March 16, 2022

Dr. Mike Hegedus
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Simon Fraser University
Burnaby, British Columbia, V5A 1S6

Subject: ENSC 405W Design Specification for Project Zeta

Dear Dr. Hegedus,

Halcyon has prepared this design specification document for Project Zeta for ENSC 405W. Our Capstone mission is to establish a radically new bracing methodology to enable adolescents who are afflicted with Adolescent Idiopathic Scoliosis to become fully functioning and contributing members of society by optimising their brace treatment for an improved and accelerated recovery.

We strive to establish a new additive manufacturing methodology utilised by orthotists by creating a sensing system to measure pressure and force between the torso and brace, and then perform a digital topology optimization process for brace design in the treatment of AIS.

This document provides justification for our design specifications for Project Zeta's hardware, firmware, and software components, as well as how we will meet safety constraints for biomedical devices. We also provide appendixes outlining our design alternatives and test plan.

Our team consists of Systems and Computer Engineering students, namely Roy Ataya, Aidan Cook, Hamza Kamal, Kirill Melnikov, Paige Rattenberry, and Aki Zhou. Among others, we will also be collaborating with our industry contact, Carl Ganzert, a Certified Orthotist and the Acting Director of the Hodgson Orthopaedic Group's Research Division.

We can be contacted through our Chief Communication Officer, Aidan Cook at aidanc@sfu.ca.

Sincerely,

Aidan Cook
Chief Communication Officer
Halcyon (Company 8)

Halcyon

Design Specification Document

Project Zeta

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Issue Date:
March 16, 2022

Abstract

Adolescent Idiopathic Scoliosis (AIS) is a 3D spinal deformity that accelerates during growth periods and can progress to necessitate surgical intervention [1]. Orthotists are limited to relying strictly on their experience and anecdotal evidence to develop braces, but there are no accurate methods of quantitatively measuring brace fit and effectiveness outside of full spinal X-ray imaging, which can only be performed about once a year due to their harmful long-term severe radiation consequences.

Project Zeta is a pressure sensing system and topology optimization methodology that will allow for frequent collection of pressure measurements, enabling orthotists to make quantitative, data-driven decisions based on success trends in spinal curvature correction. This will eliminate the need for manual customization of the standard brace by orthotists, and the efficient creation of optimised and perforated 3D braces, that are comfortable, breathable, and lightweight, offering a significant improvement over the clinical standard 3mm thick, rigid plastic hard shell brace, without compromising biomechanical correction.

The design specifications for our optimised brace design workflow for the treatment of AIS will be detailed in this document. We provide justification for our design specifications based on crucial requirement specifications of our customers; orthotists, orthopaedic clinics and hospitals, for our pressure sensing hardware system, firmware components, software processing, user interface, and topology optimization technology. Each design specification will be classified by a development stage, split concisely between proof of concept, engineering prototype, and production. The appendixes describe our design alternatives and test plan.

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Glossary

The following table includes a list of terms mentioned in throughout the document

Term	Definition
AIS	Adolescent Idiopathic Scoliosis
CAD	Computer Aided Design
HW	Hardware
SW	Software
FM	Firmware
GUI	Graphical User Interface
DMM	Digital Multimeter

1 Introduction/Background

Impact of Scoliosis on Adolescent Lives

Adolescent Idiopathic Scoliosis (AIS) is a 3D spinal deformity, characterised by a vertebral/trunk rotation and lateral spinal curvature, that accelerates during growth periods and can progress to necessitate surgical intervention [1]. Therefore, early and optimal treatment is crucial because most optimal curvature correction results can only be achieved while a child is still growing. AIS has significant physical, psychological, surgical, and financial impacts on both patients and the medical system. Severe AIS cases have an increased risk for morbidity problems and mortality, musculoskeletal back pain, deformity, psychosocial distress, and pulmonary disorders [2].

Problem Background

Screening, diagnosis, treatment, and follow-up of AIS present several challenges because patterns of scoliotic spine evolution have not been well defined [1].

Curve magnitude, skeletal maturity, and curve morphology are important factors in brace treatment efficiency [3]. However, clinically relevant AIS spinal curvature classification and monitoring of brace correction is based on 2D back and lateral spinal X-ray images, which cannot describe the 3D deformity completely. Curve magnitude and angle is measured using the Cobb method, but reliability has been limited and have led to variations and suboptimal brace design, treatment, therapeutic management, and surgical results [4].

As a further complication, there is no consensus on the required magnitude of corrective pressure for ideal therapeutic results, and commercially available pressure sensor systems are too expensive and user-unfriendly, especially for long-term use [5]. Evidently, without concrete data and the ability to take multiple frequent snapshots of spinal curvature correction, orthotists are prevented from providing patients with the most optimal recovery scoliosis brace treatment they require from the start, and therefore suffering children cannot get the most optimal treatment that they deserve.

Limitations to Current Brace Treatment

We have been in direct communication with Carl Ganzert, a certified orthotist and the acting director of the Hodgson Orthopaedic Group's Research Division. Mr. Ganzert has emphasised that orthotists are currently limited to relying strictly on their experience and anecdotal evidence to develop torso braces which aim to push the spine into the correct position. However, there are no accurate methods of quantitatively measuring the fit and effectiveness of braces outside of full spinal X-ray imaging, which can only be performed about once a year due to their harmful long-term severe radiation consequences.

Furthermore, X-rays are not conducted by orthotists, so there is high variability in the images produced, and consequently, the degree of reliability is a concern.

Current Solutions and Research

Research endeavours have been mostly aimed at developing real-time sensor monitoring systems for brace wear compliance in AIS patients using measurements such as force and temperature [6, 7, 8, 9]. These products are not commercially available, nor are they used within a clinical setting on a common basis. In contrast, our project is aimed at taking the data from the pressure sensors a further step through a software process to create an optimised and sustainable brace design.

Project Mission and System Overview

We strive to establish a new brace design methodology utilised by orthotists by creating a sensing system to measure pressure between the torso and brace, and then perform a digital topology optimization for brace design used in the treatment of AIS.

With our system, pressure measurements could be collected frequently, allowing orthotists to make quantitative, data-driven decisions based on success trends in spinal curvature correction, enabling the efficient creation of optimal braces for treatment, and eliminating the need for manual customization of the standard brace by orthotists.

Force-sensing resistors will be connected to a microcontroller to obtain the pressure readings, which will be sent to a computer to be processed and displayed on a graphical user interface, to enable non-technical users to easily use this technology. The pressure data will then be converted to a point map that will be overlaid onto a general CAD brace model and fed into nTopology software. nTopology is expected to generate a mesh of an optimised and perforated 3D brace, that is comfortable, breathable, and lightweight, offering a significant improvement over the clinical standard 3mm thick, rigid plastic hard shell brace, without compromising biomechanical correction. The braces will also be built from environmentally friendly and recyclable material.

