



# Non-Invasive Blood Glucose Measurement Using Laser Technology (NIBGM)

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**Abstract:** The non-invasive glycemic meter has become a concern of biomedical engineering and scientists. This medical device has been designed by many scientists to serve diabetics. This paper provides a convenient way to meet all the successful features of this biomedical device at low cost, high performance and reliable capabilities. The suggested glucose meter is based on a specific wavelength that plays a major role in the system that interacts with glucose concentration in the bloodstream. Therefore, optical spectroscopy renders the technique completely non-invasive by avoiding frequent acupuncture defects. Blood glucose monitors are used to measure the amount of glucose in the blood, especially in patients with symptoms and an elevated or abnormal history of blood glucose levels. More commonly, it enables diabetics to give appropriate insulin doses. The traditional process of measuring the level of glucose in the bloodstream can be uncomfortable and chaotic and should be repeated several times every day. In this work, a new non-invasive blood glucose meter has been introduced, and it will be very beneficial for diabetics by freeing them from daily, weekly or monthly glucose testing using finger prick and expensive disposal strips.

**Keywords:** Diabetes, Noninvasive Device, Fingers Prick, Glucose Meter, Laser Technology

## 1. INTRODUCTION

Diabetes is a major health problem worldwide with many patients and colossal costs. The number of diabetics is currently around 366 million, and the World Health Organization (WHO) estimates that this number will double by 2030. The blood sugar level can be a low blood sugar level (hypoglycemia), normal blood sugar, or high blood sugar Blood (hyperglycemia). There are two common types of diabetes, the first type known as insulin-dependent diabetes Mellitus (IDDM) [1] and they represent 5-10% of all cases [2], and the second type or Non-insulin-dependent diabetes Mellitus (NIDDM) [3] that occurs in childhood and requires insulin doses to maintain life. In addition to healthy eating and exercise. NIDDM occurs later in life perhaps after 40 years and may require or control insulin with weight loss for oral medications, a nutritious diet and regular exercise [4, 5]. Blood glucose measurements allow to detect diabetes and are widely used in hospitals such as Operation Theater, ICU, ER and Labor Room.

Diabetes is a medical condition in which the body does not produce the amount or quality of insulin needed to maintain blood glucose. Insulin is a hormone that enables glucose (sugar) to enter the cells of the body for

energy use. Chronic metabolic disorder is an important cause of morbidity and mortality due to a series of common secondary metabolic complications, such as the development of severe skin lesions and a slow recovery [6]. Hyperglycemia and hypoglycemia are medical conditions that show an abnormal increase or decrease in the level of glucose in the bloodstream [7]. In the event that the biological pancreas fails and stops working properly, this condition is well known as diabetes, as the causes of this disease are still unknown, and it is listed in the medical field as an idiopathic disease. The main function of the pancreas is to produce the insulin hormone responsible for converting sugar into the energy needed to keep the cells of the body alive. Therefore, it is absolutely necessary to control the level of glucose in the bloodstream and maintain its balance compared to the usual normal condition, otherwise the patient has fallen into serious problems and effects that cause miserable life or even death. This will require a continuous blood supply from the patient as the current measuring devices monitor the levels of sugar in an invasive way, sometimes leading to other complications such as bleeding, blood loss and other irritations [8]. Non-invasive techniques solve the problems of blood requirements. This article explores and applies a non-invasive approach to blood sugar control.

Traditionally, patients had to prick their fingers and put blood on a tape to get a blood sugar reading, estimate the number of grams of carbohydrates they planned to eat, and mentally calculate how much insulin they needed [9]. The system left a lot of room for error, with the wrong calculation that could lead to a dangerous or high level of blood sugar. As already mentioned, diabetes suffers from monitoring blood glucose levels using traditional techniques, and therefore, finding an easy, inexpensive and workable approach to reaching the patient's skin and knowing the exact glucose level has become a necessity especially the burden on biomedical engineering. Consequently, a new technique has been proposed to monitor the level of glucose in the blood without the need to access blood to measure it through the application of non-invasive techniques using laser light. This approach will free diabetes from a finger prick to supply a drop of blood as it does in traditional analyzers. The non-invasive blood glucose measurement (NIBGM) provides the advantage of providing additional wireless information over time periods where no finger prick is required and making glucose control more accurate and closer to normal through the use of a smart insulin pump that is the future action.

The measurement of non-invasive glucose (NIBGM) has many benefits including pain prevention and transmission of potential infectious diseases, reduced need for trained personnel, relatively short measurement time, and absence of biologically hazardous waste. Since it has been found that NIBGM penetrates deep into biological tissues, NIBGM has been developed as a non-invasive method for biomedical sensing and clinical diagnosis.

