Halcyon

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Scoliosis Brace Optimization

Aidan Cook, Aki Zhou, Hamza Kamal, Kirill Melnikov, Paige Rattenberry, Roy Ataya

Our Team

Aidan Cook - CCO 	Aki Zhou - CEO 	Hamza Kamal - CIO 
Kirill Melnikov - CTO 	Paige Rattenberry - CRO 	Roy Ataya - CFO 

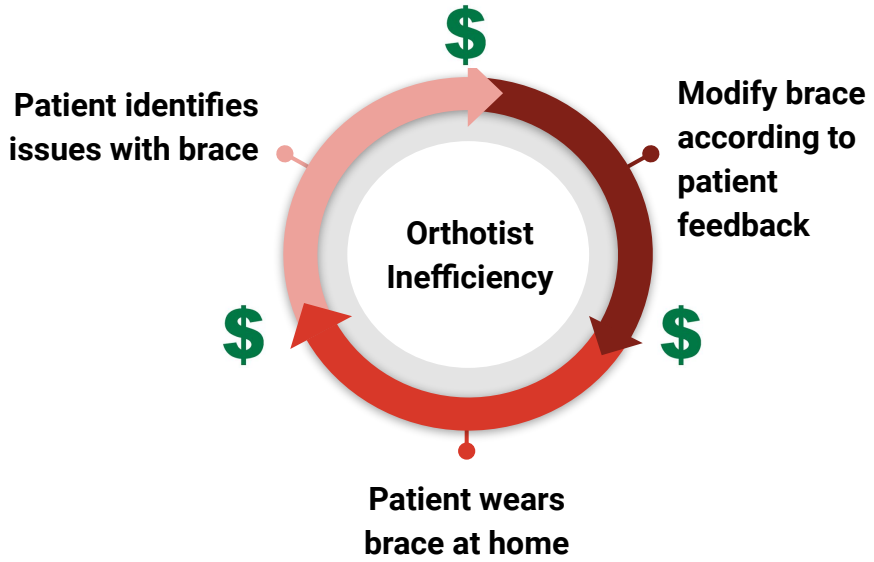
Presentation Overview

- The Problem, Solution, and Business Pitch
- Technical Case
  - Hardware
  - Firmware
  - Software
- Engineering and Safety Standards
- Risk Management
- Team and Product Build Reflection
- Future Optimizations

The Problem We Solve

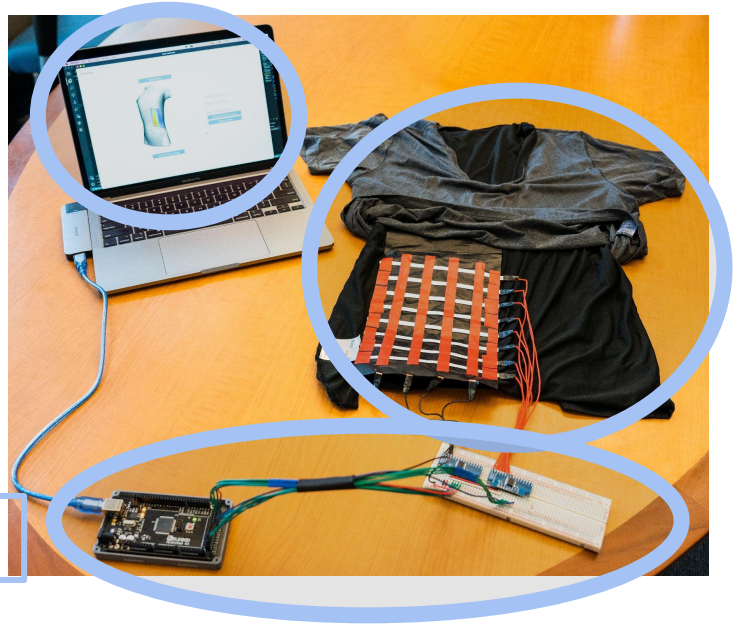
- Scoliosis affects 3-5% of children but it can be reversed through the use of bracing
- There are no systems for measuring scoliosis brace effectiveness by analyzing pressure applied on the torso

- Many iterations to optimize the brace
- Each optimization costs time and money



The Solution

GUI visualization



Pressure sensing shirt

Prototype control hardware

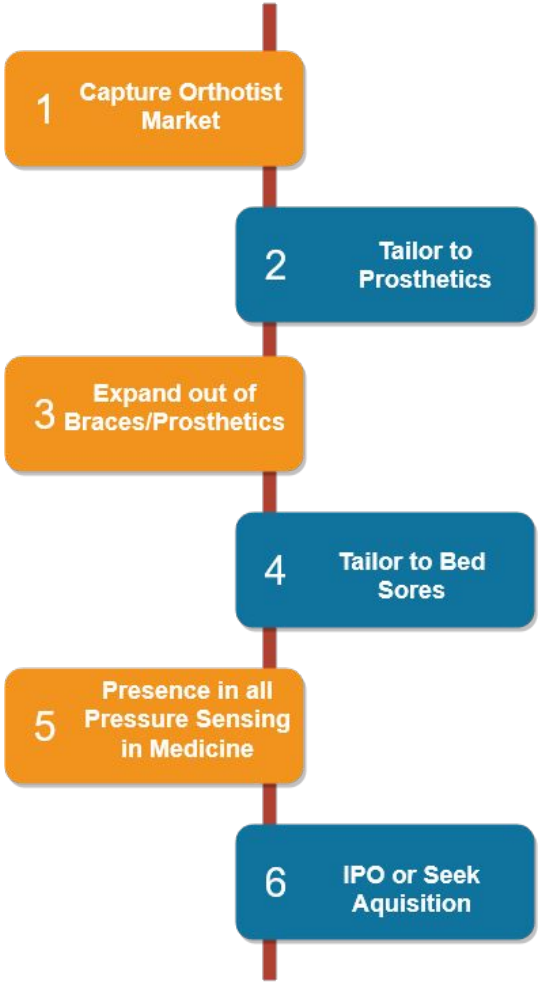
Better & quicker treatment for more patients → More revenue generated by clinics

Halcyon’s Entrance / Sales Strategy

- Generally, medical devices are expensive due to safety regulations and high standards
- Our industry contact has stated that he would be willing to pay thousands for our system
- We plan to sell at a flat cost of $2400, avoiding serviceability issue

Halcyon’s Exit Strategy

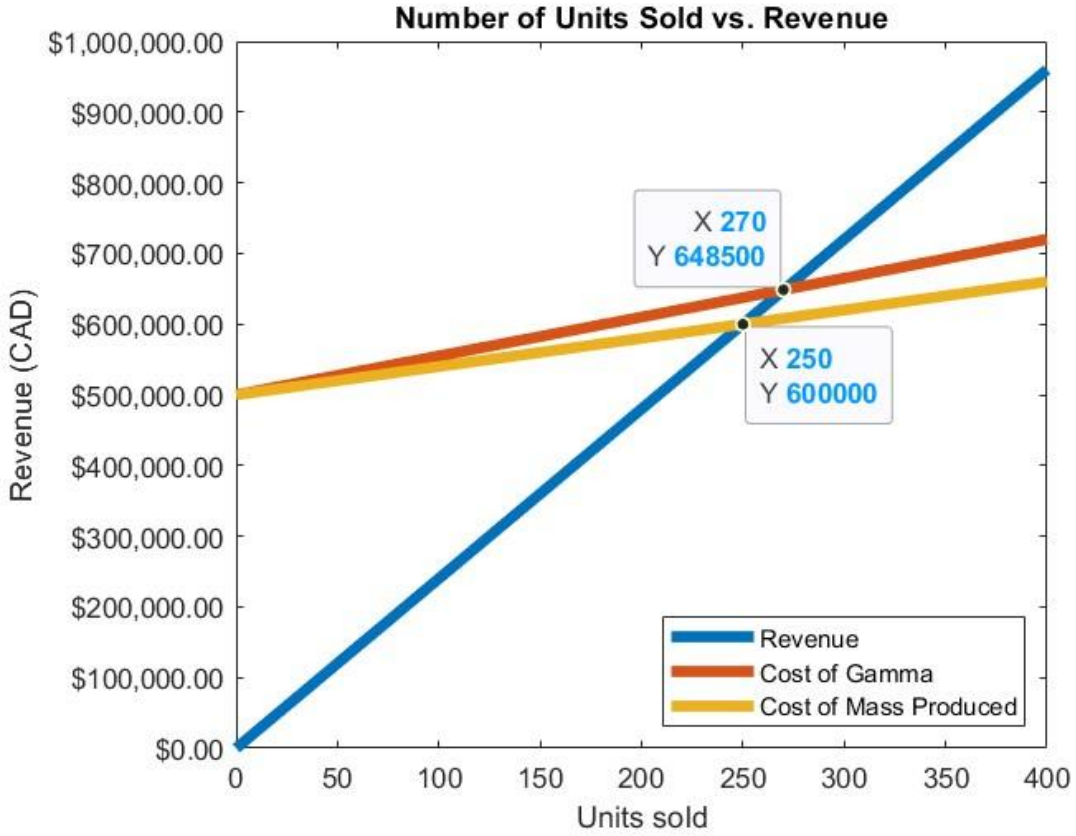
- Our primary path is a merger/acquisition
- Going public would require us to pivot to satisfy a larger market cap and customer base which would occur at a later stage of growth



Market and Sales Strategy

Market Outline	
Total Addressable Market	Total number of orthotists, prosthetists, and orthopedicians in North America, totals to 33,000.
Serviceable Addressable Market	10k+ Orthotists and Prosthetists in North America.
Serviceable Obtainable Market	Expected 30% of our serviceable addressable market.

