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# COMSOLE Final Presentation

**MEEN Senior Capstone Design Team**

**402 - Section 504**

- Matthew Monson - **Project Manager**
- Tyler Gabriel - **Communication Lead and App Design**
- Will Grubbs - **Insole Design**
- Benito Tagle Ochoa - **Machine Learning/Software**
- Mark McCulloch - **Casing Design**
- Ian Lansdowne - **Manufacturing/Electrical Integration**
- Dr. Ya Wang - **Faculty Sponsor**
- Dr. Haili Liu - **Faculty Support**
- Ibrahim Almuteb - **Faculty Support**
- Duc Pham - **Student Researcher**
- Dr. Ni Wang - **Studio Instructor**

# Team Picture



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- Project Introduction
- Project Management
- Design Justification
- Design Selection
- Manufacturing
- Software Development
- Full System Breakdown & Demonstration
- Data Collection
- Validation Test Results
- Final Takeaways & Future Work
- Acknowledgements & Q/A

# Solution Neutral Problem Statement



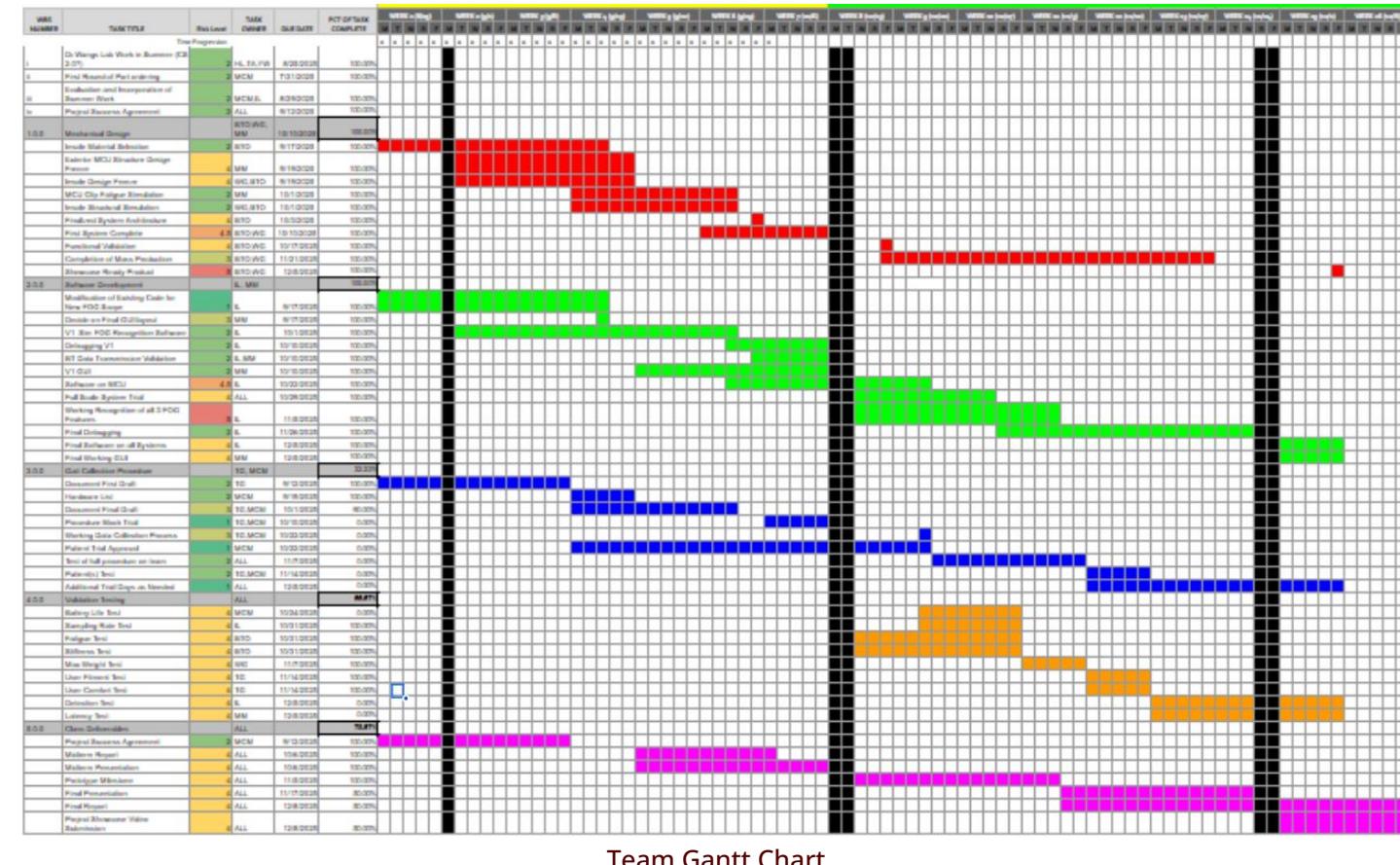
An insole-based prototype with an integrated mobile application to improve the quality of life for Parkinson's Disease patients who deal with Freezing of Gait through real-time detection and intervention.

- FEA - Finite Element Analysis
- FoG - Freezing of Gait
- GUI - Graphical User Interface
- IMU - Inertial Measurement Unit
- ML - Machine Learning
- PCB - Printed Circuit Board
- PD - Parkinson's Disease
- TPU - Thermoplastic Polyurethane

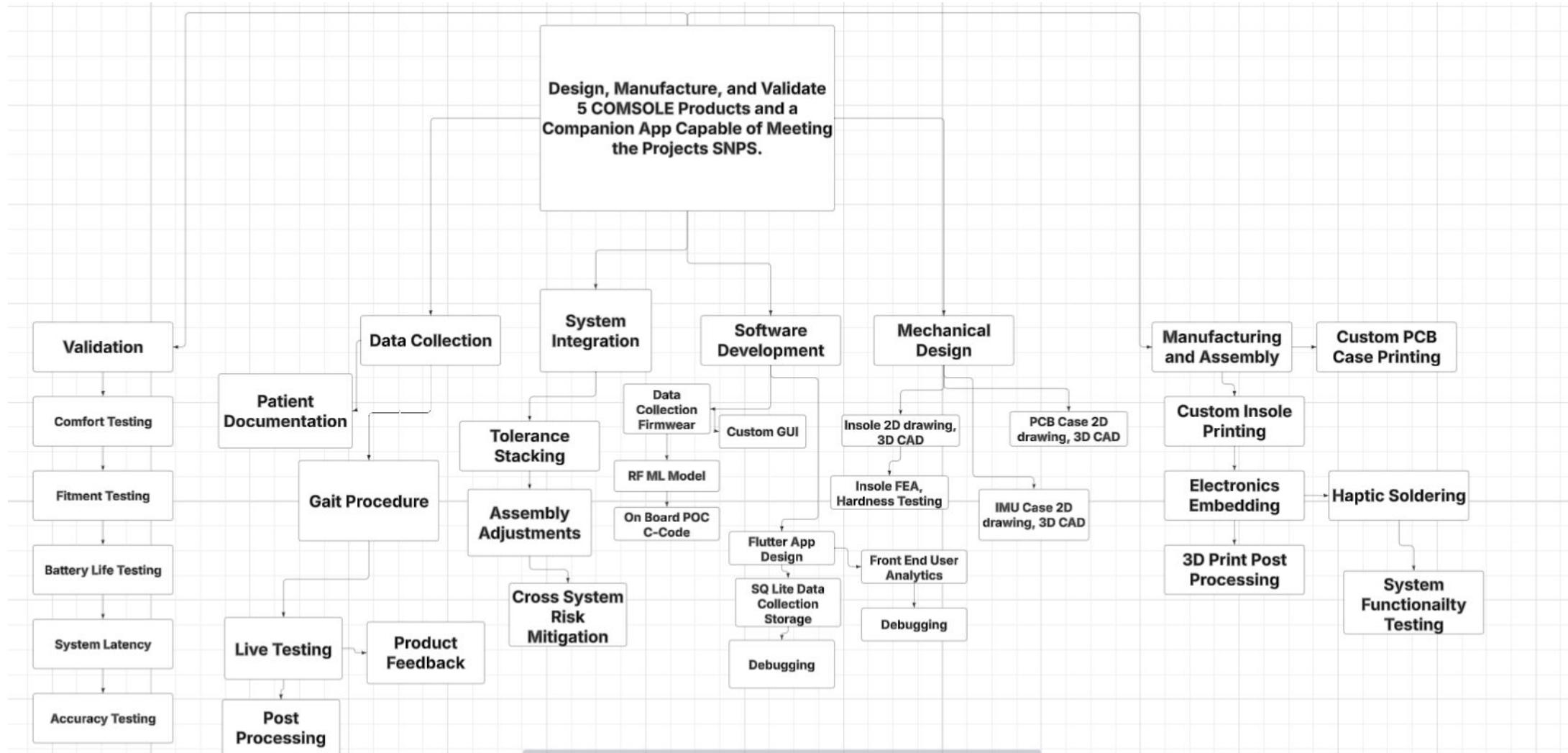
# Project Management

# Project Management

- Task Distribution and Project Timing
- 402 Gantt Chart
  - Subteam Breakdown
- Weekly Communication and Deliverable Updates
- Timeline Adjustments



# Work Breakdown Structure



Work Breakdown Structure Diagram

# Financial Management and Analysis



- Budget Documentation
- Part Ordering
- Final Product Cost Model

Total Cost Model	<b>\$1,914</b>
Individual Product Cost	<b>\$199.33</b>

Total Project Cost Model.

Job	Hourly Rate	Hours Logged
Software Dev	40	10
Insole Assembly	15	15
PCB Assembly	15	20
Wages Occured	925	
Per Product	132	

Projected hourly rates for production and assembly.

Subcategory	Item	Quantity	Cost	Cost Type	Vendor	Order Date	Status
Electronics	ESP32 Microcontroller	1	\$19.95	Sponsor Funded	Adafruit	03/27	Delivered
	Li-ion Batteries	1	\$8.99	Sponsor Funded	Digikey	03/27	Delivered
	Motor Driver	1	\$7.95	Sponsor Funded	Adafruit	03/27	Delivered
	I2C Cables	5	\$1.95	Sponsor Funded	Digikey	03/27	Delivered
	Haptic Motor	5	\$1.95	Sponsor Funded	Digikey	03/27	Delivered
	ICM-20948 9-DOF IMU	1	\$14.95	Sponsor Funded	Adafruit	03/27	Delivered
	Micro SD Breakout	1	\$3.50	Sponsor Funded	Adafruit	03/27	Delivered
	28 Gauge Wire	1	\$18.91	Self Funded	Mcmaster Carr	9/20	Delivered
	Haptic Motors (High RPM)	10	\$1.95	Sponsor Funded	Digikey	9/29	Delivered
	Li-ion Batteries	5	\$8.99	Sponsor Funded	Amazon	10/29	Delivered
Materials	85A TPU Filament, 1kg	1	\$45.00	Sponsor Funded	Bambu Lab	03/27	Delivered
	Silicone Resin	1	\$21.00	Sponsor Funded	Amazon	3/27	Delivered
	85A TPU Filament, 1kg	1	\$44.00	Sponsor Funded	Bambu Lab	9/29	Delivered
	95A TPU Filament (Red), 1kg	1	\$44.00	Sponsor Funded	Bambu Lab	9/29	Delivered
	Self Adhesive Fabric	1	\$9.00	Sponsor Funded	Amazon	05/01	Delivered
	E6000 Super Glue	1	\$10.00	Sponsor Funded	Amazon	10/29	Delivered
Fasteners	Metric Fastener Set	1	\$14.00	Sponsor Funded	Amazon	9/29	Delivered
	Velcro Fabric	1	\$8.00	Sponsor Funded	Amazon	10/29	Delivered
	Heat Set Inserts	1	\$17.00	Sponsor Funded	Amazon	10/29	Delivered
	Metal Retainment Clips	1	\$9.00	Sponsor Funded	Amazon	9/29	Delivered
Misc	Clorox Wipes	1	\$5.00	Self Funded	Walmart	11/11	Delivered
	Thankyou Cards	8	\$4.00	Self Funded	Walmart	11/11	Delivered
	Custom PCB Boards	10	\$14.10	Sponsor Funded	PCBWay	Summer	Delivered
	ESP32 S3 Microcontrollers	10	\$20.00	Sponsor Funded	Adafruit	Summer	Delivered
Sponsor Provided	ICM-20948 9-DOF IMU	10	\$14.95	Sponsor Funded	Adafruit	Summer	Delivered
	Test Shoes	3	\$10.00	Sponsor Funded	Lab Provided	Lab Provided	Delivered
	3.7v, 1200mAh Li-ion battery	8	\$6.52	Sponsor Funded	Amazon	Summer	Delivered
	Solder Material	-	-	Sponsor Funded	Lab Provided	Lab Provided	Delivered
				Hardware Total	<b>988.86</b>		
				Sponsor Funded	<b>932.95</b>		

Cumulative Capstone Budget.

- Design Methodology and Integration
  - Prototype Iteration
  - Production Quantity vs Quality
  - “Proof of Concept” Focus
- Conflict Resolution and Progress Delay
- Event Scheduling and External Communication

# Design Theory and Justification

## Surveys identified critical needs:

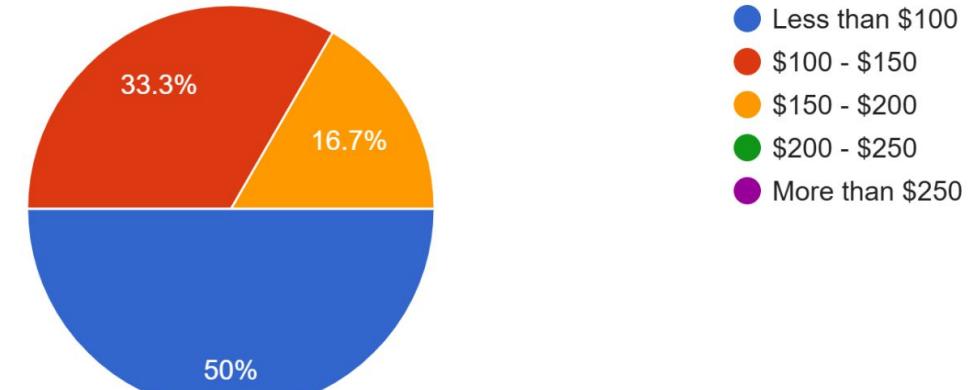
- On-demand cueing
- Low cost
- Vibrational cueing

## Reasons patients avoid similar devices:

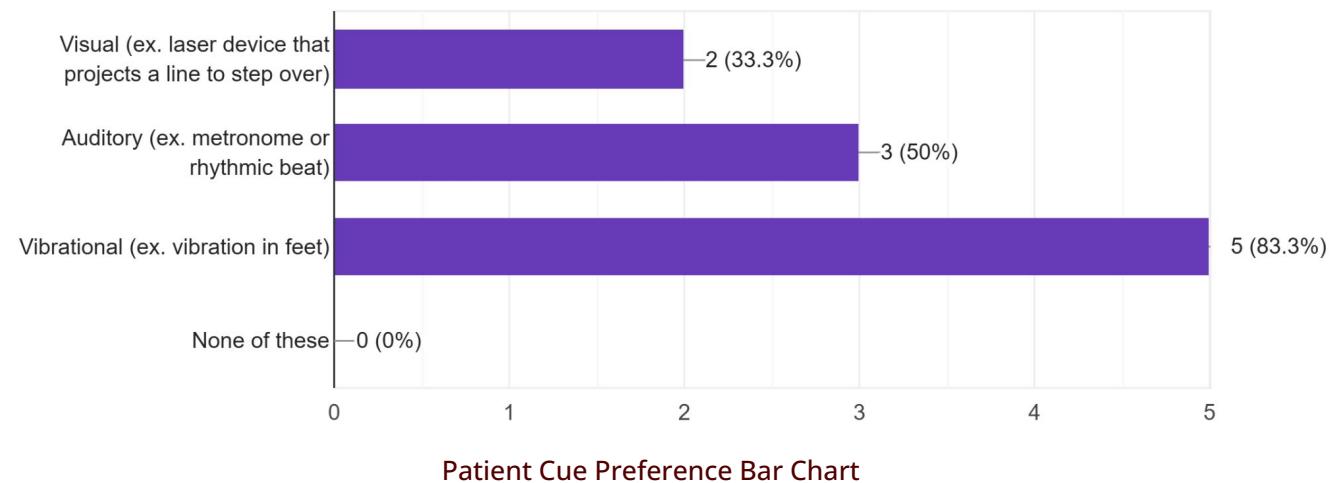
- Weight
- Ease of use
- Accuracy

## Determined the device must be:

- Comfortable
- Lightweight
- Simple to use
- Accurate
- Affordable



Patient Cost Preference Pie Chart



Patient Cue Preference Bar Chart

- **Data Collection**

- Movement is detected and recorded by onboard IMU

- **Determine FoG Occurrence**

- Data is filtered and processed by a Machine Learning model

- **Implement Cue**

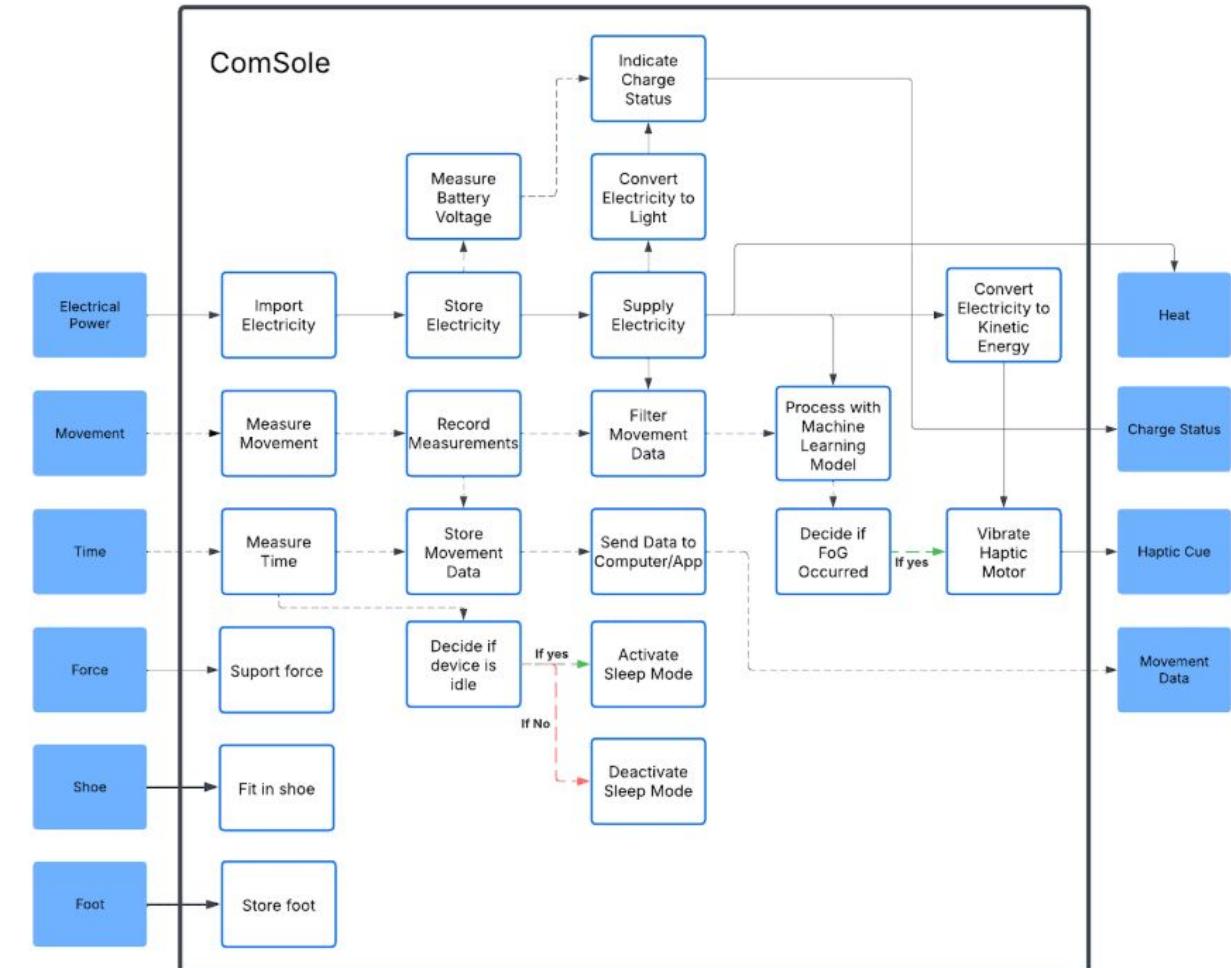
- When FoG is detected, activate a haptic motor to deliver feedback

