February 13, 2022

Dr. Mike Hegedus
School of Engineering Science
Simon Fraser University

Subject: ENSC 405W Requirements Specification for Project Zeta

Dear Dr. Hegedus,

Halcyon has prepared this requirement specification document to outline our requirements for Project Zeta for ENSC 405W. Our Capstone mission is to establish a radically new methodology to optimize treatment to significantly impact the lives of children suffering from Adolescent Idiopathic Scoliosis.

We strive to accomplish this through the creation of a pressure sensing system that orthotists would use to collect pressure measurements, which could then be utilized by software such as nTopology to generate more comfortable, breathable, and lightweight brace models. With our system, pressure measurements could be collected frequently, as opposed to only once per year which is currently the case with X-ray imaging, thereby 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.

This document will address the overall project scope, requirements, safety concerns, and engineering standards. 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 Orthopedic Group's research division.

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

Sincerely,

Aidan Cook
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Halcyon (Company 8)

Halcyon

Requirements Specification
Project Zeta

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Abstract

This document outlines the requirements of Project Zeta to be met by our team at Halcyon. It provides a general overview of our product and describes the requirements that will be met. This includes the general functional requirements that describe the system, as well as requirements for each subsystem, split between hardware, software, and firmware. Each requirement will be classified by a development stage, split concisely between proof of concept, engineering prototype, and production. This document also outlines the constraints imposed on the system and details the Engineering Standards and efforts towards Safety and Sustainability.

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Glossary

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

Term	Definition
AIS	Adolescent Idiopathic Scoliosis
CAD	Computer Aided Design
FW	Firmware
GUI	Graphical User Interface
HW	Hardware
nTopology	Generative design software
PoC	Proof of Concept
SW	Software

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1 Introduction

Adolescent Idiopathic Scoliosis (AIS) is a 3D spinal deformity which progresses rapidly during growth periods, and therefore early and optimal treatment is crucial.

Halcyon is striving to create a digital optimization methodology that utilizes a pressure sensing system to measure pressure and force between the brace and torso of children suffering from AIS, which then applies the data acquired into software to optimize treatment. The sensors will be connected to a microcontroller to obtain the pressure readings, which will be processed into text file format and converted to a point map that would be overlaid onto a general CAD brace model and fed into nTopology software. nTopology could generate a mesh of an optimized 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.

The pressure measurements could be collected on a much more frequent basis than X-rays which pose serious long-term harmful radiation consequences, and the additional data snapshots could be used to see trends in spinal curvature correction overtime to optimize brace design.

This brace optimization workflow process will provide the foundation to generate a predictive analysis model through machine learning based on trends in pressure measurements to improve accuracy, sensitivity, and specificity of predicting AIS curve severity & progression, brace design & effectiveness. This would thereby eliminate the need for anecdotal, manual customization of the standard brace by orthotists.

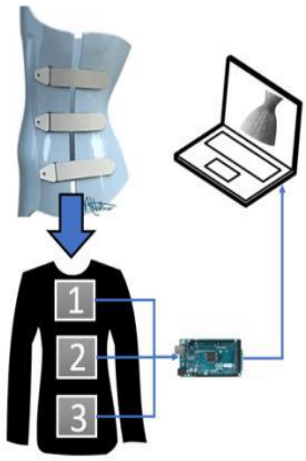

Figure 1: High level design

1.1 Background

Adolescent Idiopathic Scoliosis (AIS) is a 3D spinal deformity characterized by a vertebral/trunk rotation and lateral spinal curvature. Untreated AIS progresses rapidly during growth periods [1]. Early treatment is crucial because most optimal curvature correction results can only be achieved while a child is still growing. Severe AIS cases have an increased risk for morbidity problems and mortality, musculoskeletal back pain, deformity, psychosocial distress, and pulmonary disorders [2].

