



Advancing Glucose Monitoring: A Near-Infrared Device for Continuous Non-Invasive Assessment

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A B S T R A C T

Diabetes is a chronic disease that affects millions of people worldwide, with the number of newly diagnosed cases continuing to rise at an alarming rate. Patients diagnosed with diabetes require routine monitoring of their blood glucose levels, which is commonly done through invasive and minimally invasive techniques. However, these methods are often painful, prone to infection, and costly in the long run. Therefore, it is necessary to develop non-invasive, pain-free, affordable glucose monitoring techniques. Near-infrared spectroscopy has emerged as a promising technique among the non-invasive techniques for glucose monitoring, with several studies reporting its efficacy in detecting glucose concentration. This study designed and developed a near-infrared system based on an 1150nm wavelength for continuous non-invasive glucose monitoring. The system gave the output voltages that vary with increased glucose concentrations. It was ascertained from the Clark error grid analysis that the glucose concentration falls within region A and region B. This implies that the device is suitable for measuring glucose concentration non-invasively. As per Bland Altman's analysis, the majority of the data points were within both limits of agreement except one data point that was outside the upper limit of agreement, indicating 93% degree of accuracy, and the residual plot indicates that the regression model for the system is appropriate for predicting non-invasive glucose measurements.

INTRODUCTION

There has been an alarming increase in the number of newly diagnosed diabetic cases across numerous communities globally. This is due to either insufficient insulin release or a body's inability to respond to insulin. The major problems that are associated with the disease are heart failure and blindness, amongst many others [1].

It is estimated that by 2040, 642 million people between the ages of 20 and 79 are expected to have diabetes, according to the WHO's 2015 to 2040 estimate [2]. The estimated annual worldwide death rate is 5 million people. The estimated global spending for disease control is Kshs 74.7 trillion [2].

Kenya, in particular, has a 3.4% prevalence of diabetes and the number of diabetics is expected to reach 500 million by 2044. The average cost of the treatment is Kshs 77,081 per individual. This is about Kshs 38.5 billion [3]. Patients maintain a healthy diet and take insulin to keep their blood sugar levels stable, and routine blood glucose monitoring using invasive and minimally invasive techniques is necessary [4]. Despite being functional, these methods are painful, prone to infections, and expensive [5].

Significant research and development efforts are being made to use a variety of optical approaches to test blood glucose non-invasively. These include Raman Spectroscopy, Fluorescence, Mid Infrared (MIR), Bio-impedance, and Near Infrared (NIR) Spectroscopy. These new technologies present a hope of providing diabetic patients comfort, hope, and relief because they do not require body pricking and are affordable [6]. The quantification of blood glucose is made possible by the variation of light intensity in correlation to transmittance and reflectance. It is established that glucose absorption takes place at 940nm, 1150nm, 1400nm, and 1600nm peak points [7] [8], [9]. In addition, research indicates that compared to other non-invasive techniques, near-infrared (NIR) spectroscopy gives acceptable results, and its accessories are readily available and inexpensive [10]. The application of the NIR method is conceivable since NIR spectroscopy can penetrate the skin up to a depth of 1-100 mm. Water content in blood can be readily avoided by selecting the right wavelength range [4], [11].

As a result of the promising nature of outcomes obtained by using near-infrared techniques to determine glucose non-invasively, numerous studies have been carried out, particularly with the use of near-infrared techniques [12].

The investigation done by [13] used two distinct, independent circuits in their study to estimate blood glucose with IR spectroscopy. The first circuit is a two-step impedance spectroscopy that operates on the electrical property that indirectly influences changes in human tissue, such as blood glucose level. The second circuit used three NIR wavelengths of 850nm, 940nm, and 1300nm. The system addressed the estimation inaccuracy by comparing the outputs of the two circuits and using an artificial neural network via an external processor. The gadget can also dispense insulin automatically to a diabetic patient who is bedridden in the event of a sudden rise in glucose levels. Notwithstanding the positive outcome, the system is bulky and unadaptable. It is not versatile and exclusively designed for bedridden individuals [13].

In their study, [5] adopted an optical approach. They utilized an LED with a wavelength of 940 nm as a transmitter and a phototransistor as a receiver. The findings from their system produced workable results. However, the technique is vulnerable to noise interference. To eliminate interferences, they suggested using signal conditioning in the circuit [5]. In their system, [14] used wavelengths of 940 nm, 1550 nm, and 1650nm and demonstrated that bilirubin and glucose concentrations are monitored non-invasively.

