FINAL CONCEPT IMPLEMENTATION

Group B

Need Statement

“A method to identify the potential risk of getting diabetes foot ulcers to preventing complications and improving patient care.”

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Initial concept selection

I. Enhancing the current assessment process using sensors and microcontroller-based devices.

II. A Deep Learning Method for Early Detection of Diabetic Foot Using Decision Fusion and Thermal Images

III. Use electromyography for early diabetic foot ulcer detection.

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FINAL CONCEPT

Develop an advanced insole system, we propose integrating pressure and temperature sensors within the insole to map the foot's distribution in these parameters, aiding in assessing the risk of Diabetic Foot Ulcer (DFU) development.

This system will be complemented by a non-invasive method for measuring transcutaneous oxygen diffusion, which will help identify damaged tissues and guide anatomy-specific clinical interventions.

Furthermore,Using vibratory sensory technology to assess nerve functionality in the extremities and leveraging deep learning based decision fusion and thermal image processing techniques, aims to significantly reduce amputation rates and offer substantial time and cost savings for healthcare services, by improving early detection and targeted treatment strategies for DFU.

Scientific Feasibility of the Concept

foot ulcers are a significant concern due to impaired blood flow (peripheral vascular disease) and neuropathy (nerve damage). Here's how these factors interrelate:

Pressure Distribution:

Increased pressure on specific areas of the foot can lead to the formation of calluses and, eventually, foot ulcers.

Temperature Distribution:

Abnormal temperature distribution in the foot can be indicative of poor blood flow or inflammation, both of which are risk factors for ulceration.

Inflammation can increase local temperatures, while poor blood flow can lead to cooler temperatures. Both extremes can contribute to tissue damage and delayed wound healing.

Transcutaneous Oxygen Tension (TcPO2):

TcPO2 measures the partial pressure of oxygen through the skin. Reduced TcPO2 values are indicative of poor oxygen supply to tissues.

In diabetes, peripheral vascular disease can compromise blood flow to the extremities, leading to lower TcPO2 levels. Inadequate oxygenation hinders wound healing and makes the foot more susceptible to ulcers.

Neuropathy:

Diabetic neuropathy can affect both sensory and autonomic nerves, leading to loss of sensation and impaired regulation of blood flow.

Reduced sensation increases the risk of trauma and pressure injuries, as the individual may not feel pain signals that would typically prompt them to adjust their position or address potential foot issues.

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Testing and Prototyping

Testing and Prototyping

1. First Bench Model Prototype

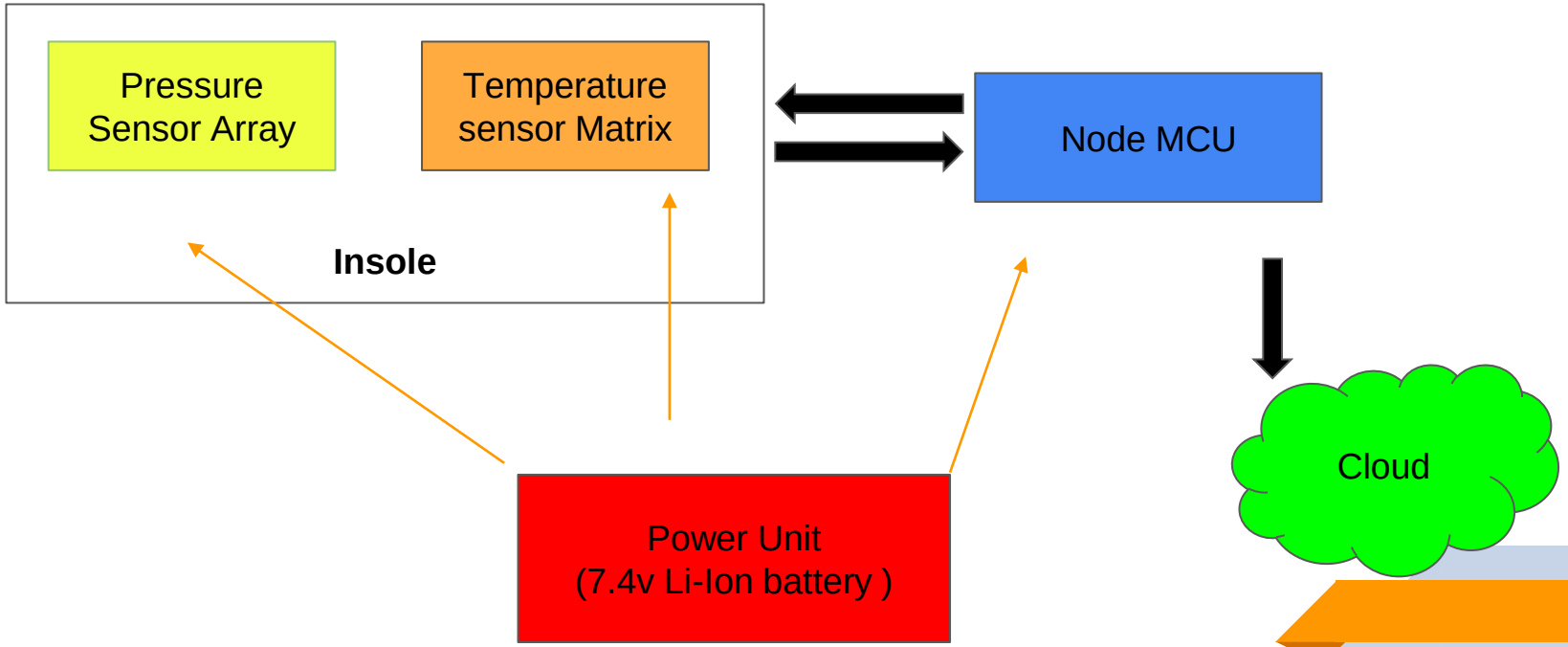
We have engineered a sophisticated insole capable of measuring both pressure and temperature distributions across the foot. This innovative device transmits collected data to a cloud-based platform, enabling advanced visualization through detailed graphical representations. Utilizing this technology, variations and potential areas of concern across the foot can be accurately identified and monitored, providing a critical tool for foot health management.