Design and System Illustrations

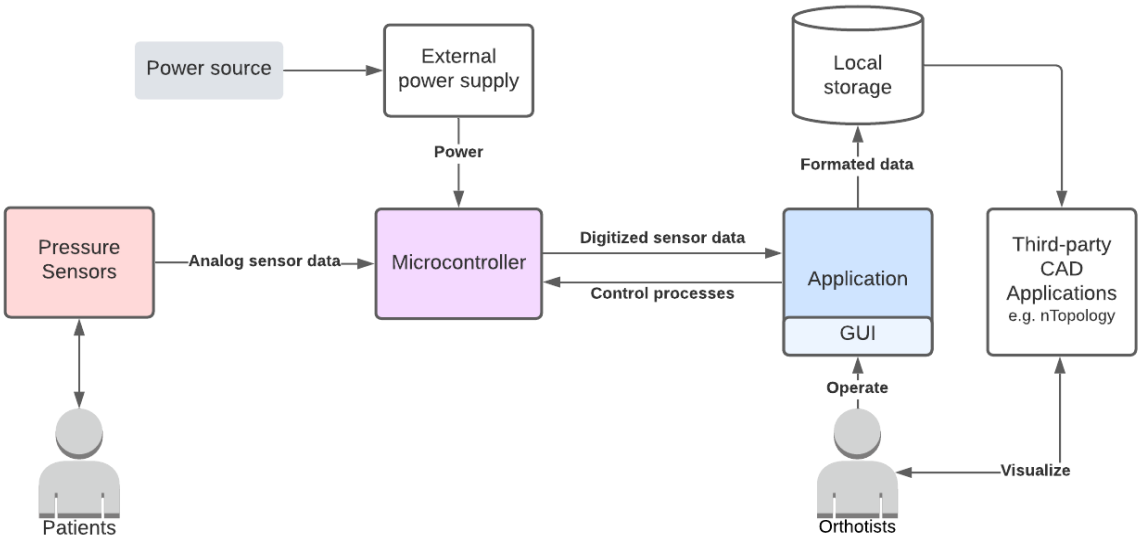

Figure 1 - Overall System Design

Expected Technical Challenges and Risks

Rendering a CAD model may be slow or too computationally demanding for the average orthoist's computer. The way we plan to mitigate this risk is to first only render the model with as little detail as required. We think ThreeJs's strong feature set will allow us to choose the right settings for our needs. If this is still too intensive, we have decided to use SceneJS which is built to render CAD models without any extra features. As a final contingency plan, we will use static images of each type of brace rather than a CAD model.

Furthermore, the sensors need to be connected to a microcontroller and must record accurate and precise pressure measurements. However, a risk is that the sensors may not be sensitive enough to record accurate readings due to our financial constraints. To mitigate this risk, we did research based on prior studies and articles to determine the general boundary conditions for pressure measurements that we can expect to achieve. Using these conditions we've selected sensors that will meet our requirements for pressure range.

Finally, the pressure data must also be processed into text file format and converted to a point map to be overlaid onto a general CAD brace model that must be fed into nTopology software to generate a mesh of an optimised and perforated 3D brace. However, nTopology is a very complex and complicated application that has many capabilities beyond what we require for the brace optimization process, so it may be challenging to

find the most relevant resources and understand the user interface and data input requirements. For example, Mr. Ganzert has provided us with a couple of example CAD brace models, which are in .obj and .igs format. However, these CAD geometries are currently not loading properly when trying to import them into nTopology , as they are not in an accepted file format. Therefore, a challenge we are encountering is converting the CAD files provided into a compatible format for use in nTopology.

1.1 Design Types & Classification

Similar to our requirements specifications, we chose to split the design specifications into four categories: General, Hardware (HW), Software (SW), and Firmware (FW). We also have general specifications, which exist to explain the integration of the system, and also any design details that do not fit into a specific category [10].

We split the design specifications into three phases of development:

Project Tag	Project Stage
A	Proof of concept
B	Engineering prototype
C	Production / User-testing

Table 1 - Development Stage Encoding

This document will reference requirements from the requirements specifications in order to link the customer needs to our design details. We do so through the following convention:

Req {Section}.{Requirement Number}
D {Section}.{Design Number}

The requirement numbering is referenced from the requirements document.

1.2 Intended Audience

This document serves as the design specifications for Project Zeta to the potential clients and partners, Dr. Mike Hegedus, Dr. Andrew Rawicz, and teaching assistants. Our potential clients would be orthotists, orthopaedic clinics and hospitals to aid in their brace treatment of children suffering from AIS. This document can also be used for reference when in discussion with industry professionals.

2 General Design

This includes generic details of our system, and aims to explain the design considerations made to have full integration.

Below is the requirements table from our previous document, which will be used as a reference for our general design specifications.

ID	Tag	Requirement Description
Req 3.1.1	A	The mats will be attachable to the brace.
Req 3.1.2	A	There will be a process which will consistently read out pressure on a mat for calibration.
Req 3.1.3	A	Sensors will be able to withstand the distributed pressure of a young adult, or basic curvature deformation.
Req 3.1.4	A	Mats will be able to be moved to sense different areas within the brace.
Req 3.1.5	B	Electronic components will be isolated from the user.
Req 3.1.6	B	Hardware will be protected and/or cushioned from impact.
Req 3.1.7	B	Positions of the mats will be known relative to the brace.
Req 3.1.8	B	The user should have low setup time to activate the pressure sensor system.
Req 3.1.9	C	Final product will cost under $500.

Table 2 - General Requirements

Des ID	Req ID	Tag	Design Specification Description
D.2.1	Req 3.1.3	A	Sensors will be aligned with adhesive pads to distribute force equally across the FSR.
D.2.2	Req 3.1.1, Req 3.1.4	A	Mats are attached using nano adhesive tape to easily detach and move the mats over the brace.
D.2.3	Req 3.1.3, Req 3.1.6	B	The pressure sensors will have cushioned mats surrounding them to avoid being easily broken.

Table 3 - General Design Specifications

Our general design specifications are mostly dealing with the connection of the mats to the brace. We wanted to ensure that it was easy to use, and simple to reattach into different locations. Tape is the simplest solution, in terms of functionality and for comfort, as it has small surface area and is easily placed in between the brace. In terms of D.2.1 and D.2.3, these dealt with the mat outer layer. We are planning on putting a cushioned mat in order to make force distribution more even, while also making it more comfortable for the patient to wear, and also protecting the sensors from breaking.

