SPARK CHALLENGE 22/23

ENTC
Electronic and Telecommunication Engineering

EC

Details of the team

Group name: Nightwatch

Group leader's name : A.Vishagar

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External support you received to derive the solution from peer

Dr. Prasanga Bandara (RD - Ampara District) - Problem Identification

Dr. Upulani Abeysooriya (MO - Rural Hospital, Udupila) - Idea Validation

Problem Description

Primary area of development : Healthcare Improvement

Other Supporting Areas :

Digital Health and Telemedicine , Data Analytics and Research , Home healthcare , Pharmacies and medical suppliers.

The Problem

Hypoglycaemia, or low blood sugar, poses a significant health risk to individuals, particularly those with diabetes. When blood glucose levels drop below a certain threshold, it can lead to various complications, including confusion, dizziness, seizures, and, in severe cases, unconsciousness or even death. This danger is further exacerbated when individuals are asleep, as they may not be aware of the symptoms or able to respond promptly. Currently, there is a critical need for a reliable and effective alert system that can accurately and timely notify individuals, particularly during sleep, when their blood glucose levels are dangerously low. The objective of our project is to develop a solution that actively monitors blood glucose levels **non invasively** and provide real-time alerts, empowering individuals to take immediate action to prevent and manage hypoglycemic episodes, even during sleep, thus minimizing the potentially life-threatening consequences associated with nocturnal Hypoglycaemia.

Validation Process

Diabetes is a major cause of death and disability. In 2019, diabetes was the ninth leading cause of death in the world. It is also a major cause of blindness, kidney failure, heart disease, stroke, and amputation.

According to the International Diabetes Federation (IDF), as of 2021, there are an estimated 537 million adults (20-79 years) living with diabetes worldwide. This number is predicted to rise to 643 million by 2030 and 783 million by 2045.

The majority of people with diabetes live in low- and middle-income countries. In 2021, 78% of people with diabetes lived in these countries.

Hypoglycaemia is a common complication of diabetes. It is estimated that up to 50% of people with diabetes experience Hypoglycaemia at some point and it is estimated that nocturnal Hypoglycaemia may be responsible for up to 10% of deaths in people with diabetes.

However, according to the American Diabetes Association, about 1 in 10 people with diabetes experience nocturnal Hypoglycaemia. This means that there are an estimated 24 million people in the United States who are affected by this condition. Nocturnal Hypoglycaemia is more common in people with type 1 diabetes, but it can also occur in people with type 2 diabetes.

When contacting doctors related to this, it was pointed out to us that such a device would be immensely supportive to the diabetic community in Sri Lanka.

But, when searching for existing solutions, we found out that currently there are continuous blood glucose measuring systems, even if they are not available for the local community of Sri Lanka. The most prominent devices that answer our solutions are invasive. However, even so, it was observed that the price of such a device is about 400,000 LKR, which is not a viable option for Sri Lankan community. The high price is due to the added features such as regulating the blood glucose level through automated monitoring of glucose level and automatic iinjection of insulin.

These extremely high prices causes the diabetic community of Sri Lanka to be more tend towards the invasive glucometer without continuous glucose level monitoring, which costs around 10,000 LKR. However, this does not support the risk of nocturnal hypoglycaemia.

Affected User Segment

The target community is the people affected with type 1 and type 2 diabetics as they are in risk of nocturnal Hypoglycaemia. However, the target population can be further thinned to the diabetic population who are not in favor of invasive methods for blood glucose monitoring, and also the community who cannot afford the required safety devices even if they are in favor of invasive methods. The affected user segments for this problem also includes the caregivers and healthcare providers as it supports them in being aware of the patients and can help with to manage their condition.

Problem Description

Arriving at Solution

First thing we had to decide was which technology we would use to measure glucose level. From our research about existing solutions we have found out that there are existing products which use invasive methods to measure glucose level. But due to some problems those products were not able to fill the market void. Users were not satisfied with those existing products.