- **Store Electrical Energy**

- Battery stores power and supplies it to all electrical components

- **Support Foot**

- Insole must comfortably support foot and house components



Functional Requirements Diagram

## 4 Main Subsystems:

- Physical Insole
- Embedded Electronics
- Control and Power
- Software

## Potential Weaknesses:

- Dependencies on IMU
- Water/Sweat Damage to PCB
- Damage to embedded electronics

Controls have been implemented to help mediate

Subsystem	Part # and Functions	Potential Failure Mode
External PCB System	1.1. Flex PCB connection to IMU board	Component Disconnect
	1.2. PCB Bluetooth Communication	Bluetooth failure
	1.3. Battery	Early loss of charge
	1.4. Battery	Thermal Runaway
	1.5 Casing Structure	Backout of PCB mechanical Fasteners
	1.6 Casing Structure	Backout of Clip mechanical Fasteners
Insole Structure	2.1. TPU Insole	Insole shearing
	2.1. TPU Insole	Insole delamination/ warping
	2.2. Electronics Adhesive	Hardware Pullout from Insole
Insole Electronics	3.1. Wire connection to Haptic Motor	Component Disconnect
	3.2. Haptic Motor responsible for stimulation	Haptic Motor Failure
	3.3. IMU board responsible for data collection	IMU board Failure
	3.4. All Insole Electronics	Water damage
Software Systems	4.1. Embedded Data Collection Code	non-functional or buggy code
	4.2. Embedded FOG Recognition Code	non-functional or buggy code
	4.3 External Computer Side GUI Code	non-functional or buggy code

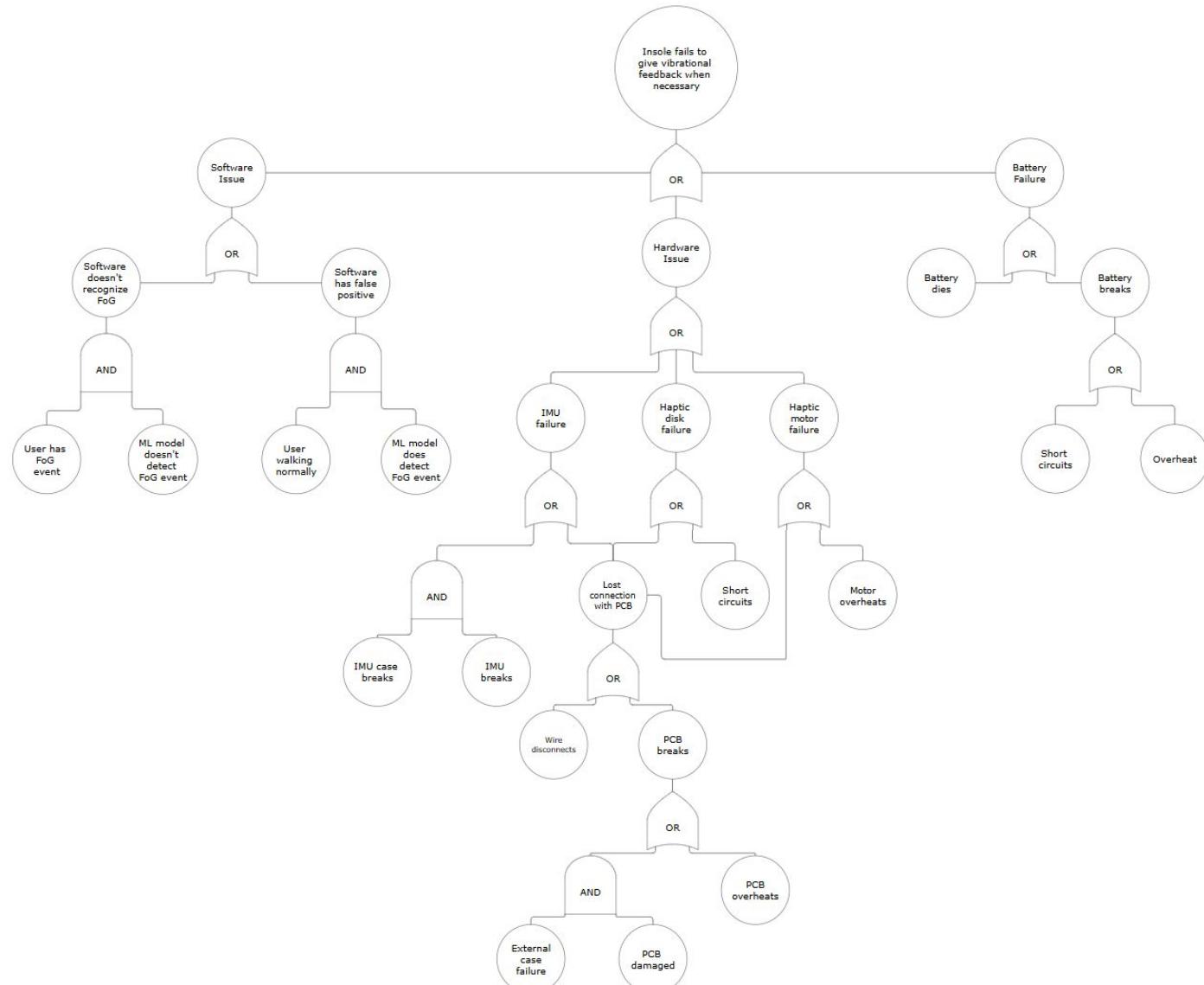
Assessment						
Potential Effect(s) of Failure	Severity (S)	Potential Causes and Mechanisms of Failure	Occurrence (O)	Design Control	Detection (D)	RPN
Component malfunctions or is no longer usable	9	Too much strain/friction	2	User Wear	1	18
Data cannot be communicated to the app	4	Faulty signal	3	Antenna signal test	2	24
Insole no longer tracks FOG or activates cues	8	Over-tracking of gait parameters	3	Battery life test	2	48
Thermal Event, burning and degradation of PCB board and nearby items. Potential harm to user.	10	Battery Puncture or Defect	2	Adequate Casing Design	1	20
Loose PCB, leading to potential disconnection or electronic damage.	6	Improper Installation of Fasteners	3	CAD design and Installation Procedures	1	18
Separation of Clip and Casing, leaving casing hanging on by flex PCB line.	7	Improper Installation of Fasteners	3	CAD design and Installation Procedures	1	21
Insole cracks or falls apart, making it less comfortable or unusable	7	Faulty Insole Print	2	Instron tensile strength test	1	14
Insole cracks or falls apart, making it less comfortable or unusable	7	Faulty Insole Print/ abuse of insole	2	Instron tensile strength test and linear fatigue test	1	14
Loose Insole, Electronics Damage, Data Noise	6	Inadequate Strength of adhesive.	4	Early Prototyping and User Wear	2	48
Component malfunctions or is no longer usable	9	Too much strain/friction	4	Instron bend test	2	72
Motor ceases to function, preventing cues from being administered	8	Cable becoming unplugged	2	Instron linear fatigue test	1	16
Loss of IMU data, preventing detection of gait abnormalities.	8	Crushing of IMU	3	FEA Simulations	1	24
Short circuits, electronics failures, potential for overheating	9	Water/sweat ingress	4	Data collection tests	2	72
Loss of ability to collect/process, and store gait data	5	Lack of debugging code/ hidden edge cases	2	Patient Trials	4	40
Loss of ability to recognise FOG patterns and give haptic motor signal in sufficient time.	7	Lack of debugging code/ hidden edge cases	2	ML Accuracy Test and System Latency Test	3	42
Loss or Inaccurate gait data being displayed.	2	Lack of debugging code/ hidden edge cases	2	Patient Trials	4	16

Recommended Actions		Action Results					
Description of Action	Responsibility & Target Completion Date	Actions Taken		Sev (S)	Occ (O)	Det (D)	RPN
Ensure Firm Solder connections and monitor strain on flex line.	Benito/Ian/Will 10/15	Refinforce PCB with electrical tape		9	1	1	9
Move antenna to a spot with less interference	Tyler 11/1	Testing showed no bluetooth connectivity issues		4	1	1	4
Program stricter sleep mode settings	Ian/Tyler/Mark 11/1	Future work should include using a larger battery		8	6	2	96
Design Casing to protect battery from damage.	Mark 10/10	Case has been redesigned for improved air flow		10	1	2	20
Ensure all fasteners are installed at the adequate location and torque spec.	Benito/Ian/Will 10/30	Testing showed no backout events		6	2	1	12
Ensure all fasteners are installed at the adequate location and torque spec.	Benito/Ian/Will 10/30	Clip attachment changed to velcro, no disconnections during testing		7	2	1	14
Controlled epoxy measurement and mixing	Benito/Ian/Will 10/15	N/A					
Controlled epoxy measurement and mixing	Benito/Ian/Will 10/15	N/A					
Test proper adhesive types and quantity in initial prototypes and iterate as necessary.	Matt/Benito/Will 10/30	Insole redesigned so no adhesives necessary. No events during testing		6	1	2	12
Try different epoxies	Benito/Ian/Will 10/15	Instron bend test not possible. Testing showed no such event occurrences.		9	3	2	54
Adding stiff inserts near electronics	Benito/Ian/Will 10/15	N/A					
Run FEA simulations and user wear to assess max deformations.	Will 10/6	FEA showed appropriate displacement. Test showed no issues.		8	1	1	8
Increase print infill	Benito/Ian/Will 10/15	No water retention events during testing.		9	2	1	18
Debug and improve/improvise code structure from feedback during usage in trials.	Ian/Tyler 11/1	No connectivity issues during data collection observed.		5	1	1	5
Use test results to validate changes made in code and debugging.	Ian/Tyler 11/1	Testing showed sufficient reaction time to detected events		7	1	2	14
Debug and improve/improvise code structure from feedback during usage in trials.	Ian/Tyler 11/1	N/A					

Based on highest level insole  
function - **vibrational cue**

## Highest Failure Dependencies:

- Software
  - ML model
- Hardware
  - Haptic disc
  - Haptic motor
  - IMU
- Battery



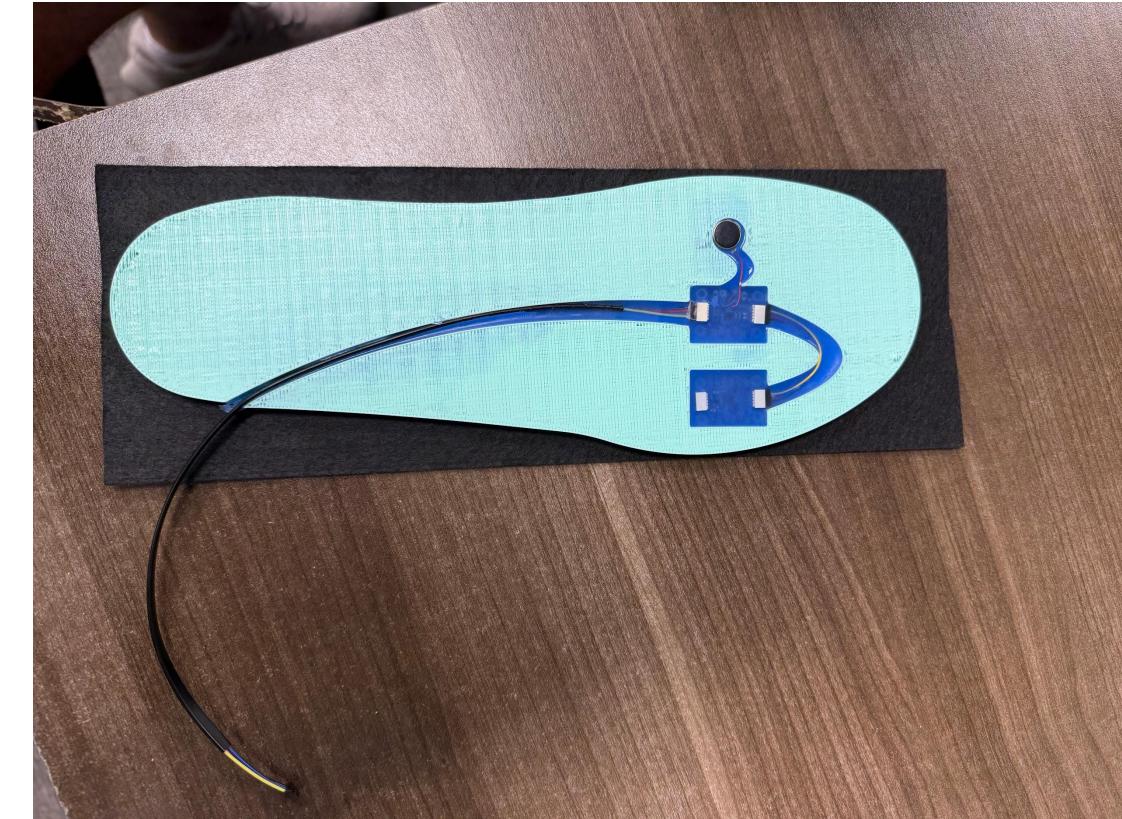
# Design Selection

## Key Design Choices:

- Silicone epoxy filling to hold electrical components
- Very 2D insole
- Haptic driver inside insole
- IMU up by the toes
- No PCB, breakout boards used

## Learnings:

- Epoxy acted more like a mold
- Wasn't very comfortable
- Too many components inside



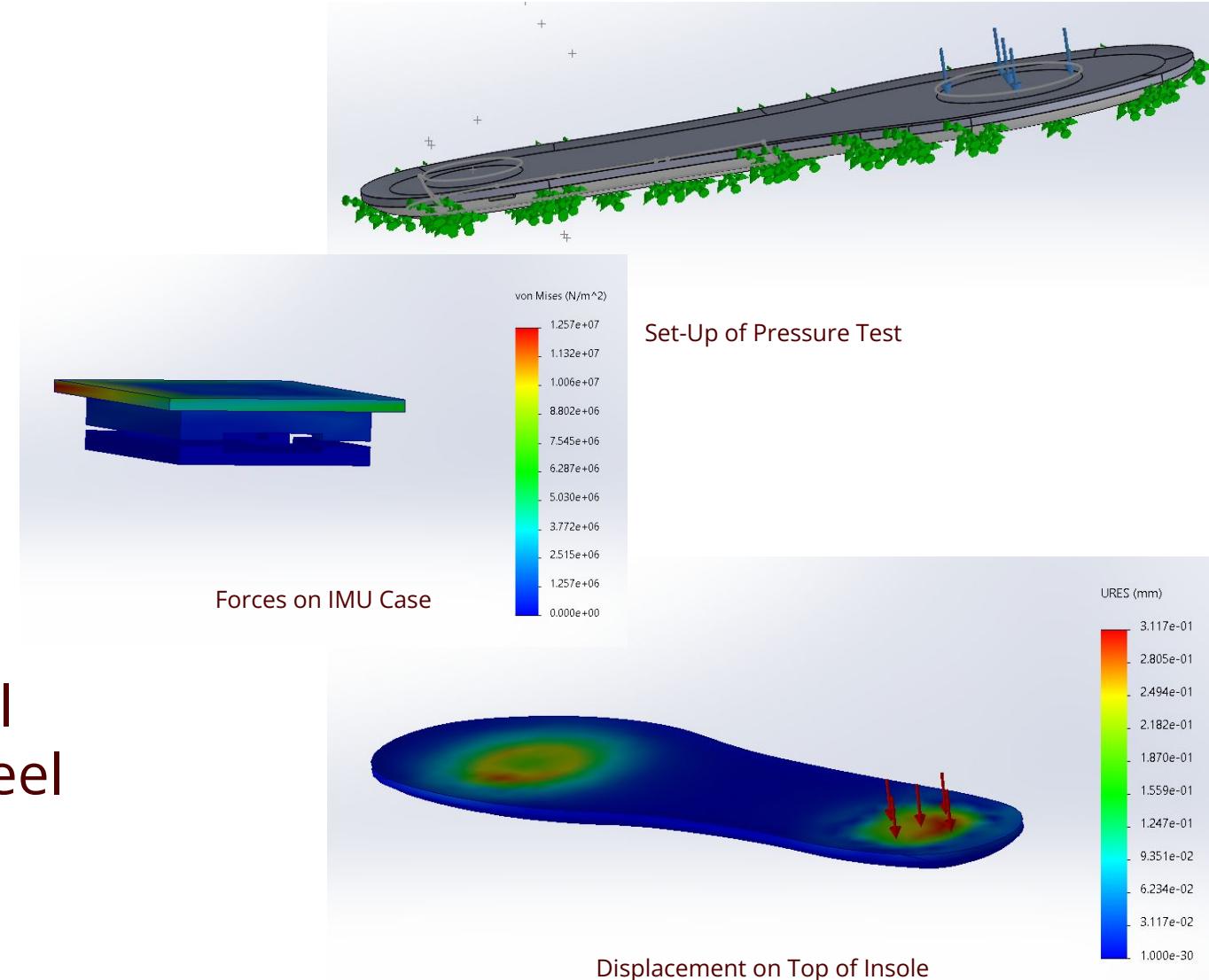
Final Prototype at End of MEEN 401

## Set-up:

- Applied 65.6 psi of pressure to toe and heel (based on 300 lb person)
- Fixed the bottom of insole

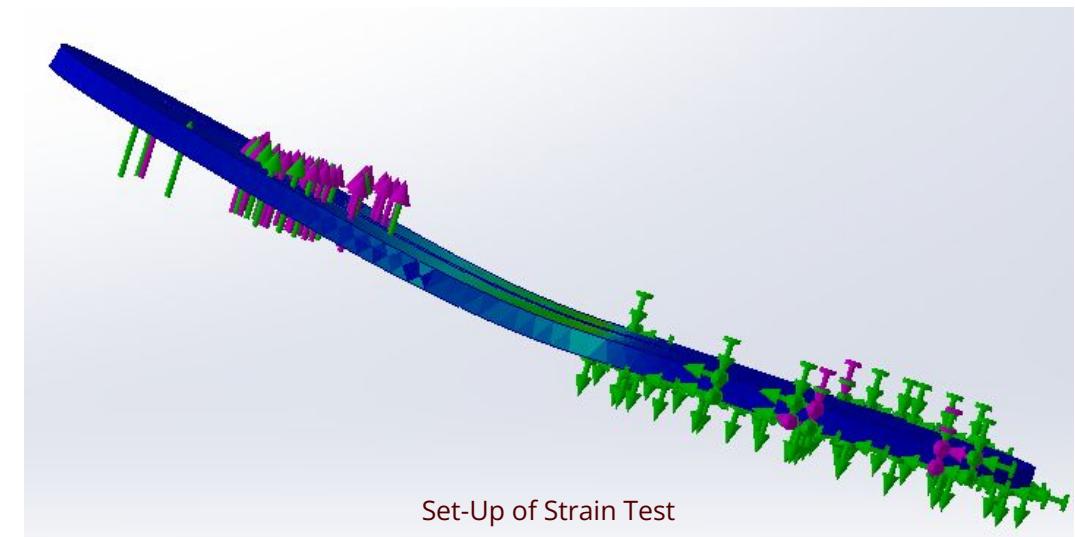
## Result/Learnings:

- ~12 MPa applied to IMU case
- ~0.3 mm of deformation at heel
- Need to make sure air gap in heel is large enough