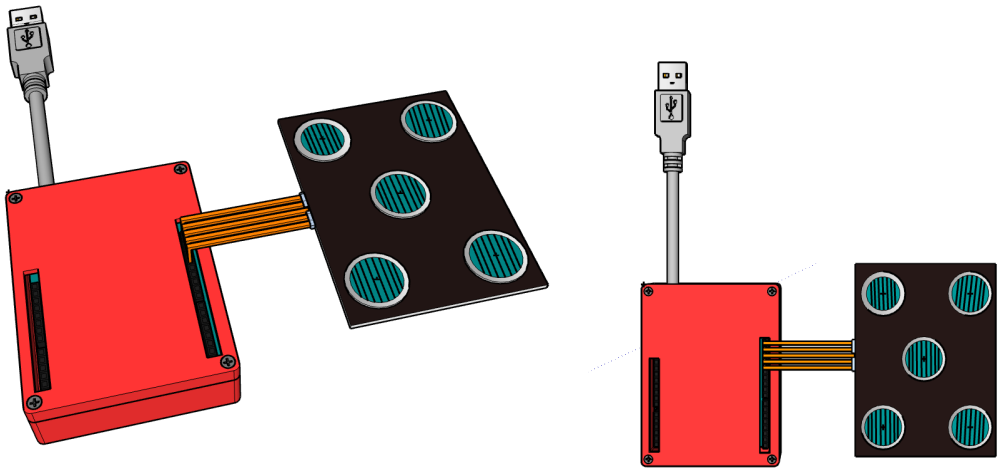

Figure 2 - Sensor Mat System Design

3 Hardware Design

Hardware is a key subsystem, as it deals with the pressure sensors, which is the fundamental object which is used to capture the relevant pressure data. This section focuses on key details related to sensor design. Below, we have a listing of the hardware requirements

ID	Tag	Requirement Description
Req 3.2.1	A	System is designed so a faulty sensor is able to be swapped out.
Req 3.2.2	A	The microcontroller will send data to a laptop or desktop computer.
Req 3.2.3	A	The user should be able to connect the microcontroller to a desktop.

Req 3.2.4	B	Pressure sensors will have a working range sufficient enough to measure up to 1.35Mpa [6] of pressure.
Req 3.2.5	B	Pressure sensor system is unobtrusive and thin.

Table 4 - Hardware Requirements

Des ID	Req ID	Tag	Design Specification Description
D.3.1	Req 3.2.1	A	Sensors will be wired in parallel.
D.3.2	Req 3.2.2	A	Microcontroller ADC will convert analog voltage signals to digital signals.
D.3.3	Req 3.2.3	A	Microcontroller will be powered by a 5V DC signal, through a USB connection.
D.3.4	Req 3.2.2, Req 3.2.5	A	Each mat will have a single connector that connects to the microcontroller.
D.3.5	Req 3.2.4	A	FSRs will be Interlink 402 UX models with a dynamic force range of 0.5 to 150N.

Table 5 - Hardware Design Specifications

The hardware specifications are presented here to detail the work that must be done on the sensors. The focus is to make the sensors easy to handle, and to ensure it is comfortable for a patient to wear. To ensure this, our specifications include that the sensor system has good cable management. It should be intuitive to use the mats, with nothing sticking out that is unnecessary for the user to know.

By having specific connectors, and parallel wiring, the sensor system ends up an organised and compact object. Other considerations of importance are data broadcasting. The simplest solution is through a USB connection, which also will provide a 5V power supply. This is the upper maximum for the voltage values that the microcontroller can read.

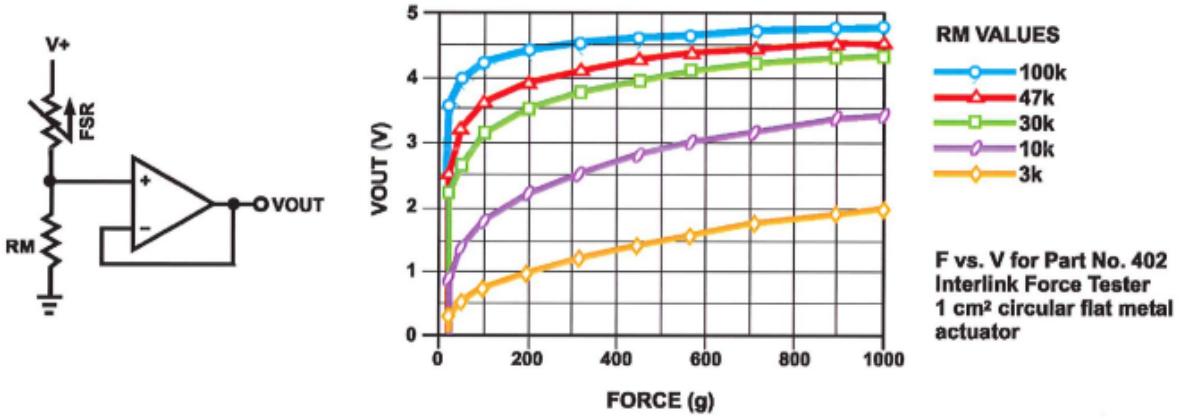

Figure 3 - Basic sensor setup from Interlink [11]

Figure 3 shows the basic recommended circuit setup for Interlink FSRs. In this set up, a unity gain amplifier is used to measure VOUT. The high input impedance of the amplifier keeps the voltage measurement from changing drastically when the amplifier is added to the circuit. This is its main purpose. However, the ADC on the microcontroller is optimised for this sort of operation and if we carefully choose our RM to be less than 10k Ohms [12], we do not have to worry about using an amplifier in our circuit. This means we can simply attach the output of the voltage divider to our input pins and achieve roughly the same results as the recommended circuit.