The hybrid of NIR absorption and Bio-Impedance techniques were utilized by [14]. When compared to the other individual methods, the system produced increased accuracy. This is because of 90% and 10%, established from Clarke Error Grid. These are in the accepted zones A and B, respectively. However, it is subjective because it can only be used by trained individuals and is also sensitive to background light [15].

The study by [8] used 940nm and photodiode and constructed a device for non-invasively measuring patients' blood sugar levels. They obtained promising results and suggested more validation on various data samples for increased accuracy. The research by [16] with IR LED of 980nm and photodiode obtained good results, but the system requires noise filtering and amplification to get accurate results. Also, the use of 1310nm by [10] in their research indicates that red laser light at the band detects glucose non-invasively. The comparative study of [17] using dual IR LEDs of 1300nm and 940nm indicates improved performance, efficiency, and accuracy. However, there is still a challenge of noise interferences and calibration. The investigation by [18] using 860nm and 940nm NIR LEDs posited feasible results but were still affected by noise and calibration issues.

The investigation of [19] and [17] pointed out that indirect measurement, calibration, and systemic noise of non-invasive glucose measuring devices are barrier-inhibiting devices for glucose monitoring non-invasively. On the other hand, the report by [17] shows that there is a high potential for the realization of non-invasive glucose measuring devices because of the promising results obtained, irrespective of the limitations.

The current commercially available devices, which are invasive and minimally invasive despite having benefits, are prone to shorter sensor lifetime, prone to infections, and expensive in the long run [20], [21], [22], [23].

As a result of the challenges encountered, the systems already developed have issues of in-accuracy, noise interferences, and calibration [24], [25], [26], [23]. In addition, some of the developed NIR-based systems use 850nm, 940nm, 1300nm, 1450nm, 1550nm, and 1650nm.

Therefore, from the foregoing discussion, it is apparent that no NIR-based device utilizes a transmitter of 1150 nm, irrespective of the fact that this is one of the peak points for glucose absorption. With this perspective, we propose a precise, non-invasive NIR system utilizing 1150-nm wavelength to ascertain the usability of 1150nm for glucose measurement, eliminate noise, and increase accuracy.

MATERIALS AND METHODS

Methods

The principle of transmittance, as per Beer-Lambert's law, was adopted. The law states that “when a beam of monochromatic light is passed through a solution of an absorbing substance, then the rate of decrease in intensity of radiation with the thickness of absorbing solution is directly proportional to intensity as well as to the concentration of the solution.” [4], [27],[28].

The relationship between absorbance (A) and concentration (C) is illustrated in equations (1) and equation (2).

Therefore, absorbance(A) is given by:

$$A = \log \left(\frac{I_0}{I_t} \right) = \epsilon Cl \tag{1}$$

where;

ϵ =absorptivity, l =path length, C =concentration

Hence;

$$A \propto C \tag{2}$$

Beer-Lambert’s conditions were observed during the research. The IR LED produced monochromatic light; homogeneous glucose concentration was prepared, and non-electromagnetic materials were used to eliminate interferences. Furthermore, a distance of 1.9cm was maintained between the IR LED and the photodiode. This allows incident radiation to travel an equal and uniform distance in all the samples while testing. Furthermore, the IR light used does not influence the sample’s molecules or atoms, so glucose concentration is not affected by IR light [27].

Testing was done by in-vitro method. The samples for testing were prepared following the table 1. The purpose was to make solutions that fall into all these categories.

Table 1. Glucose Sugar Levels Ranges

Glucose Levels (mmol/L)	Glucose Levels (PPM)	Indication
3.8 and below	69 and below	Low
3.9 - 5.5	70 - 99	Normal
5.6 - 6.9	100 - 124	Pre-Diabetic
7.0 and above	125 and above	High

Materials

The materials used are IR LED (L13072-0120P) and InGaAs PIN photodiode (G12180-003A) from Hamamatsu Photonics. The

RESULTS AND DISCUSSION

Results

The testing was done by using the in-vitro testing method. Fifteen glucose samples were prepared randomly and used for testing. The output voltages were measured, observed, and tabulated as shown in Table 1.

Table 2. Output Voltages for 1150nm

Glucose Concentration (ppm)	Voltage (mV) ± 5
324	2110
270	1850
216	1520
162	1250
126	950
100.8	870
94.68	755
88.56	720
82.44	675
76.32	650
70.2	630
66.6	595
63	556
59.4	530
55.8	515

It was observed that voltage output also increases as glucose concentration increases. This is determined by the amount of glucose concentration present in the samples. It is also evident that there is a linear relationship between the glucose concentration and the voltage outputs. The results of Table 1 are used to plot a scatter plot graph of voltage output against glucose concentration as shown in Figure 3.

