow gait while bearing weight (Jonsdottir et al., 2007). Eight steps were taken in trials 7 and 8 and measured precisely by both the systems (Figure 4.41).

4.4.4.8. Fast gait speed

Although during rehabilitation, walking stick users are recommended to walk at low or moderate pace, trials 9 and 10 were performed with a fast gait speed of (2.1 ± 0.1 m/s), as a further test of the response of the BfT (Latt et al., 2007; Nascimento et al., 2016). The BfT measured 12 steps in both iterations, whereas the OptoJump counted 8 steps, a difference of 4 steps. There was a difference of 1 – 2 steps observed in the 'very small step' gait trials and 2 – 4 steps in the 'fast gait speed' trials (Figure 4.40), this will be discussed in more detail in the chapter 6. In general, a correlation was found to exist between the BfT and the OptoJump system, which was put to the test by altering the gait speed and step length at which measurements were made.

4.5. Summary

Comparing any proposed system against state-of-the-art calibration and validation tools is the gold-standard for testing (Rago et al., 2018). Due to the MHRA regulatory issues, conducting experiments with the healthy volunteers/ research participants was not possible. Hence, a proactive approach was adopted from the literature to validate and test the repeatability and reliability of the BfT against the gold standard equipment's. The force measuring capability of the BfT was tested against the force plate, whereas the orientation and step count measuring capability were tested against the 3D motion capture systems (Qualisys and Codamotion) and the optical measurement system (Optojump). Force sensor (load cell) of BfT showed good accuracy in measuring the force exerted by the user, as previously mentioned in the section (4.4.1.6) a difference of 100N and more was observed between the BfT and the force plate, this was due to the BfT landing outside the force plate, hence the force plate showing zero at that particular timeframe. Furthermore, an error of 14N to 15N recorded between the force plate and the force sensor. The reason for this error was due to the additional weight of BfT (1.47 Kg) being applied on the force plate, whereas the BfT was only capturing the force exerted by the user. In all the orientation trials, the measure of angles in both static and dynamic tests for roll and pitch were precise with good correlation between the angles of the BfT and the 3D motion capture systems, however a discrepancy of 1° was observed. Thou, the 3D design of the IMU housing in the solid work software, shows 90-degree alignment of the IMU sensor but the discrepancies in the 3D print could be a possible reason. The real-time alert feature for incorrect weight and orientation also worked as designed, with the user alerted via audio, vibration and text displayed on the OLED. The BfT's step count mechanism showed promising results under typical walking situations, although discrepancies between the BfT and the OptoJump system were noted when steps were very short, or the walker moved rapidly.

To determine, whether the experimental results were in the acceptable range bound, statistical analysis was performed with the collected experimental data. Hence, different data analysing techniques were reviewed such as the Pearson correlation coefficient, Spearman rank correlation coefficient and Bland & Altman test. All of them have different benefits, however Pearson correlation coefficient was chosen to be the most appropriate method for the statistical analysis because this method not only determines presence or absence of a co-relation among two variables but also their direction i.e., positive or negative and the linear relationship (Myers, 2004).

Overall, the results from the experiments demonstrated good accuracy, robustness, repeatability, and reliability of the BfT, which was designed and developed considering the gaps in the literature and informal discussions with the PPIs. Hence, as per the PPI model, it was important to get feedback on the developed prototype, thus, in order to ensure the prototype meets the requirements of the stakeholders, semi-informal interviews were conducted with them.

Chapter 5. Stakeholders' feedback on Biofeedback Stick Technology

3.1. Introduction

This chapter builds on the discovery in prior chapters of a gap in the research from the extant literature and discussion with stakeholders. The next logical step was to evaluate the suitability of the prototype for the purpose for which it was developed by obtaining feedback from end users of this technology—walking stick users and healthcare professionals (physiotherapists).

Given the intention of developing a user-friendly technology designed to improve QOL for walking stick users, user feedback occupied the central role in this research project. Past studies have emphasised the importance of involving users throughout the development of such medical technologies. For instance, Chiu et al. (2004) argued that a product's safety improves by involving users. Other studies also reveal that the non-involvement of users in the design and development of medical technologies might lead to negative consequences and errors (Bennet et al., 2005). Similarly, involving users and incorporating their feedback is imperative as it determines the success or failure and quality of the proposed technology (Berger et al., 2020; Cahil et al., 1994; Keiser and Smith, 1994).

3.2. Method

Stakeholders primarily comprised walking stick users and physiotherapists who prescribe the walking sticks to the users. To get the feedback from various stakeholders on the prototype of the BfT, a semi-structured telephone interview was conducted. Prior to the commencement of this study, the researcher attended multiple workshops on qualitative research to gain the knowledge and skills required to conduct such a study

Upon obtaining ethics approval from the Birmingham City University ethics committee (see Appendix C), a 15-minute user training video (see Appendix B) demonstrating the features, aesthetic design, and usage instructions of the prototype was developed. Subsequently, a call for participation was disseminated through leaflets in the local community and an email was circulated throughout the university. The leaflet contained detailed information about the project, its purpose, inclusion and exclusion criteria for participation, the step-by-step plan (as illustrated in the Figure 5.1 and as included in the participant information sheet (in Appendix C), and other relevant information as per the university's ethical guidelines.

In response to the call for participation, interested participants contacted the researcher to volunteer. A total of six participants volunteered for the interviews, out of which three were physiotherapists and three were walking sticks users. The mean age of the participants was 53 with standard deviation of 7±. Past studies suggest that a sample size of anywhere from 5 to 50 is appropriate for qualitative research (Dworkin, 2012). Information sheets (see Appendix C) regarding the study were sent to participants via email. Prior to data collection, these participants completed consent forms (see Appendix C) and received links to the user training video. Following this step, a mutually convenient date and time was agreed upon for recorded, semi-structured telephone interviews. At the start of each semi-structured interview, participants had already watched the video through the link. Finally, the researcher gathered all the telephonic interviews and transcribed them verbatim, prior to detailed analysis. The following step-by-step approach was adopted for data collection (Figure 5.1).

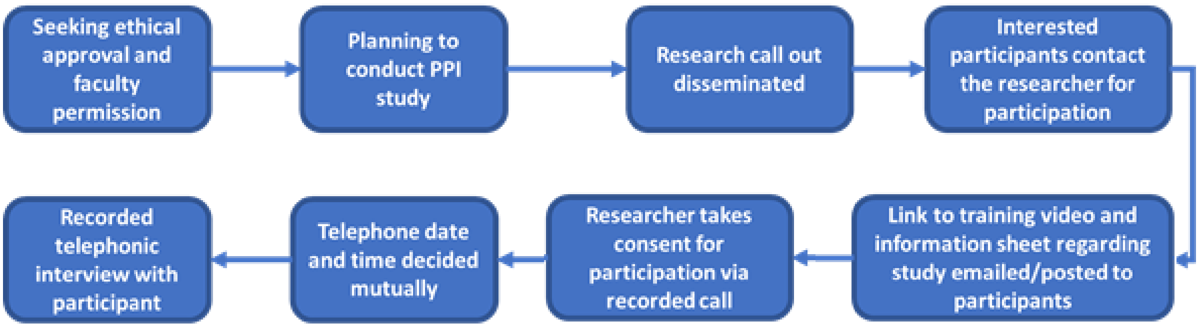


Figure 5.1 Step-by-step data collection model

3.3. Data analysis techniques

Several techniques to analyse qualitative data are reported in the literature, including the grounded theory approach, content analysis, thematic analysis, discourse analysis, and template analysis. A brief overview of these types of analysis is given below.

3.3.1. Grounded theory approach

The grounded theory approach is a structured technique used to simultaneously collect and analyse data (Charmaz and Thornberg, 2021). This methodology is both structured and flexible and is most suitable when the researcher has little knowledge about a phenomenon (Tie et al., 2019). Glaser and Strauss (1967), considered the founders of this method, tried to address quality challenges in the qualitative research domain. In this method, data and analysis are conducted simultaneously, which helps researchers focus on developing meaningful concepts from the data and collect further data to filter out their initial findings

(Charmaz and Thornberg, 2021). The advantages are that its findings are well backed by data and are more authentic and transparent. However, it is more time-consuming, expensive, and requires a highly skilled expert to conduct the research.

