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Design and Development of a Non-invasive Glucometer System

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Abstract: *The outbreak of Covid-19 disease has caused issues in public health, and its impact has grown in population with non-communicable diseases like diabetes, a life-threatening condition, worldwide. Individuals in low-income countries with limited diagnosis and monitoring systems require continuous and regular blood glucose monitoring. Invasive or minimally invasive blood glucose monitoring has been utilised with good accuracy but a high risk of infections and complications. Non-invasive monitoring technology is critical and recommended worldwide, with the potential of improving safety and reducing workload in blood glucose control. The design, development, and evaluation analysis of a non-invasive GSM (Glucose Screening Measurement) module glucometer using near-infrared sensors at 1550nm wavelength as an emitter, transmitting through the fingertip and the ATMega38 microcontroller as the controller to determine the glucose level in human blood are presented in this study. A total of forty individuals were recruited in the investigation. Repeatability, validity, and reliability were evaluated using the Bland and Altman Analysis, the concurrent validity, and the reliability analysis. Passing and Boblok Regression Analysis was used to assess the statistical significance further. Repeatability showed no significant difference with a 95% confidence interval and 0.6895 bias. The linear relationship showed 99.72% agreement and 99.9% reliability using regression analysis. This study revealed that using a non-invasive GSM module glucometer to measure blood glucose effectively enhances patient surveillance in diabetes insulin treatment.*

Keywords: *Non-invasive Glucometer, Diabetes, Blood Glucose, Sensors, Reliability*

1. Introduction

Global cases, widespread transmission, and deaths have escalated geometrically since emergence of a novel disease in Wuhan, China, called Covid-19 (Sun et al., 2020; Lu et al., 2020). Around 12.5 million cases and 574,000 deaths have been reported outside China, posing substantial concerns for public health (WHO, 2019; Li et al., 2020; Huang et al., 2020).

Over 600,000 confirmed cases have been reported in Africa and Sub-Saharan Africa. To prevent the transmission, a procedure to promote prognosis, guidelines, methods, and management are gradually constructed (WHO, 2020; Jin et al., 2020; Huang et al., 2020; Zhu et al., 2020). The impact of the pandemic has increased the population of individuals living with non-communicable diseases (NCD) related morbidity and mortality such as cardiovascular diseases, cancer, respiratory diseases, diabetes, and other complications. Because of rapid spread of this global pandemic disease, prevention and control of diabetes patient is critical (WHO, 2018; Wang et al., 2020).

Diabetes is a chronic metabolic disease and one of the most common epidemic diseases, with more than 215 million individuals diagnosed in 2015 (IDF, 2015). Nigeria ranked 19th in Africa in terms of the persistence of the NCD, with the number growing every year (WHO, 2016). More than 25% of hospitalised patients develop diabetes due to blood glucose swings outside the normal range (90-140 mg/dL) (Al-dhaheri et al, 2020). Diabetes presents significant challenges for individuals, governments, and national health systems, including a disproportionately high human, societal, and economic impact. Diabetes-related issues are the most significant cause of liability (Bahartan et al., 2017). Elevated blood glucose levels (hyperglycemia) and the associated increased likelihood of diabetes-related complications during inpatient care. In addition, a medical condition with low sugar levels (Hypoglycemia) is harmful and should be avoided (Umpierrez et al., 2012; Moghissi et al., 2019). These required constant monitoring because of their linkage with increased mortality and may worsen in irregular blood glucose processes in patients with high levels of the insulin-like growth hormone (Hermanides et al., 2010). The disease, which shows low blood sugar, may go unreported or undocumented.

Self-monitoring of blood glucose (SMBG) adherence is key to maintaining good blood sugar levels. SMBG sensors have a strong connection with standard laboratory apparatus (Lode, 2005; ADA, 2013). SMBG is a key factor in attaining precise glycemic control to reduce the risk of complications and improve survival rates associated with the disease (Kirk and Stegner, 2010). More so, SMBG tools have been used to assess the impact of medicines and lifestyle factors such as exercise (Bahartan et al., 2017).

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Continuous blood sugar monitoring is necessary to maintain physiological homeostasis and measure therapeutic insulin intake because insulin resistance and stress-induced hyperglycemia are most common in critically ill patients. Glucose management has been shown to enhance outcomes; however, some studies were unable to replicate these improvements (Kalfon et al., 2014).

Due to ease of use and the small size of clinical samples required, invasive testing and point-of-care testing have been utilised to monitor glucose levels. Low-cost, portable, and user-friendly biosensors developed to measure glucose content in a liquid specimen have been proposed. The technology produces more precision compared to other approaches, allowing clinicians to make faster decisions on treatments to be used. The main drawbacks of this approach are the long-term costs, uneasiness, risks and complications, and the fact that it is painful and uncomfortable. Minimally invasive technologies were used to monitor blood sugar, and the approach has helped minimise the danger of infections (Vashist, 2012). Dachao et al. (2010) proposed measuring glucose levels through an ultrasonic technique. Due to the direct interaction with the blood tissue, erroneous measurements were linked to noise and artefacts. Jui et al. (2011) proposed potentiostat-based electrochemical equipment using glucose test strip and automated testing device. Schichiri et al. (2012) developed an electrode implanted in the body to measure blood sugar levels. Their approach aids in the prevention of infection and embolism.

