DEPARTMENT OF ELECTRONIC & TELECOMMUNICATION ENGINEERING UNIVERSITY OF MORATUWA

Biomedical Device Design

Feasibility report

Group B:

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1. Introduction

This report includes the process of come up with a solution for one of the previously identified problems. It details our process, which includes the phases of idea generation and concept evaluation, as outlined in the reference material.

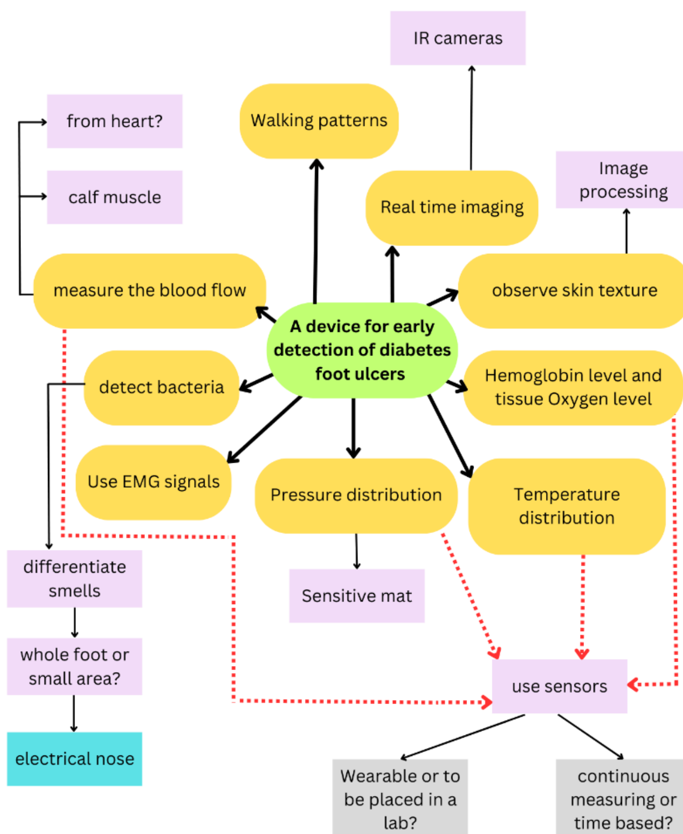
2. Need statement.

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

Diabetic foot ulcers (DFUs) pose a serious threat to the well-being of individuals with diabetes, often resulting from neuropathy and reduced blood flow to the lower extremities. These ulcers can lead to severe complications such as infections, gangrene, and even amputations if not detected and managed in a timely manner. Currently, DFUs are often diagnosed at an advanced stage when patients experience pain or visible symptoms. This delayed detection leads to increased morbidity and mortality rates among diabetic patients, coupled with elevated financial burdens on healthcare systems.

3. Ideation

A brainstorming session was held to produce ideas to address the requirement. The offered ideas are listed below as part of the process of identifying answers.



