WALKING ABNORMALITY DETECTOR

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INTRODUCTION

NEED

“A way to perform gait analysis in children to detect gait abnormalities.”

A need exists for a method to comprehensively perform the gait analysis in children, which are often a result of incorrect gestures during childhood development. As many young individuals adopt improper stepping methods, gait abnormalities can manifest, potentially leading to conditions such as osteoarthritis.

PROPOSED CONCEPT

A system with a wearable insole to detect gait abnormalities.

In this wearable insole, there is a pressure sensing unit installed in the base to sense, pressure. That sensed data will be feed to a microcontroller. After processing, the pressure distribution will be displayed. By analyzing the pressure distribution, predictions can be made regarding the condition.

GAP ANALYSIS & MITIGATION STRATEGIES

KEY REGULATORY REQUIREMENTS FOR FDA APPROVAL

01 DEVICE CLASSIFICATION

02 INTENDED USE AND INDICATIONS FOR USE

03 RISK MANAGEMENT

04 CLINICAL EVALUATION

05 LABELING AND PACKAGING INFORMATION

06 QUALITY SYSTEM REGULATION

07 ENVIRONMENTAL ASSESSMENT INFORMATION

DEVICE CLASSIFICATION

CLASS II DEVICE

- Has a moderate risk
- Existing products that closely matches our device falls under class II

510(K) PREMARKET NOTIFICATION

510(K) PREMARKET NOTIFICATOIN PROCESS

01 IDENTIFY A PREDICATE DEVICE

01

02 PREPARE DEVICE CHARACTERIZTION

03 CONDUCT COMPARATIVE ANALYSIS

04 COMPILE DESIGN CONTROL DOCUMENTATION

05 SUBMIT TO FDA

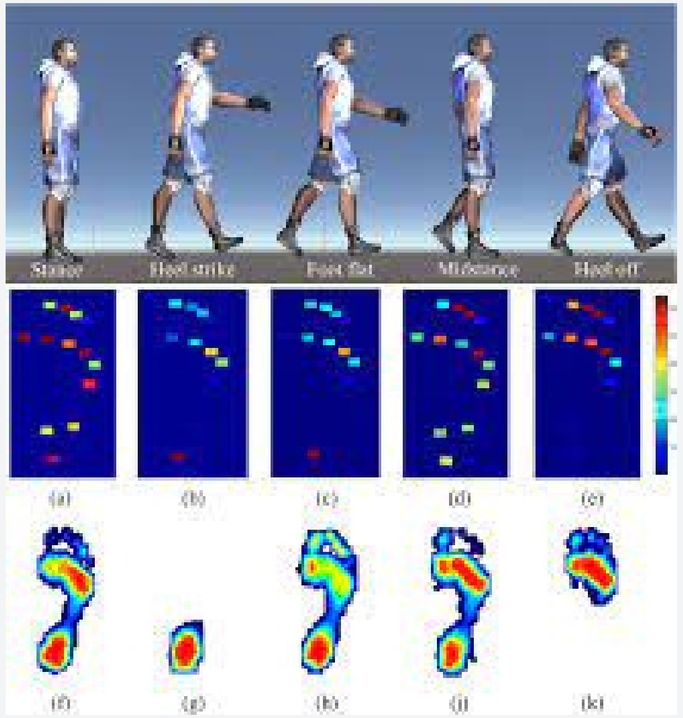
PREDICATE DEVICE

TEKSCAN STRIDEWAY-TM SYSTEM

- Provides spatial parameters for analysis like step length
- Captures multi-sequential steps
- Better understanding of foot and arch type through barefoot data collection
- Easier to use with patients with walking aides
- Available in a variety of lengths to accommodate your needs, but does require space for the system to be set-up

INTENDED USE AND INDICATIONS FOR USE

INTENDED USE – Measure the pressure distribution of the feet and analyze them to detect any gait abnormality



RISK MANAGEMENT

Skin Irritations

Some skin irritations might caused using the the proposed system because it needs to be wear

Solution -
cover the interior of the device using comfortable material

Electric Shocks

A little electrical shocks can be caused because the device base has some circuitry and current flowing.

Solution -
Cover the base area using a insulation material

CLINICAL EVALUATIONS

Result Validation

Verify for the results of the device by checking them on known healthy people

Comparability with predicate intruments

Identify the **gaps** between proposed device and the predicate device. And compare the results from the devices.

Carryout Clinical studies

The device should be test in local clinics.

Ex: MOH

LABELING AND PACKAGING INFORMATION

Labeling and packaging information is a crucial part of a 510(k) premarket notification (PMN) submission.