Non-invasive implementation using bodily secretions such as saliva, tears, urine, breath and skin, and the aqueous humour of the eyes, tongue, and oral mucosa, has been suggested. (Oscar et al., 2013; Barb, 2013) presented the use of sweat to evaluate the glucose level. The method uses the electronic nose technique and 32 metal oxide semiconductor (MOS) systems functioning under varying temperatures. Raman spectra were obtained using a simple spectroscopic setup with 784nm laser excitation wavelength, and the findings showed that glucose detection was possible (Barb, 2013). (Mantele, 2015; Ojo, 2015) presented a spectra difference of the mucosal membrane of the lips and the blood sugar level using a mid-infrared technique. Their result shows a correlation coefficient of 0.92. Temperature variations hamper the measurement, and the apparatus is indeed costly. Guo et al. (2012) reported 0.68% accuracy using breath signals for non-invasive glucose measurement. This implies this cannot be used in healthcare settings.

In another report, Artificial Neural Network (ANN) was trained to map acetone concentration, pressure, temperature, and humidity to glucose proportion in estimating glucose concentration. However, the dataset utilised was too small for a neural network to train adequately, and the results may be over-fitted to such a short sample (Thati et al., 2015). Hassan et al. (2018) developed a breath signal analyser for non-invasive blood glucose testing. The MQ138 sensor was used to measure the acetone concentration in the breath. A linear regression classifier was constructed on data from 100 patients to map acetone yield in breath to blood glucose level, which shows a correlation coefficient of 0.995.

In the last two decades, studies have focused on the use of optical techniques employing near-infrared light of different wavelengths. Guevara and González (2010) developed a non-invasive glucometer coupling the Near Infrared (NIR) (700-1000 nm) and impedance spectroscopy (1-200 MHz). Measurement was taken from ten non-diabetic people's forearms in a controlled environment. The Root Mean Square Error of Prediction (RMSEP) was estimated to be 21.96 mg/dL. Shinde and Prasad (2011) suggested a non-invasive glucose monitoring approach using near infrared light sent over the fingertip. Applying 30 seconds of over-systolic pressure to the finger obstructs blood flow. The result from the optical signal was investigated using a spectrum analyser and fast Fourier transform (FFT) analysis. Similarly, Chi Fuk So et al. (2012) reported that the optical approach is one of the most painless tests available. Srivastava et al. (2013) proposed an optical and non-invasive method of testing blood glucose on the finger using 940 nm infrared light as the input signal. The output signal was digitised, amplified, and analysed on the microchip. The proposed approach, however, was not validated.

Pavithra et al. (2014) exploited occlusion NIR spectroscopy to construct a non-invasive method of assessing blood glucose and haemoglobin. Two NIR sensors detecting haemoglobin at 870 nm and glucose at 1000 nm in the circuit were used and tested on individuals with varying glucose and haemoglobin levels. The maximum photodiode voltage was varied between 3 and 3.8 V, depending on the individual's concentration of the two proteins in respective blood. Yadav et al. (2014) developed a continuous and non-invasive blood glucose monitoring device utilising continuous waves from an infrared transmitter. The technology was put through its paces in vitro and in vivo. The optically measured signal and actual glucose concentrations had a significant relationship and reduced signal amplitude. Chua et al. (2014) proposed a non-invasive blood glucose glucometer using two Light Emitting Diodes (LEDs) of the same wavelength, one acting as a photo emitter and the other as photo detector. A similar approach was carried out with a total of 8 LED pairs. Sensitivity was tested for different glucose concentrations. Out of the two LEDs tested, the NIR LED with a wavelength of 1450 nm was the most effective (Yadav et al., 2015).

Guo et al. (2015) reported new non-invasive blood glucose monitoring using four NIR spectra and a double artificial neural network analysis. The transmission of photoplethysmogram signal for the four fingers was concurrently using wavelengths of 820, 875, 945, and 1050 nm. The result revealed that the prediction's RMSE ranged was from 0.97 to 6.69 mg/dL, with an average of 3.80 mg/dL. Tamilselvi and Ramkumar (2015) suggested a non-invasive blood glucose testing

utilising 940 nm NIR spectroscopy. The global positioning system module communicates the user's location information and messages to the physician. The proposed procedure, however, was not validated. Pande and Joshi (2015) presented a non-invasive glucose determination. Their result shows that the transmitter of wavelength 1450 nm was more appropriate than the one with a shorter wavelength. Bobade and Patil (2016) reported a non-invasive blood glucose system for diabetics and non-diabetics population. Optical light having wavelength of 940 nm was emitted on the patient's finger, and the amount of light transmitted was determined. The signal processing results were presented on the liquid crystal display (LCD). The procedure, however, has not been evaluated. Narkhede et al. (2016) reported a non-invasive approach for detecting reflected signals by positioning the emitter and detector on the same side of the finger. The glucometer measurements utilising the system shows satisfactory correlation. Their findings demonstrate the viability of the non-invasive blood glucose testing techniques based on the NIR. Daarani and Kavithamani (2017) presented the design and development of a non-invasive blood glucose testing system using a 940 nm wavelength NIR light source. The measured glucose concentration and the date and the time were displayed and saved in a text file using an Android application (app).