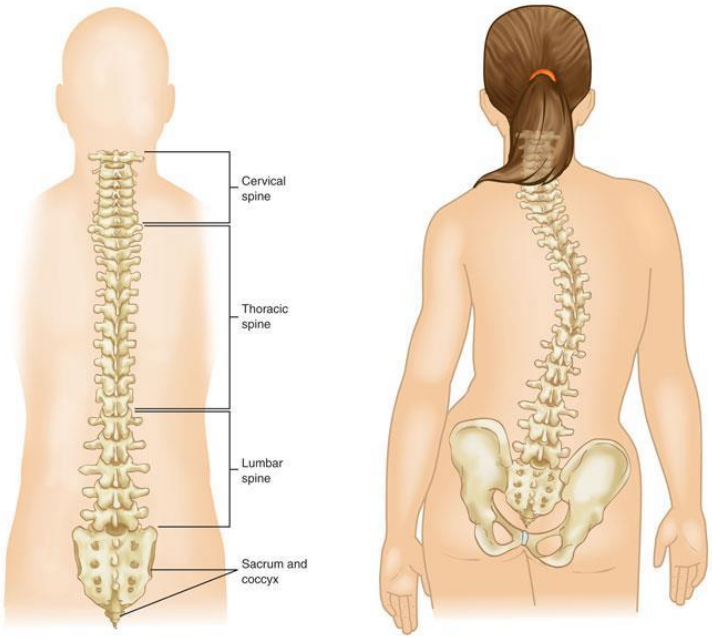

Figure 2: Idiopathic Adolescent Scoliosis (AIS) [3]

Screening, diagnosis, treatment, and follow-up of Adolescent Idiopathic Scoliosis (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 [4]. 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 [5].

Therefore, orthotists are currently limited to relying 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.

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 [6]. 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 they require from the start, suffering children cannot get the optimal care that they deserve.

1.2 Current Solutions and Research

Research endeavors have been mostly aimed at developing real-time monitoring systems for brace wear compliance in AIS patients using measurements such as force and temperature [7, 8, 9, 10]. These products are not commercially available, nor are they used within a clinical setting on a common basis. For example, a 2021 project attempted to validate the accuracy and precision of a pressure sensing system for use within scoliosis braces. The project demonstrated great design by enabling a versatile pressure sensor system that is directly linked inside to the brace. As a result, they were able to gather and plot the pressure data with a root mean square error of around 12% [6].

1.3 Further Potential Optimizations

Our three-point pressure sensing system could be further expanded into a comprehensive system with sensors surrounding the entire torso, which our orthotist industry contact Carl believes would allow orthotists to determine if any other unknown locations are crucial to the AIS spinal correction treatment process.

Furthermore, the 3D optimized mesh brace model generated by nTopology could be further refined by cutting 3 separate panels into the back of the 3D brace to allow for ultrasound visualizations that would be collected in the clinic more frequently than X-rays, as ultrasound does not emit damaging and long-term harmful radiation consequences. The pressure/force and ultrasound data could be algorithmically analyzed together to refine optimization and treatment.

As increased data is obtained through mapping of force scenarios, this will set the foundation for the development of a machine learning predictive analysis model that should be able to be generated to improve the accuracy, sensitivity, and specificity of predicting AIS curve severity, curve progression, brace design and effectiveness. In the future, a predictive analysis treatment model would algorithmically look for success trends in previous patients with similar spinal curvatures using machine learning, leading to faster, more responsive, and precise AIS correction progress. This would thereby eliminate the need for anecdotal, manual customization of the standard brace by orthotists.

1.4 Intended Audience

This document serves as 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, orthopedic 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 Process Details

2.1 Problem Statement

The overall goal is to enable pressure data acquisition within the professional field of an orthotist. Because brace creation is an anecdotal practice, optimizations of the brace that must be done for patient comfort are done mostly based on experience. By incorporating data acquisition within this field, we can enable large scale optimizations that can potentially be commercialized to make braces more efficiently and of higher quality.

2.2 System Overview

On a high level, the overall system starts with the FSR pressure sensors, which would be the primary data acquisition nodes that will enable us to capture pressure data. To ensure each sensor is operating correctly, we would connect a calibration system to each of the mats. This would be a piece of software that would test and verify that the sensors are working correctly for known values. Once the data is captured, it would be sent to a computer running software which would process and format the data sent by a microcontroller. This file is then overlaid onto a CAD brace model in a third-party software such as nTopology to generate an optimized 3D mesh brace design.