3.3.2. Content analysis

Defined by Krippendorff (2004) as the type of research technique where the author captures data and information from meaningful texts, a fundamental premise for content analysis is that large data sets can be reduced to such themes, models, or concepts that capture the whole gist of those large data sets (Hsieh & Shannon, 2005). There are three phases of the content analysis method: (i) preparation, in which relevant data is collected and organised based on the unit of analysis; (ii) organization, in which data is coded and categorised; and (iii) reporting of the findings, in which the findings are reported and discussed (Elo et al., 2014). Some of the advantages of this method are that the researcher can examine the communication directly, it can be applied to both quantitative and qualitative research design, it can provide more potent cultural and historical data, etc. However, this method can be extremely time-consuming and expensive, and it often does not follow a theoretical base and is limited to word count only, etc.

3.3.3. Thematic analysis

The third approach to analyse data is thematic analysis, which is considered important for rigorous qualitative analysis. It is iterative to process messy data and extract meaningful themes based on the most common answers across different respondents (Kiger and Varpio, 2020). Data collection via a qualitative approach is transcribed, coded, and extracted to obtain meaningful themes. Among the advantages of this technique is its extreme flexibility, allowing researchers from diverse disciplines to use it and generate meaningful data (Lester et al., 2020). It is a prevailing tool for data analysis when the researcher wants to capture the users' experiences, feelings, or behaviours (Kiger and Varpio, 2020)

3.3.4. Discourse analysis

Another approach to analyse qualitative data is discourse analysis which can also be used for diverse fields. Discourse analysis is an arrangement of connotations that exist due to the interactions and sociocultural discourse, (i.e., how people interact during social gatherings and the language they use) (Gee and Hanford, 2012). This technique is used to make sense of the social challenges faced by people. It aims to systematically study the unclear associations between broad social practices, texts, and events fixated in an ideological struggle between power and politics (Locke, 2004).

3.3.5. Template analysis

Template analysis is an example of thematic analysis (Brooks et al. 2005), however, it follows a strict structure of hierarchical coding. Data are organised according to common themes, applicable across diverse disciplines (King, 2012). It is a flexible approach that gives freedom to the researcher in generating common themes from areas where the concentration of data is high. This method of data analysis can be applied to different research methods such as interviews, focus groups, existing document analysis, and open-ended questions.

After researching different data analysis techniques, the thematic analysis technique was adopted for this study to qualitatively evaluate medical devices (Braun and Clarke, 2006). This approach is useful because it is commensurate to the project's requirements. After all, this method classifies and presents common themes/patterns in the data. This approach explains the data in detail and is considered the most appropriate for studies prioritizing user feedback on medical devices (Ibrahim, 2012).

To get a feel for how walking stick users responded to the BfT, data were first transcribed verbatim, analysed twice for confidence and tabulated in an MS Word document (Bogdan and Biklen, 2007). This allows for a broader picture and to establish connections between common responses from the participants. Subsequently, sentences that could be used for analysis were highlighted while keeping in view the study objectives, and excerpts from participants' responses were carefully analysed. Finally, the highlighted sentences were broken down into common themes and patterns and the content was re-read to ensure that key information was not excluded and that the themes identified were accurate (Ryan and Bernard 2003).

3.4. Results and Discussion

3.4.1. Feedback from Stakeholders: Walking Stick Users

After viewing the user training video, three interviewed participants were asked a total of eleven questions (Table 5.1). The results suggest that all participants had used walking sticks for three or more years and so all users had knowledge of the specific requirements and challenges associated with walking sticks. The usage of walking sticks was prescribed by AHPs, and they were used for walking every day. Participants were asked about the usefulness of the three features of the BfT (i.e., real-time incorrect orientation alert, real-time false weight-bearing alert, and distance travelled display). Based on their responses, real-time incorrect orientation alert was the most liked feature followed by a real-time weight-bearing alert and then display of distance travelled. The initial set of questions (1 to 4) were associated with users experience of using a walking stick and newly real-time feature introduced in the BfT. Further, the participants were asked about the usefulness of the three various types of alert methods embedded within BfT (i.e., alert through vibration, audio, and text message displayed on the OLED screen; Question 5). Two participants preferred vibration alert, while one preferred audio. One of the vibration alert supporters said:

> *"I think vibration is better, you know we can just feel it in your hand, and at the time when you're outside, you see? Buzzer, you might not be able to listen. Because you know when you are holding it, and vibrate that means, you can immediately you got the message, for text message on the screen you have to stop and then read it, you know what I mean, it might be difficult." (Participant 3)*

The results showed that although all the features were admired by the participants, the vibration was ranked highest followed by audio and OLED text messages. Participants believed that text displayed on the OLED screen might not have enough utility in terms of alert because the user would have to stop to read the text message.

In response to question 6, all participants appreciated the feature of monitoring the progress remotely by health experts with user consent. However, one participant was worried about monitoring his location, whereby it was clarified to the participant that the prototype monitors only the BfT's orientation, not GPS location. Question 7 referred to the home testing feature of the BfT to help the user practice BfT usage and monitor progress. All the participants agreed that this feature was "very good." In question 8, participants were asked whether any of the features in the BfT were good enough to motivate them to use it regularly. Participants responded in the affirmative and said that the features are very useful for the users and would motivate them to use the BfT.

In question 9, participants were asked about the design of the BfT. All the participants agreed that the design was very good. One participant responded positively that the design resembles a traditional stick. Finally, participants were asked about the price of BfT, which had been proposed at just under £100. Two of the participants said that it is reasonable while the other said it would be too high for unemployed people. His original statement was:

"Cost is reasonable, but I think many people who are unemployed may not be able to afford it you see, unless they get it directly, from health authority." *(Participant 3)*

The overall impressions and feedback from the three participants were very good. They liked the prototype and its features. They also liked the price but highlighted that unemployed people may not afford it and therefore the health authorities should provide these walking aids.

Table 5.1**:** Common Themes/Patterns from Walking Stick Users

S.No.	Questions	Answers - User 1	Answers - User 2	Answers - User 3
1	How long have you been using the walking stick?	Since 2014	A good number of years	About three to four years
2	Who prescribed the walking stick to you?	From the hospital	The physiotherapist from the hospital	The health keeper and Healthcare professionals
3	How often do you use the walking stick?	Every day	All the time, when I'm moving about, mainly when I go out of the house	Whenever I'm out, you know, out of the house
4	Which feature of the BfT do you think would be very useful? • Real-time Incorrect Orientation Alert • Real-time Incorrect Weight-bearing alert • Display of distance travelled	The orientation correcting, weight-bearing all looked interesting.	All of them	Real-time incorrect orientation Real-time incorrect weight bearing alert
5	If you were to receive a warning about improper use, which of the following would you want to have happen first—a vibration, a sound, a message on your OLED screen, or all three?	Audio	Vibration	Vibration is better, and one may not listen to audio at times
6	Would it be useful to have a feature where the health professional can remotely monitor the user's walking stick use and intervene if required with the user's consent?	It's very good, very, very good. Their location should not be tracked	That's very good	Yeah, this is a good suggestion.
7	In most cases, a person who uses a walking stick must	Very good, very nice	Very good	That's a good thing, particularly for the people in bad health

	rely on the assessment of a medical professional in a clinic to learn about the user's improvement in walking with the use of the device. How useful do you believe the BfT's home testing option, which you mentioned, could be for keeping track of a user's progress?			condition yeah, it’s a good feature
8	The health professionals and walking stick users I've spoken with in the past have all emphasized the importance of motivation in maintaining the use of walking sticks. Is there anything about Stick, including BfT, that you think would encourage regular BfT use?	Yep	Yes, of course. They are very useful.	Yeah, it’s a good feature.
9	What do you think about the aesthetic design of the BfT?	It looks like a traditional walking stick, so I think it is quite good	It’s very good. Yeah, and it seems light	design is good, it has got many features, yeah, good design
10	The overall cost of this walking stick would be under £100, what do you think about it?	Yeah, OK	Very reasonable	Cost is reasonable
11	General Feedback	Inquired about GPS location	Everything is useful	Really good work for the community

3.4.2. Feedback from Stakeholders: Prescribers of Waking Sticks (Physiotherapists)

Physiotherapists were asked 11 separate questions after they watched the user training video (table 5.2).

In question 1, each participant was asked their opinion of proper patient use or disuse relating to the prescription of a walking stick. Two out of three participants said that patients do not use the walking stick properly, while one participant said it depended on the illness for which the walking stick was prescribed. For example, if prescribed after surgery, they tend to use it for six weeks. If it is prescribed for permanent use, they tend not to use it properly. Reasons not to use a prescribed walking stick included stigma around being 'old', a lack of training, or purchasing the wrong size. One participant said that patients used them outside of home as needed and properly but neglected usage indoors. In response to question 2, all participants stated that they provide training when prescribing walking sticks; however, if walking sticks are purchased without a prescription, training is unlikely to occur.