Non-invasive approaches have proven effective, and numerous methods have been proposed, with the results proving a significant link between processes. More so, a simple, low-cost, portable, real-time non-invasive glucometer has been proposed. However, the validation and reliability of such a device compared to standard measurements are still absent. Therefore, validation and reliability are essential in this study. Furthermore, while a recent study found that non-invasive blood sugar testing devices are acceptable, there is no evidence that they are reliable. As a result, the goal of this study was to compare the concurrent validity of a non-invasive GSM module glucometer to a conventional model as a standard reference and obtain the reliability of blood glucose monitoring. The performance of the designed non-invasive GSM module glucometer was assessed in terms of repeatability, validity, and reliability in this study.

2. Materials and Methods

2.1 Materials

In this study, the non-invasive GSM module glucometer design and implementation include the following; microcontroller (ATMEGA328), near-infrared sensor transmitter (LED1550E), photodiode receiver (FGA10), GSM module, and liquid crystal display (LCD). All of the supplies are reasonably priced and widely available locally.

2.2 System Design

2.2.1 Design Architecture

Figure 1 shows the flow block diagram of the proposed device. When the finger were exposed to the near-infrared sensor transmitter, the blood flow signal as an infrared signal is received by the receiver photodiode and late converted to an equivalent voltage. The microprocessor utilised the voltage signal as a variable to estimate the glucose content. The LCD screen displays the information and sends data out via the GSM Module using the push button. The hardware and software implementation were all included in the design and development.

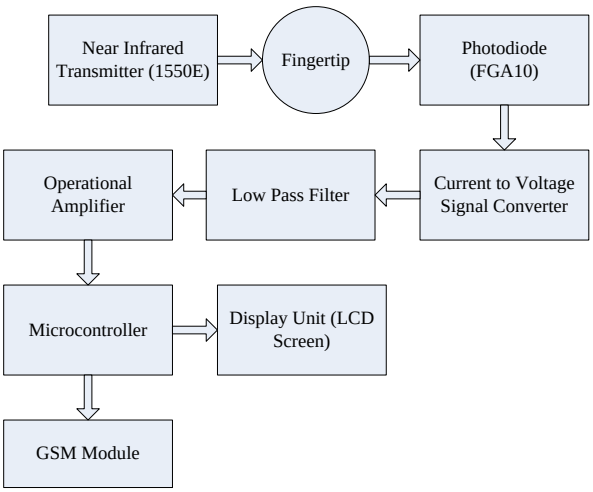

Figure 1. Flow Block Diagram of the Non-Invasive GSM Module Glucometer

2.2.2 Hardware Implementation

This sub-section provides the circuit diagram and all of the steps involved in designing and developing the non-invasive glucometer, as illustrated in Figure 2.

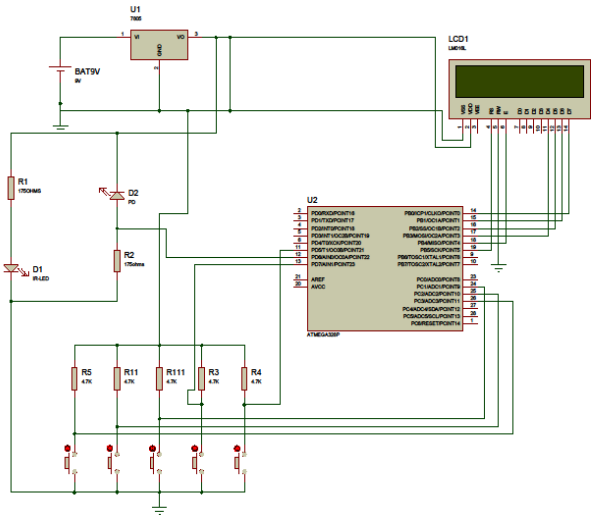

Figure 2. Non-Invasive GSM Module Glucometer Circuit Diagram

2.2.3 Power Supply

Figure 3 shows the power circuit diagram. A 5V dc power supply was required; therefore, a 9V battery current source is used. The voltage output was regulated to 5 V using an LM7805 voltage regulator.

