Solegait

October 19, 2015

Dr. Andrew Rawicz
School of Engineering Science
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Burnaby, British Columbia
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Re: ENSC 440W Functional Specification Document for Solegait Pods

Dear Dr. Rawicz,

Please find attached our functional specification document for a mobile gait analyzer. We would like to build an insole with embedded pressure sensors to observe how a patient walks, which then sends data to a mobile device to see whether their planted foot rolls slightly inward or outward.

The functional specification document details the system overview, the insole and circuit design, the data processor, the mobile application, user documentation, and safety and sustainability. It also goes over various requirements such as physical, electrical, environmental, performance and engineering standards.

Our company is founded by five engineering students in various fields of study. The members include Shaquile Nijjer, Zachary Nunn, Karsten Harder, Alexandra Talpalaru, and Ashley Lesperance. If you have any questions or concerns, feel free to contact me by phone at 604-939-1780 or by email at snijjer@sfu.ca.

Sincerely,

Shaquile Nijjer
CEO
Solegait

ENSCLOSED: Functional Specification Document for Solegait Pods

Solegait

Functional Specification for an Assistive Rehabilitation Device Named:

Pods

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Issue date: October 19th, 2015

Revision: 2.1

Executive Summary

We have all heard the hype about being physically active. To restate, walking and running is proven to decrease the chances of developing osteoporosis, heart disease, diabetes, obesity and even dementia [1]. Not to mention that walking is what allows us to get places and interact with other people. Therefore, walking and running is not just for the athletes. The ability to walk without pain is something that all able people take for granted. As physical beings, injuries or disabilities that prevent us from walking without pain cause immense physical and psychological traumas.

The biomechanics of walking is formally termed gait. Gait is the repetitive process of moving a relatively large mass using only a subset of muscles, nerves, tendons, and joints. Although performing the actions of walking requires a small portion of our muscles and joints, it is not isolated from the remaining organ systems. Improper gait over time not only causes stress on the lower body but can also affect the hips, knees, posture and the spine.

The development of this device will be broken down into three main phases. The first stage is the proof-of-concept and it will highlight a couple key features including:

- **FSR Sensors:** Apply pressure to increase conductivity, thus causing a change in voltage

- **Insole Development:** Building a four by four matrix of sensors, applying known mass to various points to collect output sensor data

In addition to the interactive proof-of-concept model, the next development stage will consist of a prototype phase. Additional functionality and further software development will be met in order to have a marketable consumer product. A few key features include:

- **Circuit Design:** Two sensors are placed on the heel, three on the arch, two on the ball of the foot, and two on the toes

- **Microcontroller:** Analog pins to connect to each sensor to read data

- **Software Algorithm:** Collected data is processed and analyzed where pressure distribution plots can be obtained

The final product will consist of 64 pressure sensors embedded into the insole. There will also be a mobile specialized application to analyze data to display to the user. The present document will outline the functional specifications for the Solegait Pods, including all parts and components. The document will also cover engineering standards, safety concerns, and sustainability considerations. We expect to complete the project by November 30th, 2015.

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Glossary

MCU: Microcontroller Unit

MATLAB: A technical computing language for algorithm development

ANSI: American National Standards Institute

CSA: Canadian Standards Association

Pedobarograph: Pressure fields acting between the foot and a supporting surface

FSR: Force sensitive Resistor

1 Introduction

Gait analysis, analyzing movement patterns of the entire body during walking, is a critical first step for physicians and physical therapists in assessing the severity of a patient's lower limb injury. Typically, the therapist will observe (from the rear) the degree in which the patient rolls their planted foot inward (inversion) vs. outward (eversion) during one typical stride. If the patients planted foot typically rolls too inward, or too outward, it can lead to improper rehabilitation of the injured structure and multiple long-term debilitations.

However, when physicians and therapists observe a patient's foot dynamics during gait, it is difficult to provide a precise analysis. As they observe, they estimate the degree of inversion and eversion; therefore, they may only be aware when large variances from normal tendencies are present, and smaller variances often go unnoticed. These smaller variances may lead to long term chronic or severe injuries.

Solegait Pods is a solution for physicians and therapists to provide an accurate depiction of their patient's foot dynamics during gait. The objective of this project is to create a pressure-sensitive insole, which transmits data to an application on a mobile device. This application will create a plot of the pressure distribution across the patient's entire sole.

Given this information, the therapist can determine the correct amount of inversion and eversion of their patient's foot, which will help create a more specialized, and effective rehabilitation program. The product will therefore be useful throughout the entire rehabilitation process in order to track the patient's progress.