Break-Even Analysis



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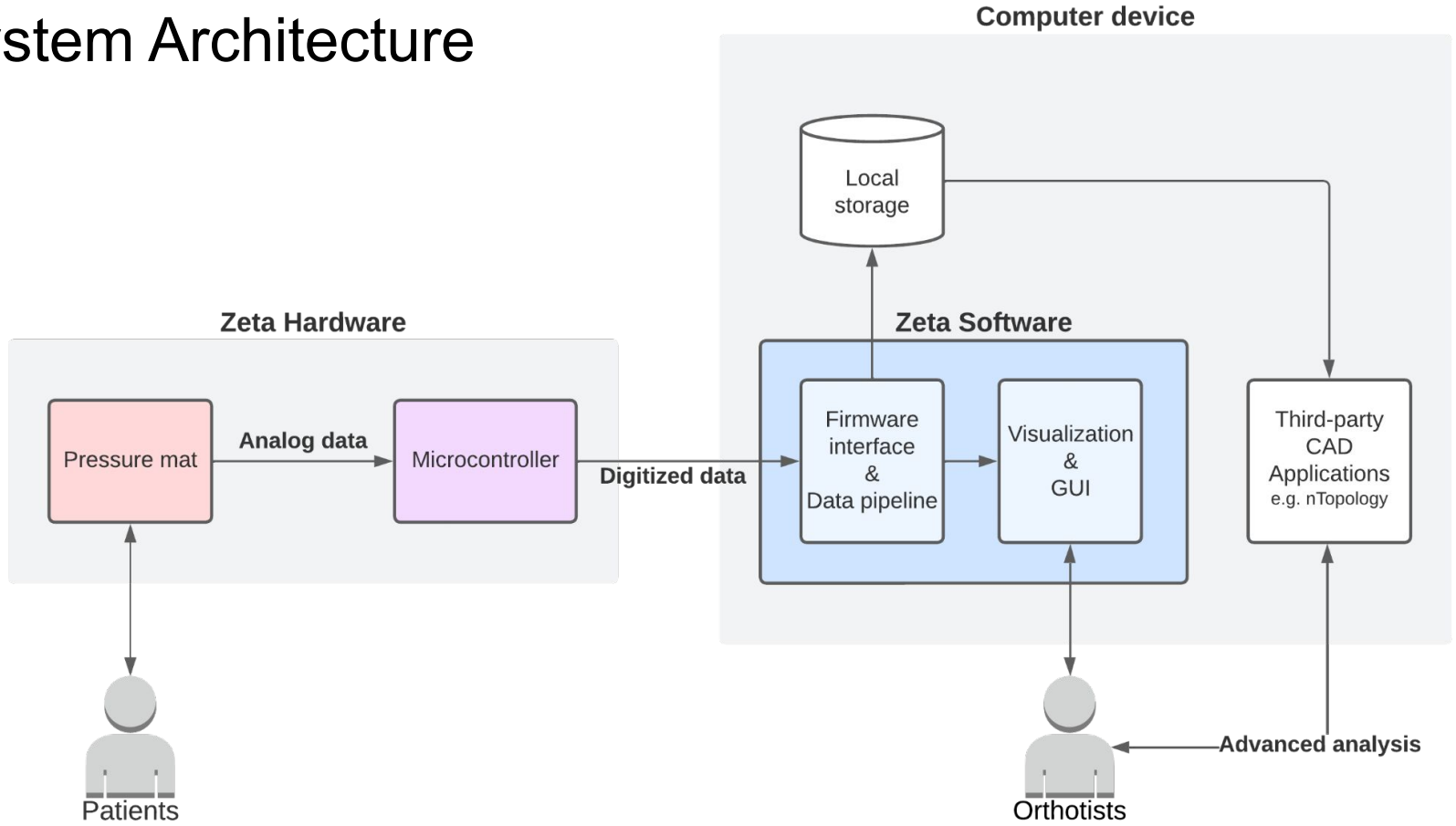
Technical Case

System Architecture



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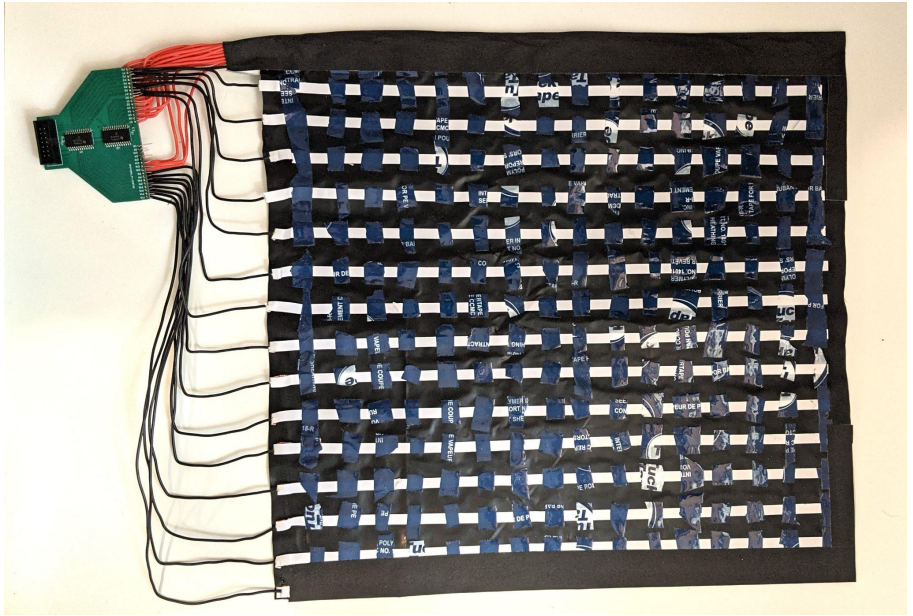
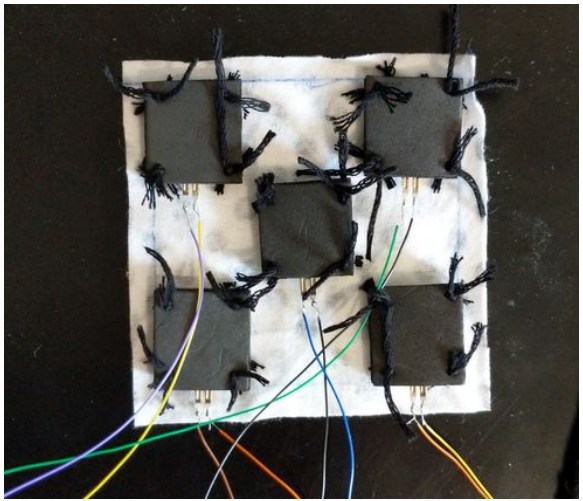
Hardware

Velostat Sensor Matrix

- Sewed velostat matrix onto a shirt that can be worn by patients
- Copper lead matrix on a velostat surface
- 2 Velostat mats covering the full coverage of the brace
- Allows ~2 cm resolution of pressure across entire torso
- Multiplexing signals to scale up number of pressure points



Transition from FSR to Velostat Sensor Matrix



Low resolution

Less managed cables

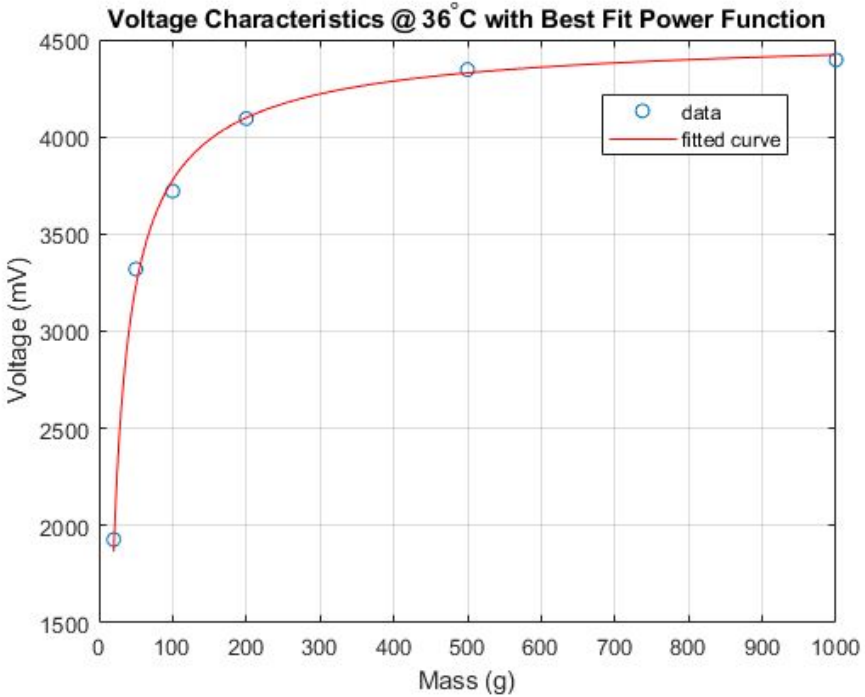
Free floating positions on the torso

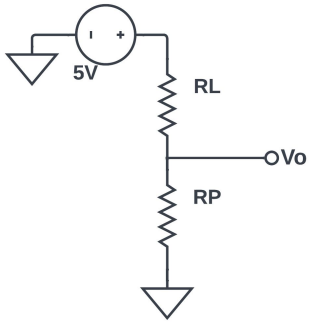
Higher resolution

More managed cables

Fixed positioning across the entirety of the torso

Pressure Calculation





$$V_o = V_i \frac{R_P}{R_L + R_P}$$

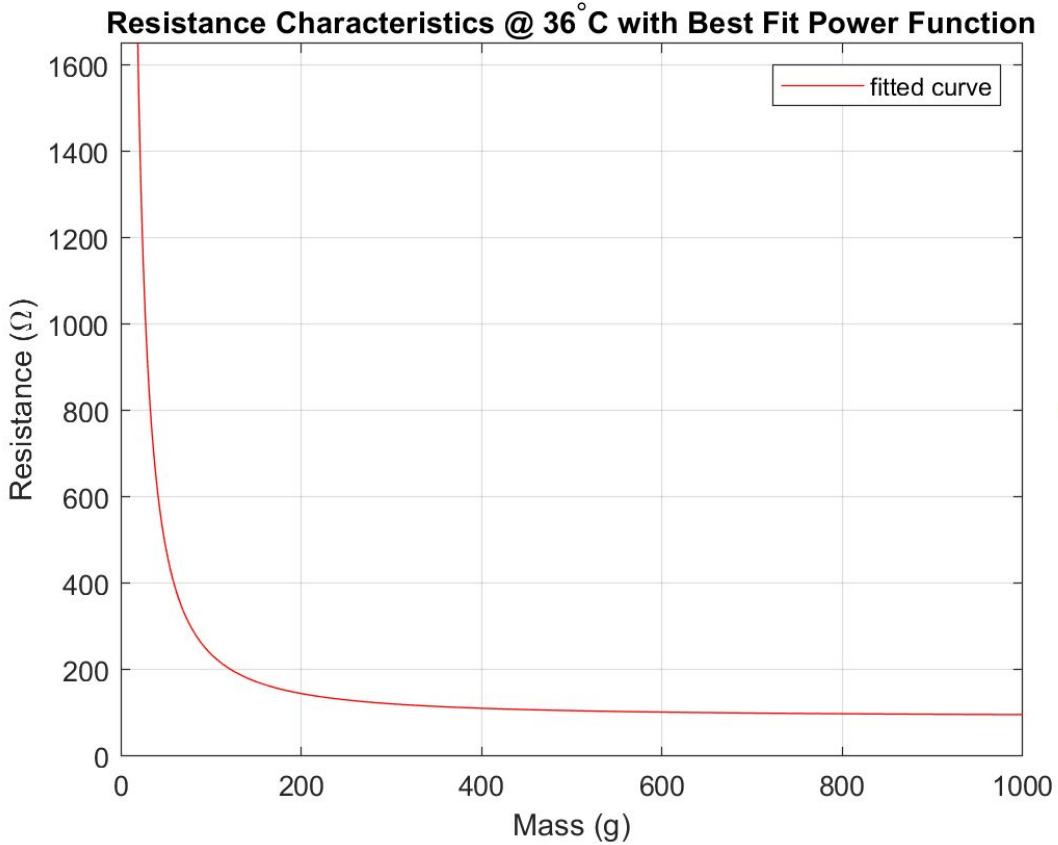
$$V_o R_L + V_o R_P = V_i R_P$$

$$R_L = \frac{V_i R_P - V_o R_P}{V_o}$$

$$R_L = R_{\text{Velo}} + R_{\text{Lead}_i} + R_{\text{Lead}_o}$$

```
General model Power2:
f1(x) = a*x^b+c
Coefficients (with 95% confidence bounds):
  a =  -2.702e+04  (-4.187e+04, -1.217e+04)
  b =     -0.7834  (-0.9804, -0.5865)
  c =        4523  (4308, 4738)
```