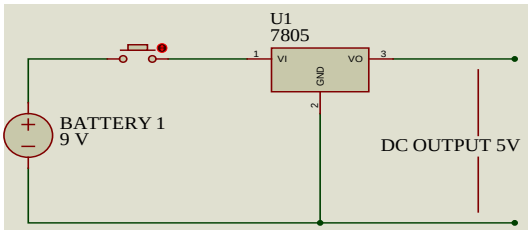

Figure 3. Power Supply Circuit Diagram

2.2.4 System Development

A near-infrared sensor that generates infrared light of wavelength 755 nm to 2550 nm was used in this study. Its transmitter was composed of heterostructures built on an indium gallium arsenide phosphide substrate and housed in a 5 mm diameter hemispherical clear epoxy case (Zissis et al., 2021). The near-infrared sensor consists of a transmitter and receiver circuit that can penetrate 1mm to 110 mm deep into physiological tissue with a wide range of wavelength properties (Vashist, 2012).

NIR spectroscopy has become a prominent approach for monitoring numerous physiological indicators due to recent breakthroughs in microelectronics, as it enables simple, economical, safe, and pleasant measurement. In the near-infrared region, there are three bands: (i) the combined overtone region (2000-2500 nm), (ii) the first overtone region (1400-2000 nm), and (iii) the second or higher overtone region (750-1400 nm) (Javid et al., 2018). In the study, 1550 nm was selected due to the high signal-to-noise ratio (SNR) for glucose signals and its maximum glucose absorption. The light transmitters and receptors around a wavelength of 1550 nm are relatively low-cost compared to other wavelengths with equal or higher responses to glucose. Figure 4 shows the schematic of the near-infrared circuit, which incorporates a filtering stage and an amplification stage.

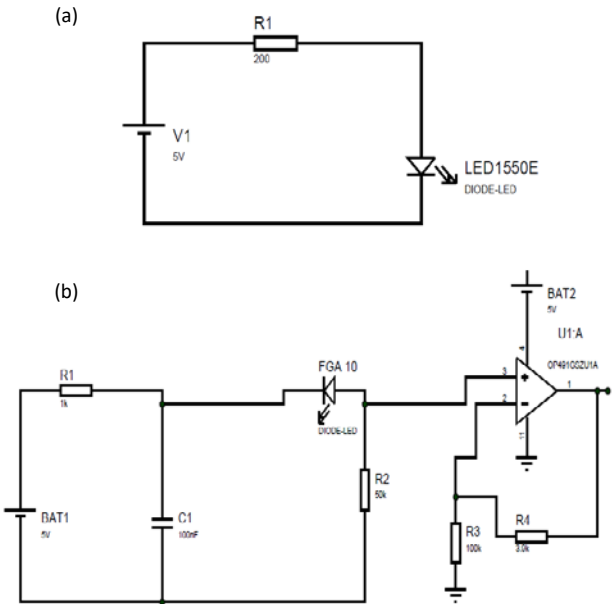

Figure 4. Near-Infrared (a) Transmitter and (b) Receiver Circuit Diagram

Photo-detector with peak sensitivity at 1550 nm wavelength was used to detect the glucose concentration's attenuated optical signals in the finger's blood. The photo-detector successfully detected the transmitted signal at this wavelength. Load resistance of R_4 = 50 k was placed on the anode side of the photodiode to convert the output current to a voltage signal. The signals were filtered and amplified to reduce noise and improved the resolution, respectively. Because the voltage output of the photodiode was reduced, an operational amplifier was used to enhance the output signal. The cut-off frequency of the low-pass filter was designed to give 1.59 kHz in other to reduce the frequency of the low-pass filter;

$$LPF = \frac{1}{2\pi R_1 C_1}$$

$$= {}^{1}/_{[2\pi(1 \times 10^3)(100 \times 10^{-9})] = 1.59KHz}$$

Voltage gain;

$$= 1 + [(100 \times 10^3)(3.9 \times 10^3)] = 26.64$$

The Atmega328 microcontroller was used in the design as a controller with an open-source (integrated development environment, IDE) that is simple to program and upload to the input/output (I/O) board. The programme was written in the C-language before converting to hexadecimal code file. The C-language was created using the code block Arduino compilers. Figure 5 shows the design algorithm flow chart.

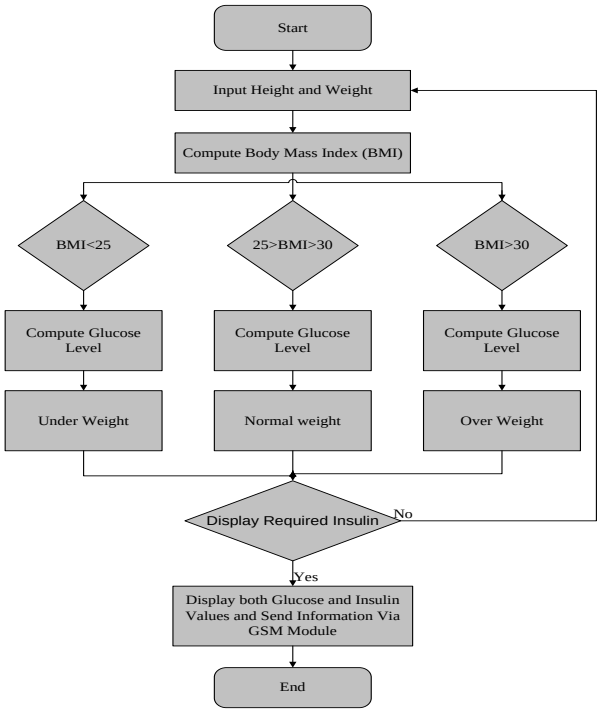

Figure 5. Flow Chart Diagram of the Device

During the development stage, pre-fabrication was conducted before being relocated to the vero-board with precision soldering and all distance connections made utilising connecting wires. The components were first attached to a breadboard to validate the working condition of the circuit diagram design. Properly

