# Generating Music from Movement to Improve Gait of Individuals with Spastic Cerebral Palsy

by

Melissa Marable, Kevin Supakkul, Nicole Salz, Bradley Immel

Final Report for
ME 170B Mechanical Engineering Design
Integrating Context with Engineering

Spring Quarter, 2021

June 3rd, 2021

ABSTRACT

Cerebral palsy (CP) is a neurological condition that impacts 764,000 people in the United States [1]. Individuals with spastic CP often experience gait disorders. A high dose of repetitive exercises can be beneficial for patients with neurological conditions, including patients with spastic cerebral palsy, in improving muscle strength and overcoming impaired selective motor control. Therapies that are currently being used to address impaired gait behavior are potentially unmotivating and limited to therapy time. They are used roughly three times a week for an hour as they require patients to physically go to a hospital or a physical therapy center. This is a relatively low frequency and thus requires a long period of time to yield improvement in gait behavior. Thus, the goal of this project is to provide a new form of physical therapy that uses music to encourage patients to engage in these repetitive exercises. We propose and have developed a generative music technology intended to motivate high repetition and encourage gait pattern improvements. This system gives users the means to actively create music as opposed to following along to an existing song or pattern. Users can generate different types of music and chords as they walk to encourage these repetitive patterns. To meet these user needs, we established technical requirements addressing performance, reliability, and enjoyability.

To fulfill these goals and requirements, we've built a full system containing a footswitch, knee angle-detection sleeve, and iOS app, which all communicate with each other wirelessly. The footswitch enables precise detection of initial contact and toe-off through the use of two force resistive sensors: one on the heel and one on the toe. We then mapped these gait events to music for user feedback and enjoyment. The knee sleeve provides data on knee angle by measuring the angle between two Inertial Measurement Units (IMUs), one located on the shin and one located above the knee. This provides user information about knee flexion angle which is then used to provide positive feedback to our users. We tested our device against our technical requirements and made design changes to ensure that we met each requirement.

# Acknowledgments

Thank you to Stanford Orthopedic Surgery and especially our project liaisons, Doctor Jessica Rose and Doctor Kornél Schadl, for providing us with the motivation, knowledge, and resources to work on this incredible project. We would also like to thank the Director of Capstone Course and our coach, Jeff Wood, and course assistant, Gal Ziedman, for the guidance and thoughtful feedback on all of our assignments and prototypes. Thank you to our user testers for their feedback on our musical implementations and on our system's ability to help individuals with gait abnormalities. Also thanks to Romain Michon for his guidance with integrating Faust into our app. Our team would also like to thank Emma Morgan for her willingness to share her previous work on gait analysis that we could build off of. We would like to thank Taghi Rostami niri for his collaboration on a project in ME 281: Biomechanics of Movement related to Rhythmic Auditory Stimulation and gait improvement. Thank you to the Mechanical Engineering Department for providing the capstone course and generous funding that has allowed us to work on a project that we not only are passionate about but also have learned so much from. Lastly, we would like to thank our friends and family for the endless support (and for being extraordinary test subjects!).

# Table of Contents

# List of Figures

# List of Tables

# 1. Introduction

Cerebral palsy (CP) is a neurological condition that results from a brain injury around the time of birth affecting approximately 764,000 people in the United States [1], impacting movement, muscle tone, and posture. The most common type of CP is spastic CP, which affects about 80% of people with CP [1, 2]. Spastic CP is caused by injury to the corticospinal tract and is characterized by weak and short muscles, spasticity, and impaired selective motor control that leads to gait abnormalities [3, 4]. People with spastic CP commonly experience gait disorders of flex-knee gait and stiff-knee gait. Flex-knee gait is characterized by an overly bent or flexing standing leg, while stiff-knee gait occurs when the hip, knee, and ankle do not flex sufficiently in the swing phase of gait when going to take the next step.

There are several therapies that are used to address impaired gait for individuals with CP. However, many of these are unmotivating and ineffective due limited therapy time. Current therapies, like muscle strengthening and treadmill training, are provided at most 2-3 times per week for an hour, as they require patients to physically go to a hospital or a physical therapy center [4]. This is a relatively low dosage and thus requires a long period of time to actually generate improvement in gait behavior.

If individuals are able to receive appropriate feedback on their gait outside of therapy and they are motivated to do so, there is potential for an increased improvement. Music can serve as both a source of gait feedback and a motivator for increased walking activity [5]. Additionally, research suggests that uniform or patterned beats can be used to improve gait in CP [6]. Thus, a device that provides a clear connection between music and movement has the potential to improve the gait of individuals with spastic CP.

Our goal is to create music from movement to build a satisfying experience which will encourage users to consistently practice repetitive exercises that build neuron connections, leading to lasting improvements in their respective gait pattern.

# 2. Background

This combination of gait and music requires the integration of research from two distinct areas: spastic CP gait and music therapy.

## 2.1 User Research

### 2.1.1 Gait Abnormalities in Spastic Cerebral Palsy

Individuals with spastic CP often experience gait disorders including flex-knee gait and stiff-knee gait. Through speaking with Dr. Jessica Rose, the director of the Motion and Gait Analysis Lab at Lucile Packard Children's Hospital at Stanford, we have learned how specific gait parameters of people with flex-knee gait and stiff-knee gait differ from those of people with typically-presenting gait. To help understand this, we studied the gait cycle as shown in Figure 1. The gait cycle is composed of the stance and swing phases; the transition between phases occurs at gait events of initial contact and toe-off.

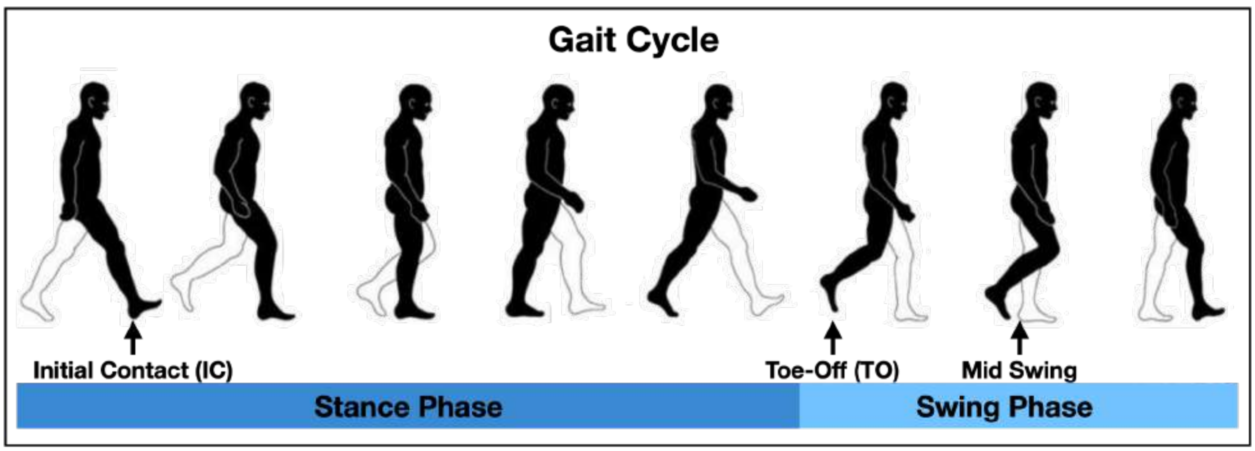



**Figure 1:** The Gait Cycle is composed of the Stance and Swing phases [7].

Stiff-knee gait, seen in Figure 2, occurs when there is not enough hip, knee, and ankle flexion in the swing phase, which results in the dragging of the foot.

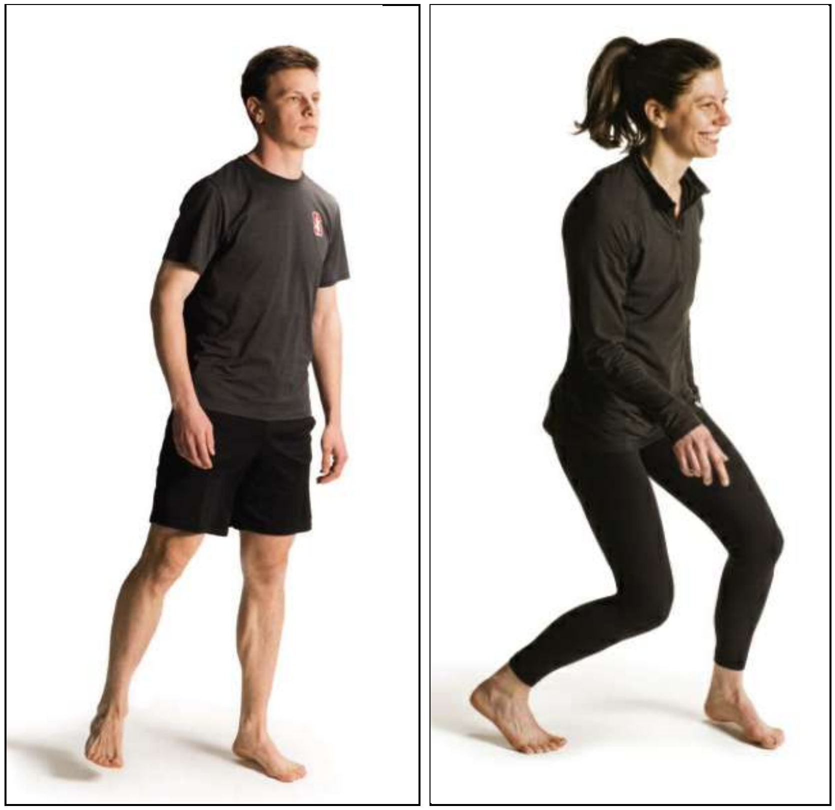


**Figure 2:** Gait disorders common among individuals with spastic CP: stiff-knee gait (left) and flex-knee gait (right) [8].

This is noticeable at the beginning of the swing phase. Individuals with flex-knee gait will have an overly bent or flexed standing leg, also shown in Figure 2. Flex-knee gait often leads to fatigue due to excessive energy expenditure. People with this gait disorder can also have difficulty combining hip flexion and knee extension, as shown in Figure 3, at the end of the swing phase when walking.

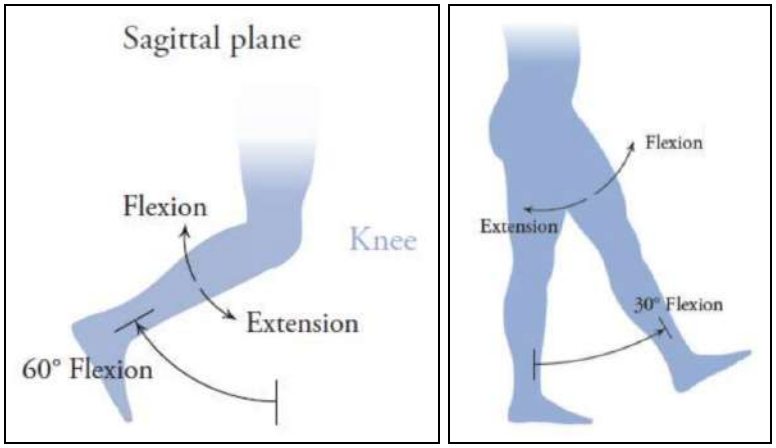



**Figure 3:** Normal motion of the knee in the swing phase of gait in the sagittal plane (left) and motion of the hip in the sagittal plane (right) [8].

In comparison to Figure 3, notice that the individual walking with stiff-knee gait (Figure 2) has limited knee flexion in swing phase, while the individual with flex-knee gait (Figure 2) has limited knee extension in the stance phase as well as at the end of swing phase of gait.

A typical gait will have a wide range of knee flexion angles. Individuals with stiff-knee gait will have a diminished and delayed knee flexion angle during swing as shown in Figure 4.

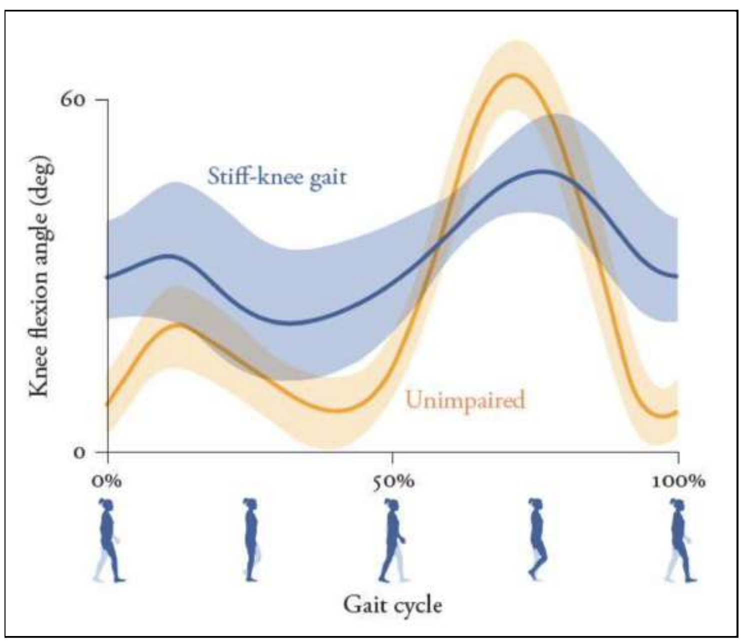



**Figure 4:** Knee flexion angle plotted over the gait cycle for individuals with unimpaired gait and for those with stiff-knee gait [8]. Notice after toe-off, at approximately 62% of the gait cycle, the blue curve representing stiff knee gait has a delayed and diminished peak knee flexion angle compared to the yellow curve representing unimpaired gait.

People with flex-knee gait also have knee flexion angles across the gait cycle that differ from people with typically presenting gait. As flex-knee gait becomes more severe, the overall range of knee flexion angles across the gait cycle decreases while the knee flexion angle increases as shown in Figure 5.

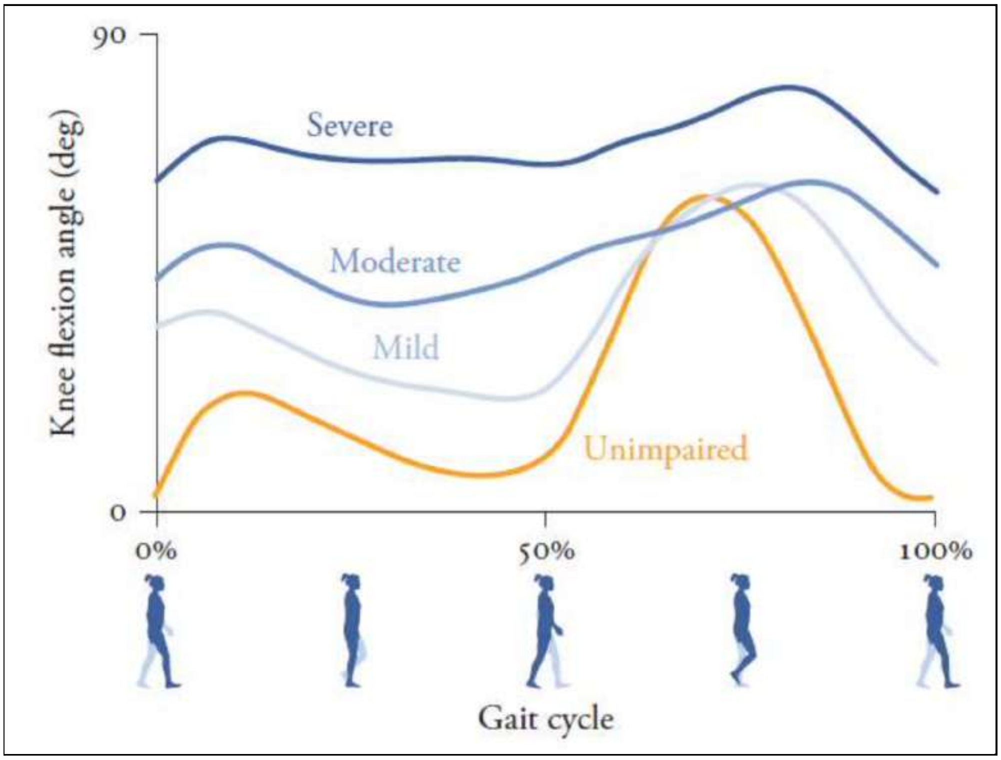



**Figure 5:** Knee flexion angle plotted over the gait cycle for individuals with unimpaired gait and for those with mild, moderate, and severe flex-knee gait [8]. Notice the yellow curve, representing unimpaired gait, spans a wide range of knee flexion angles while the dark blue curve, representing severe flex-knee gait, spans only approximately 10 degrees.

Another gait parameter that differs in the CP population is stride length, defined as the distance traveled in one gait cycle, or two consecutive steps, shown in Figure 6. Individuals with CP often have asymmetric step length and decreased stride length and frequency, compared to typically developing individuals [8, 9].

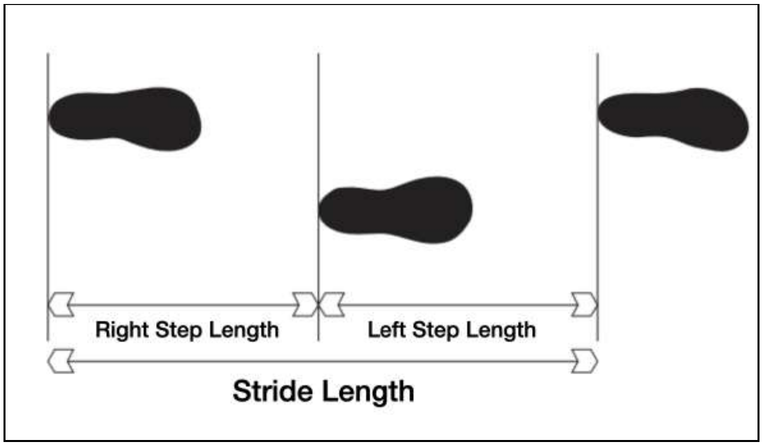



**Figure 6:** Stride length is the distance traveled in one gait cycle or in two consecutive steps [8, 10].

While we will be discussing some of the current physical therapy interventions for movement difficulties, there exist other interventions including Ankle Foot Orthotics (AFOs), medication, and surgical procedures, which are generally effective, but expensive and intrusive [11].

Physical therapy for spastic CP often consists of muscle and treadmill training. Muscle training involves lower body exercises with weights, rubber bands, and body weight, which benefit gait by improving muscle strength and increasing stride length [12]. Treadmill training, as seen in Figure 7, where a patient walks while partially suspended, can improve stride length and frequency as well as endurance, balance, and symmetry [13].

**Figure 7:** Weight-relieved treadmill training therapy where the patient is partially suspended [14].

Recently, a robotic training method in which a light, wearable robot applies a downward pelvic pull to a user walking on a treadmill, seen in Figure 8, has shown improvements in the muscle coordination, range of the lower limb angles, toe clearance, and heel-to-toe pattern of children with CP [15, 16].

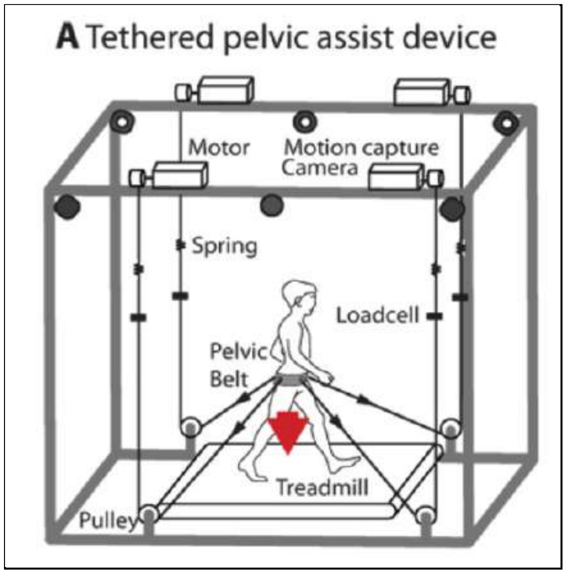



**Figure 8:** Robotic Training Method; system diagram of tethered pelvic assist device [16].

Therapies for stiff-knee gait often entail a therapist delivering timed auditory cues upon their patient's toe-off to prompt rapid hip, knee, and ankle flexion to clear the foot during early swing phase. This can be monotonous and fatiguing for both the patient and the therapist and takes a significant portion of the therapist's attention.

While each of these therapies has been shown to improve gait parameters, they are limited to the clinical setting.

### 2.1.2 Music Therapy

Music therapy has been successful in both psychological and neurological contexts. Music serves to motivate individuals to continue tasks by making them more enjoyable [5]. Neurologic Music Therapy (NMT) is the therapeutic application of music for sensorimotor training, speech and language training, and cognitive training, assisting by rerouting neural pathways to achieve motor control improvement [17].

Research has demonstrated music's motivating ability. A study that examined the effects of music on motivation and gait in persons with multiple sclerosis, a disease affecting the central nervous system that can also impact gait, found that participants reported higher motivation levels when walking to music [18]. Music has also been shown to enhance physical performance; one study found that participants ran greater distances in a given period of time when there was music [19]. Additionally, a study conducted on bone marrow transplant patients found that patients' exercise endurance increased when music was involved [20]. These studies suggest that music increases motivation for better performance and longer engagement during physical activity.