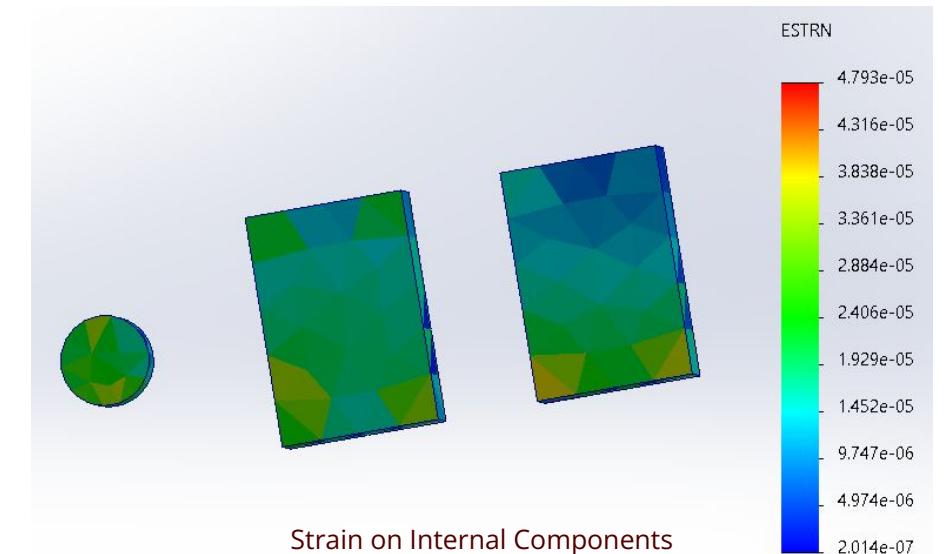
## Set-up:

- Applied enough pressure to toe box of insole to get the typical bending seen during a step
- Fixed the heel side of the insole



## Result/Learnings:

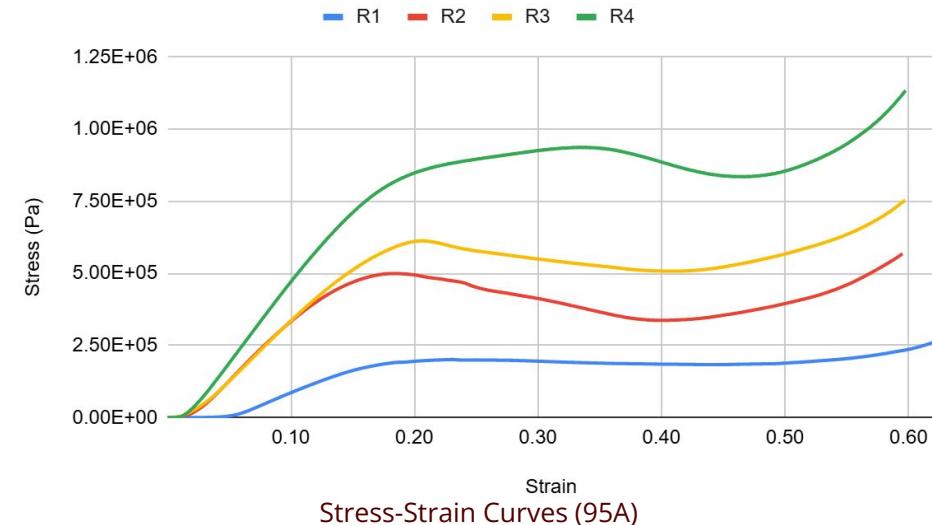
- ~.004% strain applied to haptic disk in the insole
- Not going to cause any issues with yielding or fatigue



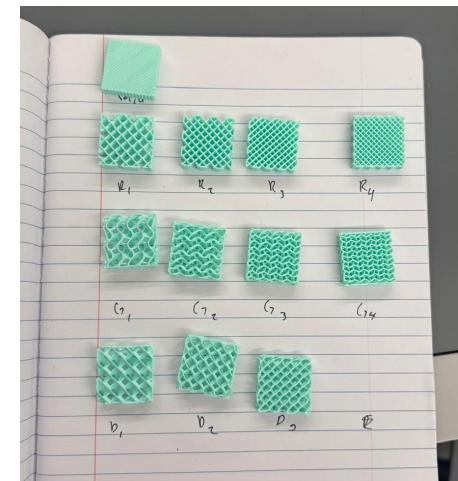
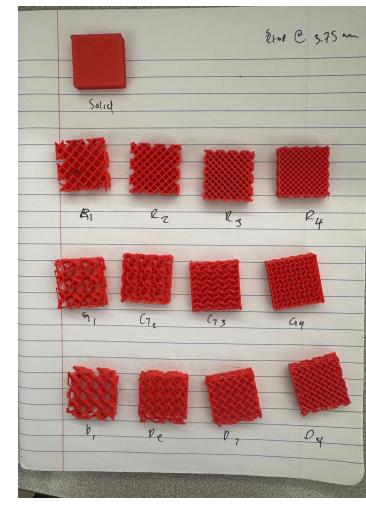
## Hardness Testing:

- Created different samples of 85A and 95A TPU using different infill patterns
- Tested samples using an Instron Tensile Tester
- Used the data to create stress-strain curves and force-displacement curves for each sample
- Helped determine material properties and elasticity to select optimal material

Stress vs Strain Curve (Rectilinear - Red)



Stress-Strain Curves (95A)

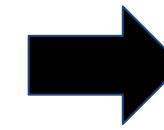


## Design Choices:

- 85A TPU with 30% rectilinear infill
- Increased curvature from MEEN 401 prototype
- Put only necessary components inside insole
  - Haptic disc and IMU
- Increased thickness for longevity and comfort
- Casing around IMU with air underneath to account for compression
- Insoles can be easily scaled in Solidworks based on shoe size

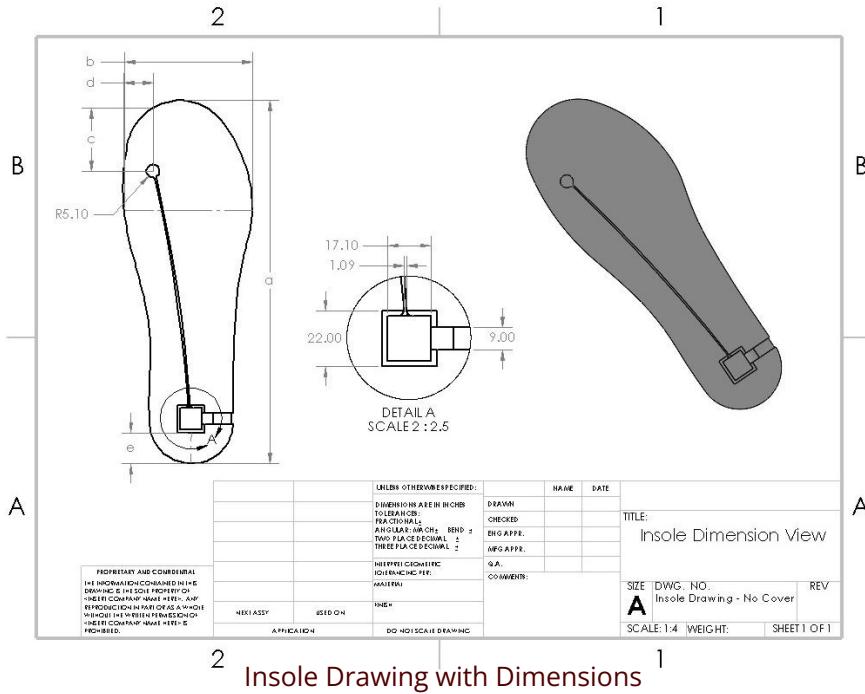


MEEN 401 Prototype



Final Prototype

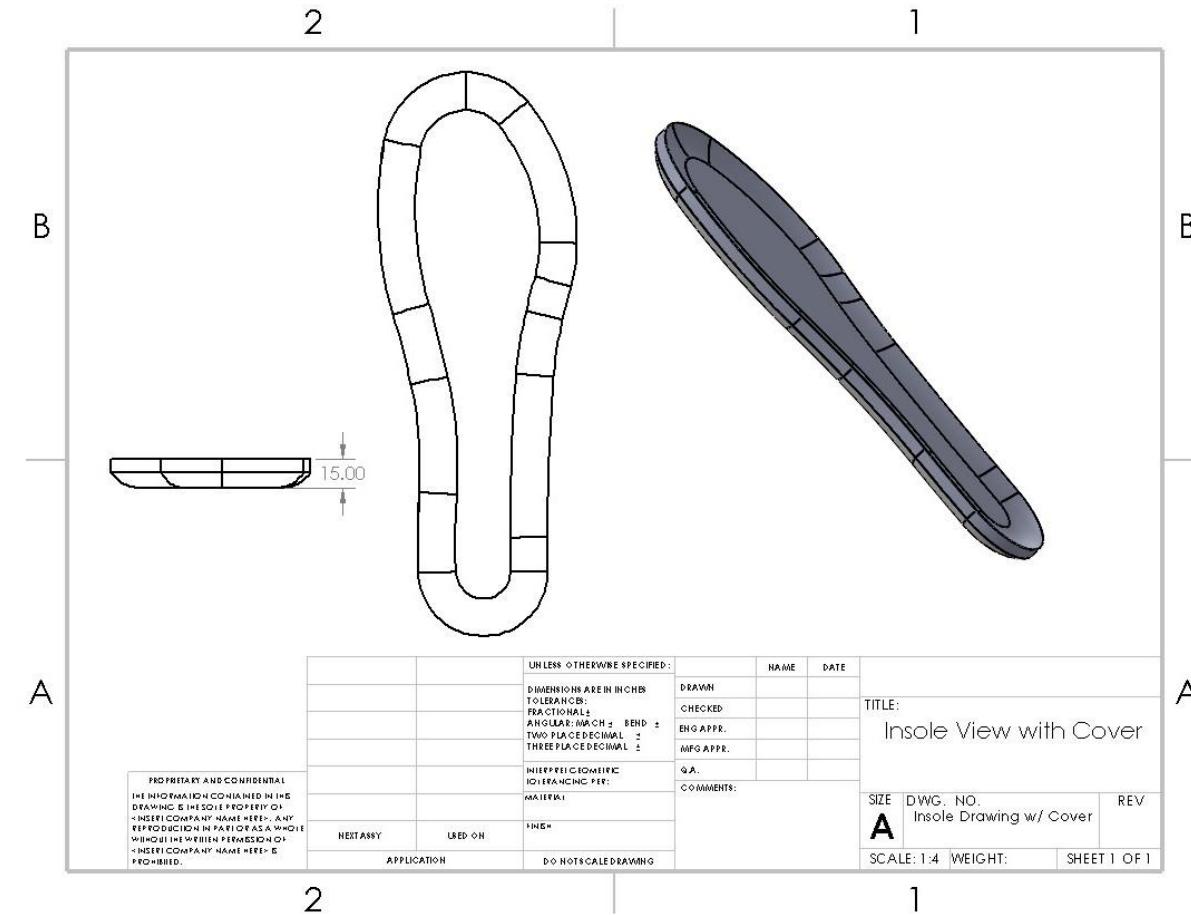
# Insole Drawings



2 Insole Drawing with Dimensions 1

Size	Length (a)	Toe box width (b)	Disk from toe (c)	Disk from side (d)	IMU from heel (e)	Cover Radius
M5.5/W7	240.34 mm	84.9 mm	45 mm	20.5 mm	24 mm	34 mm
M6.5/W8	250.35 mm	88.45 mm	46 mm	21 mm	24.5 mm	35 mm
M8/W9	260.36 mm	92 mm	47 mm	21.5 mm	25 mm	36 mm
M9/W10	270.38 mm	95.53 mm	48 mm	22 mm	25.5 mm	37 mm
M10/W11	279.39 mm	98.71 mm	49 mm	22.5 mm	26 mm	38 mm
Mens 11	287.40 mm	101.54 mm	50 mm	23 mm	26.5 mm	39 mm
Mens 12	295.42 mm	104.38 mm	51 mm	23.5 mm	27 mm	40 mm

Insole Dimensions Based on Size



2 Insole Drawing with Cover 1

## Electronic Hardware Case Design:

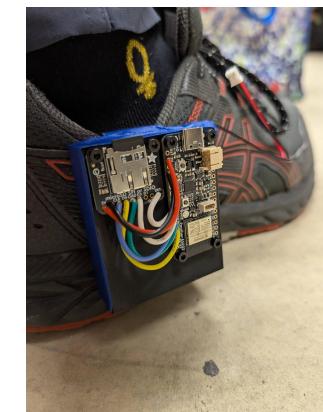
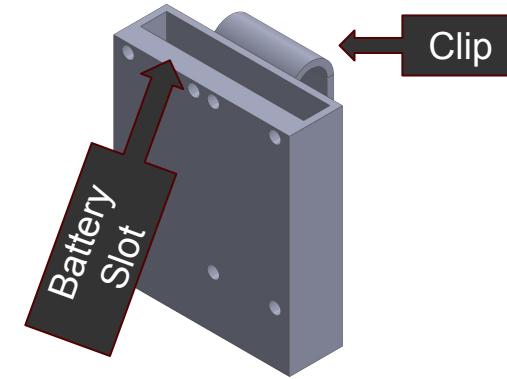
- Protects all essential components (ESP32, battery...etc)
- Rigid structure prevents component movement during walking
- Supports consistent haptic feedback by securely mounting the microcontroller and battery
- Provides USB charging access and simple internal layout for maintenance
- Isolates electronics from the foot to prevent irritation and ensure safety
- Allows rapid prototyping and precise tolerances through PLA additive manufacturing



Front Cover

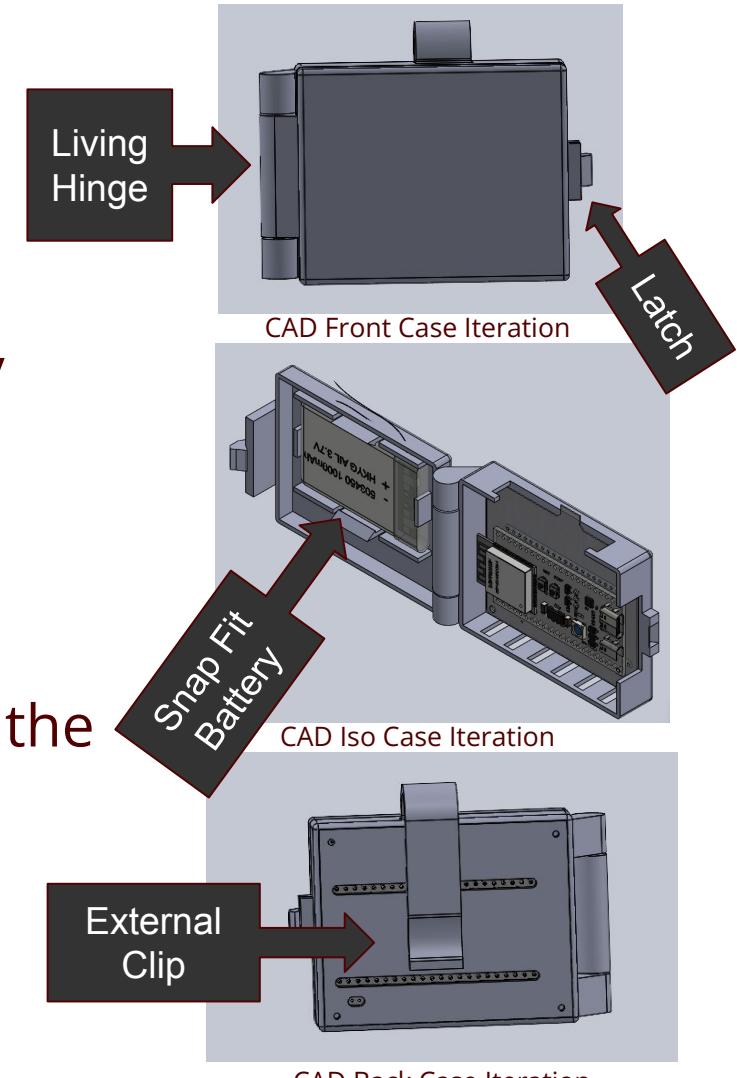
## Original Design:

- Hardware fastened externally
- Exposed electronics and battery
- Frictional Clip



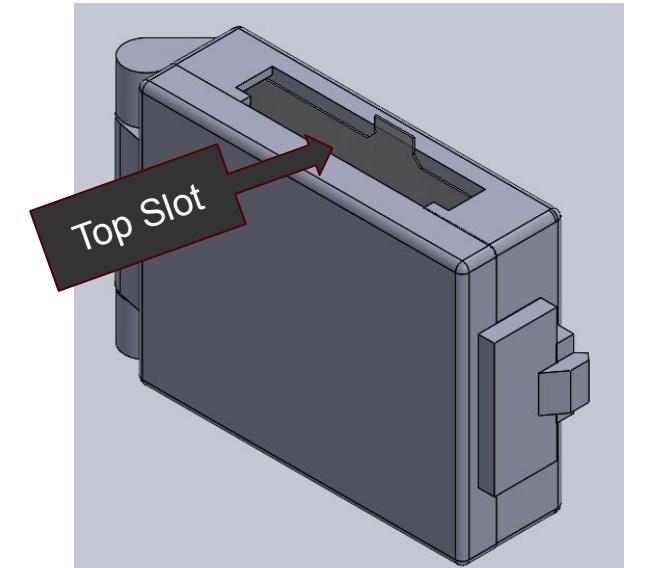
## Iterations:

- Living Hinge
- Snap-Fit Battery Mount
- Snap-Fit Latch
- PCB Mount
- Clip that routes the PCB wiring



## Further Iterations:

- Top Slot Expanded for Easier Assembly
- Clip Substituted for Velcro on the backside of the case
- Improved Battery Mount Tolerancing



Final Case Design CAD



Functional Design But Difficult to Repair and Assemble

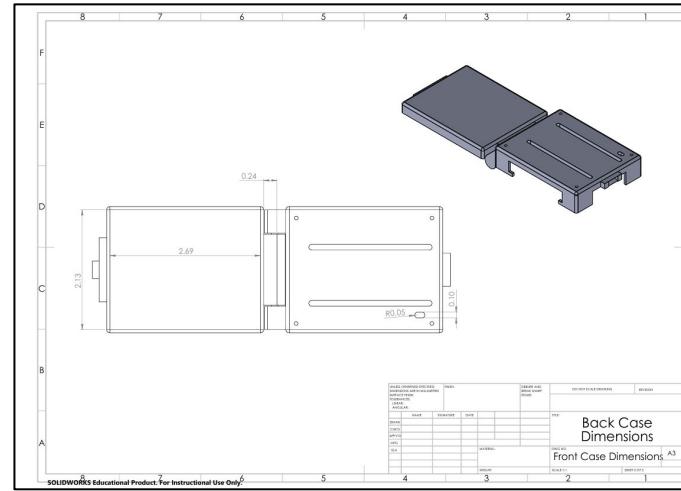


Final Case Design Integration

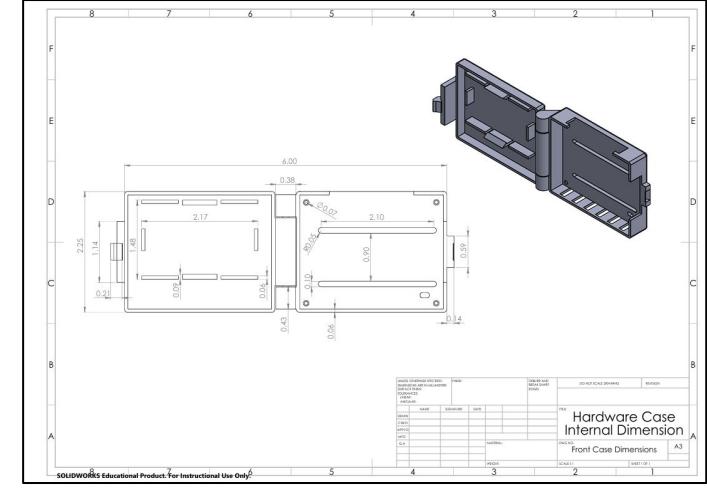
Limited  
Space for  
Extra  
Wiring

## Final Design & Manufacturing:

- Excess Wiring Space
- Improved Battery Tolerancing
- Deeper & More Secure Snap-Fit Latch
- Vertical Vents
- Mass PLA Production



