February 17, 2014

Dr. Andrew Rawicz
School Of Engineering Science
Simon Fraser University
8888 University Drive
Burnaby, British Columbia
V5A 1S6

Re: ENSC 440 Functional Specification Document for PresTrack's *Plantar Foot Pressure Analysis System*

Dear Dr. Rawicz,

Please find the attached the functional specification document for a *Plantar Foot Pressure Analysis System* by PresTrack. The *Plantar Foot Pressure Analysis System* is a sensor equipped shoe insole that characterizes the pressure distribution on the plantar surface of the foot during everyday tasks. Our goal at PresTrack is to create a system that is cost effective, portable and provides reliable and repeatable results.

The functional specification document details the system overview, the system requirements, proof of concept and the different phases of the project. This document encompasses all the system's functionality from it's inception till its completion and will be primarily used by the executive members of PresTrack for the development of the Plantar Foot Pressure Analysis System.

If you have any inquiries or comments regarding this project, please feel free to contact Riddhi Bhide at 778.386.6115 or by email at rbhide@sfu.ca.

Sincerely,

Riddhi Bhide
Chief Executive Officer

FUNCTIONAL SPECIFICATIONS FOR THE PLANTAR FOOT PRESSURE ANALYSIS SYSTEM BY PRESTRACK

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REVISION 1.0	

Having the ability to wake up everyday without a clinching pain in your feet should be given to each and every person. However, this is not a living reality for those suffering with plantar fasciitis. The plantar fascia aids in stabilizing the foot by absorbing the energy imposed on the heel with each heel strike, but can become the source of great pain with this characteristic inflammatory disease. Generally characterized as “inferior heel pain”, its causes are difficult to infer due to its” multifactorial nature.” [1] A published study for converging on risk factors for plantar fasciitis found that obesity and prolonged strain on the feet due to body weight were one of the leading causes for this condition. [2]

Studies show that “Ten percent of the [population] in United States can experience this disorder [...and] 83% of these patients” are in the working age.” [3] Traditionally diagnosed by a physician, most treatment is reactive in nature as plantar fasciitis is diagnosed using emerging symptoms such as foot pain. This demonstrates a need for an early diagnosis system as a part of a proactive and preventative treatment plan. At PresTrack we hope to deliver a solution to this problem with our *Plantar Foot Pressure Analysis System*, a system that delivers excellent data quality with portability functioning while being cost effective.

Development of the device will occur in three Phases: two prototyping stages and the final product. The details of the three stages proposed are detailed below:

1st Prototyping Stage	**2nd Prototyping Stage**
Hardware: FSR sensors Arduino Uno Multiplexer Data logger SD Card insole modification	**Hardware:** Accelerometers Gyroscope
Software: Receives voltage proportional to the pressure applied to the sensor and interprets the data which is readable by the user	**Software:** Will be able to deliver by calculating the angle of dorsiflexion

The final product is due on April 2nd 2014. It will be incorporated onto an insole that fits into a standard closed toe shoe, capable of receiving an insole, as well as a wearable ankle brace which will be available through any health institutions having successfully upheld its safety standards.

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ADC	Analog to Digital Converter
CSA	Canadian Standards Association
Diabetic Ulcers	Neurogenic ulcers, also known as diabetic ulcers, are ulcers that occur most commonly on the bottom of the foot [5]
IEEE	Institute of Electrical and Electronics Engineers
LED	Light Emitting Diode
MCU	Microcontroller Unit
MUX	multiplexer
PC	Personal Computer
PFPAS	Plantar Foot Pressure Analysis System
Plantar	an anatomical reference; of or relating to the sole of the foot
Plantar Fasciitis	Plantar fasciitis is inflammation of the thick tissue on the bottom of the foot. This tissue is called the plantar fascia. It connects the heel bone to the toes and creates the arch of the foot. [4]
SD	Storage Device

The *Plantar Foot Pressure Analysis System (PFPAS) is* a shoe insole system that is used to quantify and diagnose the risk of plantar fasciitis, a musculoskeletal disorder characterized by the inflammation of the plantar fascia. The system senses the distribution of pressure during quiet standing as well as walking, the peak force at heel strike, the amount and speed of pronation as well as the angle of dorsiflexion.