Rhythmic Auditory Stimulation (RAS), a type of NMT, is a therapeutic application of pulsed rhythmic or musical stimulation in order to improve gait or gait-related aspects of movement [21]. RAS can be used to enhance gait performance in individuals with neurological diseases, such as cerebral palsy [6]. RAS's potential for gait improvement arises from the observation that humans are exceptionally good at both recognizing the periodicity of repeated loops of audio – even when it is not an exact repeat, such as in most songs – and synchronizing a motor function to that period, like tapping along to the beat. In Figure 9, we can see a hypothetical example of someone self-adjusting their motor function to synchronize to the period of a drum loop.

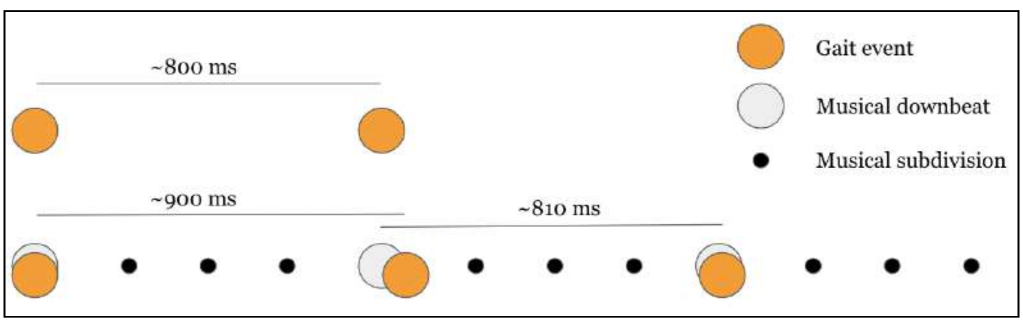



**Figure 9:** Diagram showing an implementation of RAS using musical subdivisions to reinforce periodicity. The user would self-correct to align their step frequency with the period of the music [22].

This phenomenon, referred to as Period Entrainment, is a temporal locking process in which the motion or signal frequency of one system entrains the frequency of another system. It is expected that as the understanding of the mechanisms behind rhythmic entrainment grows, use of other musical elements, such as harmony and melody, might be considered for rehabilitation purposes [22].

The specific benefits include increased stride length and stride frequency [6] both of which would benefit an individual with spastic CP. Tying musical events to gait events, such as initial contact and toe-off, is one potential method of implementing RAS to improve these parameters.

One solution that closely addresses our project needs was developed by MedRhythms. MedRhythms, a digital therapeutics company, has taken advantage of RAS by using sensors, music, and software to build evidence-based neurologic interventions to measure and improve walking [23]. They focus mainly on populations outside of individuals with CP including those with chronic stroke, multiple sclerosis, and Parkinson's disease. MedRhythms' devices attach to the shoe and use Inertial Measurement Units (IMUs) to track gait data [23]. As an individual walks, the music adapts to their steps. Currently, MedRhythms requires a separate device to play the music.

The IMU solution by MedRhythms is of particular interest to us because of their device's ability to be taken home and used outside of a physical therapy setting, as IMUs are small, light, and inexpensive. However, MedRhythms' system has several drawbacks. Namely, music cannot be played directly from the user's or their parent's phone, as a separate device is required, and MedRhythms' devices are incapable of measuring knee angle, an important parameter in both stiff-knee and flex-knee gait. Due to these limitations, MedRhythms' devices do not thoroughly address our problem statement.

An easy-to-use app-based device that can be used both during and outside of therapy should encourage the repetitive exercises necessary to improve gait behavior in a shorter period of time [4].

### 2.1.3 User Requirements

We kept the user and project motivation in mind when determining our user requirements and their priorities. Our first two high priority user requirements are to allow the user to generate music through their movement (UR1) and to improve gait in individuals with spastic CP (UR2).

The third high priority requirement is to create an enjoyable and motivating musical experience (UR3), which will encourage increased use and thus increase the potential for gait improvement. Music can be used as motivation for both improved physical performance [20] and increased endurance (which implies an increase in engagement time for physical therapy) [19]. Furthermore, it has been proven to specifically help improve gait performance in individuals with neurological disorders, including those recovering from brain injuries and individuals with Parkinson's disease [4, 6].

We also require that the device be capable of at-home personal daily use (UR4). Allowing easy daily use is the best way to build neuron connections that promote control of movement [4]. Finally, the device must output consistent sensor data over the duration of its use (UR5), as inconsistent knee angle readings will negatively affect music-movement correspondence. Refer to Appendix F for a full listing of user requirements.

## 2.2 Technical Requirements

Our high priority technical requirements are designed to provide quantifiable metrics for our high priority user requirements.

The first high priority user requirement is to actively generate real-time music based on the user's gait (UR1). There are two technical requirements associated with this. First, any sound triggered by a gait event should occur within an imperceptible window of the actual gait event (ER1-1). While 40ms is the recommended latency for audio-visual consumer electronics [24, 25], we take advantage of the cushioning period of impact (due to shoes, socks, and skin) to allow for a wider acceptable range. Our testing, in which we manually increased event-to-audio latency until the user signaled that they felt a disconnect between their heel contact and the produced beeping sound, suggested an upper bound of 150ms [26]. This discrepancy is due not only to the cushioning period but also to the use case – someone generating music by walking will not need the same timing precision as a pianist playing a keyboard, nor as a person watching a video of speech. The second technical requirement associated with UR1 is that the knee angle shall be within 5 degrees of reality (ER1-2), which is the mean error limit accepted by the American Medical Association regarding the clinical evaluation of movement impairments [27].

The next high priority user requirement is to improve gait performance for individuals with spastic CP (UR2). We intend to quantify this by demonstrating a statistically significant improvement towards typically presenting gait (ER2-1) in parameters such as knee flexion angle, toe-off timing, and stride frequency. To obtain this data, we propose using Optical Motion Capture and force plates in Dr. Rose's lab to capture these gait parameters and others before patients begin using the device, and after they have used it for 8 weeks [28, 29]. Unfortunately, this timeframe is outside the scope of ME 170, so we have detailed methods (Appendix H) for an experiment that can be conducted by others in the future. For now, we rely on our review of current studies and discussions with Dr. Rose to determine the project's potential to significantly improve gait performance.

The next high priority user requirement is to create an enjoyable and motivating musical interaction (UR3). This is important as it will encourage increased movement [5]. The enjoyability of music has been qualified through user testing and approached with the methodology of functional harmony – a system of guidelines for creating tension and release with interval-based chord relationships (ER3-1). Functional harmony guidelines allow us to navigate the musical space that is both pleasant and interesting, as shown in Figure 10, to maximize user engagement and enjoyment.

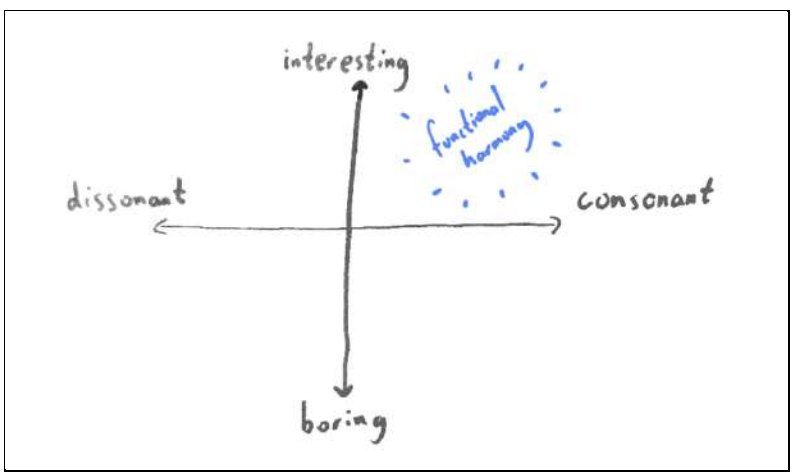



**Figure 10:** Functional harmony can make music both comforting and interesting.

It is important to note that a strictly Western-informed system will not provide a satisfying musical experience for all users, nor will any single-genre system. To appeal to people of various backgrounds and age groups, our framework offers a variety of instrumentation, harmony structures, and genres pulling from a wide range of cultures, styles, and generations.

Another high priority user requirement refers to environment conditions of use: the device must be portable for personal daily use outside of a clinical setting (UR4). The relevant technical requirements are that the device must be wireless so as not to interfere with walking, introduce tripping hazards, or diminish the user experience (ER4-1), have a rechargeable battery lasting for two hours of continuous use (ER4-2) to allow for practical daily activities such as walking in the park or visiting the grocery store [28], and extend no more than 15mm from the user's skin to avoid bulkiness and discomfort (ER4-3). The maximum thickness of 15mm is based on the thickness of Rolex Watches [29], which are elegantly sized wearable electronic devices for a user base that emphasizes usability and entertainment.

The final high priority user requirement is that the device must reliably output consistent sensor readings over the duration of use (UR5). The associated technical requirement is that the device should survive two hours of walking without having statistically significant deviation on sensor readings, based on a hypothesis test for the difference of means (ER5-1). Refer to Appendix F for a full listing of technical requirements.

Table 1 contains a summary of each of the high priority user and technical requirements. We used these above requirements to drive our brainstorming process for solutions.

**Table 1:** High Priority User and Technical Requirements Summary

| User Requirement | | Engineering Requirement | |
|---|---|---|---|
| UR1 | Generate music as users walk--let them make music through movement | ER1-1 | If focusing on initial contact point, music produced from step event should occur within 150ms of actual event |
| | | ER1-2 | If focusing on knee angle: measurement of angle has a precision of ± 5 degrees |
| UR2 | Improve gait for people with spastic cerebral palsy | ER2-1 | Statistically significant improvement towards typical gait |
| UR3 | Enjoyable and satisfying musical interaction | ER3-1 | Music produced should follow functional harmony guidelines and be enjoyable/motivating to users |
| UR4 | Device can be used at home for personal daily use. | ER4-1 | Wireless |
| | | ER4-2 | Battery-powered (rechargeable), lasting over two hours of continuous use |
| | | ER4-3 | Extend no more than 15mm from skin |
| UR5 | Device must output consistent sensor data over the duration of use. | ER5-1 | During use, demonstrate no significant deviation in knee flexion angle after two hours. |

## 2.3 Ethical Considerations

By creating a musical software and hardware system aiming to impact the gait performance of individuals with gait-related disorders, we invoke questions of beneficence, nonmaleficence, and financial and cultural accessibility.

We intend for our system to be used to significantly improve the gait patterns of as many people as possible. Initially, we approached development from a proof-of-concept perspective, with musical intrigue guiding our design. This led us to develop a dynamic song-generation system that could be used recreationally or as an at-home Rhythmic Auditory Stimulation solution. However, Dr. Rose, an expert in the field of spastic CP-related gait disorders, informed us that simpler implementations would be the most clinically useful. In order to most effectively address

ER2-1 (statistically significant gait improvement), we deferred to her feedback to develop more directly-applicable modes of our system. Because the scope of our project limited us to implementing a select number of musical options, Dr. Rose's feedback was crucial in reminding us to prioritize gait improvement over musical complexity.

While developing a system to reduce tripping hazards by encouraging rapid hip, knee, and ankle flexion in early swing phase, we must be sure not to introduce any new tripping hazards. For example, many of our modes involve rhythmic loops with tempos that are determined by the pace of the user's first couple of steps. These rhythmic loops are intended to encourage a consistent stride frequency; however, if the user becomes fatigued and needs to slow down, we do not want to encourage them to sustain a faster pace, as that may lead to tripping. This and other considerations of the implications of our design features, alongside Dr. Rose's guidance, informed design changes to ensure that we are not introducing any potential to injure a user or cause a deterioration in gait performance.

Our goal is for anyone who could benefit from using our device to be able to use it regardless of their socioeconomic status. The hardware system enabling the musical flexibility to address several different aspects of the gait cycle comprises a knee sleeve containing IMUs to accurately measure knee flexion angle and a footswitch containing force-sensitive resistors to capture precisely-timed gait events. This hardware, including the aforementioned sensors along with microcontrollers, batteries, and other miscellaneous electronic and housing components, sums to $200 in our current working prototypes. In order to avoid presenting a significant financial barrier for users hoping to improve their gait or augment their therapy, we intend for hospitals to own several devices to check out to patients. Additionally, we present hardware cost reduction as a high-priority next step for future developers.

Fortunately, we can choose to make our software freely available. However, due to time constraints, we have thus far only developed an app for iOS, as we ran into latency issues with Android audio. This provides access to just 27% of smartphone users [30], and because Apple devices cost more than many Android devices, it potentially offers access only to a more financially privileged group of users. This again informs a significant next step for future developers – building out an equivalent system for Android in order to enable up to 99% of smartphone users to use our app [30].

Our goal is to make our system not only accessible but also engaging for all potential users. People raised in different cultures and parts of the world have different tastes and familiarity regarding timbre, genre, harmony structures, and rhythm. To enable our system to play any style of music, we built out a system which can play any sampled instrument and any melody within the Western chromatic (12-note) scale. This informs two key future steps: expanding upon our code to enable microtonal music such as the 22-note shruti system often heard in Indian classical music and building upon our catalog of sampled instruments and songs available in the app (Appendix G), supporting our goal of making gait training more engaging for people of all backgrounds.

# 3. Approaches and Design Solutions

To achieve our higher priority user and technical requirements, we built a system (shown in Figure 11) with a footswitch, a knee sleeve, and an app that outputs music, which all communicate wirelessly via Bluetooth.


**Figure 11:** Full System Design made of the footswitch, knee sleeve, and app/musical framework.

## 3.1 Footswitch

The footswitch component allows for a precise and timely capture of gait events, specifically heel strike and toe-off. This concept involves a flexible shoe-insert that contains multiple force-sensitive resistors (FSRs), shown in Figure 12.

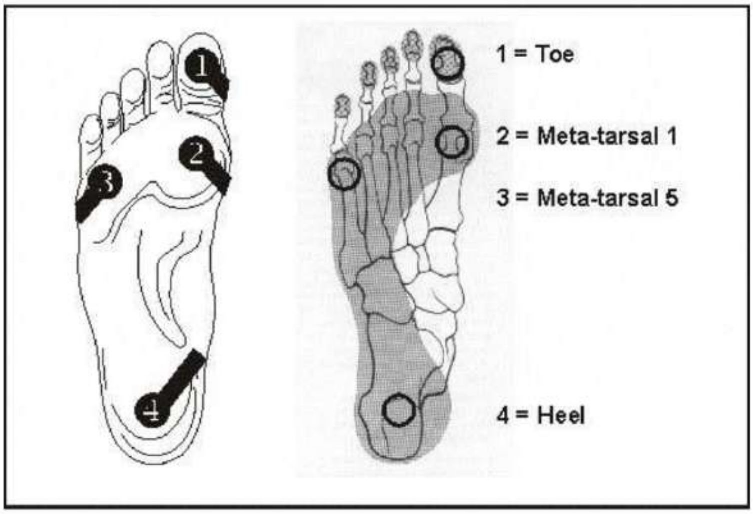



**Figure 12:** Force sensitive resistor sensor placement in footswitch [31].

Our design focuses on the FSR in the heel, which detects initial contact when pressure is applied, and the FSR in the toe, which detects toe-off when pressure is released. Both force sensors are controlled by an nRF52 microcontroller which allows for Bluetooth communication to the user's personal device. These gait events are then mapped to music to encourage gait pattern improvements.

### 3.1.1 Footswitch Hardware

The shoe insert is thin (ER4-3), like any other sole-insert device one could buy off the shelf. The footswitch uses an nRF52 microcontroller and a 3.7V lithium-ion battery, which are located in a 3D printed PLA case that easily clips on the collar of a close-toed shoe, as shown in Figure 13.


**Figure 13:** Footswitch insole with FSRs (left) and footswitch insole and battery case attached to the shoe (right).

The case is optimized to be as small as possible and allows for access to the USB port on the nRF52 microcontroller so that the battery can be easily recharged. The case closes with a snap fit lid that the user can easily remove and close. This addresses ER4-1 (wireless) and ER4-2 (2 hour battery life), since it does not require wires to any device located away from the shoe, and the battery pack is easily supported for two hours of use due to low power consumption from the footswitch (see Section 3.3 for detailed battery calculations). We chose to use the footswitch because of its potential for reliable and quick event detection (initial contact and toe-off) and thus for low latency from movement to music (ER1-1). It is user-friendly, since a device that lives in the shoe only needs to be set up once. The hardware components are oriented to minimize wire crossings, as seen in Figure 14. This is to decrease the force on the soldering joints and optimize for user comfort.

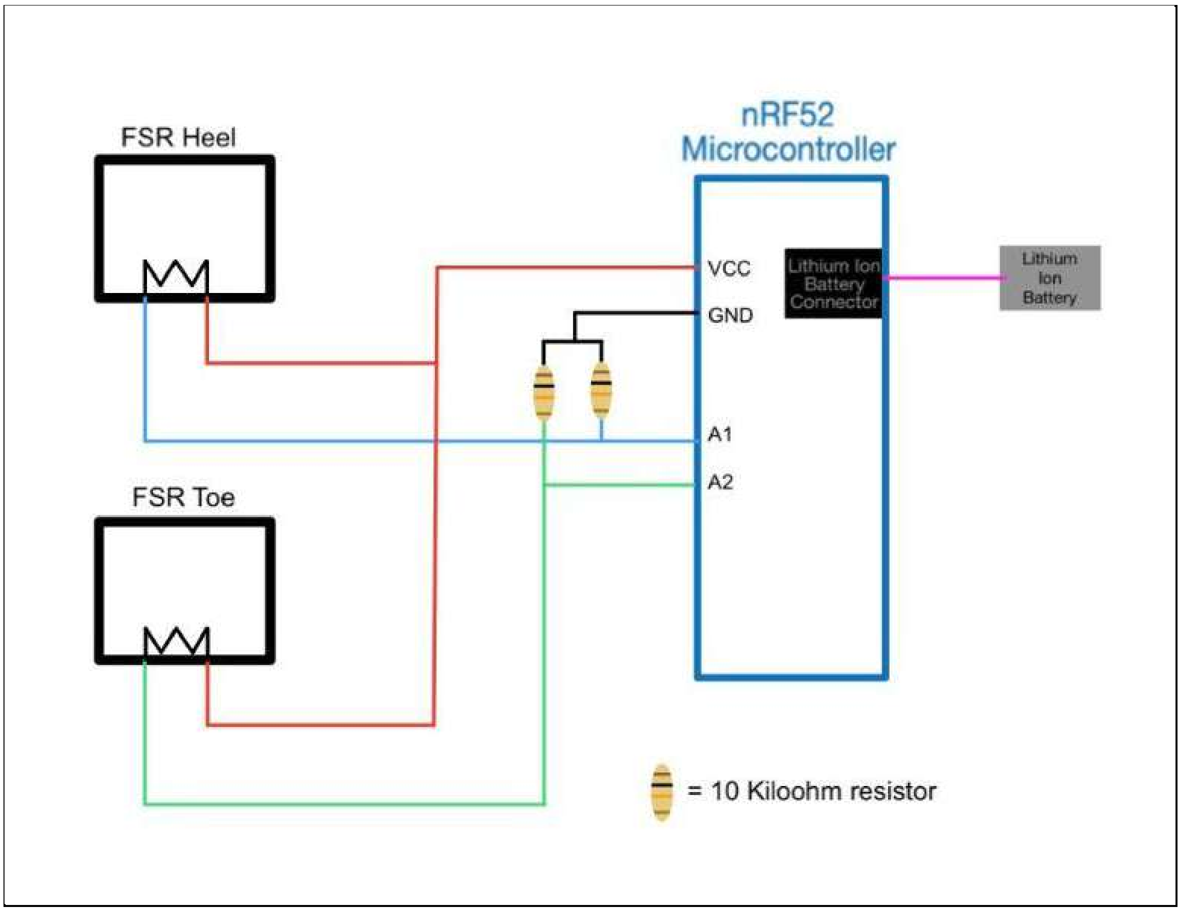



**Figure 14:** Circuitry of Footswitch.

### 3.1.2 Footswitch Software

For our use, each force-sensitive resistor (FSR) in the footswitch acts similarly to a push button, triggering a binary on/off when it crosses a force threshold. The initial contact event is defined by an impulse on the heel FSR, and the toe-off event is defined by a release of the toe FSR. These allow us to time musical events to follow or cue the user's movements.

For our musical implementations, there is an element of rhythm. During the calibration period, stride period is calculated by recording the first four steps and averaging the times between those steps. With each subsequent step, this array of times shifts so that it always contains the four most recent steps, and stride period is recalculated as an average of those times to gradually adjust as the user speeds up or slows down.