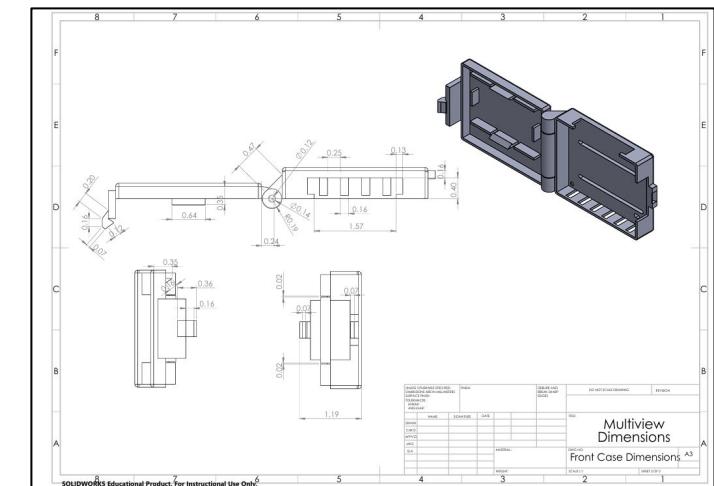
Back Open Case Drawings



Open Iso Case Drawings



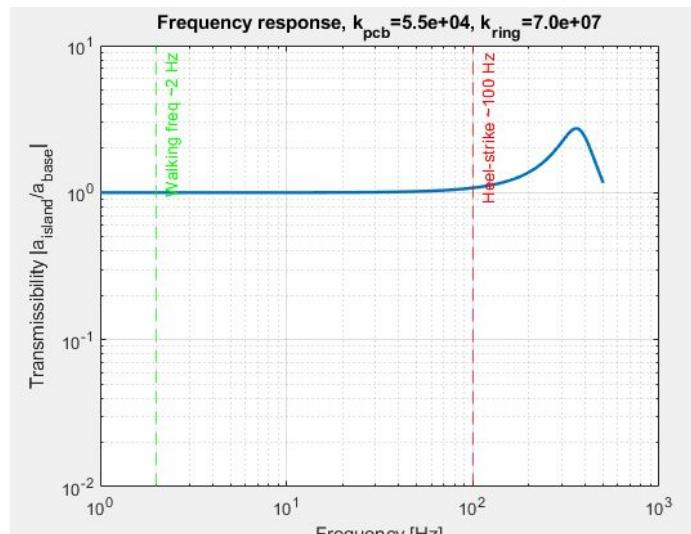
Final PLA Printed Cases



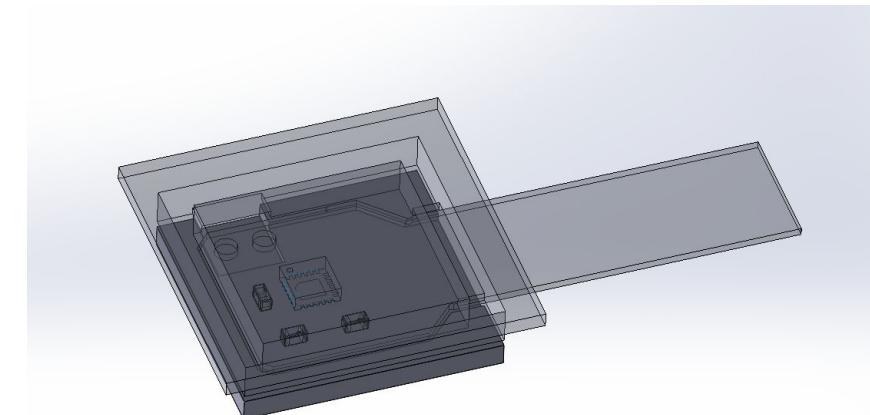
Side Views Case Drawings

# IMU Case Functionality:

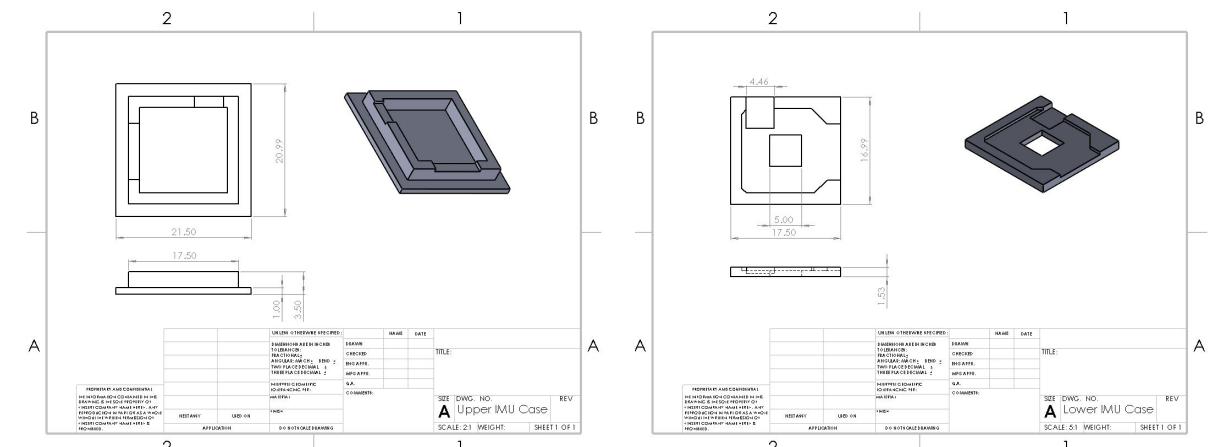
- 2 part design
- Upper case has a lip that glues to the top of the insole
- Allows it to compress at the same rate as the insole



## IMU Case Frequency Response



## IMU Case 3D Model



## IMU Case CAD Drawings

# Manufacturing

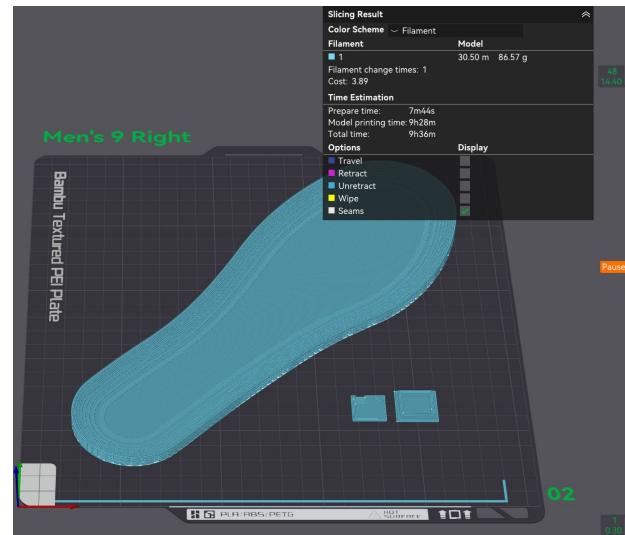
# Insole Manufacturing



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## Insole Manufacturing Overview:

- 3D Printed on Bambu Lab P1S printer
- Requires larger **0.6mm nozzle**
- **7.5 - 11 hours** to print
- Insole components are **printed in place**
  - Print pauses to insert components
  - Allows manufacturing without adhesives



Insole design sliced for printing



PCB inserted in 3D printed insole



Final 3D Printed Insoles



3D printing setup

## Material Selection for Case Enclosure:

- **PLA** — Chosen Material
  - Rapid prototyping, precise tolerances, rigid (perfect for snap-fit/screws), stiff, low warping, easy to print, inexpensive
- **PETG**
  - More flexible than PLA, high heat resistance, prone to stringing, bed adhesion issues, slower printing, worse surface finish
- **Resin**
  - High-detail prints, excellent for complex geometry
  - Brittle (not ideal for snap-fit/screws), Sensitive to UV and heat, messy post-processing, resin-hinge interference



Resin Printing Attempts

## Shoe System Installation:

- Quick, Slip-in Design
  - Works for  $\pm 1$  Shoe Size, Standard Toe Box
- Multiple attachment methods considered for Case
  - Velcro chosen for ease of use and non-intrusive ergonomics
- 5 Different Shoe Sizes made for Trial Testing Clientele



Comparison of PCB Case attachment methods.

## Electronics designed from team specifications:

- ESP32 Microcontroller
  - Bluetooth Low Energy (BLE) data transmission
  - Processing and Machine Learning
- Inertial Measurement Unit (ICM 20948 IMU)  
for gait data collection
- Haptic vibration motor as cue
- Flexible Printed Circuit Board (PCB)
- 1200mAh Lithium-ion battery
- Battery voltage regulators

## Firmware written in C++ for ESP32

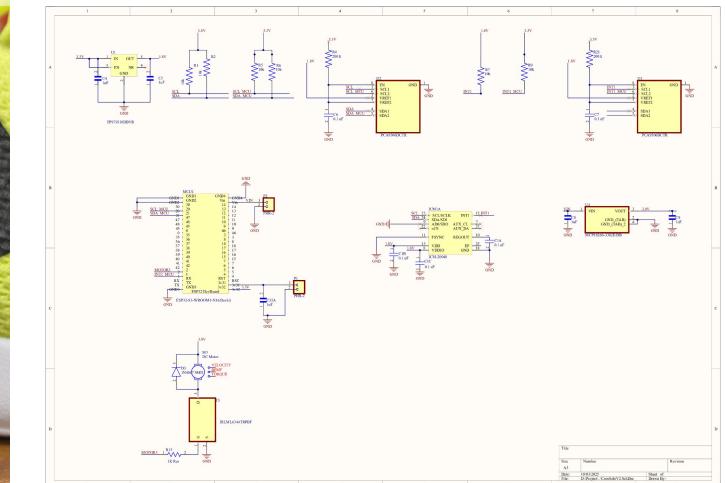
- Collects timestamped IMU data
- Runs machine learning model
- Administers FoG cue



ESP32 Microcontroller on PCB



PCB inserted in 3D printed insole

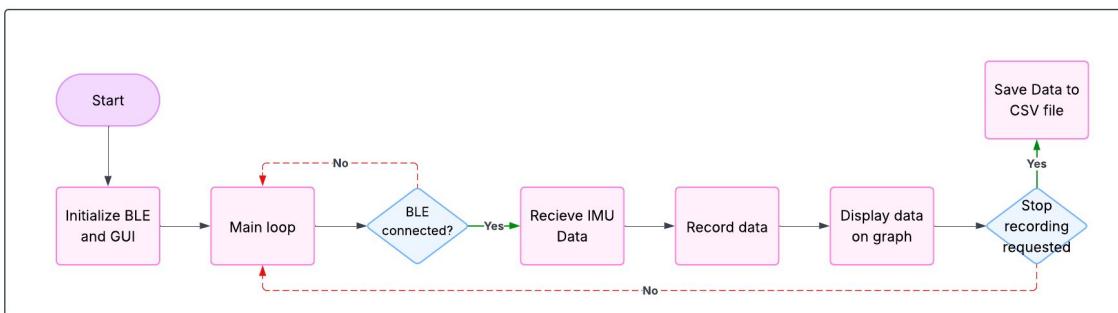


PCB Schematic

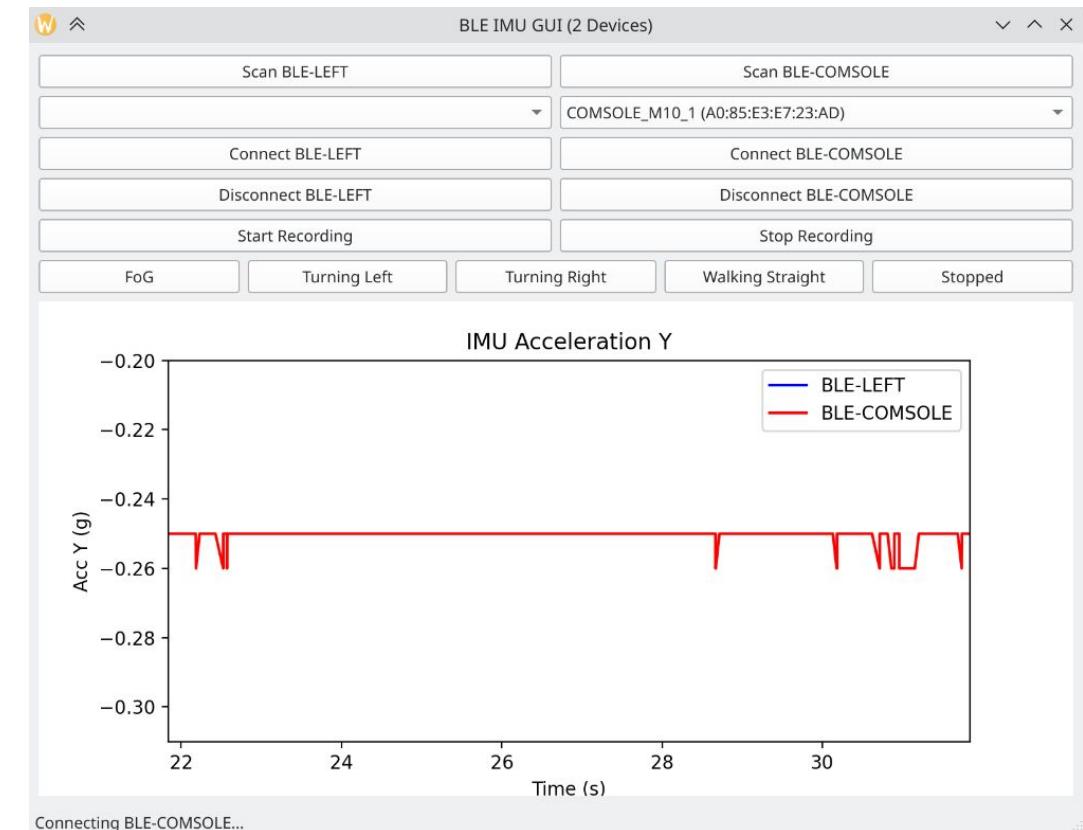
# Software Development

## Data Collection Overview:

- Data collection software written in python
- Records live IMU data (linear acceleration, angular velocity) at 100 Hz
- Connects to insole over BLE serial
- Automatic CSV file creation



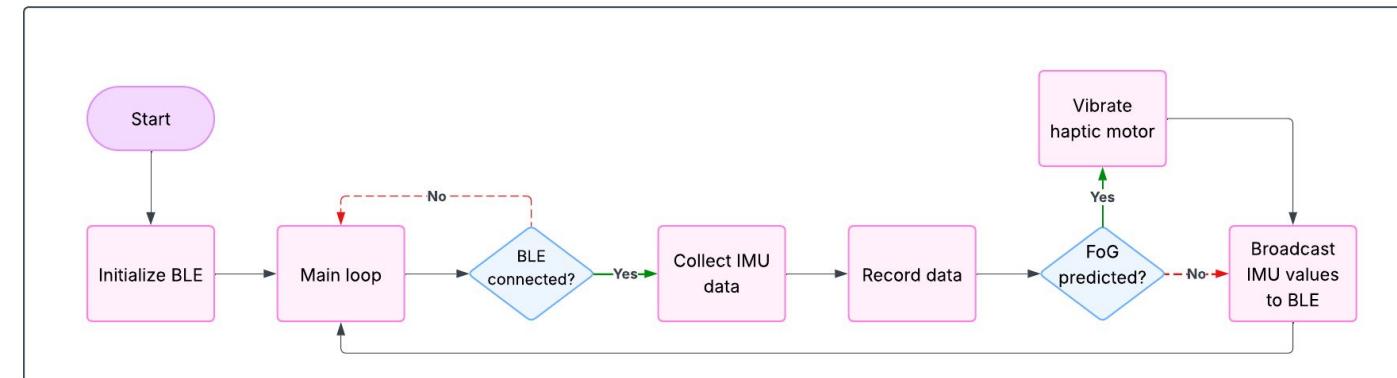
Data Collection Flowchart



Data Collection Graphical Interface

## Firmware Overview:

- Firmware written in C++ for ESP32 with PlatformIO
- Collects IMU data over I<sup>2</sup>C with ICM 20948 library
- Predicts if FoG is occurring with ML model
- Activates haptic vibration motor using a digital output
- Broadcasts IMU data to GUI & Mobile App over BLE

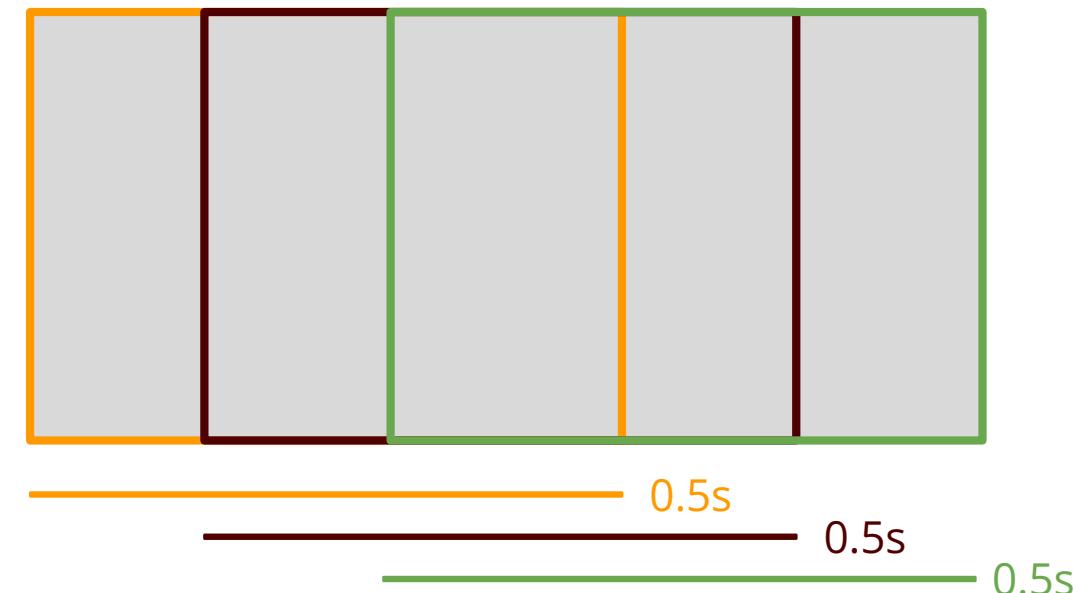


Firmware Flowchart

## Data Pipeline and Feature Engineering:

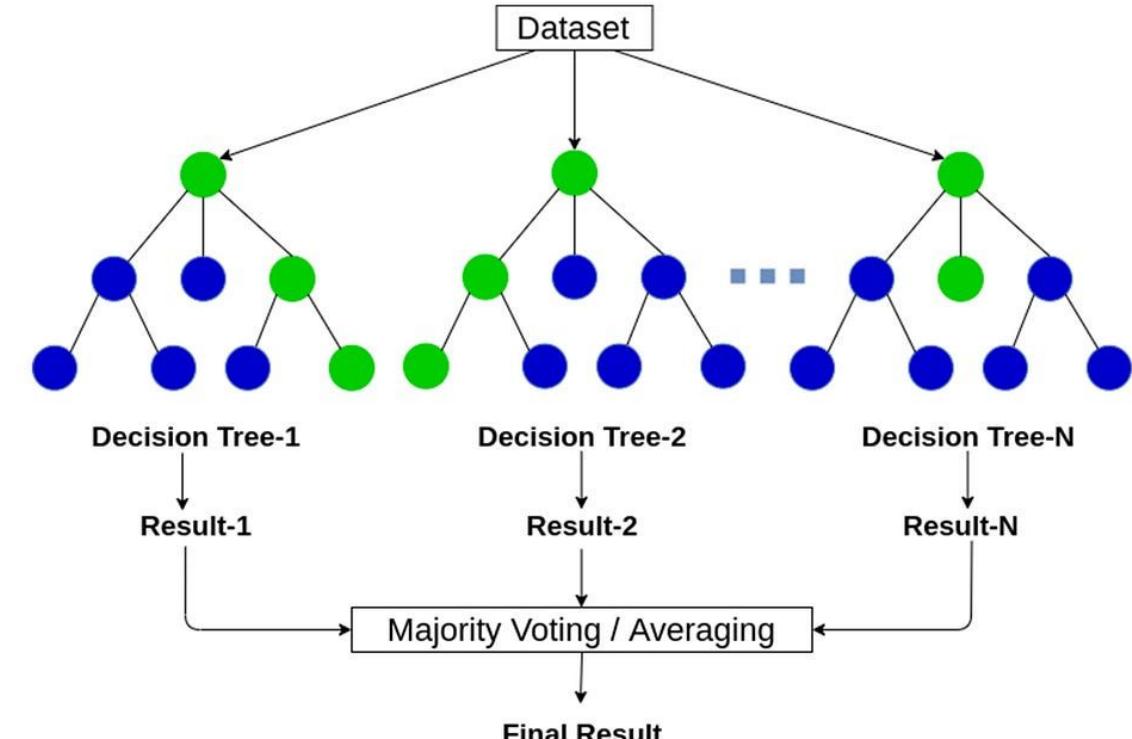
- Sliding window segmentation
  - 0.5s windows, 0.125s steps, overlapping.
- Per-window features extracted from 6 sensor channels (accel & gyro)
- Total feature vector: 48 features:
  - Statistical: mean, stdv, max/min
  - Frequency: RMS, energy
  - Signal pattern: Zero-crossing
  - Cross-axial correlation