Therefore we hypothesized that maybe if we use non-invasive techniques to measure glucose level and warn extreme glucose levels it would solve our problem and succeed in filling the market void by providing satisfactory products to end users.

There are a number of currently existing non-invasive blood sugar measurement technologies. Some of the most promising technologies include:

- Near-infrared spectroscopy (NIRS):
- Optical coherence tomography (OCT):
- Electromagnetic spectroscopy (EMS):
- Microwave spectroscopy
- Breath analysis: Breath analysis is a technique that uses the composition of breath to measure the amount of glucose in blood. It works by measuring the levels of certain molecules in the breath, such as acetone, which are produced when glucose is broken down.

These technologies are still under development, but they have the potential to revolutionize the way that blood sugar is measured. Non-invasive blood sugar measurement technologies would be a major improvement over current methods, which require a finger prick to draw blood. Non-invasive blood sugar measurement would be more convenient, less painful, and more accurate than current methods.

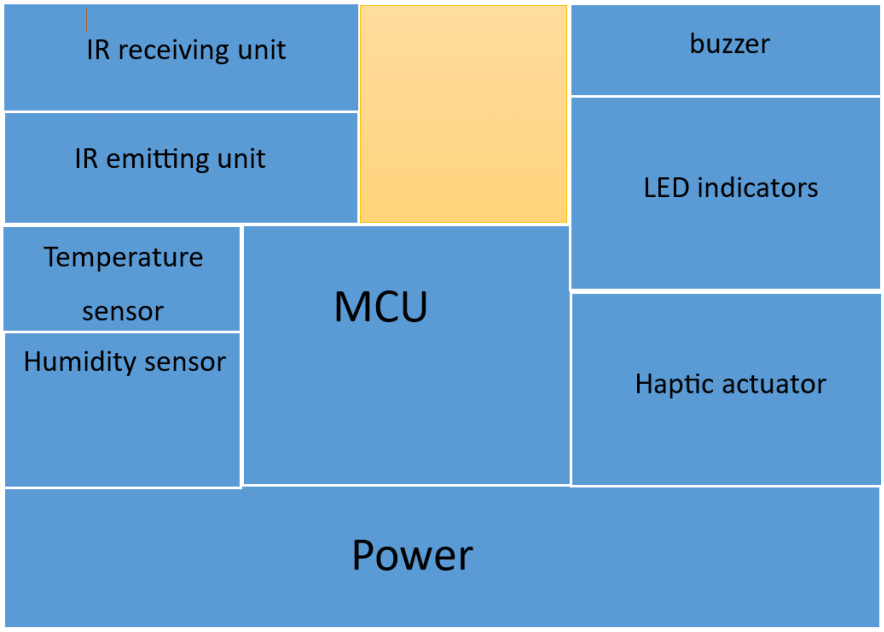
Here are some of the advantages of non-invasive blood sugar measurement technologies:

- Convenience: Non-invasive blood sugar measurement would be more convenient than current methods, which require a finger prick to draw blood.
- Painlessness: Non-invasive blood sugar measurement would be painless, unlike current methods, which can be painful.
- Accuracy: Non-invasive blood sugar measurement would be more accurate than current methods, which can be inaccurate.

Non-invasive blood sugar measurement technologies have the potential to improve the lives of people with diabetes. They would make it easier for people with diabetes to manage their condition and reduce the risk of complications.

Proof of Concept

After finalizing that we are going to use NIR technology to measure glucose level in blood, we have come-up with a high level block diagram for our device.



Power: The power unit of our device consists of a micro battery, a power management circuit, and a voltage regulator. The micro battery is the primary power source for the device and is a lithium-ion battery. The power management circuit regulates the power from the micro battery to ensure that the device does not draw too much power. It also protects the micro battery from damage. The voltage regulator converts the voltage from the micro battery to a voltage that is compatible with the device.

