Design and Development of continues Non-invasive Glucometer Systems using Near-infrared spectroscopy

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1. Abstract

Diabetes is a chronic disease that affects millions of people worldwide. One of the most important aspects of managing diabetes is monitoring blood glucose levels regularly. However, traditional methods of glucose monitoring such as finger pricking can be painful and inconvenient for patients. In recent years, noninvasive methods for glucose monitoring have gained significant attention in the medical community. Near-infrared spectroscopy (NIRS) is one such technique that has shown promising results in non-invasive glucose monitoring. In this graduation project proposal, we aim to present the history of the design and development of noninvasive glucometer systems, explain why we chose NIRS technology and the essential components of the design and development of non-invasive glucometer systems using NIRS. The proposed system will provide maximum accuracy in obtaining estimated glucose values, which falls within the clinically acceptable regions, which enable the system to give an even more accurate diagnosis using Machine Learning technique.

2. Introduction:

The World Health Organization (WHO) listed diabetes as one of the most prevalent epidemic diseases due to its increasing prevalence and impact on global health. Diabetes is a chronic disease that affects the body's ability to produce or use insulin, leading to high levels of glucose in the blood. According to WHO, the number of people with diabetes has risen from 108 million in 1980 to 422 million in 2014. This increase is attributed to several factors, including aging populations, unhealthy diets, physical inactivity, and obesity. Diabetes is also a major cause of premature death and disability worldwide. It can lead to serious complications such as heart disease, stroke, kidney failure, blindness, and amputations. WHO estimates that diabetes caused 1.5 million deaths in 2019 alone. Given its significant impact on global health and the increasing number of people affected by it, diabetes has been listed as one of the most prevalent epidemic diseases by WHO. The organization has called for urgent action to prevent and manage diabetes through public health interventions such as promoting healthy lifestyles and improving access to healthcare services.

Self-monitoring of blood glucose (SMBG) is a critical component of diabetes management. It involves checking one's blood glucose levels regularly using a glucose meter or continuous glucose monitoring system. The need for SMBG is to maintain optimal blood glucose levels, prevent complications (such as nerve damage, kidney disease, blindness, and cardiovascular disease), adjust medication dosage, identify patterns

(such as high or low blood glucose levels) and to improve quality of life.

Non-invasive glucose monitoring techniques provide a more comfortable, convenient, safe, and cost-effective way to monitor blood sugar levels compared to invasive methods. They also provide continuous monitoring without interrupting daily activities or sleep patterns. This proposal is going to discuss why the using of NIRS technology in non-invasive glucose monitoring systems is an attractive option for people with diabetes who want an accurate, painless, and convenient way to monitor their glucose levels.

3. Problem statement:

- The need for a non-invasive blood glucose monitoring system that can obtain estimated glucose values that are accurate enough to be clinically acceptable.
- Most NIRS glucometers are not small enough to be wearable nor mobile at the same time.
- The patient has to go to a physician or have his results been sent to one in order to get a proper diagnosis, which make the conventional systems are not practical in some emergency vital cases.

4. Objectives:

- To review the historical development of noninvasive blood glucose measurement systems.
- Explain the reasons behind choosing the proposed system.
- Identify the components and working principle of the proposed system.
- Identify the best algorithm that provide the most accuracy

5. Literature Review

a. History of Design and Development of a Noninvasive Glucometer Systems:

The first non-invasive glucometer system was developed in the

1970s by Dr. Leland Clark Jr., who invented the first glucose electrode in 1962. The system used infrared spectroscopy to measure blood glucose levels without the need for a blood sample. However, this system was not commercially viable due to its high cost, complexity and not accurate enough for clinical use

In the 1990s, researchers began exploring the use of optical techniques such as near-infrared spectroscopy (NIRS), Raman spectroscopy, and optical coherence tomography (OCT). These methods were based on the principle that different molecules absorb light at different wavelengths, allowing for the measurement of glucose levels in the blood.

In 1997, a team at MIT developed a noninvasive glucometer system based on NIRS technology. The device used a small sensor placed on the earlobe to measure glucose levels in real-time. However, this device was not commercially successful due to its high cost and limited accuracy.

In 1998, a company called GlucoLight Corporation developed a non-invasive glucometer system based on NIRS technology. The device used a small sensor placed on the skin to measure glucose levels in the interstitial fluid. However, this device was not accurate enough for clinical use.

In 2017, researchers at the University of Leeds developed a device that uses a combination of NIRS and ultrasound technology to measure glucose levels in real-time with high accuracy.

In 2019, researchers from University of Saskatchewan, Saskatoon provided a study reported that Near-Infrared Spectroscopy can be modeled with appropriate machine learning techniques for noninvasive blood glucose monitoring. The experiments were performed on artificial blood sample with different concentrated glucose solutions, and had not been applied to real blood. Thus the collected data does not fully mimic actual varieties of blood glucose levels.