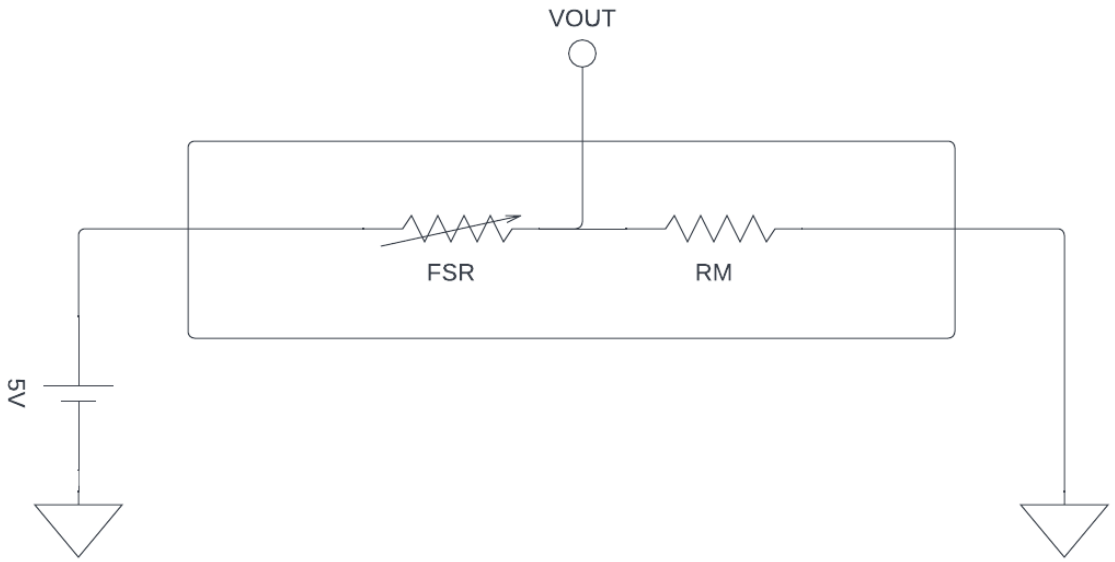

Figure 4 - Single FSR circuit

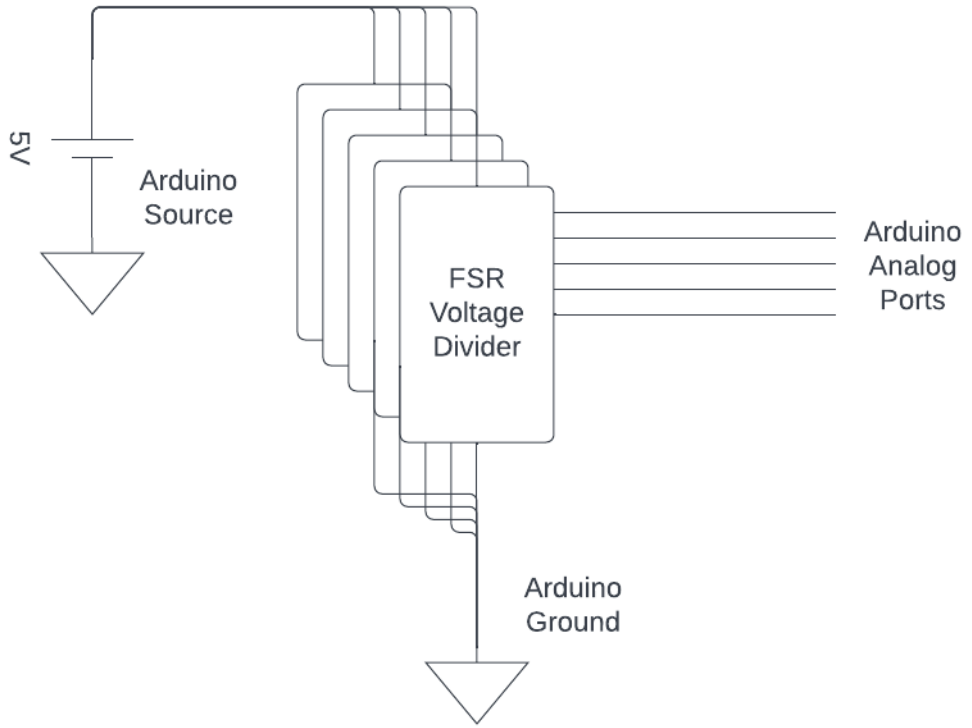

Figure 5- Multiple FSRs attached in parallel to an arduino

Figure 5 shows multiple FSRs connected in parallel to help demonstrate how a mat would be constructed out of five sensors. The FSRs share the input voltage and ground, but each individual sensor gets its own analog input port. With this parallel design, the failure of a single sensor will not compromise an entire mat or system.

The sensors chosen are the Interlink 402 UX series FSRs. These sensors were chosen as they have a force sensing range of 0.5N to 150N. The 402 model has an circular active sensing area with a diameter of 12.70 mm. From this we can calculate the pressure boundary conditions of these sensors.

$$P = \frac{F}{A}$$

$$A = \pi(0.0127)^2 = 1.2668\,x\,10^{-4}\,m^2$$

$$F = 0.5N \rightarrow 150N$$

$$P_l = \frac{0.5}{1.2668\,x\,10^{-4}} = 3.947\,kPa \qquad P_h = \frac{150}{1.2668\,x\,10^{-4}} = 1.185\,MPa$$

As you can see, this sensor model gets us close to our researched boundary condition of 1.35 MPa, while being accurate and cost effective.

4 Firmware Design

The Firmware design specifications show the interface between the hardware and microcontroller. The design specification should address how this interaction takes place, and how it is used to enable data communication between the two. Below is shown the requirements for the firmware from the requirements specification document.

ID	Tag	Requirement Description
Req 3.4.1	A	Data collected from the microcontroller will be in-sync across pressure sensors relative to time collected.
Req 3.4.2	A	Microcontroller data input should be accurate enough to capture all valid pressure sensor input
Req 3.4.3	A	Sends accurate digital data to a connected computer device.

Table 6 - Firmware Requirements

Des ID	Req ID	Tag	Design Specification Description
D.4.x	Req 3.4,1, Req 3.4,2, Req 3.4.3	A	Firmata[13]is used as a communication protocol for microcontroller to send data to our software
	Req 3.4.2	A	Microcontroller will have a 10-bit resolution ADC.

Table 7 - Firmware Design Specifications

The microcontroller will communicate with a host computer using the firmata communication protocol. This is the interface that will be used to ensure we have accurate, and valid data brought into our software. This also allows the software to take control of the port to be reading data from, and also when to read data.

5 Software Design

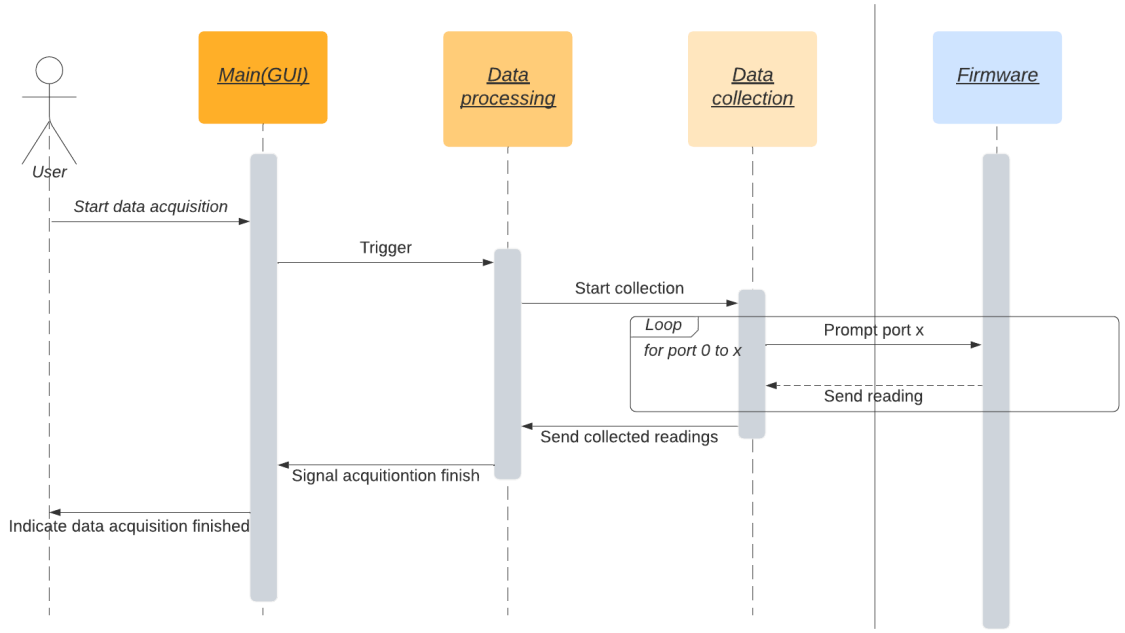

Figure 6 - Pressure data acquisition sequence diagram

The software design specifications deal with communicating with the microcontroller, the analysis of the data to be used by nTopology, and the actual data formatting to ensure it is in an acceptable form for nTopology to use. In short, It should show the full cycle data from the firmware of the microcontroller to the passing of data into nTopology.