6.5. Scope

This functional specifications document shows the requirements that need to be met by the Plantar Foot Pressure Analysis System. This document will explain the proof of concept and the production of the device as it will state what the device will do, how it will work and how it will be used. The list of requirements will be used to effectively design the Plantar Foot Pressure Analysis System

1.2. Intended Audience

The intended audience for this document is all the engineers at PresTrack. This includes the project manager, the design engineers, the programmers and the test engineers. The project manager will use this to determine the progress of the project. The test engineers are going to use this document to show that the system works to the required specifications. This document will also be used to resolve issues in terms of the design and production should they arise. The functional specifications document will also be used by any parties in the future who want to develop this technology further.

1.3. Classification

Throughout this document, the following convention will be used to the functional requirements:

[SC-##-p] where

SC – the abbreviated section title, where the first letters of the section title are used e.g SR is System Requirements
##- the requirement number
p- The priority number

The priority of the functional requirements are denoted by the values below:

I The requirement applies to proof of concept
II The requirement applies to proof of concept and final production
III The requirement applies to the final production of the device

The requirements of the PFPAS as a complete system are described in the following section

2.1. System Overview

The system is of the PFPAS is shown in the block diagram below

Figure 1: Block diagram of the PFPA

As shown in the diagram the system will capture the input through ten force resistive sensors placed at strategic landmarks on the insole, three accelerometers and a gyroscope. From these force resistive sensors shown in Figure 2, the heel strike and the impact forces on the heel strike will be determined, as well as onsets and offsets of each gait cycle. The pattern of toe off (particularly whether it is along the medial or lateral side) will be captured, the speed of the gait will be used to measure the force of impact during pronation. The accelerometers shown in Figure 3 will be placed on the lateral aspect of the foot to determine the angle of dorsiflexion. Lastly, the gyroscope shown in Figure 4, placed above the arch of the foot will measure the speed of pronation, and determine the degrees of pronation as well as its frequency.

Figure 2: Placement of FSR Sensors under the foot on the insole

Figure 3: Placement of accelerometers on the lateral side of the device

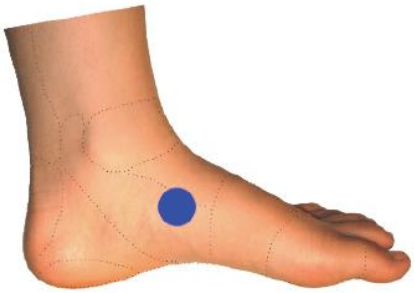

Figure 4: Placement of gyroscope on the medial side of the device

All of these inputs signals will be entered into the microcontroller where they will be conditioned and analyzed using various algorithms. They will be presented in the output, as the pressure distribution images, graphs showing peak forces and the angles of pronation and dorsiflexion.

Our system will be portable, and will incorporate the previously mentioned sensing components, whose data will be logged onto an SD card, to be analyzed by an accompanying program. Future goals of the project will be to transmit the data wirelessly to an electronic smart device. All will be controlled with a user interface, that doesn't require any previous medical or technical experience.

2.1.1. Prototypes

Prototype stage 1

The first stage of the system development encompasses the utilization of ten sensors strategically placed on the plantar foot to help identify and quantify the pressure mapping typical to risk factors for Plantar Fasciitis.

The PFPAS's main method of identifying abnormal pressure distribution across the feet is by placing the sensors in the insole and measuring the pressure across the gait cycle of the patient, as well as during quiet standing. The data from the sensors are initially extracted through the multiplexer in order to accommodate for the lack of analog input ports in the

Arduino Uno. The data logger shield is additional device utilized to save data onto external storage which can be later analyzed by the medical professional.

Prototype stage 2

The second stage of prototyping involves building on to the first prototyping stage by incorporating an accelerometer and gyroscope to measure the angle of dorsiflexion. These additional features will serve to act as supplementary information to help better diagnose Plantar Fasciitis.

The final production device would have incorporated both the prototypes with signification efforts put into its esthetics while ensuring that comfort, safety, and environmental factors are taken into consideration.