## 3.2 Knee Sleeve

The knee sleeve component provides the user information about their knee flexion angle during walking. This gait parameter is important for both individuals with stiff-knee gait and individuals with flex-knee gait. Our design addresses our high priority technical requirements ER1-2 (knee angle within 5 degrees of reality), ER5-1 (reliable knee angle output throughout use), and ER2-1 (statistically significant gait improvement). The design also addresses ER4-1 (wireless) and ER4-2 (2 hour battery life), since it will not require wires to any device located away from the knee sleeve, and the battery pack is easily supported for two hours of use due to low power consumption from the knee sleeve (see Section 3.3 for detailed battery calculations).

The knee sleeve requires two inertial measurement units (IMUs), we are using MPU-9250 IMUs, which each contain an accelerometer and gyroscope. One IMU is placed above the knee and measures the thigh angle from vertical. The other IMU is placed below the knee and measures the shin angle from vertical. The placement of these two IMUs allow for the calculation of knee flexion angle as seen in Figure 15.

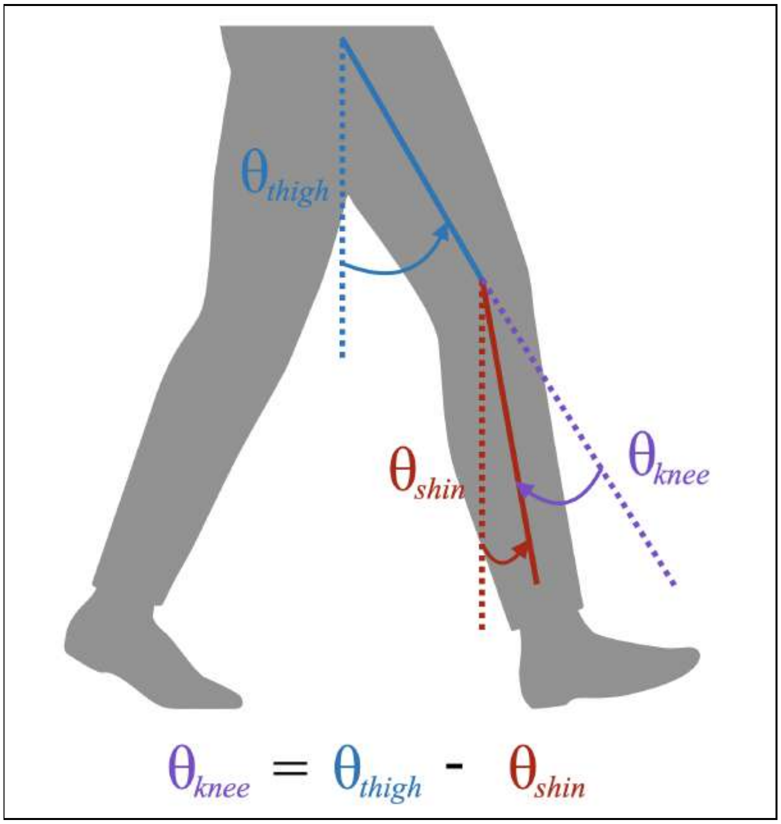



**Figure 15:** Knee flexion angle calculation

The knee flexion angle is then mapped directly to musical parameters or the thresholds for transitioning between gait states.

### 3.1.1 Knee Sleeve Hardware

The bottom layer of the knee sleeve component shown in Figure 16 is a knee sleeve with attached hardware components.


**Figure 16:** Bottom layer of knee sleeve: Front view (left) and back view (right).

We chose to use this specific product for its comfort, elasticity, and aesthetic. In addition to the two IMUs, the knee sleeve has an nRF52 microcontroller, a 3.7V lithium-ion battery, and a battery switch. The hardware design and battery allow the device to meet ER4-1 (wireless), ER4-2 (battery-powered), and ER4-3 (extend no more than 15 mm from skin). Each hardware component, except for the battery switch, is contained in a 3D printed PLA case, shown in Figure 17, with a snap-fit lid.

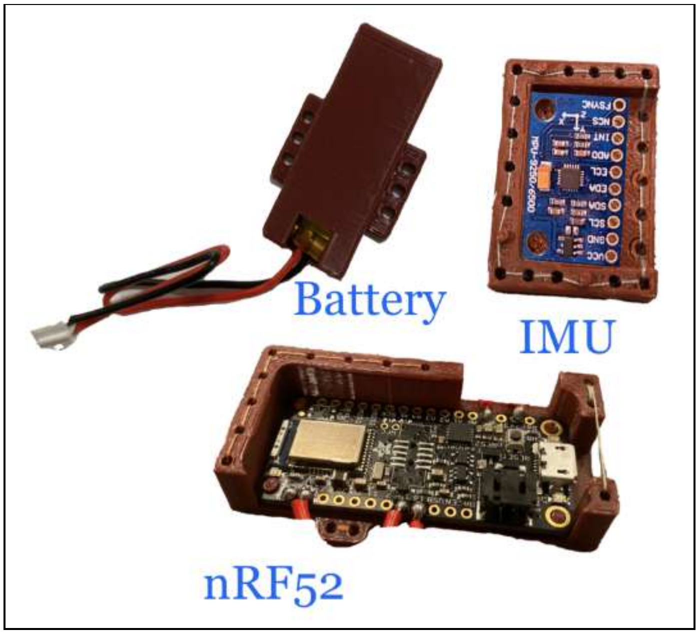



**Figure 17:** 3D printed cases for the lithium-ion battery, IMU, and nRF52.

Additionally, each hardware component is secured inside its 3D printed case with double-sided electronic tape. The cases are designed to meet ER4-3 (extend no more than 15mm from the skin). The 3D printed cases are sewn to the knee sleeve through the holes in the PLA. The hardware components are oriented to minimize wire crossings and to reduce the potential force put on the soldering joints as seen in Figure 18.

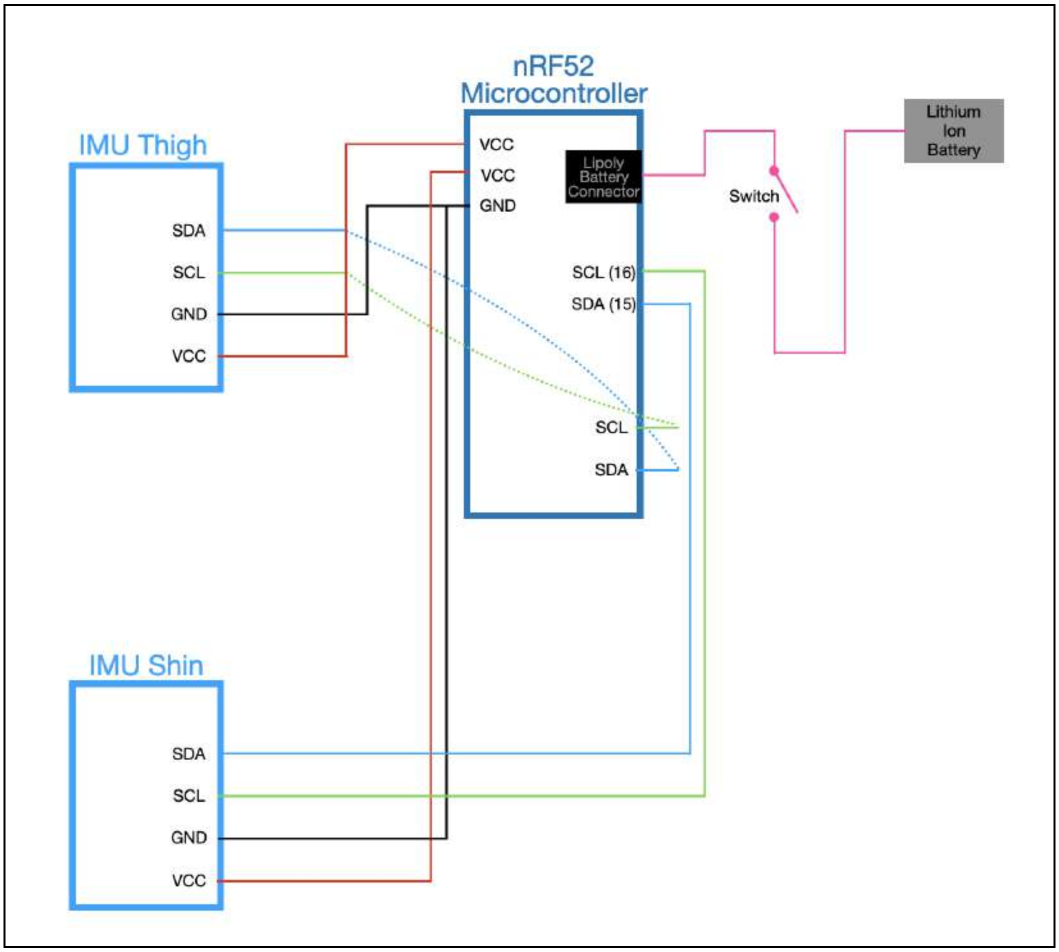



**Figure 18:** Circuitry of Knee Sleeve.

To optimize for user comfort and avoid additional sensor movement, we did not place any components on the inside of the knee sleeve, which may result in hardware movement if the user brushes against their other leg. Finally, to mitigate the risk of battery combustion, as discussed in the FMEA Summary section 3.6, we placed the battery behind the knee, where it is unlikely to undergo any high-pressure impact.

A second knee pad is sewn to the first, covering the hardware components. The purpose of the second layer, seen in Figure 19, is to contain and better stabilize the wires and hardware components, as well as for aesthetic purposes.


**Figure 19:** Knee Sleeve Component Hardware Design.

The use of electronic tape, the 3D printed cases, and the second knee pad layer were all design choices made to better stabilize the hardware components and assist in achieving ER5-1 (reliable knee angle output throughout use).

### 3.1.2 Knee Sleeve Software

Calculating knee angle from 2 IMUs is a nontrivial task. Even if we assume the knee is a 2D joint, computing knee angle requires some careful math. Each IMU contains both a gyroscope and an accelerometer; integrating gyroscope data alone is subject to significant drift over time, whereas accelerometer data alone is subject to noise [32, 33]. However, we can implement an algorithm that combines the two sensors to reduce drift and noise, using either a complementary filter or a Kalman filter [32]. First, we will describe how to obtain angle calculations from a gyroscope and accelerometer separately, then we will elaborate on how to combine the equations from the two sensors.

Computing angle from gyroscope data involves numerical integration:

$$\theta^{(t)}_{gyro} = \theta^{(t-1)}_{gyro} + \varpi\Delta t \tag{3.1}$$

where

$\theta^{(t)}_{gyro}$ is the current gyro angle about a given axis,

$\theta^{(t-1)}_{gyro}$ is the gyro angle from the previous time step,

$\varpi$ is the angular velocity about the same axis as $\theta^{(t)}_{gyro}$,

$\Delta t$ is the size of the time step.

Note that $\theta_{gyro}$ at t = 0 is not defined in this equation. When we implement Sensor Fusion, we use the accelerometer angle for t = 0, since that is accurate relative to Earth's reference frame. Calculating angle from an accelerometer requires us to define our reference frames as demonstrated in Figure 20.

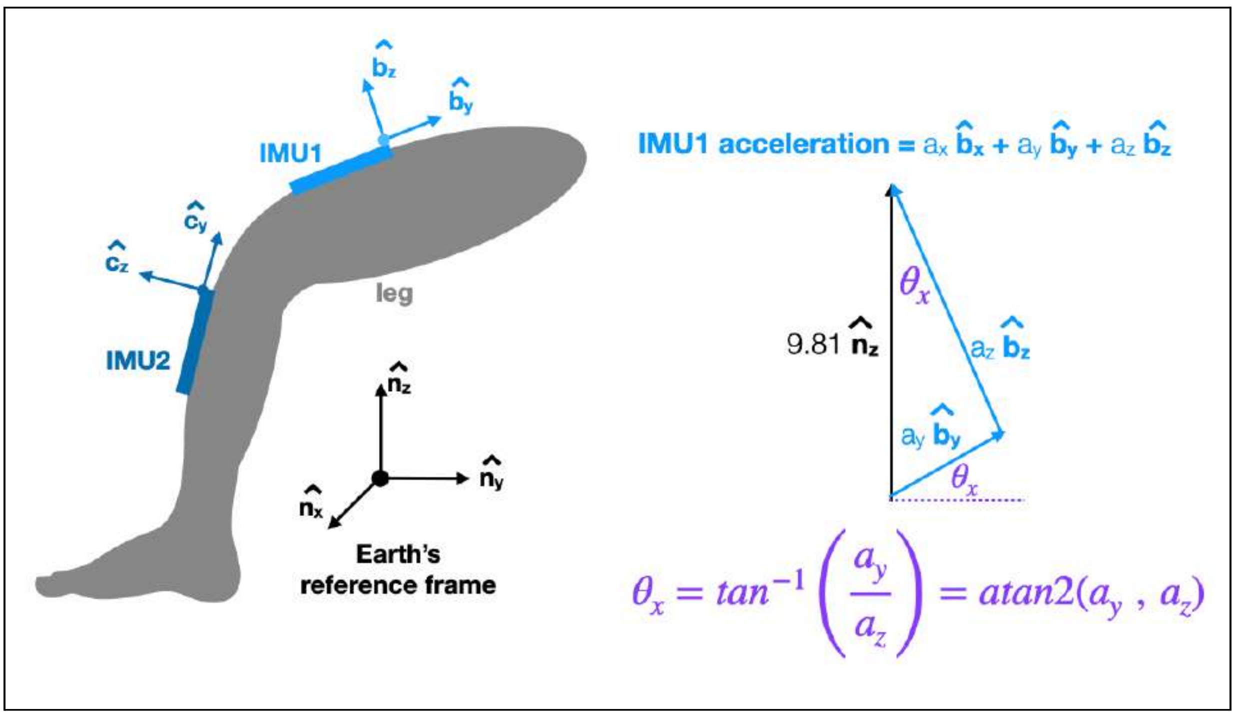



**Figure 20:** The diagram shows how the reference frames of Earth and the IMUs relate to each other in terms of angles and accelerometer values. An accelerometer with no external forces will measure 9.81 $m/s^2$ in the positive $n_z$ direction, which we can use to compute $\theta_x$.

Due to the design of accelerometers, when no external forces are present the resultant acceleration vector equals 9.81 m/s$^2$ pointing away from Earth's core. We can use this relationship to compute the angle of each IMU relative to Earth [32].

$$\theta^{(t)}_{x,\,accel} = atan2(a_y, a_z) \quad (3.2)$$

where

$\theta^{(t)}_{x,\,accel}$ is the angle between the IMU y direction and the Earth y direction,

$a_y$ is the IMU acceleration measurement in the IMU y direction,

$a_z$ is the IMU acceleration measurement in the IMU z direction.

From here, we can use a complementary filter to implement Sensor Fusion. We chose the complementary filter over the Kalman filter for now because a complementary filter is less computationally complex, so there are fewer hardware requirements [32, 34].

$$\theta^{(t)} = \alpha\,(\theta^{(t-1)} + \varpi\Delta t) + (1 - \alpha)\,\theta^{(t)}_{accel} \quad (3.3)$$

where

$\theta^{(t)}$ is the current angle between the IMU y direction and the Earth y direction,

$\theta^{(t-1)}$ is the angle from the previous time step,

$\varpi$ is the angular velocity about the same axis as $\theta^{(t)}$,

$\Delta t$ is the size of the time step,

$\theta^{(t)}_{accel}$ is the accelerometer angle about the same axis as $\theta^{(t)}$,

$\alpha$ is the weight parameter of the complementary filter.

Once we have the angles of both IMUs relative to Earth's horizontal, we can compute the knee angle by subtracting the thigh IMU angle from the shin IMU angle (equation 3.4), which is also illustrated in Figure 21.

$$\theta^{(t)}_{knee} = \theta^{(t)}_{x,\,shin} - \theta^{(t)}_{x,\,thigh} \tag{3.4}$$

where

$\theta^{(t)}_{knee}$ is the knee angle,

$\theta^{(t)}_{x,\,shin}$ is the x angle of the shin,

$\theta^{(t)}_{x,\,thigh}$ is the x angle of the thigh.

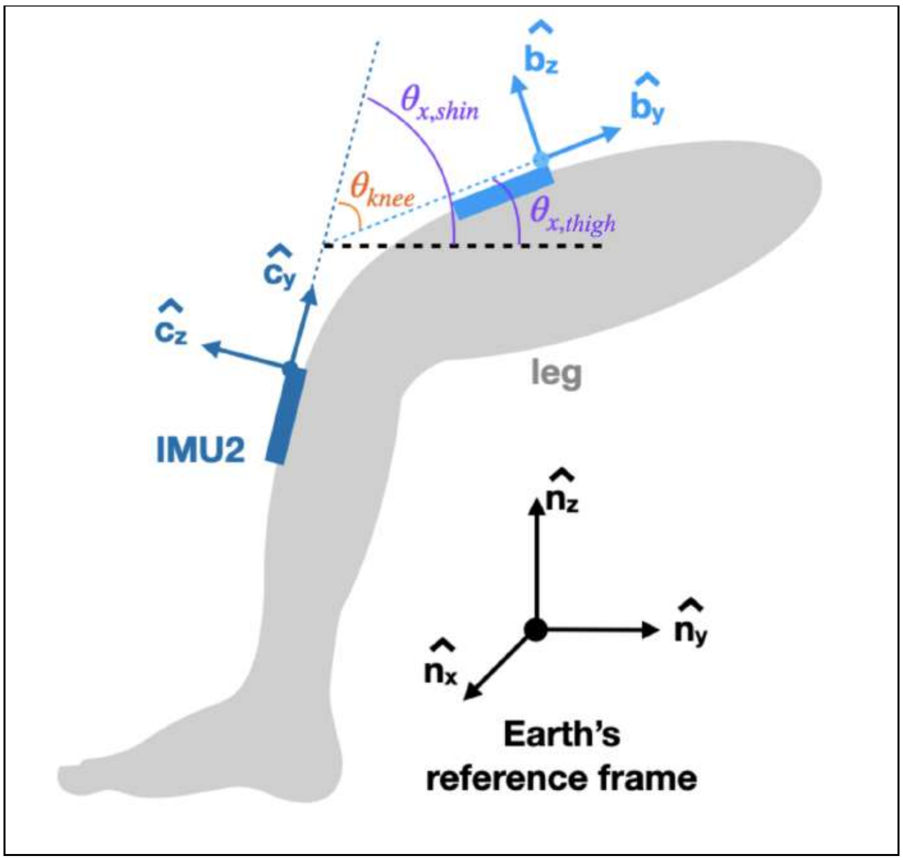



**Figure 21:** Diagram illustrates calculating knee angle from two IMU angles.

Our software implementation of this calculation can be found in GitHub [35].

## 3.3 Batteries

In order to select the properly sized battery for both the knee sleeve and footswitch, we performed a power consumption calculation to anticipate worst case power consumption. Table 2 contains the numbers gathered from the product specification sheets, which we use to perform our calculations.

**Table 2:** Electrical Component Specifications

| Specification | Value |
|---|---|
| Gyroscope operating current [36] | 0.0032 A |
| Accelerometer normal operating current [36] | 0.00045 A |
| MPU9250 supply voltage [36] | 3.3 V |
| nRF52832 CPU current use [37] | 51.6 μA / MHz * 64 MHz = 0.0033 A |
| Bluetooth peak current [37] | 0.0054 A |
| Adafruit nRF52832 LED current | 0.0033 A |
| Lowest resistance of foot sensor (measured) | 400 Ω |

We can calculate power consumption and subsequent battery capacity:

$$P = VI = V^2/R \tag{3.5}$$

$$E = Pt \tag{3.6}$$

where

$P$ is power,

$V$ is voltage,

$I$ is current,

$R$ is resistance,

$E$ is battery capacity,

$t$ is the time to drain all energy from the battery.

We can compute maximum power consumption for the knee sleeve, which contains 2 IMUs:

$$P_{knee\ sleeve} = V_{supply} * 2((I_{gyro} + I_{accel}) + I_{CPU} + I_{bluetooth} + I_{LED}) \qquad (3.7)$$

$$P_{knee\ sleeve} = 3.3V * 2((0.0032A + 0.00045A) + 0.0033A + 0.0054A + 0.0033A) = 0.064W$$

From equation 3.7 we see that the battery would need to supply 0.064W * 2hrs = 0.128Wh of energy according to ER4-2.

We can perform a similar computation for the footswitch, which contains a force sensitive resistor:

$$P_{footswitch} = (V_{supply})^2 / R_{sensor} + V_{supply} * (I_{CPU} + I_{bluetooth} + I_{LED}) \qquad (3.8)$$

$$P_{footswitch} = (3.3V)^2 / 400\Omega + 3.3V * (0.0033A + 0.0054A + 0.0033A) = 0.067W$$

From equation 3.8 we see that the battery would need to supply 0.067W * 2hrs = 0.134Wh of energy according to ER4-2.

We selected a 0.37Wh battery, which is larger than our required battery capacity, so the anticipated worst case battery life is 5.8 hours for the knee sleeve and 5.5 hours for the footswitch.