Labels should contain all the information necessary as shown in the example for users to safely and effectively use the device, including:

- Device name and intended use
- Instructions for use
- Warnings and precautions
- Adverse event reporting information
- Contact information for the manufacturer
- Lot number and expiration date
- Unique device identifier (UDI)

IP ANALYSIS OF EXISTING CLOSELY MATCHING DEVICES

- “Malalignment syndrome diagnosis apparatus based on plantar pressure and body movement and method thereof,” KR101902551B1, Sep. 28, 2018 Accessed: Dec. 10, 2023. [Online]. Available: https://patents.google.com/patent/KR101902551B1/en?q=(malaligment+syndrome+diagonosis)&oq=malaligment+syndrome+diagonosis

- “Systems and methods for gait analysis,” KR20230038133A, Mar. 17, 2023 Accessed: Dec. 10, 2023. [Online]. Available: https://patents.google.com/patent/KR20230038133A/en?oq=KR20230038133A

- S. Eim, G. Lim, H. Shim, and J. Chi, “Shoe for acupressure with pressure sensors,” EP3061386B1, May 02, 2018 Accessed: Dec. 10, 2023. [Online]. Available: https://patents.google.com/patent/EP3061386B1/en?oq=EP3061386B1

PLAN TO DEVELOP PRODUCT

PLAN TO DEVELOP THE PRODUCT TO SATISFY REGULATORY REQUIREMENTS

CONCEPT FOR A DEVICE AS A SOLUTION FOR THE NEED

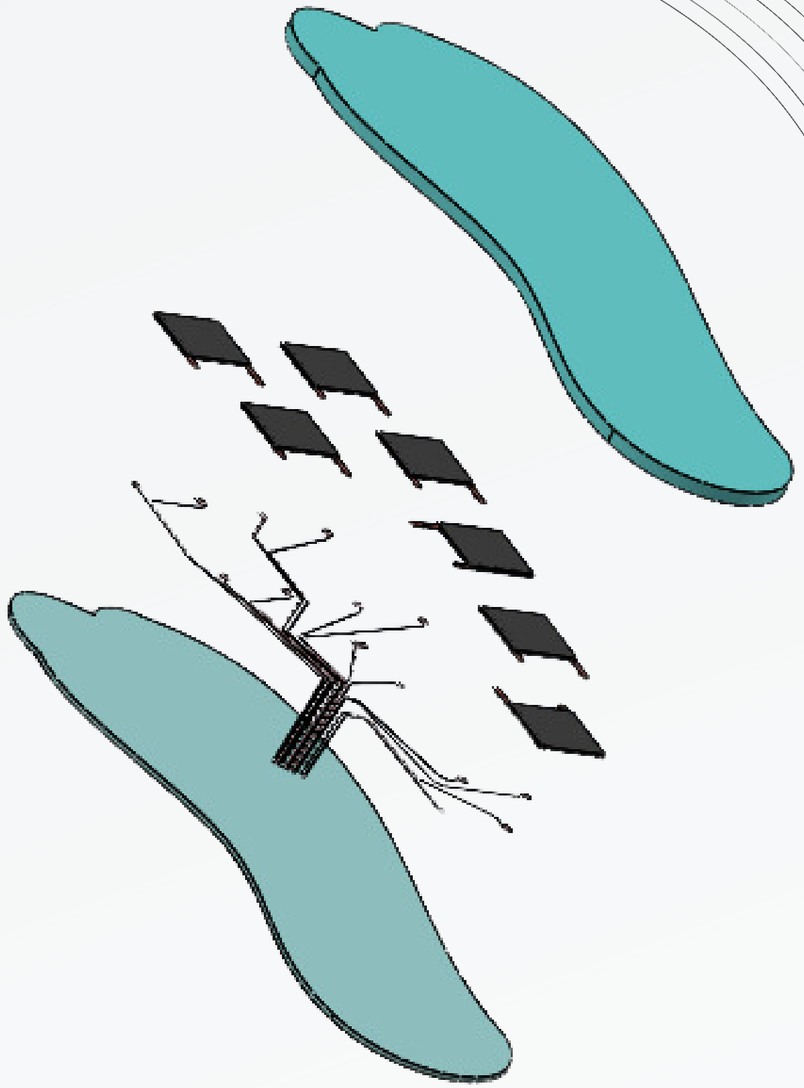
IDENTIFY THE NEEDED REGULATORY PROCESS

IDENTIFY THE REQUIREMENTS THAT SHOULD BE SATISFIED FROM THE PRODUCT

DEVELOP THE PRODUCT THROUGH THE PROPOSED CONCEPT WHILE SATISFYING THE REQUIREMENTS

DEVICE OVERVIEW

Proposed device is a wearable insole with a pressure-sensing unit installed in the base. The data will be fed to a microcontroller. After processing, data will be transmitted to the computer through serial communication. the pressure distribution will be displayed on the computer through an application. y analyzing the pressure distribution, predictions can be made regarding the condition.



DIFFERENCES BETWEEN THE PREDICATE DEVICE

- Wearable insole instead of a pressure mat.