MCU: The EFM8BB52F32I-C-QFN20 is an 8-bit microcontroller (MCU) based on the Energy Micro EFM8 microcontroller platform. It is designed for battery-powered applications and features a 32 kB Flash memory, 2.3 kB RAM, and a 50 MHz CPU. The MCU also includes a variety of peripherals, including a 16-bit timer, a 12-bit ADC, and a UART. The EFM8BB52F32I-C-QFN20 is available in a small, 20-pin QFN package and is well-suited for a variety of battery-powered applications, such as wearables, sensors, and Internet of Things (IoT) devices.

Here are some of the key features of the EFM8BB52F32I-C-QFN20 MCU:

- 32 kB Flash memory
- 2.3 kB RAM
- 50 MHz CPU
- 16-bit timer
- 12-bit ADC
- UART
- Small, 20-pin QFN package

The EFM8BB52F32I-C-QFN20 MCU is a powerful and versatile MCU that is well-suited for a variety of battery-powered applications. It offers a number of features that make it ideal for these applications, including a large Flash memory, a fast CPU, and a variety of peripherals. The MCU is also available in a small, 20-pin QFN package, which makes it easy to integrate into a variety of designs.

IR emitting unit: It is made up of a array of infrared-emitting diodes (IREDs) that are arranged in a linear or two-dimensional array. The IREDs are typically made of gallium arsenide (GaAs) or indium gallium arsenide (InGaAs). In our device we use gallium arsenide (GaAs).

The IR emitter diode array in a NIR spectroscopy glucometer is used to provide a broadband source of infrared light. The broadband light is then passed through the skin, and the amount of light that is absorbed is measured. The absorption spectrum is then used to calculate the blood glucose level.

IR emitter diode arrays offer several advantages over other types of infrared light sources, such as tungsten halogen lamps. They are more efficient, produce less heat, and have a wider spectral range. This makes them ideal for use in NIR spectroscopy glucometers, where high sensitivity and accuracy are required. Here are some of the key features of IR emitter diode arrays:

- · Broadband light source
- · High efficiency
- · Low heat output
- · Wide spectral range

IR emitter diode arrays are a versatile and powerful tool that can be used in a variety of applications. They are particularly well-suited for use in NIR spectroscopy glucometers, where high sensitivity and accuracy are required.

IR receiving unit: The InGaAs photodiode array is a type of IR receiving array that is commonly used in NIR spectroscopy devices. It is made up of a series of indium gallium arsenide (InGaAs) photodiodes that are arranged in a linear or two-dimensional array. The InGaAs photodiodes are sensitive to infrared light in the near-infrared (NIR) spectrum, which makes them well-suited for use in NIR spectroscopy devices.NIR spectroscopy devices use IR receiving arrays to measure the absorption of infrared light by materials. The absorption spectrum can be used to identify and quantify the chemical composition of the material. InGaAs photodiode arrays are a valuable tool for NIR spectroscopy devices because they are sensitive to NIR light and have a wide spectral range.

Temperature and humidity sensor:The amount of absorption can also be affected by temperature and humidity. This is because the absorption of infrared light by water and other molecules in the skin increases with temperature and humidity. This can lead to errors in the measurement of glucose levels.

To correct for these errors, glucometers that use NIR technology must take temperature and humidity readings into account. They do this by using a calibration curve that has been generated for different temperature and humidity conditions. The calibration curve shows how the amount of absorption changes with temperature and humidity.

By taking temperature and humidity readings and using a calibration curve, glucometers that use NIR technology can provide accurate measurements of glucose levels, even in changing environmental conditions.