### Data windowing



## Model and Training Strategy:

- Model Chosen: Random Forest Classifier
  - Resistant to noise and signal drift
  - No need for large datasets
  - Easier to tune and deploy
  - Low computational cost
  - Handles non-linear boundaries between FoG and normal walking

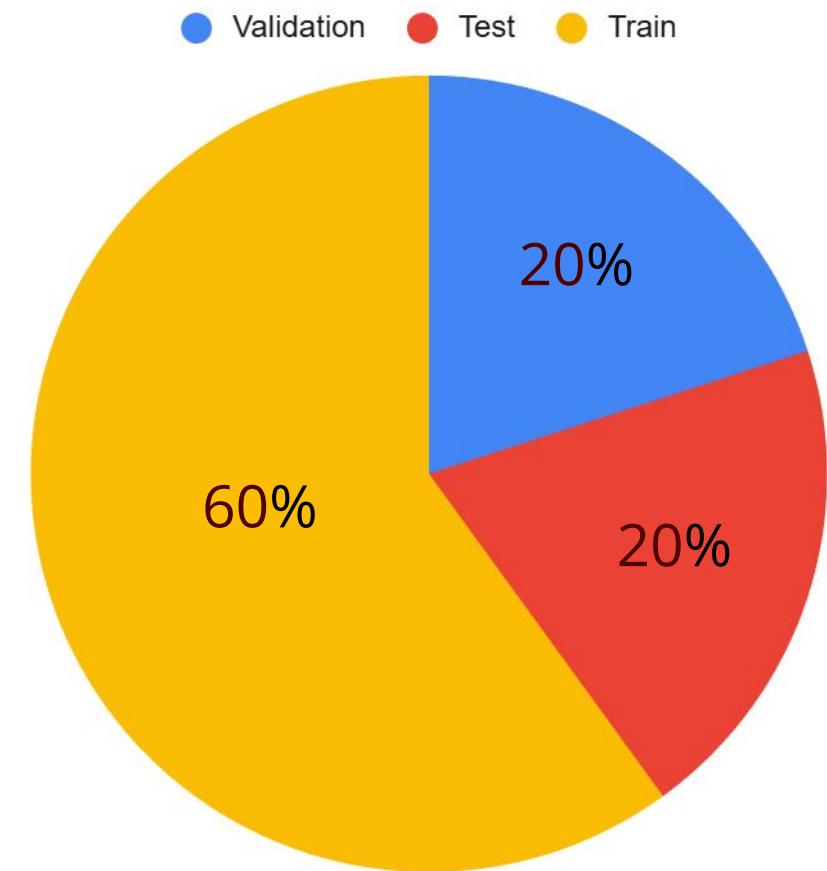


Random Forest Classifier model visual representation (Jain, 2024)

## Training Strategy & Class Imbalance:

- Training Strategy:
  - Random shuffling between Train/Val/Test
  - Prevents leakage between same-subject windows
- Hyperparameter Tuning - GridsearchCV on:
  - n\_estimators, max\_depth, min\_samples\_split
  - Best model: 1200 trees, depth=none, split=5
- FoG events are much rarer than non-FoG.
- Class\_weight was set to “balanced” to prevent model from learning to “always predict non-FoG”
- Ensures FoG samples have equal influence during training

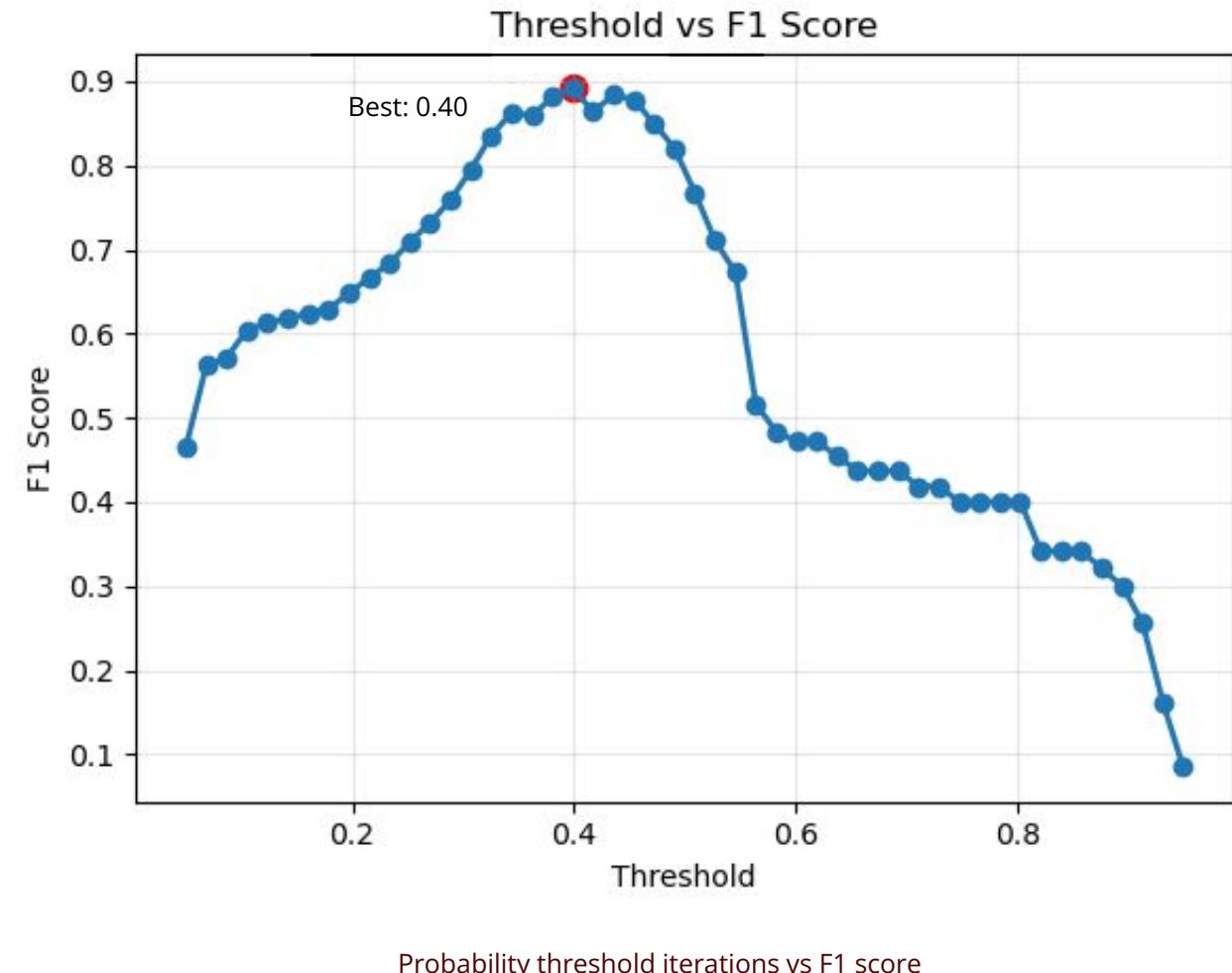
## Model Data Split



Model data split for training, validation and testing

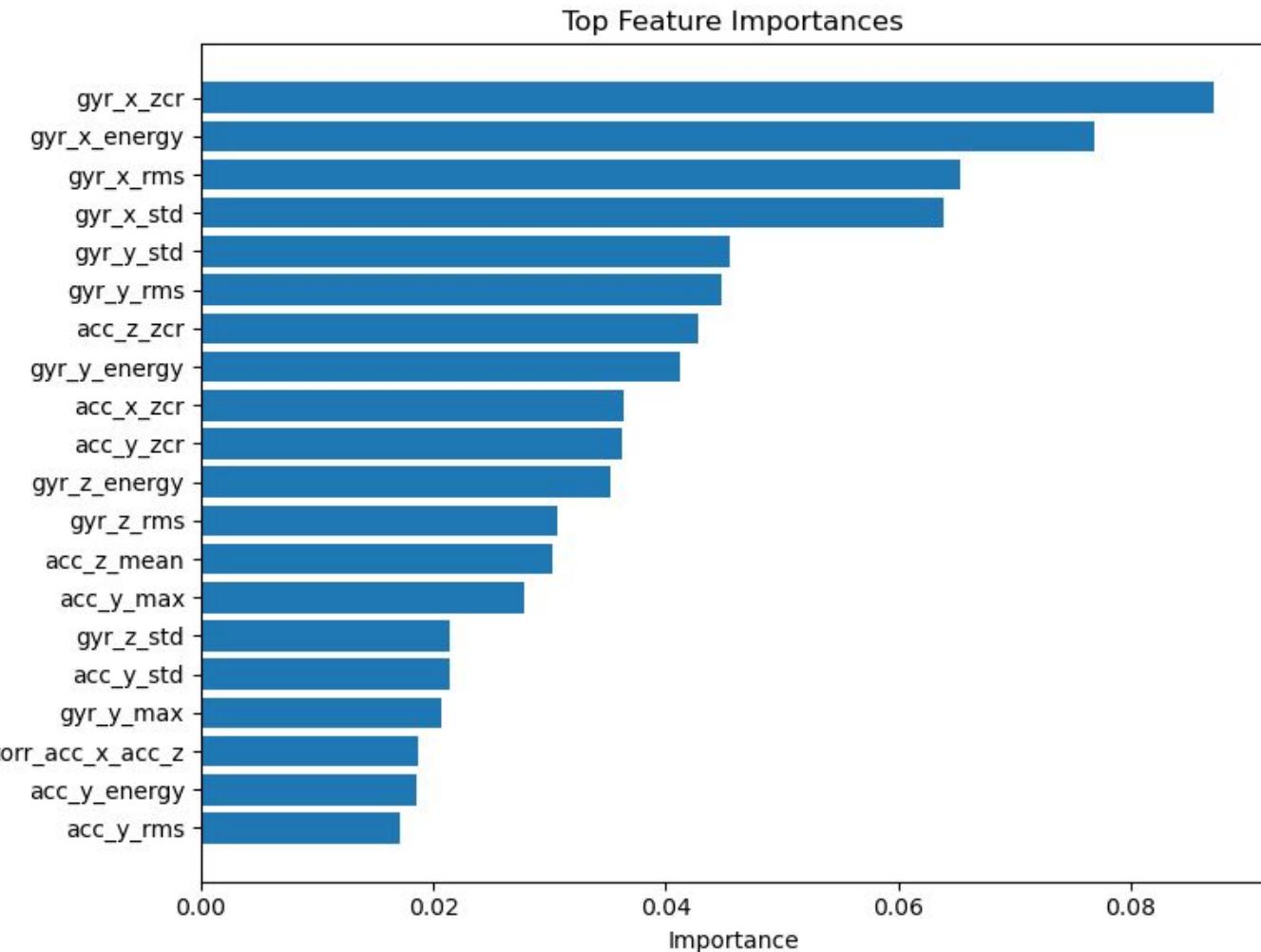
## Threshold Optimization:

- Instead of default 0.5, threshold selected empirically.
- Sweep performed on validation set.
- Final threshold: 0.40
  - Giving best F1 score and Recall
- Balances false positives vs false negatives



## Model Interpretability:

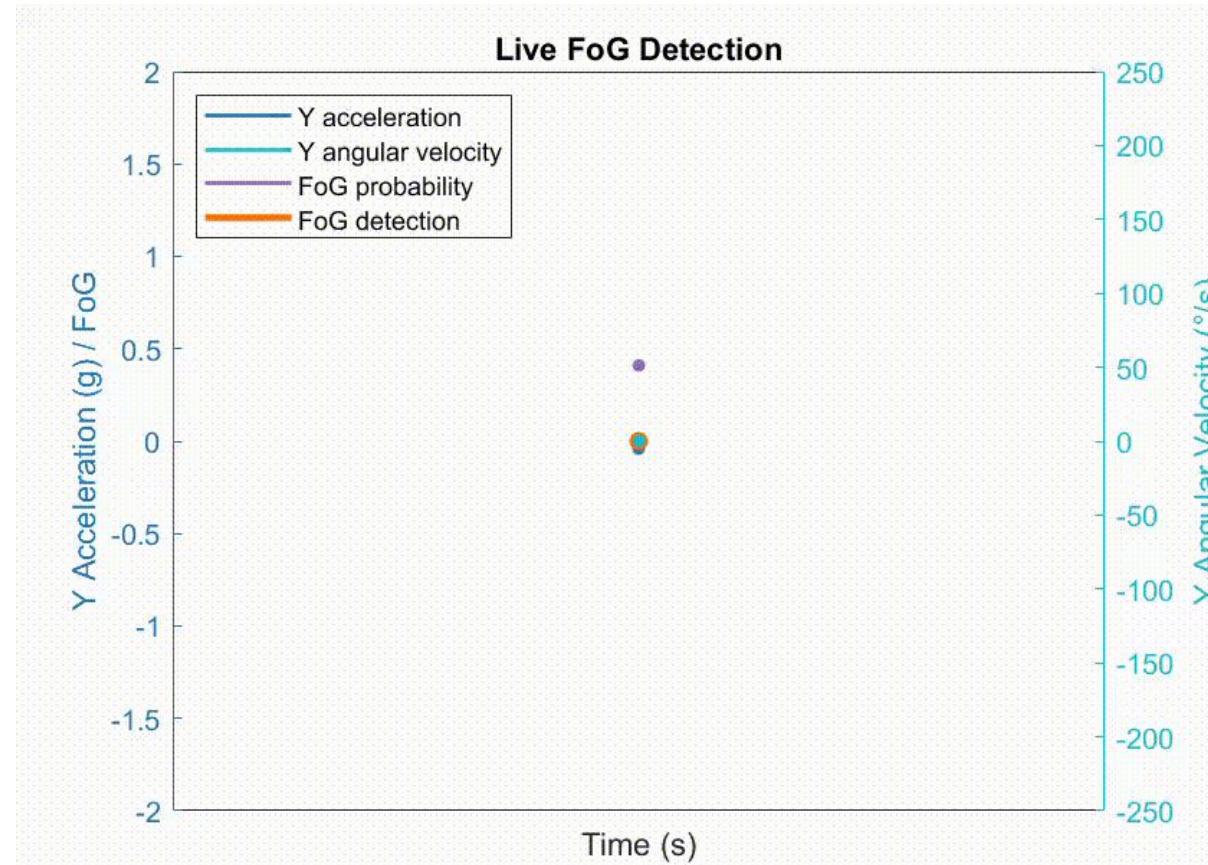
- Top contributing features indicate what motions characterize FoG.
- `gyr_x` most dominant feature
- High relevance of `acc_zcr` - Stuttering is oscillatory
- Confirms original prediction of linear and angular irregularity during shuffling events

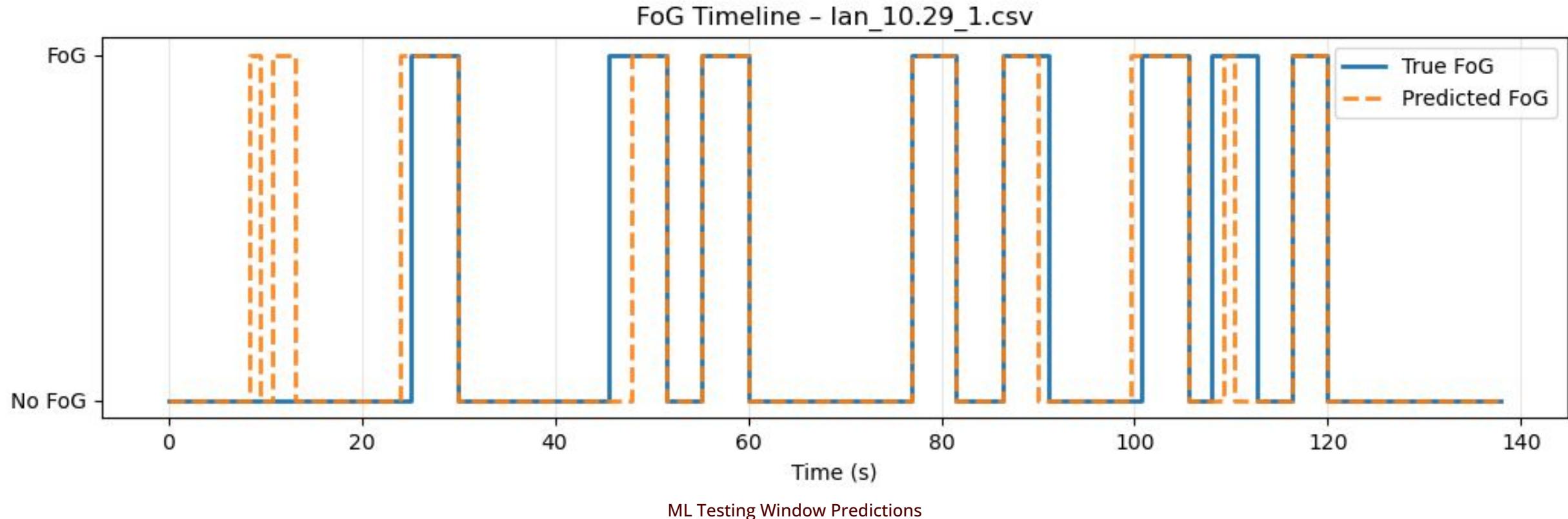


Statistical features with the highest impact on the machine learning model

# FoG Timeline and Integration:

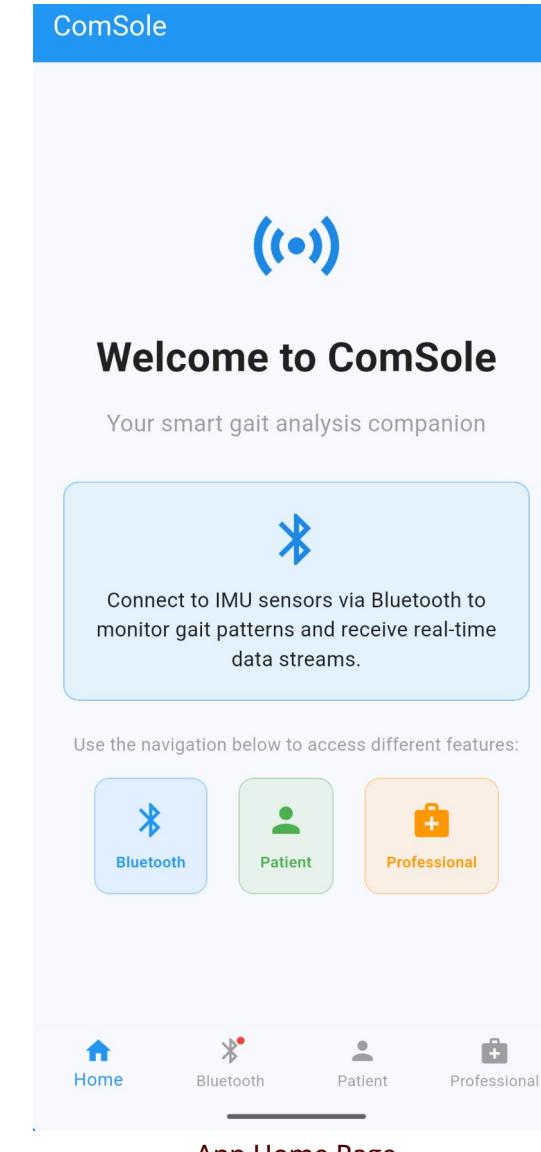
- Model outputs per-window FoG probability and classification.