Details of the insole

- **Modules used**
  1. FSR 402 pressure sensor
  2. Node MCU -ESP8266
  3. DS18B20 Waterproof Digital Temperature Sensor Probe with 1m Cable (MD0094)
  4. 7.4V LiIon Battery Pack
  5. Few Resistors

Details of the Insole

- **Modularity Design**



Prototype

Initial level prototype for testing purposes

2.Second Tissue Testing Model Prototype

- As the second Milestone of our product development strategy ,we are planning to add a non-invasive **transcutaneous oxygen tension (TcPO2)** monitoring method on our insole to measure transcutaneous oxygen diffusion. This technique involves placing a sensor on the skin to measure the partial pressure of oxygen (PaO2) through the skin. The sensor doesn't penetrate the skin, making it a non-invasive approach.
- The integration of our advanced sensor technology into the insole design is anticipated to significantly enhance the accuracy of our measurements. This precision will be instrumental in detecting Diabetic Foot Ulcers (DFU) at their nascent stages, thereby enabling timely intervention and improving patient outcomes.

Here's a bit more detail on the non-invasive nature of TcPO2 monitoring:

- **Sensor Selection:**One commonly used type of sensor for TcPO2 monitoring is a Clark-type electrode
- **Sensor Placement:** The sensor is Contacted to the patient's skin using an adhesive. It contains electrodes that come into contact with the skin's surface.
- **Heating Element:** In addition to the electrodes, the sensor often includes a heating element. This element helps in increasing local blood flow and maintaining a constant temperature, ensuring a reliable measurement of oxygen diffusion through the skin.
- **Measurement**: The sensor measures the oxygen tension in the capillaries beneath the skin, providing a continuous and non-invasive monitoring of the oxygen levels in the tissue.

In patients with diabetes, the complication of peripheral vascular disease often leads to a significant reduction in blood circulation to the extremities. This condition manifests as decreased transcutaneous oxygen tension (TcPO2) levels, an indicator of the oxygen supply available to the tissues. When TcPO2 values are low, it implies that the tissues are receiving insufficient oxygen, a critical factor necessary for effective wound healing. This compromised state of oxygenation in the tissues, particularly in the lower extremities, significantly impedes the healing process of any wounds, rendering the feet more vulnerable to the development of ulcers.

3. Adding Vibratory sensing to assess nerve functionality and Deep Learning based Decision fusion and thermal Image Processing to Insole

As the final step of our implementation,We are Planning to Assess nerve functionality in the extremities using vibratory sensory technology and employing deep learning based decision fusion and thermal image processing as an innovative approach to early detect diabetic foot ulcers (DFU) and reduce the number of lower limb amputations as well as the burden and cost of ulceration.

So Here's a general roadmap for implementing such a system:

- **Vibrator Sensing**

1.Identify Critical Sensory Points in the foot which are directly correlated to DFU by collaborating with medical officers

2.Develop the vibrator on the insole which can stimulate identified sensory points.