2.2. General Requirements

[SR-01-I] The PFPAS will be worn inside a closed toed shoe during quiet standing and walking
[SR-02-I] The sensors will detect the pressure and peak forces during standing and walking
[SR-03-I] The system will have an on and off button to that will allow the system to start and stop collecting data
[SR-04-III] The sensors will be thin and covered with layer of silicon rubber so as not to interfere with normal walking
[SR-05-I] The data collected will be stored on an SD card and this will be analyzed by an accompanying program
[SR-06-I] Data will be collected for at least 1 hours
[SR-07-I] The retail price will of the PFPAS will be about CDN $1000

2.3. Electrical Requirements

[SR-08-I] The power supplied by the battery will be enough to support the sensors, the accelerometers, gyroscope and the microcontroller unit
[SR-09-I] The power will last for at least 5 hours
[SR-10-I] The voltage and current required by the system will be between 7V-12V and 40mA respectively
[SR-11-I] The wires connecting the system will be no longer than 60 cm
[SR-12-I] The batteries powering the system will be non-rechargeable

2.4. Physical Requirements

[SR-13-III] The PFPAS is comprised of two shoe insoles, an ankle wrap, and the enclosure housing the MCU and power source

[SR-14-II] The sensing elements (FSR) on the insole, and the accelerometer and gyroscope on the ankle wrap, neither the electrical components of the MCU will not be in direct contact with the wearer and will not harm the user

[SR-15-II] The sensors will be firmly attached on the insole and ankle brace, and the MCU will be firmly attached to the ankle brace, and neither will shift while the user is wearing them

[SR-16-III] The insoles and ankle braces will be of varying sizes to cater for varying foot sizes

[SR-17-II] The MCU shall not exceed 4 by 14 by 10 cm in dimension

2.5. Environmental Requirements

[SR-18-II] The PFPAS will operate at any between 0 – 40 degrees centigrade

[SR-19-II] The PFPAS will operate at both indoors and outdoors

[SR-20-II] The PFPAS will not be used in rainy conditions

2.6. Reliability and Durability

[SR-21-II] The PFPAS will withstand regular day to day standing, walking and running

[SR-22-II] The PFPAS will stop functioning if any of the sensors are damaged

[SR-23-III] The PFPAS will withstand 100 hours of activity

[SR-24-III] The PFPAS will be sweat and moisture resistant

[SR-25-I] The PFPAS will be able to log data for 1 hour continuously

2.7. Safety Requirements

[SR-26-II] The Microcontroller Unit and the power source will be enclosed

[SR-27-III] The battery to power PFPAS will not overheat cause discomfort to the user

[SR-28-III] There will be a water resistant film to avoid any electric shock

[SR-29-II] All wires will be insulated to avoid any direct contact with wearer and electric shock

[SR-30-II] The sensors will not protrude from the insole

2.8. Performance Requirements

[SR-31-II] Upon turning on the system, the PFPAS will calibrate itself and perform a self diagnostic

[SR-32-III] The data will be logged and stored for 1 hour continuously

[SR-33-II] The frequency of data collection is 50Hz

2.9. Usability Requirements

[SR-34-II] The on, off, and error state will be recognizable and controlled by the user

[SR-35-III] The user will be able to assemble the system rapidly and with ease

[SR-36-III] Parts that need to be assembled as part of the system will be clearly labelled

Force, flexion angles, and degrees and rates of pronation will be sensed by the sensing elements (force sensing resistors, gyroscope and accelerometers), and this data will be transferred via wires into the microcontroller. The microcontroller will move on to log this data on an external memory storage device.

3.1.General Requirements

[PD-37-II] Analog and Digital data from the sensors shall be logged by the microcontroller unit and analyzed by an accompanying program
[PD-38-II] The sensors will be placed such that there is no discomfort to the user
[PD-39-II] The sensors attached at the on the foot and above the arch of the foot will be reused

3.1.1. Force Sensitive Resistor (FSR) Requirements

[PD-40-II] The resistance of the FSR should be reduce when pressure is applied to it
[PD-41-II] Each FSR should be able to withstand 1.2Mpa of pressure
[PD-42-II] Each FSR should produce repeatable results within a 5% tolerance
[PD-43-II] Each FSR should function independently and not interfere with those adjacent or around it
[PD-44-II] Each FSR should follow the non linear relationship between the output voltage and the pressure applied
[PD-45-II] The FSR will be placed on the critical foot landmarks where pressure changes where pressure changes are relevant to detecting symptoms of Plantar Fasciitis
[PD-46-II] The FSR will detect a change in pressure when the user is standing, walking or running
[PD-47-II] The FSR will function in their specified locations and not in any other location