constructed connections along with low resistance that provides good electrical continuity and a reasonable degree of mechanical strength in a firmly made joint were created, while a thin film of solder connects the parts to be connected. The controller provides bias voltages to the transmitter and the photodiode with the photodiode and amplifier outputs.

The amplified output voltage was interfaced to the microcontroller's analog port A (pin 12), thereby converting the analog signal to digital values. The digital value corresponds to the glucose concentration from the finger. GSM module controls the modems using the attention command to communicate the data from the device to a third party. For the experiment, anthropometric measurements were obtained in accordance with the requirements of the various systems models (height, weight, and body mass index for both systems). The device was utilised to measure the blood glucose of diabetic and healthy participants at two separate locations simultaneously, respectively.

The first phase was operating the device and collecting data based on the participant's anthropometry. Keying in both the height and weight measured using the push button, the participant's right and left first index fingers were clipped between the sensors. The BMI (body mass index) calculated were displayed on the LCD automatically. The second phase involves pressing the MODE button to activate the sensors to measure the required glucose levels in mg/dL within the blood stream within 60 seconds. The system automatically calculates the required insulin dose equivalent to the glucose concentration measured and displayed on the LCD screen. The SMS (short message service) alert push-button ensured that the displayed messages were sent to a third party phone as SMS for assessment and treatment purposes. The light travelling through the fingertip carries electromagnetic energy that flows in its propagation direction. The polynting equation gives the penetration power of the light.

$$E = H_o \cos\ (K\,.r - \omega t) \tag{1}$$

Then, the absorption of this light depends on the number of molecules present. This is explained by beer-lamberts law, as shown in Equation 2.

$$A = -\log\frac{V}{V_o} \tag{2}$$

The basic principle of blood glucose measurement is based on glucose absorbed by infrared light. By measuring the light intensity transmitted through the top of the finger, the glucose concentration in the blood can be estimated. The infrared light exposed by the LED has suitable wavelength penetration. The transmitted light was absorbed, reflected and scattered by tissues and blood at the top of the finger. By placing a photodiode detector at the opposite side of the LED, information about the coefficients in the blood can be evaluated. By reading the voltage values achieved before and after placing the finger on the device, we enable the calculation of light intensity before and after absorption as:

$$V = \frac{V_o}{\Re R_L} \tag{3}$$

The general Beer-Lambert law is the linear relationship between absorbance and concentration of an absorbing species and is usually written as;

$$A = \epsilon \times \ell \times c \tag{4}$$

$$c = \frac{-\log\frac{V}{V_o}}{\epsilon \times \ell} \tag{5}$$

Where;

K = Concentration of light in direction of its propagation
r = Speed of passage of light through a medium
ω = Angular frequency
t = Time
ϵ = molar extinction coefficient
ℓ = path length or thickness of the finger
c = concentration

2.2.5 Participant

The study involved forty participants. The inclusion criteria for this group were: 1) patients under the age of 20, 2) diabetic patients, and 3) non-diabetic patients. Pregnancy, immune disorders, systemic neurological disease, diabetic ketoacidosis, acute complications, other diseases with a life expectancy of less than one year, severe allergies, and severe circulatory disturbances were all excluded. The current research was approved by a local health research ethics committee from a university teaching hospital and followed the Declaration of Helsinki's standards. All eligible participants who accepted participating in the study signed a written informed consent form.

2.2.6 Experimental and Statistical Analysis

Glucose concentration was monitored for forty individuals for different conditions such as before and after a meal using the devised system and most popular commercially available, One Touch Ultra glucometer (Narkhede et al., 2016), and the associated values were recorded.

Statistical analysis was performed using the IBB SPSS Software v22 (SPSS Inc., Chicago, USA). All datasets were generated using Microsoft Excel. Then the average, standard deviation and error (mg/dL and percentage) were evaluated. At a significance threshold of $p < 0.05$, all tests were accepted. The Bland–Altman test was used to assess repeatability and validity between groups. The Passing and Boblok regression analysis was used to determine the degree of agreement. In addition, the absolute offset was calculated using the root mean square error (RMSE) method. The RMSE was defined as:

$$\mathrm{RMSE} = \sqrt{\frac{1}{\mathrm{N}}\sum_{\mathrm{i}=1}^{\mathrm{N}}(\mathrm{y_i} - \hat{\mathrm{y}}_\mathrm{i})^2} \tag{6}$$

Where,

y_i = blood glucose values obtained from the proposed instrumentation device,
$\hat{y}_i$ = reference (standard measurement),
N = number of samples
i = sample number.