4. Initial concept selection

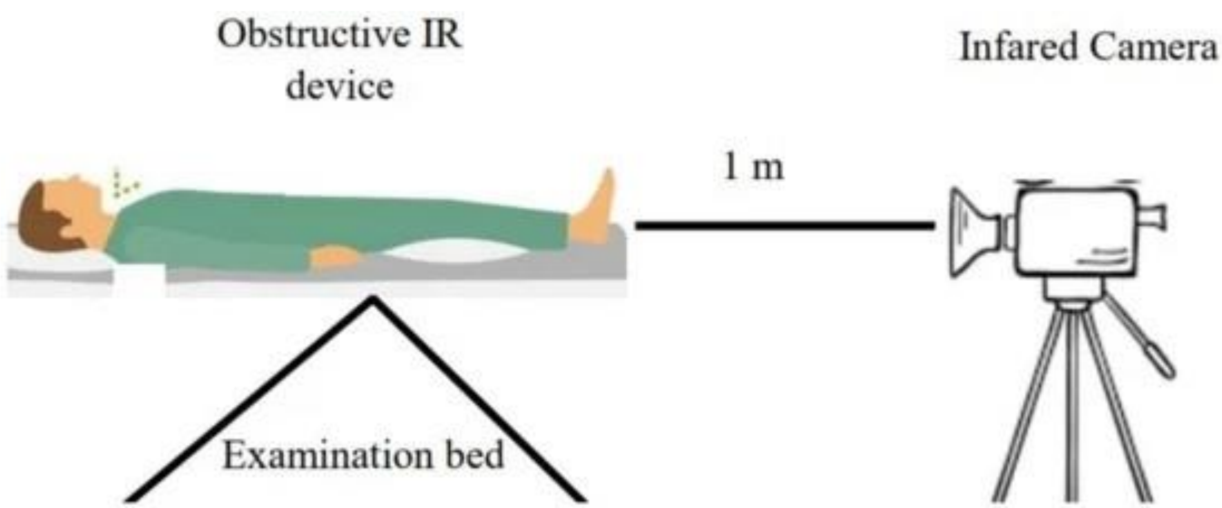
In the progression of our biomedical design project, we commenced formulating a precise need statement as a foundational step. In the pursuit of innovative solutions, we convened a deliberative brainstorming session involving our peers and associates. From the profusion of ideas generated, a rigorous selection process was meticulously undertaken, emphasizing criteria such as feasibility and potential impact. Consequently, we have identified and retained three particularly promising concepts for further exploration: "A Deep Learning Method for Early Detection of Diabetic Foot Using Decision Fusion and Thermal Images," "Enhancing the current assessment process using sensors and microcontroller-based devices," and "Utilizing electromyography for early diabetic foot ulcer detection."

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

Enhancing the current assessment process using sensors and microcontrollers involves integrating these technologies into the existing assessment methods to gather more accurate and objective data. Generally Diabetic peripheral neuropathy, structural abnormalities of foot deformities, peripheral artery occlusive disease are the most frequent risk factors for DFU. Currently in assessment process dermatologic and musculoskeletal inspection, neurologic assessment, and vascular assessment are common and here the idea is to develop a device to integrate those procedures using sensors and a microcontroller IC.

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

Infrared thermography, coupled with deep learning, is a powerful tool for this purpose. It captures and displays real-time images of thermal energy emitted by the monitored area, provided the temperature is above absolute zero. Deep learning algorithms, particularly Convolutional Neural Networks (CNNs), can be trained to analyze these thermal images rapidly and accurately.



III. Use electromyography for early diabetic foot ulcer detection.

Electromyography (EMG) examines muscle electrical signals, crucial for identifying muscle and nerve disorders often linked to diabetes complications like neuropathy. To enhance diabetic neuropathy (DN) and diabetic foot ulcers (DFU) diagnosis, we propose leveraging machine learning using EMG and ground reaction forces (GRF) data. This pioneering approach aims to improve early condition detection, ultimately enhancing patient outcomes in diabetic neuropathy management, marking a significant stride towards proactive healthcare for individuals with diabetes.

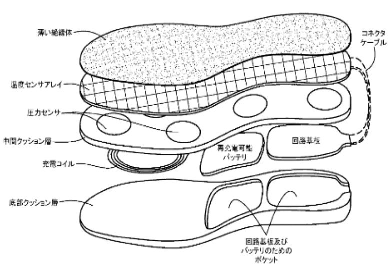
5. Concept screening

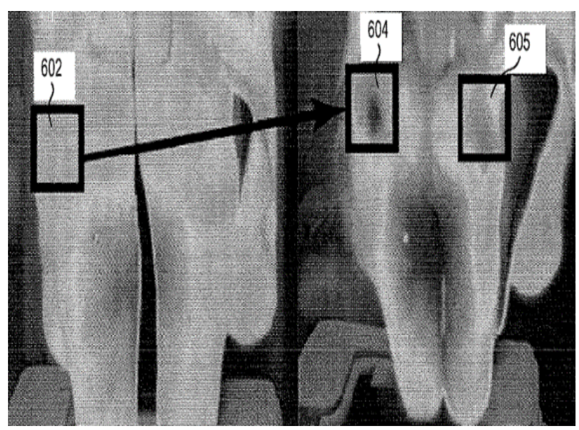
I. Intellectual Property (IP)

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

wearable textile with integrated plurality of sensors to detect pressure and temperature and with that raw data they predict the risk amount for ulcers. And also, there exist footwear systems with multiple temperature sensors to determine the development of an ulcer.