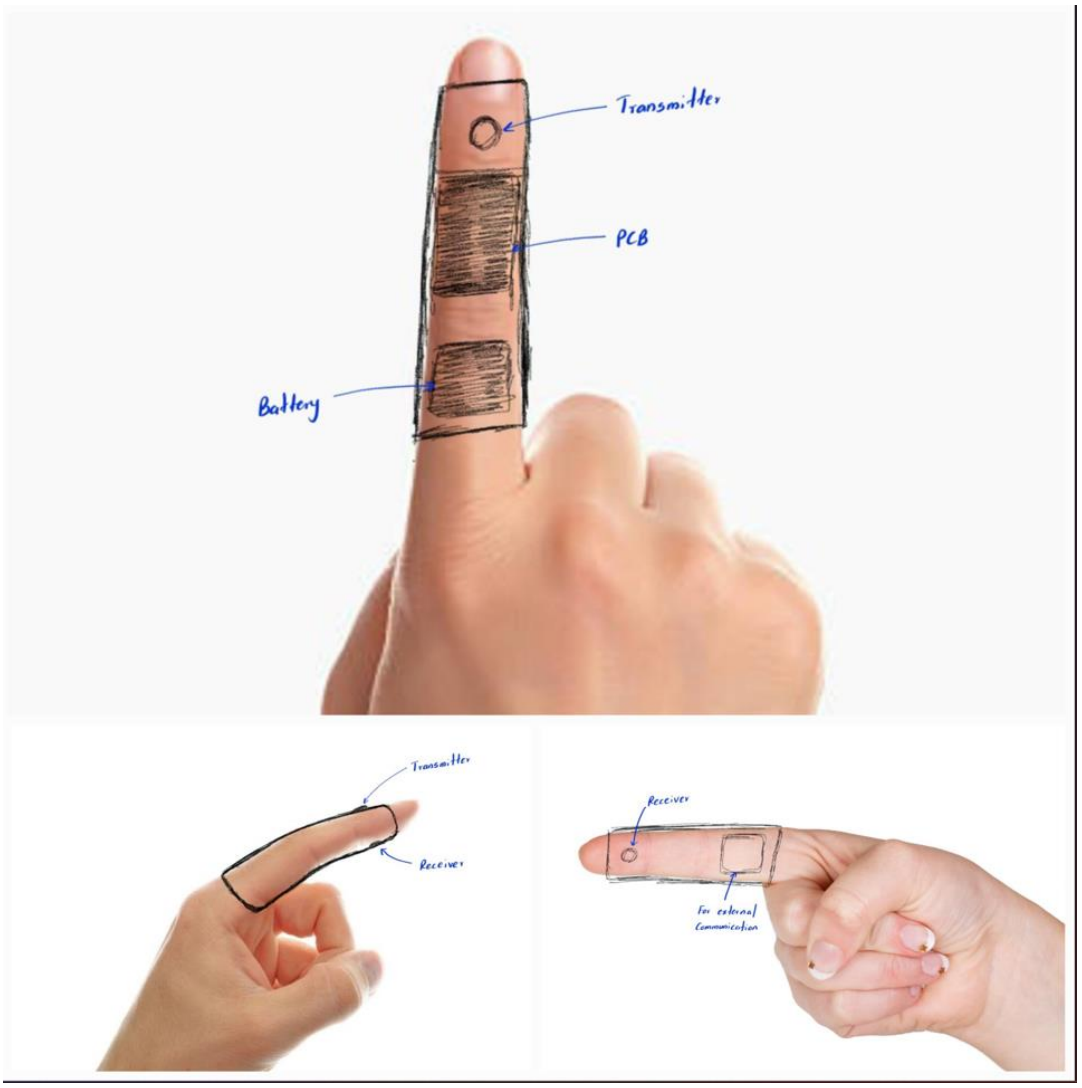
Here are some additional details about how temperature and humidity can affect NIR spectroscopy measurements:

- Temperature: The absorption of infrared light by water and other molecules in the skin increases with temperature. This is because the molecules vibrate more rapidly at higher temperatures, which causes them to absorb more light.
- Humidity: The absorption of infrared light by water vapor also increases with humidity. This is because water vapor molecules are more abundant in humid air, which means that there are more molecules to absorb light.
- The effects of temperature and humidity on NIR spectroscopy measurements can be significant. In some cases, the errors can be as large as 10%. This is why it is important for glucometers that use NIR technology to take temperature and humidity readings into account.