To assess concurrent validity and reliability (CIs), intra-class correlation (ICCs) (two-way mixed effects, one rater/measurement, absolute agreement) with 95% of class intervals was used. The ICC is a value between 0 and 1, indicating the degree of correlation and agreement between measurements. Low (ICC < 0.60), uncertain (0.60 > ICC < 0.70), acceptable (0.70 > ICC < 0.80), good (0.80 > ICC < 0.90), or excellent (ICC > 0.90). For medical instrumentation, acceptability based on established statistical thresholds for significance analysis was adopted, with such a reference threshold of 5% proposed (Webster, 2011). Clinically significant differences were defined using a minimum clinically important difference (MCID) of less than 10% (Alam et al., 2020).

$$\text{Reliability, ICC(3,1)} = \frac{MS_R - MS_E}{MS_R + (k-1)MS_E + \frac{k}{n}(MS_C - MS_E)} \quad (7)$$

Where

MS_R = mean square for rows
MS_W = mean square for residual sources of variance
MS_E = mean square for error
MS_C = mean square for columns
n = number of subjects
k = number of raters/measurement

$$\text{Reliability Index} = \frac{\text{True Variance}}{\text{True Variance} + \text{Error Variance}} \quad (8)$$

$$\text{Inaccuracy} = \left(\frac{G_{(\text{invasive method})} - G_{(\text{proposed non-invasive method})}}{G_{(\text{invasive method})}} \times 100\%\right) \quad (9)$$

3. Results and Discussion

In this study, a GSM module non-invasive glucose monitor device was developed to measure blood glucose concentration in the blood, with the findings displayed on an LCD as shown in Figure 6 (a-d). The device's set of data was collected on forty individual, with the results of each test shown on the device's LCD screen. Table 1 shows that the average age of the participants was 44.50±14.64 years.

Figure 6a. Constructed GSM Module Non-invasive Glucometer

Figure 6b. Result of Measurement Displayed on LCD of both Height and Weight Computed

Figure 6c. Result of Measurement Displayed on LCD of BMI, Glucose and Insulin computed

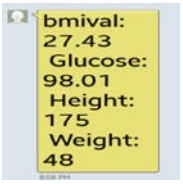

Figure 6d. Result of SMS Message on Mobile Phone sent via GSM Module

According to the calibration results, the sensor's output voltage rises directly to the increase in glucose wavelength absorption, as illustrated in Figure 7. As seen in equation 10, the relationship between glucose absorption rate and voltage is linear:

$$\epsilon \times \ell = 0.5131V + 0.0093 \quad (10)$$

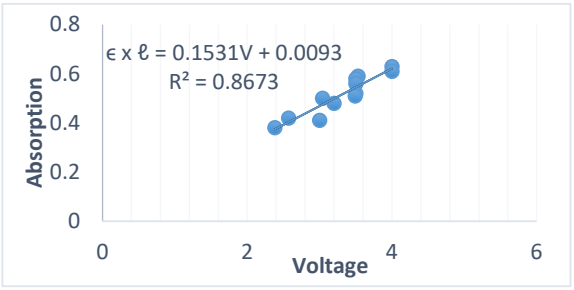

Figure 7. Calibration of Glucose Absorption Rate and Voltage

Both the proposed device and a one-touch glucometer were used to test blood glucose levels. The comparison of the collected test results for 40 individuals is shown in Table 1. The developed device provides about 99.48% accuracy compared to intrusive approaches. Based on the results of 40 people tested, the percentage inaccuracy of each test of our suggested device compared to the invasive approach is less than 20%. It is regarded as clinically accurate if the percentage error for the glucose reading is less than 20%. (Daarani and Kavithamani, 2017; Rahmat et al., 2017; Alam et al., 2020).

Table 2 revealed baseline height, weight, and body mass index of 175.60±7.53, 81±10.49, and 27.48±4.49, respectively. The findings also revealed that the Body Mass Index (BMI) is a good predictor for determining a patient's health and sickness status. BMIs greater than 30 are more likely to cause significant illness. The standard error mean (SEM) of 6.39 was estimated using mean difference and standard deviation of difference at

Table 1. Comparison between Invasive and Non-invasive GSM Module Glucose Measurement