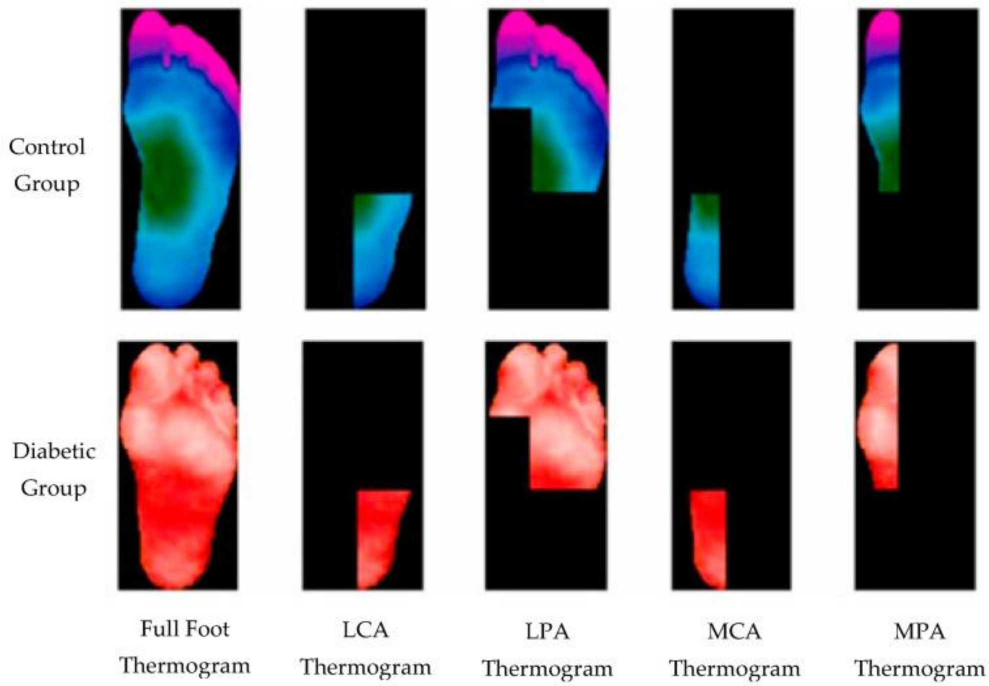
Patent 1: US10993654B2 and patent 2: JP2018536472A





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

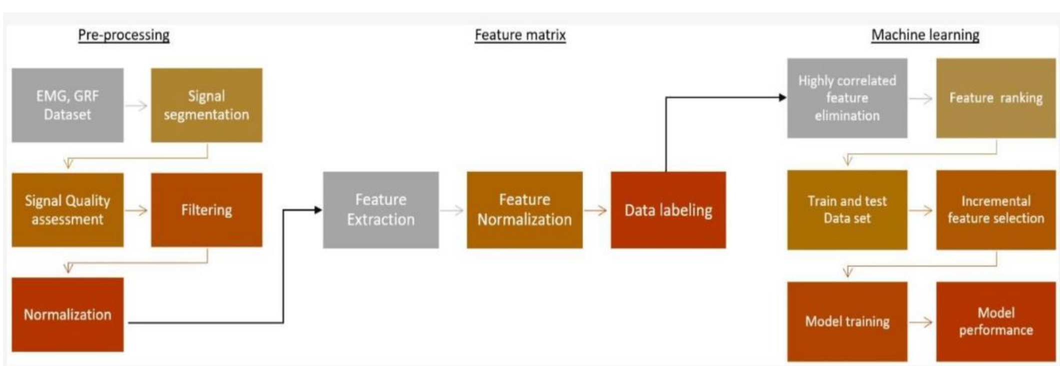
In diabetic patients, fluctuations in plantar foot temperature can occur due to factors such as neuropathy, ischemia, or infection. An abnormal temperature difference of more than 2.2°C (4°F) between the right and left foot is considered significant, while the typical difference is less than 1°C. Using a thermal-imaging camera equipped with deep learning algorithms can help identify these temperature discrepancies early on, resulting in potential time and cost savings in the long term.



iii. Use electromyography for early diabetic foot ulcer detection.