## 2. SYSTEM METHODOLOGY

### A. Interaction of Laser Light and Human Body Tissues

Frequency and wavelength are the two parameters that represent light photons. The light spectrum starts from ultraviolet light through dim light to infrared, for each radiation a specific range of energy and frequency with a wavelength that is inversely proportional to those ranges. The incident light interacts with the tissues in different ways, as shown in Fig. 1. The transmittance value can be readily calculated based on the measured reflected light and the intensity of the incident light, such as the light intensity;  $I$ , related to the wavelength of light, and the light reflection density is inversely proportional to the absorption of light. While the refractive index plays a major role in direct reflection, it is the difference between air and medium. Therefore, light on the surface can be reflected in one external direction when the tissue illuminates instead of spreading it widely, diffuse reflection refers to direct reflection and posterior scattering. Direct reflection and transmittance together is combined the incident light, while light transmittance

equals absorption and internal scattering; as shown in Fig. 2.

For each wavelength of light passing through the spectrometer, the intensity of the light passing through the reference cell is measured. This is usually referred to as  $I_0$  - that is  $I$  for Intensity. Whereas the intensity of the light is passing through the sample cell is also measured for that wavelength; given the symbol,  $I$ . If " $I$ " is less than  $I_0$ , then obviously the sample has absorbed some of the light, which is called the absorbance of the sample - which is given the symbol,  $A$ . By applying Beer-Lambert Law, the relationship between  $A$  (the absorbance) and the two intensities are given by:

$$T = \frac{I}{I_0} \quad (1)$$

The light intensity at the inputs and outputs definitely determines the interaction of light that occurred in the tissues. Often the transmitted light may be less or equal to the incident light, and each has its own function and cursor to indicate some interpretations of the reactions that occurred within the tissues [10].

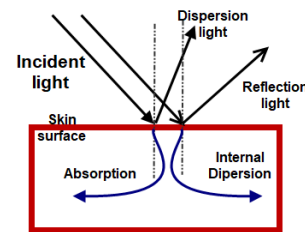


Figure 1 Light interacts on the surface of the skin, where incidental light branches into dispersion and reflection; Externally, absorption and dispersion are internally, and the rest is transmitted and penetrates into tissues.

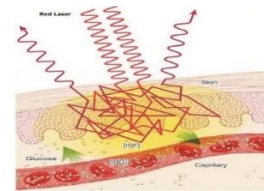


Figure 2. Absorbing Laser in Blood [10].

When working in concentration units of molarity, the Beer-Lambert law is written as:

$$A = \epsilon \times l \times c \quad (2)$$

where  $A$  is the measured absorbance, " $\epsilon$ " is the wavelength-dependent molar absorptivity coefficient with units of  $M^{-1}.cm^{-1}$ ,  $l$  ( $mm$ ) is the path length that the light travels distance through the material, and  $c$  is the analyte concentration of the absorbers in the material; ( $g/ml$ ), where Data are frequently reported in percent transmission ( $I / I_0 \times 100$ ) or in absorbance  $A = \log_{10}(I / I_0)$ . The latter is particularly convenient.



### B. Blood Optical Properties

The interaction of light with blood components in the tissues of the human body has been studied using various techniques and the most common technique is optical spectroscopy. Most of the blood components of interest to scientists are blood plasma and red blood cells for their large amounts and reasonable effect. Therefore, the optical properties of white blood cells (WBCs) and platelets (PLTs) for dispersion and assimilation [12] are ignored. The red blood cells scattering depends on shape, volume, refractive index and orientation [13]. Hemoglobin appears inside the thin plasma membrane, which is one of the main components of red blood cells, and therefore, the optical properties of a red blood cell membrane in a complete hemoglobin solution absorb and scatter the laser by erythrocytes 2-3 times higher than other blood components [14]. Hemoglobin in its functional form, linked to oxygen, has a leading effect on the absorption of light by erythrocytes [15]. Light absorption by RBCs can be caused by water, which is another important component of RBCs, especially in the NIR range. Since erythrocytes are essentially a bundle of hemoglobin solution, the Beer-Lambert law can be used to measure the absorption of light transmitted into this solution [16]. At the same time, The light that travels through the tissues leads to different optical paths that increase the time the light remains and cause the internal components to be subjected to more interactions, which means short optical path length, faster penetration and less interaction taking place within the tissues, and there are two phenomena that must be considered as they play a role in absorbing light, which are the effect of the sieve and the effect of detour, while reducing the absorption of light resulting from the first, and the latter effect increase it. Each effect has its own mechanism [17]. Thus, the calculation of the probability of absorption must take into account the structural factors that influence light diffusion in reality. Because the biological sample is not homogeneous within the tissue, light can spread without facing these tissue components, due to the influence of the sieve [18, 19]. These two effects make a big difference between the optical properties of whole blood cells and hemoglobin solutions [20]. Meanwhile, whole blood cells contain both types of hemoglobin either non-oxygenated and oxygenated and each absorbs lighter than the other, but the overall result of the absorption process remains increased by the entire blood cells, accordingly.