1.1 Scope

This document will outline the devices functional requirements at each phase of development. The listed requirements adhere to various engineering standards, and ensure that the Solegait Pods device is a safe and reliable solution to gait abnormalities.

1.2 Intended Audience

This functional specification is intended to be used by all members of Solegait. All design engineers are required to adhere to the safety requirements and safety standards. The project manager will use this document as a reference while assessing the projects progress. Test engineers will refer to this document while assessing certain functionalities and requirements of the device.

1.3 Requirement Classification

The requirements for this device will follow the following classification system:

[Rn-p]

'R' denotes Requirement, 'n' denotes Requirement Number, and the letter 'p' denotes the development phase to which the Requirement Number applies. The development phase is classified as one of the three:

I. Proof-Of-Concept stage
II. Both proof-of-concept and final production stage (I and III)
III. Final production stage

2 System Requirements

The overview and requirements of the Solegait Pods are described in the following section.

2.1 System Overview

The Solegait Pods device consists of a shoe insole embedded with pressure sensors, a microcontroller unit (MCU) to collect the data, and a Bluetooth communication system to send the data to a mobile phone. A workflow diagram of the Solegait pods device is illustrated in Figure 1 below. The input to the device is provided by the user wearing the insole in the form of a step. The pressure applied over the area of the insole is detected over small areas by the respective sensor.

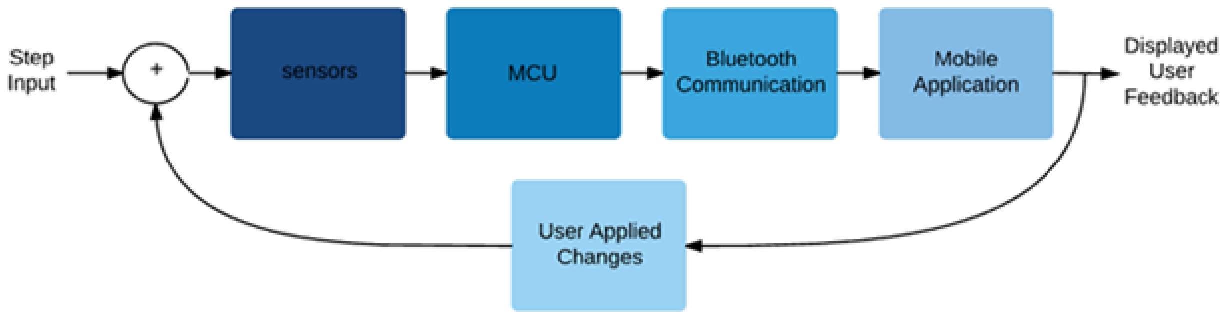

Figure 6: Graphical flowchart of Solegait Pods device

The Solegait insoles contain many layers that make up the pressure sensors as outlined in Figure 2. The top and bottom layers of the insole contain wires that are placed in opposite directions. In this configuration, the locations of the pressure sensors correspond to the areas where the horizontal and vertical wires overlap. The amount of pressure in these areas depends on how much the insole is depressed under the user's weight. These sensors are fixed onto the insole in a pattern that ensures that more sensors are present in higher contact areas, such as the calcaneus, arch, metatarsal heads, and the toes. As shown in the flow chart of Figure 1, the pressure sensors are then read by the MCU board.

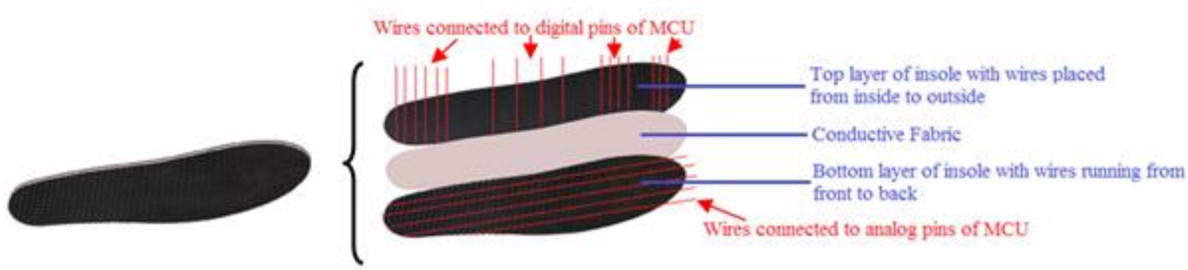

Figure 7: Layers of the Solegait insole

The MCU collects voltage data produced by the sensors when they undergo a change in pressure. Communication of the voltage data between the MCU and the user interface is facilitated by a Bluetooth system. This data is then conditioned and processed in an application on the mobile phone. This application will then display the data as a real-time pressure plot on the screen allowing the user to fix input elements of gait prior to the next step.