PROTOTYPE

MARKET READY PROTOTYPE

Wireless Connectivity

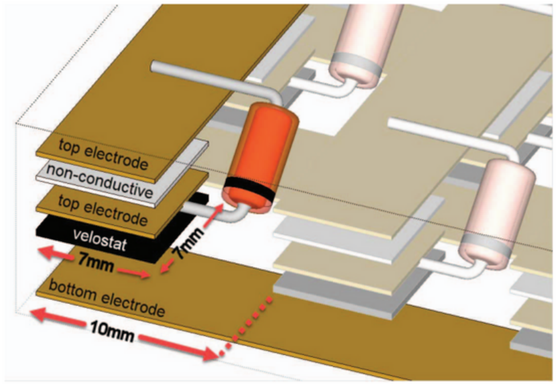
Our market-ready prototype features seamless WiFi communication, enabling real-time data transmission to a secure database for efficient and immediate storage of patient information.

Portability

Designed for on-the-go use, our portable device ensures flexibility in healthcare monitoring, allowing medical professionals to access critical patient data anytime, anywhere.

Intuitive App

The accompanying app provides a user-friendly interface, empowering healthcare providers to monitor and manage patient data with ease, fostering a more connected and responsive healthcare ecosystem.



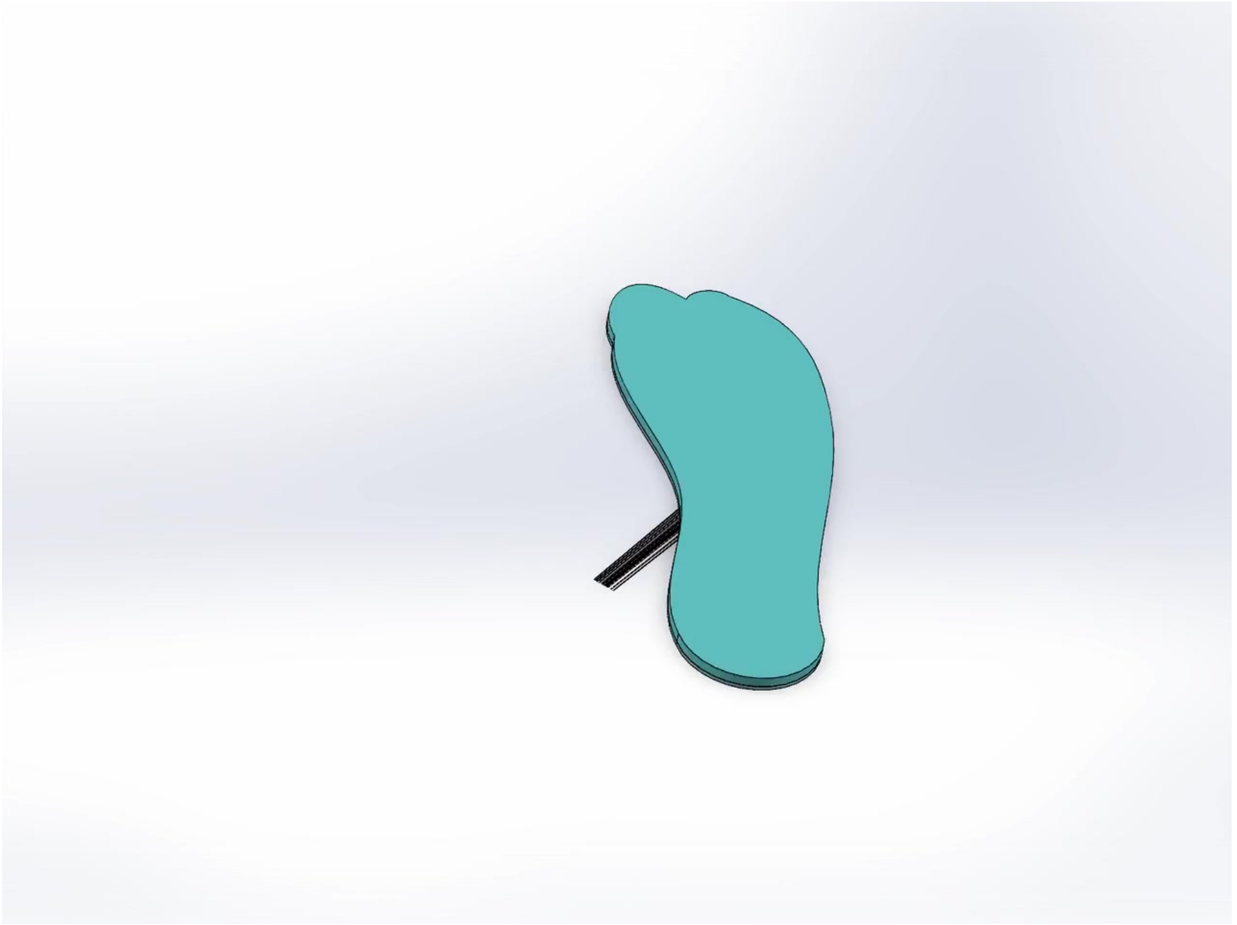
Innovative Pressure Sensing Technology

Our custom pressure sensors, crafted from cutting-edge velostat material, boast unparalleled accuracy and sensitivity. These sensors respond dynamically to pressure changes, ensuring precise data collection for enhanced diagnostics. The high sensor density further optimizes the device's ability to capture and interpret subtle variations in pressure, elevating diagnostic capabilities to new heights.

