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Original Article

Non-Invasive Blood Glucose Monitoring System Using Near-Infrared Spectroscopy: A Prototype Design

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Abstract *- This research study focuses on designing a non-invasive prototype for monitoring blood glucose levels using near-infrared spectroscopy. Diabetes is one of the most common chronic diseases globally, and the invasive methods do not always offer accurate readings as they are affected by several factors, such as the presence of dirt on the skin, not applying enough blood to the strip, and more. Hence, discovering non-invasive methods is essential for painless and accurate detection of blood glucose concentrations. The rationale for this new research lies in the development of novel methods to monitor blood glucose levels. The research methods involve ideating and designing a prototype of the device, involving the required hardware components as well as the key software filters needed for the device to function effectively. The study's significant findings demonstrate that it is possible to detect blood glucose levels using NIR light and analyze them using a photodiode and a microcontroller, making future enhancements in this field possible. The significance of this study lies in its contribution to improving the current methods for monitoring glucose levels by making sure the newer method is painless, reliable and not impacted by external factors.*

Keywords *- Blood glucose levels, Light intensity, Near-Infrared Spectroscopy, NIR wavelength, Tissue.*

1. Introduction

The prevalence of diabetes occurs when blood glucose or blood sugar is excessive. [1] It arises when the body is not reacting appropriately to the effects of insulin or when the pancreas does not generate enough or any insulin at all. People with diabetes affect people of all ages.[2] In 1990, 7% of adults aged 18 and over had diabetes; by 2022, that number had risen to 14%.[3] Diabetes was the cause of 1.6 million fatalities in 2021, with 47% of all diabetes-related deaths occurring in people under 70.[3] High blood glucose is responsible for about 11% of cardiovascular deaths, and diabetes also contributes to 530,000 deaths from kidney disease.

[3] One of the most common methods of checking blood sugar glucose levels is finger-stick glucose monitoring. However, there are several drawbacks, including the physical pain of finger pricking as well as numerous inaccuracies associated with it. Accuracy can be further compromised by potential user errors, such as adding too little blood to the strip, using outdated or excessively moist or humid strips, or forgetting to enter the correct code (which is necessary for certain but not all systems).[4]Furthermore, severe temperatures, alcohol, dirt, or other contaminants on the user's skin, as well as the quantity of red blood cells in the user's blood, are additional factors that impact accuracy. [5]

Some of these obstacles may be removed by potential non-invasive devices, which may also improve adherence to blood glucose tests.[6] While minimally invasive blood glucose monitoring devices are more stable and have a shorter lifespan, intrusive devices are uncomfortable and inconvenient.

[7] One technique that uses the near-infrared portion of the electromagnetic spectrum (about 700–2500 nanometres) is NIR spectroscopy. Without changing the sample, NIR reflectance spectra can be used to rapidly determine a material's characteristics by measuring the amount of light scattered off and through it.

[8] In order to quantitatively analyze glucose concentrations, NIR spectroscopy depends on the interaction of NIR light with biological tissues, wherein particular wavelengths are absorbed or scattered by glucose molecules.[9] By measuring the amount of near-infrared radiation that a compound or solution absorbs, NIR spectroscopy, also known as near-infrared spectrophotometry (NIRS), is an absorption spectroscopy technique that aids in determining the chemical composition of the substance. [11] Wavelengths of near-infrared radiation span the 700–2500 nm range and are marginally longer than visible light.[11]