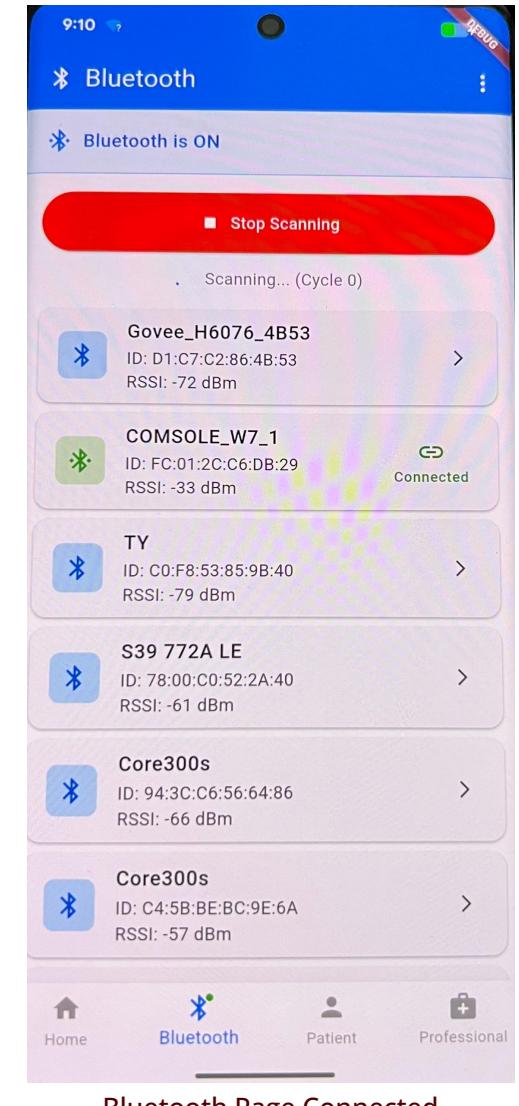
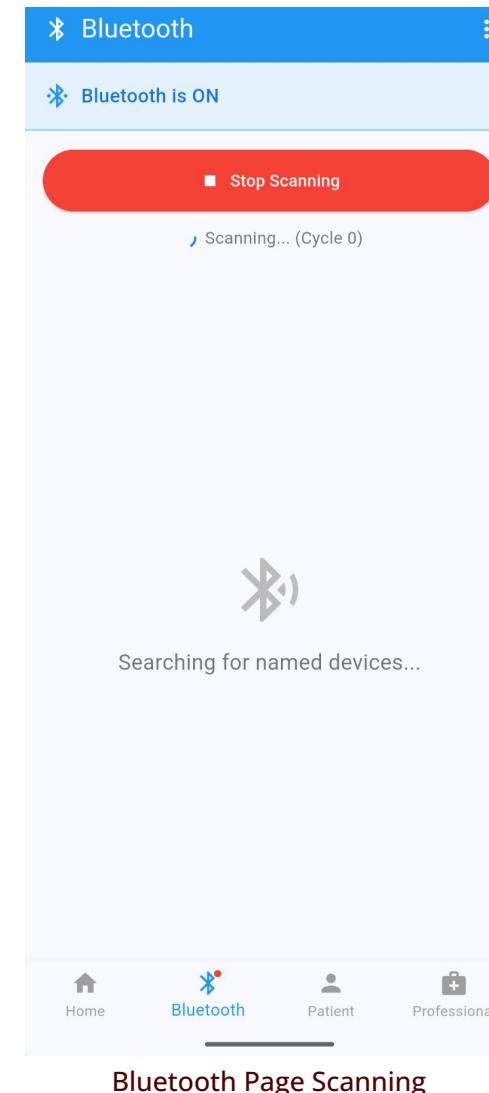
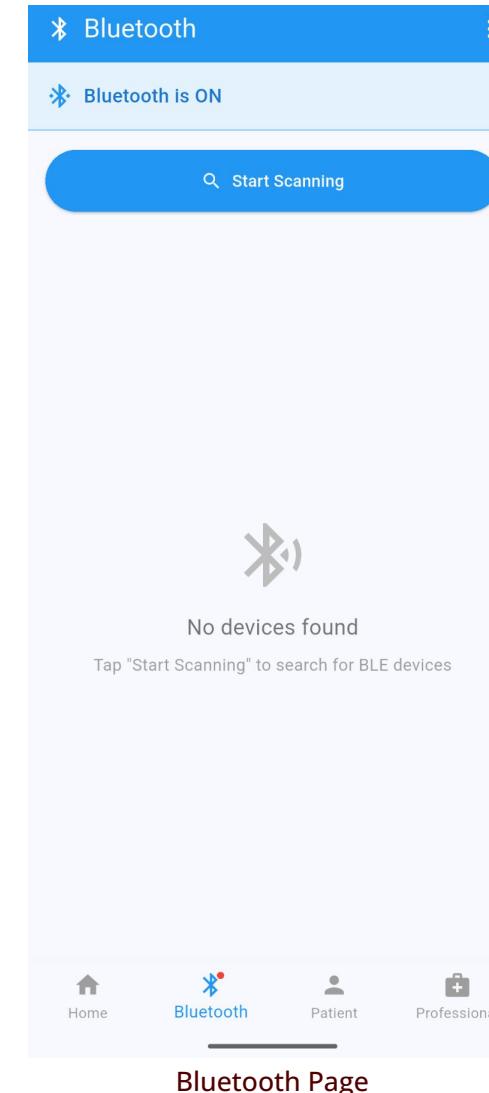
## Welcome Page Overview:

- App designed for both Android and iOS
  - Created using Flutter
  - flutter\_ble\_plus bluetooth package
  - sqlite local database package
  - Home, Bluetooth, Patient, and Professional pages
- Current version ready for deployment or continued development
  - Code package is in the Google Drive and shared with Yang



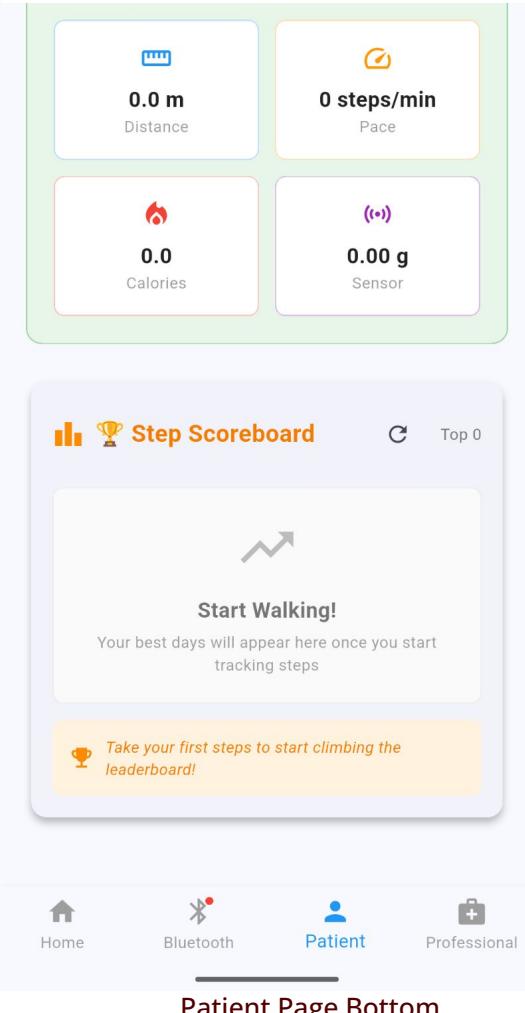
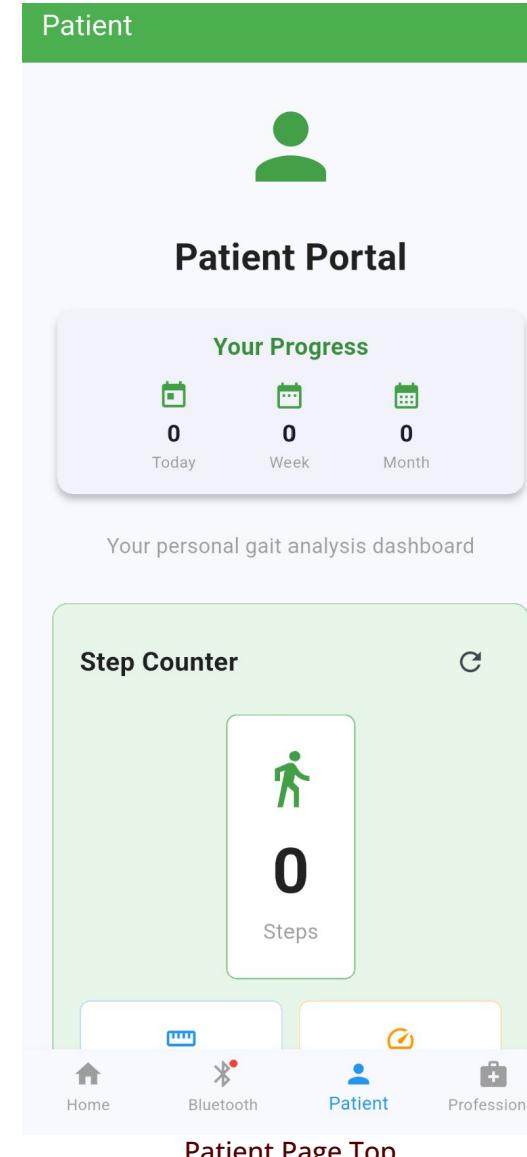
## Bluetooth Page Overview:

- Simple bluetooth page allows users to easily connect to their COMSOLE device
- Bluetooth scanner finds all named bluetooth devices in the area
- Once the user's device is located, simply click on the device name to connect



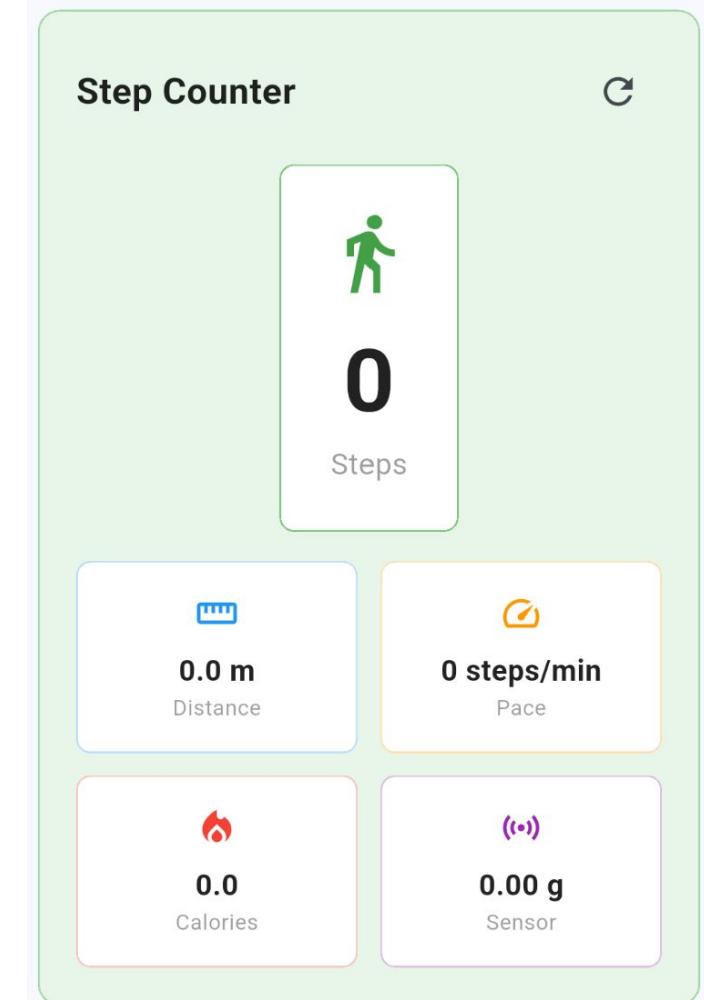
## Patient Portal Page Overview:

- Patient page shows simple gait metrics intended to give patients a greater look at their movement health
- Shows daily, weekly, and monthly step counts
- Displays current connection steps, distance traveled, pace, calories burnt, and g-force
- Step scoreboard shows top 5 step days as a way to motivate users to continue moving even on difficult days



## Step Counter:

- Acceleration magnitude must reach 1.1 g to register a step (experimentally determined)
  - Use 5 point moving average to reduce false detection
- Must be at least 0.3 seconds between steps
  - Prevents actions such as shaking from registering as steps
- Since the COMSOLE device is in a single insole, all detected steps are counted twice to make up for the non-monitored foot



- **Distance**

- Distance is calculated using double acceleration integration

- **Pace**

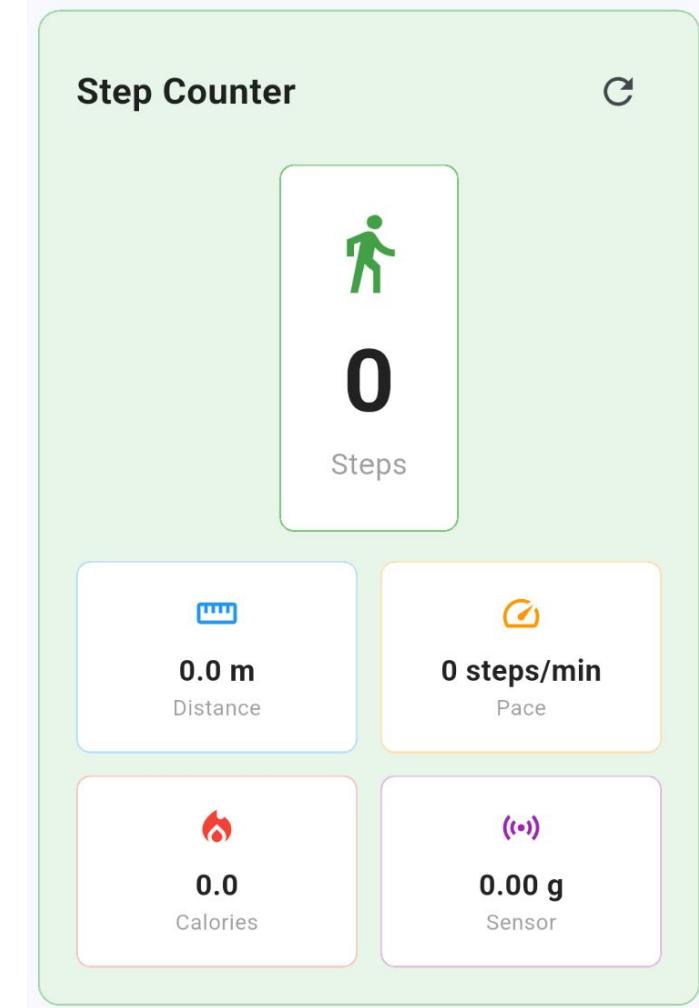
- Pace is determined by dividing the total number of steps of the connection by the time since the first step occurred

- **Calories**

- Calories are calculated by dividing steps by 20
  - Online sources stated this was the best estimate you can make from step count

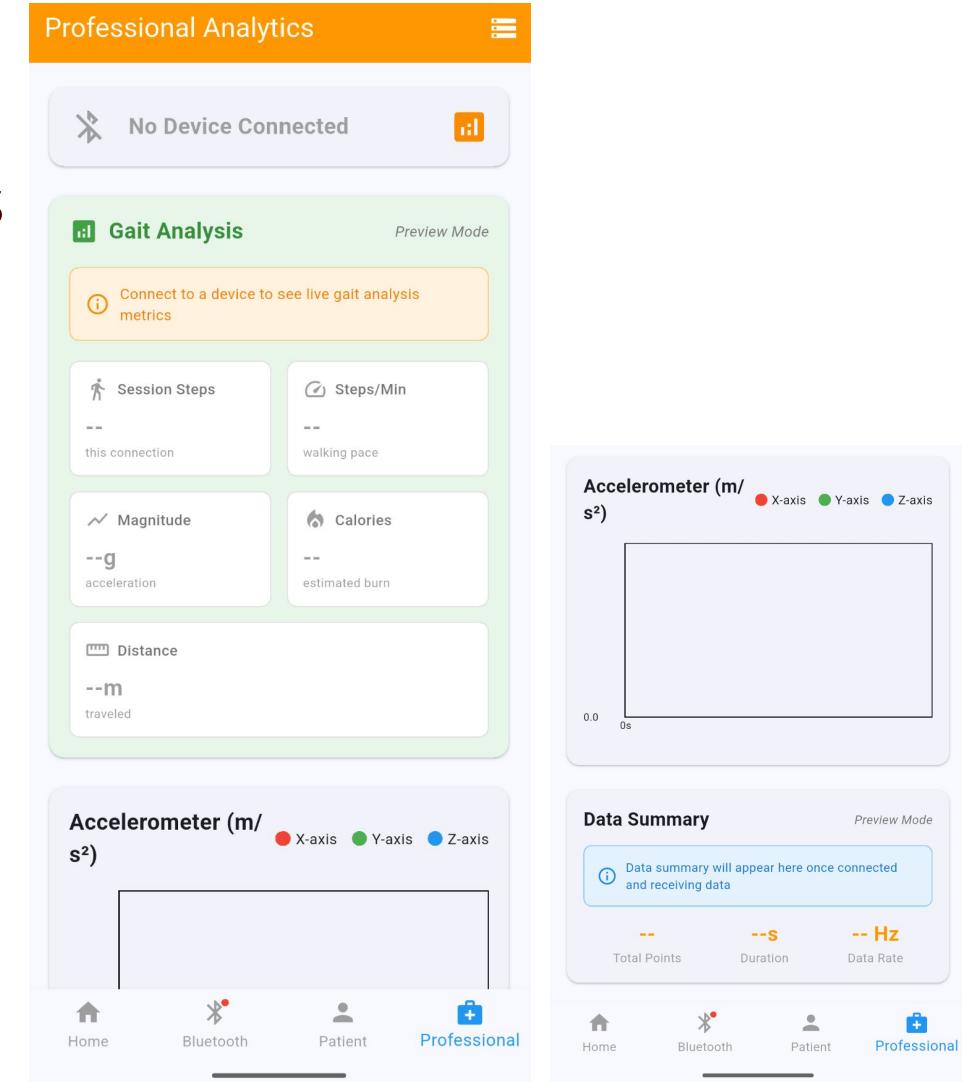
- **G-Force**

- G-force is calculated by taking the magnitude of the accelerometer data



## Professional Analytics:

- Currently shows all of the same parameters as the patient portal
  - Main area of suggested future work
- Shows live chart of measured accelerometer data
- Displays connection information such as data points being stored, connection duration, and data rate