-Strategically place vibratory sensors in areas most sensitive to neuropathy symptoms, typically the plantar surface of the foot.

-Integrate vibration motors within the insole, aligning with sensor placement for targeted stimulation.

3.Gather the physical reactions of the patient and use Sensors which are capable of detecting variations in neural sensitivity. Options include accelerometers, piezoelectric sensors, or contactless capacitive sensors.

4.Record those data to a well-developed Database

-Implement continuous monitoring, providing healthcare professionals with access to real-time data for intervention when necessary

- Deep Learning based decision fusion and thermal image processing

  1.**Framework Proposal**: The framework is based on decision fusion rules using thermal images of DFUs. It utilizes pre-trained CNN architectures like ResNet, DenseNet, XceptionNet, ShuffleNet, MobileNetV2, and EfficientNet, which have shown superior performance in biomedical thermal image classification. The pre-trained models were initially trained on the ImageNet dataset.

  2.Transfer Learning: This concept involves using a model trained on a specific dataset for classifying a new dataset with limited images. This approach addresses the issue of insufficient datasets during the training process. Models like ResNet, MobileNet, and ShuffleNet, trained on the ImageNet dataset, are employed for thermal image classification.

  3.Decision Rule: MobileNetV2 and ShuffleNet, will be developed on the MobileNetV1 architecture, were chosen as baseline classifiers. They have shown excellent performance in classifying medical and thermal images. ShuffleNet can accurately classify negative DFU images, while MobileNetV2 is effective in classifying positive DFU images. The decision fusion rule was applied at the decision stage to enhance the overall classification performance of the CNN models.

4.**Simulation Setup:** The simulation involved several stages:

- Dataset preparation.
- Training with validation (Stage 1).
- Fusion deployment and validation (Stage 2).
- Testing to measure the model's performance using metrics like accuracy, sensitivity, specificity, and F-measure.

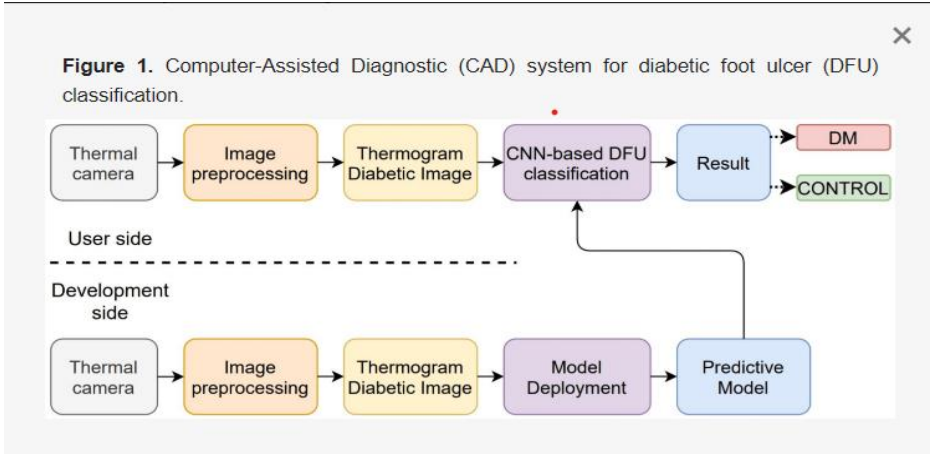


Figure 1. Computer-Assisted Diagnostic (CAD) system for diabetic foot ulcer (DFU) classification.

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IP ANALYSIS AND STRATEGY

IP ANALYSIS AND STRATEGY

We have conducted a IP and Patent research to find the similar concepts to the methods we mentioned above which are already published.As the result of our research we found below patents,related to our concepts.

1.Patent -US11596832B2 (Link)

The patent US11596832B2 is titled "Method and apparatus for early detection of diabetic foot disorders by analyzing foot temperature and vertical and shear forces on feet." It describes a system designed to minimize the risks of ulceration and limb amputation in diabetic patients by analyzing changes in foot temperature and the forces exerted on the feet. Key components of this system include:

- **Sensors:** The system integrates motion, force, and temperature sensors into footwear insoles.
- **Data Processing and Analysis**: A processing element is configured to analyze data from these sensors, measuring ground reaction force (GRF) and changes in foot temperature.
- **Smartphone-based Application:** The data from the sensors is communicated to a smartphone application via a wireless radio interface. This app processes the data and compares it with predefined criteria and rules.
- **Alerts and Monitoring:** If the data exceeds any set criteria, the system generates alerts for both the user and a remote medical supervisor.
- **Haptic Actuators:** The insoles may also include haptic actuators, which are used to determine the level of neuropathy in the user by measuring the vibration perception threshold (VPT).