## 3.4 App

Our mobile app receives data from the nRF52 microcontrollers via Bluetooth, which it then translates into an audio output that can be heard by the user through the speaker on their phone. The app runs on an iPhone and is the point of interface for the user, allowing them to select from various gait modes and musical instruments. We built our app in the Objective C language to minimize latency (ER1-1) and allow for interface with the Faust Application Programming Interface (API). All of our code can be found on our Andante-ME170 public GitHub repository [35]. We also analyzed the latency of our software stack as it is an important technical requirement (ER1-1). There are three potential sources of latency in terms of music latency: event detection from the footswitch, iOS Bluetooth latency, and iOS music output (Faust, etc). The latency of a footswitch has been computed in previous literature, so we expect it to be 25ms [38]. From Apple's documentation, we anticipate the iOS Bluetooth latency to be 30ms [39]. From Faust documentation we expect music output latency to be 20ms [40]. Our total expected latency is 75ms delay from gait event to sound output. We later test this latency, as seen in Section 4.

### 3.4.1 Communication Protocol

The app incorporates Core Bluetooth, a framework in iOS that allows us to write custom Bluetooth communication with a peripheral device. To communicate with the knee sleeve and footswitch devices, we wrote code that uses the BLE protocol to receive bytes of data from the nRF52 microcontrollers [35]. Since we are able to manipulate data at the byte level, this allows us to customize the type of data we want to send and receive. For example, for some use cases, we chose to receive MIDI notes directly from the footswitch, which means the footswitch sends an encoding for a music note that then plays sound from the phone. However, the knee sleeve sends a knee angle instead of a note, and our app is able to parse that data differently since we wrote our own implementation for handling bytes from Bluetooth. All audio from the phone can be sent through Faust objects for further filtering before output; we recommend exploration of filtering options as a future step. The full signal chain is shown in Figure 22.

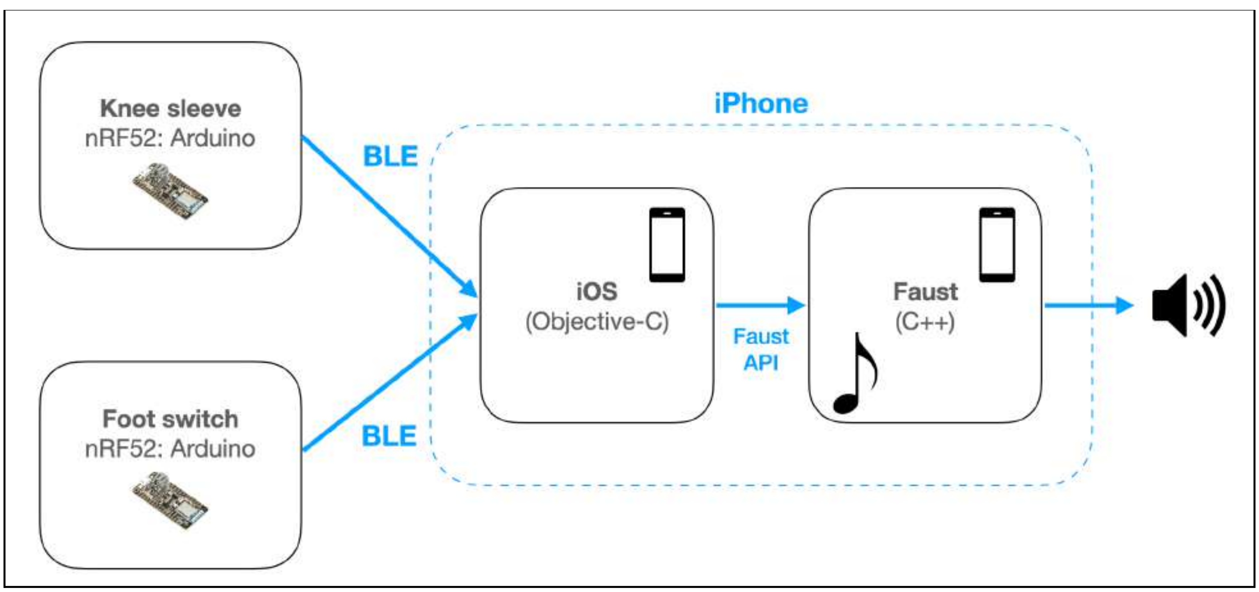



**Figure 22:** Full software stack in which components communicate through BLE (Bluetooth Low Energy).

### 3.4.2 Music Production

The app produces music in two different manners, providing musical design flexibility, which assists with ER3-1 (music follows functional harmony guidelines). The first is through the Faust API. Faust is a programming language for sound synthesis and audio processing that was developed at Stanford's Center for Computer Research in Music and Acoustics (CCRMA) and allows for real-time digital signal processing. For our specific application, the API allows us to translate Faust audio processing objects into the C++ programming language. Our other musical framework uses pre-recorded samples of instruments to allow for a wider variety of sounds. The app contains dictionaries with the wav files of instruments and drumkits that provide the user with musical variety (see Appendix G for catalog) as they can select any combination of instrument and drum kit. The two different manners of music production complement each other: Faust provides real-time audio processing, which enables us to apply filters based on the user's gait. The pre-recorded samples on the other hand allow for more musical variety, which assists in making the device more appealing for users from different backgrounds. In both musical implementations, MIDI notes are received by the app from the nRF52 microcontroller and translated to an object that plays audio data either from Faust or a wav file.

### 3.4.3 User Interface

Our app user interface shown in Figure 23 is designed to be intuitive for users.

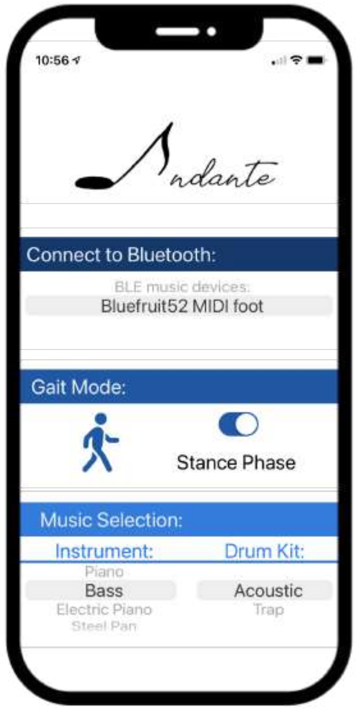



**Figure 23:** User interface of the app, designed to help users intuitively connect to devices, switch between gait modes, and select instruments and drum kits.

The interface controls are easy to access and understand. The UI includes a picker to connect to the microcontrollers through Bluetooth. To inform users of a successful Bluetooth connection, an audio cue is played. The gait mode section contains a switch that enables users to select from one of two gait modes, discussed in the Musical Implementation section (Section 3.5), to best suit their goals. The music selection section contains two pickers: one for an instrument and one for a drum kit. Users are able to select any combination of instrument and drum kit.

## 3.5 Musical Implementation

We worked closely with Dr. Rose and Dr. Schadl when designing for our two gait modes – swing phase and stance phase – and their respective musical implementations to ensure users could benefit from the device. In each mode, our device has potential to meet ER2-1 (statistically significant gait improvement).

### 3.5.1 Swing Phase Mode

Swing Phase Mode is geared toward individuals with stiff-knee gait. The purpose of this mode is to encourage rapid hip, knee, and ankle flexion in early swing phase. This mode, in its simplest form, utilizes a musical cue upon toe-off to prompt the user to rapidly flex their hip, knee, and ankle in order to clear their foot before the subsequent heel strike. To relieve the user of monotony while maintaining a simple system, one implementation uses a simple chord progression as seen in Figure 24.

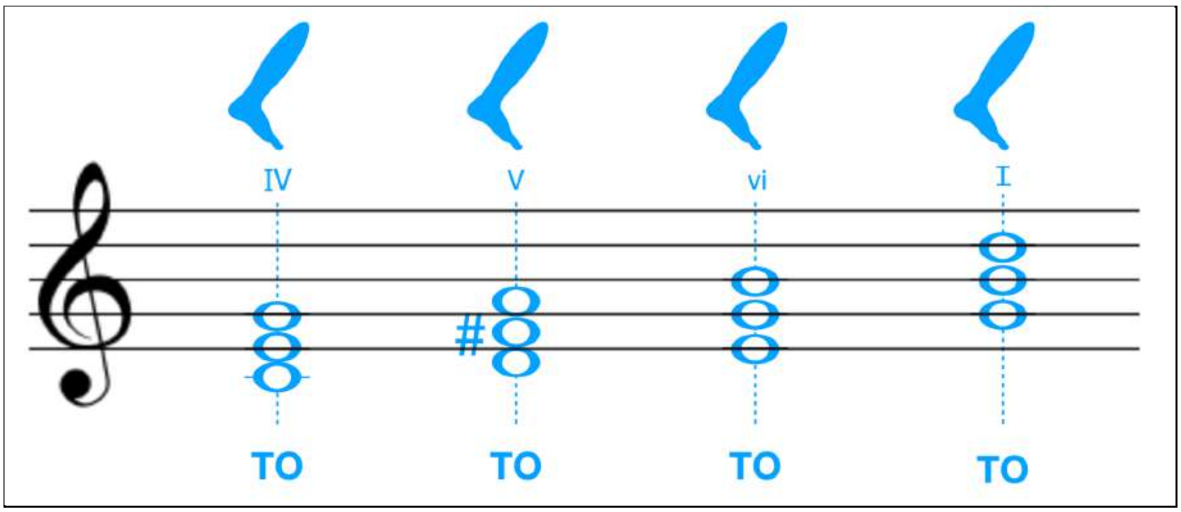



**Figure 24:** Swing Phase Chord Musical Implementation.

Another musical implementation involves a major scale, which is one of the most commonly used scales, especially in Western music. For this implementation, it is necessary to know not only when toe-off occurs, but also when initial contact occurs.

Through discussions with Dr. Rose and Dr. Schadl, we learned that patients with spastic CP would benefit from encouragement for proper toe-off timing. Toe-off occurs at 62% of the gait cycle in a typically presenting gait [4]. When an individual has stiff-knee gait, they will drag their foot, which often results in a longer stance phase as seen in Figure 25.

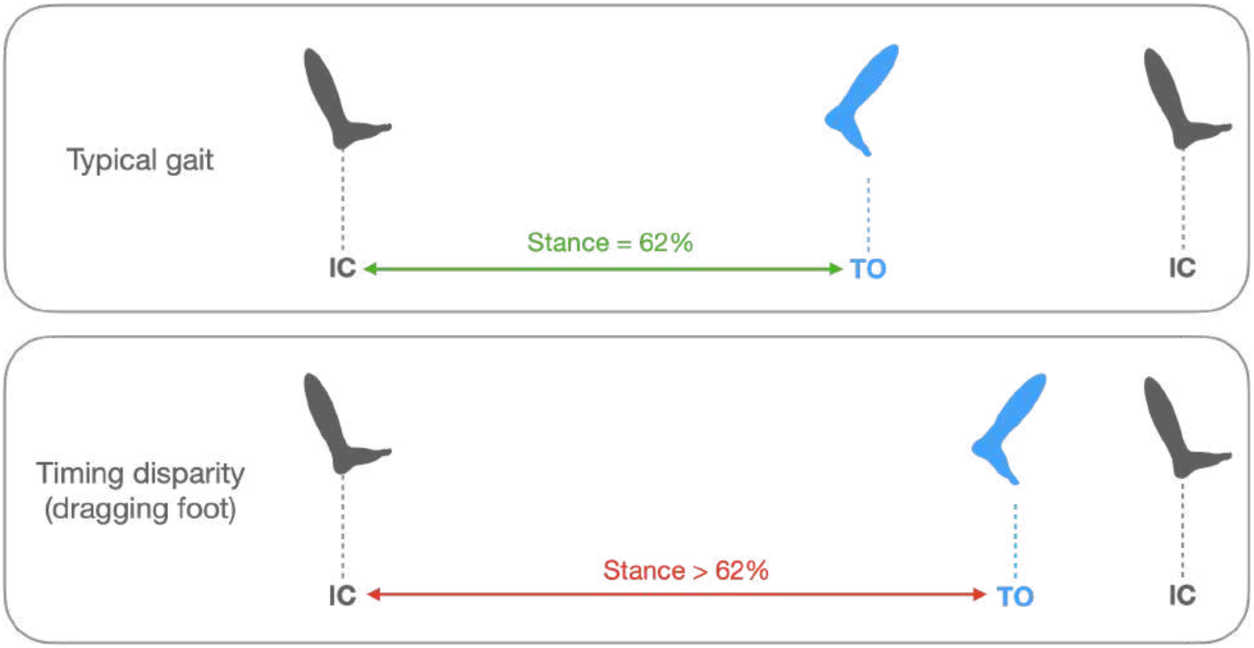



**Figure 25:** Timing of toe-off for typical gait (top) and for stiff-knee gait (bottom).

This information can be mapped to music with the help of a major scale, which is composed of eight notes. 5/8th of the scale is approximately equivalent to 62%, the moment in the gait cycle at which toe-off should occur. Because toe-off is mapped to the 6th note in the scale, the user is encouraged to lift their toe off the ground at that time with the guidance of music. If the user drags their foot, the music will be delayed and the 5th note will not be played at the proper time in the scale, as shown in Figure 26.

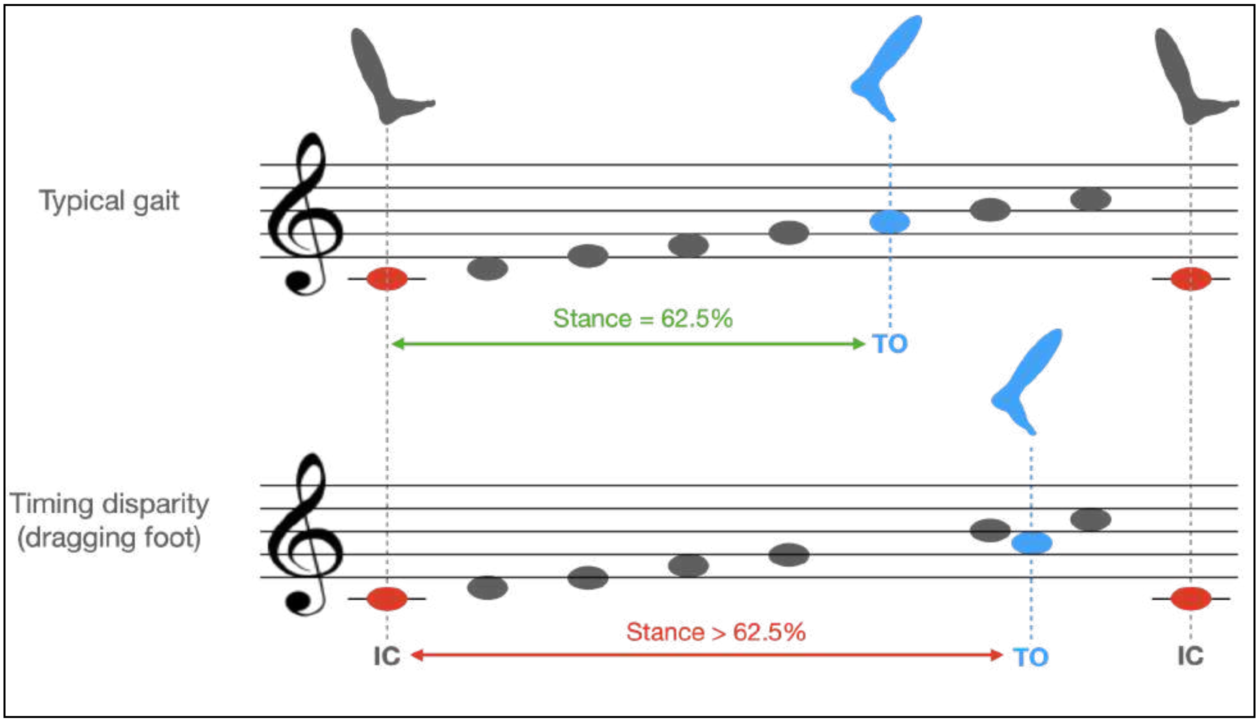



**Figure 26:** Toe-off major scale musical mapping for typical gait (top) and for stiff-knee gait (bottom).

Additionally, people with stiff-knee gait do not achieve enough knee flexion at the beginning of swing phase. To provide auditory feedback on knee flexion angle and encourage increased flexion, the starting note of the next scale is changed if the knee angle during swing exceeds a determined threshold. We can set this threshold to be 50°, which is the difference between max knee flexion during swing and average knee flexion during stance for typical gait [41]. Figure 27 illustrates the calculation for sufficient knee angle.

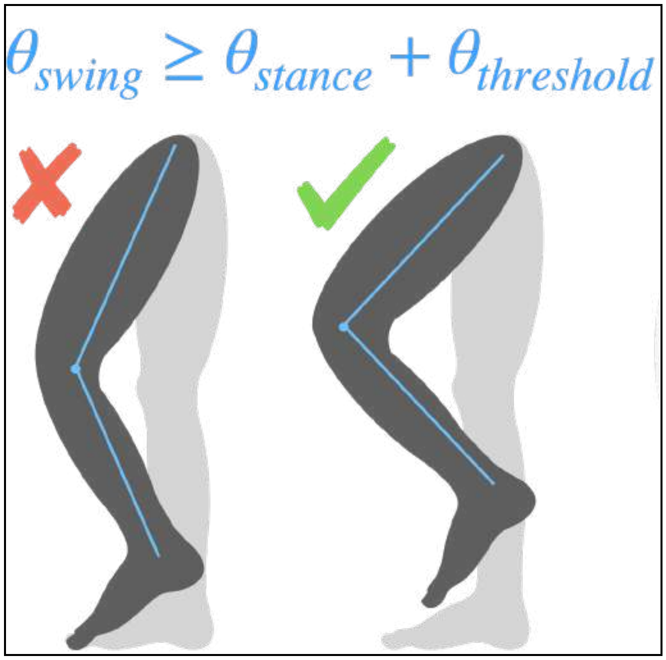



**Figure 27:** Left image shows insufficient knee flexion, whereas right knee shows sufficient knee flexion during swing. The sufficiency of knee flexion angle is determined by whether the peak angle during swing surpasses the average angle during stance plus a threshold angle.

In order to change keys in a consonant manner to keep the experience both dynamic and pleasing (ER3-1), we follow the Circle of Fifths (shown in Figure 28), a Western theory standard for modulating through all 12 keys [42].

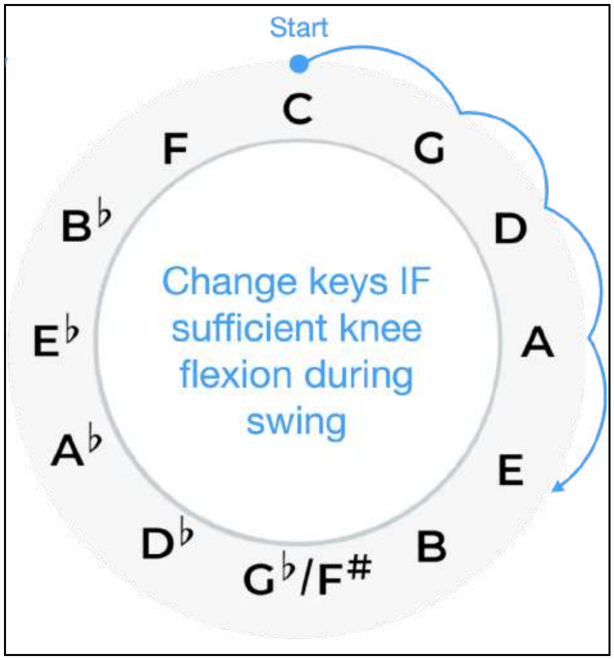



**Figure 28:** Circle of Fifths.

This positive reinforcement encourages individuals with stiff-knee gait to increase their knee angle during swing phase without being too punishing if the threshold is not reached. If the threshold is not met, the starting note of the scale will remain the same, leaving the user with a constantly repeating scale until they meet the threshold for proper knee flexion.

### 3.5.2 Stance Phase Mode

Stance Phase Mode is an adaptation of Rhythmic Auditory Stimulation aimed toward helping users keep a consistent pace, which has been shown to improve measures including stride length and stride frequency (ER2-1), and motivating increased physical activity, including repeated practice of at-home physical therapy exercises. Any song can be stored as a melody, chord progression, and drum loop, with downbeats triggered by each initial contact event, as seen in Figure 29.