In question 3, participants were asked when and how they tracked their patients after prescribing the walking sticks. All of them said that if they patients were admitted to hospital for surgery, they regularly visited them and observed how they used the stick. However, for outpatients, AHPs only checked at the time of prescription in the clinic, as when the participants leave the clinic, physiotherapists usually take their word and enquire again upon the patient's next visit. In question 4, participants were asked how they were aware if patients did not use the walking sticks. Two participants said they do not usually know for certain but trust the patients' word-of-mouth. One participant said that they observed patients in their next visit and recognise improper use if patients do not hold the stick correctly.

In question 5, participants were again asked about the usefulness of the three features of the BfT (i.e., real-time incorrect orientation alert, false weight-bearing alert, and distance travelled display). All the features were regarded as useful by the participants. Where the first participant highlighted the real-time feedback features i.e., real-time orientation and weight bearing alert to be the most useful. Whereas the other two participants considered the real-time weight bearing alert and the distance travelled features as the most useful ones, particularly highlighting the benefits of the real-time weight-bearing alert feature. To quote an excerpt from the participant:

> *"Absolutely genius. This stick has the ability to support weight-bearing. So, I think there's a lot of use for it in Falls rehab, but I think where it will be really useful is in inpatients postoperatively. So, we really struggle when we're giving the direction that a patient needs to be partial weight-bearing or toe, touch weight-bearing or non whatever because that's really hard to understand. So, for a patient to have the feedback that they are putting too much weight through that bone. That's pretty, that's so clever." (Participant 3)*

In question 6, participants were again asked about their feedback on the three alert systems in the BfT (i.e., vibration, audio, and test message displayed on the OLED screen). Consensus was found among all three respondents favouring vibration over the other two alert systems. They also highlighted reasons why the other two systems might not work. For example, one participant commented:

> *"I'd probably go for the vibration if I was a patient because it's less obvious if you're out in public and the tactile thing is quite helpful. I think if you're having to look down then that could actually impact balance and people if you are checking in. And then they end up looking at the stick rather than walking. So, if it's visual, that needs to be accompanied with something else, I think the auditory could be quite startling and it's, and if you're walking in public in that is going off. You don't want people looking at you. So, I think in terms of discreteness and safety the vibration, probably the best" (Participant 2).*

Participants highlighted that with any potential hearing impairment and auditory issues with some of the patients the value of audio and visual display alerts, will be hugely compromised.

In question 7, participants were asked about their feedback regarding the consensual monitoring of the patients by AHPs. All of them agreed that it is an important feature and should be useful.

In questions 8 and 9, participants were asked to share their opinion about the self-tracking feature in BfT and whether all the features motivated patients for its regular and proper use. All participants responded in the affirmative and agreed that it would help track their progress, and that it would also motivate them to use the BfT properly. To quote the extract from one of the participants:

> *"Yeah, that would be really good so they can kind of track their progress and see what's going on and I think anything, where people are getting some feedback, is really good because not only does it correct any problems quickly but I think it keeps that motivation going as well because you just think well is that it now do I just carry on and actually it would be good to know that they feel yeah I'm doing things right and that's working well" (Participant 1).*

In questions 10 and 11, participants were asked about the design of the BfT, including the option of different colors as well as pricing. All participants agreed that the design is good. Aesthetics were considered similar to traditional walking sticks, but more futuristic with advanced technology and added features. The choice of color was generally favoured by all participants. They agreed that in the existing market, patients have no options for color choice despite a desire to personalize the design of their mobility aid. One of the participants responded that:

> *"Yeah, I gotta tell you there's a definite market for walking sticks that don't look like traditional walking sticks because like I said earlier, they do not seem to be, you know, particularly cool or so. I think having to be cut away, looking a bit more futuristic and it is looking a little bit more up to date is*

really good. That might encourage younger people to use walking sticks. It might encourage people to be more, you know, more engaged with their walking stick. So, the ability to change color is really good, you know, a sleek black walking stick with a funky looking LED on top is fab, isn't it? People are going to really like it, you could, you know if we're using this with children, to have a design on it, perhaps to be able to put, you know, a design or perhaps, they could put their favourite character on it or something like that. That would be really, really nice for them. And again, as long as it still can have the fissure handles as long as you you've got a weight-bearing surface. That's good for. So yeah, I think that's really good." *(Participant 3).*

As far as cost, all participants agreed that the price is reasonable. In addition, participants were asked if they had any suggestions for improvements. One participant suggested that "if the black circle at the base and normal ferrule can be blended together, that might look better." Another participant suggested expanding the technology to other type of walking sticks too in the future, such as the tripod and quadpod walking sticks.

Table 5-2 Common Themes/Patterns from Physiotherapists

S.No.	Questions	Answers - Physio 1	Answers - Physio 2	Answers - Physio 3
1	Do you think most of the patients use the walking stick when it is prescribed to them? If not, have they mentioned any specific reasons why they prefer not to use them?	I think so; yeah, I think it depends on what they are prescribed for.	1. They don't use it properly 2. Don't use it as often as it should 3. They must use it around the house	I don't, and I think there are many reasons. 1. Stigma, 2. Not properly trained 3. Wrong size
2	Is training provided to the patients on how to use a walking stick?	Personally, I always do Some people might not have training or may have taken the instruction for granted because of the information load	I've always done so	Yes, if prescribed by a physiotherapist. A lot of people will start using walking sticks in the community without that being prescribed
3	Do you track if the patient is using a walking stick as per your recommendation? If so, then how do you track?	Depends on the kind of patients. 1. Seeing them at regular intervals, 2. Observing their walking style 3. Just asking them if they don't have it at times	1. At the time of prescribing the stick 2. More informally through observation in the clinic 3. Asking them during the community work	Depends on the setting. 1. Checking in clinic at the time of prescribing it, but after that, no. 2. In the Orthopedic ward, you do see them 2 or 3 times
4	How would you know the patient is not using the walking stick as per your recommendations?	Through observation, Sometimes it's in the wrong hand or the wrong height	You don't know until you see it or someone reports it to you in the hospital environment	You don't know if they go home and never contact you again

5	Which feature of the Biofeedback Stick do you think would be very useful and why? • Real-time Incorrect Orientation Alert • Real-time Incorrect Weight-bearing alert • Display of distance travelled	Real-time feedback is very good. Good for the clinician as well	1. Distance travelled 2. Real-time weight-bearing alert	Absolutely genius. 1. Real-time weight-bearing alert 2. Display of distance travelled is good
6	Which method of alerting the biofeedback stick user for incorrect usage you would prefer the most; vibration, audio, display on the Oled, or all of them?	The Vibration was really good. Alarms can be switched off some may have auditory or visual problems too.	Vibration	Vibration is brilliant Noise will be an issue for hearing impaired people. I would not want my patients looking down at the screen.
7	Would it be useful to have a feature where, with the user's consent, the clinician can remotely monitor the user's walking stick use and intervene if required?	Yeah, that sounds good.	Yeah, definitely helpful to have a monitoring	Yes
8	Usually, the walking stick user depends on the clinician's assessment in the clinic to provide them with the progress of their walking stick usage. Do you think the home testing feature developed in the mobile application could help the user monitor their progress? • Enabling the BfT user the ability to view the usage data of their BfT in real-time. Furthermore, a novel feature is introduced by the BfT where the user can assess their usage of the BfT c and whether it is being used as per	Tracking progress is really good.	That would be interesting to see	That's really good. Having that reminder at home would be really good

	the clinician's recommendation or not. This feature is called 'Home Testing.'			
9	In my previous discussion with health professionals and walking stick users, I was informed that motivation is a key ingredient for walking stick users not abandoning the use of walking sticks. Do you find BfT or any feature of Biofeedback Stick that may motivate users to use the BfT regularly? • Displaying the daily number of steps walked by the user on the LCD embedded within the BfT.	Yes, it will motivate	It's really very beneficial	Yes, it will motivate.
10	What do you think about the aesthetic design of the BfT? • BfT will be available in different colors and will have an ergonomic handle	The look was good. Choice of color is a really good idea.	Doesn't look too dissimilar (If the black circle at the base and normal Farrell can be blended together, that might look better)	1. Looking a bit more futuristic and looking a little bit more up to date is really good 2. The ability to change color is really good 3. A sleek black walking stick with a funky looking LED on top is Fab
11	The overall cost of this walking stick would be under £100, what do you think about it? • Commercial smart walking sticks are available for £700, which has fewer features than the BfT.	sounds very good	I was suspecting more than that. I think that's very reasonable cost-wise	That's fine.