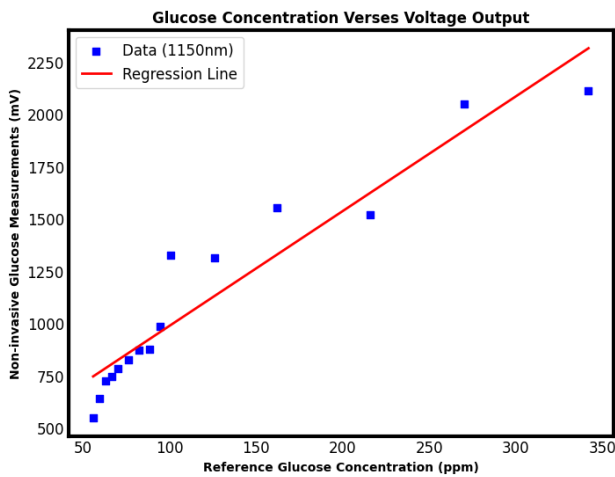


Figure 3. Glucose Concentration Verses Output Voltage

In Figure 3, it is evident that an increase in glucose concentrations gives a corresponding increase in voltage output. Additionally, the output voltage changes in small steps; at high glucose concentrations, the output voltage changes in large steps. The regression equation (3) obtained from the results as a linear fit line was incorporated into the software.

$$y = 5.4820x + 440.33 \tag{3}$$

System Validation

Clarke Error Grid Analysis

The proposed system's efficacy for medical treatment was determined using Clark Error Grid analysis. Figure 4 shows the Clarke Error Grid analysis

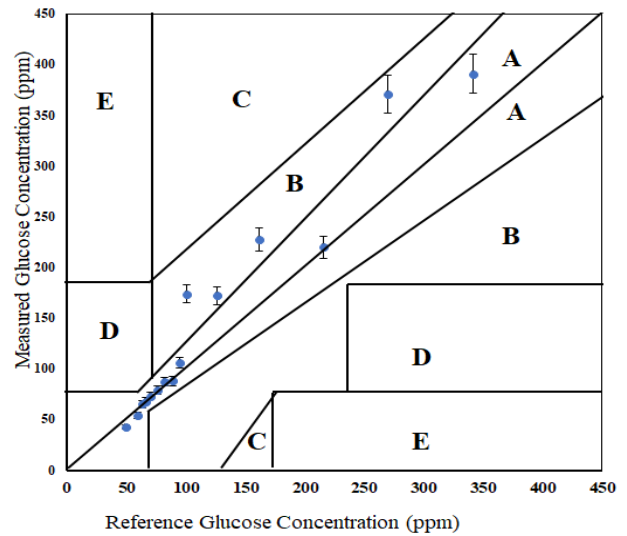


Figure 4. Clarke Error Grid Analysis

The grid has five regions; Region A-20% of values within the reference glucose concentration, hence clinically accurate; B-20% of values are outside the reference glucose concentration, slightly inaccurate but clinically acceptable as it will not lead to inappropriate treatment; C- unnecessary, measurements will lead to overtreatment; D- potentially dangerous, the device fail to detect, and region E-confuse detection of glucose hence will give erroneous results [31].

The results were superimposed onto the Clarke error grid using Excel. According to the Clark Error Grid analysis of Figure 4, 93% of the values fall within region A and 17% within region B. No values are falling within regions C, D, and E. Therefore, the proposed system is suitable for non-invasive monitoring of glucose.

Bland Altman analysis

Bland Altman's plot examines the agreements between two measurement methods of the same variables [32], [33] and are used to determine the degree of accuracy by constructing limits of agreements. The limits of agreement are arrived at as follows: Limits of agreement(upper/lower) = mean of the differences ± 1.96 × standard deviation of the differences. As per [33], Bland Altman recommends that the data points plotted have to fall within the two limits of agreement for the new measurement method to be 95% accurate. Figure 5 shows Bland Altman's plot with data points from the system plotted.

From the observation of Figure 5, most data points fall within the upper limit of agreement and the lower limit of agreement except for one data point that falls outside the upper limit of agreement; this indicates that the proposed device is 93% accurate.