A Research Which analyzed EMG data from thigh and calf muscles during the stance phase of gait of 45 adult participants categorized into control, diabetic neuropathic, and diabetic neuropathic groups with a history of plantar ulcers revealed the substantial delays in specific muscle peak occurrences in the group with a history of plantar ulcers compared to the control group. Importantly, the delay in the lateral gastrocnemius muscle's peak correlated with a reduction in the second vertical peak in diabetic subjects, while the delay in the vastus lateralis muscle's peak had no significant impact on the initial vertical peak. These insights into EMG patterns and gait analysis constitute valuable intellectual property, forming the foundation for a pioneering approach that leverages machine learning utilizing EMG and ground reaction forces (GRF) data.

The effect of diabetic neuropathy and previous foot ulceration in EMG and ground reaction forces during gait - ScienceDirect



II. Regulatory

All three require class II FDA approval and can be marketed via the 510(k) procedure.

III. Reimbursement

In Sri Lanka, the majority of the patients do not have insurance, Most hospitals are run with government funds. Only about a quarter of Sri Lanka's hospitals are private. Out of the three ideas, the doppler EMG idea will have a lower reimbursement than the other two because it will be more costly and needs well trained persons to implement.

IV. Business Model

As our initial implementation will take place in Sri Lanka, our early foot ulcer detection device should be priced within an affordable range. Furthermore, the solution should be tailored to align seamlessly with the prevailing resources and economic conditions of the country. By adopting this approach, we aim to produce a way for healthcare professionals to detect diabetes foot ulcers at early stage and treat those patients, preventing complications and improving healthcare outcomes.

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

The objective is to develop a system that provides real-time and accurate analysis of diabetic foot ulcers, aiding healthcare professionals in monitoring and treating these ulcers effectively.

Currently in Sri Lanka there is not this kind technology in usage, but to check about Diabetic peripheral neuropathy medical professionals use 10 g monofilament test and also physical inspections to detect ulcers. We can introduce a new device which integrates existing methods to new methods to have more accurate results within minimum effort.

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

In addition to significantly reducing both the cost and time required for traditional Diabetic Foot Ulcer (DFU) early detection techniques, our device's user-friendly nature, coupled with its near-automatic procedure driven by deep learning, empowers patients to perform tests independently. This not only alleviates the burden on hospital accommodations and staff hours but also results in substantial cost savings for government healthcare systems. While the technology may represent an initial investment due to its advanced and sophisticated nature, its track record of delivering highly accurate early DFU detections is well-established.

iii. **Use electromyography for early diabetic foot ulcer detection.**

Our business model for early diabetic foot ulcer detection using EMG is focused on affordability and accessibility, particularly in Sri Lanka. We aim to align our solution with the country's unique socioeconomic conditions, making it both effective and sustainable within the local healthcare ecosystem. By simplifying the diagnostic process and enhancing efficiency, our approach improves patient care and reduces the associated risks and complications. Ultimately, our goal is to address a critical healthcare need, reduce mortality from diabetic foot ulcers, and position our solution as a valuable asset in Sri Lanka's healthcare infrastructure, with the potential for global replication in resource-constrained settings.