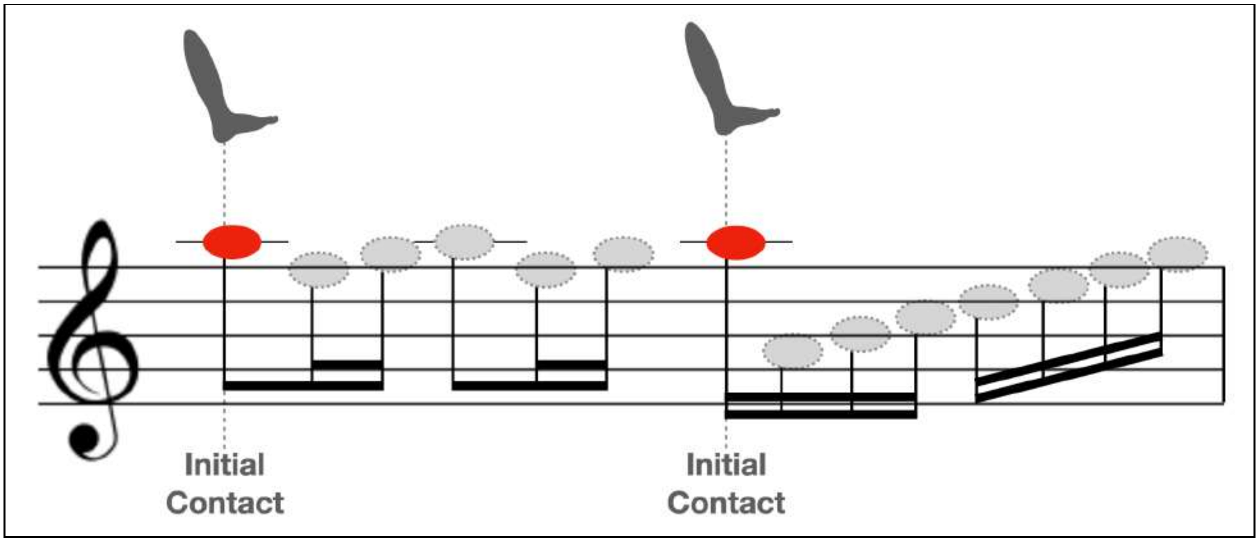



**Figure 29:** Stance Phase Mode melody triggered by initial contact events.

Upon each initial contact event, a beat is triggered containing eight notes or rests evenly distributed throughout that beat. The tempo is determined by the user's stride frequency, which is captured during their first four steps and constantly updated as a moving average of their most recent four steps. This allows the music to speed up or slow down with the user, helping to avoid tripping hazards introduced if the user were required to keep a rigidly constant tempo.

We intend for this solution to address ER2-1 (statistically significant gait improvement) in two ways: the constant rhythm encourages a consistent stride frequency and the progressing melody and chords reward the user for each step taken.

## 3.6 FMEA Summary

To identify and mitigate risks surrounding reliability and safety, we conducted Failure Mode Effects Analysis (FMEA) for several potential failure modes.

The biggest concern brought about through our FMEA analysis was the combustion of our battery due to a puncture from a user falling on the device or battery impacting case during movement. We made design changes based on our FMEA because this is a safety critical issue. During walking, the ground reaction peak force can reach approximately 1.47 times body weight [8]. The 90th weight percentile of a person in the US is 110.7 kg [43] and during walking, the ground reaction peak force is 1.47 time body weight [8], so if we want to ensure that the battery case on the footswitch or knee sleeve will not break under maximum force, it must be able to withstand a 1600N calculated in equation 3.9.

$$walking\ ground\ reaction\ peak\ force\ *\ mg\ =\ F \tag{3.9}$$

$$1.47\ *\ 110.7\ kg\ *\ 9.81\frac{N}{kg}\ =\ 1596.37\ N$$

As a design control, we created a hardshell case made from PLA, which has a yield strength of 70MPa, to protect the battery from this force. We modeled the cases on CAD and then performed FEA tests to determine how well the battery would be protected if a user were to fall on the device with a distributed load of 1600N.

Figure 30 illustrates the FEA analysis for the footswitch battery case modeled with a distributed load of 1600N on the top surface to simulate someone falling on the device.

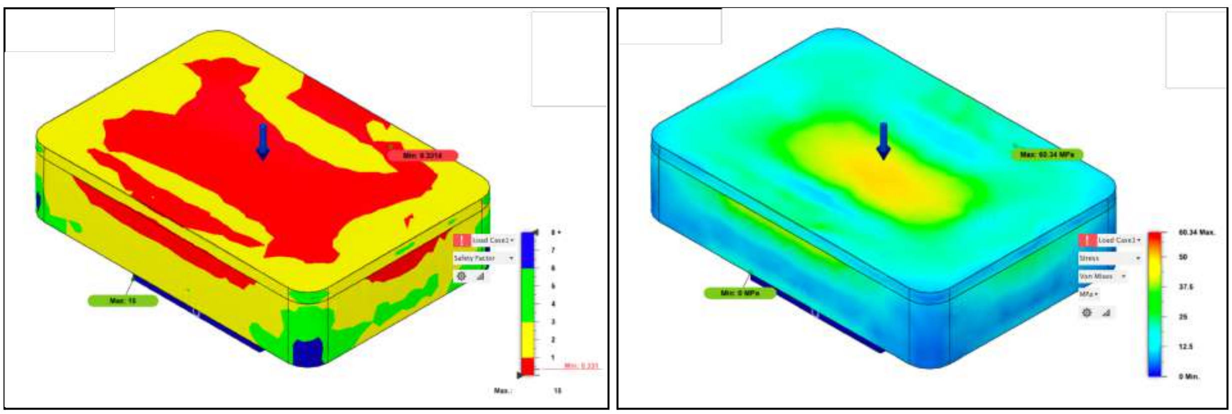


**Figure 30:** FEA Analysis of Footswitch Battery Case modeled with 1600N: Min/Max Factor of Safety (left) and Von Mises Stress Analysis (right).

Although the Von Mises stress is 60.34MPa and thus under the yield strength of the PLA material, this FEA analysis shows that the case will permanently bend or break under this load as the minimum factor of safety of the case is 0.331. Similarly, Figure 31 shows the PLA knee sleeve battery encasing, again with a distributed load of 1600N.

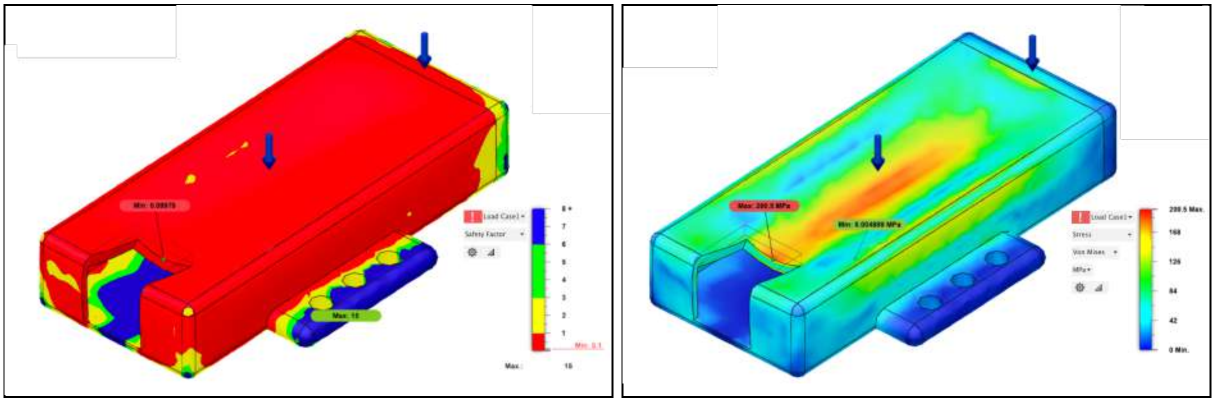



**Figure 31:** FEA Analysis of Knee Sleeve Battery Case modeled with 1600N: Min/Max Factor of Safety (left) and Von Mises Stress Analysis (right).

These results show the casing breaking or permanently bending as the minimum factor of safety is 0.09975 which is extremely low. Additionally the Von Mises stress if the case is 200.5MPa which is well above the 70MPa yield strength of PLA. From this, we concluded that the PLA material we are currently using is not strong enough to support one of our potential failure modes. Thus, we should modify the material of our device to ensure that the combustion of the battery will not occur due to heavy impact. For the purpose of this course, we used PLA. For future work, we recommend using a lightweight metal such as aluminum.

However, we still wanted to ensure that the battery would not combust during our preliminary testing. The risk case we were most worried about was a user tripping and falling directly on the battery. We identified that the user would likely fall on the front of the knee sleeve if they were to trip. As a result, we moved the battery case to the back of the knee sleeve since it is much less likely for a user to fall directly on the back of their knee.

Another potential risk we identified was the disconnection of wires due to weak soldering joints on the device. In our initial prototypes, the wires that were used were quite thick and caused a large shear force that ultimately resulted in the solder joints weakening over time and occasionally disconnecting. This is a user-inaccessible repair and thus a big risk. To prevent this, we used 30 AWG Silicone coated stranded wire. This was the smallest thickness of stranded wire found online. Using the thinner wire decreases the shear force on the solder joints and thus reduces the likelihood of disconnection.

Although we incorporated other potential failure modes in our FMEA, as seen in Appendix C, these were primarily covered by our technical requirement testing.

# 4. Tests, Results, and Discussion

## 4.1 Testing setup

We designed and performed tests in order to verify that our device meets our user and technical requirements. Here we first present how the tests were set up, then present the results in the next subsection.

### 4.1.1 Latency

Our objective for this test was to verify that the latency from gait event to music is less than 150ms as defined in ER1-1. To set up this test, we used a slow-motion camera to film the device in action, using an LED to indicate gait event detection. We also programmed the phone app to print a statement upon receiving the Bluetooth signal so that we can observe the Bluetooth latency. Upon capturing slow-motion video, we analyzed the recordings by counting the frames of separation and multiplying the value by milliseconds per frame.

### 4.1.2 Angle Accuracy

Angle accuracy testing was performed to ensure ER1-2 (knee angle within 5 degrees of reality). Images were captured as the test subject walked. Measurements were taken as the subject's leg swung both forward and backward to ensure there is no hysteresis effect. Each image was analyzed to determine the knee flexion angle reality as shown in Figure 32. Each angle from these images was compared to its corresponding knee angle output from our knee angle algorithm that used IMU data.


**Figure 32:** Calculation of knee flexion angle from image.

### 4.1.3 Wireless

This technical requirement did not require any specific testing, since our design ensures the device is wireless. We used Bluetooth communication and rechargeable battery power to enable a wireless device. Figure 33 demonstrates the wireless system.

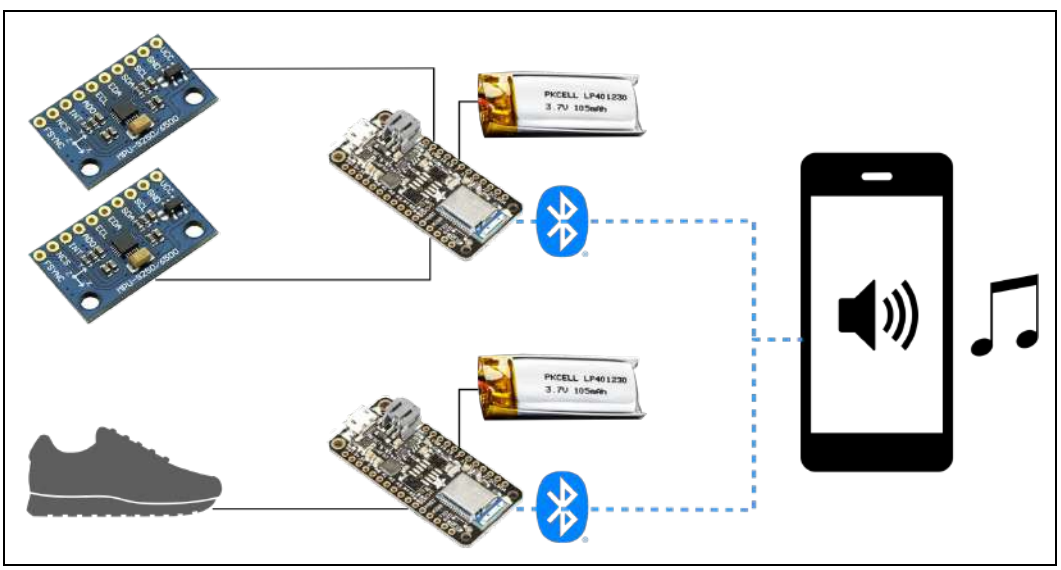



**Figure 33:** Wireless system with Bluetooth communication and battery power.

### 4.1.4 Battery

From calculations performed in Section 3.3, we expected battery life to exceed 5 hours. We tested this by running our battery until failure. We first charged the battery fully, then attached it to the microcontroller, then connected the device to the phone app via Bluetooth and let it run continuously until the battery drained. The code contained a command to illuminate an on-board LED light while the battery supplied sufficient power, which allowed us to monitor when the battery ran out of charge.

### 4.1.5 Reliable Output over Time

To ensure the reliability of the data from the knee sleeve, we set the technical requirement that the device should survive two hours of use without statistically significant deviations in knee angle output (ER5-1).

Therefore, we had to verify that the knee angle readings have statistically similar values after two hours of use. In order to test this, we collected knee angle readings from the IMUs on the knee sleeve as our test subject walked one cycle of the gait cycle. The test subject then walked around for two hours with the knee sleeve on their leg. After this two hour period, we collected knee angle readings from the IMUs again as the same test subject walked another cycle of the gait cycle.

### 4.1.6 Size

Since we intend for the device to be portable for personal daily use outside of a clinical setting (UR4), we set the maximum thickness of our device to be 15mm (ER4-3) based on consumer electronic devices [29]. In order to test this, we simply measured the nominal thickness in CAD and accounted for manufacturing tolerances.

### 4.1.7 Enjoyability

We also wanted to test user enjoyability and motivation of our device. We conducted user testing with 5 individuals who have typical gait. Subjects wore the device for 20 minutes and tested the different modes and musical implementations. The first two musical implementations were in swing phase mode in which users experienced chords at toe-off or a major scale guided by toe-off (further explained in section 3.4.1). The last test was the stance mode application in which users tried to keep a consistent stride frequency with their heel strike (further explained in section 3.4.2). Users ranked these modes on a 1-5 scale of enjoyability and motivation.

## 4.2 Results

In the following sections, we provide the results from our technical requirement testing.

### 4.2.1 Latency

First, for latency our sample means from testing are as follows: 13ms for the footswitch, 38ms for iOS Bluetooth, and 20ms for iOS music output (seen in Table 3 and Figure 34).

**Table 3:** Latency Test Results

| | **Footswitch event detection** | **iOS BLE** | **iOS music / Faust** | **combined** |
|---|---|---|---|---|
| Expected latency from documentation or literature (ms) | 25 | 30 | 20 | 75 |
| **Sample mean of latency (ms)** | **13** | **38** | **20** | **71** |
| Sample standard deviation (ms) | 6 | 5 | 5 | 9 |

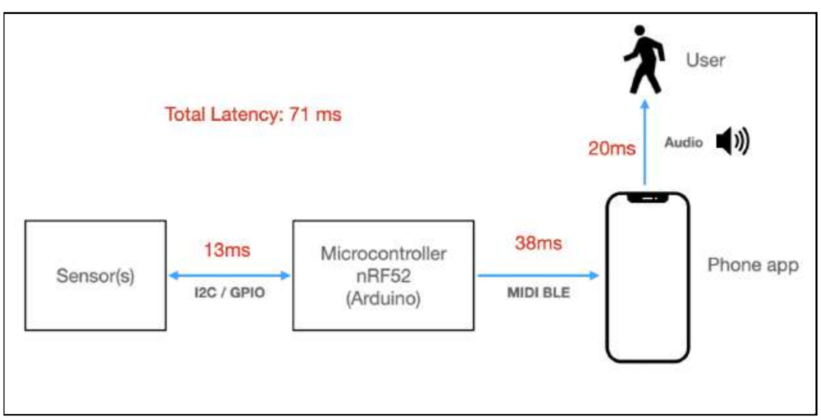



**Figure 34:** Latency Diagram: there are 3 sources of latency. Latency between gait event and software detection is 13ms, BLE latency is 38ms, and audio latency is 20ms.

The total latency sums to 71ms total, which is very close to our expected latency of 75ms. We are comfortable with this performance since our testing results show a latency of less than half of our technical requirement of 150ms.

### 4.2.2 Angle Accuracy

The average difference between actual and calculated knee angle was 3.85°, shown in Table 4, which is less than 5°, so we have met our technical requirement for angle accuracy.

**Table 4:** Angle Accuracy Results

| Measurement Number | Angle from Sensors and Knee Angle Algorithm | Angle from Image | Magnitude of Difference |
|---|---|---|---|
| 1 | 46.8° | 44° | 2.8° |
| 2 | 30.4° | 31.5° | 1.1° |
| 3 | 57.3° | 61.5° | 4.2° |
| 4 | 12.6° | 5.5° | 7.1° |
| 5 | 55.5° | 58° | 2.5° |
| 6 | 37.5° | 32° | 5.5° |
| 7 | 26.4° | 23° | 3.4° |
| 8 | 43.5° | 48° | 4.5° |
| 9 | 64.8° | 71° | 6.2° |
| 10 | 7.2° | 6° | 1.2° |
| **Average Angle Difference** | | | 3.85° |

### 4.2.3 Wireless

Each time we operated the device, we demonstrated successful operation of wireless communication.

### 4.2.4 Battery

The tested sample comfortably exceeded 5 hours of continuous use, after which we stopped monitoring the test unit since this was far above our technical requirement of two hours.

### 4.2.5 Reliable Output over Time

The reliability test compared knee angle output before and after two hours of usage. Dynamic time warping (DTW) was used to compare the two data sets. Dynamic Time Warping is an algorithm used to measure two temporal sequences that may have varying speeds, which is commonly used in gait analysis [44]. This algorithm maps two different sequences onto a single plot where the walking speed is ignored. Therefore, if the two sequences follow a similar trajectory in a dynamic time warping graph, then the data from these two sequences are similar after standardizing the plot for walking speed. From Figure 35, it is apparent that there is no significant shift in angle readings after the test subject uses the device for two hours thus satisfying our technical requirement (ER5-1).

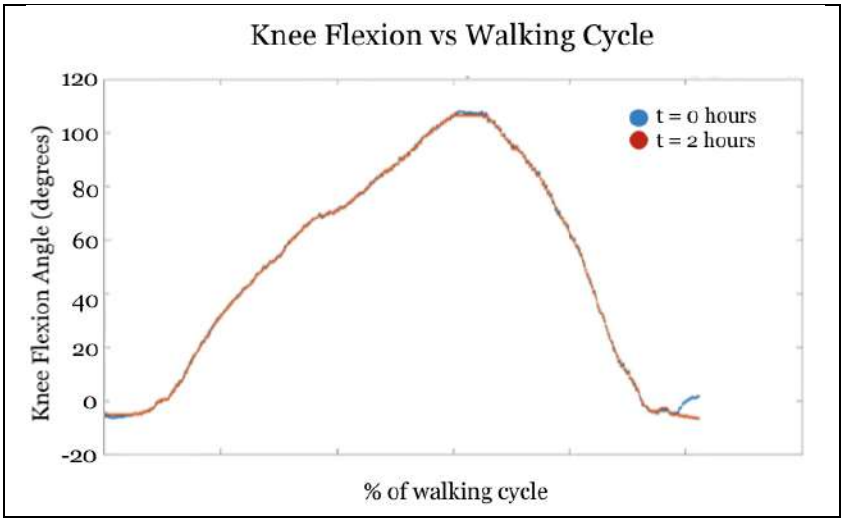



**Figure 35:** DTW on knee flexion vs % gait cycle at t = 0 hours and at t = 2 hours. There is no noticeable offset between the curves, indicating similar angle output for both scenarios.

### 4.2.6 Size

Regarding size, we verified that both the footswitch battery case and the knee sleeve nRF52 hardware case were under our 15mm technical requirement (ER4-3) as these were the thickest components on our design. Figures 36 and 37 show the nominal CAD dimensions for the thickness of the footswitch and knee sleeve cases, which are 13mm and 12.25mm respectively.

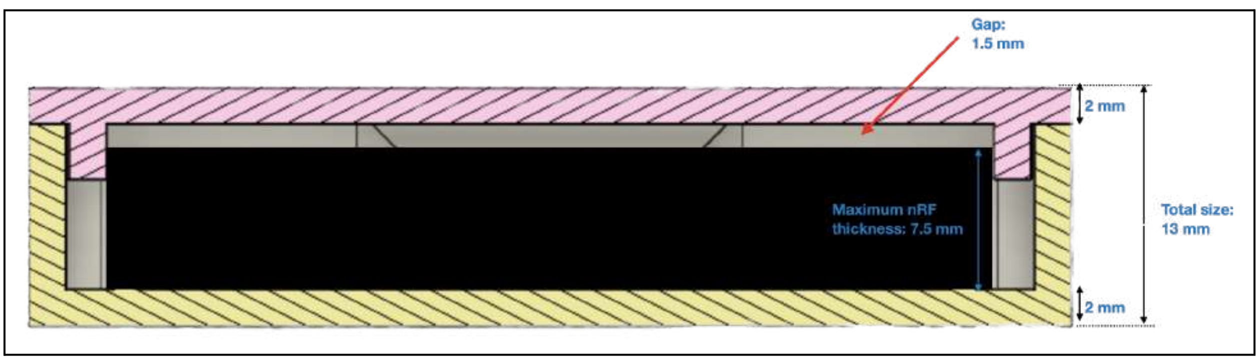



**Figure 36:** Cross-sectional view of footswitch battery case. Total thickness is 13mm ±0.25mm which is less than our max 15mm from ER4-3, demonstrating that the ER has been met.