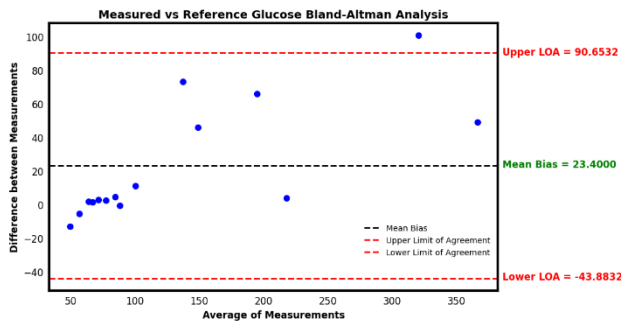
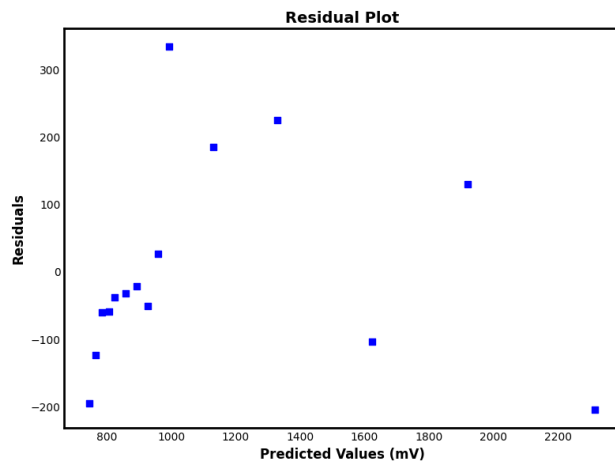


Figure 5. Bland Altman's Analysis

Residual Plot

The random scattering of data points around the zero line in a well-designed residual plot suggests that the residuals are randomly distributed and lack any discernible pattern. The residuals do not capture the underlying relationship between the variables if patterns or trends are observed [34].



The residual plot of the 1150 nm data has no discernible trend, just a random spread of points around the horizontal axis. This shows that the variance of the residuals is essentially constant for various levels of the predictor variable - reference glucose concentrations. As such, it indicates that the homoscedasticity assumption is fulfilled, suggesting that the reference concentrations of glucose do not systematically influence the variation of the non-invasive sugar readings.

Additionally, there is no observable typical pattern from the residual plot, such as funneling or curvature. The residuals' precise random distribution along the horizontal axis indicates a linear relationship between the non-invasive glucose readings and the reference glucose values. Based on the residual plot, the linearity assumption appears to be reasonable.

Moreover, the residual plot lacks any noticeable outliers or pivotal points. Therefore, there appear to be no extreme observations that could adversely affect the regression model. This is because all data points are clustered within a reasonable range around the horizontal axis.

Given this, the residual plot for the data at 1150 nm indicates that the regression model adequately captures the relationship between the non-invasive glucose measurements and reference glucose concentrations. The absence of regular patterns, the random distribution of residuals, and the presence of outliers all

suggest that the model satisfies the requirements of linear regression and offers an acceptable fit to the data.

CONCLUSIONS

The results show that 1150nm gives an output corresponding to the glucose concentration applied. Therefore, the system can be used to measure glucose non-invasively. Additionally, when compared with other experimental results of 940nm devices by [17], [18], it is seen that there is a similar relationship in which an increase in glucose solution gives a corresponding increase in voltage output.

As per Clark Error Grid analysis, the system shows values within regions A and B. In Region A, we have 93% of values, and in Region B, we have 17% of values. This agrees with Clark Error Grid since the values for the system meet the 99% criteria stipulated. Given the Bland-Altman analysis, most data points are within the two limits of agreement except for one data point above the upper limit of agreement. This indicates that the system gives a 93% degree of accuracy.

In the analysis of the residual plot, the regression model for the system is appropriate for predicting non-invasive glucose measurements.

LIMITATIONS AND RECOMMENDATION

The scope of the study was limited to in-vitro testing only. Additionally, the transmitter used was 1200nm±50 peak sensitivity.

In our future research, we will use animal subjects, engage large sample sizes, and use commercially available glucose measurement devices to validate the system.

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NOMENCLATURE

WHO	World Health Organization
mV	Millivolt
KΩ	Kiloohm
Ω	Ohm
μF	Microfarad
nm	Nanometer
NIR	Near-infrared
LED	Light Emitting Diode
PPM	Parts Per Million
Mmol/l	Milimoles Per Litre
GSM	Global System for Mobile Communication
TFT	Thin-Film-Transistor Liquid-Crystal Display
UART	Universal Asynchronous Receiver / Transmitter
GPIO	General Purpose Input/Output
Tx/Rx	Transmit and Receive
AT	Attention

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