ID	Tag	Requirement Description
Req 3.3.1	A	Software will read the correct pressure sensor values.
Req 3.3.2	A	Data will have positional information corresponding to the geometry of the brace model.
Req 3.3.3	A	Data will be formatted into a text file that matches the requirements needed by nTopology to convert the file into a point map.
Req 3.3.5	A	Users will be able to save data locally.
Req 3.3.6	B	Data will be associated with a patient.
Req 3.3.7	B	Users will be able to interact with the software using a GUI and receive visual feedback.
Req 3.3.8	C	GUI will be easy to use and intuitive for users.
Req 3.3.9	C	Users will have the ability to group multiple readings for a single patient.

Table 8 - Software Requirements

Des ID	Req ID	Tag	Design Specification Description
D.5.1	Req 3.3.1	A	Software will read serial data from the Firmata client library.
D.5.2	Req 3.3.3	A	The sensor data is written into a CSV with columns of x, y, z positioning and pressure value.
D.5.3	Req 3.3.5	A	Users can select the directory to save the readings to.
D.5.4	Req 3.3.2	B	Each sensor knows its position through the user selecting its location within the CAD model render in the GUI.
D.5.5	Req 3.3.6	B	Users can select a file name, or use default name which includes patient name, and timestamp of data collection.
D.5.6	Req 3.3.7, Req 3.3.8	B	User action on buttons will have a visual interaction once clicked.
D.5.7	Req 3.3.9	C	Users are given the ability to save file location, and structure through it the organisation as needed.

Table 9 - Software Design Specifications

The software interacts with the microcontroller and the firmware through the Firmata library.

The position of the pressure sensors relative to the patient's body is done through the GUI. The GUI will render the CAD model brace with a grid overlaid on top. The user will then be able to select the cell which the sensing mat is placed in and thus correspond the mat to a position on the brace. The GUI acts as the interface to select positioning since it is a quick way for the user to specify the location of a brace without having to measure out the location. Since the user is an orthotist with deep knowledge of their braces, they will not have trouble corresponding the real location to the CAD model.

The GUI will have features to save and organise the readings. It was chosen to have the readings saved to the user's computer local file system rather than a database since the amount of different records that need to be saved is quite minimal.

Below is shown a wireframe for the GUI. The shirt will represent a CAD diagram which will be rendered using a Javascript library. We want to ensure that the GUI is intuitive to use, and is easy to visualise. This is why the app has a limited amount of buttons, which focuses the user onto the important sections. Within the design details, particularly D.5.4

and D.5.6, it was specified that button clicks should have visual reactions. This is mainly pertaining to the CAD diagram. For every brace region selection, an equivalent position will be marked in the diagram showing the user what they selected. Of other particular interests is the 'File Directory' and the 'Capture Data' button. These are the actions that will fulfil the specifications of D.5.3, D.5.5, and D.5.7. A button is the easiest way for a user to complete these actions, which is why the GUI was designed this way.