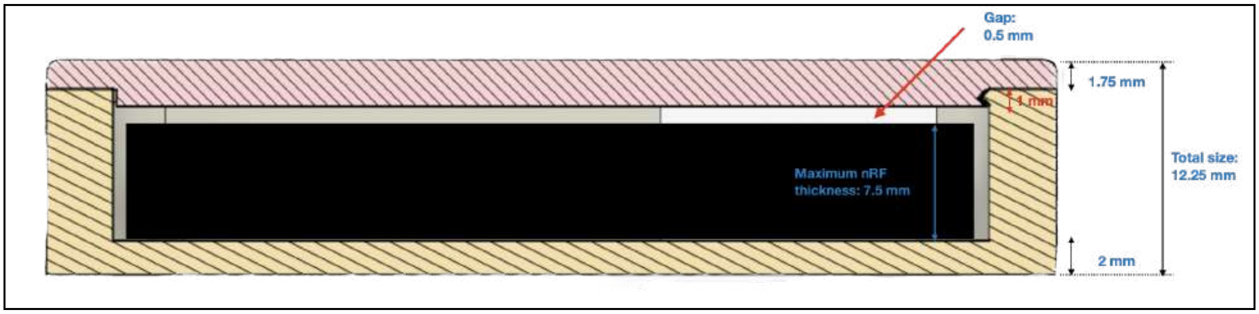



**Figure 37:** Cross-sectional view of knee sleeve nRF52 hardware case. Total thickness is 12.25mm ±0.25mm which is less than our max 15mm from ER4-3, demonstrating that the ER has been met.

If this device eventually becomes mass produced for consumption, the casing should either be CNC-machined or injection molded; even after accounting for potentially large manufacturing tolerances of ±0.25mm, our design is still within the 15mm technical requirement [45].

### 4.2.7 Enjoyability

The results of user enjoyability testing can be seen in Table 5. On average, users ranked enjoyability at 4.6 and they ranked motivation at 4.2. These numbers suggest that our device provides significant motivation and enjoyability (ER3-1) to encourage increased walking, potentially leading to improved gait performance.

**Table 5:** User Testing Results

| Test Subject | Enjoyability | Motivation |
|---|---|---|
| #1 | 5 | 4 |
| #2 | 4 | 3 |
| #3 | 5 | 5 |
| #4 | 5 | 5 |
| #5 | 4 | 4 |
| **average** | 4.6 | 4.2 |

#### 4.2.7.1 Qualitative User Feedback

Users enjoyed the device and found it motivating to continue to practice these repetitive exercises. Individuals found it especially enjoyable that their movements would generate such interesting sounds and that they could adjust so many different aspects of the music through our app. Users especially found the stance phase mode enjoyable as they recognized the song and were generating the melody with each step.

We were also able to receive feedback on our device and ways in which we could improve user enjoyment. Some of our subjects found that resetting the Arduino between different modes was a hassle and diminished the enjoyment of the experience. As a result, we added a battery switch so that the user can easily turn the device on and off to reset the Arduino. Additionally, it allows the user to save battery by turning the device off when it is not in use. Some of our users were nervous to try the knee sleeve on as our first iteration showed a lot of the visible hardware and subjects worried about breaking some of the hardware components when putting the sleeve on. As a design change, we added an overlaying cover to the knee sleeve that not only protects and holds the hardware further in place but also provides added comfort to the user and improves the aesthetic of the device. Once we added this overlaying cover, subjects said they would be more likely to use the device out in public as it looks like a simple compression sleeve (shown in Figure 38) that many athletes use daily.

**Figure 38:** Test Subject wearing device with overlaying knee cover.

Additionally, all 5 test subjects were unsure about when the Bluetooth of the device was actually connected. The only way to tell was by looking at the microcontroller to see if a blue light was lit up. However, this light was not visible through the encasings. Therefore, we added an audio sound to indicate when the Bluetooth connection of each device was successful.

We were also able to get feedback on our device from an individual with stiff-knee gait who watched video demonstrations (seen in Appendix I) of our device in action. This subject claimed that "music always helps me move and walk." She also emphasized the importance of making sure the music has a melody as well as rhythm. Overall, the subject really enjoyed our device and is looking forward to the future applications of music that our device offers. We recommend collecting more feedback from users with atypical gait who test our device in the future.

## 4.4 Discussion

As seen in the previous tests, our device comfortably meets the testing requirements for our high priority user and technical requirements. Compared to the limits set by our technical requirements, the device has low latency, accurate knee angle readings, wireless design with good battery life, reliable sensor outputs, portable size, and enjoyable music.

However, there is one technical requirement that was not discussed: we were unable to test ER2-1, which involves whether the device statistically significantly improves users' gait. We initially wanted to access the gait lab at Stanford and test the device on patients over a prolonged period of time, but due to time constraints and COVID-19 restrictions, we were unable to do this. We recommend this testing be done in the future, as it is important to verify the benefit of the device. Otherwise, we are comfortable claiming that the device meets our desired performance. See Table 6 for a summary of our engineering requirements testing and results.

**Table 6:** Engineering Requirements Testing Summary

| User Requirement | | Engineering Requirement | | Testing Results | Requirement Met |
|---|---|---|---|---|---|
| UR1 | Generate music as users walk--let them make music through movement | ER1-1 | If focusing on initial contact point, music produced from step event should occur within 150ms of actual event | 71ms < 150ms | ✓ |
| | | ER1-2 | If focusing on knee angle: measurement of angle has a precision of $\pm$ 5 degrees | 3.85° < 5° | ✓ |
| UR2 | Improve gait for people with spastic cerebral palsy | ER2-1 | Statistically significant improvement towards typical gait | N/A | Future Step |
| UR3 | Enjoyable and satisfying musical interaction | ER3-1 | Music produced should follow functional harmony guidelines and be enjoyable/motivating to users | Enjoyability: 4.6/5<br><br>Motivation: 4.2/5 | ✓ |
| UR4 | Device can be used at home for personal daily use. | ER4-1 | Wireless | Demonstrated in operational testing | ✓ |
| | | ER4-2 | Battery-powered (rechargeable), lasting over two hours of continuous use | At least 5 hrs. > 2 hrs. | ✓ |
| | | ER4-3 | Extend no more than 15mm from skin | 12.2mm and 13 mm < 15mm | ✓ |
| UR5 | Device must output consistent sensor data over the duration of use. | ER5-1 | During use, demonstrate no significant deviation in knee flexion angle after two hours | No significant deviation of knee flexion vs. walking cycle after 2 hrs | ✓ |

# 5. Conclusion

Individuals with spastic CP commonly experience gait disorders of stiff-knee gait and flex-knee gait. Stiff-knee gait occurs when there is insufficient hip, knee, and ankle flexion in the swing phase of gait – a common cause of trip and falls. Flex-knee gait is characterized by an overly bent or flexed standing leg and can lead to fatigue due to excessive energy expenditure. Gait therapy for patients with spastic CP and other gait-related disorders can be significantly augmented by a musical system that provides auditory cues and feedback to assist with a variety of gait training goals. Therapies often comprise timed auditory cues; such as a repeated verbal reminder from a physical therapist at a crucial point in the gait cycle. To this end, we have designed a flexible hardware and software system which can be adapted to replace or augment a therapist's auditory cues as well as provide other feedback. In addition to encouraging users to continue therapy exercises at home with high repetition, the device offers precise and automatic feedback, which can relieve the therapist of their role as cue-giver, allowing them to provide more holistic feedback on their patient's gait.

Our hardware comprises two main components: a footswitch to detect gait events and a knee sleeve to measure knee flexion angle, each of which communicates with our mobile app via Bluetooth. The footswitch contains a padded insole with embedded force-sensitive resistors connected to a microcontroller to capture precisely-timed gait events such as initial contact and toe-off. The knee sleeve uses two inertial measurement units, one above and one below the knee, to accurately measure knee flexion angle at any given time. These hardware components work together with the software to generate music from the user's gait.

Our system currently contains two modes of gait training, each of which targets a unique aspect of the gait cycle and has its own musical implementation. Swing Phase Mode is designed for individuals with stiff-knee gait. In this mode, the device gives a musical cue upon toe-off as a reminder to the user to rapidly flex their hip, knee, and ankle in order to clear their foot before the next step. Stance Phase Mode is aimed toward helping users keep a consistent stride frequency and motivate increased physical activity, including repeated practice of at-home physical therapy exercises. This mode plays a rhythmically-timed melody, chord progression, and drum loop where downbeats are triggered by initial contact events. This encourages a consistent stride frequency and rewards the user for each step taken. These musical implementations are preliminary approaches based on insight from Dr. Rose, and we intend for in-lab use and testing to inform further applications of our system.

We have successfully built and demonstrated a functioning device that satisfies our high priority technical requirements, namely latency, accurate knee angle reading, musical enjoyability, wireless, rechargeable battery-powered, portably-sized, and reliable knee angle output throughout use. We performed testing on these requirements and confirmed that the device performs as required. However, we could not perform gait testing on patients with CP (another high priority technical requirement) due to time constraints and COVID-19 restrictions, so we recommend that future developers will further test this device in a medical context. From our user testing, we received positive feedback that users enjoyed the device and found it motivating for practicing repetitive exercises. Individuals found it especially enjoyable that their movements would generate different melodies at varying speeds and that they could adjust so many different aspects of music through our app. We also recommend future developers will build off the framework we have developed the past two quarters by developing the app for Android, improving software design, and reducing the cost of the hardware implementation. Following further testing of the various musical options offered by our framework, we are optimistic that our system has the potential to improve the gait of individuals with spastic cerebral palsy.

By creating a musical software and hardware system aiming to impact the gait performance of individuals with gait-related disorders, we invoke questions of beneficence, nonmaleficence, and financial and cultural accessibility. While developing a system to reduce tripping hazards by encouraging rapid hip, knee, and ankle flexion in early swing phase, we must be sure not to introduce any new tripping hazards. This and other considerations of the implications of our design features, alongside Dr. Rose's guidance, informed design changes to ensure that we are not introducing any potential to injure a user or cause a deterioration in gait performance. Although our goal is for anyone who could benefit from using our device to be able to use it regardless of their socioeconomic status, our hardware sums to $200 in our current working prototypes. In order to avoid presenting a significant financial barrier for users hoping to improve their gait or augment their therapy, we intend for hospitals to own several devices to check out to patients. Additionally, we present hardware cost reduction as a high-priority next step for future developers. Due to time constraints, we have thus far only developed an app for iOS, as we ran into latency issues with Android audio. This again informs a significant next step for future developers – building out an equivalent system for Android in order to enable up to 99% of smartphone users to use our app [30]. To enable our system to play any style of music from different cultures, we built out a system which can play any sampled instrument and any melody within the Western chromatic (12-note) scale, supporting our goal of making gait training more engaging for people of all backgrounds.

# 6. Future Work

The framework we have developed can be expanded upon in the future. The most important next step is to test the device on individuals with CP in a gait lab. This would involve examining the efficacy of the gait modes we have created to determine how the device can best be used for gait improvement. On the platform side, next steps are to develop the app for Android as well as build a larger song and genre catalog. In terms of hardware the main priority is to reduce the cost so the device can be more accessible to potential users.

## 6.1 Testing on Patients with Spastic CP

The highest-priority next step is for our device to be tested on patients with CP in a gait lab, which we were not able to conduct due to time constraints and COVID-19 restrictions. This testing would assist with determining how the device can best contribute to gait improvement. It would involve examining the efficacy of the two gait modes we have created and verify the medical benefit of the device. The study would divide participants into a control and intervention group. Individuals in the control group would be asked to go about their regular routine while individuals in the experimental group would be encouraged to use our device. After 8 weeks, participants' gait would be reevaluated. For the Swing Phase Mode, this involves examining knee flexion angle at the beginning of swing phase and the percent of the gait cycle at which toe-off occurs. In the Stance Phase Mode, this involves examining knee range of motion and stride frequency. We will then compare the percent improvement in the gait parameters between the experimental and control groups. Our proposed study, seen in Appendix H, has been modeled off of other gait studies and with the input of Dr. Rose.

## 6.2 Development

Due to timeline constraints, we prioritized gait therapy functionality and thus left some software development as future work. Notably, we think future developers should develop for Android, utilize SoundFont files, and enable two-way Bluetooth communication. Developing for Android is important for accessibility, since Android devices account for 72% of the market share for mobile phones [30]. Additionally, we would like future developers to investigate using SoundFont files for better storage of audio files. A SoundFont is a file that contains an array of 128 audio files, allowing for much more compact code when reading and playing these files. Furthermore, we think it is crucial to enable two-way Bluetooth communication. Currently, the knee sleeve and footswitch devices can send Bluetooth data to the phone, but they cannot yet receive data back from the phone. Enabling two-way communication would allow the user to trigger a change in song from the app alone. Alternatively, another solution is to use the knee sleeve and footswitch as devices that send data only, allowing the app to toggle music without requiring two-way Bluetooth communication. This is perhaps the more robust implementation, but it requires much of the music generation algorithm that is currently written in Arduino to be rewritten in Objective C for the phone app.

## 6.3 Features

We have many ideas for further musical development, addressing potential gait therapy for folks with various gait training goals, as well as for more robust or efficient control within the systems we have already created. In Table 5 we list some of the most important next steps for future developers.

**Table 7:** Future Work Features

| Area of Development | Feature |
|---|---|
| App | Wider range of sampler instruments, representing a range of genres and cultures |
| Footswitch Stance Mode | Wider range of songs, representing a range of genres and cultures |
| Footswitch Stance Mode | 2 independent melodic voices (bass, lead); 2 independent harmonic voices (chords, i.e. guitar, piano) |
| Footswitch/App | Single repeated note upon toe-off for most direct therapy application |
| App | Migrate to Swift (newer, better documentation than Objective-C) |
| App | Allow the option of user-selected mp3 files (perhaps from their music library), and parse the songs into downbeats / measures using machine learning. Then let these downbeats be triggered by gait events. (Similar to Medrhythms' approach) |
| Code efficiency | Use sound fonts instead of folders full of .wavs |
| Sound file DSP | Allow for filtering of any musical sound |
| Hardware | CNC or injection mold battery cases from aluminum |
| Hardware | Velcro for knee sleeve |
| Hardware | Custom Flexible PCB for smaller electronics footprint (allows for smaller and thinner device overall). |
| App | Build system to read midi files for song input (rather than |

## 6.4 Hardware

The device hardware currently costs approximately $200. We believe that this cost can be reduced through more intentional component sourcing and larger-scale ordering to mitigate any financial barriers presented by our device.

To further reduce the size and improve the elegance of the knee sleeve, future developers can create a flexible custom printed circuit board and utilize conductive fabric instead of solid wires. Finally, as discussed in our FMEA, the battery cases should be made of a lightweight metal, like aluminum, to prevent the combustion of the battery.

# 7. References

[1] Poinsett, Pierrette Mimi. “Cerebral Palsy Facts and Statistics.” Cerebral Palsy Guidance, March 21, 2020. https://www.cerebralpalsyguidance.com/cerebral-palsy/research/facts-and-statistics/#:~:text=Statistics%20of%20People%20With%20Cerebral,each%20year%20with%20cerebral%20palsy.

[2] “What Is Cerebral Palsy?” Centers for Disease Control and Prevention. Centers for Disease Control and Prevention, December 31, 2020. https://www.cdc.gov/ncbddd/cp/facts.html#:~:text=Spastic%20Cerebral%20Palsy,their%20movements%20can%20be%20awkward.

[3] “Spastic Cerebral Palsy,” last modified 2018, https://cerebralpalsy.org.au/our-research/about-cerebral-palsy/what-is-cerebral-palsy/types-of-cerebral-palsy/spastic-cerebral-palsy/.

[4] Rose, Jessica, and Schadl, Kornel. "Dr. Rose and Kornel compiled notes," Google Doc, Accessed February 25, 2021, https://docs.google.com/document/d/1OHVkEdrLXk7yHvz83wRF3vIJN_nwGR2uEhPT97JAb0w/edit?usp=sharing.

[5] Porges, Seth. 2015. “The Science of Picking the Right Music at Work.” *Bloomberg.Com*, October, N.PAG.

[6] Ghai S, Ghai I, Effenberg AO, 2018, “Effect of rhythmic auditory cueing on gait in cerebral palsy: a systematic review and meta-analysis,” Neuropsychiatr Dis Treat. pp 14:43-59

[7] "Phases of the Gait Cycle: Gait Analysis " ProtoKinetics." ProtoKinetics. September 21, 2020. Accessed March 18, 2021. https://www.protokinetics.com/understanding-phases-of-the-gait-cycle/.

[8] Uchida, Thomas K., Scott Delp, and David B. Delp. *Biomechanics of Movement: The Science of Sports, Robotics, and Rehabilitation*. Cambridge, MA: MIT Press, 2020.

[9] Ma, Ye, Yali Liang, Xiaodong Kang, Ming Shao, Lilja Siemelink, and Yanxin Zhang. "Gait Characteristics of Children with Spastic Cerebral Palsy during Inclined Treadmill Walking under a Virtual Reality Environment." *Applied Bionics and Biomechanics* 2019 (2019): 1-9. doi:10.1155/2019/8049156.

[10] Michael H. Thaut, and Volker Hoemberg. 2014. *Handbook of Neurologic Music Therapy*. Vol. First edition. New York, NY: OUP Oxford. https://search-ebscohost-com.stanford.idm.oclc.org/login.aspx?direct=true&db=nlebk&AN=876545&site=ehost-live.

[11] "How Much Does An AFO (Ankle Foot Orthosis) Cost?" Rinella Prosthetics & Orthotics. March 13, 2021. Accessed March 14, 2021. https://rinellapo.com/how-much-does-an-afo-cost/.

[12] Eek, Meta Nyström, et al. "Muscle Strength Training to Improve Gait Function in Children with Cerebral Palsy." *Developmental Medicine & Child Neurology*, vol. 50, no. 10, 2008, pp. 759–764., doi:10.1111/j.1469-8749.2008.03045.x.

[13] Alliance, Cerebral Palsy. "Treadmill Training for People with Cerebral Palsy." Cerebral Palsy Alliance. Accessed February 25, 2021. https://cerebralpalsy.org.au/our-research/about-cerebral-palsy/interventions-and-therapies/treadmill-training-for-people-with-cerebral-palsy/.

[14] "Partial Body-weight Support Training (PBWS): A Good Strategy for Walking Training in Neuropediatrics: High Hopes: Pediatric Therapy Center Dubai." High Hopes. June 10, 2020. Accessed March 14, 2021. https://www.highhopesdubai.com/partial-body-weight-support-training-pbws-a-good-strategy-for-walking-training-in-neuropediatrics/.

[15] Ana De Barros, PhD. "Robotic Training Method May Improve Gait, Posture in Kids With..." Cerebral Palsy News Today. August 14, 2017. Accessed February 25, 2021. https://cerebralpalsynewstoday.com/2017/08/14/robotic-training-method-may-improve-gait-posture-cerebral-palsy-children/.

[16] Kang, J., D. Martelli, V. Vashista, I. Martinez-Hernandez, H. Kim, and S. K. Agrawal. "Robot-driven Downward Pelvic Pull to Improve Crouch Gait in Children with Cerebral Palsy." *Science Robotics* 2, no. 8 (2017). doi:10.1126/scirobotics.aan2634.

[17] "WHAT IS NEUROLOGIC MUSIC THERAPY." NMTSA. Accessed February 25, 2021. https://www.nmtsa.org/what-is-nmt.

[18] Moumdjian, Lousin, Bart Moens, Pieter-Jan Maes, Fanny Van Geel, Stephan Ilsbroukx, Sophie Borgers, Marc Leman, and Peter Feys. "Continuous 12 min Walking to Music, Metronomes and in Silence: Auditory-motor Coupling and Its Effects on Perceived Fatigue, Motivation and Gait in Persons with Multiple Sclerosis." *Multiple Sclerosis and Related Disorders* 35 (2019): 92-99. doi:10.1016/j.msard.2019.07.014.

[19] Ramji, Rathi, Ulrika Aasa, Johan Paulin, and Guy Madison. "Musical Information Increases Physical Performance for Synchronous but Not Asynchronous Running." *Psychology of Music* 44, no. 5 (September 29, 2015): 984–95. https://doi.org/10.1177/0305735615603239.

[20] Boldt, S. "The Effects of Music Therapy on Motivation, Psychological Well-Being, Physical Comfort, and Exercise Endurance of Bone Marrow Transplant Patients." *Journal of Music Therapy* 33, no. 3 (October 1, 1996): 164–88. https://doi.org/10.1093/jmt/33.3.164.