Plasma is the fluid part of the blood, which shows malabsorption and dispersal behavior when compared to erythrocytes. These depend on the differences that may increase the length of the path of light that traverses red blood cells, this increases the possibility of light absorption into the bloodstream [21]. The whole blood cells are largely affected by the state of their measured movement with respect to the gradual velocity in the normal direction of the flow, where the two main

phenomena of diffused light and absorption are available and affect the condition of the entire blood cells [22]. The movement of blood cells in the bloodstream must be considered, as this is related to the phenomena of light and their effect in relation to the direction of blood flow and the orientation of the components that determine the relative position of the components within the bloodstream. As the shear rate increases, red blood cells begin to correspond to the direction of the flow, and thus the orientation of the components changes, and as a result, the light reflection increases, thereby reducing the intensity of the penetration light, accordingly [23].

### C. Glucose Absorbance

Monitoring the body's blood glucose concentration is a major challenge. Equipment development is the effort in diagnosing and treating diabetics to achieve optimal metabolic control by measuring repeated blood glucose. Non-invasive glucose sensing in the bloodstream becomes increasingly important as the number of diabetics increases. One of the most promising methods is the 635 nm laser. Concentration is an essential component of Beer Lambert's Law. The concentration affects absorption in all its components. Absorption, dispersion and attenuation, these components are commensurate to the path length, accordingly. If the solution's concentration is increased, there are more light particles to be struck as it passes. As the concentration increases, more molecules are present in the solution, and more light is prevented from penetrating. Glucose concentrations is inversely proportional to absorbance at specific wavelength [24]. The higher the glucose concentration, the lower the absorbance. Therefore, this leads to a dispersion of light in the solution and leads to a more luminous medium.

The interaction of light with matter depends on a number of parameters, such as wavelength, energy, spot size, exposure time, and more. As a result of this reaction, to name a few, reflection, dispersion, turbidity, absorption and attenuation, have a serious effect on the remainder of the light that is a transmission, which reflects the concentration of a particular substance in the medium, such as sugar in the bloodstream [25]. In optical spectroscopy. Light emission is reflection or dispersion by a substance. It is the scattered light from a substance, which differs from the light that travels through matter. Absorption in tissues causes the absorbed molecules to move from their ground state to excitation. Laser is a state of light with some conditions that give special properties to light, and these properties are coherent, directional, monochromatic, brightness and intensity. Laser energy varies with respect to wavelength, so the penetration of this light in tissues varies according to the specific wavelength that contains a certain level of energy. Therefore, the depth of penetration depends on the energy of the wavelength. Therefore, the depth of penetration is directly proportional to the energy of the wavelength,

which means the lower the energy that the wavelength possesses, shallow penetration occurs on the surface of the skin, such as a green laser. On the contrary, the more wavelength energy, the greater the penetration, until light travels to the other side of the tissue, i.e. the earlobe or fingers, such as infrared radiation. [26]. Tissue dispersion factor and refractive index are visual parameters within tissue specifications, and their values depend on the concentration of glucose. Tissue permittivity and connectivity are parameters that are also considered electrical specifications for tissues that are also sensitive to glucose concentration. Glucose dispersion factor is important in determining the behavior of the dispersion reaction with light, as the refractive index varies according to the type of tissue and its contents, and is inversely proportional to that in the interstitial fluid, and the refractive index that belongs to the dispersion of molecules, thereby reducing the dispersion factor [27].

#### D. The Mechanism of Light on The Blood Content

Human blood contains many biological substances, and leads to it being a heterogeneous medium, which makes the media mysterious. Therefore; refractive indices should be considered here. These different components have different refractive indices. While the predominant component of the bloodstream is the sugar concentration, it may cause a serious change in the refractive index of the medium [28]. When the laser is applied vertically to the tissues; Such as earlobes or fingertips. As a result, more phenomena occur, such as dispersion, attenuation, absorption and the penetration of residual light. The Beer-Lambert's Law strongly present, and all its variables play an important role in this field. The concentration of sugar in the bloodstream is the most important component related to this work. The length of the optical pathway is also important, as light passing through the medium will affect the intensity of the transmitted light. Phenomena, such as dispersion, attenuation, turbidity, and absorption, vary according to the sugar concentration, optical path length, and permittivity. permittivity is a function of pH, temperature, and blood viscosity. The concentration of glucose changes the length of the light path. The higher the glucose concentration, the shorter path length was achieved [29]. The amount of blood in the detectable area should be considered as there must be a threshold for the detection of glucose in the bloodstream.

### 3. MATERIALS AND METHODS

The proposed medical device consists of a type of electronic component, which is Arduino Nano, i.e. ATmega328 produced by Gravitech. Laser transmission unit; LD-635-5I, (Red), gives a small intense beam. Power consumption: 30 mA at 5V. This model features high quality and low cost, wavelength from 635 nm to 640 nm, output power from 5 mw-100 mw. A light-emitting diode (LED) is a semiconductor diode that incandesces when applying a voltage. in case of a primary

light sensor is required, the LDR circuit can be used as the one in Fig. 3.