V. Screening matrix

With the above analysis, the feasibility of the products is analyzed. The following screening matrices explain the process. The abbreviations used in the matrix are as follows:

IP - Intellectual Property
RR - Regulatory Requirements
RI - Reimbursement
BM - Business Model

Idea	IP	RR	RI	BM
Decision Fusion and Thermal Detection				
Using Sensors and Microcontroller Devices				
Use EMG				

Accuracy : capable of providing the required accuracy
Non-invasive : able to take measurements uninvasively
Continuous : provide a continuous diagnosis for the patient
Accessibility : easy to use by the patient or the medical staff

Objectives	Weight	(1)	(2)	(3)
Accuracy	5	+0.5	+0.5	+0.5
Non Invasive	4	+1	+1	+1
Continuos	3	+1	0	0
Accessibility	5	+1	+0.5	0
Final Score		**14.5**	**9**	**6.5**

(1):Enhancing the current assessment process using sensors and microcontroller-based devices.

(2): A Deep Learning Method for Early Detection of Diabetic Foot Using Decision Fusion and Thermal Images

(3) Use electromyography for early diabetic foot ulcer detection.

6. Final concept selection

After analysis, the method Enhancing the current assessment process using sensors and microcontroller-based devices found to be most feasible among the three concepts.

I. Concept exploration and testing

- Prototyping

A device for predicting the risk of a diabetic foot ulcer is a portable electronic apparatus that uses an array of sensors and advanced algorithms to assess the likelihood of a diabetic patient developing a foot ulcer (Algorithm part is for future improvements). The device incorporates sensors to measure various parameters such as temperature, pressure, blood flow rate, skin nature and foot pulse in the patient's feet. It collects data through non-invasive measurements. Then all sensors are combined through ATMEGA microcontroller IC and then transferred to respective parties through a mobile application or via a relevant medium for further analysis.

In the initial steps it gives collection of data as a help for a medical professional. We have planned to use machine learning and IR cameras as further improvements for this device to analyze raw data using machine learning algorithms to identify patterns and indicators associated with foot ulcer development.

This device can be modified to be used either in homes or hospitals. By continuously monitoring the foot health of diabetic individuals, this intuitive device helps detect early signs of ulcer development and encourages appropriate preventive interventions, like adequate footwear, regular examination, and lifestyle modifications.

Overall, the device serves as an invaluable tool in diabetic foot care, empowering both healthcare providers and patients to take timely measures and minimize the risk of foot ulcers, ultimately improving health outcomes and quality of life for individuals living with diabetes.

II. Technical Feasibility

Most of the components mentioned above are basic building blocks that are being used by. So, designing the electronics would not require a much R&D effort. However, designing this device as wearable can be challenging and portable device that can externally measure those parameters can be solution for that.

7. Conclusion

In conclusion, our pursuit of an early detection device for diabetic foot ulcers using Sensors and Microcontroller Devices represents a critical step in proactive diabetic care. Our innovative approach promises to enhance patient outcomes significantly. This cost-effective and accessible solution, tailored to Sri Lanka's unique healthcare landscape, embodies our commitment to reducing complications, mortality rates, and healthcare costs while improving the quality of life for individuals with diabetes.

References

- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10453276/
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10297618/
- patent 1: https://patents.google.com/patent/US10993654B2
- patent 2: https://patents.google.com/patent/JP2018536472A
- The effect of diabetic neuropathy and previous foot ulceration in EMG and ground reaction forces during gait - ScienceDirect
- Sensors | Free Full-Text | Machine Learning-Based Diabetic Neuropathy and Previous Foot Ulceration Patients Detection Using Electromyography and Ground Reaction Forces during Gait (mdpi.com)
- Electromyography (EMG) and Nerve Conduction Studies: MedlinePlus Medical Test

Appendix: Brainstorm canvas

The original image taken from the brainstorming session is given below.