[21] Mainka, Stefan, Jörg Wissel, Heinz Völler, and Stefan Evers. "The Use of Rhythmic Auditory Stimulation to Optimize Treadmill Training for Stroke Patients: A Randomized Controlled Trial." *Frontiers in Neurology* 9 (2018). doi:10.3389/fneur.2018.00755.

[22] Thaut, Michael H., Ruth R. Rice, Thenille Braun Janzen, Corene P. Hurt-Thaut, and Gerald C. Mcintosh. "Rhythmic Auditory Stimulation for Reduction of Falls in Parkinson's Disease: A Randomized Controlled Study." *Clinical Rehabilitation* 33, no. 1 (2018): 34-43. doi:10.1177/0269215518788615.

[23] "MedRhythms." MedRhythms. Accessed February 25, 2021. https://www.medrhythms.com/.

[24] "Qualcomm® AptX™ Low Latency Synchronised Audio," Accessed February 24, 2021. https://www.aptx.com/aptx-low-latency.

[25] EBU. "The relative timing of the sound and vision components of a television signal," EBU Recommendation R37-2007, Geneva, Switzerland, February, 2007.

[26] Immel, Bradley. “Acceptable Latency User Test.” *Andante*. February 24, 2021. https://docs.google.com/document/d/1ni8S7U6FWALI4I8R4wo8-Ms2ihuzwnGe-lawbXkvDNM/edit?usp=sharing.

[27] Zheng, Huiru, Norman D. Black, and Nigel D. Harris. "Position-sensing technologies for movement analysis in stroke rehabilitation." Medical and biological engineering and computing 43, no. 4 (2005): 413-420.

[28] Anesbury, Zachary, Magda Nenycz‐Thiel, John Dawes, and Rachel Kennedy. "How do shoppers behave online? An observational study of online grocery shopping." Journal of Consumer Behaviour 15, no. 3 (2016): 261-270.

[29] A&E Watches. “Rolex Case Sizes.” Accessed May 30, 2021. https://www.aandewatches.com/rolex-case-size.

[30] statcounter. “Mobile Operating System Market Share Worldwide.” Accessed May 30, 2021. https://gs.statcounter.com/os-market-share/mobile/worldwide

[31] "DTS Footswitch User Manual." Noraxon USA. January 21, 2021. Accessed February 25, 2021. http://www.noraxon.com/wp-content/uploads/2015/05/P-5008-Rev-G-DTS-Footswitch-Manual.pdf.

[32] Wetzstein, Gordon. "EE 267 Virtual Reality Course Notes: 3-DOF Orientation Tracking with IMUs," Course notes, Accessed February 25, 2021, https://stanford.edu/class/ee267/notes/ee267_notes_imu.pdf.

[33] Seel, Thomas, Jörg Raisch, and Thomas Schauer. "IMU-based joint angle measurement for gait analysis." *Sensors* 14, no. 4 (2014): 6891-6909.

[34] Raitoharju, Matti, and Robert Piché. "On computational complexity reduction methods for Kalman filter extensions." *IEEE Aerospace and Electronic Systems Magazine* 34, no. 10 (2019): 2-19.

[35] Immel, Bradley, Melissa Marable, Nicole Salz, and Kevin Supakkul. "Andante-ME170." GitHub. Accessed June 04, 2021. https://github.com/Andante-ME170.

[36] IvenSense. "MPU-9250," Online documentation, Accessed February 25, 2021, https://invensense.tdk.com/products/motion-tracking/9-axis/mpu-9250/#:~:text=Gyroscope%20Features&text=Gyroscope%20operating%20current%3A%203.2mA.

[37] Nordic Semiconductor. "nRF52832 Product Specification v1.4," Spec sheet, Accessed February 25, 2021, https://infocenter.nordicsemi.com/pdf/nRF52832_PS_v1.4.pdf.

[38] Martini, Elena, Tommaso Fiumalbi, Filippo Dell'Agnello, Zoran Ivanić, Marko Munih, Nicola Vitiello, and Simona Crea. "Pressure-sensitive insoles for real-time gait-related applications." Sensors 20, no. 5 (2020): 1448.

[39] Apple. "Accessory Design Guidelines for Apple Devices. Release R14." Accessed May 30, 2021. https://developer.apple.com/accessories/Accessory-Design-Guidelines.pdf.

[40] Michon, Romain. "Faust Tutorials." Accessed May 30, 2021. https://ccrma.stanford.edu/~rmichon/faustTutorials/.

[41] Rakib, Muhammad, Imtiaz Choudhury, and NA Abu Osman. "Development of a Prefabricated and User Friendly Stance-Control Orthosis." In 2014 3rd International Conference on Environment Energy and Biotechnology, vol. 70, pp. 80-83. 2014.

[42] Team, Musical U. "The Ultimate Guide to the Circle of Fifths." Musical U. April 17, 2020. Accessed June 04, 2021. https://www.musical-u.com/learn/how-to-use-circle-fifths/.

[43] "Weight Percentile Calculator for Men and Women in the United States." DQYDJ. September 04, 2020. Accessed February 25, 2021. https://dqydj.com/weight-percentile-calculator-men-women/.

[44] Wang, Xingchen, Maria Kyrarini, Danijela Ristić-Durrant, Matthias Spranger, and Axel Gräser. "Monitoring of gait performance using dynamic time warping on IMU-sensor data." In 2016 IEEE International Symposium on Medical Measurements and Applications (MeMeA), pp. 1-6. IEEE, 2016.

[45] American Micro Industries. "Machining Tolerances." Accessed June 3, 2021. https://www.americanmicroinc.com/machining-tolerances.html

[46] Efraimidou, Vasiliki, Maria Sidiropoulou, Paraskevi Giagazoglou, Miltiadis Proios, Vasileios Tsimaras, and Anastasios Orologas. "The Effect of a Music and Movement Program on Gait, Balance and Psychological Parameters of Adults with Cerebral Palsy." *International Journal of Special Education*, December 2016. https://doi.org/10.7752/jpes.2016.04217.

[47] Bella, Simone Dalla et al. "Gait improvement via rhythmic stimulation in Parkinson's disease is linked to rhythmic skills." *Scientific reports* vol. 7 42005. 24 Feb. 2017, doi:10.1038/srep42005

Calabrò, Rocco Salvatore, et al. "Walking to your right music: a randomized controlled trial on the novel use of treadmill plus music in Parkinson's disease." *Journal of neuroengineering and rehabilitation* 16.1 (2019): 1-14.

[48] Leow, Li-Ann, et al. "Individual Differences in Beat Perception Affect Gait Responses to Low- and High-Groove Music." *Frontiers in Human Neuroscience*, vol. 8, 2014, doi:10.3389/fnhum.2014.00811.

[49] "Swing Phase Mode, Chord Progression.MOV." Google. Accessed June 03, 2021. https://drive.google.com/file/d/1fCOoTB77cz6G07KYIyYV9UDKDWDse0Dy/view?usp=sharing.

[50] "Swing Phase Mode, Typical Gait, Scale.MOV." Google. Accessed June 03, 2021. https://drive.google.com/file/d/1bKzNqQhiERMwu-iJoKDvP7Luyvp3nE4o/view.

[51] "Swing Phase Mode, Stiff-knee Gait, Scale.MOV." Google. Accessed June 03, 2021. https://drive.google.com/file/d/1WwfOaRtkUIUGHPYZSf4xi3W8hxpkrG6B/view?usp=sharing.

[52] "Stance Phase Mode, Canon in D.MOV." Google. Accessed June 03, 2021. https://drive.google.com/file/d/1UrPP133hJvc1nZga1eFKvlv2NmYvHeOB/view.

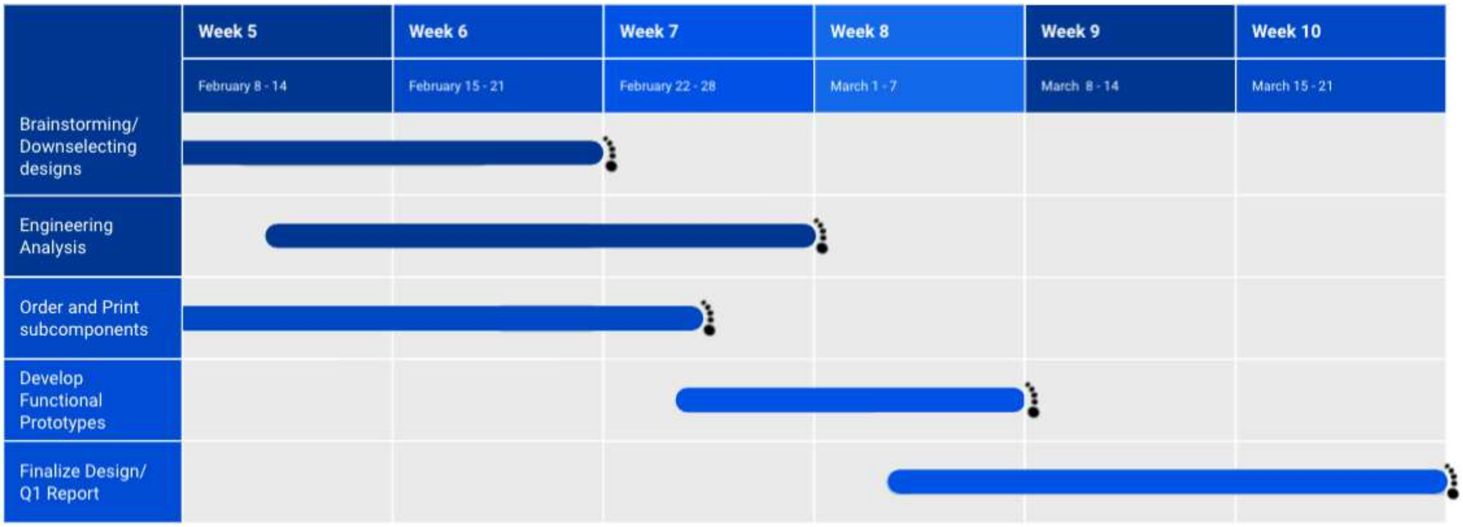
[53] "Stance Phase Mode, The Hammer.MOV." YouTube. May 25, 2021. Accessed June 03, 2021. https://www.youtube.com/watch?v=5z_EEswRdqU.

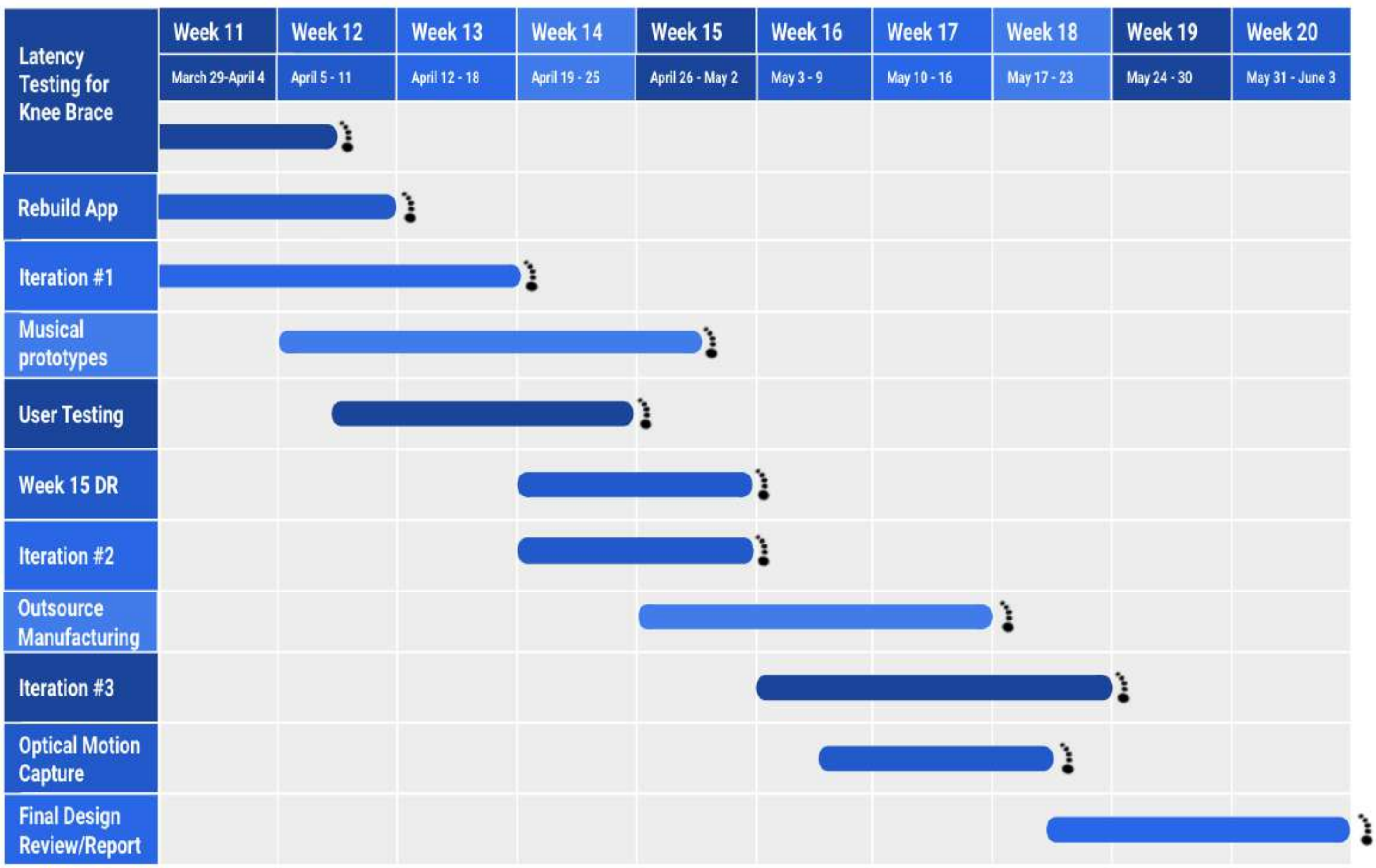
# 8. Appendices

## Appendix A: Team Members, Roles and Responsibilities

| Team Member | Role | Primary Responsibility |
|---|---|---|
| Melissa Marable | Software Developer/P3D | Responsible for translating dynamics to code and working with embedded systems |
| Kevin Supakkul | Hardware Engineer/P3D | Responsible for circuitry and dynamic analysis of system |
| Nicole Salz | Mechanical Designer/PM | Responsible for any CAD and hand analysis of mechanical system |
| Bradley Immel | Audio Engineer/FO | Responsible for sound design and audio software |

# Appendix B: Gantt Chart



# Appendix C: FMEA

| | Functions | | Potential Failure Mode(s) | | | Potential Causes | | | | | | Recommended | | | Action Results | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| dFMEA line item | Component | Item / Function | Potential Failure Mode(s) | Potential Effect(s) of Failure | Sev | Potential Cause(s)/ Mechanism(s) of Failure | Prob | Current Design Controls | Det | RPN | Crit | Recommended Action(s) | Responsibility | Target Completion Date | Actions Taken | New Sev | New Occ | New Det | New RPN | New Crit |
| d1 | Battery | Provide electrical power supply | combustion | burning the user, full product destruction | 10 | battery punctured or deformed due to heavy impact | 3 | hardshell case that can withstand force of human stepping on device (roughly 1600N), adhesive connection to case so battery doesn't move around. Analysis on case has not yet been performed.<br><br>Current level of analysis: geometry intuition (DET = 9) | 9 | 270 | 30 | CAD, FEA testing, preliminary prototype testing | Nicole Salz, Melissa Marable | Next iteration of CAD, FEA testing (4/15)<br><br>prototype testing (4/18) | | | | | 0 | 0 |
| d2 | Battery | Provide electrical power supply | combustion | burning the user, full product destruction | 10 | electrical short caused by poorly manufactured electronics and improper connections during assembly (ignore water-proofing) | 2 | careful wiring during assembly, buying reputable batteries<br><br>Current level of analysis: successful execution of prototype circuits, careful evaluation of manufacturers' safety standards (DET = 3) | 3 | 60 | 20 | n/a (Crit < 20, RPN < 80) | | | | | | | 0 | 0 |
| d3 | Battery | Provide electrical power supply | battery drains quicker than engineering requirement | degradation of performance until eventual product shut off | 5 | battery capacity less than power demand from device | 2 | Using a battery larger than worst case power consumption.<br><br>Current level of analysis: performed detailed calculations of worst case power and selected a battery that is 3x more capacity than needed to acheive our technical requirements, which is defined as 2 hours of uninterrupted operation which is 0.11Wh (DET = 5).<br><br>Due to this meticulous design, we anticipate probability to be at worst 1 in 150000. | 5 | 50 | 10 | n/a (Crit < 20, RPN < 80) | | | | | | | 0 | 0 |
| d4 | Wires | Allow current between microcontroller/sensor | disconnection | product failure (user-inaccessible repair) | 5 | shear force on wires during use causes disconnections | 5 | hardshell case for microcontroller/sensors/wires, careful wiring paths<br><br>Current level of analysis: geometry intuition (DET = 9) | 9 | 225 | 25 | CAD, preliminary testing | Nicole Salz, Melissa Marable | Next iteration of CAD (4/15)<br><br>prototype testing (4/18) | | | | | 0 | 0 |
| d5 | IMU | Produce sensor readings | sensor physically offset during use | incorrect data, product malfunction | 3 | Shifting of IMU due to use or material stretch | 6 | Secure attachment to knee brace device<br><br>Current level of analysis: geometry intuition (DET = 9) | 9 | 162 | 18 | secure material to hold IMU in place on knee brace. preliminary testing | Melissa Marable | 4/26 (Week 5) | | | | | 0 | 0 |
| d6 | Software | convert sensor readings to music | sensor drift over time (algorithm-based issue, not hardware) | incorrect data, music inaccurately represents user's gait | 3 | Accumulation of integration inaccuracies, simplistic 2D model | 6 | Sensor fusion, using robust algorithms from literature<br><br>Current level of analysis: geometry intuition and preliminary testing of knee algorithm (DET = 7) | 7 | 126 | 18 | Reevaluate knee angle algorithm, test over longer periods of time | Kevin Supakkul | 4/26 (Week 5) | | | | | 0 | 0 |
| d7 | Software | convert sensor readings to music | high latency (>150ms) | lack of association between movement and music from a user experience perspective | 4 | inefficient software complexity (big-O analysis) and hardware communication latency | 6 | Use iPhones (iOS has much lower audio latency than Android)<br><br>Current level of analysis: User testing for acceptable latency, iOS platform testing, detailed latency experiment n > 30 (DET = 3) | 3 | 72 | 24 | user testing for satisfaction/enjoyment, migrate platform to Objective-C / Faust<br><br>(Note: Crit < 20 and RPN < 80, but we still intend to improve latency to meet our technical requirements) | Bradley Immel, Kevin Supakkul, Melissa Marable | functional app demo (4/28) | | | | | 0 | 0 |
| d8 | Software | convert sensor readings to music | false event detections | lack of association between movement and music from a user experience perspective | 4 | inaccurate algorithm for event detection, bad hardware | 2 | using a pressure sensor for the foot switch significantly reduces risk of false detection<br><br>Current level of analysis: Event detection testing and proporiton z-test against hypothesis H = 0 false detections. Probability of false detection is significantly low, and tested on a sample size of 30. Calculations involve looking at a research paper that compared foot switch to IMU event detection, which affirmed that a foot pressure sensor is much more accurate (DET = 3) | 3 | 24 | 8 | n/a (Crit < 20, RPN < 80) | | | | | | | 0 | 0 |
| d9 | Bluetooth | Communicate between hardware and app | Cannot connect | No communication between components, no musical output or movement data collected | 5 | hardware chip malfunction from poor manufacturing, device is out of range and unable to connect, software bluetooth protocol compatibility issue | 6 | buy hardware from reputable manufacturers; use requires a relatively fixed range between devices<br><br>Current level of analysis: Bluetooth connection tested on 3 different phones (DET = 6) | 6 | 180 | 30 | validating connection with several different devices (on each end), including different generations of iPhone | Everyone | 4/26 (Week 5) | | | | | 0 | 0 |
| d10 | Knee brace | Hold hardware that enables the device to determine knee angle while on user's leg | Brace slips down leg | lack of association between movement and music from a user experience perspective | 3 | Mass of hardware is too high and overcomes the friction and normal forces provided by fabric | 6 | Minimize and distribute weight of hardware evenly<br><br>Current level of analysis: Initial calculations (DET = 5) | 5 | 90 | 18 | 2-hour use-case walking tests on several different users | Melissa Marable | (4/22) | | | | | 0 | 0 |
| d11 | Knee brace | Hold hardware that enables the device to determine knee angle while on user's leg | Brace slips down leg | lack of association between movement and music from a user experience perspective | 3 | Fabric interface with leg is loose or otherwise not secure | 6 | Velcro adjustment, snug on user<br><br>Current level of analysis: Initial calculations (DET = 5) | 5 | 90 | 18 | 2-hour use-case walking tests on several different users | Melissa Marable | (4/22) | | | | | 0 | 0 |
| d12 | Footswitch | Detect gait events based on foot pressure to ground | eletronics enclosure becomes unattached from shoe | product failure and tripping hazard for user | 9 | Weak mechanical clip that either breaks or loosens during use | 7 | Making adjustable mechanical clip that can secure tightly on any size shoe<br><br>Current level of analysis: geometry intuition (DET = 9) | 9 | 567 | 63 | CAD, FEA testing, preliminary prototype testing | Nicole Salz, Melissa Marable | Next iteration of CAD, FEA testing (4/15)<br><br>prototype testing (4/18) | | | | | 0 | 0 |

## Appendix D: Additional Tests

Although not directly related to a specific technical requirement, we also performed a false-positives test to make sure that the footswitch was reliable. We wanted to determine if the false detection rate of the footswitch is statistically greater than 0. We set a null hypothesis that the proportion of false detections was 0, and we tested if we could reject this null hypothesis at the 5% significance level. Our experimental data showed a p-value of 1.0 for footswitch false detection rate, meaning we could strongly accept the null hypothesis that the footswitch false detection rate was 0.