3.1.2. Gyroscope Requirements

[PD-48-II] **The gyroscope will be powered by the system power supply (battery)**
[PD-49-II] The gyroscope will be placed on the accompanying ankle brace
[PD-50-II] The gyroscope will be connected to the microcontroller using wires of no longer than 60 cm
[PD-51-II] The reading from the gyroscope will be converted to angular velocity using a number of equations
[PD-52-II] This data will be logged and stored in the storage unit (SD Card)
[PD-53-II] This data will also be used to calculate the angle and frequency of pronation
[PD-54-III] If the component does not respond as expected, the red LED should start flashing

3.1.3. Accelerometer Requirements

[PD-55-II] The accelerometers will be powered by the system power supply (battery)
[PD-56-II] The accelerometers will be placed on the accompanying ankle brace like sock that will accompany the PFPAS
[PD-57-II] The accelerometers will be connected to the microcontroller using wires of no longer than 60 cm
[PD-58-II] This data will be logged and stored in the storage unit (microcontroller unit)
[PD-59-II] The data collected will be used to calculated the angle of dorsiflexion at the ankle
[PD-60-II] If the microcontroller receives less than three readings from the three accelerometers, the PFPAS will stop functioning

3.2. Shoe Insert and Ankle Brace Requirements

[PD-61-III] Shoe inserts and ankle braces will come in varying sizes, to cater for varying foot sizes
[PD-62-III] Shoe inserts will be made of polyurethane foam as directed by literature [14]
[PD-63-II] Sensors (FSRs) will be embedded on the insole at critical pressure landmarks of the feet as indicated by literature research [15]
[PD-64-II] Wires connecting the sensors and the microcontroller will be non discernable by the user on the insole.
[PD-65-II] The wires will be protrude on the lateral side of the insole and connect to the microcontroller
[PD-66-III] The sensors will be covered by silicon rubber as indicated in literature research [13]

3.3. Electronic Infrastructure

The battery will provide power to the microcontroller unit using the wires as a conduit to connect it to the sensors placed on the insoles. The wires will be located close to one another and it is important that there is no interference between them.

3.3.1. General Requirements

[EI-67-II] The battery should have enough power to power the microcontroller unit during data logging
[EI-68-I] The battery will be non rechargeable and will need to be replaced once the power has run out
[EI-69-II] The LED will turn green when the system is turned on and red when the system is malfunctioning
[EI-70-II] The wires that transmit the pressure measurement to the microcontroller should be insulated

3.3.2. Physical Requirements

[EI-71-II] The battery will be small, however, it will have enough power to power the PFPAS

[EI-72-II] The microcontroller and the power supply shall be placed in an enclosure away from any direct contact with the user

[EI-73-II] The enclosure will be big enough to hold the power supply and microcontroller

[EI-74-II] FSRs will all be located on the insole and none of them will protrude from the insole

[EI-75-II] The wires connecting the sensors to the microcontroller will be embedded on the insole and hidden under some fabric

[EI-76-II] The wires should be no longer than 60cm

3.4. Software

The software of the PFPAS comprises of two soft wares. One that interfaces the sensors with the microcontroller in order to collect data, and the other interfaces with the user and/or the clinician who will interpret the data for diagnostics.

3.4.1. MCU Software Requirements

[EI-77-II] The software shall be written in software supported by Arduino (syntax is similar to C)

[EI-78-I] Upon turning the system on, the software will turn on the green LED, and run a calibration script before logging useful data

[EI-79-II] If there is an error in the PFPAS (due to displacement of sensors or any other problem) the LED will turn red and data will not be collected until the unit is fixed

[EI-80-II] If the are no errors**,** the software shall collect and log data at 50Hz (every 2ms)

[EI-81-II] The software will ensure that the date, time and duration of data collection is noted

[EI-82-I] The software will ensure that the data is stored on the SD card in a spreadsheet format for analysis at a later period

3.4.2. Analysis Program Requirements

[EI-83-II] The analysis program will be written in MATLAB

[EI-84-II] The data analysis equations and processes will be hidden from the person to interpret the data

[EI-85-I] The program will set floor and ceiling thresholds in order to ascertain whether data is valid or not

[EI-86-I] The interpreter will only see the results in graphics and icons, guided by prompts

[EI-87-I] The pressure distribution will be shown as isobars (equal pressures shall be represented in the same colour) . This user interface will also be accompanied by a legend

[EI-88-I] A table will show peak impact force, frequency of pronation, and the angles of pronation and dorsiflexion

[UD-89-I] User documentation will come in the form of a user manual included as part of the product package.