3.5. Summary

This chapter covered the methodology used for obtaining stakeholders' feedback regarding the BfT (prototype). All participants had an opportunity to view the 15-minutes video prior to engaging them in a recorded telephone interview. A total of six semi-structured interviews were conducted with three physiotherapists and three walking stick users. A thematic analysis approach was adopted for analysis of the interviews. Data were first transcribed from the recorded taps into MS Word, and the procedure of thematic analysis was followed to make sense of the data. Overall, the participants had a positive response to the prototype and its features. The walking stick user group preferred vibration as the source of feedback, over the audio or visual feedback. While the walking stick user group liked all the features offered by the BfT (orientation alert, correct weight alert, and distance travelled alert), however the correct weight alert feature was viewed as the most important by the allied health professionals. Overall, the prototype received a positive response from all the research participants.

Chapter 6: General Discussion and Conclusion

Mobility is essential to a healthy and productive lifestyle, activeness and agility both traits generally correlated with higher levels of success (Musich et al., 2018). This thesis has focused on an innovation geared towards helping individuals with compromised mobility, due to injury or otherwise compromised health. A critical review has been presented in this chapter summarising the BfT's journey through design and development. This chapter provides a summary of the research stages discussed in each chapter followed by limitations and a conclusion centred around key aspects of the BfT. It concludes by highlighting key contributions to knowledge and setting the stage for future improvements and recommendations related to diversifying the functionality of the BfT.

6.1. General discussion

The current research examined the typical course of recovery for a wide range of mobility-compromising health issues, underlining the fact that most patients follow a similar path to recovery. The AHPs may provide this service through therapy sessions or the dispensing of mobility aids. Chapter 1 discussed the pros and cons of various mobility aids. This review not only compared the features of several walking aids, but also looked at how often each was recommended by AHPs. Thereafter, the review was split into two sections. The first section analysed cost aspects on both the individual and national levels, highlighting that the NHS is under financial deficit and suffering from a labour shortage, leading to a concerted effort on the part of the government to devise a solution. The second section focuses on mobility aids, with walking sticks emerging as the clear frontrunner for this research's focus.

It was discovered that after receiving a walking stick prescription, patients must contact AHPs on a consistent basis to receive training and feedback on how to properly use their walking sticks. However, when outside of a therapeutic setting, users of walking sticks have no access to feedback on their usage, increasing likelihood of injury through improper use of the device. Research suggests that over 67% of people who rely on walking sticks do not have prescriptions from their doctors. This means that many people who end up using walking sticks do so without ever having been instructed by an AHP. As a result, issues including gait asymmetry and imbalance are very common (Liu et al., 2011). Many other systems (Table 1.1), addressed in Chapter 1 have been proposed by researchers as solutions to this problem. However, these alternatives did not offer a device to replace the traditional walking stick, but rather a clinical instrument, for individuals who rely on walking sticks to perform activities of daily living.

In addition, the planned systems only aimed to serve a select demographic (i.e., stroke or knee arthritis patients). Whereas people of varying health statuses have used walking sticks for a long time. There was a need, then, for a device that could give users feedback outside of clinical settings, collect relevant data, and be used by more people.

It was also shown in prior studies (Table 1.1) that only a small percentage of studies actively involved stakeholders in developing their proposed solutions. Researching and analysing the process of creating a medical device revealed that patient and care provider input is essential to the success of a product and failure to obtain this input could result in the medical device being abandoned. Considering this study's second objective (discussed in Chapter 1.9), a user involvement method of PPI was chosen. The PPI model ensured that the end-service users were involved in every step of the design process. Since the PPI model has been shown to have a favourable effect in prior studies, the National Institute for Health Research (NIHR) has recommended its use by researchers. However, it appears that PPI models have not yet been utilised in the design and development of a biofeedback medical device or instrument, making this a novel contribution of this thesis (Staniszewska et al., 2011). From the PPI model, discussions concerning issues with conventional walking sticks were held with stakeholders (i.e., walking stick users and AHPs).

Considering the gaps in existing literature, the needs of the product, and the outcomes of the informal PPI-based stakeholder discussions, a comprehensive design was developed using the framework presented in Chapter 3. The idea behind the proposed framework for BfT's creation originated from a heuristic method. Following a thorough search, a final list of features was compiled and chosen for inclusion in the BfT. The plan called for a three-fold approach to creating the final product, with the electronic, mechanical, and user interface components all playing crucial roles.

The crucial steps in creating and testing the prototype were covered in depth in Chapters 3, 4, and 5. The experimental work and data analysis included in this thesis took a total of 36 months to complete. Chapter 3 shows that a total of 24 months were spent on the design and development phase. This includes time spent deciding on and purchasing any necessary electronic components. After the design phase, the system underwent static and dynamic validation, calibration, and bench testing against gold standard systems. The validation and bench-testing phase (detailed in Chapter 4) was completed in 7 months. Following the PPI approach, semi-formal recorded interviews with stakeholders (walking stick users and physiotherapists) were done to gather their opinions on the built system (BfT) described in chapter 5. This process took five months. A brief overview of the timespan covered in Chapters 3-5 is provided below.

Table 6.1: *Timeline for BfT development*

S.No	Chapters	Time taken for designing, developing and testing the BfT
1.	Chapter 3	24 Months
2.	Chapter 4	7 Months
3.	Chapter 5	5 Months

Electronics design was the first step in the development process. This involved the selection of all sensors and feedback modules that would be used to provide information about the different feedback modes. The BfT's mechanical design, which included the housing for its electronics, its handle, and its load cell, was the focus of the second phase of development. Interface design for mobile devices and desktop computers was the focus of the third stage of development.

In order to accommodate the electronics within the limited space of the handle, the decision was made to focus on the electronic design rather than the mechanical design at the outset of development. Progress on the mechanical design was held back until the electronic design was complete. This was because updating the electronic design would necessitate adjusting the mechanical design to accommodate new standards. This method lowered administrative costs and improved productivity. After evaluating previous research and the informal discussions with stakeholders, it was clear that the end users required the smart stick to not be bulky in size or weight. Consequently, the electronic components were chosen not only for performance but compactness as well.

A high-end variant 6-degrees-of-freedom IMU and load cell with a high-resolution analog-to-digital converter were among the chosen devices. The ESP32 Firebeetle's central processor unit was chosen because of its high processing power, multiple power-level operating capabilities, and numerous communication interfaces (including Bluetooth and Wi-Fi). Since Bluetooth was chosen as the interface for connecting with the graphical user interfaces (GUIs) designed for stakeholders, its availability was crucial. The microcontroller was the primary focus of the electronics design, and the functioning of each module was initially verified on a test bench. The force values were calculated by the load cell, while the angles and acceleration for orientation were calculated by the IMU utilising raw data from the gyroscopes and accelerometers to incorporate Euler angles. The AHPs may analyse the user's gait based on the tabular data stored from the sensors on the SD card which can store data for 200 days. Based on the anticipated runtime in normal operation mode, the

BfT has a 3-day battery life. The proposed system uses a battery with a 6000 mAh capacity; however, this might be improved upon by increasing the size of the battery.

Only haptic and audio feedbacks have been deployed in previously designed systems (described in Chapter 1), with the BfT being the first smart walking stick to incorporate a display screen. Therefore, to make this product useable for the wider user group, a mini display screen 'OLED' was embedded within the BfT. Adding visual feedback through the OLED screen may expand the usage of this proposed system to individuals with hearing issues and lower sensation capabilities. However, as per the final feedback from the PPI members in Chapter 5, inclusion of the OLED display was not seen as an essential feature. This could be a consequence of non-inclusion of the PPI members with hearing issues and lower sensation capabilities. Therefore, for future studies individuals with diverse capabilities should be included within the PPI members to get a better perspective.

Based on the feedback from stakeholders, it was ensured that the aesthetics of the stick should not be compromised. Under these constraints, along with financial considerations, the mechanical design was considered without entirely abandoning the pre-existing conventional walking stick. It was found that several walking stick users had chosen to abandon its use solely based on poor aesthetics and colors. Therefore, the plastic folding of the existing traditional walking stick was removed, and a 3D printed cover was installed to support the housing of the electronics system without increasing the dimensions of the grip. The existing walking stick's metal handlebar was left in place for reinforcement as well.