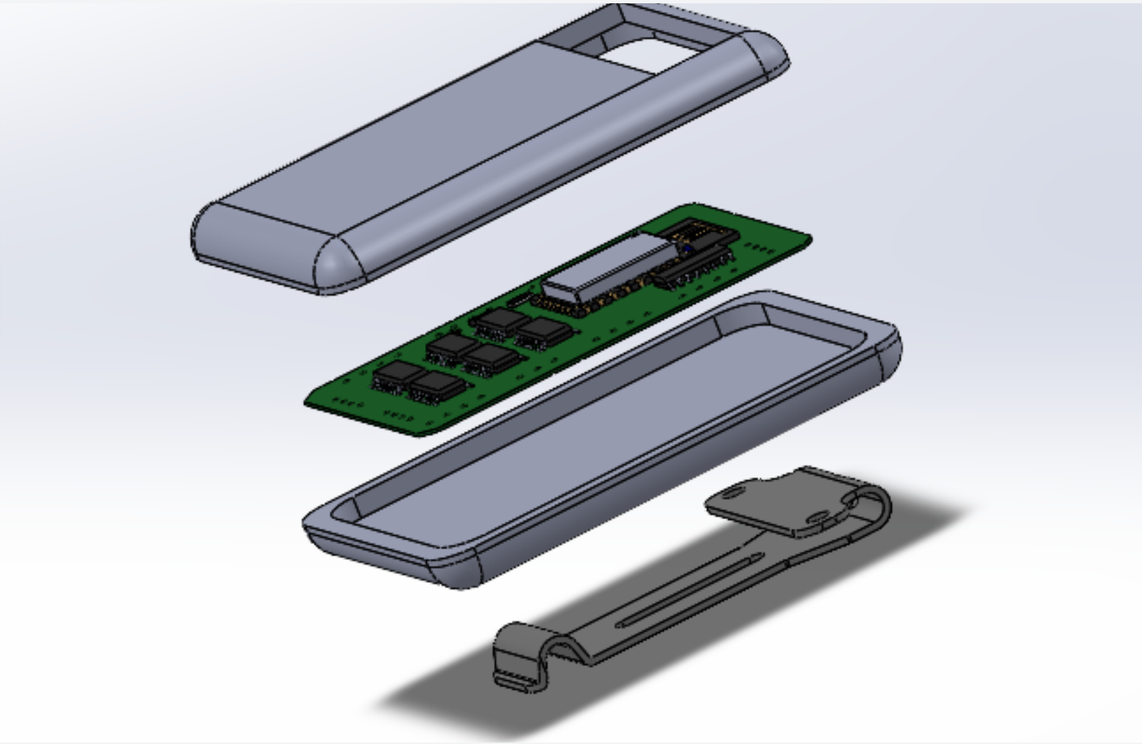
Expected Prototype

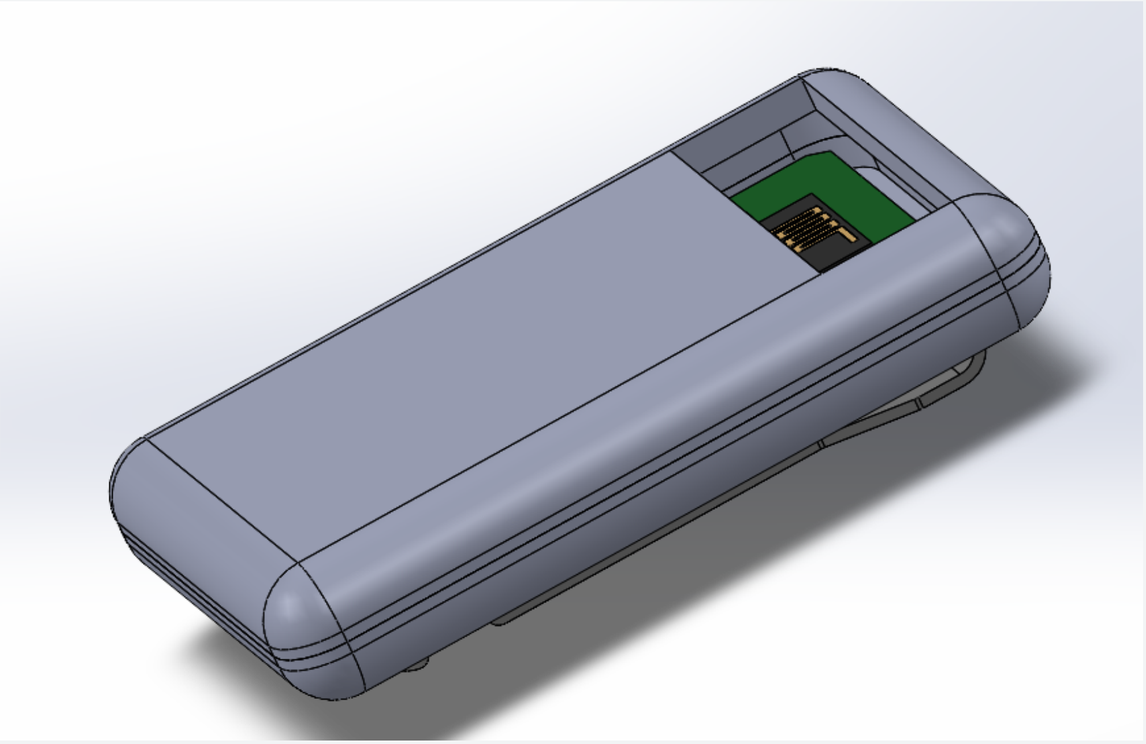
- Custom Pressure Sensing Technology
- Insole Designs in different shoe sizes.
- TPU (Thermoplastic Polyurethane)