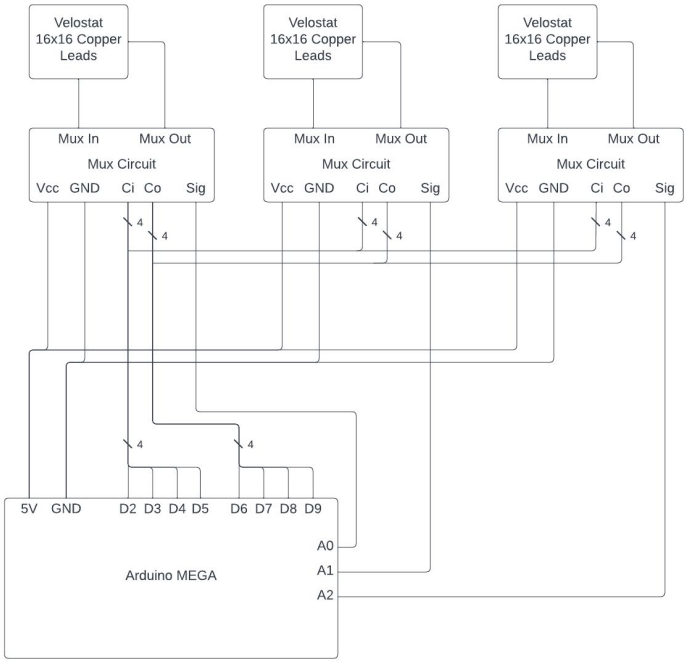
Resistance Profile

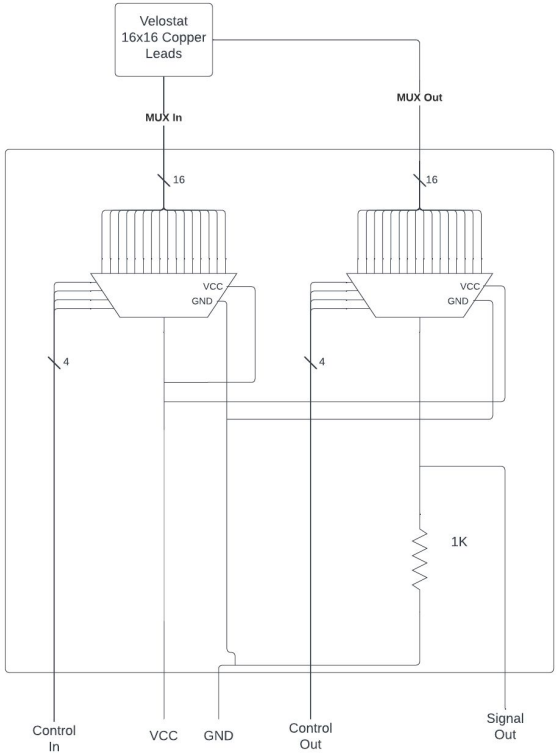


After we calculate the resistance from the analog voltage, this function will be used to find the force on the mat.

```
r(x) = a*x^b+c
Coefficients (with 95% confidence bounds):
  a =   1.024e+05  (-1.483e+04, 2.197e+05)
  b =      -1.423  (-1.811, -1.035)
  c =       90.87  (8.189, 173.5)
```

Circuit Diagrams

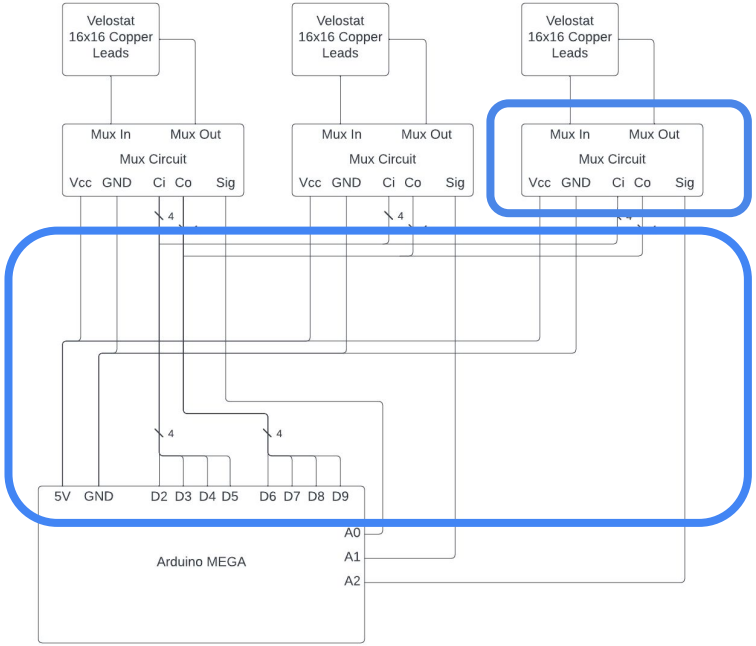




PCB Design

Two PCB boards

- InOut MUX board
- Arduino Shield to interface the wires coming from MUX boards



InOut MUX board interfacing with each pressure mat

Connected via IDC cables

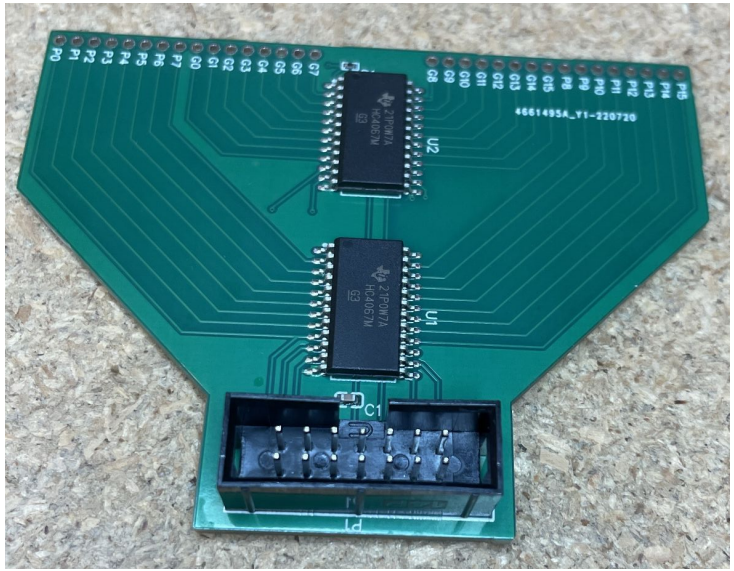
- Arduino shield to handle wire splicing of VCC, GND, and control signals
- LED indicator that will be seen from outside the casing

PCB Design Cont.

In-Out MUX PCB Components

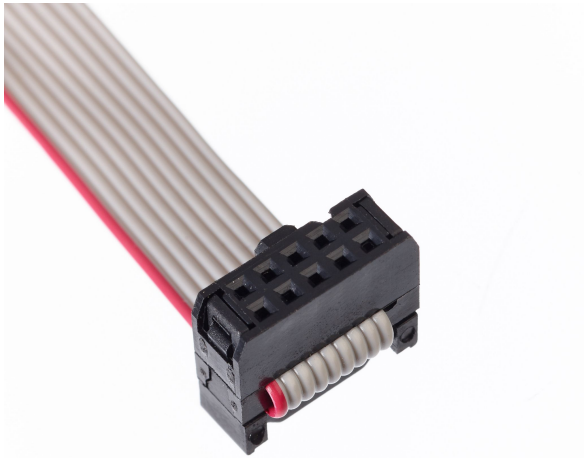
- **1** female IDC connector
- **2** multiplexer chip (CD74HC4067M96)
- **32** soldering through holes to be connected with velostat mats

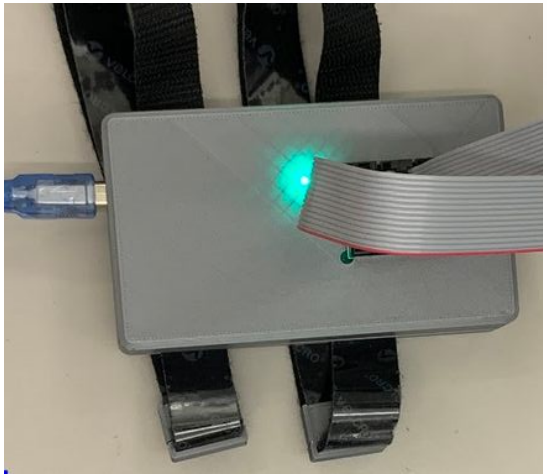
A decoupling capacitor is added
to filter undesired noise



Multiplexer Connections & Wiring

- A single IDC connector is attached to all the wires allowing a quick set up time for the orthotist
- Multiplexers and larger electronics are all encased within a plastic housing





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Firmware

Firmware

- Transitioned from Firmata library to custom firmware
  - Increased scan time by about 3 times
  - Enabled status indication on LED as a hardware feedback
  - Reduced sample time which made the temperature drift negligible

File Format

- Concatenates values from 3 mats to one matrix
- Matches the physical sensing resolution
- Creates an intuitive formation of the collected data

Pressure Conversion Data Pipeline

From microcontroller

$$[\frac{V_{in}}{V_{out}}]_{16\times32} \Rightarrow R_L = R_P(\frac{V_{in}}{V_{out}} - 1) - R_{Leads} \Rightarrow [R_L]_{16\times32}$$