The mechanism of LED lights depends on enough light falling on the LDR resistor. The variable resistor, 10K, is used to adjust the semiconductor diode above the threshold value for LED start. The most common type of LDR is characterized by reduced resistance with increased light intensity on the device. LDR resistance usually has the following resistance: daylight = 5 K $\Omega$ , Dark = 20 M $\Omega$ . Therefore, there is a big difference between these numbers. The liquid crystal display (LCD), i.e. a 16 x 2 screen, is used in this device to display input data and measured values as an option but not the only option that can also be used as USB, Bluetooth and wireless to transmit patient data; Input and output for history and search purposes. There are reasons to use a 16-character, two-line LCD screen, from economical cost to the ability to display unlimited characters. A light-

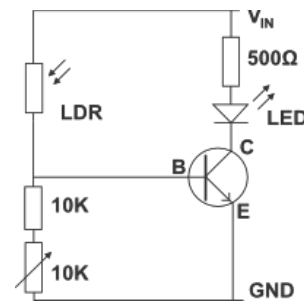


Figure 3. Basic light sensor.

dependent resistor (LDR) that is instead called photoresist, photoconductor, or photovoltaic cell, LDR is light sensitive as its resistance is inversely proportional to light. Where light, as energy, raises electrons from the ground state to the conduction band that will release electrons and reduces sensor resistance. External contacts responsible for linking the system on-chip with the real world are called Ohmic contacts. This contact should be at a very low resistance and sensitive to reduce the interference feature of the output signals and maintaining the output signal is limited to the difference of incident light only. Since the laser light is red, this may be a moderate problem and can be avoided by isolating the system to prevent the external impact parameter from interfering with the desired results. But for the near infrared light source, the conventional optical detector must be replaced by a higher technical detector like Indium Gallium Arsenide photodiode (InGaAs), which can be used to sense other wavelength ranges; green, red and infrared. A resistor is a component used in any electronic design to control electronic circuits as is well known. Resistors are either fixed or variable, their use depends on the application needs. The breadboard is used to quickly build and test the circuits before completing any circuit design and forming the required circuit on the printed circuit board (PCB). The breadboard has many

holes in which circuit components can be inserted like integrated circuits and resistors. The connections between the different components are formed by placing their legs in a common knot. The upper and lower rows of holes are usually used for power source connections. The rest of the circuit is built by laying the components and connecting them together with the connecting wires.

**4. PROTOTYPE DESIGN AND SIMULATION**

Fig. 4 shows a schematic diagram of a prototype design using Proteus 8 Pro.

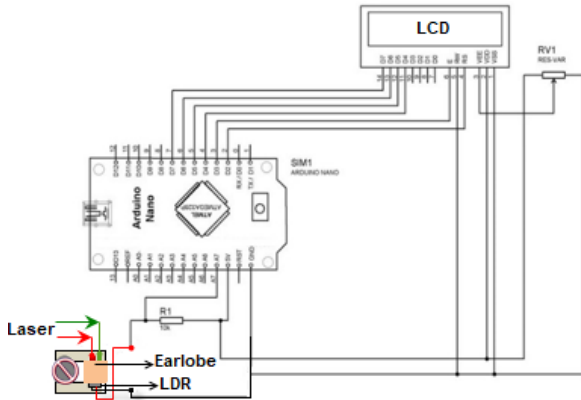


Figure 4. Prototype Design.

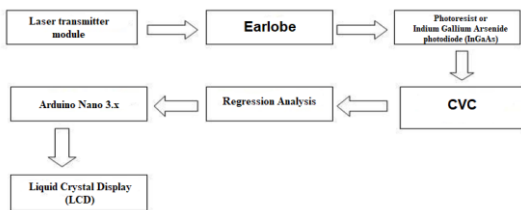


Figure 5. Diagram of a laser glucose meter (NIBGM).

The components are connected and simulated to verify the algorithm system for Arduino Nano, because this is necessary to fine tune and adjust the entire system to improve it and make it reliable for diabetics. The design is based on a flowchart that handles the signal transmitted in steps that end up with the required measurement of the concentration of glucose in the patient’s bloodstream. The NIBGM laser flow chart is shown in Fig. 5. It consists of the following stages; Laser transmitter, Earlobe, photodiode, current to voltage converter (CVC), regression analysis, Arduino Nano, and LCD. The used laser sensor operates along a 635 nm wavelength (red).

The laser light signals are passed through the earlobe and the remaining light detected in the photodiode is proportional to the concentration of glucose in the bloodstream, which varies from patient to patient in terms of earlobe thickness. The photodiode output is converted

to a voltage signal by CVC. This product is filtered, amplified, and adapted for a better result. The output is then fed to the Arduino Nano; microcontroller (MCU), to perform a voltage change analysis of the received signal, to monitor whether the obtained value is within the threshold. Here the intensity is inversely proportional to the voltage.

**5. METHODOLOGY OF THE DEVICE**

Earlobes were chosen due to a lack of bone tissue; as shown in Fig. 6. In addition, their thickness is relatively small, and the site causes no problem for the patient. The intensity of the laser penetrated through the earlobe depends on the concentration of glucose in the bloodstream. The earlobe contains a lot of blood vessels, which will provide the system with sufficient and always stable information due to immobility. This is very important to exclude this parameter from the contrast and determine the difference to the main parameter, which is the concentration of glucose in the blood. The medical earlobe clip contains a light source on one side and a light detector on the other; as shown in Fig. 6. Then the transmitted light signals are collected and processed.