Invasive Measurement	Non-invasive Measurement	Inaccuracy (% Error)	Invasive Measurement	Non-invasive Measurement	Inaccuracy (% Error)
157.89	157	0.563684	101.03	103	-1.94992
151.05	148	2.019199	105.75	108	-2.12766
172.4	171	0.812065	205.71	205	0.345146
203.67	200	1.801935	91.23	90	1.348241
151.74	151	0.487676	189.21	188	0.639501
204.39	208	-1.76623	195.23	195	0.11781
124.3	121	2.654867	97.93	99	-1.09262
97.43	97	0.441343	108.75	108	0.689655
105.01	106	-0.94277	100.31	101	-0.68787
91.21	89	2.42298	151.57	153	-0.94346
137.5	139	-1.09091	148.97	149	-0.02014
101.57	98	3.514817	177.11	175	1.19135
147.95	145	1.993917	153.25	154	-0.4894
130.5	127	2.681992	103.53	102	1.477833
89.45	91	-1.73281	97.79	98	-0.21475
197.74	203	-2.66006	117.12	115	1.810109
151.34	147	2.867715	200.13	198	1.064308
140.57	139	1.116881	191.57	191	0.297541
99.79	97	2.795871	87.95	89	-1.19386
107.73	105	2.534113	200.03	200	0.014998
				Average	**0.519828**

Table 2. Physical Characteristic Distribution of Participants (Gender, Age, Height, Weight, and BMI)

	Age	H(cm)	W(Kg)	BMI
Mean	44.50	175.60	81.60	27.48
St. Dev.	14.64	7.53	10.49	4.49
Minimum	23	168	65	19.94
Maximum	65	190	93	32.18

Sample Size = 40

a significance level of t = 0.05. This demonstrates no significant variation in the means of the measured samples employing both the standard reference measurement and the designed device.

Figure 8 shows that 95% of the changes between the two measurements are within 1.96 SD (standard deviation), indicating acceptable repeatability. The bias was 0.6895, with a limit of agreement (LOA) range of -3.47 to 4.84. As a result, the proposed developed design device is 3.47 units less or 4.84 units more than the measurement, using the standard reference framework. There is no clinical difference in the measurements taken from both positions and procedures.

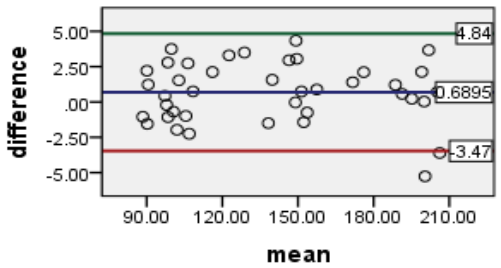

Figure 8. Bland Altman Scatter Plot

The outcomes are showed in Table 3 and Figures 9. The Bland and Altman plot, which includes class intervals and significant areas of confidence around the mean difference and the agreement of bounds, reveals mean difference class intervals of 2.22 and 4.38, respectively. Both for the mean and agreement limits, the evaluation of the difference between the approaches reveals narrow class intervals. Figure 10 shows that the difference between measurements is normally distributed.

Table 3. Bland and Altman Plot Statistics Including the Elements to Calculate Confidence Intervals.

P	unit	Se	t	Se*t	95% CI From	To
N	40					
Df	39					
D	0.68	0.34	2.04	0.68	0.0054	1.37
SD	2.12					
d-1.96s	-3.46	0.58	0.04	1.18	-4.65	-2.28
d+1.96s	4.84	0.58	2.04	1.18	3.66	6.03

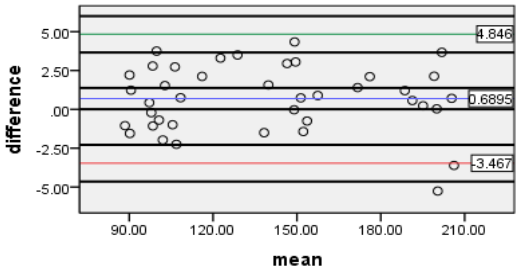

Figure 9. Bland and Altman Plot, with the Representation of Confidence Interval Limits for Mean and Agreement Limits

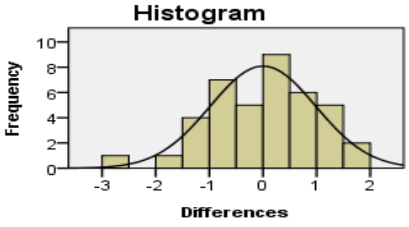

Figure 10. Distribution Plot of Differences between Measurements

Figure 11 illustrates the Passing-Boblok regression analysis with a 95% confidence interval, a slope coefficient of 1.00 and an intercept coefficient of -2.11. The R^2 (0.997) correlation score indicates a high level of agreement. The developed device produces measurements that are sufficiently similar to a standard reference system.

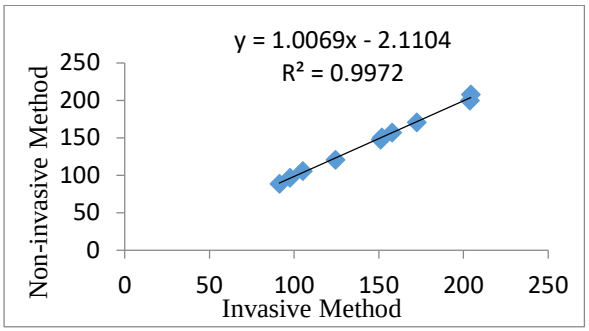

Figure 11. Passing-Boblok Regression Analysis Plots of both System

Table 4 shows that the intra-class correlation coefficients (ICCs, 0.90) for the between-system differences were acceptable to excellent. The proposed device's relative reliability ranges from acceptable to excellent (ICC 0.90-1.00). The validity of a clinical measurement assessment by both systems was shown by demonstrating clinically acceptable absolute reliability and between-system differences.