  Material for health safety with flexibility

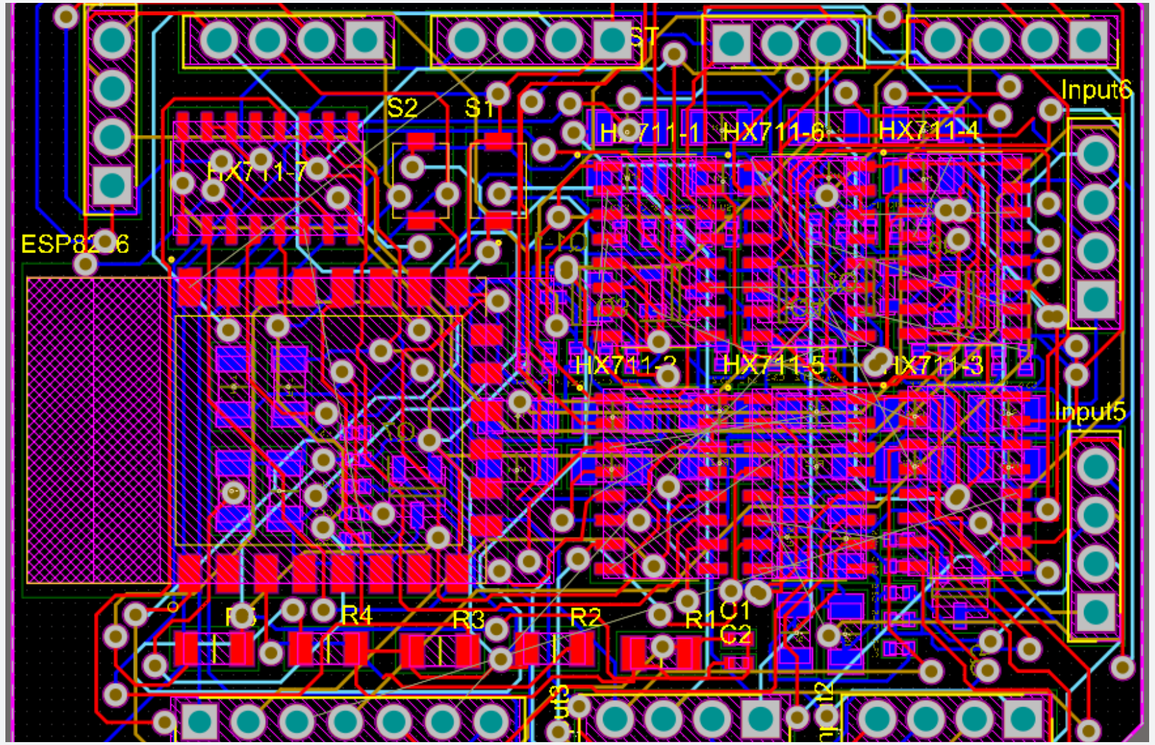


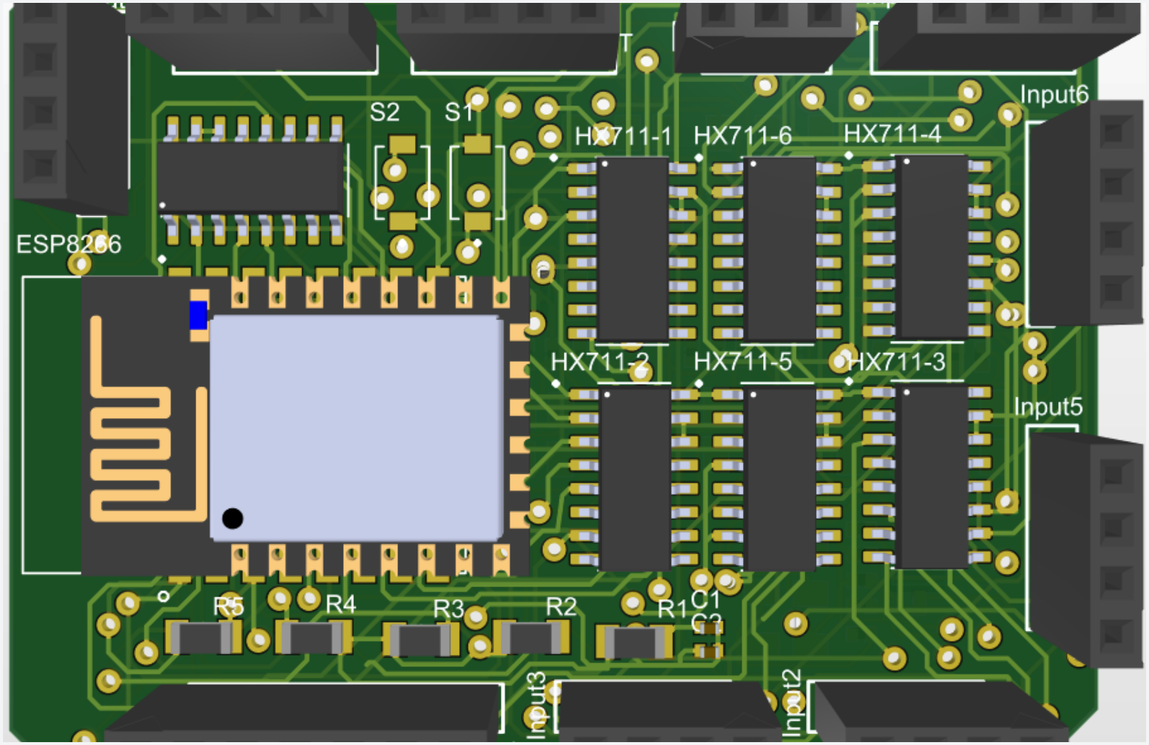
ENCLOSURE DESIGN





PCB DESIGN


S2
S1
HX711-1
HX711-6
HX711-4
HX711-7
Input6