[UD-90-III] This will detail how the PFAS is to be assembled and installed

[UD-91-II] The user manual will be written in simple everyday English targeted to an audience with minimal technical knowledge

[UD-92-III] An online version of the user manual will also be found on the company website written in English, Simplified Mandarin and Japanese

[UD-93-III] Technical documentation will also be provided on the company website

[ES-94-III] The PFPAS will comply with the International Electrotechnical Commission Standard IEC 61508 concerning Functional Safety of electronic and software based related systems [4]

[ES-95-III] The PFPAS will conform to the CSA standards under the Medical, Laboratory and Health Care Section [9]

[ES-96-III] The PFPAS will comply with the standards set by the Institution of Electrical and Electronics Engineers (IEEE) particularly the Standard for Sensor Performance Parameter Definition [10]

[ES-97-I] The PFPAS will conform to the Institution of Electrical and Electronics Engineers (IEEE) Standard for Medical Device and Communications [11]

The System Test Plan will be divided into five in-depth testing stages: individual component testing, sensor calibration, integrated unit testing, qualitative testing, and software testing. These stages will ensure that the hardware and software components function correctly on their own and as a unit. The prototype is designed such that the system can be test for usability and functionality.

6. 1 Individual Component Testing

6.1.1 FSR Sensors

The pressure sensor's ability to measure the pressure across the plantar part of the feet with little noise or error will be compared to that extracted from the F-Scan system. The following test cases shall be considered:

1. On the insole – outside the shoe/no foot
2. On the insole – inside the shoe/no foot
3. On the insole – inside the shoe/foot in shoe
    a. quiet standing
    b. foot elevate with no contact with the floor
    c. during dynamic motion

Hence, the pressure sensors will be calibrated using the customizedn pressure map and customized to accommodate the pressure loss due to its placement inside the insoles of the shoes.

6.1.2 Microcontroller unit

The Arduino UNO is tested to ensure that the resolution can accommodate the data acquired from the pressure sensors. The Arduino UNO is tested to ensure that the embedded software can be executed accurately to process the data from the pressure sensors and the position and orientation sensors. This is accomplished by testing each of the required ports of the Arduino for its performance. Additionally, the compatibility of the various add-ons to the microcontroller ports have to be tested for its operation as well.

6.1.3 Multiplexer

The multiplexer is tested to ensure that all the sensor inputs are accounted for and output the desired data points. This is verified by simulating a sample program for reading and recording the data.

6.1.4 Data logging shield

The data logging shield is tested to ensure that the processed values are accurately recorded without corruption and delay.

6.1.5 Battery

The battery will be tested to determine the amount of time it can power the Arduino.

6.1.6 Accelerometer and Gyroscope

The gyroscope measures degrees per second while the accelerometer measures acceleration in three dimensions. Both output the measurements as a digital signal. [5] [7] Additionally, tests will be conducted with prepared test case scenarios to ensure that the gyroscope and the accelerometer are functioning properly and can be calibrated accurately.

6.2 Sensor Testing

Sensor placement is of paramount importance to ensure that the collected data is of prime quality and accuracy. Sensor placement customizedn testing will be performed on each sensor to determine optimal location and performance standards.

6.2.1 FSR Sensor Placement

The placement of the sensors is customize to better understand the correlation between the symptoms exhibited by the patients with the abnormal pressure distribution on the foot. Plantar Fasciitis is an inflammatory disorder of the plantar aponeurosis, most commonly at the proximal insertion on the medial tubercle of the calcaneus. Clinicians agree that patients with plantar fasciitis report pain and palpable tenderness in the area of the medial tubercle of the calcaneus. [12] Hence, we choose to place four sensors on the rearfoot, five on the midfoot and lateral forefoot, and one on the big toe. This is customized to measure the distribution of pressure across the whole gait cycle in addition to placing the sensors on the surfaces that experience the most force.