This system represents a comprehensive approach to monitoring and managing foot health in diabetic patients, emphasizing early detection and intervention to prevent serious complications like ulcers and amputations.

2.Patent-WO2021096994A1 (Link)

The patent WO2021096994A1, titled "Capillary pressure measurement," focuses on several methods and apparatus for evaluating blood flow in damaged or healing tissue. This includes:

- **Evaluating Blood Flow:** Methods for assessing blood flow in tissues that are either damaged or in the process of healing.
- **Identifying and Treating Patients at Risk of Pressure Ulcers:** The patent describes methods to identify patients at the onset risk of pressure ulcers, employing transcutaneous oxygen diffusion measurements for treatment decisions.
- **Stratifying Patient Groups and Reducing Tissue Damage:** It includes approaches to stratify patient groups based on the risk of wound development and offers methods to reduce the incidence of tissue damage in care facilities.
- **Detecting Tissue Damage and Identifying Damaged Tissue:** The patent also covers methods to analyze transcutaneous oxygen pressure measurement trends to detect tissue damage before it becomes visible and compare bisymmetric transcutaneous oxygen pressure measurements to pinpoint damaged tissue.

These methods are integral to early detection and intervention in the management of conditions like diabetic foot ulcers, aiming to prevent severe complications such as amputations.

3.Patent- JP2018536472A (Link)

The patent JP2018536472A describes a footwear system equipped with multiple temperature sensors for detecting ulcers or pre-ulcer lesions in a human foot. This system functions by generating discrete temperature data values from the sensors, forming a temperature map that substantially represents the current geometric shape of at least one part of the foot and its temperature distribution. The system then assesses whether the temperature map matches any of a set of predefined patterns. Based on this assessment, it generates output information indicative of the presence or risk of an ulcer or pre-ulcer lesion in a specific part of the foot. This output is contingent upon the determination of the temperature map matching one of the predefined patterns.

4.Patent- JP7261883B2 (Link)

The patent JP7261883B2, titled "Machine learning system for wound assessment, healing prediction and treatment," focuses on a method for predicting wound healing using a system for assessing or predicting wound healing. The method includes:

- **Illuminating a Tissue Region:** This is achieved using light of at least a first wavelength, with at least a portion of this light being reflected to a photodetector.
- **Generating Scalar Values:** The system generates at least one scalar value for assessing or predicting wound healing.
- **Determining Healing Predictive Parameters:** After a predetermined period, the system determines healing predictive parameters, such as the expected wound area reduction rate (%) after this period.
- **Additional Processes**: In some embodiments, the method also involves updating at least one machine learning algorithm with the image and actual healing amount as training data, and selecting standard or advanced wound care therapy based partially on the healing predictive parameter.

This patent encapsulates a comprehensive approach to wound healing assessment, leveraging machine learning algorithms and advanced imaging techniques.

IP Analysis and Final Observation

Based on the comprehensive patent research conducted, it has been observed that numerous existing patents independently address various aspects of the technology envisioned in our project. These patents encompass a range of concepts, from integrated sensor systems in footwear to advanced methods for detecting and monitoring diabetic foot ulcers. However, our extensive analysis reveals that there currently exists no single patent that encapsulates the entirety of our proposed product's multifaceted approach.

This finding leads to the conclusion that our product, while incorporating elements covered under different patents, stands as a unique amalgamation of these technologies. Consequently, we assess that our product faces a moderate level of Intellectual Property (IP) risk. This assessment is based on the premise that, although individual components of our product align with existing patented technologies, the innovative integration of these components into a cohesive system presents a novel and distinct product in the market. As such, we maintain a cautious yet optimistic outlook regarding the IP landscape surrounding our product, and we are committed to ongoing diligence in this area to navigate and mitigate potential IP challenges.

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Regulatory

Regulatory Pathway: 510(k) Premarket Notification

- Device Classification: Class II
- Regulatory Pathway:
  - ❖ The primary regulatory pathway for our medical device in the U.S. is the 510(k) Premarket Notification.
- Demonstration of Substantial Equivalence:
  - ❖ We will demonstrate that with more modifications and enhancements our device is substantially equivalent to a legally marketed predicate device.