It has been claimed that standard reference systems suffer from modest blood glucose issues that may predispose them to poor functional outcomes. The agreement between two separate systems was analysed using the Bland Altman plot. The mean difference between the two approaches (d) was used to define bias. The limit of agreement (LOA) reflected the 95% confidence interval's boundary, d±1.96s and clinically acceptable LOA was defined as a value of less than 20%. The results achieved in this study show good correlation between the two measuring technologies evaluated in terms of variability, characteristics, repeatability, validity, and reliability (Bland and Altman, 1986).

Validity and reliability were deemed adequate for detecting clinically significant variations. In terms of absolute dependability, measurement error was clinically acceptable. The proposed device appeared to be sensitive enough to detect changes in blood glucose levels. As shown in a sample reliability analysis result, the reliability analysis in this study computes the ICC values and the 95% class intervals (see Table 3). The IBB SPSS statistical package version 22 (IBB SPSS Inc, Chicago, IL, USA) was used to calculate ICC estimates and their 95% confidence intervals.

Although the calculated ICC value is 0.999 single measurements and 0.999 average measures (showing great dependability), its 95% confidence interval is 0.999 to 1.000, indicating that the true ICC value has a 95% probability of landing on any point between 0.999 and 1.000. As a result, it would be more reasonable to say that the level of reliability is "outstanding" because the exact ICC is still better than 0.9 even in the worst-case condition. The suggested non-invasive glucometer's validity and reliability are unaffected by the presence of illness.

The absolute dependability results show a 0.52% measurement error and a 99.48% accuracy. Compared to earlier studies, the results obtained from the suggested device revealed that the value of the evaluation measure was greatly improved compared to previous studies. Table 5 shows the differences between the proposed device and past research.

Table 4 Intraclass Correlation Using a Single Rater/Measurement, Absolute Agreement, 2-way Mixed-effects Model with 2 Raters across 40 Subjects

		95% Confidence Interval		F Test with True Value 0			
	Intraclass Correlation	Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	0.999	0.997	0.999	1448.085	39	39	0.000
Average Measures	0.999	0.999	1.000	1448.085	39	39	0.000

Table 5. Comparison between the Non-invasive GSM Module Glucometer and the Previous Work

Previous work	Methods/Mobile Communication	NIR Light Wavelength	Cost	Glucose Detection	RMSE/R^2	Reliability (ICC)	Accuracy
Proposed non-invasive glucometer	Transmission/GSM Module	1550 nm	Low	Good	27.9mg/dl/0.9972	0.9999	99.51%
Al-dhaheri et al. (2020)	Transmission	940 nm	Low	Good	10.44mg/dl/0.8392	No report	No report
Hassan et al. (2018)	Breath Analysis	None	Low	High	11.81mg/dl/0.995	No report	No report
Yadav et al. (2018)	Diffuse Reflectance	940 nm	Low	Good	14.9248mg/dl/0.87	No report	No report
Javid et al. (2018)	Transmittance and Reflectance/ Android apps	942, 1550 and 1650 nm	Low	Good	18.52mg/dl	No report	91.73%
Mohi-ud-din (2017)	Transmission	1550 nm	Low	Good	No report	No report	No report
Ali et al. (2017)	Refraction and Transmission	650 nm	Low	Good	No report	No report	No report

Our findings suggest that clinical conclusions can be drawn using either technique despite the differences in data sources. Furthermore, there are no statistically significant difference in the blood glucose readings from the two devices. The non-invasive GSM module glucometer could be highly useful for monitoring blood glucose levels both at home and in the hospital because the patient are exposed to minimal risk. If this technology is commercialised and made widely available to patients, it can improve continuous blood glucose monitoring and decrease the risk of consequences, particularly in remote areas and clinics.

4. Conclusion

A simple, inexpensive, and real-time monitoring non-invasive GSM module glucometer has been designed and developed in this study. The glucometer works on the principle of transmission and GSM module of operation through the fingertips when placed on the glucose sensor to detect blood glucose concentration. The non-invasive glucometer was put to the test on forty individuals. The results showed 99.9% reliability and accuracy of 95.1% with no significant difference.

The non-invasive glucometer has been found to be useful in monitoring the blood glucose levels with good accuracy and is more reliable in detecting blood glucose concentration when compared with other studies. The non-invasive GSM module glucometer could be useful in a resource-constrained context where diagnostic medical devices are few. The non-invasive technology will allow patients to preserve their autonomy, avoid complications, and save money on healthcare.

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