Printing the handles with a 3D printer was not only a cost-effective alternative, but it also meant that they could be designed in a variety of colors. This enabled the BfT to fulfil the aesthetic requirement of users, along with provision to house the electronics. Solidworks, a popular 3D design program, was used to create the electronic housing and handle in three dimensions. PLA was selected as the 3D-printing material for the proof-of-concept model, based on strength and other qualities citied. For commercialization, polycarbonate may be a more reliable alternative; however, printing this material requires industrial 3D printers (Marciniak et al., 2019). The first objective (Chapter 1.9) of this study was met through the design and development of the BfT, which can successfully record, analyse, provide real-time feedback, and communicate the BfT usage data wirelessly.

With the aim of reducing the number of times walking stick users have to visit AHPs, a dedicated mobile application was developed for the Android platform using the application 'Flutter.' With this mobile application, the BfT user can visualise and analyse their usage of the BfT. The use of the BfT is not dependent on the mobile application; rather, the provision of the mobile application is an additional technical feature provided to support the BfT user.

This mobile application introduces a novel feature of home testing allowing the BfT user to observe and practise the day-to-day usage of the BfT per the guidelines of the AHP. Concurrently, a PC based GUI was developed to assist the AHPs with monitoring, analysing, and storing data, with options included to set the threshold parameters of the BfT. This eliminates the requirement of a computer programmer to be present along with the AHPs, thereby minimizing the cost. Hence, the third and fourth objective (Chapter 1.9) of this research study were achieved.

A 3D printed case for the BfT was assembled after the electronic sensors were calibrated and bench tested (described in Chapter 4) successfully. The intention was to validate the BfT by recruiting at least 10 healthy people from within the University to test the BfT. The MHRA (Medical Healthcare Regulatory Authority) was approached at the suggestion of Birmingham City University's ethics committee to learn more about the procedures involved in carrying out such tests. Upon receiving all pertinent information on the research project, the response from MHRA classified the proposed tests with healthy volunteers/research participants within laboratory / University premises to be deemed as clinical trials, given that the normal walking stick is classified as a class 1 medical device (United Kingdom Medical Devices Regulation 2002) (MHRA, 2022). While the research governance to investigate medical devices with healthy volunteers, within the university laboratory premises, is currently being developed by the university and the faculty, as an emerging independent researcher, a proactive approach was taken to ensure that the developed product (BfT) was still fit for the purpose. The literature was reviewed and, similar to previous studies, a concurrent validity approach was adopted. The BfT was tested and validated against the gold standard equipments such as the 3D motion capture systems (Qualisys and Codamotion Systems), Force Plates and the optical measurement system (OptpJump). However, due to the potential of the ongoing work, a collaborative agreement is currently being set up between the University and a third-party medical devices SME (which holds all the necessary approval and licenses to act in the capacity of a notifying body to MHRA) to facilitate the clinical trial/scientific testing of the medical device (with healthy volunteers) in the near future. This, however, is outside the scope of the PhD program.

Prior to the commencement of the concurrent validity, force sensor (load cell) and the IMU sensor of the BfT were bench tested. Various methods have previously been used for bench testing of the force sensor (load cell). Laohapensaeng et al., (2015) used a universal testing machine, in this method, the force sensor was placed with in the universal testing machine and a known input was applied by the machine. The output from the force sensor was then compared with the input of the universal testing machine. Another method is the standard weight method (Xiong et al., (2018); Song and Fu, (2019)), in which known weights are placed on the force sensor and the input is compared with the output from the force sensor. Both methods have shown satisfactory results for the calibration of the force sensor. However, given lack of universal testing machine within the university, the standard weight method was utilised. Cylindrical, stainless-steel weights ranging from 1 kg to 10kg were placed on the force sensor. An error of 0.2 N was observed in the output of the force sensor (load cell), which was compensated by taking it off from the output value of the force sensor. Further trials with the known weights did not show a similar error, with the input values matched with the output. For the calibration of IMU, researchers have previously used external equipment such as rate turntable (Skog and Handel 2006, Syed et al., 2007; Nieminen et al., 2010; Dong et al., 2018). However, this was not an affordable solution for this work given the access to specific technical equipment within wider university. As an alternative to the use of external equipment, Li *et al* (2012) proposed a non-equipment method of IMU calibration. However, the accuracy of the calibration was quite low compared to the rate turntable method. Considering these issues, a pre-calibrated IMU was selected. To ensure the IMU was calibrated, the IMU was bench tested as explained in chapter 4, which showed no error in the values.

The force, orientation, and distance measuring capability of the BfT was validated against the gold standard equipment. The force sensor was tested against the force plates while the IMU sensor was tested against the 3D motion capture systems (Qualisys and Codamotion Systems) and the optical measurement system (OptpJump). Tests between the BfT and the gold standard equipment were conducted simultaneously, and the results were compared as illustrated in chapter 4. Initially a time lag was observed between the two systems. Further investigation found that the delay function programmed within the feedback function of the main code was causing the lag. Consequently, the delay function was removed from the main code, ensuring that the BfT alerts the user instantly upon the breach of the threshold limit without lag between the two systems. The sampling frequency of the force plate and the force sensor (load cell) were set at 1000 Hz and 50 Hz (Lansade et al., 2021), respectively. Conversely, the IMU and two 3D motion capture systems were set at 100 Hz. According to Zhou et al. (2020), these sampling frequencies were sufficient for capturing ADLs such as walking or picking up objects. During the static and dynamic trials of the force and IMU sensors, each activity was performed 3 times, as the averaging of the vital performance variables across more than one trial is a widespread technique in biomechanical studies. The wide variety of trials generally range from three to thirty plus (Forrester, 2015). However, even within the same kind of studies, the number of trials has differed. For example, inside the scientific literature for the breast biomechanics, the quantity of trials for gait analysis ranged from five, fifteen, and thirty (White et al., 2011; Zhou et al., 2012; McGhee et al. 2013). None of these studies strongly justify the number of trials used. It is usually assumed that an appropriate number of trials are used, and the average of the results provides "reasonable" estimates of the key performance variables (Forrester, 2015). Since variability is inherent in each human motion, a very small number of trials may not effectively represent an individual's long-term technique. At the same time increasing the range of trials can help overcome this limitation, but there are some restrictions on the range of trials an individual can complete, e.g., due to time constraints or fatigue (Forrester, 2015).

The results of the BfT's force sensor Vs force plate showed good correlation between each other as illustrated in chapter 4, thereby validating the accuracy of the BfT's force measuring capability. The p value was less than 0.0005 and the Pearsons correlation coefficient, r, greater than 0.94 for most of the experiments. However, an error of 14N (16%) to 15N (17%) was observed throughout the experiments. Researchers in the past have reported errors in using force plates and force sensors ranging from 1% to 5% (Seiberl et al., 2018; Faber et al., 2020), but the percentage error in our case was quite high. The difference in value between the two systems was discovered after some research revealed that the force plate was recording not only the user's force but also the weight of the BfT (1.4kg/14N), whereas the BfT's force sensor was recording only the user's force because, during the development stage of the BfT, the extra weight of the assembly of BfT was taken off. This means that the BfT was only recording the force being applied by the user, and that the stated discrepancy between the BfT and force plate was no more than 1%. As a result, the force measuring capability of the BfT was successfully validated, demonstrating a good level of accuracy, robustness, and reproducibility.