Measured

Predefined

$$V_{out} = V_{in}\frac{R_P}{R_L + R_P}$$

$$R_L = R_{Velostat} + R_{Leads}$$

$$Copper\ lead\ overlap\ area = 36mm^2$$

$$[R_L]_{16\times32} \Rightarrow \text{Velostat characteristic curve} \Rightarrow \text{Mass to pressure} \Rightarrow [pressure]_{16\times32}$$

To renderer

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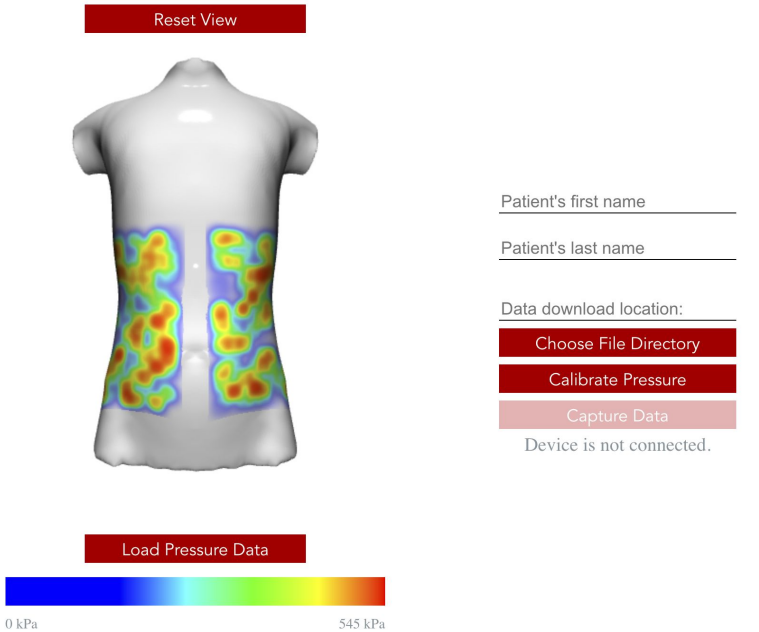
Software

Software

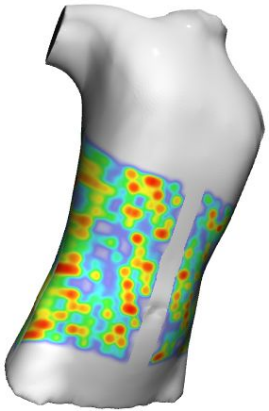
1. **Data capture**
   - Allows user to store captured pressure data into a csv with specific file format
   - Csv can be imported to third-party softwares, such as nTopology
2. **Visualization of mat**
   - User can view the data captured on a 3D model of a child's torso. Used for validation
3. **Heatmap legend**
   - Gradient legend has been created for user feedback



Software: Value of Visualization

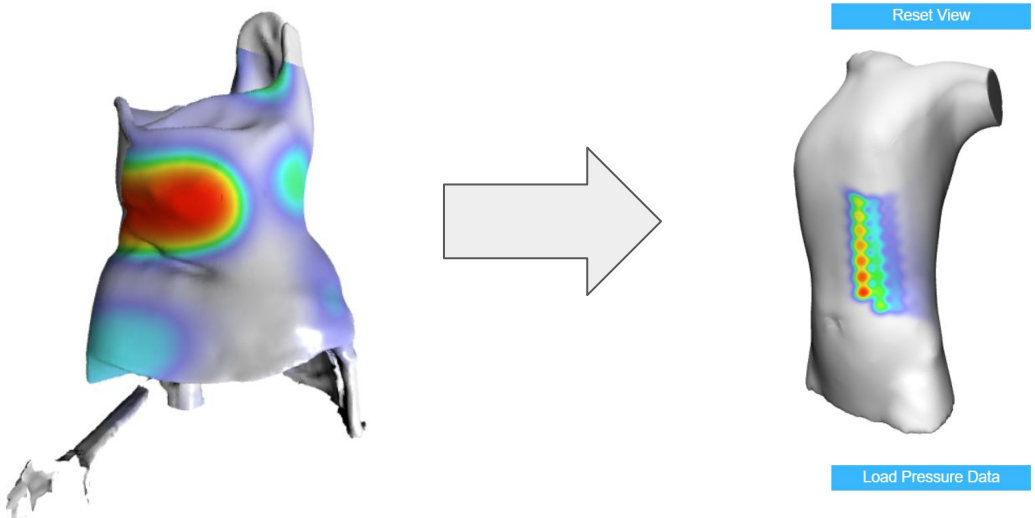
- Allowing an individual to validate csv output, without using external resources
- Visuals are used purely for validation, and not for medical diagnoses
- Originally, nTopology was previously planned to be used for visualization

nTopology



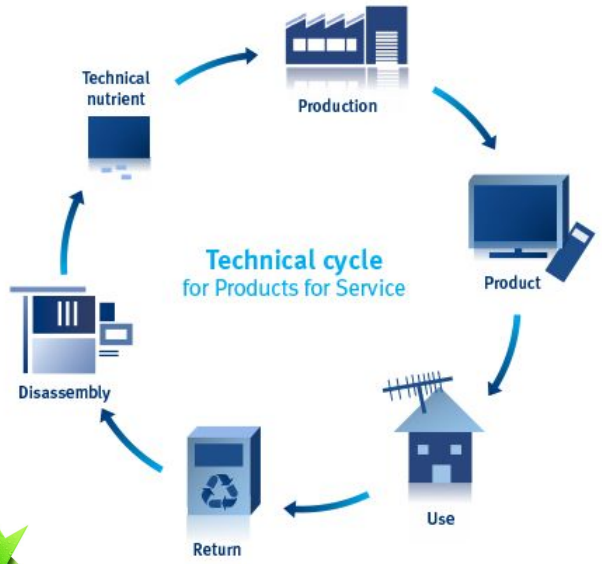
Software: Brace to Torso

- Originally, planned to have a 3D brace design for visualization
- This was moved to a 3D torso representation
- Data plotted on torso better represents the information orthotists seek



Cradle-to-Cradle

- Halcyon will offer servicing of the product to ensure the lifetime of the product is extended
- Warranty system where users can send in their faulty products to be fixed



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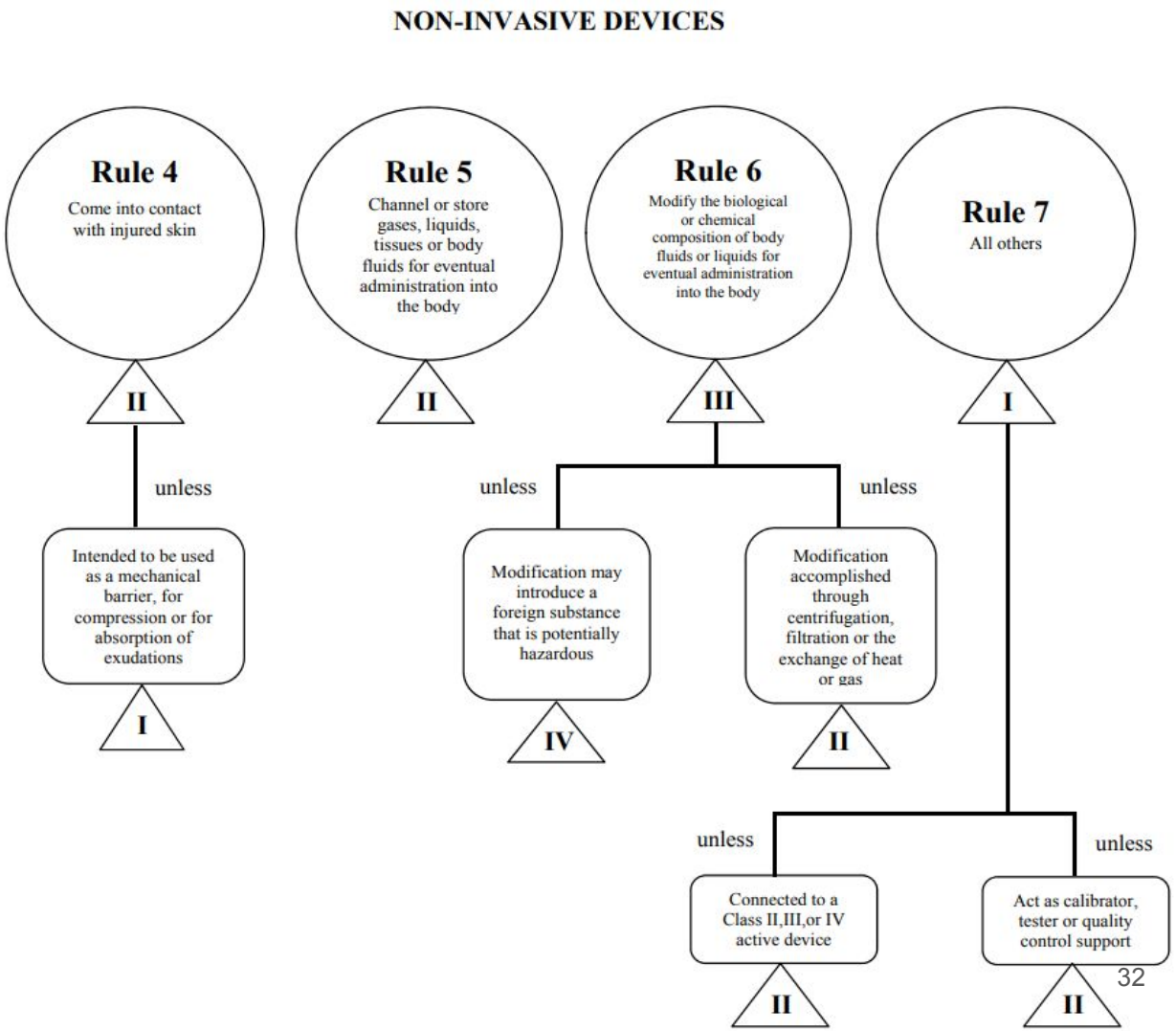
Engineering Standards

Engineering Standards

Standard	How we followed it
IEC 80601-2-49:2018: Remove hazards, mitigate hazards, and finally warn users about hazards	The device is low power and the user is notified through the GUI on electronics failure
IEC 62304:2015-Ed.1.1 : Software life cycle process uses software configuration management	Npm is used alongside electron to ensure development environments are unified resulting in fewer bugs
IEC 62366-1:2015: Application of usability engineering to medical devices	Velostat material is flexible. Whole product is self contained within the shirt and housing so can be easily moved and stored