Haptic actuator and buzzer: are used to warn when glucose level deviates from usual range. A haptic actuator is a device that can create a tactile sensation, such as vibration or a pulsing sensation. This can be used to provide feedback to users, such as to warn them when their glucose level is out of range.

LED indicators: are used to indicate user different conditions.(for instance battery low condition)

Proposed Design concept.



Calibration process

1. Data acquisition: Gather a dataset of NIR spectral data along with corresponding blood glucose levels from many individuals. This dataset should include measurements obtained from the device and reference glucose values obtained through invasive methods.

2. Preprocessing: Preprocess the NIR spectral data by removing noise, artifacts, and any inconsistencies. Apply techniques such as spectral smoothing, baseline correction, or outlier removal to ensure high-quality data.

3. Model selection: Evaluate existing calibration models that have been developed for non-invasive blood glucose monitoring using NIR technology. Consider factors such as their performance, accuracy, and suitability for your specific device and dataset.

4. Model modification: Select the most appropriate existing model and modify it to suit your device. This modification may involve adjusting model parameters, incorporating device-specific characteristics, or adapting the model to the specific data preprocessing steps used.

5. Model evaluation: Assess the performance of the modified model by validating it with a separate dataset or using cross-validation techniques. This evaluation helps determine the model's accuracy, precision, and reliability in predicting blood glucose levels from the NIR spectral data.

6. Iterative refinement: If the modified model's performance is not satisfactory, refine and optimize it by adjusting parameters, modifying preprocessing techniques, or exploring alternative algorithms. This iterative process aims to improve the model's accuracy and ensure it meets the required performance criteria.

7. Independent validation: Validate the final modified model using an independent dataset that was not used during the modification process. This validation step verifies the model's performance with new, unseen data and helps establish its generalizability and reliability.

8. post-market monitoring: Continuously monitor the device's performance and the accuracy of the calibrated model in real-world settings. Collect data from users and compare the non-invasive measurements with invasive blood glucose tests to ensure ongoing accuracy and reliability.

> During the calibration process, it is important to adhere to relevant regulations, standards, and guidelines governing non-invasive medical devices. Collaborating with experts in spectroscopy, medical device development, and data analysis can help ensure the successful modification and calibration of the blood glucose monitoring device using NIR technology.

> **Sustainability**
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> Under this, there are 13 targets and our product goes under target 3.4 which is, *" By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being"*. Under this we are fulfilling the indicator which is reducing mortality rates attributed to cardiovascular disease, cancer, diabetes or chronic respiratory disease.

Good Health and Well-being (SDG 3): Our goal is to reduce the mortality rate whilst supporting the movement of making healthcare affordable and accessible for everyone, including the population of developing countries. Our device helps individuals with diabetes maintain better health and well-being by providing timely alerts in Hypoglycaemia situations. By preventing and managing hypoglycemic episodes, it supports overall health and reduces the risk of complications.

Industry, Innovation, and Infrastructure (SDG 9): The development of Our device represents innovation in healthcare technology. It contributes to the advancement of infrastructure in the medical field by introducing a new tool that aids in monitoring and managing blood glucose levels effectively.

Sustainable Cities and Communities (SDG 11): Our device enhances the quality of life for individuals with diabetes, enabling them to live more safely and comfortably within their communities. By helping them avoid hypoglycemic situations, it promotes independence and active participation in community life.

Responsible Consumption and Production (SDG 12): Our device supports responsible consumption by assisting individuals in managing their blood glucose levels optimally. By avoiding unnecessary fluctuations and emergency situations, it reduces the need for excessive consumption of medical resources and minimizes waste.

Partnerships for the Goals (SDG 17): Collaborating with healthcare professionals, organizations, and communities to implement our device fosters partnerships aimed at achieving the Sustainable Development Goals. By working together, you can ensure widespread access to the device, knowledge sharing, and continuous improvements in diabetes management.

These contributions highlight the positive impact your device can have on health, innovation, community well-being, resource efficiency, and collaborative efforts towards sustainable development.