ESP8266
HX711-2
HX711-5
HX711-3
Input5
R4
R3
R2
R1
C1
C2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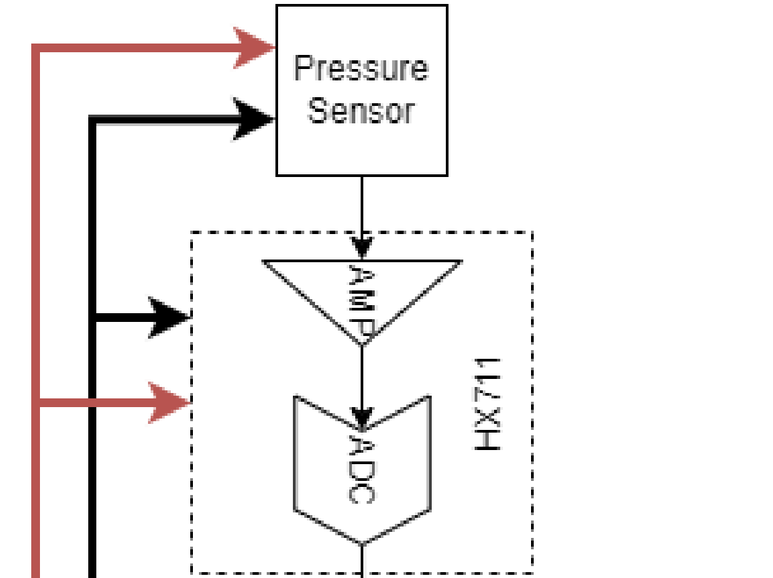
HX711-5
HX711-3
Input5
R5
R4
R3
R2
R1
C1
C2
Input3
Input2