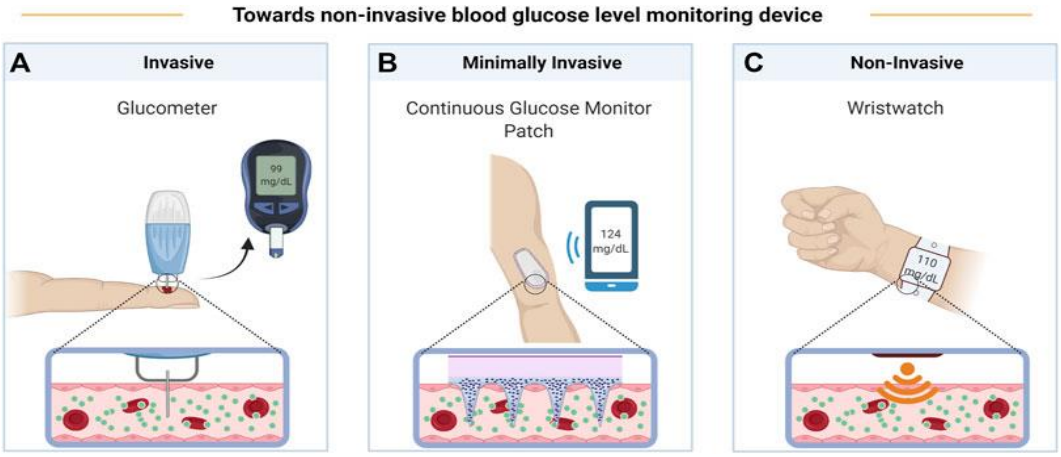

Fig. 1 Different methods for monitoring blood glucose levels[11]

There are multiple ways that light can interact with biological tissues. When light enters the tissue, it is often absorbed, dispersed, or reflected by molecules in the tissue.[13] The most important wavelength range for glucose absorption is 1.2 to 2.5 μm.[14] NIR light travels into the tissue, and the amount of light reflected to a detector is measured as part of the non-invasive glucose monitoring procedure. The amount of NIR light that is absorbed or reflected varies as blood passes through the tissue, making it possible to detect glucose.[15] The Bouguer–Beer–Lambert equation has been used to precisely characterize the linear connection between absorbance and the concentration of an absorbing chemical in near-infrared spectroscopy (NIRS).[16] According to this law, a substance's ability to attenuate (or absorb) light is determined by its chemical composition.[17] According to the Beer-Lambert law, the amount of light attenuation via a medium (Aλ) is proportional to the optical characteristics of the light absorber (εK(λ)), the concentration of light absorbers in the substance (CK), and the optical path length (L) that the light beam travels. [18] The constant DPF, or differential pathlength factor, is the increase in the light pathlength caused by scattering, and d is the distance between the light emitter and detector.[18] Therefore, by employing the Beer-Lambert law, the light absorption can be related to the glucose concentration.

(1)[18]$A\lambda = \varepsilon(HHb\lambda)C(HHb) + \varepsilon(HbO2\lambda)C(HbO2) * d * DPF + G$

Since tissue penetration is at its highest in the red to near-infrared window (650–1360 nm), this is the therapeutic window for light propagation.[19] At a depth of 3 cm, NIR with a power range of 10–15 W at 810 and 980 nm can produce fluence within the range that has been demonstrated to be biologically advantageous.[20] Due to the low scattering and absorption coefficients of light for the tissue in this window, light diffuses through the tissue more easily, increasing penetration.[19] High glucose sensitivity occurs between 1350 and 1700 nm. However, the 1500–1700 nm range is thought to be more appropriate for glucose sensing due to the significant absorption of water around 1450 nm.[21]Therefore, the ideal wavelength range chosen for this paper is the range of 1500-1700nm.

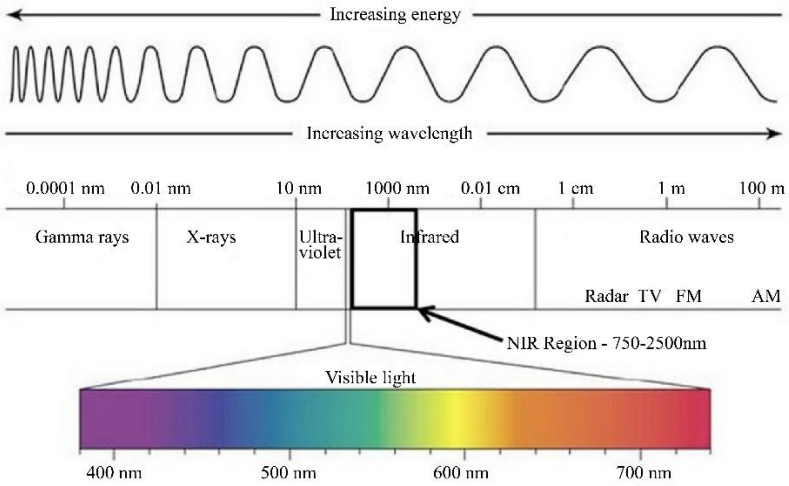

Fig. 2 Highlighted NIR region on electromagnetic spectrum [13]

The prevalent research gap is that minimal research is conducted on developing a prototype that is simple, reliable, and affordable. Most of the research conducted focuses on the theoretical aspect of near-infrared spectroscopy for determining glucose levels. Instead, this research paper explores the creation of a practical and tangible medical device prototype, outlining both its hardware and software facets.