In terms of production design, we would have a GUI that can be used to start the data acquisition process, to ensure non-technical users can easily use this technology.

Figure 3 illustrates the system.

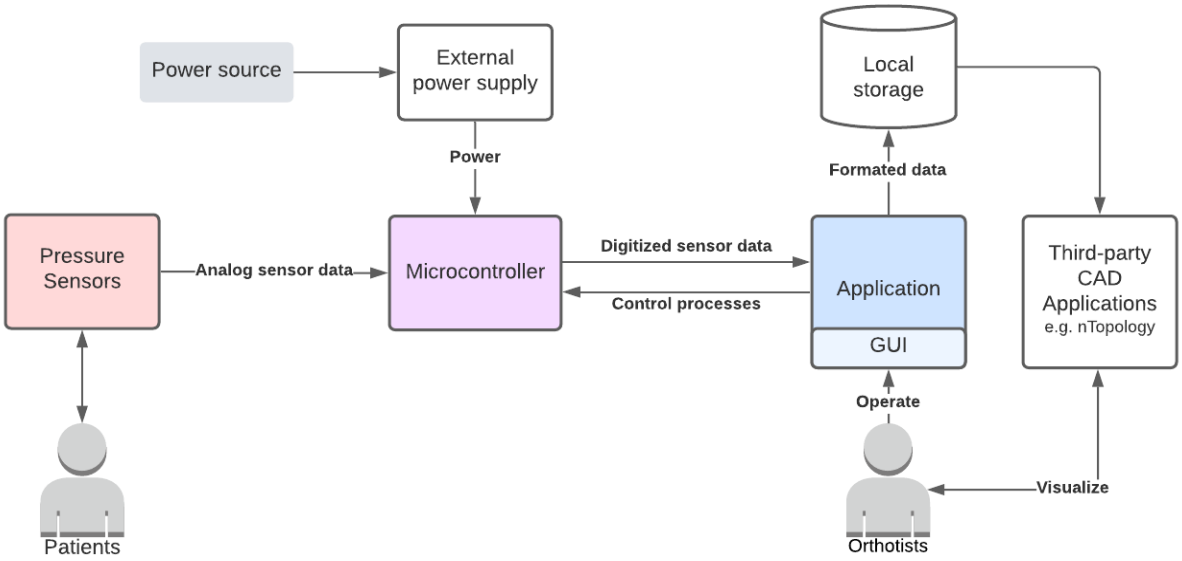

Figure 3: Overall system design

The pressure sensing mats contain uniformly distributed pressure sensors, which would measure and map forces between the brace and torso. The mats would be held in place underneath the brace. Scoliosis braces generally work using a three-point pressure system. These mats would each sit on one of these pressure points, highlighted in the green areas shown in Figure 4. They are areas that see constant pressure, which is why we want to measure them specifically for scoliosis patients.

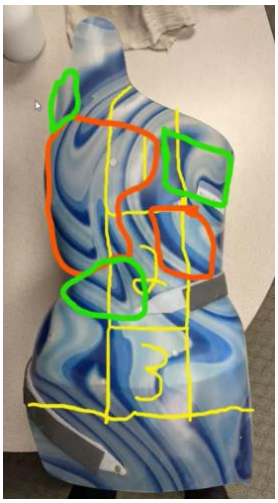

Figure 4: Existing brace and pressure areas (green) and low contact areas (orange)

2.3 Requirement Types & Classification

The requirement types we chose are split into four categories: General, Hardware (HW), Software (SW), and Firmware (FW). The reason we chose to split the requirements into these classifications is because tracing a measurement from the patient to a usable state by the orthotist flows from hardware to firmware, to software. These three classifications are explicitly flowing from one to another, like a channel. Above these exist general requirements, which are attempting to specify the integration effort of the system, and any non-specific requirements that do not fit into the above-mentioned classifications.

The requirements are split under the three tags:

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

Table 1 - Development Stage Encoding

The requirements in this document will follow the following convention:

Req {Section}.{Requirement Number}

3 Requirements

3.1 General Requirements

General requirements are explicitly related to the overall system that we are attempting to implement. It should highlight the integration effort of the three categories SW, HW, and FW. Overall, what our goal with this section is to explain the system interaction that must take place to achieve a working solution. This also deals with any components that are not electrical.

