The Smart Sole: Using Hybrid AI Analysis to Inform Patients On Foot Pressure Anomalies For Peripheral Neuropathy

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ABSTRACT

Diabetic Peripheral Neuropathy (DPN) is a disorder with a prevalence level of 50% in people with Diabetes. This Neuropathological disorder can have substantial impacts on those who suffer from it, including ulcers, infected ulcers, foot deformities, Charcot foot, irregular gait pattern etc. These said complications contribute largely to substantial consequences suffered by those who suffer from DPN such as amputation, or in severe cases, death. The primary reason this is such a significant issue is because those who suffer from DPN lose all sensation in their feet, and therefore are completely unaware of the occurrence of such complications. Moreover, the present treatment for Diabetic Peripheral Neuropathy does not provide substantial aid, being mainly physical therapy, or prescribed medication, and there is no existing cure. The reasoning behind this is because our knowledge of the pathogenesis of DPN is relatively limited, and thus it is challenging to develop treatment without this knowledge.

The aim of this project, the Smart Sole, is to implement a never before seen, noninvasive method of attempting to prevent such complications by simply informing the user when an anomaly in foot pressure data is present, attempting to replace the role of the nervous system in the foot. The system utilizes hardware to collect data from the foot, and artificial intelligence to detect behavior and inform the user of anomalies in foot pressure data wirelessly on a device running the software. The Smart Sole also aims to provide periodic feedback, to try and mitigate risks in the long term as well, by creating a report utilizing generative ai.

HYPOTHESIS

Using AI to analyze foot pressure data can enable a system to provide feedback to Diabetics suffering from Diabetic Peripheral Neuropathy of anomalous foot movements, thereby reducing the risk of complications associated with this condition

BACKGROUND

Peripheral Neuropathy refers to the set of neurological disorders concerning damage to the peripheral nervous system. Diabetic Peripheral Neuropathy (DPN) is the most common, affecting approximately 50% of Diabetics. Diabetics that suffer DPN suffer loss of sensation in the foot and are therefore susceptible to many different complications, such as:

- Ulcers 25% of DPN
- infected ulcers 55% of DPN with ulcers
- deformities 27% of DPN
- Amputations 20% with DPN

Being completely unaware of these complications because of the loss of sensation can result in incredibly severe consequences, including required amputation, and even death if the complication is left untreated.

Given humanity's limited knowledge in the pathogenesis of this disorder, there is no existing cure, and the existing treatment is not impactful, being medication such as Opioids or Physical Therapy and orthotics which are primarily aimed to relieve the patient of a any pain caused by misfire by the nerves, addressing already established deformities and fixing gait patterns.

The Smart Sole project, using modern technology attempts to take a non-invasive, impactful approach to reducing the complications that are conceived by Diabetic Peripheral Neuropathy, by using artificial intelligence models to analyze foot pressure data, aiming to detect movements and habits that are likely to cause such complications to the user, and informing them in real time, as well as providing them with detailed feedback on their progression in text using a language model. Basically, the Smart Sole is simulating the biological way of informing a person that they are injured (pain) and trying to provide more detailed feedback on how they can progressively get better at avoiding these complications.

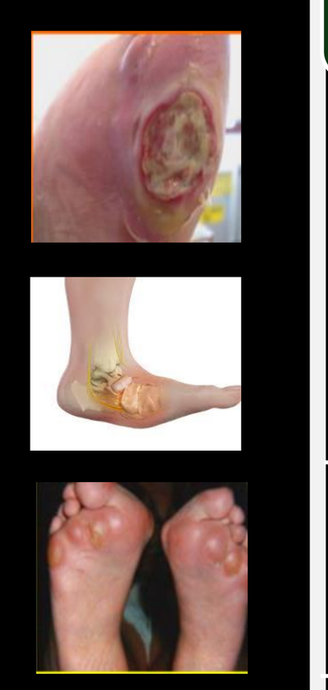


FIGURE 1

Figure 1 shows 3 images of the said complications, including ulcers, deformities and calluses

MATERIALS, PARTS AND SOFTWARE

MATERIALS AND PARTS (*per model*):

ELECTRONICS:
- -XIAO *ESP32-S3* MCU BOARD
- *x2 LiPo Battery 3.7v, 400mAh*
- *X2 402 UX FSRs*
- *408 UX FSR 100mm*
- BLE Antenna
- *X3 10KΩ* resistors
- *X2* LiPo Battery ports
- Jumper Wires
- 5V Linear Voltage Regulator
- Computer