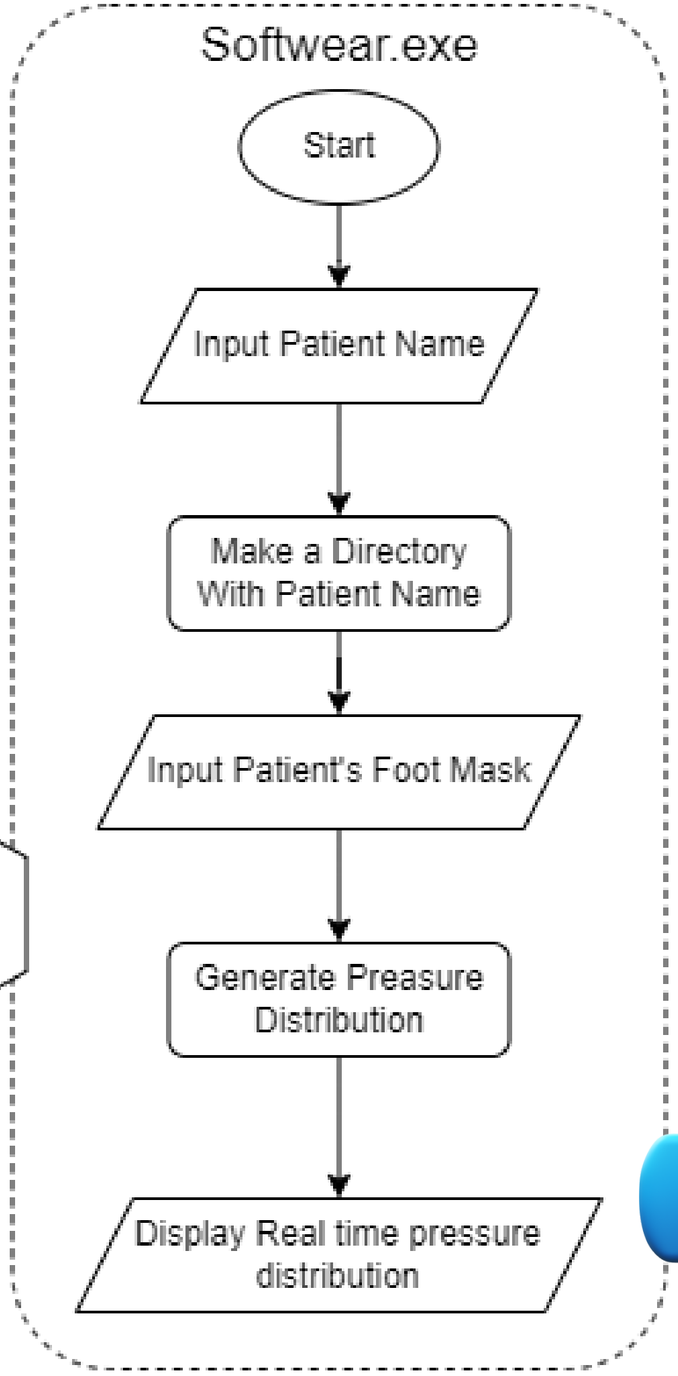
Functional Block Diagram



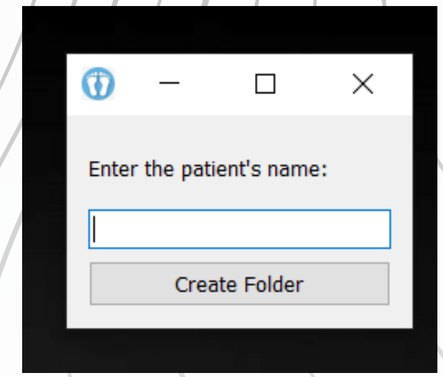
Serial Communication

pyserial

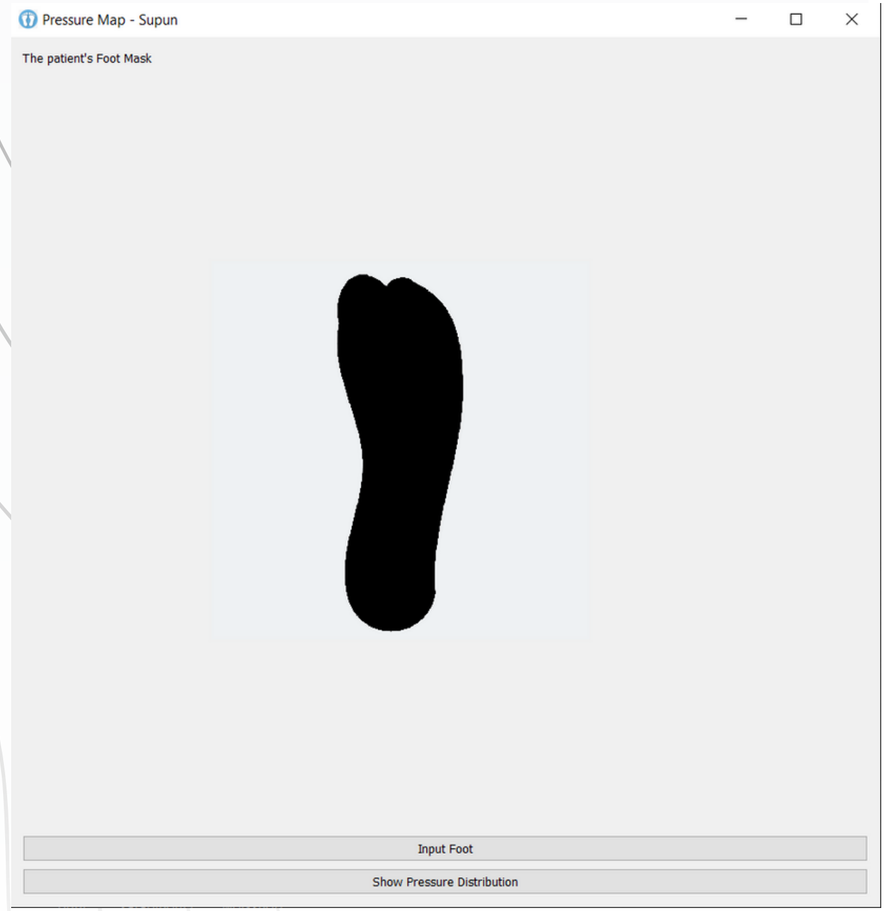
Softwear (GUI)