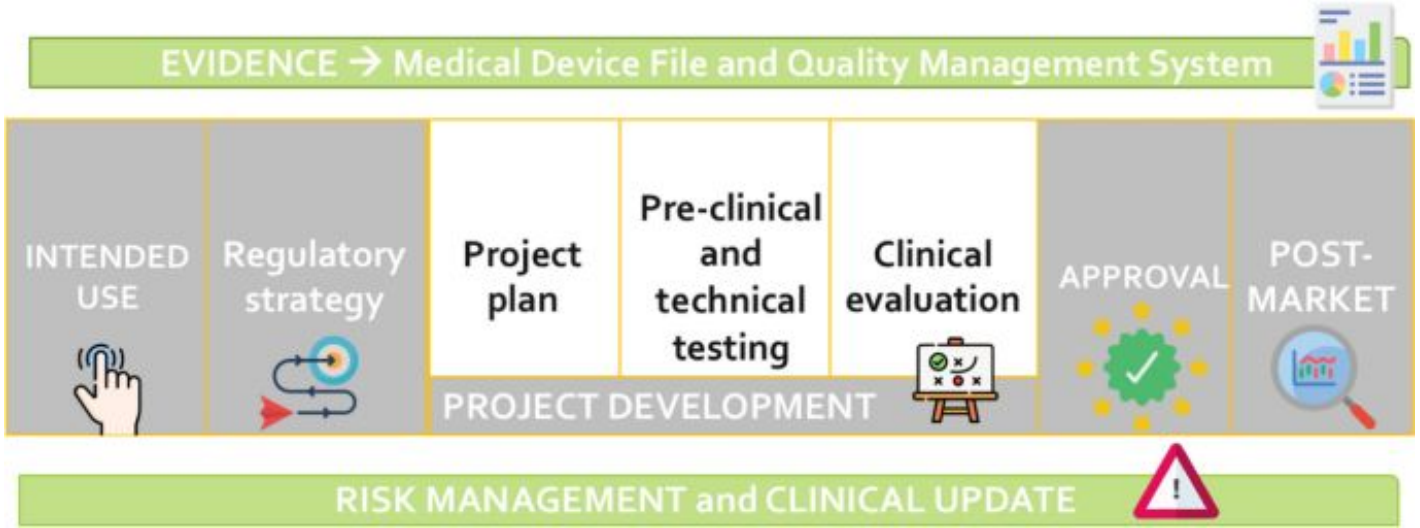
Engineering Standards

- Health Canada -> Guidance on the Risk-based Classification System for NonIn Vitro Diagnostic Devices (non-IVDDs)
- Non-invasive
  - Does not contact eye surface or penetrate inside body



Engineering Standards Cont.

- Class I product - low to moderate risk to patient
  - premarket notification application & FDA clearance not required before marketing device in US
  - Medical Device Establishment Licence required in Canada -> faster to obtain than Medical Device Licence (required for Class II, III & IV)
- Least restrictive medical device
- Avoids the need for clinical trials



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Risk Management

Hardware

Sensing mat uses Velostat anti-static material

- Anti-static, passive sensing

Microcontroller away from body

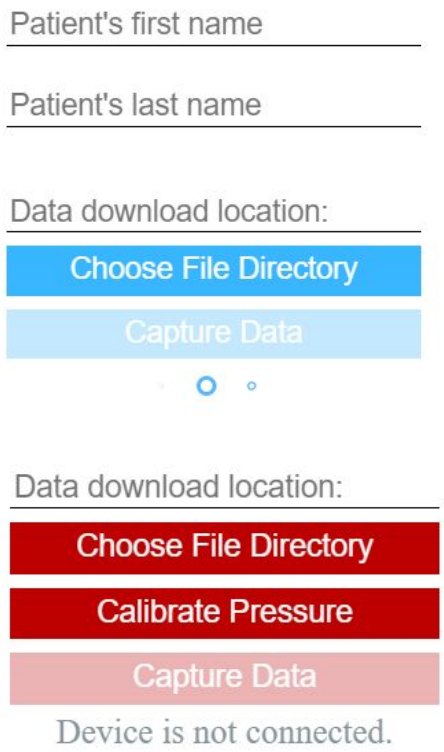
- Minimizes safety risks of microcontroller electromagnetic properties interfering with life-changing electrical devices(e.g. pacemaker)
- If microcontroller attached to extension cord off body, it increases resistance & electrical noise
- Strapping it to the thigh reduces calibration and bias optimization issues

Hardware (Cont.)

3. **IDC connector**
    - Allows all wires from shirt to come down to a single component
    - Avoids wire tangling
    - Mitigates risk of the patient mistakenly tearing out wiring connections.

Firmware / Software: Human Factors

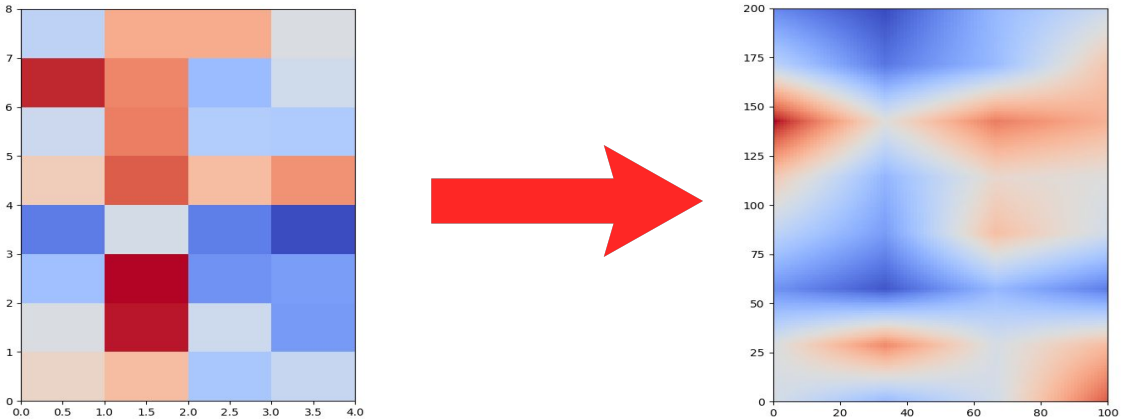
- Give feedback on user action
- Provide error messages when microcontroller is disconnected
  - Avoids user trying to take readings when device is not yet ready
- Show loading states when data is processing



Hardware Software Decoupling

Real-time relative pressure display tool

- Validates that sensor positioning is as expected
- Verifies multiplexing system of Velostat sensing mats functioning correctly.
- Ensures pressure values read into software correctly.

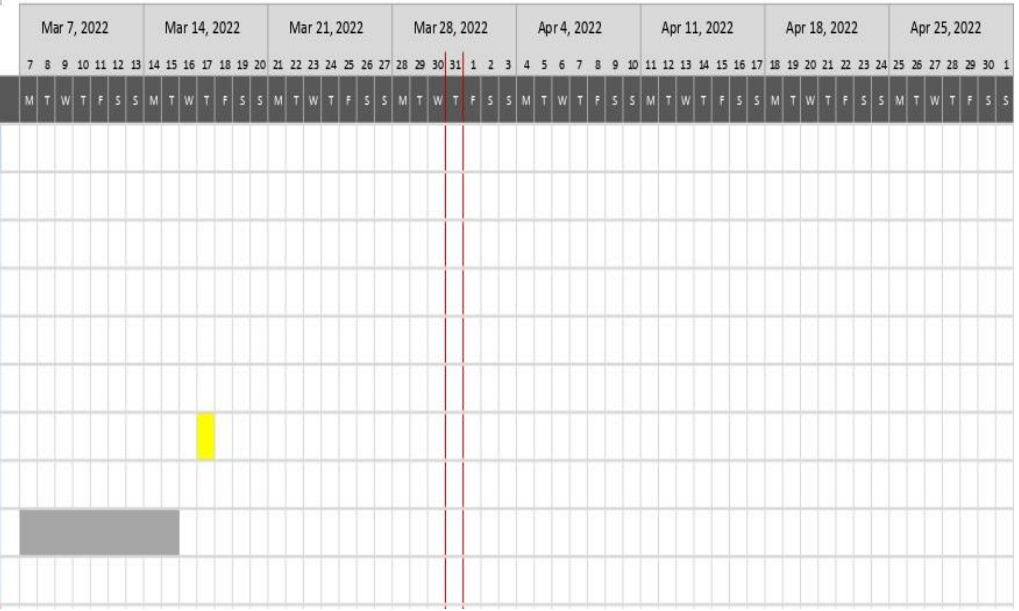


Gantt Chart - Mar 13 - Apr 25, 2022

ENSC 405W - Halcyon

Project Start: Tue, 1-11-2022

Display Week: 09-Jan



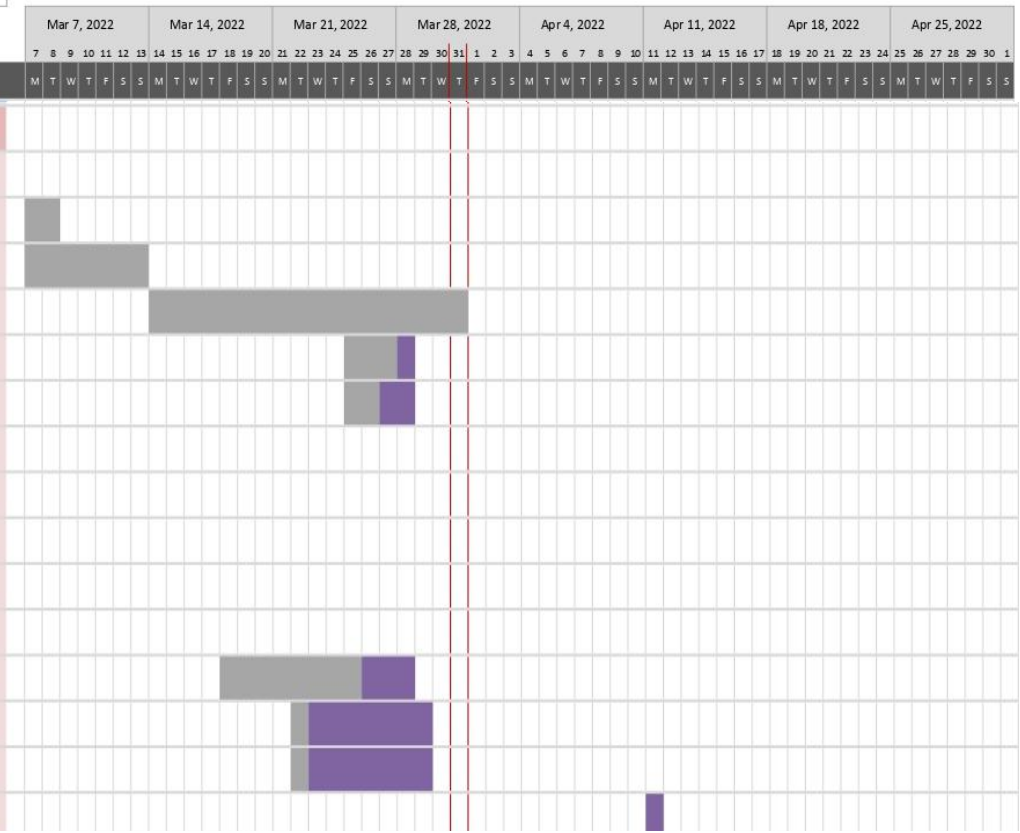
TASK	ASSIGNED TO	PROGRESS	START	END
Planning				
Establish Contact with Industry Partner	Paige	100%	1-18-22	1-19-22
Project Selection and Alternative Ideas	Everyone	100%	1-18-22	1-21-22
Devise Company Name	Everyone	100%	1-19-22	1-22-22
Company Logo	Roy	100%	1-23-22	1-25-22
Project Selection Proposal	Everyone	100%	1-21-22	1-27-22
MILESTONE: Select Project	Everyone	100%	1-27-22	1-27-22
Progress Review #1 Preperation	Everyone	100%	1-28-22	2-8-22
ICAMES Application	Paige	100%	2-12-22	3-15-22
Requirements Specification	Everyone	100%	2-6-22	2-13-22