**Table A.1:** Results From False Detection Test

| | Footswitch prototype |
|---|---|
| Sample size | 30 |
| # false detections | 0 |
| Proportion | 0 |
| Proportion standard deviation | 0 |
| Null hypothesis | $p_{footswitch} = 0$ |
| Alternate hypothesis | $p_{footswitch} > 0$ |
| p-value (z test) | 1 |

## Appendix E: Finances (Bill of Materials, Expenses, and Budget)

**Table A.2:** Expenses

| Name | Quantity | Cost Per Item | Cost |
|---|---|---|---|
| nRF52 microcontroller | 2 | $24.95 | $49.90 |
| MPU-9250 IMU | 2 | $8.99 | $17.98 |
| Knee pad | 2 | $8.99 | $17.98 |
| Foot Switch (note, we received these for free so do not know the cost. The cost listed here is that of a similar foot sensor on the market) | 1 | $85.65 | $85.65 |
| Batteries | 3 | $5.95 | $17.85 |
| Wires (bulk) | 1 | $7.99 | $7.99 |
| Battery switch | 1 | $2.95 | $2.95 |

**Total Cost:** $200.30

In total, we spent $1340.19 on research and development out of a budget of $3000. These expenses consisted of hardware purchases for development as well as overnight shipping to send parts between students in different locations.

## Appendix F: User and Technical Requirements

All tables beginning with A.3 are the user requirements, and all tables beginning with A.4 are the associated engineering requirements.

**Table A.3.1:** Performance/Features User Requirements

| Requirement | Priority | User Requirement | Justification | Source |
|---|---|---|---|---|
| UR1 | HIGH | Generate music as users walk-let them make music through movement | Active interaction with music drives motivation to keep using the device [4]. Music-related therapy has been proven to help improve gait performance in people with neurological disorders [6] . | Dr. Rose's recommendation https://docs.google.com/document/d/19Gw-stLlU8F7KtMrz0GI-CnrZ6QEhqwbGq86UWVLK8o DOI:10.1016/bs.pbr.2014.11.030 DOI: 10.1093/jmt/44.3.198 DOI: 10.1196/annals.1284.042 |
| UR2 | HIGH | Improve crouch gait for spastic cerebral palsy | Stiff-knee gait and flex-knee gait are common gait disorders among individuals with CP [4, 8]. | Project brief, Dr. Rose's brief https://docs.google.com/document/d/19Gw-stLlU8F7KtMrz0GI-CnrZ6QEhqwbGq86UWVLK8o/edit |
| UR3 | HIGH | Enjoyable and satisfying interaction | Satisfying interaction will encourage frequent, ongoing use, which has increased potential to improve gait. | Gait Disorders in Adults https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5318488/ |
| UR6 | LOW | Precisely-timed connection between movement and music | Sensory feedback of movement is less beneficial if there is a noticeable delay between action and sensory perception | Acceptable Latency User Testing https://docs.google.com/document/d/1ofLCWJ9Or69exPrhqZv5KUVECaqgdI0Q4Iub9BgUHas |
| UR7 | MEDIUM | Light enough to not impede movement | Too heavy of a device may negatively affect gait behavior | Dr. Rose's recommendation https://docs.google.com/document/d/19Gw-stLlU8F7KtMrz0GI-CnrZ6QEhqwbGq86UWVLK8o |
| UR8 | MEDIUM | Device should fit users independent of leg size | Our system should be accessible to as many users as possible and should not be limited to certain body types. | Muscle Size, Composition, Architecture https://link.springer.com/referenceworkentry/10.1007%2F978-3-319-50592-3_14-1 |

**Table A.3.2:** Environment/Operating Conditions User Requirements

| Requirement | Priority | User Requirement | Justification | Source |
|---|---|---|---|---|
| UR4 | HIGH | Device can be used at home for personal daily use. | Allowing easy daily use is the best way to build circuits that promote control of movement. If the device were constrained to a laboratory or clinical setting, it would be less beneficial [4]. | Dr. Rose's recommendation https://docs.google.com/document/d/19Gw-stLlU8F7KtMrz0GI-CnrZ6QEhqwbGq86UWVLK8o/edit |
| UR9 | MEDIUM | Device must be comfortable | Since the device may be at work for extended periods of time, the user must feel comfortable when wearing the device for proper engagement | Usability of Home Devices https://www.ncbi.nlm.nih.gov/books/NBK231078/ |

**Table A.3.3:** Reliability User Requirements

| Requirement | Priority | User Requirement | Justification | Source |
|---|---|---|---|---|
| UR5 | HIGH | Device must output consistent sensor data over the duration of use. | We want the user to reliably produce repeatable and predictable music when they perform gait patterns. Reliable knee angle output also assists with a consistent relationship between action and sensory perception [26]. | [26] |
| UR10 | LOW | Device should not malfunction from fatigue stress failures after continual regular use | This device is intended to help improve gait behavior over an extended period of time and should thus tolerate repetitive use | Fatigue Testing https://www.asminternational.org/documents/10192/1849770/06156G_Sample.pdf |
| UR11 | LOW | Water-resistant | If a user wants to wear it in the rain, it should not malfunction | Consumer electronics are water resistant nowadays. Apple Water Resistance: https://support.apple.com/en-us/HT207043#:~:text=iPhone%20XS%20and%20iPhone%20XS,meter%20up%20to%2030%20minutes) |

**Table A.3.4:** Conformance User Requirements

| Requirement | Priority | User Requirement | Justification | Source |
|---|---|---|---|---|
| UR12 | MEDIUM | Device should conform to FCC standards for wearable electronics. | If we want to make these devices commercially / clinically available, we should account for regulations in the FCC involving wearable electronics. | FCC link: https://www.fcc.gov/general/equipment-authorization-measurement-procedures |
| UR13 | MEDIUM | Device should conform to FDA standards for medical devices. | If we want to make these devices commercially / clinically available, we should account for regulations in the FDA involving medical devices. | FDA link https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation |

**Table A.4.1:** Performance/Features Engineering Requirement

| Requirement | Priority | Engineering Requirement | Measurement Method | Justification |
|---|---|---|---|---|
| ER1-1 | HIGH | If focusing on initial contact point, software detection of step event should be within 150ms of actual event | Use a slow-motion camera to capture movement, and in video analysis/editing software, measure the disparity between sound profile and gait even. | Value of delay based on recommended timing between sound and vision [25,26. |
| ER1-2 | HIGH | If focusing on knee angle: measurement of angle has a precision of ± 5 degrees | Image and sensor reading analysis. | 5 degrees is the mean error limit accepted by the American Medical Association regarding the clinical evaluation of movement impairments [27]. |
| ER3-1 | HIGH | Music produced should follow functional harmony guidelines and enjoyable/motivating to users | User Testing | Make sure music is enjoyable and motivating with the goal of increasing the amount of physical activity for users. |
| ER2-1 | HIGH | Statistically significant improvement towards typical gait | Image and sensor reading analysis after 8 weeks of use. | Observing individuals' gait behavior before and after use of our device will help determine if our device is properly helping to improve the gait of users. 6-12 weeks is a standard for noticeable gait improvement in many previous studies.<br>Gait Changes in Children https://journals.lww.com/pedpt/Abstract/2000/01230/Gait_Changes_in_Children_with_Cerebral_Palsy.3.aspx<br>Effectiveness of Rehab https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5131187/ |
| ER6-1 | LOW | Output of sound should occur no later than 40ms after the associated movement | Use a slow-motion camera to capture movement, and write software to output the sound profile graphically. Then align the starting times of the video and sound output to compare timing | 40ms is a limit where users should not significantly notice a delay from movement to sound.<br>Low Latency: https://www.aptx.com/aptx-low-latency<br>https://tech.ebu.ch/docs/r/r037.pdf |

| | | | | |
|---|---|---|---|---|
| ER7-1 | MEDIUM | Weight must be under 225g for each leg's device | Scale accurate to the gram | Dr. Rose recommended a watch weight. This is the weight of a relatively heavy steel Rolex watch, used as an upper limit:<br>Rolex Watch Weight<br>https://millenarywatcheom/rolex-watches-weight-weight-of-common-rolex-watches/ |
| ER8-1 | MEDIUM | Design is independent of the user's body (i.e. attaches to clothing) or is widely adjustable. If the device goes on the calf, the circumference should fit the range of 10.5cm - 21cm | Hand-measurements of max/min leg size, if adjustable | This range is intended to cover a vast majority of possible leg sizes. We are basing these numbers on the following data:<br>Calf Size Survey<br>https://nocturnalknits.com/2013/04/calf-size-survey-results-data/ |

**Table A.4.2:** Environment/Operating Conditions Engineering Requirements

| Requirement | Priority | Engineering Requirement | Measurement Method | Justification |
|---|---|---|---|---|
| ER4-1 | HIGH | Wireless | Nothing to measure, but make sure the system has the capability to perform on-device computations (i.e. uses an Arduino, RPi, etc) | Must be independent from any laboratory hardware - i.e., no wired connection to an external computer |
| ER4-2 | HIGH | Battery-powered (rechargeable), lasting over two hours of continuous use | Use until battery drains completely and record the time elapsed as a log file | Last long enough for practical daily use [28]. |
| ER4-3 | HIGH | Extend no more than 15mm from skin | Use calipers or micrometer | Ensure size is not obstructive for users |
| ER9-1 | MEDIUM | All user testing comfort-related feedback is addressed through design iteration of surfaces that interface with the user. | User-testing on a group of at least 10 people | We believe we can reasonably address all comfort-related feedback |
| ER9-2 | MEDIUM | Temperature will not be exceed 48C | Heat flux sensor | Temperature limit for touchable devices for prolonged use. Surface Temp of Electronics https://www.electronics-cooling.com/2016/09/surface-temperatures-of-electronics-products-appliances-vs-wearables/ |

**Table A.4.3:** Reliability Engineering Requirements

| Requirement | Priority | Engineering Requirement | Measurement Method | Justification |
|---|---|---|---|---|
| ER5-1 | HIGH | During use, demonstrate no statistically significant deviation in sensor readings after two hours. | Record knee angle output, then wear the device and walk for two hours. Then record knee angle output and compare using dynamic time warping. | We want the outputs of sounds to still correspond accurately to the user's gait parameters. |
| ER10-1 | LOW | Must pass 1000 cycles of fatigue loading that resembles knee bending. | Automated approach (if we take this to production): create a fixture with a hinge that simulates the knee, then use an Instron fatigue testing machine to run automated loading cycles. Inspect parts afterwards for any fatigue cracks | Fatigue testing is standard in industry. Instron site: https://www.instron.us/products/testing-systems/dynamic-and-fatigue-systems<br><br>Some fatigue failures can be seen in the order of magnitude of 10^3 cycles: https://www.nde-ed.org/EducationResources/CommunityCollege/Materials/Mechanical/S-NFatigue.htm |
| ER11-1 | LOW | Device can survive water falling as a spray 60 degrees from vertical (IPx3 water resistance) | Confirm device works prior to test, then use a spray can to spray the device at 60 degrees for 5 minutes, then test whether the device turns on afterwards | Chose IPx3 specifically because an angled water spray can mimic the effect of light rain.<br>IP tests are standard in industry: https://www.engineeringtoolbox.com/ip-ingress-protection-d_452.html |

**Table A.4.4:** Conformance Engineering Requirements

| Requirement | Priority | Engineering Requirement | Measurement Method | Justification |
|---|---|---|---|---|
| ER12-1 | MEDIUM | RF interference testing to verify device's generated RF signals are within the allowable frequency range. It is recommended to speak with an accredited test lab to understand specific allowable ranges. May also need to do SAR testing to avoid harmful heating of radiated RF energy on human tissue. | Follow procedures listed by FCC for the electronic components and use cases of the device. Note that if the device uses mostly pre-approved 3rd party modules, then the amount of testing needed significantly decreases. | General RF Exposure:https://apps.fcc.gov/kdb/GetAttachment.html?id=f8IQgJxTTL5y0oRi0cpAuA%3D%3D&desc=447498%20D01%20General%20RF%20Exposure%20Guidance%20v06&tracking_number=20676 Consumer Electronics: https://www.fictiv.com/articles/crash-course-in-consumer-electronics-certifications-fcc-regulations-emc-testing-and-more#:~:text=The%20Federal%20Communications%20Commission%20 |
| ER12-1 | MEDIUM | EMC testing to verify that the electromagnetic fields are within the allowable limits. This device might qualify as exempt from EMC testing. Should speak to an accredited lab if we intend to find exact specs for this test. | Follow procedures listed by FCC for the electronic components and use cases of the device. Note that if the device uses mostly pre-approved 3rd party modules, then the amount of testing needed significantly decreases. | General RF Exposure https://apps.fcc.gov/kdb/GetAttachment.html?id=f8IQgJxTTL5y0oRi0cpAuA%3D%3D&desc=447498%20D01%20General%20RF%20Exposure%20Guidance%20v06&tracking_number=20676 Consumer Electronics https://www.fictiv.com/articles/crash-course-in-consumer-electronics-certifications-fcc-regulations-emc-testing-and-more#:~:text=The%20Federal%20Communications%20Commission%20(FCC,RF%20(Radio%20Frequency)%20testing |
| ER13-1 | MEDIUM | The quality system regulation includes requirements related to the methods used in and the facilities and controls used for: designing, purchasing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices. | Quality control tests to test and inspect components or finished products against approved specifications | FDA Regulatory Approval Process https://www.fda.gov/media/94071/download FDA Device Regulation https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assi |

| | | | | |
|---|---|---|---|---|
| | | | | stance/overview-device-regulation#list |
| ER13-1 | MEDIUM | An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification 510(k) submission to FDA. | Bench testing to tease out mechanical and design flaws in devices, and to test endurance of the device in the human body without human testing | FDA Regulatory Approval Process https://www.fda.gov/media/94071/download FDA Device Regulation https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation#list |

## Appendix G: Song and Genre Catalog

| Song |
| --- |
| Canon in D |
| Mario |
| I Want You Back |
| I’m Different |
| The Hammer |

| Instrument |
| --- |
| Piano |
| Bass |
| Electric Piano |
| Steel Pan |

| Drum Kit |
| --- |
| Acoustic |
| Trap |

## Appendix H: Proposed Clinical Research Study on Patients with Spastic CP

**Proposed Research**

To determine whether our device improves the gait of individuals with spastic CP, we propose an eight-week study comparing the gait improvement of patients who use and don’t use the device. Individuals will be split into the stiff-knee gait or flex-knee gait group depending on their gait. To limit confounding variables, individuals with both gait disorders will not be included in our study.

**Stiff-Knee Gait Method:**

Twenty adult (25-35) participants with stiff-knee gait will be divided randomly into a control and an intervention group, blinded to their condition. Guided by previous gait study results [46], we estimate that 20 total subjects will ensure a two-sided t-test with a 5% significance level has 85% power to detect a modest difference of 25% change between the two groups.

Each participant will undergo initial measurements of the percent of gait cycle at which toe-off occurs using a force plate. Knee flexion angle after toe-off will also be determined using Optical Motion Capture. Participants in the experimental group will be sent home with our device and encouraged to use it and log their use time. Participants in the control group will be told to go about their regular routine.

At the end of the eight weeks, a physical therapist – the same one for all participants – will measure the percent of gait cycle at which toe-off occurs using a force plate and knee flexion at the beginning of the swing phase for each participant using Optical Motion Capture, which we have chosen for measurement due to its high accuracy. Participants from the experimental group will have measurements taken with and without the use of our device. Measurements will first be taken without the device, so that short-term or immediate effects of the device are not mistaken for the longer-term effects we are investigating.

We will then compare the percent improvement of toe-off time (with the ideal being 62%) and maximum knee flexion angle (shift toward typical gait) between the experimental and control groups.

**Flex-Knee Gait Method:**

Twenty adult (25-35) participants with flex-knee gait will be divided randomly into a control and an intervention group, blinded to their condition. Guided by previous gait study results [46], we estimate that 20 total subjects will ensure a two-sided t-test with a 5% significance level has 85% power to detect a modest difference of 25% change between the two groups.

Each participant will undergo initial measurements of sagittal range of motion of the knee during gait with a physical therapist using traditional Optical Motion Capture. Gait symmetry will also be measured with force plates. Participants in the experimental group will be sent home with our device and encouraged to use it. Participants in the control group will be told to go about their regular routine.

At the end of the eight weeks, a physical therapist – the same one for all participants – will re-measure knee range of motion and gait symmetry. Participants from the experimental group will have measurements taken with and without the use of our device. Measurements will first be taken without the device, so that short-term or immediate effects of the device are not mistaken for the longer-term effects we are investigating.

We will then compare the percent improvement of knee flexion angle and symmetry between the experimental and control groups.

**Discussion**

Improvements in gait with the use of the device could be attributed to either an increase in walking from motivation of the device or from the device being directly medically beneficial. To further be able to distinguish between these two factors, individuals from both the experimental and control group will be asked to keep a movement log beginning two weeks before they first arrive at the lab and ending after the 8th week of the study.

However, for our purposes, we are not particularly interested in one mode of improvement over the other. If the experimental group presents a statistically significant gait improvement compared to the control group, we could confidently state that our device meets ER2-1 (statistically significant gait improvement).

We hypothesize that outliers in the experimental group can be related to musical experience - either an above average amount or a below average amount. We recognize that previous exposure to music and rhythm, formally or informally, could have an effect on how much participants are able to benefit from music-related therapy, particularly RAS within the Stance Phase mode [47] and our device. For this reason, we will also conduct a beat alignment test [48] at the beginning of the study so we can take into account any confounding effects of previous rhythmic ability when attempting to draw conclusions from our results.

## Appendix I: Video Demonstrations

| Video Description | Music | Video URL |
|---|---|---|
| Swing Phase Mode | Chord Progression, Electric Piano | https://drive.google.com/file/d/1fCOoTB77cz6G07KYIyYV9UDKDWDse0Dy/view?usp=sharing [49]. |
| Swing Phase Mode, typical gait | Major Scale, Piano | https://drive.google.com/file/d/1bKzNqQhiERMwu-iJoKDvP7Luyvp3nE4o/view?usp=sharing [50]. |
| Swing Phase Mode, stiff-knee gait | Major Scale, Piano | https://drive.google.com/file/d/1WwfOaRtkUIUGHPYZSf4xi3W8hxpkrG6B/view?usp=sharing [51]. |
| Stance Phase Mode | Canon in D, Piano | https://drive.google.com/file/d/1UrPP133hJvc1nZga1eFKvlv2NmYvHeOB/view?usp=sharing [52]. |
| Stance Phase Mode | The Hammer, Steel Pan | https://www.youtube.com/watch?v=5z_EEswRdqU [53]. |

## Appendix J: Project Summary

**Project Goal:** Create music from the movement of cerebral palsy patients to encourage gait improvement.

**Background:** Cerebral palsy (CP) is a neurological condition that affects approximately 764,000 people in the United States. People with spastic CP commonly experience gait disorders of stiff-knee gait and flex-knee gait.

**Project Motivation:** Current therapies for spastic CP are provided at most 2-3 times per week for an hour. This is a relatively low-dose frequency and thus requires a long period of time to actually generate improvement in gait behavior. Additionally, therapies are sometimes not motivating for CP individuals, which can lead to less desire to engage in beneficial exercises.

**Problem Statement:** Develop a mechatronic device that generates music from gait movement, specifically focusing on musical implementations that can benefit those with spastic CP.

**High Priority Requirements:**

- Generate music as users walk -- let them make music through movement
- Improve gait for people with spastic cerebral palsy
- Enjoyable and satisfying musical interaction
- Device can be used at home for personal daily use
- Device must output consistent sensor data over the duration of use

**Ethical Considerations:**

- User safety - doesn't negatively impact gait
- Device cost related to access
- Engaging musical options for users from a variety of backgrounds and cultures

**Solution:** We designed a flexible hardware and software system which can be adapted to replace or augment a therapist's auditory cues as well as provide other feedback. The system includes a footswitch, a knee angle-detection sleeve, and an app that outputs music, which all communicate wirelessly via Bluetooth.

**Team Picture:**

**Hardware + Software:**

**Other photos:**