Portable Non-Invasive Glucometer using Near-Infrared Sensor and Raspberry Pi

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***Abstract*— This study helps monitor the blood glucose level of a patient with the help of a standalone portable non-invasive glucometer. Diabetes is a disease in which the blood glucose levels are too high and considered to be one of the leading causes of death affecting millions of people worldwide. In this study, a portable device that measures the blood glucose level was developed using the near-infrared light-emitting diode and a photodiode that works together as the NIR sensor which measures the blood sugar level. The Raspberry Pi microcontroller does the processing of the information that came from the sensor patch. The touch-screen liquid crystal display module displays the data results gathered from the tests made and a microSD card is used to store the results that will then be used in the device history. During the testing, results showed that the measured values done using the device and the commercially available glucometer had no significant difference, based on the results of t-test conducted. All test made in the device is based on the International Organization for Standardization, ISO 15197:2013 standard where 95 percent of the results should fall within the acceptable range, 97.14 percent was the percentage the researchers were able to get, where 68 out of 70 tests made the cut of having a difference of positive or negative 20 percent based on the standard.**

Keywords*— Non-invasive, ISO 15197:2013, glucose level, self-monitoring blood glucose device, near-infrared

I. INTRODUCTION

Diabetes is a metabolic pathological condition and the fastest growing long-term disease that affects millions of people worldwide [1], [2]. Across all ages, there are 2 out of 20 and in every 10 deaths there are 2 adults aged from 35 to 64 globally are related to diabetes according to the World Health Organization [3]. An estimation of 3.9 million deaths is caused by diabetes [4]. During the years of 1980 to 2016, the number of people with diabetes increased from 108 million to 422 million people [5]. In the Philippines, the number of people affected by diabetes is more than 3.7 million people based on the survey done in 2015 [6], [7].

It is important to understand the process of food intake for the body to function for us to further understand what diabetes is. When a person induces food, glucose enters the bloodstream and serves as the energy source for the body. The glucose moves from the bloodstream into the cells with the help of Insulin, if the glucose were not moved out of the bloodstream it would cause having a high blood sugar level which is then called Diabetes, which can be caused by having a poor diet and lack of exercises needed by the body, the human body metabolism decreases over time [8],[9],[20]. Commercially used glucometer offers patients to take the test to monitor their blood sugar level by pricking into the finger with a lancet and dropping blood into a glucose strip that will be inserted in the device manually. The most advanced glucose meter module available in the market cannot create a profile for multiple users and save the test readings they make [10].

Commercially used glucometer offers to measure the blood glucose of a patient, which is often in need of a blood sample that is done by pricking the finger of the patient or through hospital laboratory tests, which more often causes pain and trauma mostly on young patients such as children of ages 6 and below. Self-monitoring blood glucose device has been considered as one of the breakthroughs in monitoring the glucose level of a diabetic patient, where the patients can determine the level of their glucose level throughout the day and daily lives [11].

For someone with diabetes, a glucometer is a basic need and it should be available all the time. Overall, the test using the universal glucose meter showed acceptable accuracy. The development of this universal glucose meter will assist diabetic patients and clinics for testing glucose level using various testing strips on a single device [12], [21]. This study aims to produce a glucometer that non-invasively reads the glucose level of a patient with the use of NIR sensor, which can be worn and be used by diabetic patients and healthy people for the everyday life.

In a study conducted by Guo, Shang, Peng, Yong, and Wang, they used of NIR sensors with the help of artificial neural network (ANN) and said to produce promising results in the field of non-invasive blood glucose measurement [13]. Near-Infrared (NIR) spectrum, compared to other non-invasive method is the most explored optical techniques due to its advantages which has a high capability of penetrating deep into the skin [14]. According to the journal made by Narkhede, Dhlwar, and Karthikeyan (2016), the technique of using NIR sensors can be applied to different body parts, due to its high penetration capability, such as fingers, arm, forearm, earlobe, palm, etc. [15]. Figure 1 shows how deep the NIR LED can penetrate the skin. The light emitted by the NIR LED can penetrate the deepest part of the veins where the best results are for blood glucose measurement is gathered [16], [17].