ENSC 405W - Halcyon

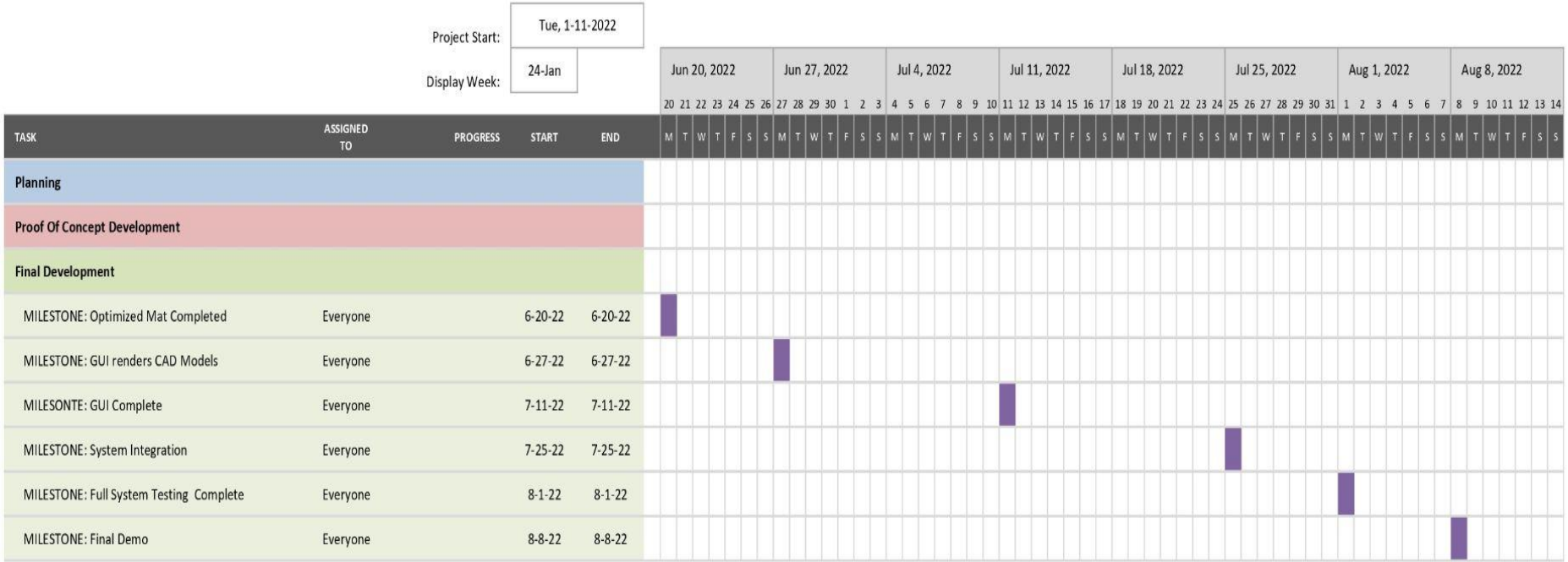
Project Start: Tue, 1-11-2022

Display Week: 09-Jan

TASK	ASSIGNED TO	PROGRESS	START	END
Proof Of Concept Development				
User Interface Design Appendix	Everyone	100%	2-14-22	3-4-22
Progress Review #2 Preperation	Everyone	100%	3-3-22	3-8-22
Design Specification Document	Everyone	100%	3-6-22	3-13-22
Final Proposal Document	Everyone	100%	3-14-22	3-31-22
Build Breadboard Circuit	Aidan	90%	3-25-22	3-28-22
Build PoC Mat	Aidan	50%	3-25-22	3-28-22
Setup GitHub Actions	Aki	100%	2-22-22	2-26-22
Determine Which FSR to Use	Aidan	100%	2-18-22	2-22-22
Prepare Hardware Testbench	Aki	100%	2-27-22	3-2-22
Research CAD Rendering	Hamza	100%	2-23-22	2-27-22
Integrate Firmata into NodeJS	Aki	30%	2-19-22	2-26-22
Create baic GUI using Vue and Electron	Kirill	80%	3-18-22	3-28-22
Investigatge nTopology	Paige	20%	3-22-22	3-29-22
GUI Interaction with Firmata	Aki	20%	3-22-22	3-29-22
MILESTONE: Proof Of Concept	Everyone		4-11-22	4-11-22



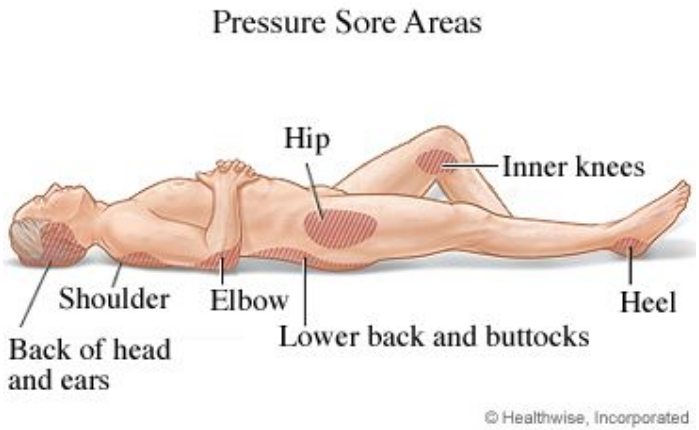
Gantt Chart - Apr 25 - Aug 8, 2022



TASK	ASSIGNED TO	PROGRESS	START	END
Planning				
Proof Of Concept Development				
Final Development				
MILESTONE: Optimized Mat Completed	Everyone		6-20-22	6-20-22
MILESTONE: GUI renders CAD Models	Everyone		6-27-22	6-27-22
MILESONTE: GUI Complete	Everyone		7-11-22	7-11-22
MILESTONE: System Integration	Everyone		7-25-22	7-25-22
MILESTONE: Full System Testing Complete	Everyone		8-1-22	8-1-22
MILESTONE: Final Demo	Everyone		8-8-22	8-8-22

Commercialization Risk

- Significant markup on product that can be lowered
- If scoliosis market too small can quickly pivot to using product in body mechanics applications,like prosthetics, orthotics & bedsore prevention



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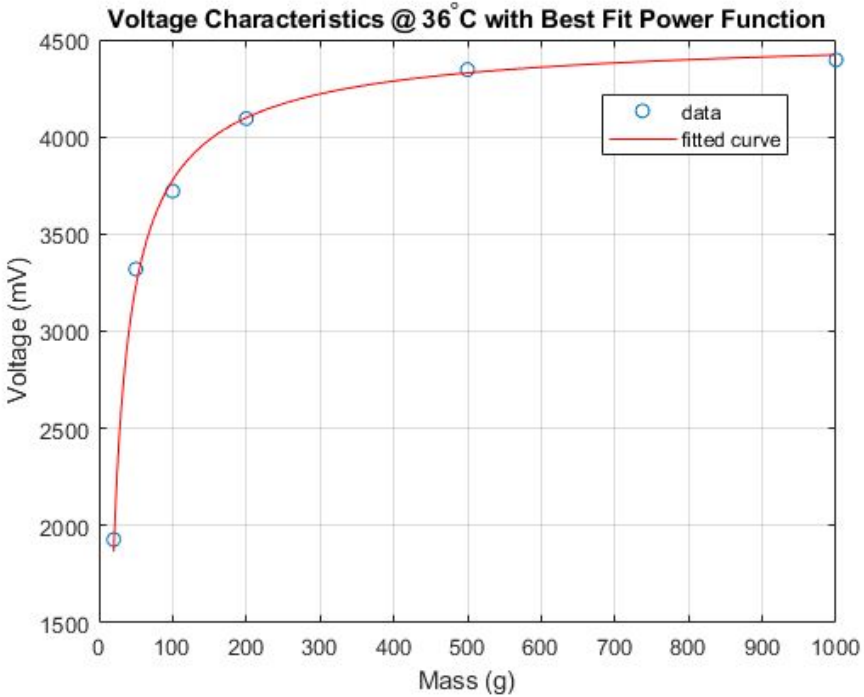
What Could Have Been Different

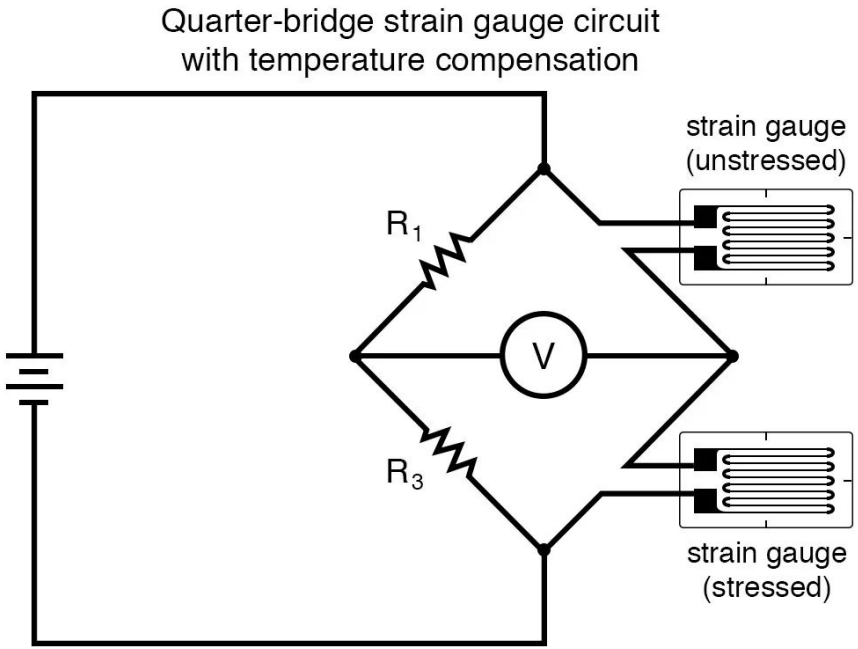
Hardware: Linearizing Sensor output

- Run raw output through an antilog amplifier.
- Corrects for high analog to digital conversion error at upper end of the output
- Reduces noise in the lower end of the output