2.1.1 Proof-of-concept
The proof-of-concept device is a simple sensor array embedded into a square piece of insole fabric. The sensor array consists of four rows by four columns of sensors placed a constant distance apart. The sensor array is then physically connected to the MCU and to a personal computer. Pressure distribution data is acquired by applying known masses to the sensing square on different pressure sensors. In this manner the device can be tested for maximum detectable mass loading on a sensor, precision, interaction with nearby sensors, and a relationship can be established between mass input and output sensor data.

2.1.2 Prototype
The prototype device involves embedding nine pressure sensors into the insole, spread over high contact areas as well as areas useful for gait abnormality detection. Two sensors are placed on the heel, three on the arch, two on the ball of the foot, and two on the toes. The prototype device is also physically connected to the MCU and to a computer. Data is collected for all of the sensors over a period of ten steps. This normal walking data is processed on the computer in MATLAB, where a pressure distribution plot can be obtained and compared to literature data. Once the algorithm is established, data for walking with pronation or supination is also collected and analyzed in a similar manner.

2.1.3 Production
The final product will consist of 64 pressure sensors embedded into the insole. Data will be collected by the MCU and transmitted to a mobile application through Bluetooth communication. The application will process the data and display real-time pressure plots as well as a running average. Once sufficient data is collected, (i.e. 10 steps) the application will provide the user with suggestions for gait improvement.

2.2 General Requirements
[R1 – II] The app should have a command to begin and end the data processing.

[R2 – III] The package should cost no more than $40 CAD.

[R3 – II] The insole design should not interfere with the user's natural gait.

[R4 – II] The insole should not exceed a distance of 3 meters from the mobile platform.

2.3 Physical Requirements
[R5 – III] Solegait will have insoles to match shoe size.

[R6 – III] The insole should have an aesthetic design.

[R7 – II] The insoles wires should be insulated.

2.4 Electrical Requirements
[R8 – III] The power supply (to the insole) should be a replaceable, rechargeable battery.

[R9 –II] The power supply should be constant and even across all sensors.

[R10 – II] The current transmitted by the sensors should not exceed 20mA.

[R11 – I] The insole device should be supplied by a 9V battery.

2.5 Mechanical Requirements

[R12 – III] The insole should fit smoothly into any shoe of the proper size.

[R13 – II] The insole should fit firmly into the shoe and not displace while walking.

2.6 Environmental Requirements

[R14 - III] All of the insoles components will be recyclable.

[R15 – III] The mobile app should not consume large amounts of the devices power.

2.7 Standards

[R16 – III] The insole shall conform to the Canadian Electrical Code and the National Electrical Code (NFPA 70) [2].

[R17 – III] The Solegait Pods device shall conform to ANSI standards.

[R18 – III] The insole should meet CSA requirement C22.2 NO.0.8-12 – safety functions incorporating electronic technology [3].

2.8 Reliability

[R19 – III] The insole should be able to withstand weights of up to 250 lbs.

[R20 – II] The mobile app should provide accurate pedobarograph data at any instance the user decides to use the device.

[R21 – II] The insole should be resistant to moisture buildup inside of a shoe.

2.9 Safety Requirements

[R22 – II] The insoles wires should be properly insulated.

[R23 – III] There should be no leakage currents inside of the insole.

[R24 – III] There should be no visible wires inside the insole.

[R25 – II] The insole should not cause any discomfort.

2.10 Performance Requirements

[R26 – II] The pedobarograph should activate once the user decides to begin the recording session.

[R27 - III] The pedobarograph should follow behind the user’s foot movement by no more than 200ms.

2.11 Usability Requirements

[R28 – II] The mobile app should have a simple interface which any user can easily navigate through.

[R29 – II] Pairing between the mobile device and smart phone should be relatively quick.

3 Insole

The sensors, force sensitive resistors, insole design and circuit design of the Solegait Pods are described in the following section.

3.1 Sensors

There are many different types of sensors that measure pressure or force, and the prices of these sensors have a large range and are listed below [4].