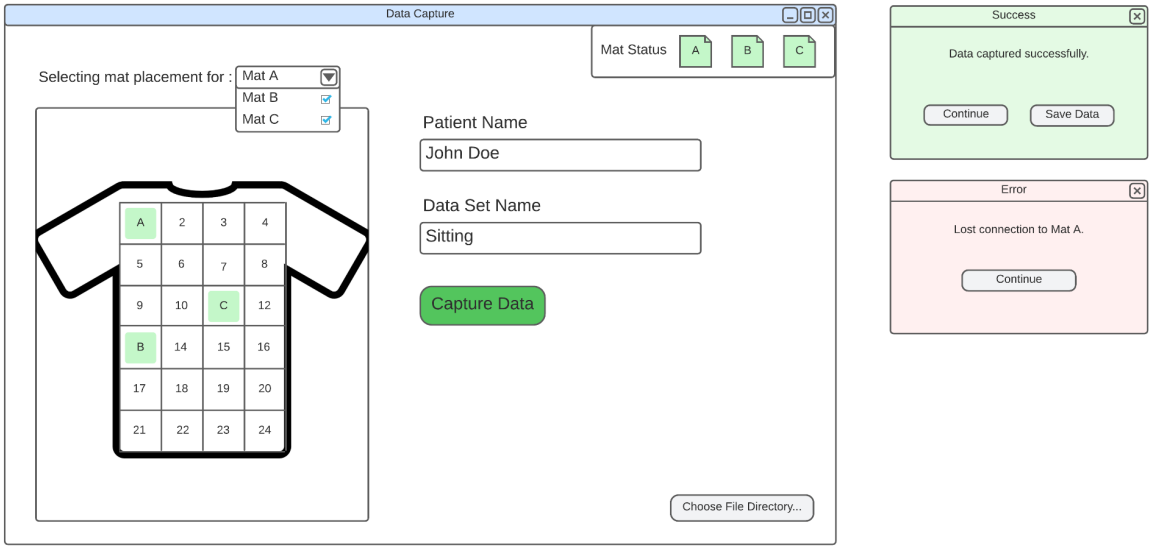

Figure 10 - Scoliosis Brace GUI Wireframe

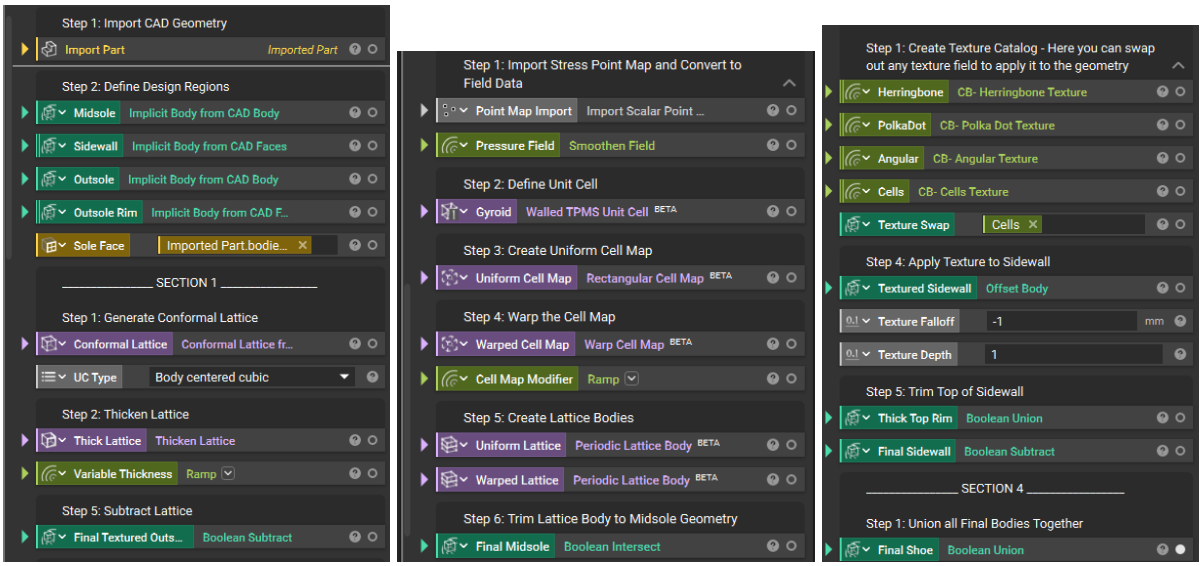

Figure 11 - nTopology Optimization Workflow Example

	A	B	C	D
1	274.2742	-6.14924	29.85847	0.000733
2	37.19882	36.50833	37.05526	0.376766
3	276.6899	-20.7928	31.06041	0.004055
4	255.1477	-45.7871	25.32559	0.432356
5	268.0383	-37.4426	28.63704	0.073047
6	259.8373	-43.4031	26.19685	0.362816
7	177.7879	-46.7001	18.55918	0.073698
8	241.0688	-50.9074	21.56833	0.183701
9	256.0905	-45.6278	25.05839	0.443004
10	248.5378	25.23706	22.36713	0.109524
11	85.75694	-29.9229	35.93104	0.42413
12	254.2701	-46.4063	24.1835	0.444715
13	168.5813	45.41957	20.62897	0.145443
14	246.7501	25.91466	22.84267	0.121741
15	261.5149	-42.0118	25.19031	0.266172
16	8.931864	-14.2807	37.30103	0.10234
17	62.87923	-35.8138	35.7217	0.151617
18	180.6739	-45.2795	19.0762	0.084875
19	67.49009	-34.3423	36.37235	0.330618
20	91.59223	37.99114	32.96283	0.157307
21	226.1682	-51.8232	18.96574	0.104684
22	275.3797	-28.3101	29.50324	0.038181
23	275.742	-27.6127	30.33119	0.021421
24	159.1543	-41.3386	21.52359	0.076982
25	158.6721	-40.7897	22.08167	0.080177
26	268.9042	7.714268	27.18506	0.005856
27	261.2735	14.18189	22.59199	0.02596

Stress Point Map

Figure 12 - CSV Input File Example with x, y, z, Coordinates & Pressure Reading at Each Specified Location

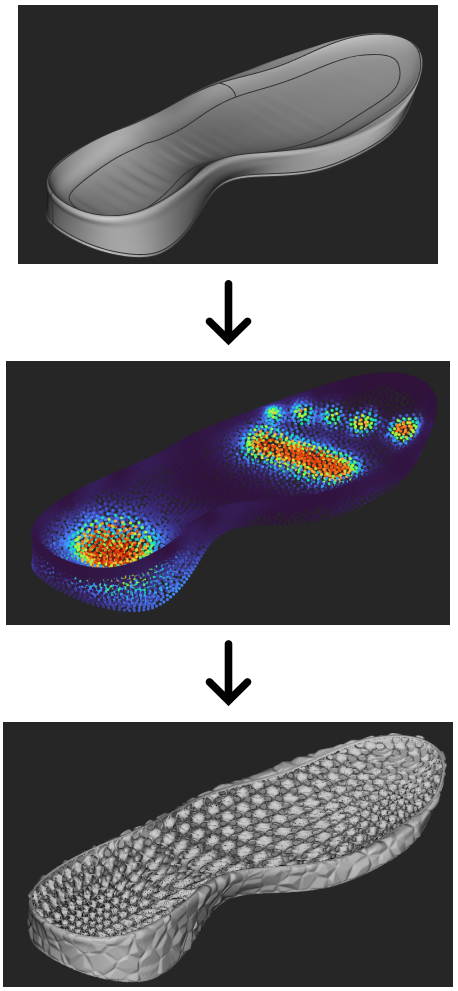

Figure 13 - nTopology Inputs & Outputs Example:
CAD Model, Stress Point Map, Optimised & Perforated 3D Design

6 Safety Design

The following table includes the sustainability/safety requirements required for the project.

ID	Tag	Requirement Description
Req 5.1	B	The device will not have any hard edges, particularly on any casings.
Req 5.2	B	Voltage and currents level will be low to not injure or shock the user.
Req 5.3	B	Mats will be durable and can not be easily torn apart.
Req 5.5	B	The device will not have any loose wiring, any tips shall not be exposed.
Req 5.6	B	Pressure sensors worn on brace should not hinder breathability, comfort, or cause any sorts of bruising/injuries.
Req 5.7	B	The device will have an automatic shut-off in the case of emergencies.
Req 5.8	C	The device's microprocessor should be shielded from shocks or drops
Req 5.9	C	Coverings will be made of fire retardant material and the wires should be sheathed in fire retardant material.

Table 10 - Safety Requirements

Des ID	Req ID	Tag	Design Specification Description
D.6.1	Req 5.5	B	Any wiring will have silicone tubing surrounding them to avoid injuries.
D.6.2	Req 5.1, Req 5.3, Req 5.6	B	Mats are surrounded by a cotton outer layer, with an inner plastic layer.
D.6.3	Req 5.1 Req 5.2. Req 5.8	B	Microcontroller is housed in an acrylic plastic mould.

Table 11 - Safety Design Specifications

Safety is a very important design specification for this product. The pressure system would be worn by scoliosis patients, which often means adolescents. Safety measures have to be in place to ensure that there is no chance of injuries.

There were several design choices that had to be made. These primarily revolved around the mats, the way the microcontroller was placed, and the wiring. We decided on several key ideas to ensure that the electronics were contained away from the patient.

FIrstly, the mats have two main components within it. We have an inner flexible plastic sheet. This is used to provide structural integrity to ensure the mats can't be easily bent. Such an action would likely break our sensors. The outer cotton layer was added to provide comfort to the patient.

For our microcontroller, our goal was to isolate the inner components, showcasing only the relevant ports. To achieve this, we would enhouse the microcontroller in an acrylic mould. To ensure that this is safe, the outer surface's edges would be sanded to ensure a smooth outer shell. This way, the inner components would be protected in the case of any drops, while isolating it from any curious hands.

4 Conclusion

Overall, our goal is to improve the lives of children and adolescents suffering from scoliosis, by empowering orthotists to make data driven decisions to optimize treatment, produce more comfortable braces, and accelerate recovery for those afflicted with AIS, enabling them to become fully functioning and contributing members of society.

Our system will be comfortable, safe, and non-invasive. It will be robust enough to handle pressure measurements along brace curvatures and not break under regular use. It will provide accurate pressure data to the user, while being easy to set up, and intuitive to use. Data will be formatted for use in nTopology, or other generative design tools, to optimize brace design effectiveness.