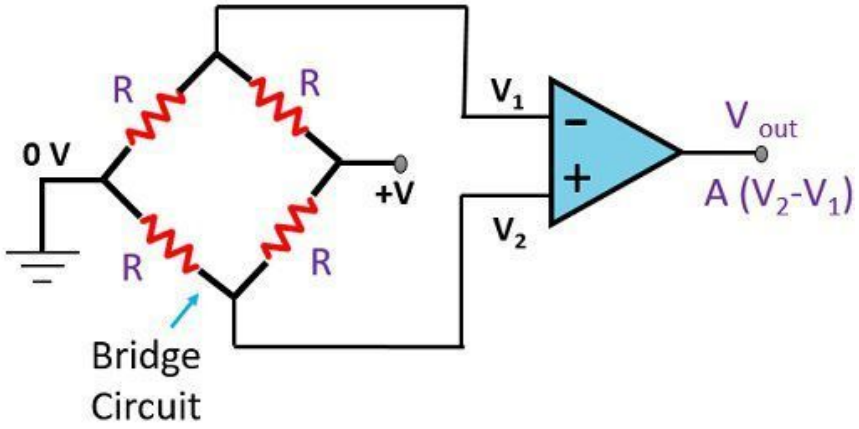
Hardware: Correcting for Temperature Drift Actively

- Temperature gets actively compensated.
- Potentially difficult to balance without highly accurate parts.
- Difficult to build unstressed pressure sensor that needs to be kept warm by the skin.



Hardware: Zeroing Output Voltage

- Zero pressure measurement is not zero voltage.
- Wasting valuable ADC resolution
- Zeroing the output in conjunction with microcontroller functions would allow for much higher precision

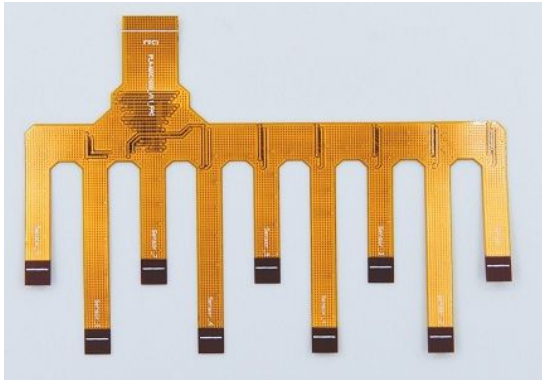


Wheatstone Bridge Differential Amplifier

Electronics Coach

Hardware: General Electronics Improvements

- Some use of flexible PCB and gold plated leads for lowest resistance
- Remove shield on arduino, extract only required MCU components
- Switch to wireless



Arduino with shield

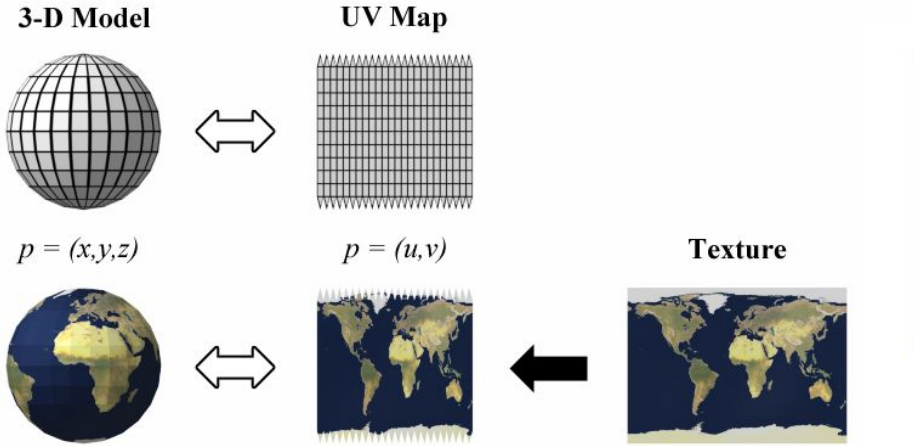
Single PCB

Hardware: Wireless vs. Wired

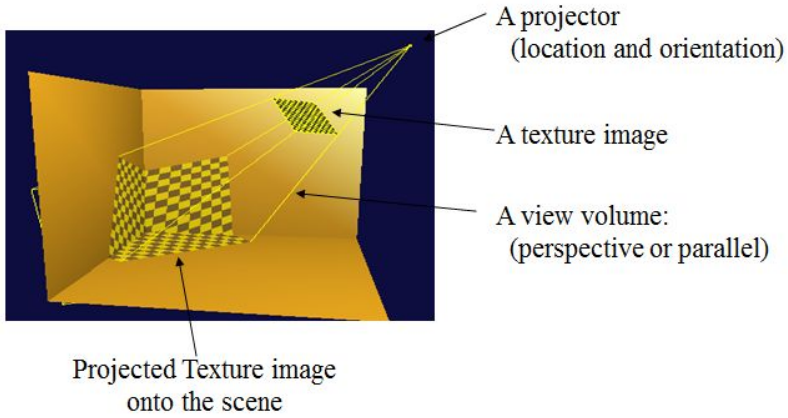
- Wireless more convenient for user
- Wired much simpler and cheaper to keep costs down

Software: What Could Be Different

- Instead of projecting the heatmap onto a model of a torso, develop texture with UV mapping to ensure a perfect fit on the surface



UV Mapping



Projection

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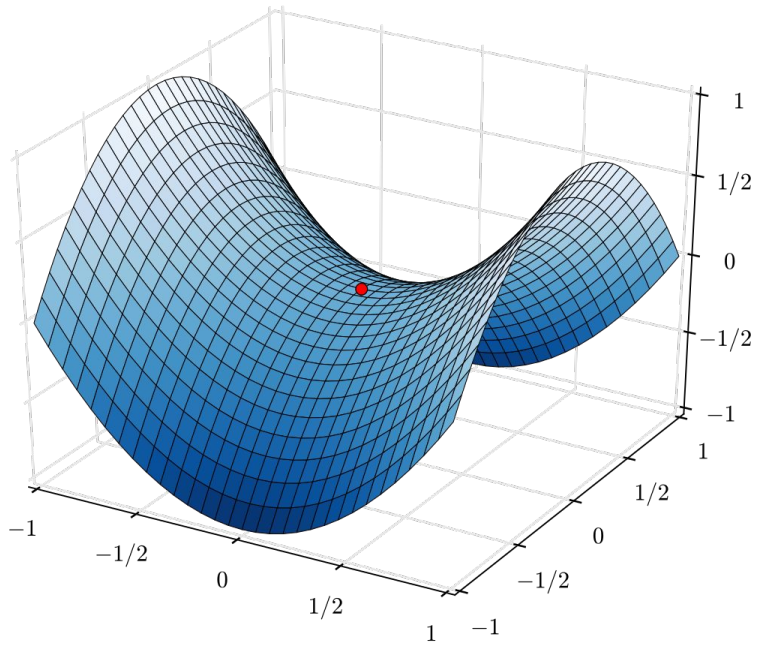
Reflection in Design

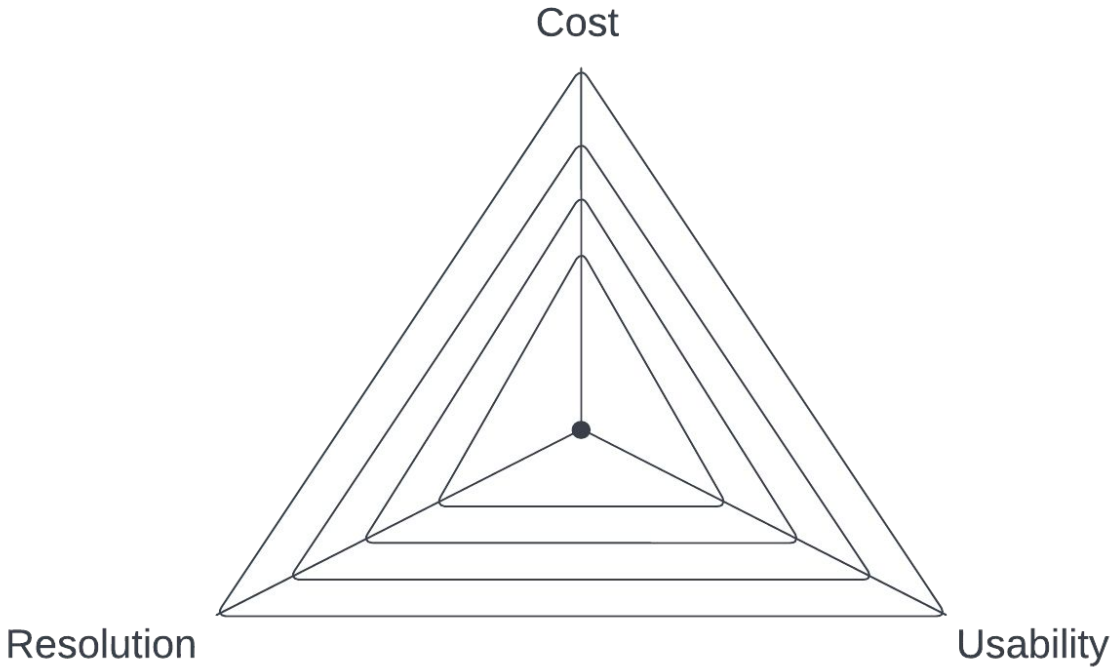
The Problem

Measuring pressure on a surface that has curvature across orthogonal axes

The surface is always different, and can also vary in scale.