The IMU was first tested against the Qualisys 3D motion capture system where static and dynamic trials were performed. The markers were placed on the subject and the BfT as shown in figure 4.24 in chapter 4. The first static test was performed by keeping the BfT perpendicular to the ground at 90º to ensure the BfT calculates the correct roll angle (sideway tilt) before moving further to test BfT with different angles. The result for the first trial showed good accuracy of BfT's orientation measuring ability with an absolute error of 1º. Although various researchers have reported errors in IMU ranging from 1º to 3º (Hilman et al., 2018; Zhou et al., 2020), the possible reason for the error could be the placement of the IMU within the BfT 3D casing. Subsequently, the roll angles of 65º and 110º were tested and calculated using the Euler's approach. It is worth mentioning here that, while the importance of correct and incorrect walking stick orientation, which may lead to falls and/or injuries hampering the rehabilitation process, has been researched (e.g. Culmer et al., 2015; Wade et al., 2019), no researcher has yet quantified the incorrect tilt (sideways) orientation values of the walking stick which is a vital information for building a real-time feedback system. Therefore, during the testing and validation phase, the BfT was held in the right hand and tilted towards the user until the edge of the BfT's ferrule was touching the ground and further tilt would make the BfT skid. This angle was observed to be 65°. The incorrect sideways (roll) tilt angle of the BfT was analysed and results showed that sideways stick angle (roll) < 65° can cause the ferrule of the walking stick to trip, which may lead to fall and injury. The roll tilt of angle 110° was performed to observe the BfT measuring capability in the opposite direction (away from user), which can be helpful while setting up parameters for left-handed users. Likewise, testing was performed for the pitch angles. After the completion of the static trials, dynamic trials were performed where the subject walked a straight platform of 10m, mimicking using the BfT with correct and incorrect orientation. The overall results of static and dynamic trials (illustrated in chapter 4) showed good correlation between the angles measured by BfT and the Qualisys system with $p < 0.0005$ and the correlation coefficient, r, greater than 0.94 for most of the experiments. Further, to test the inter-rater reliability of the BfT, which was compromised due to the MHRA regulatory issues, BfT was tested against another 3D motion capture system (Codamotion). The roll and pitch angles of the BfT were tested from 90° to 0° and 90° to 180°. The results (illustrated in chapter 4) from both the systems showed good correlation. It is important to mention here that in comparison of the two 3D motion capture systems (Qualisys and Codamotion Systems), the performance in terms of capturing the orientation of the BfT was equally good by both the systems. However, in terms of setting up the system, placement of markers and post-processing of data, the Codamotion system proved simpler and better excluding one limitation: a reduced area capturing capacity when compared to the Qualisys system.

In the last set of validation trials, the step counting mechanism of the BfT was tested against the gold standard system of OptoJump. Gaits of varying speeds and step lengths were performed during this phase of testing. Overall, the BfT and the OptoJump system showed good correlation with p-values < 0.0005 and correlation coefficients, r, greater than 0.93 for most of the experiments. There was some discrepancy observed in the gait with very small steps and the gait with fast speed. The possible reason for this could be that the IMU's sensitivity was a bit high for these extreme gait conditions. Lowering the sensitivity might reduce these errors. Overall, the testing of BfT's IMU against the gold standard systems such as the 3D motion capture systems (Qualisys and Codamotion Systems) and the optical measurement system (OptpJump) showed good accuracy, robustness, repeatability, and reliability of the BfT's orientation and steps measuring capability.

After testing the BfT for accuracy, repeatability, reliability and validity, user feedback on the developed prototype and the GUI were obtained from the stakeholders comprising of walking stick users and AHP (physiotherapists). Prior to the commencement of this study, the researcher attended multiple workshops to get acquainted to the techniques for conducting qualitative study. Due to Covid-19 restrictions, for health and safety reasons and based on government guidelines and university requirements, it was less-pragmatic to conduct focus group discussions; therefore, it was decided to conduct the qualitative study by telephonic semi-formal interviews. This method allowed enough flexibility to focus the questions in priority areas while also giving the option to add open-ended questions to acquire any key information not covered in the drafted questions. The drafted questions for this study were ratified by the supervisory team and the physiotherapist. Semi formal interviews were useful in capturing the thoughts and feeling about the BFT from participants' who had an opportunity to obtain an overview of the various functionalities of BFT via the training video. Although, one could argue that the afore mentioned approach alongside semi-formal interviews could introduce an element of researcher bias, however; it is worth mentioning that different groups of allied health professionals / physiotherapists with varying level of clinical and academic experience were part of the PPI / stakeholder group and research participants. Therefore, the integrity of their overall participation and professional responses obtained from physiotherapists alongside walking stick users, as part of the user group study, although subjective, has fully reflected on the true nature of clinical practice adopted within the NHS. The overall results showed positive and encouraging feedback from the stakeholder's (Chapter 5), hence the second objective (Chapter 1.9) of this research study was achieved.

It is surmisable that the BfT can play an important role in the evolution of biofeedback stick technology and may accommodate the end-users with using the stick properly, thereby preventing falls and injuries and further contributing to the reduction of visits to AHPs. Through this, the BfT fulfils all the objectives listed for this research in chapter 1. It is possible that this will improve quality of life for those in need of mobility accommodation and provide benefit to the economy on a national scale. However, it is also important to mention some of the limitations of this research. Even though PPI methodology was helpful in the design and development of the BfT, the number of participants in the qualitative study conducted as well as the ability to participate in every stage of the research by the PPI stakeholders suffered due to COVID-19 restrictions. Hence, the quality of research could have been improved with a higher quantity of participants in the qualitative study and the inclusion of PPI stakeholders in every stage of this research.

Another limitation of the research was the testing of the BfT. Even considering that the BfT was validated via gold standard equipment, the quality of research would have benefitted from the input of participants with mobility issues who might have spotted limitations in the system otherwise unseen by the researcher.

6.2. Key contributions to knowledge

Informal PPI conversations with key stakeholders and a comprehensive review of existing studies and products led to the conception of the BfT. Engineering disciplines as varied as electronic, mechanical, and computer were all involved in the BfT's creation. It wasn't only enough to get the electronics to function properly when working with sensors; instead, the goal was to get them to function at peak efficiency. It was also difficult to ensure optimal sensor performance while designing for electronic interconnection, wiring, and positioning. The mechanical casing and handle design presented unique challenges because they had to meet the needs of the end user while also protecting the electronics inside. This study adds significantly to the literature by providing insights such as:

1. Novel approach of incorporating the PPI model in the design and development of a medical device.
2. Investigation and quantification of the incorrect sideways tilt angles.
3. Incorporation of a novel real-time feedback mechanism based on the incorrect sideways tilt angle.
4. Incorporation of visual feedback via an OLED display in a smart walking stick.
5. Development of a novel home-based self-testing feature for users in a mobile application.
6. Development of a PC-based user-friendly GUI to assist AHPs in viewing BfT’s usage data in real-time and setting threshold limits of the BfT.
7. Evaluating two 3D motion capture systems for performance and convenience.

Therefore, the development of the BfT has bridged most of the significant gaps addressed in the literature and has proven to be an efficient system.

6.3. Future improvements and recommendations

- The OLED display was incorporated within the BfT in an attempt to widen the audience for the smart walking stick; however, feedback received from the PPI members differed from expectation. This suggests the need for versions of BfT without the OLED display as this may save cost and enhance the battery life of the BfT.

- From the PPI study, it was observed that PPI members preferred a certain feedback mode (audio/ vibration/ OLED display) for their usage. Therefore, there should be an option available on the next version of BfT stick to switch off the less preferred feedback modes.
- The positioning of the IMU within the BfT can be further improved to eliminate existing errors.
- The weight of the BfT can be further reduced by using the SMD (Surface Mount Device) technology which could make the electronics system more compact and light weight.
- Current research enabled the derivation of Yaw from the BfT, however the application of Yaw was not applicable in the scope of this research. For future research, Yaw value can be utilised to determine the cause of wrist injuries associated with the incorrect use of walking stick.
- There are a number of potential avenues for further BfT-related work to be pursued in order to advance this proof of concept towards commercialisation. While the BfT was tested against gold standard equipment and showed promising accuracy, it still must pass through stringent clinical testing as part of the medical device development cycle before it can be made available to the public. Therefore, testing the BfT with healthy and unhealthy volunteers would be the next step in its evolution.
- To further improve the quality of research studies associated with the testing of medical devices, the universities across the UK should work with MHRA in reducing the complexity surrounding the research governance issues in compliance to conducting trials with healthy volunteers / research participants. This may not only further improve the quality of research but would also contribute to the reduction of time for product commercialisation.
- Furthermore, with the evolution of machine learning techniques, data is ever more valuable in the modern day. The BfT provides sufficient data with its inbuilt storage capacity and continuous data telemetry to the mobile application. This data can be logged and fed to different prediction models using machine learning algorithms. This could enable the device to learn different usage patterns from users, assisting health institutes with monitoring, evaluating, and predicting health conditions.

6.4. Conclusion

Considering the requirements of the stakeholders and limitations of the conventional walking stick, this research led to the development of a smart walking stick ‘BfT’ to provide real-time feedback to the users during ADL and assist AHPs in gait analysis. The system was evaluated and found to be robust, useful, and reliable. Thus, the aim of the research was achieved satisfactorily. Benefits, limitations, and possible applications of the BfT were identified, demonstrating the potential of BfT as a replacement to the conventional walking stick. With room for further improvement, the BfT in its current state of the art design, has gathered attention from a number of third-party medical devices SME’s. Currently, collaborative agreements are being sought between the university and a third party medical devices SME, to fully exploit the potential of BfT in clinical trials for the purposes of commercialisation.