Additionally, no hardware or physical designs of the device have been published to further enhance and improve the structure and construction of the medical device. Moreover, there has been little research on identifying and establishing the controlled variables, such as the wavelength to be emitted by the LED and the specific part of the body where the glucose is monitored. In contrast, the earlobe or the fingertip is chosen for this paper.

Plus, no prototype has been published that is designed according to pre-established controlled variables. From an extensive literature review, "Thus, there is a need for an economic, compact, painless, and convenient non-invasive device that can facilitate frequent blood testing, thereby aiding in the control of blood glucose levels." [8]. Thus, the question of ideating, designing, and building an effective prototype has not been studied yet, and it is what this paper aims to explore. This research area of developing a prototype has not been investigated previously. Hence, through the system design methodology, this study aspires to solve the problem by researching the creation of an effective, simple, and affordable prototype and delving deeper into both its hardware and software aspects.

This project aims to develop a prototype that utilizes near-infrared (NIR) spectroscopy for non-invasive glucose detection through human tissue. The objective is to ideate, identify the required components, design, and develop a prototype that focuses on core functionality, incorporating only the necessary components, minimizing design complexities.

This will serve as an initial step toward the development of affordable non-invasive glucose monitoring technologies for future clinical and personal health applications. The findings of this study contribute towards establishing a foundational understanding of the technical feasibility as well as the limitations associated with the NIR spectroscopy for non-invasive glucose monitoring. It also allows the prototype to guide future improvements in sensor design and data processing.

2. Materials and Methods

2.1. Research Aim

This research paper aims to develop a simple, affordable, and efficient prototype of a non-invasive blood glucose level monitoring device using near-infrared spectroscopy. The paper aspires to identify the required components, design the signal flow, ideate the medical device hardware design, and build a prototype of the design.

2.2. Materials Used

Table 1. Hardware components and their use

Serial Number	Name of hardware component	Description
1	NIR Light source (LED)	The wavelength the LED emits is 1500-1700nm. The LED emits NIR light, which is absorbed by the glucose.
2	Photodiode (TEMT6000)	This detects the changes in the light intensity of NIR after the tissue interaction. It is sensitive to the NIR range.
3	LCD Display	This displays the estimated blood glucose levels to the user.
4	Analogue Front End (MAX30102)	This amplifies the weak signals from the photodiode.
5	Microcontroller (Arduino)	This reads the data and processes it using the code it stores. It stores the data and interfaces with software.
6	9V Battery	This provides the device with a power supply.

The components required for the medical device are listed in Table 1 above.

The digital tools used to build the prototype are OnShape for creating the Computer-Aided Design (CAD) and Sketchbook for creating multiple drafts of the enclosure design.

2.3. System Design

2.3.1 Signal Flow and Block Diagram

Firstly, it is essential to design a signal flow to establish the pathway that the device, as illustrated in Figure 4, follows. After identifying the required hardware components, they can be incorporated into the signal flow to create the block diagram of the prototype, as shown in Figure 5.