ID	Tag	Requirement Description
Req 3.1.1	A	There will be a process which will consistently read out pressure on a mat for calibration.
Req 3.1.2	A	Sensors will be able to withstand the distributed pressure of a young adult.
Req 3.1.3	A	Mats will be able to be moved to sense different areas within the brace.
Req 3.1.4	B	Mats should be durable enough where you can't easily tear them apart.
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.
Req 3.1.10	C	System will consist of 3 pressure sensing mats, a microcontroller, a USB power cable, and connecting circuitry between the mats and microcontroller.

Table 2 - General Requirements

3.2 Hardware Requirements

The most fundamental part of our project is to have pressure data measurements. This means the hardware used must be able to provide some form of analog signals and convert it into digital signals so the firmware can pass the data to the software for processing.

ID	Tag	Requirement Description
Req 3.2.1	A	The microcontroller will send data to a laptop or desktop computer via USB connection.
Req 3.2.2	A	Sensors will need to withstand basic curvature deformation against the inside of the brace.
Req 3.2.3	A	Sensors will be thin enough to be unobtrusive underneath the brace and attached to the mats.
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	Voltage and current will be low enough to not cause any harm should there be any contact with live wires.
Req 3.2.6	B	An amplifier circuit will amplify all sensor signals before being read by the microcontroller ports.
Req 3.2.7	C	The microcontroller will be powered by a USB cable connected to a laptop or desktop computer.
Req 3.2.8	C	The mats will be able to be detachable from the rest of the system.

Table 3 - Hardware Requirements

3.3 Software Requirements

The Software requirements deals with understanding the effort it takes to capture data from the microcontroller, format it to the appropriate types that is accepted by software such as nTopology, and the data analysis that takes place once pressure data can be successfully mapped onto a CAD body. It should highlight the movement of data across the different channels, from microcontroller to a CAD file.

ID	Tag	Requirement Description
Req 3.3.1	A	Software will read serial data sent from a connected

		microcontroller.
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 3.3.4	A	Software will be able to feed readings into a nTopology workflow to develop a brace designed model.
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	A GUI to interact with the software 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 4 - Software Requirements

3.4 Firmware Requirements

The Firmware requirements was a section made to explain the bridge between hardware and software. The main goal here is to outline the specifications needed to have successful data acquisition, as there must exist a programmable microcontroller in place to have this development.

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	Bit resolution of microcontroller data input should be accurate enough to capture all pressure sensor input that is not an outlier.
Req 3.4.3	A	Sends accurate digital data to a connected computer device via USB.

Table 5 - Firmware Requirements

3.5 Constraints

We are constrained by several things. In total, our budget is around $500. This means that we have a limited number of sensors to work with. We need many of them, and we need them to be relatively accurate, while still bearing a tolerable weight that can be applied by a person. Because of these restrictions, buying expensive high resolution and high load bearing pressure sensors was not an option. In turn, accuracy can suffer from the sensor input, where it is projected that a 12% error range or more is likely [6].

Because of the costs, performance of the microcontroller will also potentially suffer. Compared to high end models that could be bought, we decided to go with a relatively simplistic Arduino model. This means that data collection can be slow, depending on the amount of information being processed. However, there is no way around this, excluding code optimization, to enable data acquisition. On top of this, accuracy of the voltage will suffer. Bit resolution differs depending on the cost of the microcontroller, so it's expected that the possible voltage range that can be captured from the Arduino will have lower granularity, compared to high end models.

On top of performance, because the microcontroller is relatively simple, there are a limited number of ports. This in turn means we will most likely need multiple microcontrollers to be able to connect to all the pressure sensors. As such, overall performance can suffer because of the need to have multiple microcontrollers.

4 CEAB Outcomes

4.1 Responsibilities of an Engineer

The responsibilities of an engineer are relevant across all aspects of the project lifecycle. Since this product interacts with sensitive data and comes in close contact to a patient’s body, the engineering standards laid out below must be followed. The primary priority within our company must always be the safety of the patient’s body and privacy.