Table 2: Various Types of Sensors with Prices

Sensor	Price(CND)
Piezoresistive strain gauge	$85
Capacitive	$3
Electromagnetic	$120
Piezoelectric	$1.50
Optical	$10
Compression Load Cell	$190
Force Sensitive Resistor	$10

Some sensor types above are too large to be used under a user's foot except capacitive, piezoelectric, compression load cell and force sensitive resistor; the larger sensors would be too uncomfortable and impractical to step on. A capacitive sensor is only an on/off sensor, which is not useful in our application since we need pressure differences and changes. Piezoelectric are used to detect vibrations such as sound, an example is a microphone, which is also impractical because we need to detect larger pressures. A compression load cell sensor is the most accurate sensor we could use, however we will need multiple sensors across the foot, and at a price of $190 each, multiple sensors push the price out of reach for users. The best option is the force sensitive resistor because of its thin size and flexibility, as well as its price.

3.2 Force Sensitive Resistor

At a price of $10 each, multiple force sensitive resistors across the foot gets expensive quick, especially when using 40-60 sensors. This problem is solved by exploring the physics of the sensor. Force sensitive resistors are made from a polymer that has a low conductivity in an initial state, and when pressure is applied the polymer is compressed, which causes the particles inside to get closer together thus increase the conductivity where that pressure is applied [5]. This increase in conductivity, or decrease in resistivity, causes a change of voltage with pressure.

Understanding how the force sensitive resistor allows us to take advantage of its properties. Finding a material that matches the properties of the force sensitive resistor as well as having a high surface resistance means we could make multiple sensors out of one polymer sheet. It turns out the fabric used to wrap electronics so that they are anti-static in shipping have the same properties that will for fill our needs. Small quantities of these conductive sheets range from $3-$6 per 90cm^2, the price is due to the small demand for small sheets. If purchasing larger quantities, the price of this material at high quantities is reduced to roughly $0.12 per 90$cm^2$. The amount of sensors is not limited by price of the material but on how many sensors we can read.

3.3 Insole Design

Our insole design must allow for maximum mapping of a user's gait. To do this, we will place total of 64 force sensitive resistors in the insole to maximize pressure distribution and real time analysis. The sensor layout is shown in Figure 3.

Figure 8: 64 Mapped out Resistors on Insole

The sensor layout has a large concentration of sensors near the back and front of the foot. The center of the foot as the lowest amount of sensor because while every region is important in understanding the users gait, the pressure distribution in the center of the foot is somewhat linear allowing us to lower the amount of sensors in that region and place more in the front and back of the foot.

3.4 Circuit Design

Force sensitive resistors change their resistance when pressure is applied, so to read a sensor we must be able to read changes in voltage as well as reading a large number of sensors in real time, so each sensor must be read extremely quickly. To do this we must use a microcontroller that has analog reading pins that we can connect to each sensor. Finding a microcontroller with up to 64 analog pins is very costly, most affordable microcontrollers have 6-8 analog pins. To implement 64 sensors with only 8 analog pins means we must matrix them with digital pins to form an 8 by 8 matrix in which we will have 64 sensors. Figure 4 below shows a 3 by 3 matrix to better understand how we will have more sensors then analog pins.

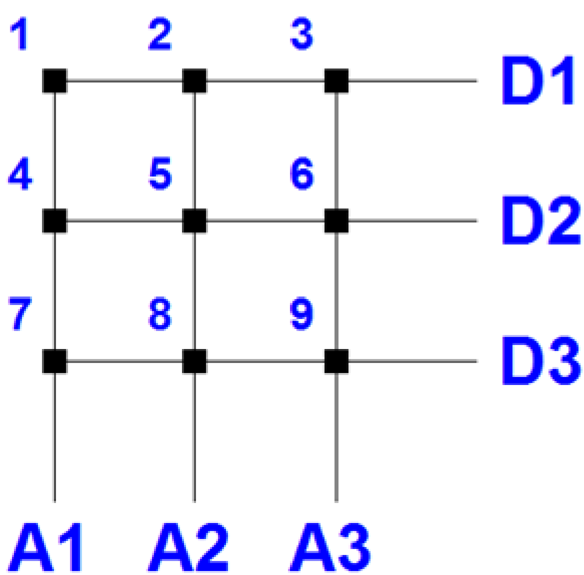

Figure 9: Analog and Digital Inputs

As you can see in Figure 4 above, we can use three analog pins matrix with three digital pins to be able to read a total of 9 sensors.

4 Data processor

Typical data curves from a normal step are presented in Figure 5. From Figure 5 we can deduce two big peaks in the data occurring at different points in time. These peaks represent the points in time at which the subject has placed his heel down, and then pushed off with his toes. From this data, we can generate a real-time plot following the pressure patterns in different regions during the time of the step.