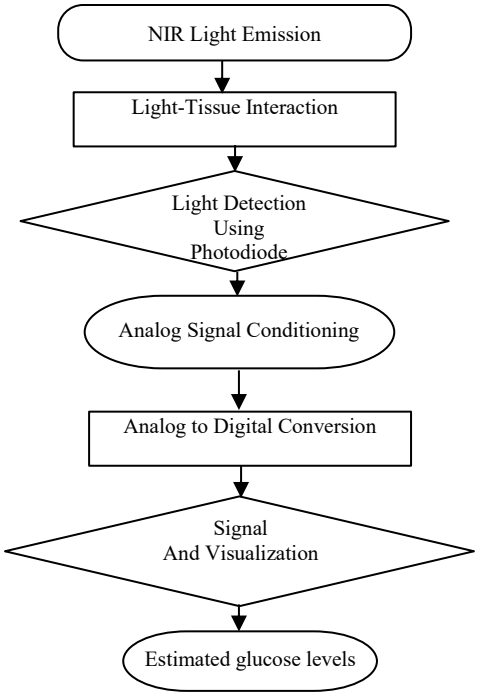

Fig. 4 Signal Flow of Prototype

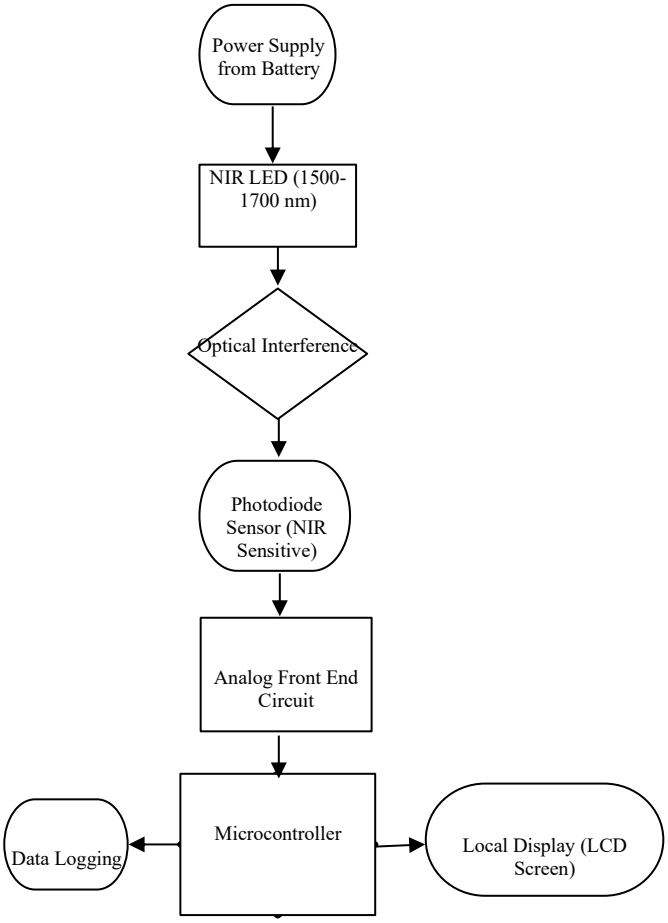

Fig. 5 Block Diagram of Prototype

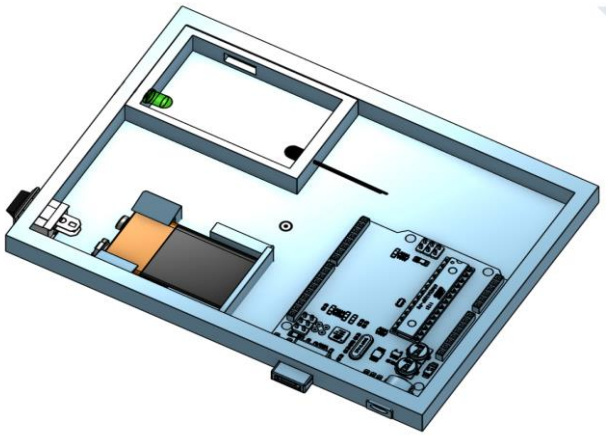

Fig. 6 Top, Front, and Side views of the Enclosure (Lid and Box)

2.3.2. Enclosure Design

The enclosure has to be ideated, sketched, and designed to fulfil all its requirements. The enclosure image concept must be created to ensure it can accommodate an LCD screen to display glucose levels to the user. It must have space to place the fingertip or earlobe, which are the specific areas where the LED emits NIR light. There must be space to house the Arduino, the LED, the photodiode, and space to code the Arduino and connect it to a laptop.

The box needs to block external light from reaching the skin to ensure that only the change in NIR light is detected by the photodiode. Figures 6 and 7 visually depict the enclosure in two and three dimensions.

2.3.3. Data Processing

Four main interactions can happen when optical or electromagnetic waves pass through biological tissue: transmission, absorption, scattering, and reflection.[22] Transmission is the movement of waves or light through tissue. Different molecules interact with the light or waves; some of these molecules absorb the light or waves, while the remainder pass through the tissue.[23] This interaction of light with glucose is detected by the photodiode, which is connected to the Arduino.