A recent study by Abiodun O. (2022) revealed that using a non-invasive GSM module glucometer to measure blood glucose effectively enhances patient surveillance in diabetes insulin treatment. It was put to the test on 40 individuals. The results showed 99.9% reliability and accuracy of

95.1%.

In 2023 a group from Ramaiah Institute of Technology, Photonics India Venture Private Limited and University of Minnesota presented a

NIRS-based non-invasive glucometer that is modeled using a PSO-ANN regression algorithm continuous glucose monitoring in a pain-free and comfortable manner. the proposed PSO-ANN algorithm achieves maximum accuracy, and minimum RMSE and converges to a global optimum much faster than the traditional BP-ANN. PSO-ANN algorithm outperforms the existing algorithms and we obtain 100% of the estimated glucose values to fall within the clinically acceptable regions. Unfortunately their device was relatively big in size and they did not provide an option for it to be connected with mobile devices.

In recent years, researchers have focused on developing noninvasive glucometer systems based on optical sensors that can be integrated into wearable devices such as smart watches and fitness trackers. These devices are more accurate and affordable non-invasive glucometer systems.

b. Current Developments:

Several companies are currently developing non-invasive glucometer systems using optical sensors. For example, Abbott Laboratories has developed a device called the FreeStyle Libre, which uses a small sensor placed on the skin to measure glucose levels in the interstitial fluid. The device can be worn for up to 14 days and provides continuous glucose monitoring without the need for finger pricking.

Another company called GluSense is developing a non-invasive glucometer system based on an implantable sensor that measures glucose levels in the interstitial fluid. The device uses radio waves to transmit data to a handheld reader, allowing for continuous glucose monitoring.

c. Why did we choose NIRS over other optical techniques?

If we consider some of the most important optical techniques:

i. Surface Plasmon Resonance

| Advantages: |
|---|
| ☐ Highly sensitive to small changes of blood glucose concentration |
| ☐ No need for statistical calibration models due to its conventional electrical model nature. |

Disadvantages:

| ☐ Sensitive to motion. | ☐ Glucose concentrations are too low for accurate detection. |
|---|--|
| ☐ Long calibration process. | |
| ☐ Sensitive to sweat and temperature. | ☐ High scattering level. ☐ Problems of selectivity for determination of glucose. |
| ☐ Bulky in size. | |
| ii. Optical Coherence Tomography | Due to ease of use, Low-cost, and user-friendly biosensors, the noninvasive glucometer (using NIR) has been chosen. |
| Advantages: | |
| \Box Very high resolution. | |
| ☐ High signal to noise ratio. | |
| ☐ High penetration depth. | |
| ☐ Not susceptible to blood pressure, heart rate and hematocrit. | 6. Methodology: Materials: |
| Disadvantages: | |
| ☐ Sensitive to temperature change on the skin and motion. | a Integrated optical sensor modules SFH 7060A |
| ☐ Susceptible to tissue inhomogeneity. | b Microcontroller (ATMEGA328). |
| iii. Near-Infrared Spectroscopy | C GSM module. |
| Advantages: | d Liquid crystal display (LCD). |
| ☐ Water transparent in the NIR band. | e Any sub-sensor needed. |
| ☐ Relatively low-cost materials needed. | Method: When the skin was exposed to the near- infrared sensor transmitter, A combined Vis-NIR is used to |
| ☐ The signal intensity is directly proportional to the concentration of the analyte . | determine a BG concentration continuously and noninvasively. Visible spectroscopy is a technique to determine solution concentration, using interactions of the visible light (380–720 nm) in the |
| ☐ Minimum sample preparation required. | electromagnetic spectrum, with a chemical species, the blood flow signal as an infrared signal is received by the receiver photodiode and late converted to an equivalent voltage, The input features to the neural |
| Method also works in presence of interfering substances, such as glass or plastic containers. | network and analyzed using PSO-ANN Calibration Algorithm. The processed data can send to LCD screen to displays the information. |
| Disadvantages: | 7. Conclusion: |
| ☐ Heterogeneous distributions of glucose can give false readings. | Over the years, there have been numerous technologies explored in the development of |

noninvasive glucometer systems. The use of NIRS

technology has shown great promise due to its ease of use, low cost and user-friendly biosensors. The proposed project aims to design and develop a non-invasive glucometer system using NIRS technology that can accurately measure glucose levels continually. This project has the potential to provide a more convenient and less invasive way for patients to monitor their blood glucose levels and maintain it throw advance technology, We hope that we could replace the invasive and the minimal-invasive devices by a non-invasive one that had good accuracy, and reliable enough to use widely.

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