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Appendices

Appendix A

Datasheets:

Link to the datasheet of Fire beetle ESP 32 IOT Microcontroller: https://www.dfrobot.com/product-1590.html

Link to the datasheet of IMU Sensor BNO055: *https://cdn-shop.adafruit.com/datasheets/BST_BNO055_DS000_12.pdf*

Link to the datasheet of Load Cell Amplifier HX711: https://www.digikey.com/htmldatasheets/production/1836471/0/0/1/hx711.html

Link to the datasheet of DC motor (316040001): https://media.digikey.com/pdf/Data%20Sheets/Seeed%20Technology/1020-15-003-001_Spec.pdf

Link to the datasheet of OLED SSD 1306: https://www.digikey.co.uk/htmldatasheets/production/2047793/0/0/1/ssd1306.html

Link to the datasheet of RTC DS3231: https://datasheets.maximintegrated.com/en/ds/DS3231.pdf

Appendix B

User Training Video

Walking Stick User: https://drive.google.com/file/d/1a2aA06cBG-38I-BGXBVsIIV8XqPLpDv_/view?usp=sharing

AHP: https://drive.google.com/drive/folders/1Ok-Kh3J2ewqYpwd4JXtqvSgBfdlb9c4s?usp=sharing

Birmingham City University policy for testing medical devices

Link: Medical Device Guidance BCU

Appendix C

<u>Ethics Approval from BCU Ethics Committee</u>

BIRMINGHAM CITY University

Faculty of Health, Education & Life Sciences Research Office
Seacole Building, 8 Westbourne Road
Birmingham
B15 3TN

HELS_Ethics@bcu.ac.uk

08/Apr/2021

Mr Salman Abdullah

salman.abdullah@bcu.ac.uk

Dear Salman ,

Re: Abdullah /#8027 /sub2 /R(A) /2021 /Apr /HELS FAEC - Design and development of an Interactive Biofeedback stick technology to help user improve their quality of life

Thank you for your application and documentation regarding the above activity. I am pleased to take Chair's Action and approve this activity.

Provided that you are granted Permission of Access by relevant parties (meeting requirements as laid out by them), you may begin your activity.

I can also confirm that any person participating in the project is covered under the University's insurance arrangements.

Please note that ethics approval only covers your activity as it has been detailed in your ethics application. If you wish to make any changes to the activity, then you must submit an Amendment application for approval of the proposed changes.

Examples of changes include (but are not limited to) adding a new study site, a new method of participant recruitment, adding a new method of data collection and/or change of Project Lead.

Please also note that the Health, Education and Life Sciences Faculty Academic Ethics Committee should be notified of any serious adverse effects arising as a result of this activity.

If for any reason the Committee feels that the activity is no longer ethically sound, it reserves the right to withdraw its approval. In the unlikely event of issues arising which would lead to this, you will be consulted.

Keep a copy of this letter along with the corresponding application for your records as evidence of approval.

If you have any queries, please contact HELS_Ethics@bcu.ac.uk

I wish you every success with your activity.

Yours Sincerely,

Dr Loukia Tsaprouni

On behalf of the Health, Education and Life Sciences Faculty Academic Ethics Committee

Participant Information Sheet

I am writing to invite you to participate in this research investigation. I am undertaking this research intervention as final part of my Ph.D. qualification. The participant information sheet aims to provide more details about this project and clarify any questions that you may have. If after reading this, you require any further information or have any questions about this study, please feel free to contact me via email: Salman.abdullah@bcu.ac.uk

Who is funding this study?

Birmingham City University ('BCU') Central Steam Funding is the sponsor for this study based in the United Kingdom.

What does the research involve?

Patient or public involvement (PPI) / Engagement with stakeholder's, is crucial part of any product development / medical devices life cycle. As a primary researcher of this investigation, I am hoping to engage with you (as an existing walking stick user, a stakeholder / service-user or as an individual caring for someone using a walking stick) to gain your feedback on the developed biofeedback stick technology (BfT). This will allow me to ensure that product is developed as per the service user requirement. You will be part of an stakeholder group to give me your feedback on the design or smart choices provided within the BFT. Feedback obtained from various stakeholders, will allow me to carefully pin down and fine tune the feasible smart features, technical and or aesthetics specifications of the BfT and enable me to accomplish the essential requirements of the product development cycle

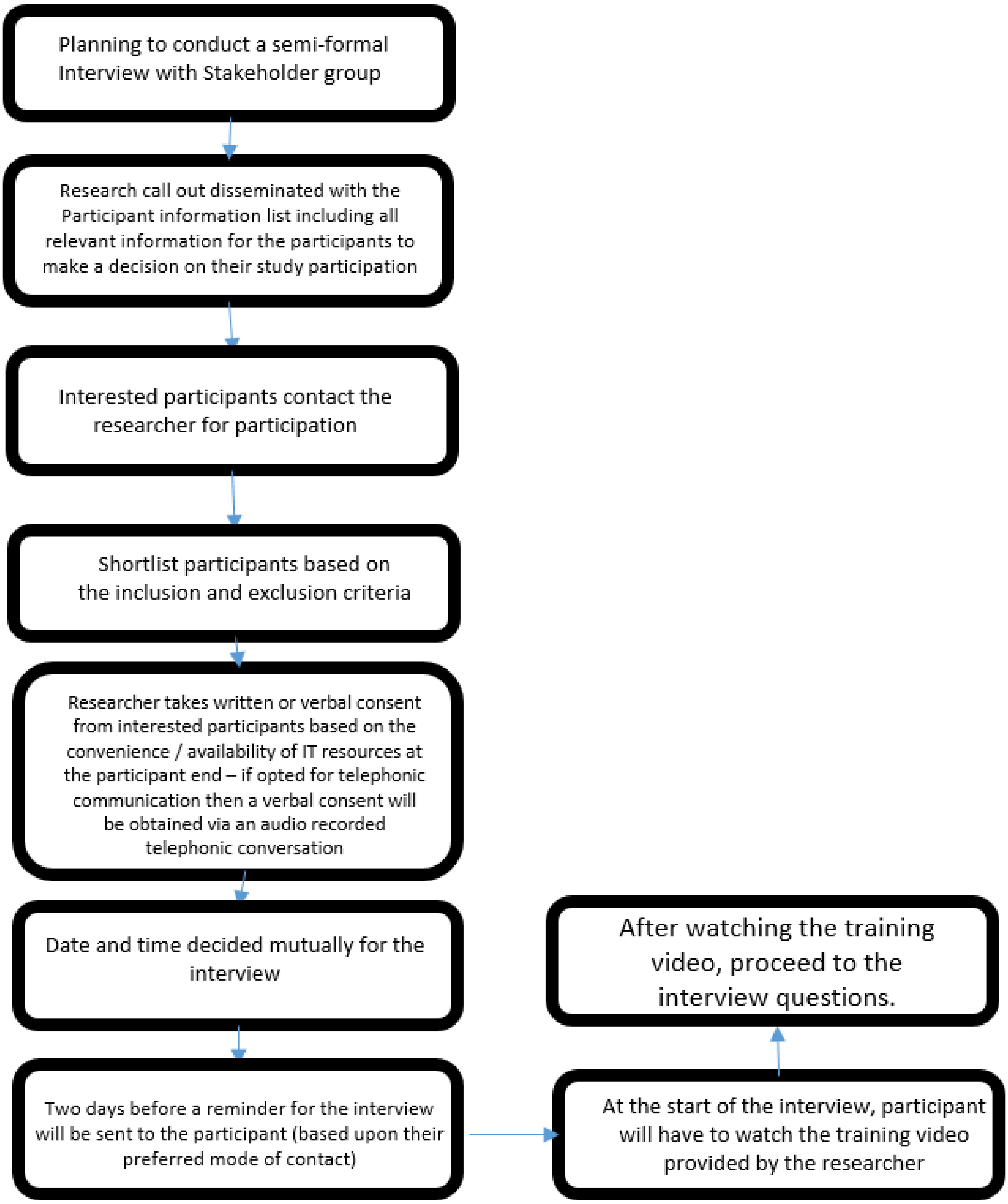
What am I required to do?