In conventional glucose meters, low blood volume plays a major role in the performance and accuracy of blood glucose meters. The volume of blood required to fill the strip is 0.32 µl, while the Freestyle meter requires a minimum volume to fill a strip with a blood volume of at least 0.3 µl, and gives results in five seconds [30]. In a non-invasive glucose meter, the glucose reading becomes independent of this feature and regardless of the amount of blood at the point of measurement, the glucose level will not be affected, and the reading will reflect the patient's condition whether normal, hyperglycemia or hypoglycemia. A large amount of glucose in the blood causes a decrease in permeability, while a decrease in blood glucose increases the permeability.

Glucose measurement may be affected by the thickness of the earlobe tissue, which must be observed, since this is the length of the optical pathway. This sounds to be a problem particularly when more than one person uses the same device. In this case, the thickness of the earlobes can be measured with a green laser and compare the results with a real micrometer calipers, which is an instrument for making accurate linear measurements of dimensions such as thickness and lengths of objects. So, it should be checked and highlighted, then based on the results of the investigation, this will definitely show its effect on the system whether it is positive or negative, and this parameter should be recorded and modified in the algorithm of the system. If there is no effect for this parameter, it will be overridden automatically. According to Beer-Lambert's Law, the thickness of the earlobe is expected to determine the "path length" of the laser. Will thicker path length lead to lower



permeability? Do they apply in this field? It unfolds later and the investigation and conclusions show a clear impact.

The thickness of the tissues determines the "path length" of the light source, so the longer the path length the lower the light transmittance in the medium. The thickness of the earlobe is measured using light with a visible long wavelength such as green light, which is suitable for measuring the thickness of the earlobe where the penetration depth is shallow. To properly address this

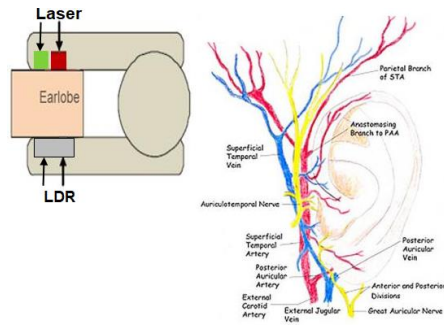


Figure 6. Lobular earlobe anatomy. Copyright © 1994-2020 by WebMD LLC. Medscape

problem, another laser diode with a green wavelength of 560 nm can be used. The same photodiode detector with a wide range of wavelength sensor has been used separately without conflict. This is a green (560 nm) and red (635 nm) light, because the optical detector has a spectral response that contains these wavelengths.

**6. RESULTS AND DISCUSSION**

The suggestion regarding the possible course of action for the regression model is to predict blood glucose concentration values for the commercial meter (y) based on the non-invasive meter values for the blood glucose concentration (x) variables. The diagram shown in Fig. 5 illustrates the steps of a flow chart created to obtain correct, accurate, and reliable data on diabetics. Based on these stages of the flow chart, the proposed non-invasive device (NIBGM) was implemented and glucose concentration measurement was taken for different patients at the local diabetes center and the data was tabulated. The results are presented in Table 1. The baseline measurement was taken without modifying the system algorithm. System behavior is shown in Fig. 7 with respect to the commercial blood glucose meter as a reference scale; which is a FreeStyle Optimum Neo blood glucose meter.

A Bland–Altman plot in analytical chemistry or biomedicine is a method of data plotting used in analyzing the agreement between two different assays [31]. The proposed measurement of the device did not meet BGM surveillance study accuracy standard, as shown in Fig. 8

and blood glucose monitoring system surveillance program, modified Bland-Altman plot confirms the results of the device mismatch, as shown in Fig. 9. A grid was created to map the accuracy of a blood glucose reading and to create an acceptable error factor whereas inaccurate reading, when compared to commercial meter quality testing, may or may not lead to improper treatment decision making. Clarke Error Grid is the predominant measurement of meter accuracy in leading manufacturers. The Clarke Error Grid Analysis (EGA) was developed in 1987 to quantify clinical accuracy of patient estimates of their current blood glucose as compared to the blood glucose value obtained in their meter [32].

One of the most important things that a blood glucose meter needs is to get accurate results. With an accuracy of 99.4% based on user testing, the FreeStyle Optimum Neo Blood Glucose Meter provides the patient with confidence in their meter. The FreeStyle Precision Neo system is designed to ensure that test errors are minimized, and it gives patients results they can trust. All measurements were <75 mg / dL with FreeStyle Lite in the range of ± 15 mg / dL. Accuracy of blood glucose readings 75 mg / dL was analyzed for four bands within ± 5%, ± 10%, ± 15%, and ± 20% [33].

Table 1. The commercial device as a reference scale and non-invasive device measurements.