A popular normalization method is multiplicative scatter correction (MSC).[24] By applying the linear least squares method to fit a linear model between a reference spectrum and other dataset spectra, MSC reduces these variances.[25] There are two mathematical phases involved in the multiplicative scatter correction of the mean spectrum (X_m). Regress each spectrum (X_i) against the mean spectrum in step one. Ordinary least squares is used for this: $X_i \approx a_i + b_i X_m$. The adjusted spectrum, $X_i^{msc} = (X_i - a_i)/b_i$, should then be computed.[26] Moreover, the plan for the project involves measuring the blood glucose levels of multiple users and creating a calibration curve to make accurate estimations of glucose concentration.

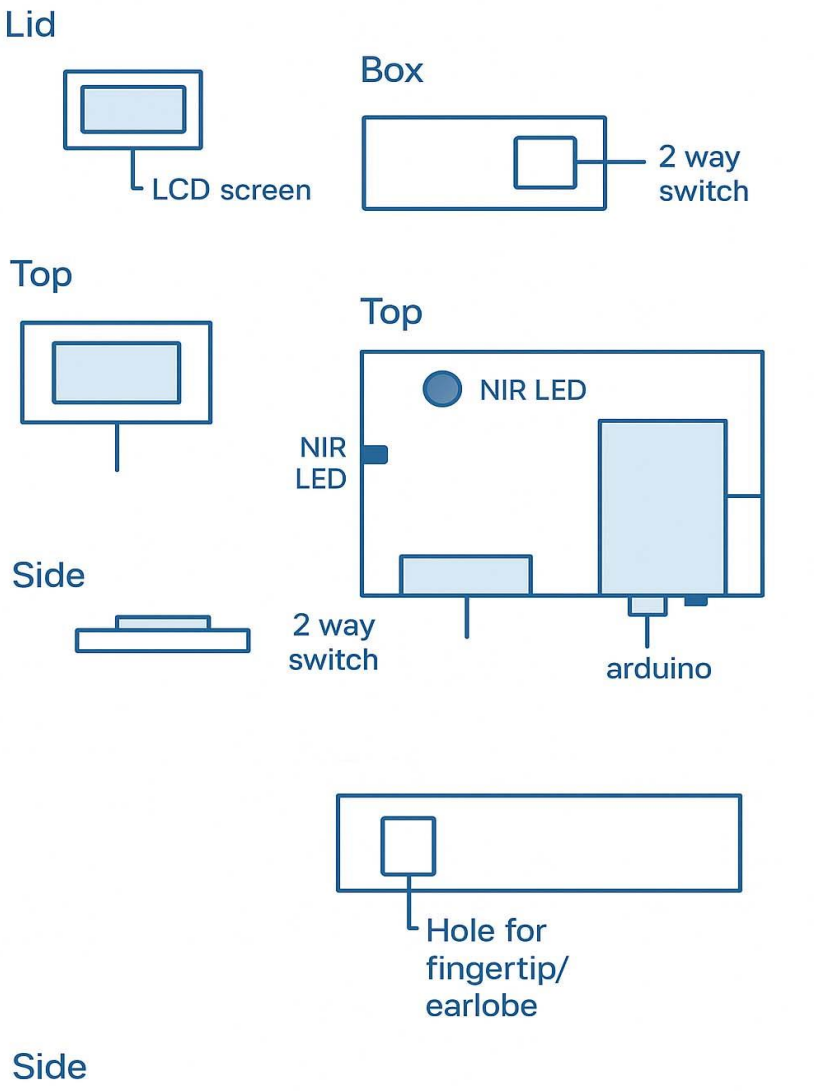

Fig. 7 CAD sketch of the box

3. Results and Discussion

As the device is still a prototype, these are the expected results for monitoring blood glucose levels using NIR spectroscopy. Primarily, the device is expected to detect light transmitted through or reflected from the user's earlobe or fingertip tissue using the photodiode. A key observation in the detected light is that there must be a drop in the light intensity due to the absorption as well as scattering effects of the biological tissue because of its inner components, such as water, fat, and haemoglobin. Moreover, when the glucose levels are measured under the same conditions involving the pressure and the position of the earlobe/ fingertip, it is expected that the device will show consistent glucose levels and become a reliable detector for monitoring blood glucose concentrations. In addition, a significant feature of the device is its ability to differentiate between the type of tissue, such as earlobe vs fingertip. There would be slight variations in the magnitude due to the changes in the skin, including the thickness, the levels of hydration, or even the vascularization. Further, the hardware and software components are expected to function according to the block diagram above, indicating that they are effectively completing their roles to determine the glucose levels. For example, the filter is expected to be implemented successfully, and the NIR LED is expected to turn on when the user turns on the two-way switch. Nevertheless, the glucose concentrations determined by the device have not been completely verified, as they have not been calibrated yet. Hence, suggesting that the device would yield blood glucose levels that are close to the accurate readings conducted by an invasive glucometer. Lastly, this prototype serves as a tool for future enhancements, such as including multiple wavelengths to reach different layers of the skin, as well as implementing a calibration curve to improve the accuracy and reliability of the blood glucose level readings.