Social and Environmental Impact Assessment

The development of a device to provide alerts for Hypoglycaemia has the potential to create significant social and environmental impacts. By addressing the critical issue of Hypoglycaemia detection and prevention, this initiative aims to improve the safety, well-being, and quality of life for individuals living with diabetes. Additionally, it presents an opportunity to empower patients, reduce healthcare costs, and even contribute to environmental sustainability.We will explore the far-reaching implications of this device, highlighting its potential to save lives, enhance patient autonomy, and foster a more sustainable healthcare system. By understanding the social and environmental impacts, we can appreciate the transformative nature of this innovation and the positive change it can bring to individuals, communities, and the world at large.

Improved Safety and Well-being: The device can significantly improve the safety and well-being of individuals with diabetes, especially during the night when the risk of Hypoglycaemia is heightened. By providing real-time alerts, it can help prevent severe hypoglycemic episodes, reduce the risk of unconsciousness or seizures, and potentially save lives.

Enhanced Quality of Life: Individuals with diabetes often experience anxiety and stress related to managing their blood sugar levels. By offering a reliable alert system, the device can alleviate some of

this burden and provide peace of mind. It can enable individuals to sleep better, knowing that they will be alerted if their blood sugar levels drop dangerously low.

Empowerment and Independence: The device promotes patient empowerment by allowing individuals to take control of their health. With timely alerts, they can take necessary actions to prevent hypoglycemic episodes or seek appropriate medical assistance. This promotes self-management of diabetes, leading to increased independence and improved overall quality of life.

Reduced Healthcare Costs: Hypoglycemic episodes can result in emergency room visits, hospitalizations, and other healthcare expenses. By preventing severe episodes and related complications, the device can help reduce healthcare costs associated with the management of Hypoglycaemia. It may also contribute to more efficient allocation of healthcare resources.

Environmental Benefits: The development of a device focused on alerting Hypoglycaemia can potentially reduce the environmental impact associated with emergency medical interventions. By minimizing the occurrence of severe hypoglycemic episodes, it can decrease the need for emergency medical services and associated transportation, thus reducing carbon emissions and resource utilization.

Overall, the device's social and environmental impacts include improved safety, enhanced quality of life, patient empowerment, reduced healthcare costs, and potential environmental benefits.

Market Space

Individuals with diabetes: Our device can directly target individuals with diabetes who are at risk of experiencing hypoglycemic episodes. This includes people with type 1 diabetes, type 2 diabetes, and other forms of the condition.

Healthcare facilities: Hospitals, clinics, and other healthcare facilities can benefit from our device by incorporating it into their diabetes management protocols. It can be used in emergency rooms, diabetes clinics, and other relevant departments.

Home healthcare: Our device can be marketed to home healthcare providers who offer services to individuals with diabetes. It can assist caregivers in monitoring and responding to hypoglycemic situations, providing peace of mind to both patients and their families.

Diabetes education and support organizations: Organizations that provide diabetes education and support, such as diabetes associations and advocacy groups, can be potential partners or customers for our device. It can be integrated into their programs or recommended as a helpful tool for their members.

Insurance companies: Insurance companies may be interested in your device as it can potentially contribute to better health outcomes for individuals with diabetes. They may consider covering the cost or providing incentives for policyholders who use our device.

Pharmacies and medical suppliers: Partnering with pharmacies or medical suppliers can help distribute your device to a wider market. These businesses can offer your device to customers as part of their diabetes management product line.

Budget Analysis

BOM of first prototype	quantity	unit price	cost
MCU	1	$9.99	$9.99
IR emitters	10	$5	$50
IR emitting contrling IC	1	$2	$2
IR recievers	10	$5	$50
temperature sensor	1	$5	$5
humidity sensor	1	$2	$2
buzzer	1	$2	$2
micro battarery(li-ion)	2	$5	$10
heptic actuator	1	$3	$3
leds	3	$1	$3
Total cost			$136.99