SOFTWARE:
- PlatformIO development platform
- Llama 3.2 1B LLM
- MS Excel (data analysis)
- KiCAD

OTHER PHYSICAL PARTS
- (generic) Insole
- 3D printed battery packs

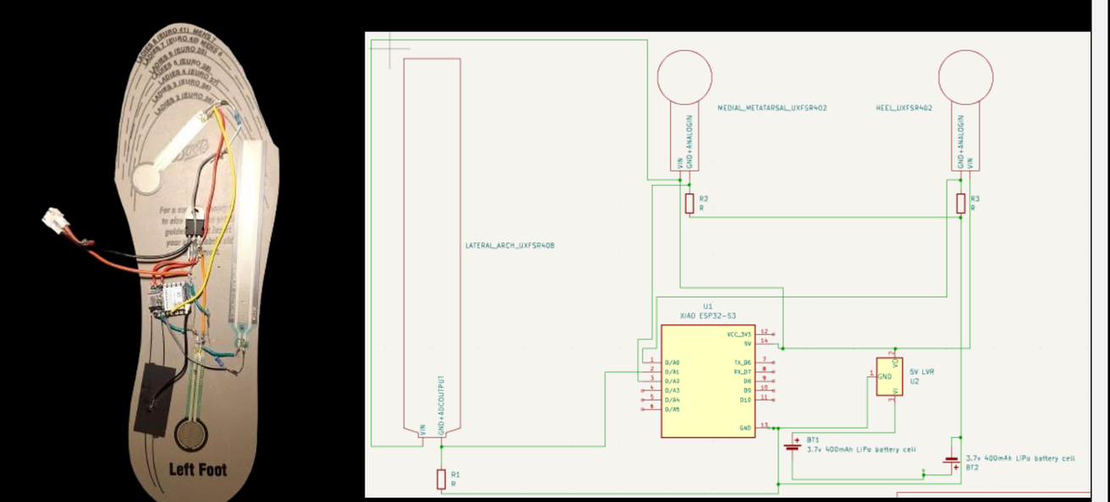


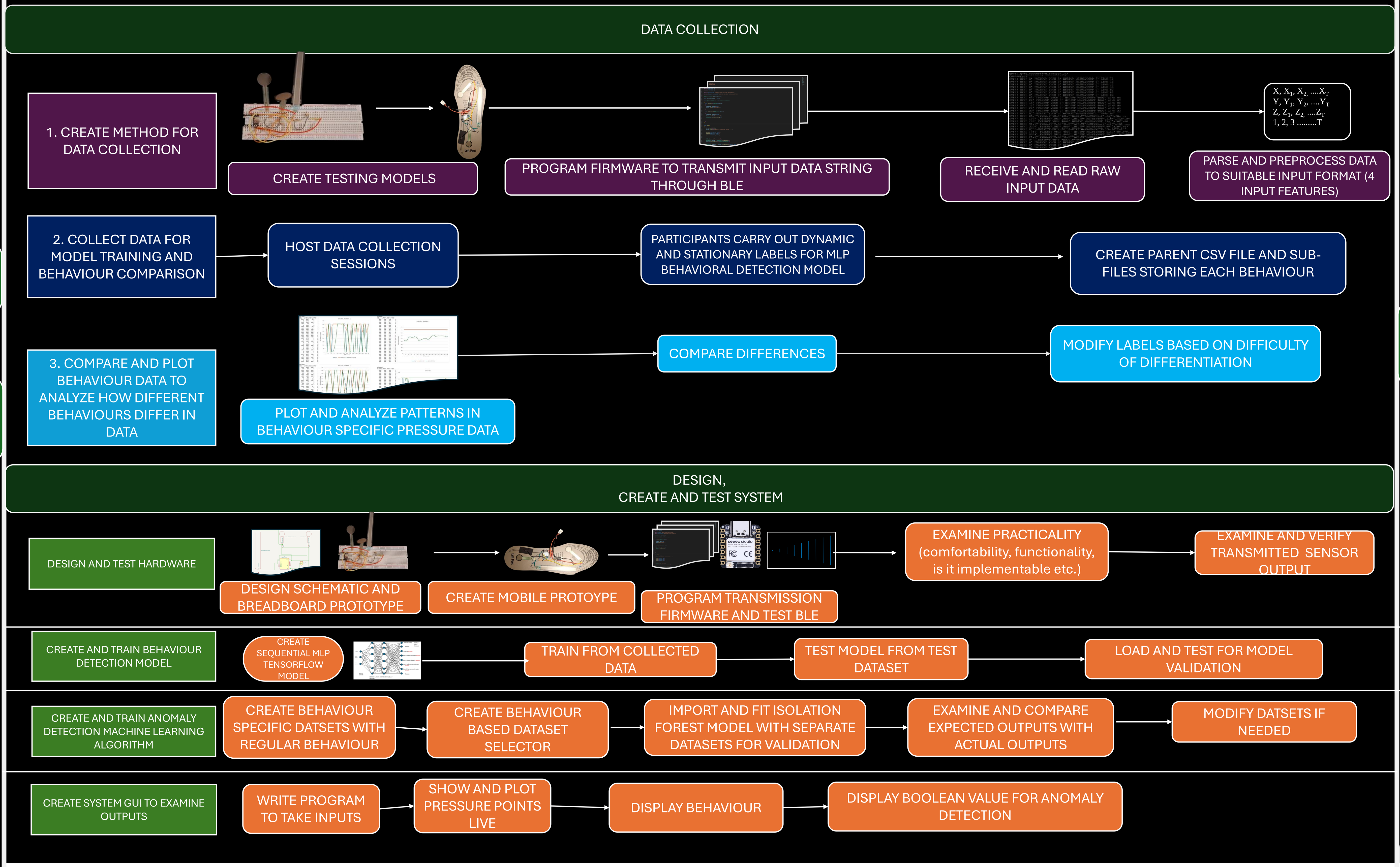
FIGURE 2

Figure 2 shows the electronics schematic, with all the mentioned components, as well as an image of an open Smart Sole model with the given schematic applied to the insole.

REFERENCES

(*02*, n.d.; *An Often Preventable Complication of Diabetes-Diabetic Neuropathy - Symptoms & Causes*, n.d.; Marmolejo et al., 2018; Gandhi et al., 2022; Armstrong et al., 2023; Margolis et al., 2002; Alam et al., 2017; Barrell & Smith, 2019; Hicks & Selvin, 2019; *Etiology, Epidemiology, and Disparities in the Burden of Diabetic Foot Ulcers | Diabetes Care | American Diabetes Association*, n.d.; *How Quickly Does Diabetic Neuropathy Progress?*, n.d.; Lawler et al., 2023; Perveen et al., 2024; Gordois et al., 2003) (*Diabetic Foot & Vascular Guidance – GP Gateway*, n.d. (FIGURE 1))