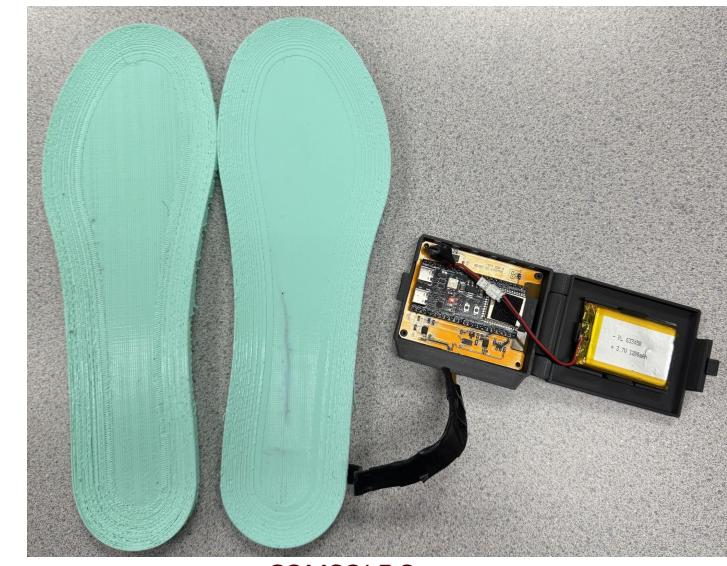
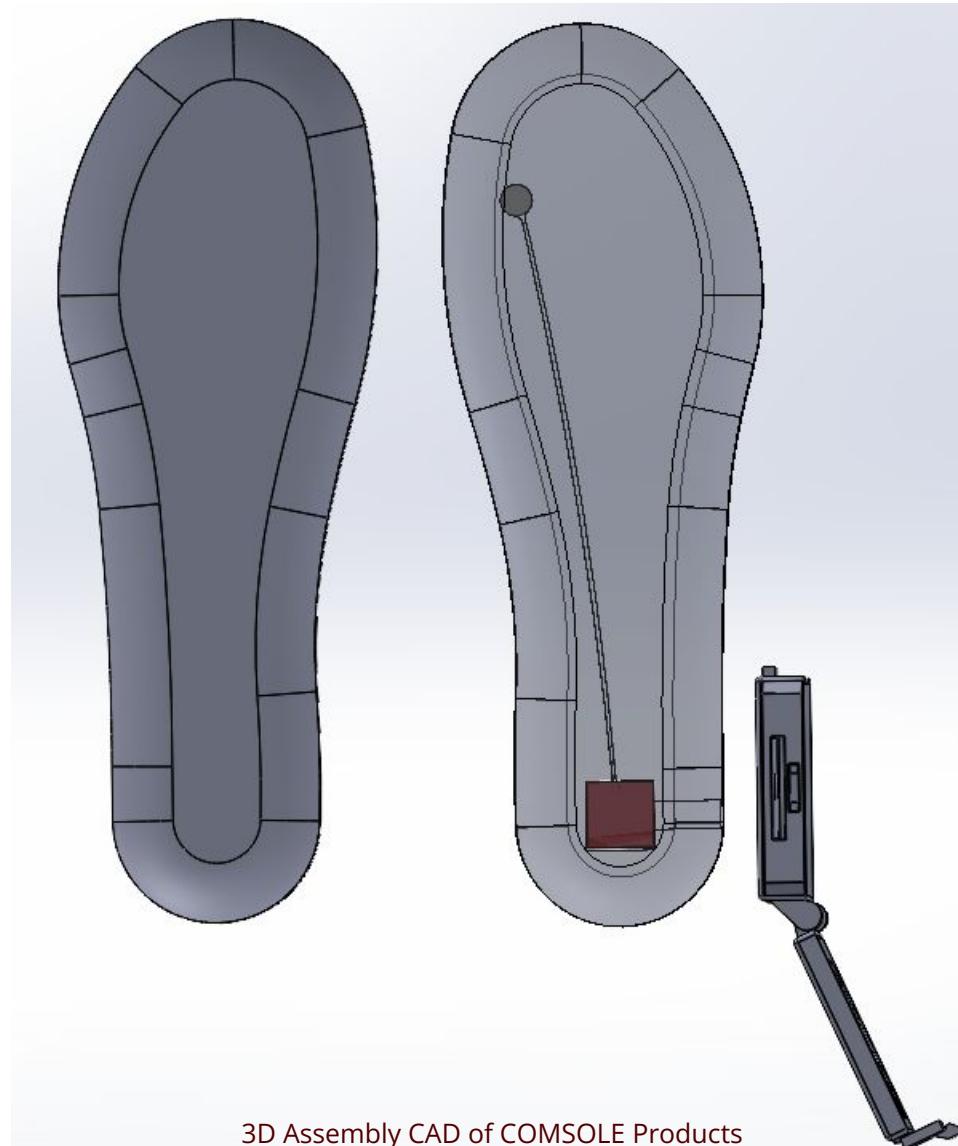


Professional Page Top

Professional Page Bottom

# Full System Breakdown

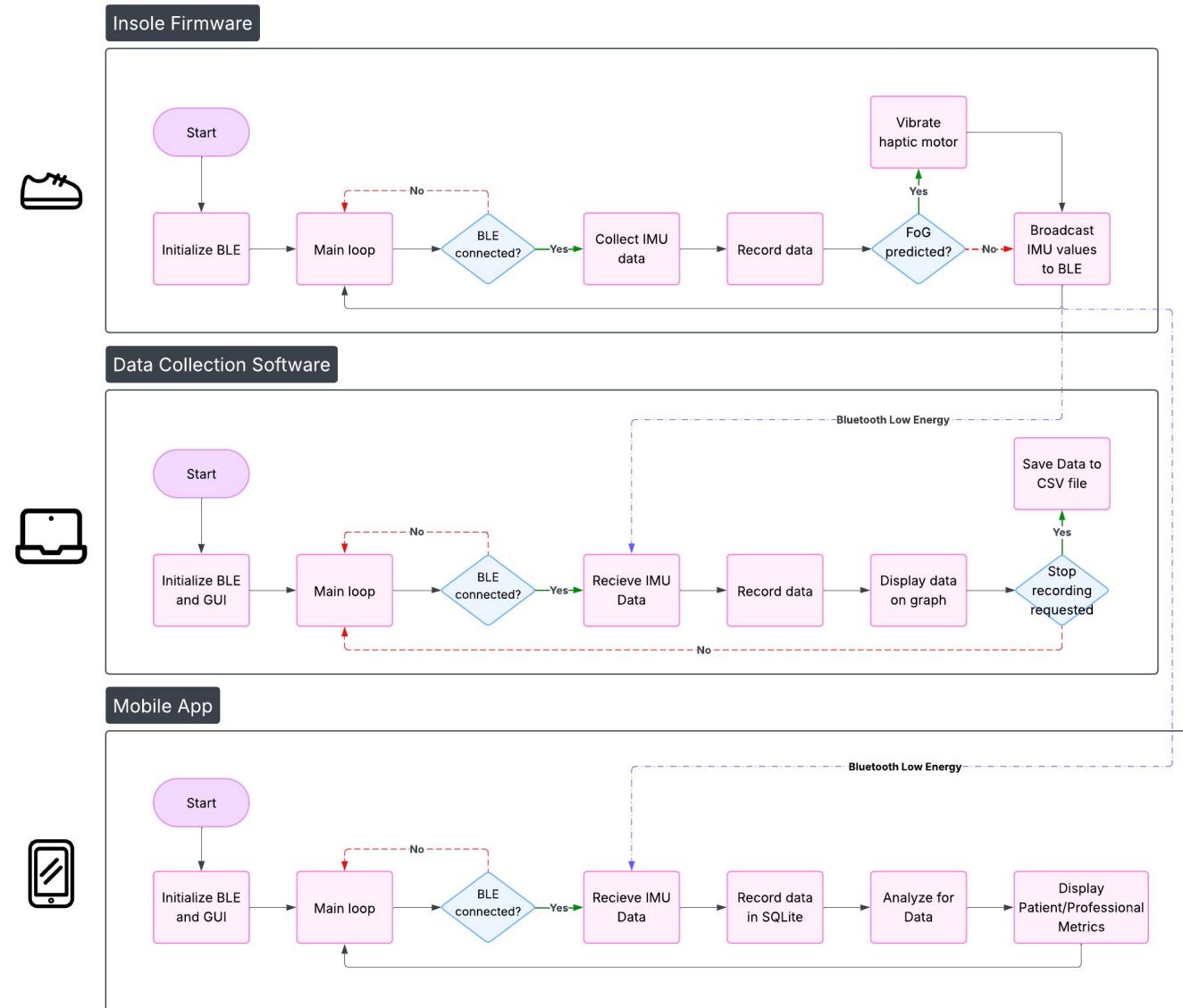
# System Breakdown



# Product Flowchart



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COMSOLE System Functional Flowchart.

# System Breakdown

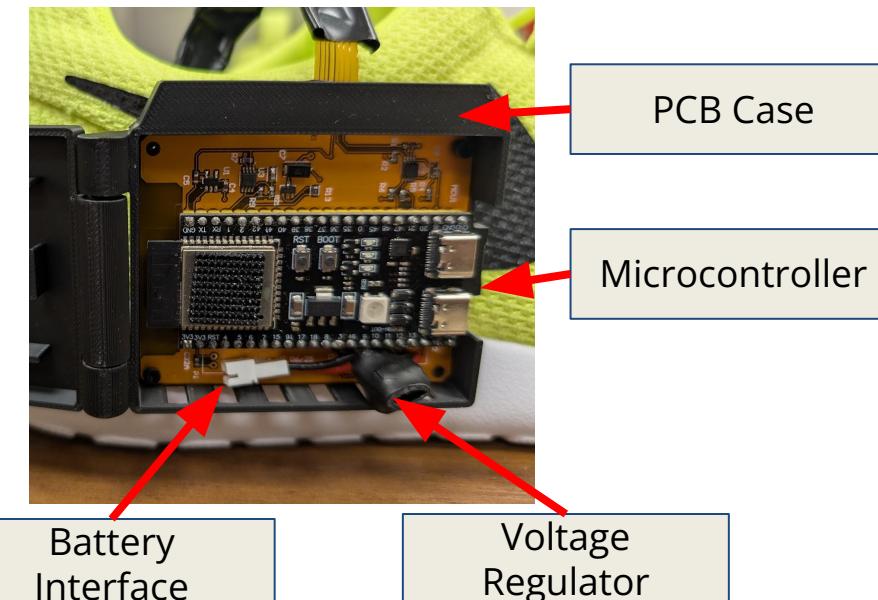
## Electronics

- Custom Flex PCB:
  - ICM 20948 9-DOF IMU
  - ESP32 Microcontroller
  - 10K RPM Haptic Vibration Disc
  - Voltage Regulator
- Li-ion Battery (3.7V, 1200mAh)



## 3D Printed Components

- Custom Insole (85A TPU, 30% Rectilinear Infill)
- Custom IMU Case (85A TPU)
- Custom PCB Case (PLA)



## High Strength Velcro Adhesive

# Product Demonstration



# Data Collection and Product Trials

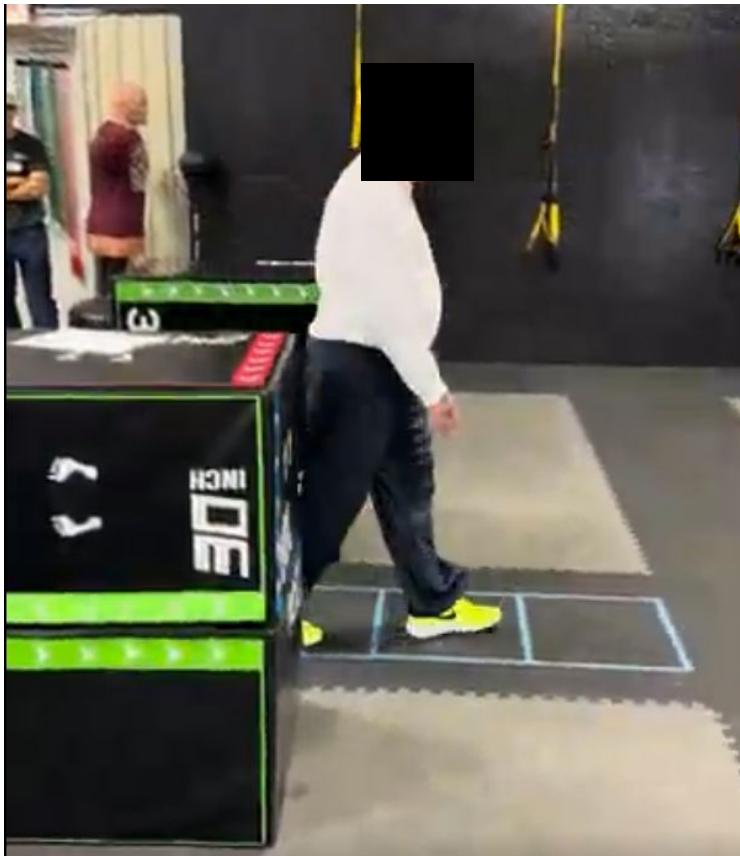
## Purpose:

- Collect Gait Data from FOG susceptible Patients
- Assess Post design feedback from realistic users
- Experience Data Collection Process for Product Use

## Testing Process:

- 20 ft Walking Loop
- 3 FOG Triggers:
  - Narrow Walkway
  - Sharp 180° Turn
  - Verbal Start/Stop
- Repeat for Error Reduction

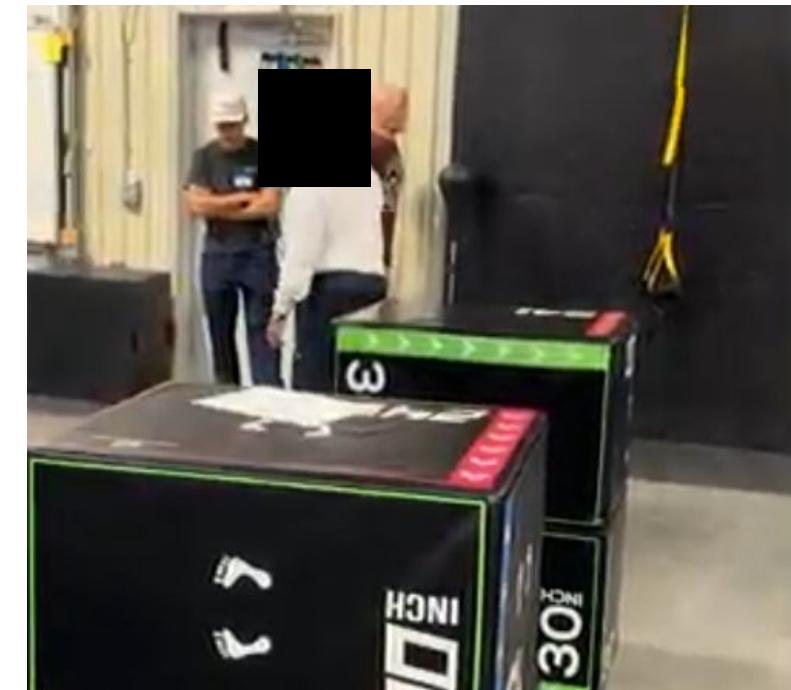
# Gait Procedure



PD Patient going through narrow walkway.



PD Patient going around 180 degree turn.



PD Patient stopping on verbal command.

# Documentation



## Physical Therapy & Vestibular Rehabilitation

### *Freezing of Gait Questionnaire (FOGQ)*

#### *1. During your worst state—Do you walk:*

- 0 Normally
- 1 Almost normally—somewhat slow
- 2 Slow but fully independent
- 3 Need assistance or walking aid
- 4 Unable to walk

#### *2. Are your gait difficulties affecting your daily activities and independence?*

- 0 Not at all
- 1 Mildly
- 2 Moderately
- 3 Severely
- 4 Unable to walk

#### *3. Do you feel that your feet get glued to the floor while walking, making a turn or when trying to initiate walking (freezing)?*

- 0 Never
- 1 Very rarely—about once a month
- 2 Rarely—about once a week
- 3 Often—about once a day
- 4 Always—whenever walking

#### *4. How long is your longest freezing episode?*

- 0 Never happened
- 1 1-2 s
- 2 3-10 s
- 3 11-30 s
- 4 Unable to walk for more than 30 s

#### *5. How long is your typical start hesitation episode (freezing when initiating the first step)?*

- 0 None
- 1 Takes longer than 1 s to start walking
- 2 Takes longer than 3 s to start walking
- 3 Takes longer than 10 s to start walking
- 4 Takes longer than 30 s to start walking

#### *6. How long is your typical turning hesitation: (freezing when turning)*

- 0 None
- 1 Resume turning in 1-2 s
- 2 Resume turning in 3-10 s
- 3 Resume turning in 11-30 s
- 4 Unable to resume turning for more than 30 s

\* Scoring from 0 to 24

\* Higher score denotes more severe freezing of gait

\* MDC not established (increased sensitivity on question 3)

## WWs FOG Questionnaire

## PHOTO AND VIDEO CONSENT FORM

*To be completed following discussion with the patient*

PATIENT NAME: \_\_\_\_\_

PATIENT'S ADDRESS: \_\_\_\_\_

This authorization grants permission to use your image (still or moving) and/or your spoken words in perpetuity for educational purposes.

By signing this document, you agree:

1. To allow the recording of your image and voice (e.g., photographs, audio, or video).
2. To distribute your image or recording in any medium, be it print or electronic form, which may include the Internet.
3. To grant permission to other entities to reproduce the images or recording for educational purposes.
4. That there is no reimbursement for the right to take, or to use your photograph or video or recording.

Nature of image and/or spoken words to be recorded: Walking With Comsole Product, Short Patient Interview

Purpose of recording, image and/or spoken words, including the intended audience:  
For Educational Purposes Only, Use in a Senior Capstone Design Project Presentation

#### RESTRICTIONS AND LIMITATIONS:

- None

Specify, if applicable: \_\_\_\_\_

I have read and fully understand the intent and purpose of this document and am signing it without reservation.

Name (please print): \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Witness: Matthew Monson

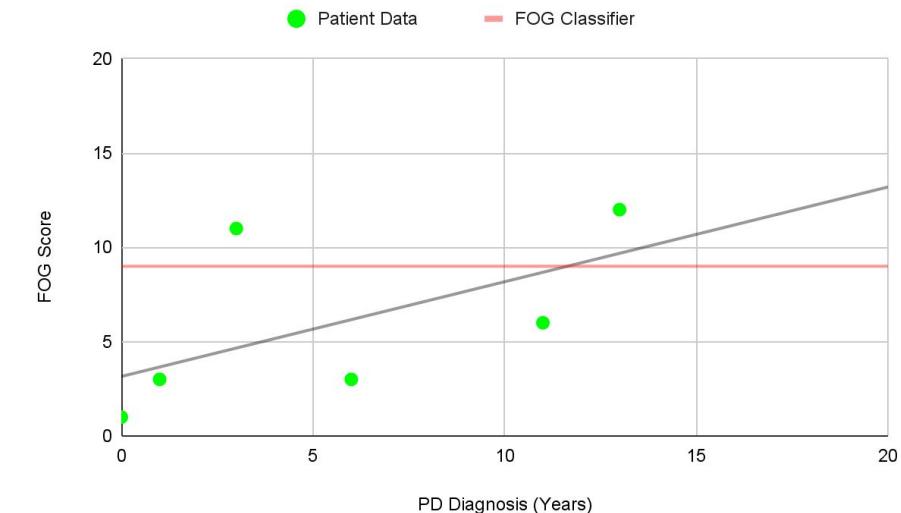
## Video Consent Form

## Patient Testing Results:

- 6 Patients Tested, 2 within FOG Range
- Linear Correlation shown between length of PD diagnosis and FOG score
- Highest gait error seen in 180° Turn
- Data used in training sets for ML model

Name	Age	PD Diagnosis (Years)	FOG Score
Gerry Brower	68	11	3
Mike Harris	83	3	6
Darren Blevins	52	12	13
James Mudd	50	1	0
Mike Thompson	67	3	1
Anya Schwalen	62	6	11
		Average Score	5.67
		Standard Deviation	5.35

Testing Results from Age and FOG status questionnaires.



Correlation graph between FOG score and PD Diagnosis length.

# Patient Interview

Removed for Privacy

PD Patient post testing interview.