At the start of the semi-formal interview you will be required to watch the training video of the BfT developed, which is of 15 minutes time duration.

During the semi-structured interview, you will be required to answer 10 questions by the researcher, related to the design and smart features of the BfT. The telephonic interview will take approximately 60 minutes of time duration and will be recorded.

Please remember some of the questions may appear to be similar throughout the interview but they are different and would be more than happy to provide you any clarifications on these if need be.

<u>Step by step plan</u>



Appendix 1 Study Protocols

Safeguarding and potential physical risk of participating in this research

No safeguarding or physical risks are associated with this study.

Why am I suitable to participate in this study?

Inclusion criteria for any walking stick users (Non-clinical):

1. Currently using a walking stick or have prior experience of using one.
2. Caring for someone who is currently using a walking stick or for someone who was using one before
3. Understand and can speak the English language fluently.
4. Over 18 years old and under 75 years old.
5. On the day of the interview participant should be able to access contactable telephone and PC with functional email ID either a personal one or an alternative or an official one where appropriate.

Exclusion criteria for any walking stick users (Non-clinical):

1. Has not used a walking stick before.
2. Users who are unable to watch the training video on the day of the interview, due to blindness or unavailability of resources.
3. Users who have hearing problems and cannot communicate well over the telephone/mobile.
4. Users having no access to a mobile or telephone.

Inclusion criteria for any walking stick users (Clinical):

1. Physiotherapists from academia or private clinical settings only.
2. Understand and can speak the English language fluently.
3. Over 18 years old and under 75 years old.
4. On the day of the interview participant should be able to access contactable telephone and PC with functional email ID either a personal one or an alternative or an official one where appropriate.

Exclusion criteria for any walking stick users (Clinical):

1. Users who are unable to watch the training video on the day of the interview, due to blindness or unavailability of resources.
2. Users from National Health Service Trusts (NHS Trusts)
3. Users who have hearing problems and cannot communicate well over the telephone/mobile.
4. Users having no access to a mobile or telephone or essential IT resources.

Who has approved the study?

The Faculty of Health, Education and Life Sciences Academic Ethics Committee - Birmingham City University has reviewed and approved this study.

What is the period of the research?

This study is part of the ongoing Ph.D. research until August 2021. However, the interviews will begin on 21st of March 2021 and will last for 2 weeks from the date of commencement.

What if I want to withdraw?

Participating in this study is voluntary and you have the right to withdraw from the research investigation at any point without providing any reason. However, if you decide to withdraw after the data collection period it will be less pragmatic to delete the data due to its impact on the study outcomes. Nevertheless, your contribution will be fully anonymised.

How will you ensure anonymity and confidentiality?

All information collected will be stored securely and strictly confidential according to the General Data Protection Regulation (GDPR), 2018. Your identity and anonymity will be protected by replacing your name with a Pseudonym (e.g. Participant A) which will be used throughout the whole study. Your other characteristics such as age will not be identifiable. Your information will not be shared with any other person including my supervisor who will be supporting me in this research will not know your identity, as I will only refer to participants as participant A for example. However, if you do disclose information where you or another individual is in harm, I will have to break confidentiality and share the disclosure with appropriate professionals at the faculty end. Should this occur, I will let you know what the process will be and whom I will be sharing the information with beforehand.

Additionally, your data will be stored in a password protected encrypted device in the University one-drive which will be stored for 2 years and will be deleted subsequently. Furthermore, if you would like to access the recorded information then in permission with the faculty ethical committee, appropriate mode of sharing such information will be decided. Alternatively, once the research is completed, the outcomes of the overall research will be shared with all the participants via appropriate communication platform.

What happens if any sensitive issues are raised?

The researcher will implement standard BCU safeguarding procedures to ensure any sensitive matter raised is dealt with throughout the research project. In addition, the researcher will be seeking appropriate advice from faculty ethics committee and if need be will consider termination of any aspect of the research study where the sensitive issue cannot be eliminated/minimised.

What will happen to the results of this research?

This is an ongoing PhD research project and results will be used to produce the doctoral thesis. However, given the anonymity of the data collected, individual feedback may not be available for participants and so an overview of the study outcomes will be made available for participants, if need be, as and when appropriate. Once published the study will also be made available in the University repository.

What if I require further details or have questions?

If you require more details or have any question related to my research project, you can contact me at any time using my details provided above. Alternatively, you can contact my supervisory team Dr. Vivek Indramohan: Vivek.indramohan@bcu.ac.uk or Dr. Bisola M: @bcu.ac.uk. Should you have any concerns about the conduct of the research please contact the HELS_Ethics@bcu.ac.uk.

Data protection and your rights

Birmingham City University ('BCU') is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

BCU will use your name, and contact details to contact you about the research study, and make sure that relevant information about the study is recorded to oversee the quality of the study. Individuals from BCU may look at your research records to check the accuracy of the research study. The only people in BCU who will have access to information that identifies you will be people who need to contact you to arrange the data collection and to disseminate findings, people who audit the data collection process and people who manage data storage and archiving.

BCU will retain evidence of your participation in this study through the signed consent form or recorded verbal consent for up to three years after the project has been completed. Therefore, we anticipate retaining some of your personal data up until September 2023. This is in accordance with the University's legal obligations and the time you have available in which you may wish to raise any issues or concerns with us about your participation in this study. After this period, BCU will securely destroy information held about you.

You can find out more about how we use your information by contacting Salman Abdullah: on Salman.abdullah@bcu.ac.uk: or the Director of studies - Dr. Vivek Indramohan: Vivek.indramohan@bcu.ac.uk.

For more information about how the University can process your personal data for research, please see the University Privacy Statement, available here: https://www.bcu.ac.uk/about-us/corporate-information/policies-and-procedures/privacy-notice-for-research-participants

If you have any concerns about how we use or handle your personal data please contact the University's Data Protection Officer using the following contact details:

By Email to: informationmanagement@bcu.ac.uk

By Telephone on: +44 (0)121 331 5288

By Post to: Data Protection Officer

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Birmingham

B5 5JU

If you are not content, with the how we handle your information we would ask you to contact our Data Protection Officer to help you who will investigate the matter. However, you do also have the right to complain directly to the Information Commissioner at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF. Information about the Information Commissioner is available at: http://ico.org.uk.

Participant Consent Form

BIRMINGHAM CITY University

Consent Form - For: Semi-structured Telephonic Interview

Study Title: Design and development of an Interactive Biofeedback stick technology to help user improve their quality of life

Name of Researcher: Salman Abdullah

Project Code: Abdullah /#8027 /sub1 /R(A) /2021 /Mar /HELS FAEC

Participant identification number:

Please initial box

1. I confirm that I have read the information sheet [20/03/2021, version 6.0] for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and I am free to withdraw at any time without giving any reason, without my medical and legal rights being affected.	
3. I agree for the telephonic interview to be audio recorded.	
4. I understand that relevant sections of my data collected during the study may be looked at by individuals from Birmingham City University and from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.	
5. I understand that personal data about me will be collected for the purposes of the research study including gender and position of my work, and that these will be processed in accordance with the information sheet [20/03/2021; version 6.0].	
6. I agree for my gender and position of my work to be anonymised and kept confidential.	
7. I agree to the use of my anonymised data in research reports and publications.	
8. The health and safety protocols of this project have been explained to me. In addition, I have had the opportunity to ask questions regarding the protocols and the project. I confirm that I understand all the protocols within this project.	
9. I agree to take part in this study.	

Name of Participant Consent Date

Researcher Name Signature Date

Appendix D

PPI Request Form

DIABETES UK
KNOW DIABETES. FIGHT DIABETES.

Patient and Public Involvement in Research Request Form

Diabetes UK is willing to help researchers with patient and public involvement in the development of their research by circulating requests to people with diabetes. Please refer to the guidance prepared for researchers to aid better patient and public involvement in research: https://www.diabetes.org.uk/resources-s3/2017-10/0983_PPI%20resource_guidance-document_DL_v5.pdf

Please note that Diabetes UK will not endorse the research highlighted in the request and any interested individuals should contact researchers directly.

Please return your completed form to research@diabetes.org.uk

What is the opportunity about? *(max 250 words)*		
What type of people would you need? *e.g. people with Type 1 diabetes*		
In what region would you like to approach the people with diabetes? *e.g. locally or nationally (please select as required)*		
North	Eastern & Midlands	Scotland
South West	Wales	Northern Ireland
London & South East		
How long is the opportunity for?		