	Noninvasive Meter	Reference Meter	Calibration	Situation
1	135	157	156	Before Eating
2	152	171	173	After Eating
3	130	151	151	After Eating
4	109	128	129	Before Eating
5	114	133	134	After Eating
6	139	160	160	After Eating
7	143	164	164	After Eating
8	153	174	174	After Eating
9	122	143	142	After Eating
10	112	134	132	After Eating
11	138	157	159	After Eating
12	125	147	146	After Eating
13	133	153	154	After Eating
14	128	146	149	After Eating
15	146	167	167	After Eating
16	124	145	145	After Eating
17	109	130	129	Before Eating
18	80	99	100	Before Eating
19	111	130	131	Before Eating

20	110	132	130	Before Eating
21	119	140	139	Before Eating
22	114	135	134	Before Eating
23	97	117	117	Before Eating
24	109	129	129	Before Eating
25	99	120	119	Before Eating
26	109	130	129	Before Eating
27	99	119	119	Before Eating
28	121	142	141	After Eating
29	102	122	122	Before Eating
30	95	115	115	Before Eating
31	123	144	144	After Eating
32	119	139	139	Before Eating
33	89	110	109	Before Eating
34	109	130	129	Before Eating

The calibration process was performed based on the selected conventional device, which is FreeStyle Optimum Neo Blood Glucose Meter for its accuracy and reliability it can be considered as a global calibration. Calibration process was performed based on the regression analysis, the system algorithm was modified, and the device was tested accordingly. The relationship between the reference and the proposed devices appears in Fig. 10. As a result, accurate and valid data was obtained and confirmed through two BGM surveillance study programs, which indicates that the modified system meets the requirements that make the device reliable for diabetics, as described in Fig. 11 and Fig. 12; respectively, and it will be revealed in detail later.

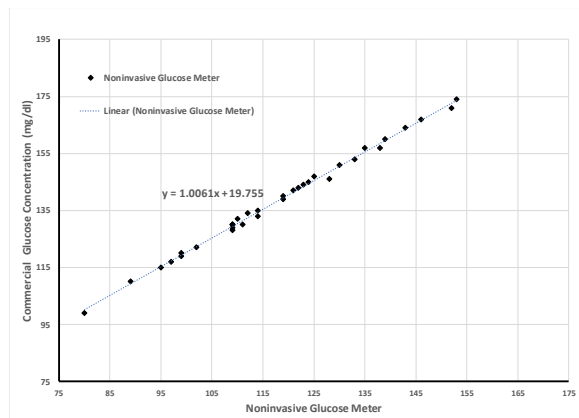


Figure 7. Non-invasive blood sugar level vs. the commercial meter for reference.

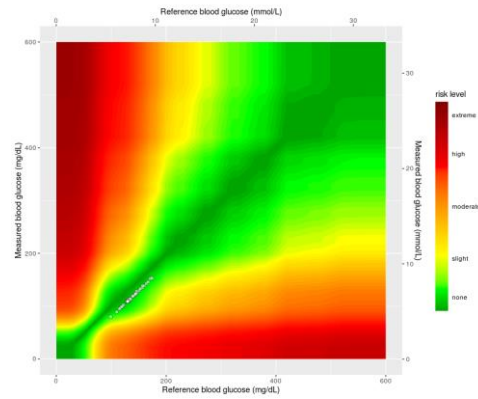


Figure 8. Clarkson Error Grid for Non-Invasive and Commercial Glucometers, before calibration.

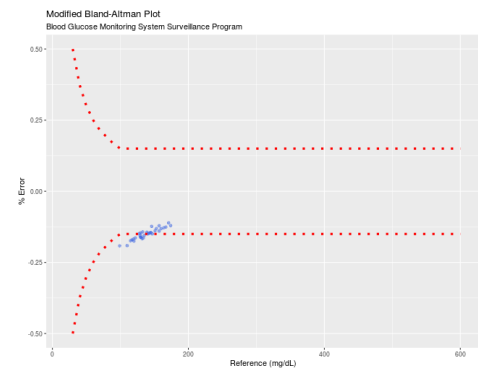


Figure 9. Modified Bland-Altman plot, for Non-Invasive and Commercial Glucometers, before calibration.

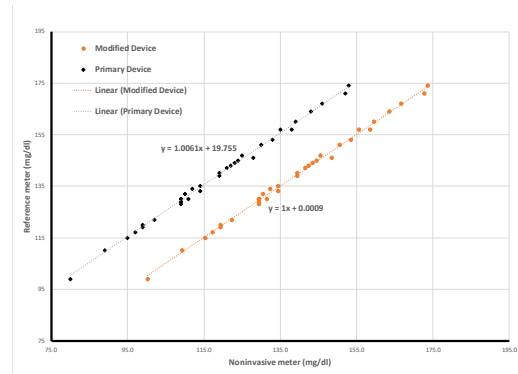


Figure 10. Non-invasive blood sugar level, before and after calibration versus the commercial meter for reference.