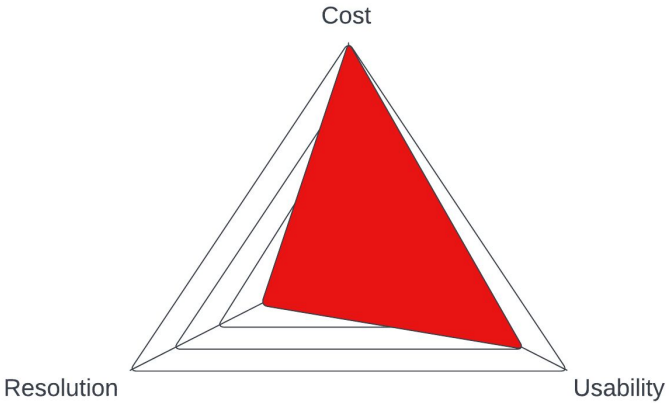


The Trade Off Triangle

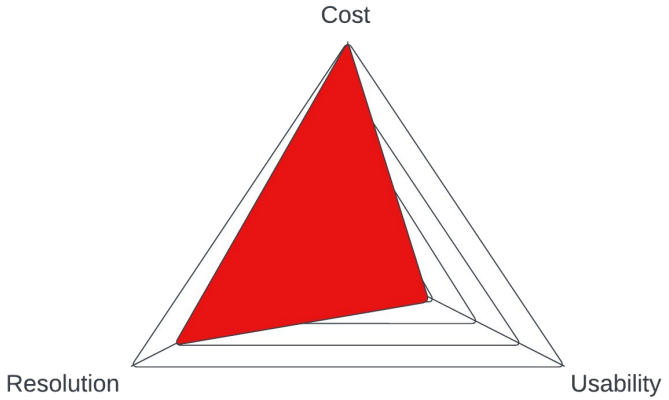


Our Designs

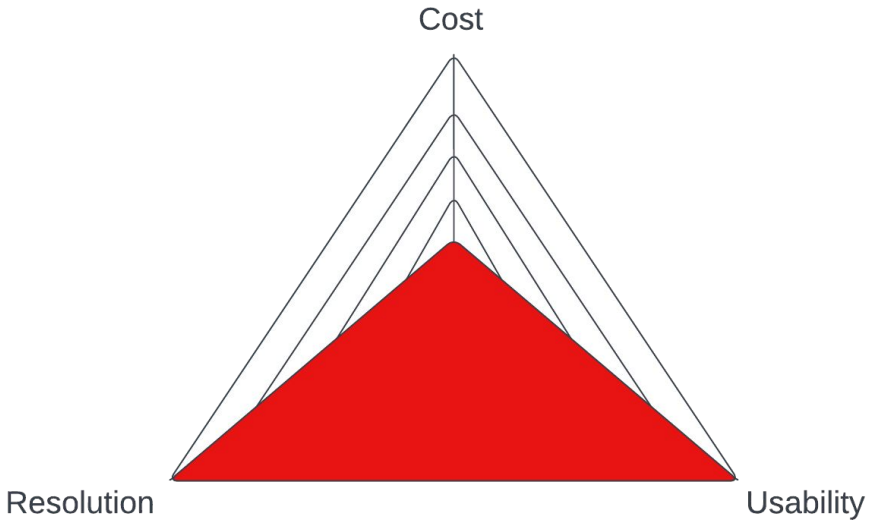
Initial POC



Gamma Prototype



The Ideal design



Would heavily rely on flexible PCB, and stretchable PCB

Potential Custom FSR solutions from companies like Interlink

Strict sizing cutoffs to maintain comparable resolutions across all sizes

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Future Optimizations

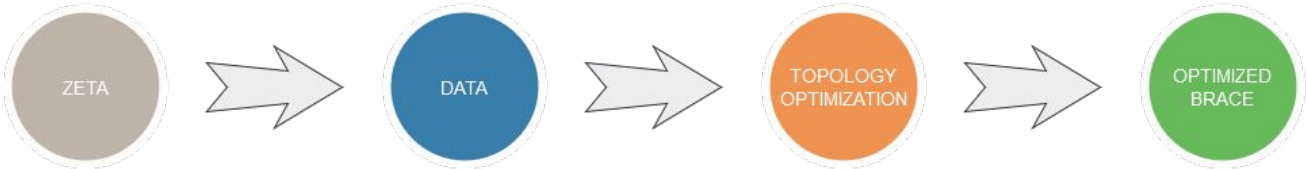
Future Optimizations

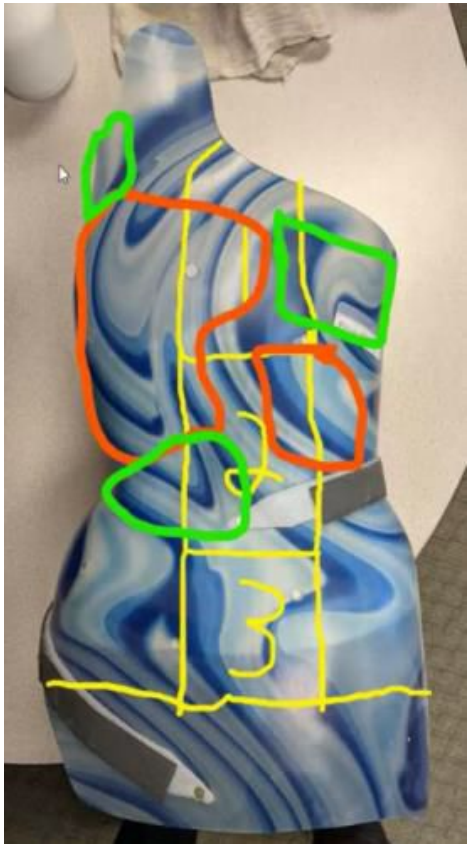
- Modify our pressure sensing system to be waterproof
- Allow for use in hydrotherapy treatment
- Hydrotherapy:
  - Removes flexibility, stability and mobility issues that scoliosis patients suffer
  - Reduces pain
  - Strengthens back muscles to improve degree of spinal curvature

Further Potential Optimizations

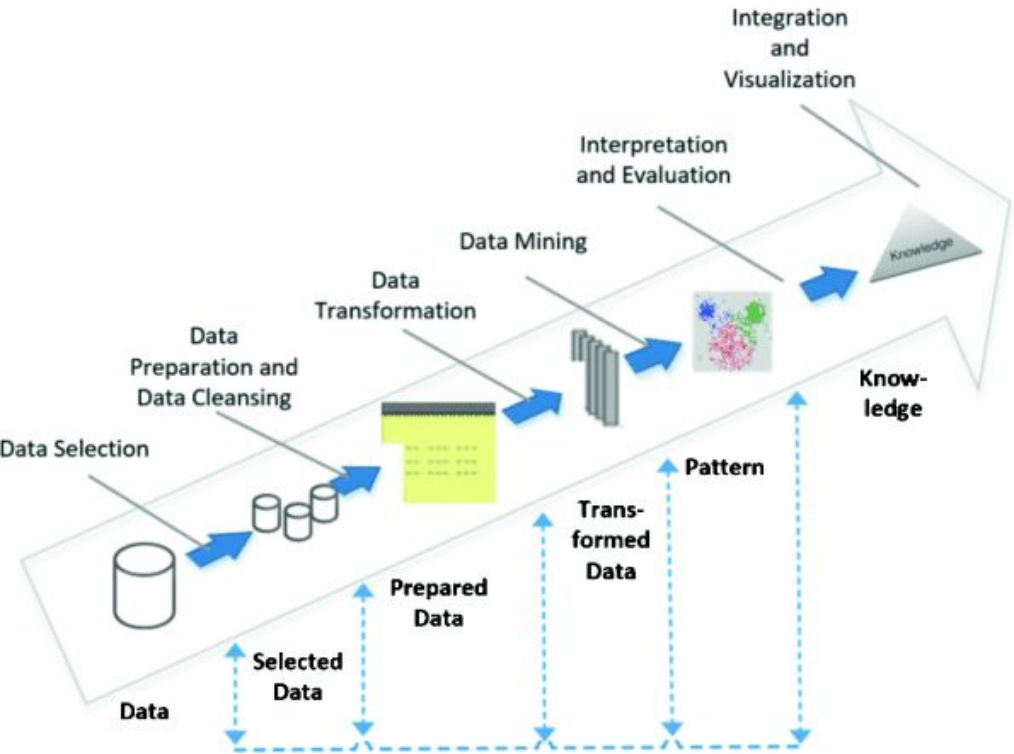
Topology Optimized Brace with Back Panel Openings

- Ultrasound instead of X-Ray spinal curvature measurements
- Cut 3 panels for frequent ultrasound visualizations → eliminate X-ray long-term harmful radiation consequences
  - Print topology optimized brace → comfortable, breathable, and lightweight → made of recyclable material
  - Ultrasound data collected frequently in clinic by orthotists
    - Reduced data collection variability
- Maintain structural brace integrity





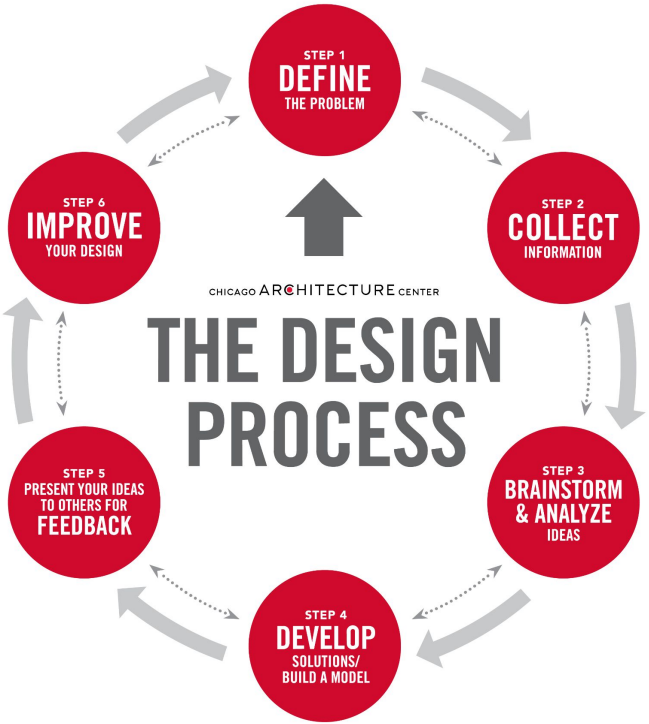
Further Potential Optimizations



AI Machine Learning Predictive Analysis Model

- Developed from obtained pressure data
  - Eliminate anecdotal, manual brace customization
  - Algorithmically spot success trends in previous patients
  - Improve accuracy, sensitivity, & specificity of predicting AIS curve severity, curve progression, brace design & effectiveness
  - Faster, more responsive & precise AIS correction progress
  - Accelerated recovery

What We Learned



- Design process -> several iterations
- Test ideas early -> build quick prototype of separate components
- Determine design flaws & update requirements
- Shipping from manufacturers is variable
- Budget extra time -> integration issues inevitable
- Industry connections, communication, role assignment, and scheduling is key

In collaboration with Carl Ganzert - Certified Orthotist

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