As Mr. Ganzert has stressed, successful completion of our project caters to the opportunity for orthotists to move beyond standard fabrication techniques which are relatively waste intensive due to current manufacturing realities which require the use of either plaster of paris or foam carvings that are discarded once braces are produced. Furthermore, the improved comfort and breathability would make the prescribed full time bracing protocols more sustainable for patients due to a reduction of hardship when it comes to brace wearing. Finally, this sustained effort caters to better treatment outcomes which at their core are focused on surgical prevention. Decreased scoliosis surgeries reduce burden on the medical system which is particularly strained due to the secondary and tertiary effects of Covid-19.

Therefore, our project will lead to enhanced environmental, medical, and social sustainability while improving patient outcomes. Through reducing the need for X-rays and using environmentally friendly material for our optimised brace, we will provide a safer and more environmentally friendly solution for treatment of children suffering from AIS, a devastating, life-threatening condition if not treated promptly and optimally.

5 APPENDIX: Design Alternatives

We had several design alternatives in discussion. The biggest issue was understanding how sensor positioning, cost considerations, and ease of use for our user. These three factors were the main things that we considered when evaluating our design choices, as they would dictate how the capstone would progress in a limited eight month period.

We originally had three main ideas, split into using either a pressure sensor shirt, worn under a brace, versus a set of pressure sensing mats, which were attached to a brace. A uniform pressure sensing shirt was the original idea of our industry contact, Mr. Ganzert. This was originally what we wanted to pursue, as it allowed an easy workflow. A patient would put on a shirt, the user would measure the patient in several poses, taking no more than several minutes, and then take it off. The main issue, as was discovered, was mapping the position of sensors. nTopology, the brace optimization software, requires as input a set of x,y,z coordinates.

To reliably get these coordinates is difficult. A patient can vary drastically, whether it be in weight, size, or posture. These elements are difficult to take into account. To have an accurate position be calculated analytically on a set of uniform sensors was not something that was possible in the scope of this capstone. To get over this issue, there were several ideas discussed. A possible solution was to use computer vision to capture sensor positioning. What would happen is that certain locations would be ‘marked,’ allowing the visual software to capture these points. These markings would represent the sensor's position. In turn, if due to patient variability these markings were shifted, the algorithm would capture the change and update the coordinates accordingly. This idea was withheld due to feature creep and scoping issues, as we did not see this as something feasible to accomplish in the given timeline.

The current design is a set of mats, which are attachable to different regions on a brace. This is the most current idea, and is the plan for development. The alternative to this was having a three mat pressure system. In general, scoliosis is limited to three main areas of interest on a torse, which is why the plan was to have pressure readings in these specified locations. This was the plan for a while, as it allowed the development process to be relatively straightforward, with a GUI that was simplistic in design. The issue with this idea

is that it was not flexible enough. nTopology needs a lot of data to have accurate optimizations, with a wide variety of coordinates. If we limited the pressure readings to only three locations, it was uncertain how reliable the data would be. In addition, the use case of the user is not set in stone. Though we say that the most important locations are the three specified positions, it does not mean that there are no other areas of interest to capture.

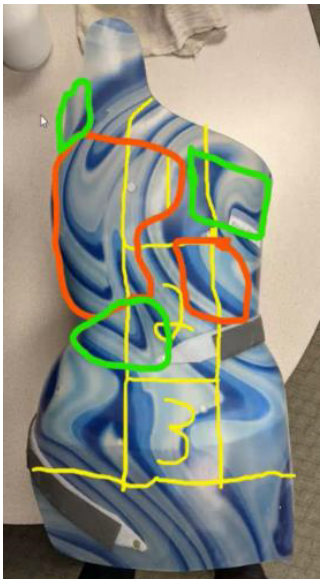

Figure 14: Standard Brace, 3-Point Pressure Regions (green), & Low Contact Areas (orange)

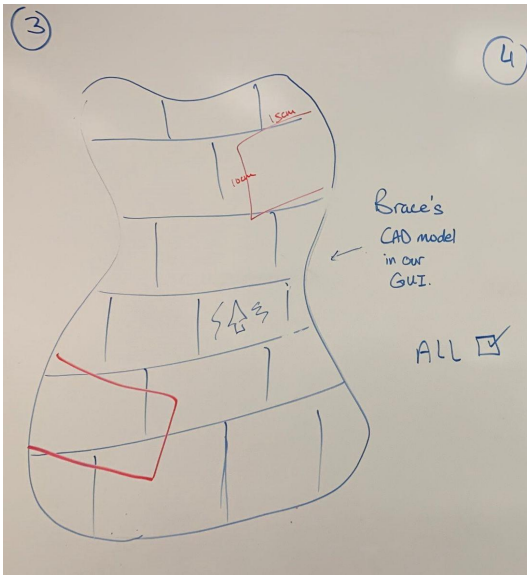

Figure 15: Sketch of Mat Positioning on Brace & GUI

Additionally, through our initial project idea generation meetings with Mr. Ganzert, it was proposed that as increased data is obtained through mapping of pressure scenarios, the brace optimization process would set the foundation for the generation of an artificial intelligence machine learning predictive analysis model.

We believe that the model could algorithmically look for success trends in previous patients with similar spinal curvatures and pressure measurements. This would in turn improve the accuracy, sensitivity, and specificity of predicting AIS curve severity, curve progression, brace design and effectiveness, leading to faster, more responsive and precise AIS correction progress. This would also thereby eliminate the need for anecdotal, manual customization of the standard brace by orthotists.

Furthermore, the 3D optimised mesh brace model generated by nTopology software could be further refined by cutting 3 separate panels into the back of the 3D brace through additive manufacturing. This would thereby allow for ultrasound visualisations that would be collected in the clinic more frequently than X-rays can be, as ultrasound does not emit the damaging and long-term harmful radiation consequences that x-rays do, which have been established as a risk factor of scoliosis management; bracing or otherwise. The

pressure/force and ultrasound data could then be algorithmically analysed together to refine optimization and treatment.

Unfortunately, we are limited by time constraints, and these ideal outcomes are not practical to achieve within the Capstone time frame. Therefore, we have narrowed down our project to creating the described pressure sensing system, achieving reliable and accurate results from the sensors, designing an interactive and intuitive GUI for orthotists to obtain and save the pressure measurements easily, performing the necessary data processing steps, and establishing a workflow in nTopology to generate the 3D optimised brace mesh. We hope that accomplishing these goals will make it possible for our ideal future potential optimizations to be achieved.

6 APPENDIX: Test Plan

This appendix details test plans for the entire system.

General Use Tests

Name	Startup testing
Description	Assemble the device. Plug the device into a computer USB port with software installed. Power on the device. Launch the software.
Expected Outcome	Computer should recognize the device and automatically list it in the software.

Table 12 - Startup Testing

Name	Data capture
Description	Fit the device to a patient. Enter necessary inputs into the software. Initiate data capture.
Expected Outcome	Software should provide feedback that data has been captured and present the user with next steps.