This research paper was able to achieve better results in designing a prototype compared to the studies because this paper focused on identifying and establishing controlled variables or constraints, such as the part of the body where the glucose is measured, which was restricted to only 2 parts, the fingertip and the earlobe. Moreover, this paper was able to utilize those controlled variables and make a physical design for the medical device. In addition, this paper was able to achieve better results as it is able to identify the key components to reduce the design complexity as well as make the device simple yet effective, as numerous other studies have significantly more complicated signal flow and block diagrams, making it more complicated to develop the medical device further. Furthermore, the current research outlines how, due to the different tissue structure, it would lead to different results, and hence establishing controlled variables would help eliminate this problem, as the same part of the body will be used in all the measurements to avoid any error in the trials. Plus, the design of the box is made from plastic, which would prevent the light from entering and affecting the results, which is not present in the current research findings, as the prototypes developed are purely theoretical. Lastly, in most of the other research findings, there is no LCD screen to immediately show the users their blood glucose levels and the sudden fluctuations or changes in them, which is incorporated into this prototype to ensure the user has a smoother experience.

3.1. Limitations

The hardware limitations of the device include the fact that inexpensive NIR LEDs may not emit light at the specified wavelength. Moreover, if the photodiode is a faulty piece, it will not be able to detect changes in light intensity, causing the device to malfunction entirely. Therefore, it is essential to test the NIR LED and the photodiode before adding them to the box. Secondly, a key limitation is the biological noise caused by the presence of fat and water, which affects the transmission of light. Additionally, there would be a slight variation in glucose concentration due to differences in tissue type, such as between the earlobe and the fingertip. This is due to differences in skin thickness, hydration, or even vascularization underneath. Further, due to the lack of a calibration curve, the readings provided by the device are close to the actual values. However, they are not entirely valid or reliable, as they are verified using a calibration curve constructed from clinical glucose readings. Plus, this device cannot be used to make medical claims; it only offers safe, personal testing.

Additionally, due to the specific style of the box, it cannot be purchased ready-made; instead, it must be 3D printed. As well as there is no lid to cover the hole, hence, the user's fingertip/ earlobe has to cover up the hole entirely and restrict the light outside from entering– considering this is not always practical due to the size and shape of the hole, this may lead to external light entering the chamber and impacting the blood glucose level readings. The placement of the NIR LED makes it very difficult to connect it to the power supply, as the photodiode is easily connected to the Arduino and the battery, as it is outside the NIR chamber. In contrast, the NIR LED is only present inside the chamber, making it challenging to connect it to the rest of the device.

3.2. Future Work

Nevertheless, the device offers considerable scope for future development, such as incorporating high-quality filters to remove the biological noise caused by fat and water molecules within the tissue, in addition to using machine learning and artificial intelligence to analyze the signal data and draw valid conclusions about blood glucose levels.

Additionally, a buzzer can be added to the device to alert the user when glucose levels fall outside the ideal range. Lastly, the system can be made wearable by incorporating it into everyday accessories, such as watches, to help monitor patients with diabetes and log their blood glucose levels throughout the day.

4. Conclusion

In conclusion, the need for non-invasive devices for monitoring blood glucose levels is essential as it allows the user to get accurate measurements of their glucose levels without the pain of daily finger pricking of the invasive monitoring methods or the inaccuracies of the invasive methods due to several reasons such as applying insufficient blood to the strip or the number of red blood cells or the presence of dirt or other substances on the user's fingers.

This prototype serves as a foundation for the development of accurate blood glucose level monitoring using non-invasive methods, such as Near-Infrared (NIR) spectroscopy. This device is very simple and easy to use, allowing users to monitor their glucose levels without finger pricking or other invasive methods. This device serves as a scope for future improvements, supports feasibility, and prioritizes user comfort.

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