To determine the ideal location for these pressure sensors after the region has been narrowed, different locations will tested replicating the gait cycle. The chosen location must allow the sensor to be easily integrated into the insoles of the shoes, provide comfort for the patient, and customize/eliminate additional setup.

6.2.2 Gyroscope and Accelerometer Sensor Placement

The placement of the gyroscope and accelerometer sensor is customize while taking into consideration that the patients requires full degrees of freedom with the device attached to them. This was customized by testing various locations around the ankle region where the

sensor will be placed. We decided to use the support of an ankle brace to customize the location of this sensor. The use of the ankle brace allowed the sensor to be held in place and provide for sufficient cover to protect and hide the wires from external damage, and protect the user from direct contact with the sensors

6.2.3 Sensor wear and tear

As the sensors are integrated into insole and within the ankle brace, multiple tests will be conducted to ensure that there are no adverse effects between the interaction of the sensors and body fluid such as sweat. In addition to this, various tests will be conducted to evaluate the performance of the sensor by measuring and comparing the output of the sensors after long periods of usage. After the analysis of this data, we can effectively decide the depth of the placement of the sensors within the insoles, which will give the accurate reading with the highest reliability rate.

6.3 Integrated unit testing

Having completed testing the individuals to ensure that they are operating to the required standards, additional tests have to be performed to test the full functionality of this system. The tests will be conducted on the following integrated units:-

6.3.1. Integration of sensors with sock/shoe insert

When the sensors are integrated with the shoe insert and the Arduino, the system will be tested to verify that the Arduino can receive the sensor data without delay or data loss. While these tests are being conducted, data processed through the Arduino will be stored in the SD card, the results will be depicted as a pressure map. The pressure map will then be analyzed to verify that the Arduino is working properly as well as to validate the location and placement of the sensors.

6.3.2. Arduino interface with MUX

The sensor outputs will be connected to a multiplexer for sequential output to the analog to digital convertor (ADC). The interface between the Arduino and multiplexer will be tested for its ability to successfully and rapidly select inputs and give desired outputs.

6.3.3. Arduino interface with Data Logger

The Arduino processes all the data from the sensors and maps out a pressure corresponding to the incoming data, this pressure map will then be stored as data points onto a memory storage device. The Arduino and the data logger have to be integrated to verify that the data can be stored in a customized manner, with separate files, while being powered with a low-voltage battery. The files should contain sequential sensor with pressure reading. The testing process will also ensure that the unit stays powered for extended periods of time without failure.

6.3.4. Electronic Infrastructure

The electronic infrastructure of the system will be tested for its ability to maintain constant connectivity and its ability to maintain its reliability after long periods of usage. The electronic hardware and sensors will also be tested for easy removal.

6.3.5. Shoe Insert

The shoe insert will be tested for its ability to provide comfort to the patient while integrated with electronics. The shoe insert will also be tested for durability while be worn in different weather conditions.

6.3.6 Ankle Brace

The ankle brace will be tested for its ability to provide comfort to the patient while integrated with electronics. The brace will also be test for comfort to ensure that it can worn for long periods of time without discomfort and different materials will also be considered for the ankle brace. Furthermore, the brace will also be tested for durability and its functioning after long periods of use in different weather conditions.

6.4 Qualitative Testing

For each prototype, the PFPAS's will be tested for ease-of-setup for the patient. The patient should be able to put on the shoe, turn on the device, and continue on performing their days work. The PFPAS will also be tested for accuracy and quality of data.

6.4.1 Usability

Throughout the design process, the engineers of PRESTRACK will be designing a shoe insert and an ankle brace with the user in mind. The shoe insert designed will be customized for a specific shoe. We aim to ensure that the patient does not have to worry about the compatibility of the shoe insert into their shoe; hence, we will offer them a customized shoe for purchase with our system installed into it. Once a model close to the final product is available, the shoe insert and the ankle brace will be worn for an hour, testing all aspects of the sensors from intuitiveness to comfort.

6.4.2 User Scenarios

There are various user scenarios that will be utilized to test how to system will function, these scenarios include different weather condition. Additionally, the system will also be tested for indoor and outdoor use. These scenarios are chosen to ensure that the user can go about their daily routine without any inconvenience.