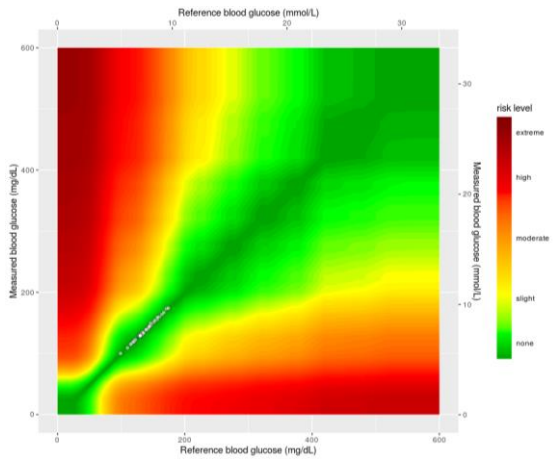


Figure 11. Clarkson Error Grid for Non-Invasive and Commercial Glucometers, after calibration.

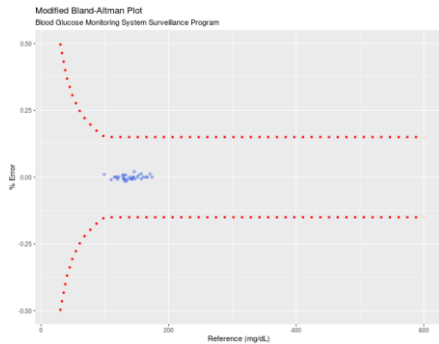


Figure 12. Modified Bland-Altman plot after calibration for Non-Invasive and Commercial Glucometers,

The proposed device (NIBGM) underwent two case studies to monitor the condition of two patients over 24 hours using the three devices, commercial and primary and modified devices, and the result appears in Fig. 13 and Fig. 14. The results of the modified and commercial devices are identical to each other and the proposed device can be considered as a reliable measure of glucose concentration without any risks.

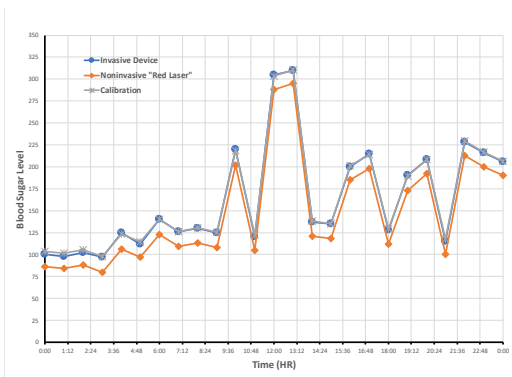


Figure 13. Case 1: Continuous monitoring of blood sugar for 24 hours.

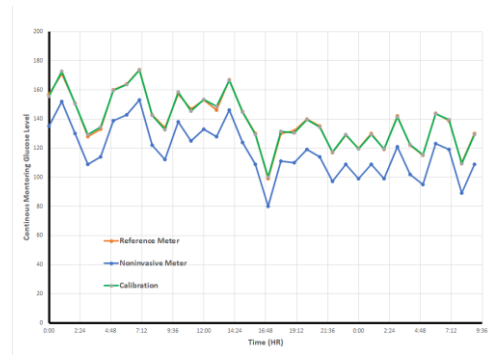


Figure 14 Case 2: Continuous monitoring of blood sugar for 24 hours.

A. System Accuracy Analysis

We would like to note that the device used to measure blood sugar compared to the results of the proposed device (NIBGM) is the FreeStyle Optimum Neo Blood Glucose measurement system. The outcome of the surveillance error grid (SEG) analysis tool contains the number of Blood Glucose Monitor (BGM) values are either less, equal, or greater than the reference values (REF). High reference values above 600 mg/dl were ignored in SIG analysis. Clinical risk is classified into values across eight levels; as shown in Table 5. The following tables and figures clearly show that the patterns indicate that the proposed device has fulfilled all requirements [34]. All results were generated in the following tables 2-7 of the program that is SEG.

Table 2. The outcome of the SEG analysis tool

Pair Type	Count
Total	34
BGM < REF	13
BGM = REF	13
BGM > REF	8
Total included in SEG Analysis	34

Table 3. SEG parameters and constrains.

Total	Bias	MA RD	CV	Lower 95% Limit of Agreement	Upper 95% Limit of Agreement
34	0.10 %	0.60 %	0.8 0%	-1.60%	1.50%

Table 4. Risk Grade for Clarkson Error Grid.





ID	Risk Grade	Number of Pairs	Percent	Risk Factor Range
1	A	34	100%	0 - 0.5
2	B		NA	> 0.5 - 1.0
3	C		NA	> 1.0 - 2.0
4	D		NA	> 2.0 - 3.0
5	E		NA	> 3.0

Table 5. SEG Risk Level for Clarkson Error Grid.

SEG Risk Level	SEG Risk Category	Number of Pairs	Percent
0	None	34	100%
1	Slight, Lower		NA
2	Slight, Higher		NA
3	Moderate, Lower		NA
4	Moderate, Higher		NA
5	Severe, Lower		NA
6	Severe, Upper		NA
7	Extreme		NA

Table 6. ISO range = difference between BGM and REF.