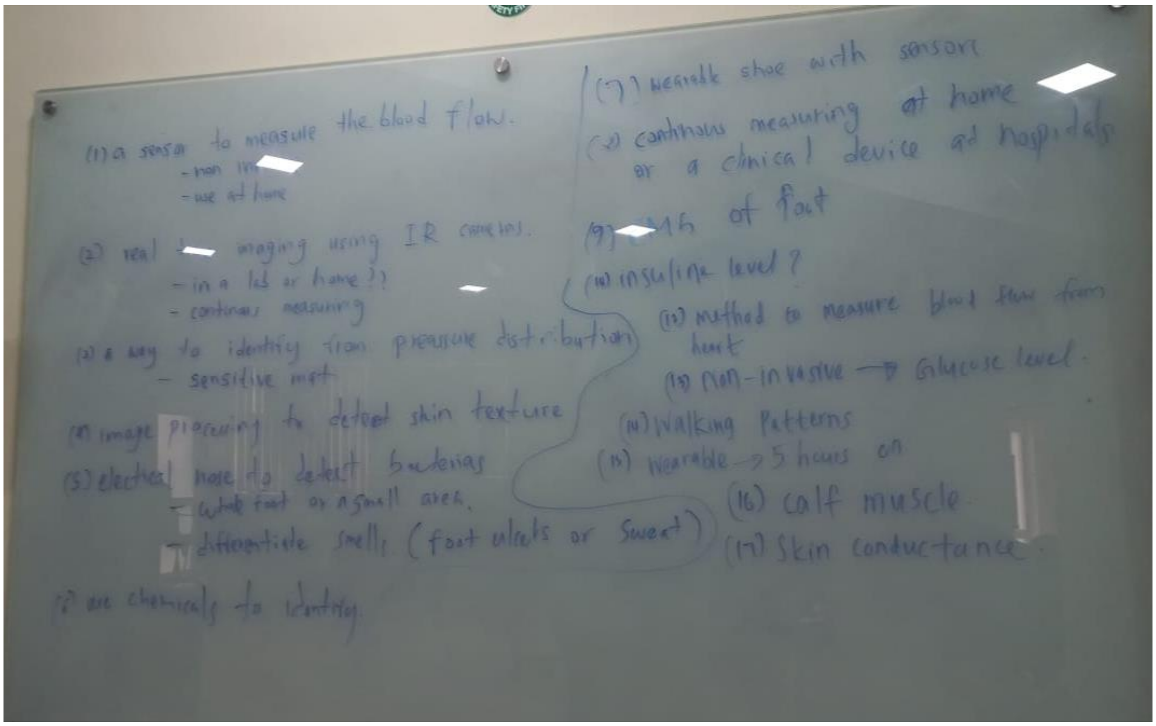


Table 4.2.1 Device classification has direct implications on the number and complexity of the requirements imposed by the FDA.

Class	Examples	Description	FDA requirements
I	Bandages, tongue depressors, bedpans, examination gloves, hand-held surgical instruments	Class I devices present minimal potential harm to the person they are being used on and are typically simple in design.	With Class I devices, most are exempt from premarket clearance. There is no need for **clinical trials** or proof of safety and/or efficacy since adequate predicate experience exists with similar devices. However, they must meet the following "general controls": • Registration of the establishment with the FDA. • Medical device listing. • General FDA labeling requirements. • Compliance with quality system regulation (**QSR**), with the exception of design controls, unless specifically called out in the regulation.
II	X-ray machines, powered wheelchairs, surgical needles, infusion pumps, suture materials	**Class II** devices are often non-invasive, but tend to be more complicated in design than Class I devices and, therefore, must demonstrate that they will perform as expected and will not cause injury or harm to their **users**.	Class II devices are generally cleared to market via the **510(k)** process, unless exempt by regulation. They must meet all Class I requirements, in addition to the "special controls" which may include: • Special labeling requirements. • Mandatory performance standards. • Design controls. • Post-market surveillance.
III	Replacement heart valves, silicone breast implants, implanted cerebellar stimulators, implantable pacemakers	Class III devices are high-risk devices. These are typically implantable, therapeutic, or life-sustaining devices, or high-risk devices for which a predicate does not exist.	Class III devices must generally be approved by the **PMA** regulatory pathway, although a small number are still eligible for 510(k) clearance. (FDA has begun the process of requiring PMAs for all of these.) Class III devices must meet all Class I and II requirements, in addition to stringent regulatory approval requirements that necessitate valid scientific evidence to demonstrate their safety and effectiveness, before they can be used in humans.