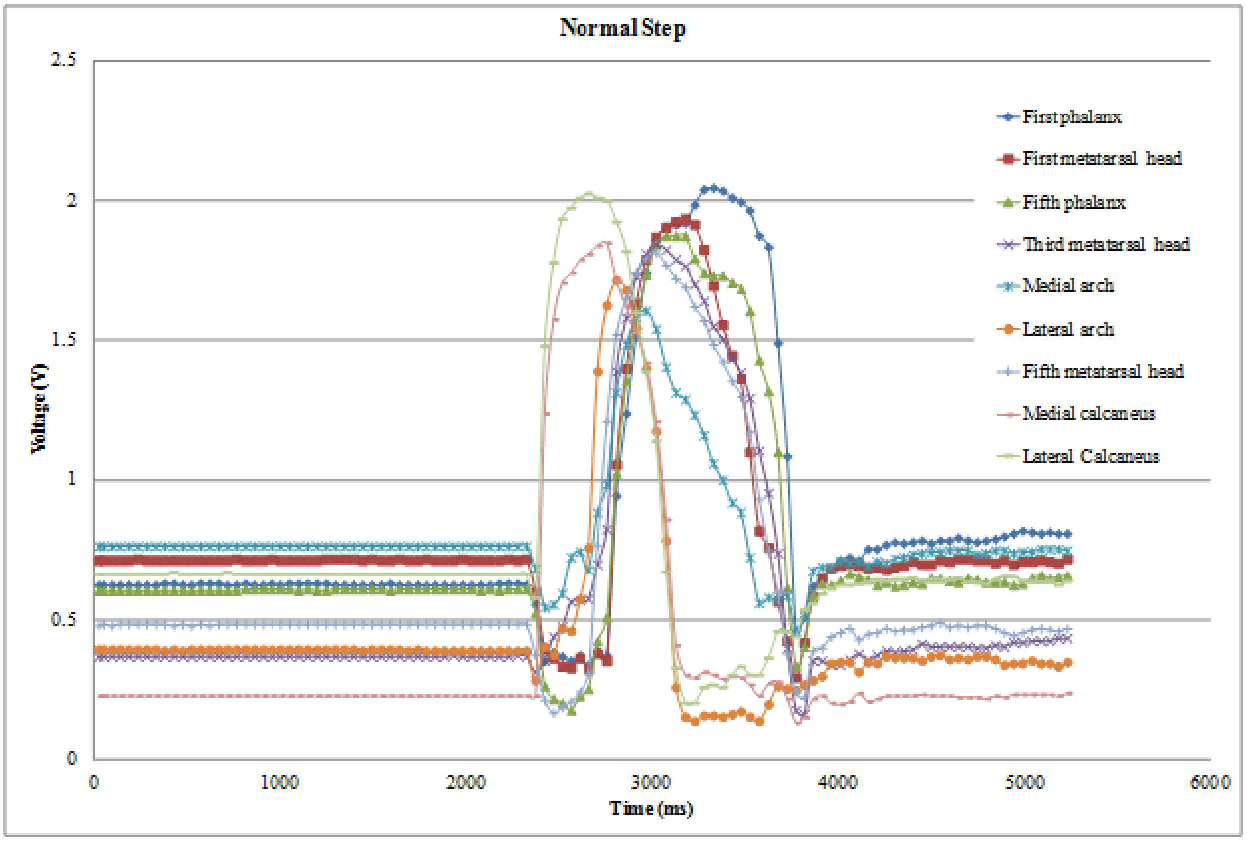

Figure 10: Normal step data

The output of the processor is discrete data with units of kg/cm^2. Each instance of time will represent one video frame, and each signal will be spatially mapped to its respective location on the pedobarograph. The output data will follow these general requirements:

[R30 – II] The data will be unsigned 8-bit integers.

5 Mobile application

The Pods Mobile application will be the main point of interaction for the end user to the system. It is here that the user can interact with the Pods and analyze the data. In the background, the application will do all the heavy lifting, getting data from the Pods and processing so that it can be displayed to the user in real-time and after the fact.