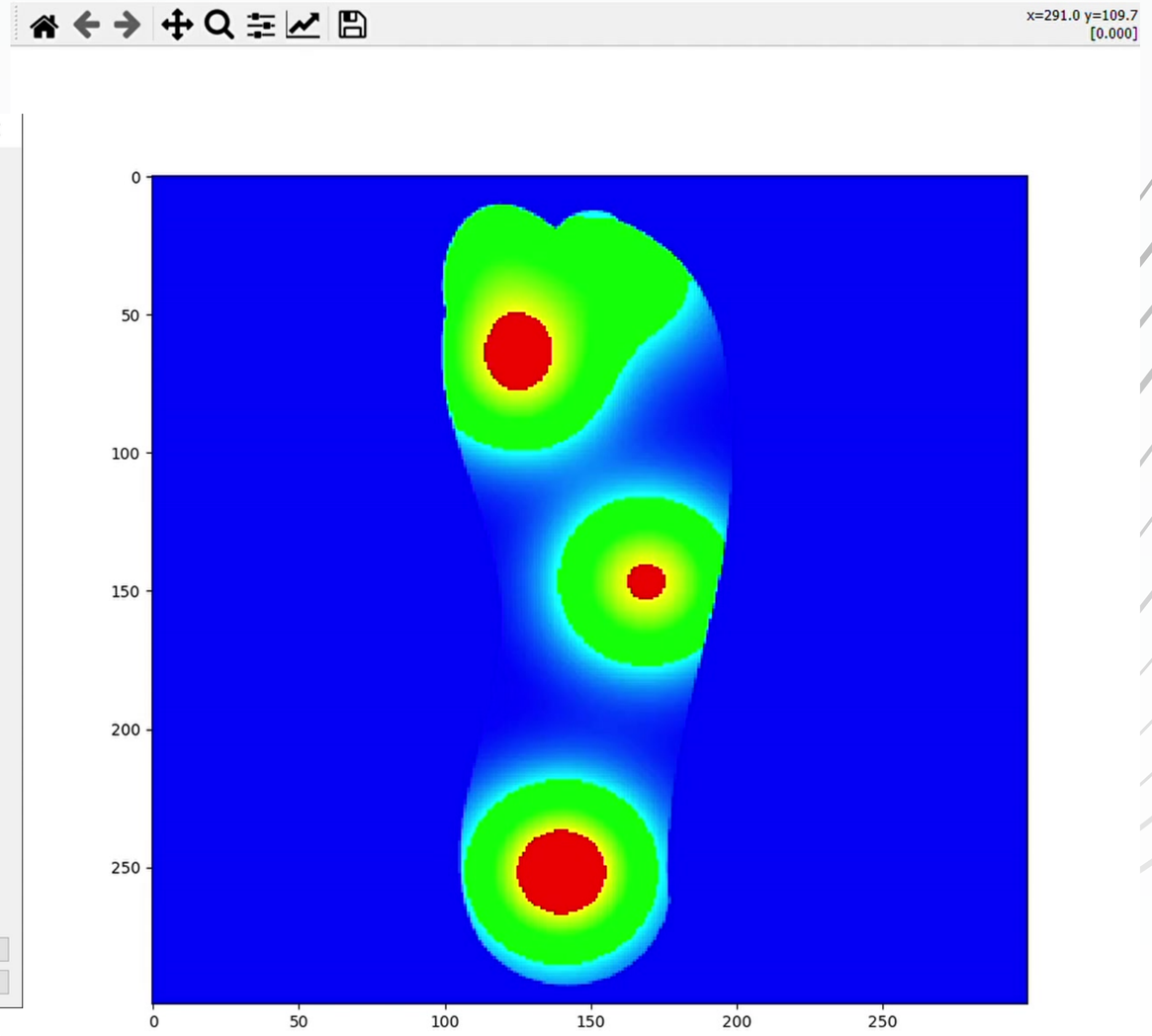
Softwear (GUI)



FIRST WINDOW ASK FOR THE PATIENT NAME, AND MAKE A FOLDER BY THE PATIENT NAME



SECOND WINDOW ASK FOR THE SHAPE OF THE INSOLE,
HERE ANY GREY SCALE PNG IS ACCEPTED



REAL TIME PRESSURE DISTRIBUTION

CONSTRAINTS AND LIMITATIONS

Using load cells instead of pressure sensors

Accurate pressure sensors are not affordable. Therefore, we have used load cells. Therefore, the accuracy is reduced.

Stationary System instead of a dynamic system

Eventhough, we proposed a dynamic system that allows to meassure pressure distribution while walking, to do that we need flexible material and flex type pcb and smd electronic components. Those are not affordable. Therefore, we managed develop a stationary system which can meassure pressure distribution of a stationary feet by using wooden enclosure and load cells.

Serial Communication instead of WiFi

Was delay and a data loss when using WiFi communication from the microcontrollers we have. Therefore, used serial communication to transmit the data.

FUTURE EXTENSIONS

Machine Learning Algorithms for Analysing purposes

Adding Poschure Tracking for complete gait analysis

Pushing Patient Data to a data base so that Medical profesionals and the patient can access data anywhere anytime

Increase the number of sensors for accurately measure the pressure

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- “Average Walking Speed: Pace, and Comparisons by Age and Sex,” Healthline. Accessed: Nov. 26, 2023. [Online]. Available: https://www.healthline.com/health/exercise-fitness/average-walking-speed

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