Device Classification: Class II

- **Integration Complexity:**

  Integration of pressure and temperature sensors, non-invasive TcPO2, vibratory tech, and deep learning for comprehensive DFU risk assessment.

- **Moderate Risk:**

  The nature of diabetic foot ulcer (DFU) management places the device at a moderate risk level.

- **Risk Mitigation:**

  Higher regulatory control is warranted to mitigate potential harm associated with DFU complications.

- **Special Controls:**

  Special controls, including rigorous testing and validation, are necessary for ensuring safety and effectiveness.

- **510(k) Alignment:**

  Aligns with the 510(k) Premarket Notification process, showcasing substantial equivalence to predicate devices.

- **Clinical Validation:**

  Clinical data, including real-world usage scenarios, supports the device's safety and effectiveness in diverse patient populations.

- **Intended Use Alignment:**

  The device is designed for early DFU detection, aligning with Class II characteristics focused on moderate-risk medical devices.

- **Technological Innovation:**

  The integration of deep learning reflects a commitment to innovative technologies for enhancing diagnostic accuracy.

- **Balanced Approach:**

  Class II classification strikes a balance between encouraging innovation and imposing regulatory safeguards, ensuring patient safety.

- **Established Controls:**

  Benefits from established regulatory standards, providing a robust framework for market access and ongoing compliance.

Demonstration of Substantial Equivalence Based on Related Patents

1. Patent - US11596832B2 ("Early Detection System")

Demonstration of Equivalence:

- shares fundamental components:

  - Sensor Integration: Like US11596832B2, our device integrates pressure and temperature sensors.
  - Data Analysis: our Device employs similar data processing techniques for GRF and foot temperature changes.
  - Application Interface: our device utilizes a smartphone-based application for data communication and real-time analysis.
  - Neuropathy Assessment: While our device doesn't directly use haptic actuators, it addresses neuropathy through vibratory sensory technology.

Performance Data:

- Our device's performance data demonstrates accuracy and reliability, aligning with the early detection goals of US11596832B2.Comparative.
- testing shows equivalency or superiority in DFU risk assessment.

2. **Patent - WO2021096994A1 ("Capillary Pressure Measurement")**

   Demonstration of Equivalence:

   - Our device incorporates methodologies for blood flow assessment, aligning with the capillary pressure measurement focus of WO2021096994A1.
   - Transcutaneous oxygen monitoring in our device corresponds to the risk identification methods outlined in the patent.
   - Our device's comprehensive approach to DFU risk aligns with WO2021096994A1's aim to prevent severe complications.

3. **Patent - JP7261883B2 ("Machine Learning for Wound Assessment")**

   Demonstration of Equivalence:

   - Our device integrates temperature sensors akin to JP2018536472A, contributing to a comprehensive DFU risk assessment.
   - While not identical, our device's approach to risk assessment aligns with the patent's focus on temperature data for ulcer detection.

4. **Patent - JP2018536472A ("Temperature Sensor Footwear")**

   Demonstration of Equivalence:

   - Our device integrates temperature sensors akin to JP2018536472A, contributing to a comprehensive DFU risk assessment.
   - While not identical, our device's approach to risk assessment aligns with the patent's focus on temperature data for ulcer detection.

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Business Model

1. Pricing Strategy: Affordable Accessibility
   - Priced affordably for Sri Lankan market.
   - Tailored to align with economic conditions.

2. Tailored Solution: Customized for Sri Lankan Healthcare
   - Adapted to specific needs of Sri Lankan healthcare.
   - Fits prevailing resources and economic conditions.

3. Objectives: Enhanced Assessment Process
   - Sensors and microcontroller-based devices.
   - Real-time, accurate analysis of diabetic foot ulcers.

4. Current Scenario in Sri Lanka: Addressing the Technology Gap
   - Introducing device to integrate existing methods for more accuracy.

5. Proposed Device: Integration of Methods
   - New device integrating existing and new methods.
   - Aiming for more accurate results with minimal effort.
6. Deep Learning Method: Cost and Time Reduction
   - Significant cost and time reduction compared to traditional methods.
   - User-friendly, deep learning-driven procedure.
7. Empowering Patients: Independent Testing
   - Allows patients to perform tests independently.
   - Reduces burden on hospital resources.
8. Cost Savings: Substantial Savings
   - Results in substantial cost savings for healthcare systems.
   - Initial investment justified by proven accuracy.
9. Technology Investment: Advanced Nature
   - Acknowledging initial investment for advanced technology.
   - Emphasis on long-term benefits and accuracy.

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Thank you

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