# Validation Testing

# Validation Testing: Comfort

## Test:

- Tested 15 friends/acquaintances
  - Had them try on the shoes and walk around for 45-60 seconds
  - Gave a score from 1-10 on overall comfort and why
- Goal was an average above 8 and standard deviation under 2



## Results:

- Average: 8.53
- Standard Deviation: 1.09
- Concluded that the IMU could not be felt by the user, insoles would benefit from a fabric cover (multiple people said the insoles felt sticky)



# Validation Testing: Fit

## Test:

- Testing that the designed insoles would fit into different types of shoes and different sizes
  - Tested all of the 7 sizes that the team printed
- Made sure that they fit and also filled up the entire shoe
- Tried multiple shoe brands

## Results:

- Overall, fit well into every type of shoe that was tested
- Snug if trying to fit a half size up from the shoe size (especially in terms of width)
- Not going to fit every shoe perfectly



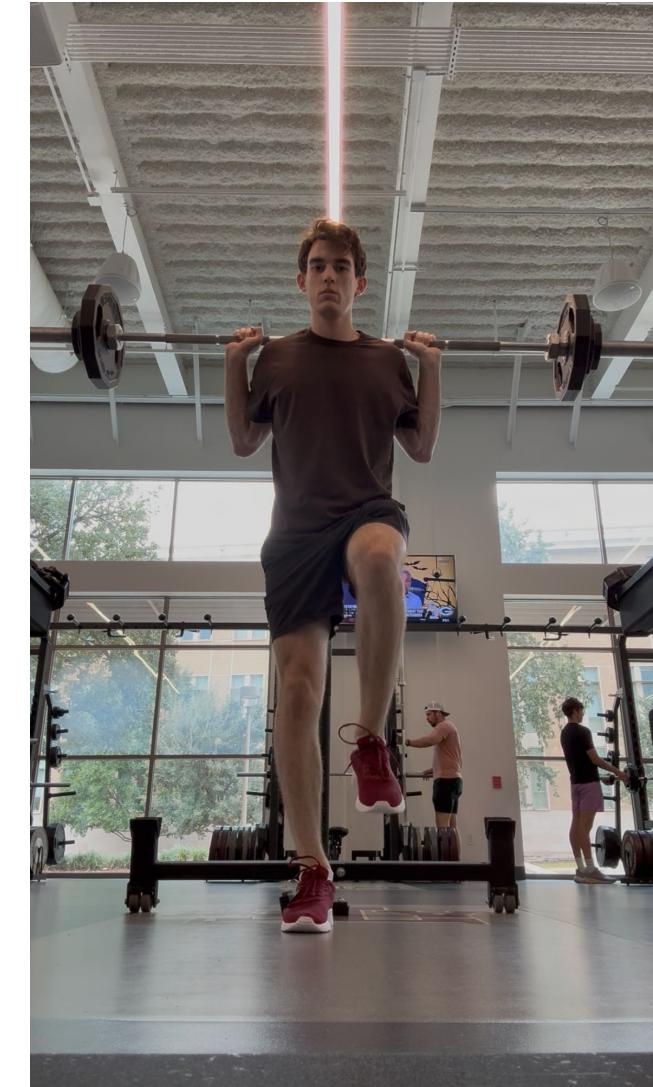
COMSOLE Product Installed In Test Shoes.

## Test:

- Tested that insole and internal electronics could withstand a 300 lb person performing normal, everyday movements (walking, jumping)
  - Stood on one foot holding from 10-110 pounds in 10 lb increments
  - Did some small jumps and movements while simulating 300 pounds

## Results:

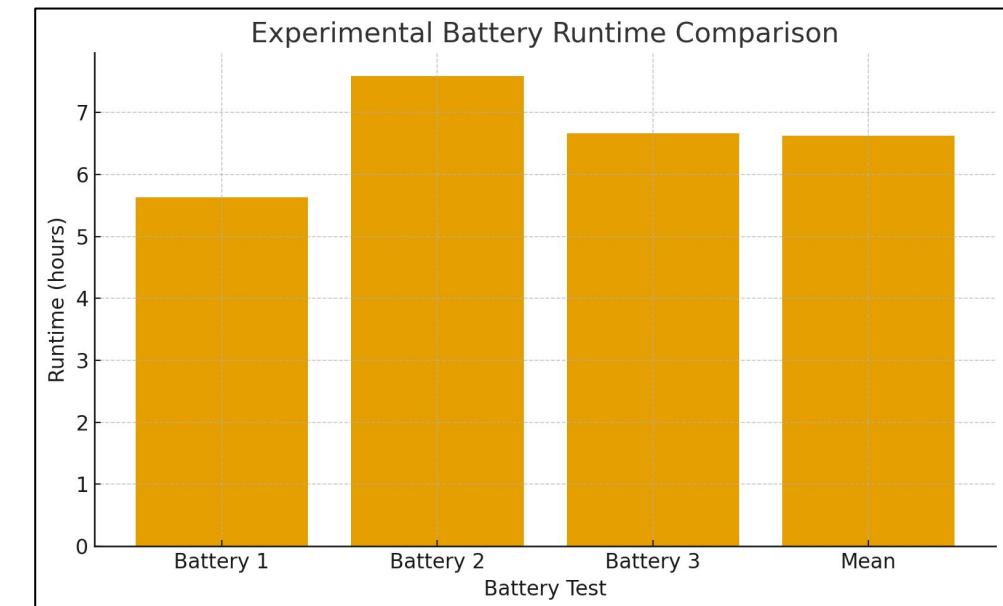
- Insole survived the test with no issues
- All electronics still ran smoothly, and none of the internal electronics could be felt with the extra weight adding compression



Testing Insole with 300 Pounds

## Main Takeaways:

- Took three PL-633450 3.7 V 1200 mAh Li-ion batteries and recorded the SOC/voltage at time intervals under continuous Bluetooth load.
- Discharge was mostly linear.
- Regulator needs about 3.0-3.1 V to keep the ESP32 running.
- Used datasheet values and load assumptions to estimate continuous BLE battery life.
- Applied a linear fit to the measured voltage drop to model runtime.



Experimental Battery Runtime

## Main Observations:

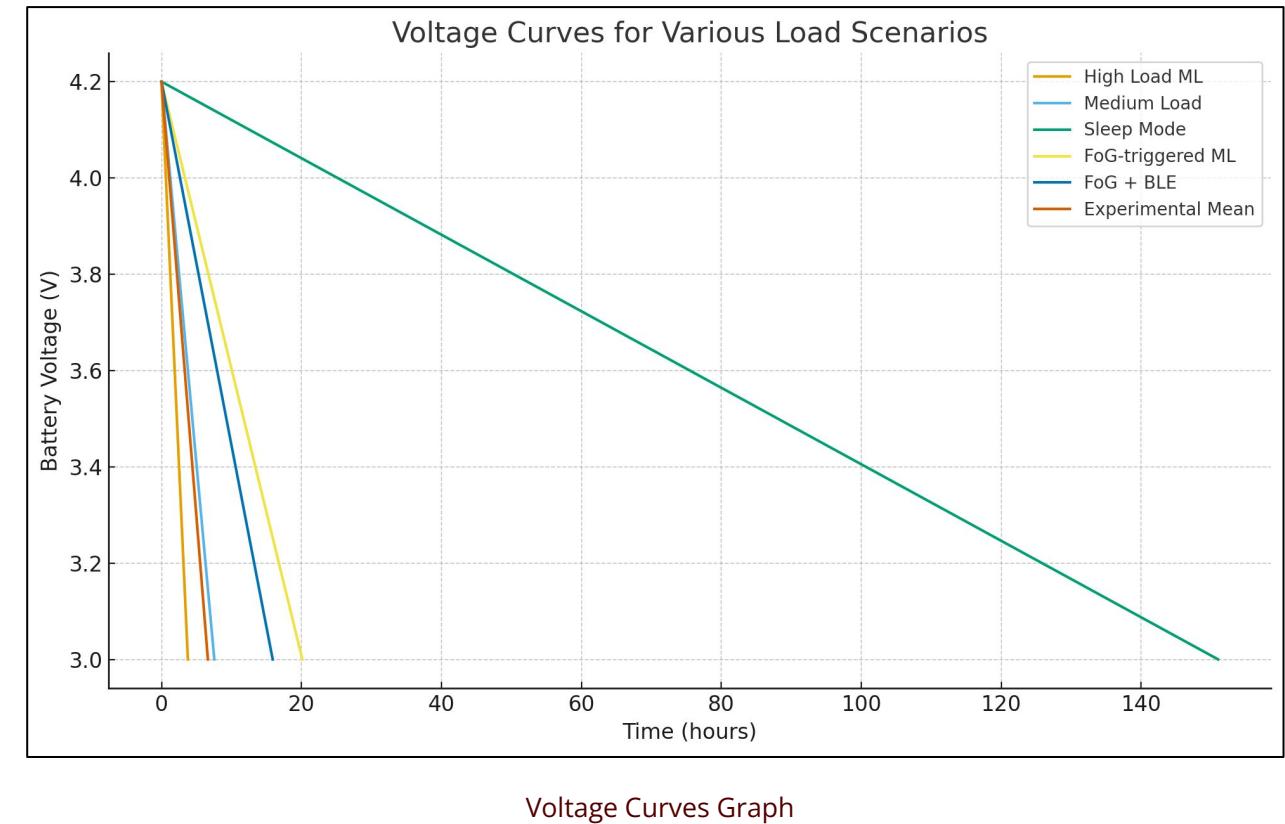
- BLE-only experimental tests matched predicted BLE-only runtime, with some normal fluctuation
- Modeled usage scenarios using measured BLE current, assumed sleep-mode current, and estimated FoG ML burst current
- Analysis confirms BLE usage, and FoG ML bursts dominate battery consumption.

Scenario	Description	Runtime (h)
Sleep Mode (Duty-Cycled, No ML, No BLE)	Ultra-low current draw	150 (~6+ days)
Moderate Load (Periodic Sensing, No BLE)	Theoretical light duty-cycled sensing	22–30
ML-Only Activation (FoG-Triggered, Duty-Cycled)	Brief gait-detection bursts	14–18
FoG + BLE Check-Ins (Periodic BLE, Rare ML)	Realistic daily usage, includes BLE transmissions	18–28
Experimental BLE-Only (Battery #2, No ML)	Continuous BLE data transmission, matches measured experimental data	6.25
Worst-Case Continuous Load (Continuous ML + BLE, No Sleep)	Maximum current draw, matches measured Battery #1	3.77

Battery Lifetime Table

## Main Observations:

- Duty-cycled operation significantly extends battery life compared to continuous operation
- Experimental BLE-only results highlight the impact of Bluetooth connectivity without ML
- Continuous ML & BLE is the absolute worst-case scenario.
- Optimizing duty cycles, ML activation, and BLE check-ins is critical for achieving full-day monitoring.
- Boost regulator efficiency and battery SOC strongly influence runtime.



## Test:

- Record the time between event occurrence and cue application
- Examine data to determine the time between FoG detection and cue application
- Total of 5 Samples

## Results:

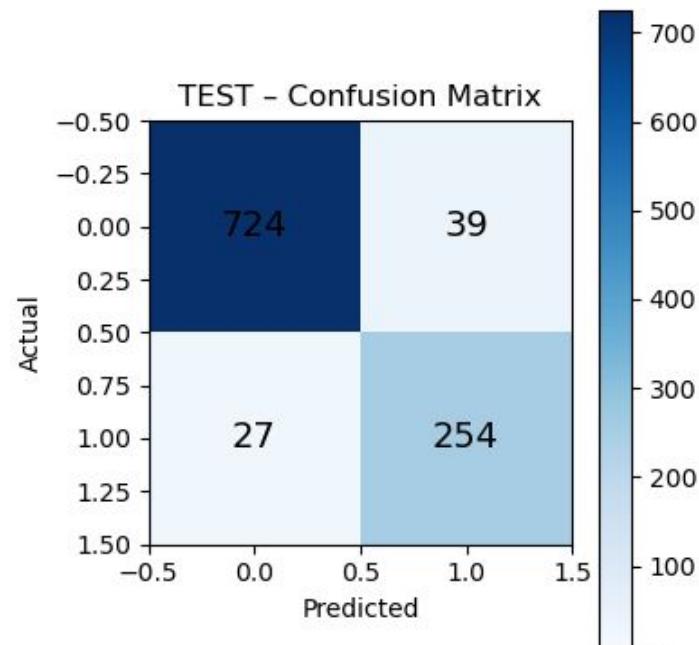
- Average Model Delay of 472 milliseconds
- Meets < 5 Second Goal
- Result of data window specification

Sample Number	Model Latency (s)
1	0.25
2	1.1
3	0.39
4	0.27
5	0.35
Average	<b>0.472</b>

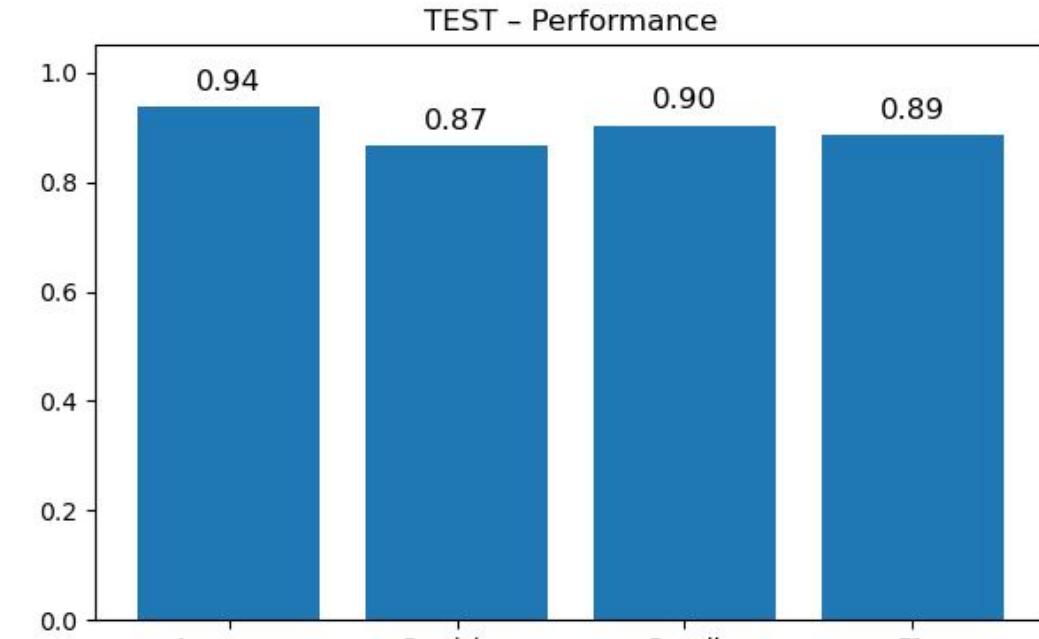
Latency Test Results

## Machine Learning Performance on Test Set:

- Balanced performance across accuracy, precision, recall and F1.
- Strong regularization in spite of small test set.
- Confusion matrix show low false positives and false negatives



ML Testing Confusion Matrix



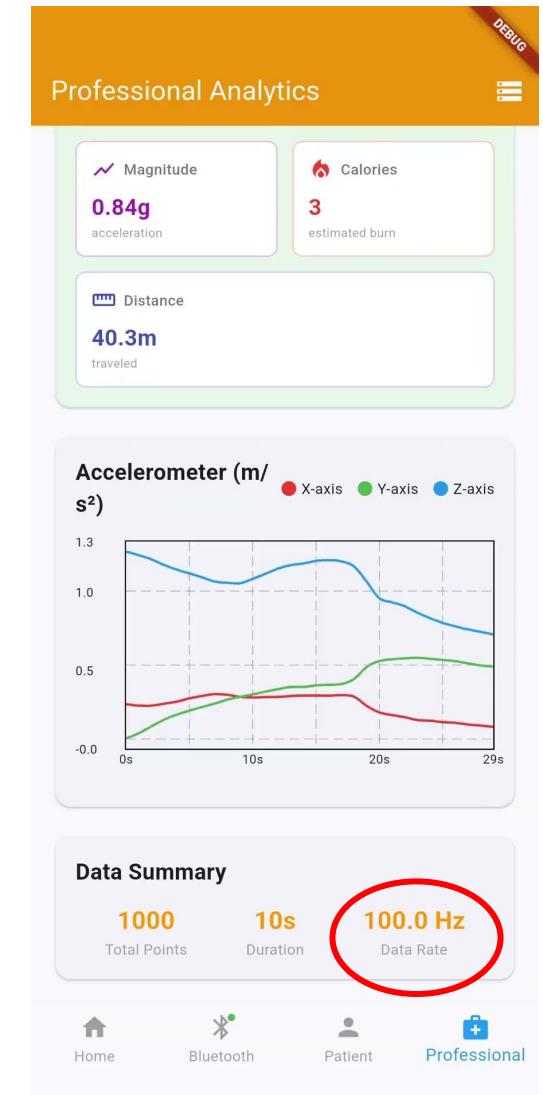
ML Testing Performance Metrics

## Test:

- Test Frequency Sampling Rate of IMU BT Transmission
- Threshold of 100Hz set for optimal gait collection frequency

## Results:

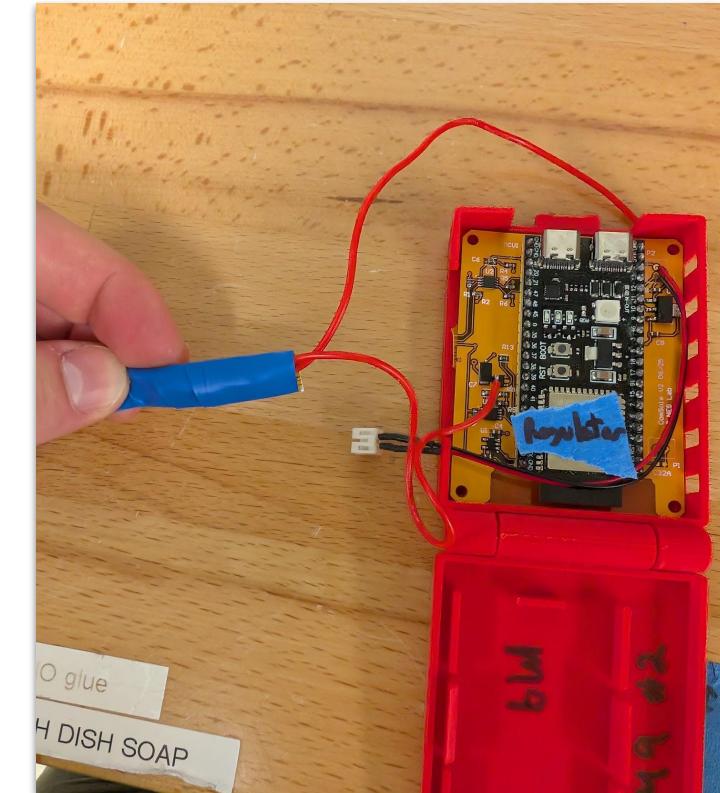
- Smooth transmission at 100Hz after GUI modification



# Capstone Conclusions

## Future Work Overview:

- Susceptibility to induced Stress Concentrations in Flex PCB
- Gait of PD patient on vs off medication
- Need more data for ML model; more development on hyperparameter tuning to improve computational efficiency
- App should continue to be developed to include additional professional analytics for greater usability



Sheared PCB Wiring

## The COMSOLE Team has succeeded in making:

- 5 Working Insole Prototypes, 1 with Haptic Feedback
  - Complete digital architecture of 2D/3D CAD
- Companion Gait Analytics App
  - Associated source code for GUI and SQLite storage
- Gait Data Collection Code with GUI data markers
  - Associated source code
- Proof of Concept ML model with 90% Accuracy in Abnormality Detection
  - Associated Source code for RF model
- Well Tested Gait Collection Procedure
  - Full documentation and process improvements

- Thanks to **Dr. Ya Wang, Dr Haili Liu, and her Lab Staff** for Supporting us in the Capstone Process
- Thanks to **Dr. Astrid Layton and Dr. Ni Wang** for advising us in 401/402 Studio
- Thanks to **Cindy Conte and the RSB staff** for allowing us to work with all the PD Patients
- Thanks to **Kate Lorkowski (Matt's Fiance)** for helping with the VPS video editing
- Thanks to **Yang Liu** for help with soldering and PCB issues



**Q/A (5-10 min)**

- All code, CAD files, ML models, etc. have been included in the drive and sent over to the sponsors in a zip file
- Dynamic analysis wasn't completed because of time and cost (buying SolidWorks premium)
  - Team believed time would be spent better elsewhere as the design had already been validated through prototype testing
  - Static FEA was also done with a factor of safety in mind