Table 13 - Data Capture Testing

Name	Saving data
Description	Initiate the data save process from within the software.
Expected Outcome	An explorer window should open and the user should be able to save to any directory location they desire. The files should be named based on the inputs provided during the start of the data capture process.

Table 14 - Saving Data Testing

Hardware Tests

Name	Sensor validation
Description	Take one mat and lay it flat facing up. Using a DMM or a microcontroller running testing firmware, press on each of the sensors individually.
Expected Outcome	Each sensor should output its own voltage difference, with the other outputs remaining unaffected if not being pressed.

Table 15 - Sensor Validation Testing

Name	Mat current draw
Description	Plug in a mat to a connector, measure the current draw coming from the 5V output pin.
Expected Outcome	The total current draw from the pin should not exceed 40mA.

Table 16 - Current Draw Testing

Name	Microcontroller housing
Description	Drop the microcontroller housing from a height of 3 feet above the ground.
Expected Outcome	The housing should not have any structural damage and the microcontroller should be in working order.

Table 16 - Current Draw Testing

Firmware Tests

Name	Serialising validation
Description	Set up testing software on the connected computer. Send serialised data from the microcontroller to the computer.
Expected Outcome	Data on the microcontroller is successfully serialised.

Table 17 - Serialising Validation Testing

Name	Mat disconnecting
Description	While a mat is plugged into a running microcontroller, disconnect the mat.
Expected Outcome	The microcontroller should detect that the mat has been disconnected and send a signal via serial port to the connected computer.

Table 18 - Mat Disconnecting Testing

Software Tests

Name	CAD model import
Description	Import multiple different obj files
Expected Outcome	Inspect that the CAD model is able to be rendered correctly and you can navigate around it

Table 19 - CAD Model Import Testing

Name	Data formatting
Description	Take multiple readings and save it to specified file directory
Expected Outcome	The readings should be format into a CSV with the suitable columns of x, y, z, and pressure for nTopology

Table 20 - Data Formatting Testing

Name	Data deserialization
Description	Once you start a reading, ensure you receive the data from the microcontroller
Expected Outcome	Incoming serial data is successfully deserialized by the software

Table 21 - Data Deserialization Testing

Name	Application stability
Description	Import a large CAD model file, take repeated readings, and click all the buttons available to ensure app stability
Expected Outcome	The application should be able to handle multiple readings, large CAD model renderings, and continued use without crashing

Table 22 - Application Stability Testing

Name	Disconnection feedback
Description	During a pressure reading, a mat is disconnected from the system
Expected Outcome	A feedback window should pop up alerting the user that a mat has been disconnected and stating where it was previously connected to

Table 23 - Disconnection feedback Testing

Name	Responsive during a reading
Description	On a reading, a user selects another GUI feature

Expected Outcome	On a reading the user should be able to select relevant GUI features

Table 24 - Responsiveness Testing

Name	Position sanity check
Description	A position is chosen on the CAD model rendering within the GUI
Expected Outcome	On a selection of a position, the position should be somewhere on the brace's surface

Table 25 - Position sanity Testing

Name	Faulty mat handling
Description	Software receives a signal that a mat is connected but without any data values being received
Expected Outcome	The software will give feedback to the user if there is no feedback received from the mat despite being connected and active.

Table 26 - Faulty Mat Testing

Safety Tests

Name	Automatic shutoff
Description	During a voltage spike, above 5V, the device should automatically shut off.
Expected Outcome	During testing of the reset circuit, it should automatically turn of

Table 27 - Automatic shutoff Testing

Name	Wire stress
Description	When running for a non-negligible amount of time, the wire should still function as intended
Expected Outcome	System works as expected; no unnecessary wear on the system, with no heat any of the components with wiring connections.

Table 28 - Wire Stress Testing

Name	Zener diode functionality
Description	Zener diode connected between the set of parallel sensor circuits should provide a constant voltage source.

Expected Outcome	The voltage read on the zener diode is the same value as was designed.

Table 29 - Zener diode Testing

7 References:

[1] H. Kuroki, “Brace treatment for adolescent idiopathic scoliosis,” Journal of Clinical Medicine, vol. 7, no. 6, p. 136, 2018.

[2] A. L. Kuznia, L. U. Lee, and A. K. Hernandez, “Adolescent idiopathic scoliosis: Common questions and answers,” American family physician, Jan-2020. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/31894928/. [Accessed: 27-Jan-2022].

[3] R. M. Thompson, E. W. Hubbard, C.-H. Jo, D. Virostek, and L. A. Karol, “Brace success is related to curve type in patients with adolescent idiopathic scoliosis,” Journal of Bone and Joint Surgery, vol. 99, no. 11, pp. 923–928, 2017.

[4] P. Phan, N. Mezghani, C.-É. Aubin, J. A. de Guise, and H. Labelle, “Computer algorithms and applications used to assist the evaluation and treatment of adolescent idiopathic scoliosis: A review of published articles 2000–2009,” European Spine Journal, vol. 20, no. 7, pp. 1058–1068, 2011.

[5] F. K. Fuss, A. Ahmad, A. M. Tan, R. Razman, and Y. Weizman, “Pressure sensor system for customised scoliosis braces,” Sensors, vol. 21, no. 4, p. 1153, 2021.

[6] C. Zhu, Q. Wu, B. Xiao, J. Wang, C. Luo, Q. Yu, L. Liu, and Y. Song, “A compliance real-time monitoring system for the management of the brace usage in adolescent idiopathic scoliosis patients: A pilot study,” BMC Musculoskeletal Disorders, vol. 22, no. 1, 2021.

[7] E. Chalmers, E. Lou, D. Hill, V. H. Zhao, and M.-S. Wong, “Development of a pressure control system for brace treatment of scoliosis,” IEEE Transactions on Neural Systems and Rehabilitation Engineering, vol. 20, no. 4, pp. 557–563, 2012.

[8] M. Kristof, R. Hudak, A. Takacova, J. Zivcak, L. Fialka, and R. Takac, “Contact pressure measurement in trunk orthoses,” 2010 International Joint Conference on Computational Cybernetics and Technical Informatics, 2010.

[9] O. Dehzangi, M. Mohammadi, and Y. Li, “Smart brace for monitoring patients with scoliosis using a multimodal sensor board solution,” 2016 IEEE Healthcare Innovation Point-Of-Care Technologies Conference (HI-POCT), 2016.

[10] Interlink Electronics, “Force Sensing Resistors, Integration Guide and Evaluation Parts Catalog, With Selected Electrical Interfaces,” Datasheet 90-45632 Rev. D Version 1.0.

[11] R. Ataya, P. Rattenberry, A. Zhou, H. Kamal, A. Cook, and K. Melnikov, Burnaby, BC, rep., 2022.

[12] Atmel. “8-bit Atmel Microcontroller with 16/32/64KB In-System Programmable Flash,” 2549Q–AVR–02/2014 datasheet, 2014.

[13] Firmata (2017) protocol [Source Code]. https://github.com/firmata/protocol/