6.4.3 Tracking data over one hour

The system will be tested for an hour to check the robustness by determining unfavorable glitches in the system. With these tests, we will be able to confirm if all the sensors are working properly with all the data properly selected by the multiplexer, processed by the Arduino and stored in the data logger. Additionally, the tests will be performed by people not involved in the design to avoid any bias and get impartial third party feedback from performance to comfort of the device. We begin to test the system for an hour. Following a successful test case scenario, we will perform longer test cases.

6.5 Software Testing

Once we have tested and verified that the components are operating correctly as one unit, software testing will need to take place to ensure all data is presented in a comprehensive manner. We will further compare our results with the industry standard system that is currently available on the market.

6.5.1 User Interface

The design of the system will take into consideration that the data will be extracted from the device by the user. The data will be collected in the SD card, hence, user interface will be kept simple and intuitive as possible and the initial software testing will be done by the members of PRESTRACK as the software is being built. The system performance will subsequently be tested for by friends and family of PRESTRACK and will eventually be tested with the public. The final software should be self explanatory with a user friendly interface and clear instructions to plug in the system to the PC and extract the data from the SD card.

6.5.2 Algorithm

The algorithm will be tested for its accuracy and ability to process vast amount data and successfully mapping of a pressure map corresponding to the pressure sensors placed on the foot as well as store the data collected from the gyroscope and accelerometer. Focus is kept to ensure the proper documentation of the pressure corresponding to the appropriate pressure sensor. Additionally, an algorithm would need to be coded to translate the output signal from the accelerometer and gyroscope to degrees.

The engineers of PRESTRACK have not only ensured that the international standards are met, they have also taken into consideration safety requirements of the system to ensure that the user is safe to use the device for long periods of time. Hence, the PRESTRACK team has taken numerous safety consideration in place to protect the user from harm such as:

1. Proper integration of electronics into the insoles and ankle brace
2. Safe wiring of components with no wires exposed
3. Ensure the user interface is clear and concise

Reliability and durability

The engineers of PRESTRACK took into consideration the safety and reliability of the product for the user during the design and manufacturing of the device. During various stages of development, we have conducted various test of the software as well as hardware to ensure the durability of our product.

8. SUSTAINABILITY

Throughout the scope of our project, we have considered and covered the cradle to cradle design. These design specification were considered from the selection of our material to the disposal of our electronic components. Cradle to cradle concept is about applying a new approach to design and developing systems and devices by taking into consideration the entire life cycle of the product, optimizing material health, recyclability, renewable energy use and social responsibility [8].

Through the various stages of development, we have used spare insoles and ankle brace for initial testing for our prototype. This was done to minimize the use of non-recyclables during the prototype and proof of concept stage for our design. We also incorporated efficient waste management skills while identifying the best for our project, this was done by borrowing sensors from fellow colleagues and other sensors used in other projects. By doing so, we have not caused any additional electronic waste for the prototype stage of development. In addition, all electronic components purchased were bought from the retail only as the last option, we tried to use spare parts wherever possible. Moreover, we ensured that the purchased parts that have suitable return policy to minimize expenditure and waste if they are not suitable for our needs.

We hope to minimize the number of components utilized for the final product by figuring out the kinks in our design during the prototype stage of our project development. Additionally, the right materials for the insoles and ankle braces will be finalized out during the prototype stage to ensure that the final product is made of environmentally friendly material that is easily disposable. Moreover, we hope to use biodegradable plastics for exterior components and the enclosure to reduce the environmental impact of our project.

We also incorporated a return policy of these devices, this program ensures the proper disposal of the product as well as ensuring the recycling of any components for another device. Plastics and electronics which are no longer usable will be sent to proper government disposal sites which specialize in proper disposal of waste in a safe and environmentally friendly way.

9. CONCLUSION

The Plantar Foot Pressure Analysis System proposed by us, is a design that is simple, effective and purposeful. With the portability function with emphasis put to comfortable user interface and upholding to the environmental and safety standards. The device designed ideally for research and diagnostic means, nonetheless, the device is expandable, with incorporating wireless transmission to obtain the real time data and commercializing for fitness and athletes to ensure prime physical fitness while under duress. The existing technology, F-scan, inhibits taking measurement while in motion, it is stationary measurement system. Additionally, the cost of an F-scan machine is significantly more with a starting price of $10,000. Hence, we intend to support the educational institutions with their research by providing them with a system that is cost-effective and reliable with an additional portability function to aid them in the research for Plantar Fasciitis.