4.2 Engineering Standards

4.2.1 Electrical

The following table includes the electrical standards required for the project.

Standard	Description
CAN/CSA-C22.2 NO. 61508-1:17	Functional safety of electrical/electronic/programmable electronic safety-related systems.
IEC 63203-406-1:2021	Wearable electronic devices and technologies - Part 406-1: Test method for measuring surface temperature of wrist-worn wearable electronic devices while in contact with human skin.
IEC TR 63071:2016	Power supplying scheme for wearable system and equipment.

Table 6 - Electrical Engineering Standards

4.2.2 Software

The following table includes the software standards required for the project.

Standard	Description
CAN/CSA-CEI/IEC 62304:14	Software life cycle processes (Adopted CEI/IEC 62304:2006, first edition, 2006-05)

Table 7 - Software Engineering Standards

5 Sustainability & Safety

Our goal is to provide orthotists with the ability to measure pressure, but this data must come from user testing, which in turn implies we are making wearable technology for children afflicted with scoliosis.

We want to create something that is hazard free. Even if there is a malfunction, it should not harm the patient. Therefore, we want to avoid any exposed wiring, and why we want to make it where any important electronic components such as pressure sensors are isolated, converted while still presenting a wearable device that is comfortable to put on.

The biggest question concerning sustainability of this project is to do with maintainability. As we know, sensors and microcontrollers aren't exactly the most robust pieces of equipment. It's easy to break and is something small enough that is prone to being stirred, grabbed, and

touched. We want to avoid this, not only to preserve the integrity of the system, but also to ensure safety standards are upheld.

Keep in mind that if this project is being user tested, it would be done in the presence of a professional orthotist. As such, this makes it less likely the user would put themselves at risk wearing, as there is someone always monitoring them. However, we still must make a project that is self-sustaining in terms of safety, irrespective of someone else's presence.

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

ID	Tag	Requirement Description
Req 5.1	B	The pressure sensors will have cushioned mats surrounding them to avoid being easily broken.
Req 5.2	B	The device will not have any hard edges, particularly on any casings.
Req 5.3	B	Any wiring will have silicone tubing surrounding them to avoid electrical shocks.
Req 5.4	B	Voltage and currents level will be low to not injure or shock the user.
Req 5.5	B	Mats will be durable and cannot be easily torn apart.
Req 5.6	B	Coverings will be made of fire retardant material and the wires should be sheathed in fire retardant material.
Req 5.7	B	The device will not have any loose wiring, any tips shall not be exposed.
Req 5.8	B	Pressure sensors worn on brace should not hinder breathability, comfort, or cause any sorts of bruising/injuries.
Req 5.9	C	The device will have an automatic shut-off in the case of emergencies.
Req 5.10	C	The device will have the microcontrollers encapsulated in a hard casing.

Table 8 - Sustainability and Safety

6 Conclusion

Overall, our goal is to improve the lives of children suffering from scoliosis, by empowering orthotists to make data driven decisions to optimize treatment. 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.

7 Appendix

7.1 Proof of Concept Deliverables

For the proof-of-concept deliverables which will be presented in April, Halcyon will be presenting the following deliverables:

- A thin pressure mat that can be calibrated and record accurate pressure readings for simple geometries, e.g. a cylinder.
- The mat will have a uniform distribution of pressure sensors within it.
- Firmware that can send digital pressure data to a laptop via USB.
- Software that can receive data over USB and format it into a valid file format accepted by nTopology, as well as saving the formatted data locally.
- Need to measure pressure accurately.

7.2 Challenges to be addressed

There are multiple challenges that need to be addressed in more detail before the completion of the PoC. They are as follows:

- The pressure sensors need to be mapped to locations on the brace CAD model accurately.
    - How exactly this can be done while ensuring a high level of user friendliness is a paramount challenge.
- A process needs to be developed to consistently evaluate accuracy and calibrate sensors.
- Data needs to be properly serialized before being sent from the microcontroller to the software.
- The nTopology software needs to be thoroughly learnt to understand data ingestion and its full capabilities.

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