5.1 Splash Screen

The Splash Screen displays relevant and concise application information, company information and disclaimers while the application loads. The Splash Screen will have the following features:

[R31 – III] An image of the application logo

[R32 – III] An image of the company logo

5.2 Status Screen

The Status Screen serves as the landing for the user. It is here that the status of the Pods can be viewed and changed. The possible states that will be displayed are disconnected, connected and tracking. The Status Screen will have the following features:

[R33 – II] An indicator showing if the pods are connected to the mobile device

[R34 – II] A button allowing the user to connect to the pods if currently not

[R35 – II] An indicator showing if tracking is currently in progress.

A feature that should be implemented is the ability to remotely put the pods in a low power consumption mode.

5.3 Tracking Screen

To allow the user to collect data and view what is happening with the pods in real time, there is the Tracking Screen. The Tracking Screen will have the following features:

[R36 – II] A button to start or stop tracking data from the Pods

[R37 – II] A real-time pedobarograph.

5.4 MyGait Screen

To provide a personalized experience to the user the MyGait Screen will be populated with useful statistics based on the user's profile. The MyGait Screen will have the following features:

[R38 – II] A gait summary graph

[R39 – II] The ability to review the pedobarograph with respect to time.

5.5 Profile Screen

The profile screen enables the user to enter personal data and preferences to better personalize their Pods experience. The Profile Screen will have the following features:

[R40 – II] A text field indicating the username

[R41 – II] An editable text field for the user's name

[R42 – II] An editable text field for the user's age

[R43 – II] An editable text field for the user's weight

5.6 App Menu Drawer

At any location in the app, the user will be able to open the Menu Drawer and access the other parts of the application. The Menu Drawer will have the following features:

[R44 – II] A Profile button that leads to the Profile screen

[R45 – II] A Status button that leads to the Status Screen

[R46 – II] A Track button that leads to the Tracking screen

[R47 – II] A MyGait button that leads to the MyGait screen.

5.7 Application Backend

The Application Backend will mainly be used as a data store to prevent large amounts of data from filling up the end users' device. Having all the data all collected on one server has other benefits such as its use for research. The backend could be extended with a set of APIs that can provide anonymous data to a researcher. The application backend will have the following feature:

[R48 – II] A data store to hold all users data

6 User Documentation

[R49 – III] User manual will be included along with the consumer product

[R50 – III] User manual will provide instructions on setup and app tutorial

[R51 – III] Contents of user manual will be written in English and can be understood with minimal technical knowledge

7 Sustainability/Safety

One main emphasis of the Solegait pods is that it is both safe and sustainable for the user to use. While planning our product, we carefully thought of all cradle-to-cradle design aspects, including material health, material reutilization, renewable energy and social fairness [6]. Keeping these design features, we will hope to minimize negative impacts on the environment and the user's health.

Our product needs to maximize recyclable material and reduce the products that may cause harm to the environment. The electronic components will be Restriction of Hazardous Substances Directive (RoHS) compliance, which means no hazardous materials such as lead [7] will be used in the final design and production phases. We plan to use a microcontroller with a reprogrammable feature, making it flexible during later development stages, as well as RoHS compliant. All electronic components will also be easily separable allowing a simple recycling process when complete. Additionally, all insoles used for testing and designing will be recyclable.

We will also take into consideration the safety requirements to ensure no harm comes to the user when using the product. Proper sewing technique and screws will be used to secure all components due to excessive walking and movement. Each component will be the appropriate distance away from each other to reduce damage to the parts while movement occurs. All wires will be properly insulated leaving no wires exposed inside the insole. We will also have proper integration of the electronics into the insoles, which ensures no leakage of current to prevent possible injuries.

Leading up to the production stage, we hope to minimize the amount of components used during the testing and development stages to reduce waste. Strategies to target cost effective and efficient parts will also be taken into consideration. Furthermore, all electronics and plastics that are no longer needed or being used will be taken to proper disposal sites to minimize environmental damage.

8 Conclusion

The functional specifications and engineering standards, which have been outlined and discussed within this document, will ensure that Solegait Pods is a viable and usable device. The proposed requirements are issued as a guideline and may be modified (to small extents) as needed during the project lifetime.

Solegait is a team of engineers who are highly dedicated to the development of an assistive device to aid a patient's rehabilitation process and correct their foot dynamics. The Solegait Pods is a low cost solution to more accurately define imbalances in the user's walking patterns, and as a result, inhibit any chronic injuries in athletes, or bone and muscle degradation of older adults.

The Solegait Pods is designed to provide therapists, physicians, and everyday users a cost effective solution to solve their gait related injuries. Furthermore, Solegait is a company that supports the advancement of medical research; therefore, with the added benefit of a cloud server, researchers have the opportunity to gather open source data for their own benefits.

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