ID	ISO range	N	Percent
1	$\leq 5\%$ or 5 mg/dL	34	100%
2	$> 5 - 10\%$ or mg/dL	NA	NA
3	$> 10 - 15\%$ or mg/dL	NA	NA
4	$> 15 - 20\%$ mg/dL	NA	NA
5	$> 20\%$ or 20 mg/dL	NA	NA

ISO range = difference between BGM and REF as percent of REF for REF > 100 mg/dL and in mg/dL for REF  $\leq$  100 mg/dL.

Table 7. BGM Surveillance Study Accuracy Standard [34].

Compliant Pairs	Compliant Pairs %	Lower Bound for Acceptance	Lower Bound for Acceptance %	Result
34	100%	30	88.20%	100% > 88.2% - Meets BGM Surveillance Study Accuracy Standard

**B. NIBGM To Measure Earlobe Thickness**

The proposed device (NIBGM) was used to examine the effect of earlobe thickness on measuring blood glucose concentration. Data were also obtained from the local diabetes center, and tabulation of the results as described in Table 8.

Table 8. Measuring the thickness of the earlobe using a non-invasive device w. r. to micrometer caliper measurements.

Age	Weight (Kg)	Gender	Green laser transmitted	Earlobe Thickness (mm)
56	70	M	189	5.24
47	64	F	190	5.25
57	92	F	190	5.25
53	72	F	192	5.26
45	80	M	193	5.26
55	63	F	193	5.26
59	63	F	193	5.26
58	80	FM	195	5.27
54	66	F	195	5.27
43	82	M	195	5.27
52	92	M	197	5.28
43	98	F	198	5.29
53	50	F	198	5.29
45	76	F	198	5.29
52	65	F	199	5.29
42	54	F	200	5.30
40	62	F	201	5.30
41	84	M	201	5.30
50	85	M	203	5.31
50	74	F	205	5.32
48	74	F	209	5.34
55	65	M	210	5.35
50	78	F	211	5.35
59	68	F	215	5.37
46	83	M	241	5.48

Fig. 15 shows the relationship between earlobe thickness measurement using a NIBGM device with green laser light in relation to patient earlobe measurements. Green laser is used because it is suitable for shallow absorption on the skin, as red laser stops in this case. The result came with unexpected results, indicating that the

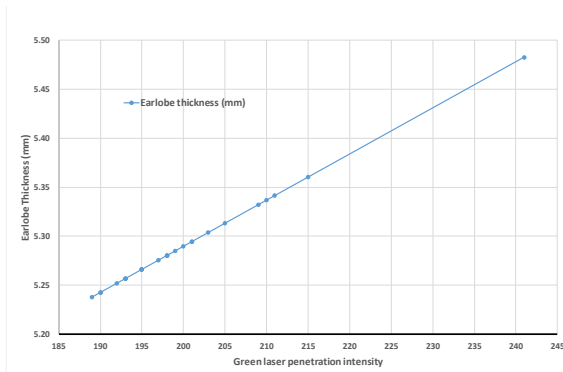


Figure 15. Measuring earlobe thickness using NIBGM device with green laser light in relation to real earlobe measurements.

thickness of the earlobe is the length of the optical pathway, this is so true but does not have a significant effect on measurement and can be ignored and not recorded in the system algorithm; as shown in Fig. 16.

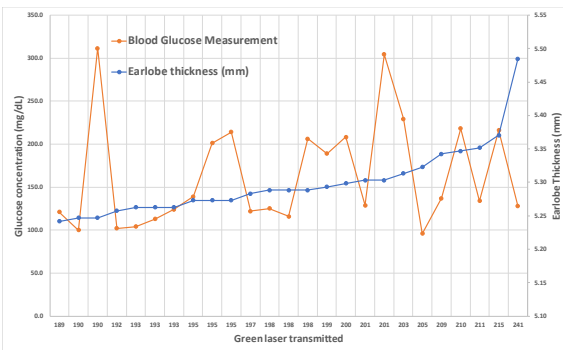


Figure 16. The effect of earlobe thickness on the performance of the noninvasive system.

## 7. CONCLUSION

The blood component has a different range of absorbance and reflection within a different range of wavelength. This work created a laser-based platform to allow diabetics to check blood glucose levels without pricking their fingers to withdraw blood that fulfills one of the safest and secure patient requirements with the least pain and cost. The system works by directing the laser beam to the patient's earlobe and measuring the remainder of the light after all other subcutaneous phenomena such as absorption and scattering occur when the laser interacts with interstitial cutaneous fluid, which is closely related to blood sugar levels. This device directly monitors blood glucose levels noninvasively. This novel, non-invasive device can change the lives of millions of people with diabetes and end the need for daily pain and disorganization from a finger prick test or the use of monitoring implants. This device also provides a simpler and possibly cheaper alternative to health care providers. The device is under development and currently not available for use with a high level of glucose.

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## DECLARATION OF CONFLICTING INTERESTS

The Authors declare that there is no conflict of interest.

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