This document can be used as framework by the engineers of PRESTRACK with regards to the required features projected for our device. The design features proposed to be incorporated are 10 individual sensors to map a pressure map of the gait cycle and an accelerometer and gyroscope to be utilized as a position and orientation sensor.

FDA Standards
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=880.6280

[1]"Plantar Fasciitis: Diagnosis and Therapeutic Consideration,"M. Roxas. [Online]. Available: http://simplyfit.com/pdfs/PlantarFasciitis-BV-5.pdf [Accessed: Jan. 20, 2014]

[2] "Risk Factors for Plantar Fasciitis: A Matched Case-Control Study," D.L. Riddle et al. [Online].
The Journal of Bone & Joint Surgery, Volume 85, Issue 5 Available: http://jbjs.org.proxy.lib.sfu.ca/article.aspx?articleID=25902 [Accessed: Jan. 20, 2014]

[3]"The epidemiology of plantar fasciitis," Lower Extremity Review. [Online]. Available: http://lowerextremityreview.com/article/the-epidemiology-of-plantar-fasciitis

[Accessed: Jan. 20, 2014]

[4] IEC 60601-1 Medical Design Standards-3rd Edition [Accessed Feb 17, 2014]. Available at http://www.cui.com/catalog/resource/iec-60601-1-medical-design-standards.pdf

[5] Ryan, Goodrich, . "Accelerometer vs. Gyroscope: What's the Difference?" [online] 2013, http://www.livescience.com/40103-accelerometer-vs-gyroscope.html (Accessed : Web. 17 Feb. 2014)

[6] Powell, M., W. R. Post, J. Keener, and S. Wearden, "Effective Treatment of Chronic Plantar Fasciitis with Dorsiflexion Night Splints: A Crossover Prospective Randomized Outcome Study." *Foot & Ankle International,* vol. 19.1, pp.10-18, 1998.

[7]"Use an Accelerometer and Gyroscope with Arduino." *Instructables.com*. [online], http://www.instructables.com/id/Use-an-Accelerometer-and-Gyroscope-with-Arduino/ (Accessed: Web. 17 Feb. 2014)

[8] ""What Is Cradle to Cradle®."*Cradle to Cradle Islands (C2CI)",* [online], http://c2cislands.org/sjablonen/1/infotype/webpage/view.asp?objectID=1233 (Accessed: Web. 17 Feb. 2014)

[9] Canadian Standards Association (2014). Medical, Laboratory and Health Care. [Online] 17 Feb,2014. Available at http://www.csagroup.org/ca/en/industries/medical-laboratory-and-health-care/health-care

[10] P2700-IEEE Standard for Sensor Performance Parameter Definitions. [Online] 17 Feb,2014

Available at http://standards.ieee.org/develop/project/2700.html

[11] 1073-IEEE Standard for Medical Device Communications-Overview and Framework . [Online] 17 Feb,2014

Available at http://standards.ieee.org/findstds/standard/1073-1996.html

[12] Riddle, Daniel L., and Susan M. Schappert, "Volume of Ambulatory Care Visits and Patterns of Care for Patients Diagnosed With Plantar Fasciitis: A National Study of Medical Doctors." *The American Orthopaedic Foot & Ankle Society,* vol. 25.5, pp. 303-11, 2004.

[13] Shu L, Hua T, Wang Y, Li Q, Feng D, "In-Shoe Plantar Pressure Measurement and Analysis System Based on Fabric Pressing Sensing Array" *IEEE Transactions on Information Technology in Biomedicine,* Vol 14, no.3 , 2010 May

[14] Viswanathan V, Madhavan S, Gnanasundaram S, "Effectiveness of Different Types of Footwear Insoles for the Diabetic Neuropathic Foot, A Follow Up Study " *Emerging Treatments and Technologies,* Diabetes Care, vol 27, no2, 2004 Feb

[15] Hening EM, Milani TL, "In-Shoe Pressure Distribution for Running in Various Types of Footwear" *Journal of Applied Biomechanics,*, vol 11, pp 299-310, 1995