SCIENTIFIC METHODOLOGY



OUTCOMES

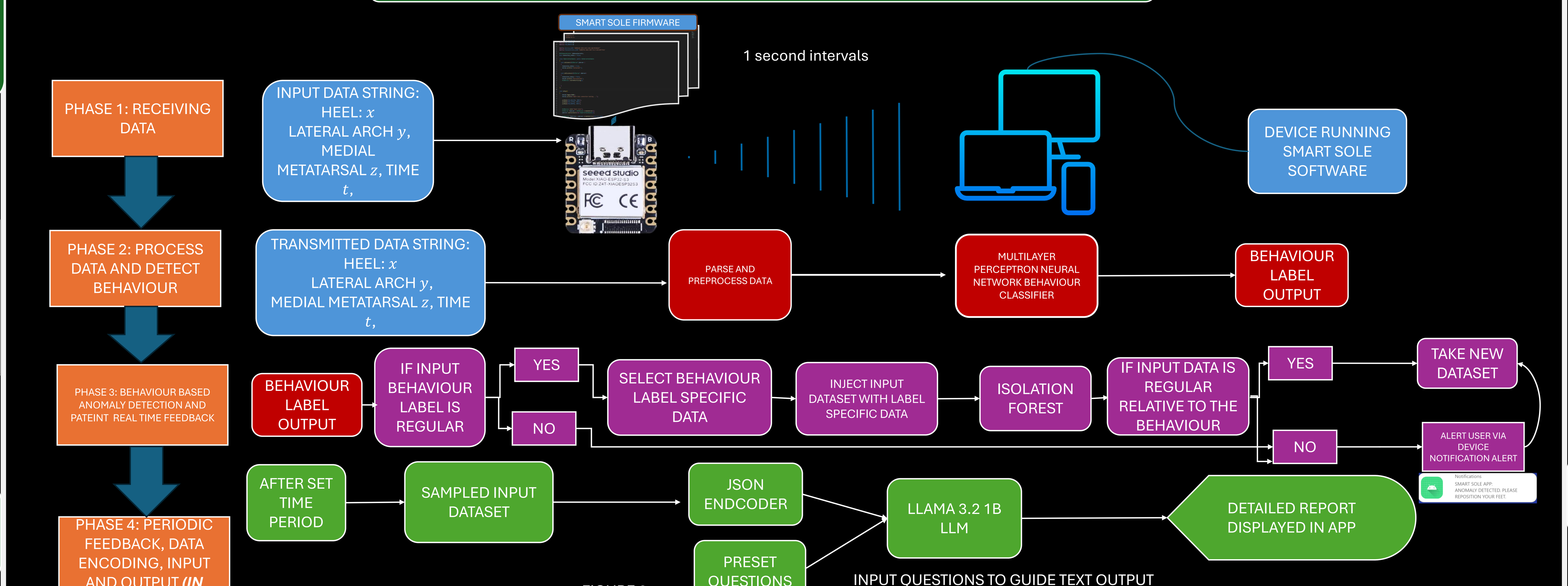


FIGURE 3

Figure 3 is a flowchart that demonstrates the system architecture, by taking in data, transmitting it to a device running the software wirelessly, parsing the data, detecting the behaviour using a Multilayer perceptron model then detecting whether or not an anomaly is present using the Isolation Forest anomaly detection algorithm.

As a result, this system provides feedback to the user on foot-pressure anomalies that are based on their behaviour to aim to prevent future complications that may occur as a result of Diabetic Peripheral Neuropathy

DISCUSSION & CONCLUSION

The primary objective of this project is to simply to give feedback to the user who suffers from Diabetic Peripheral Neuropathy when their foot is in such a position that can cause damage. The Smart Sole achieves this and successfully returns feedback to the user by:

- Detecting anomalies specific to behaviour
- Capable of alerting the user when an anomaly is present or progressing.
- Detecting Behaviour

The periodic progression tracking and detailed feedback by LLM is still in progress. This system successfully achieves it's initial aim. The system was carefully validated and tested to ensure its purpose is fulfilled.

In addition, the behaviour detection model is trained over many collected samples, from many distinct subjects to account for factors such as total mass, weight distribution throughout the foot, etc.

Ongoing development includes more training of behavioural detection model and implementation of LLM to output detailed and tracked feedback.

RECOMENDATION

There are some future modifications I would like to introduce to make this project better in implementation, efficiency, and suited for mass production.

- I would like to improve the electronics system by creating a flex PCB rather than hand soldering and wiring the circuit. In addition, to specifically try and mitigate Charcot foot, I want to implement a temperature sensor, to examine the temperature of the foot.
- I want to increase the amount of training data and expand the behavioural analysis, such that users that pursue certain activities can have one suited to them, e.g. those who often play football so that when a user is playing on the field, they do not run in a way that may cause damage.
- A concept I would like to implement to make the whole process more efficient, is having a single LLM or SLM that is capable of taking in input data in a tokenized format and able to explain exactly what is happening, whether or not there is an anomaly, and explain each event in great detail
- At current, the process requires some form of connection or use of a PC CPU or GPU. With the rapid development of Small Language models, I would like to try and put the whole process into a single app, so that Wi-Fi connection is not required and the user does not suffer in the even that the mobile device breaks contact with the computer
- Implementation would be a substantial step to this project, and attempting to work with specialists and companies in this area would be a definite next step

SIGNIFICANCE

- The Smart Sole project will contribute significantly to those who suffer from Diabetic Peripheral Neuropathy, as it is fundamentally replacing the role of nervous system in the area of their foot, and informing them virtually rather than informing them through the traditional method of pain.
- The Smart Sole is a novel idea, and as a project, it aims to help 50% of Diabetics who are destined to suffer from peripheral neuropathy and consequently foot deformities (+250,000,000 worldwide)
- Compared to the current treatment of Diabetic Peripheral Neuropathy, the Smart Sole would be a large stepping stone. The treatment that is used is mainly physiotherapy and some medication, however, there is still a substantial prevalence of the complications that come with Diabetic Peripheral Neuropathy mentioned in the Background. Because the Smart Sole specifically aims to mitigate these complications by trying to reduce habits or movements, in the long-term, the user will suffer less complications as they try to stop these habits.
- This project would also have widespread application, other than Diabetic Peripheral Neuropathy, this project can be applied to the elderly, in which this project can send an alert if they suffer a fall. This project can be applied to those who are in physiotherapy, and are relearning how to walk because of some traumatic accident. There are many existing applications for the Smart Sole.

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