According to the book written by Chase and Maahs (2006), blood sugar is measured in milligrams per deciliter (mg/dL). There are four categories in determining the blood sugar level, which is low, normal, high, and very high. Low

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blood sugar has a reading of below 60 mg/dL. Normal blood sugar reading ranges from 80 to 200 mg/dL. The reading of 200 to 400 mg/dL indicates high and having a reading above 400 mg/dL means that the patient has a very high glucose level [18].

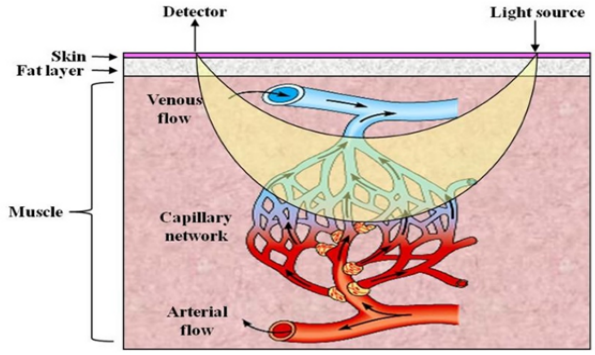

Fig. 1 NIR Sensor Skin Penetration [17]

TABLE I
BLOOD GLUCOSE LEVEL IN DIAGNOSING DIABETES [18]

Plasma Glucose Test	Normal	Prediabetes	Diabetes
Random	Below 11.1 mmol/L (Below 200mg/dL)	N/A	11.1 mmol/L or more (200 mg/L or more)
Fasting	Below 5.5 mmol/L (Below 100mg/dL	5.5 to 6.9mmol/L (100 to 125 mg/dL)	7.0 mmol/L or more (126mg/dL or more)
2 hours post prandial	Below 7.8 mmol/L (Below 140 mg/dL)	7.8 to 11.0 mmol/L (140 to 199 mg/dL)	11.1 mmol/L or more (200mg/dL or more)

Table I shows the target sugar level reading for people who are non-diabetic, prediabetic, and a diabetic person, given by the National Institute of Clinical Excellence (NICE).

II. METHODOLOGY

A. Research Process

This study uses Agile waterfall method in constructing the device. This method focuses on the steps of logical sequence in developing the device as well as cascading step-downs in the incremental waterfall, and step-ups in case that the latter process does not work.

Planning is the process where the researchers aim to look and create a solution regarding the making of the device that can meet the objectives set. The analysis emphasizes on the research background by gathering related articles and searching for different hardware that would fit in the objective to make sure each part of the device works. The design process works on the hardware and software designs that would make the device function properly according to the objectives, functionality, and features that it is intended to do. Code and Debug is where the researcher work on and test the system, whether the device would function properly and if there would be no error along the way that would make the data gathered using the device not match the input needed and if there are problems along the way, the researchers will fix the problem before proceeding to the next step. System testing, here the researchers would see if the objectives that were set beforehand are met and if the device is producing data results according to the results expected and recommended by the basis they used.

Maintenance is where repairs and updates will happen, in case the standards and other constants used in the system were to be updated in the future the researcher would then update the whole system to meet the required results. Repairs will be done if problems in either or both the hardware and software come along the way. During each step, the researcher could only proceed to the next step if the step they are in would be feasible if errors and other problem occurs after moving on to the next step then they would need to go back one step and redo the work.

B. Hardware Development

Figure 2 shows the hardware setup block diagram of the device. The power supply that makes the device function consists of three 18600 Li-ion battery. The NIR detector sensor is composed of the NIR spectroscopy sensor and a photodiode detector whose primary function is to emit and transmit the light that would produce the wavelength. Raspberry Pi is a microcomputer that processes the data gathered from the photodiode and NIR Detector Sensor and transmit the processed data to the LCD Screen.

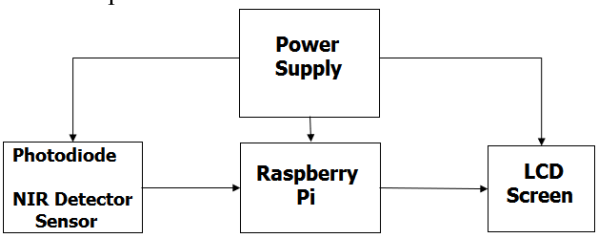

Fig. 2 Hardware Setup Block Diagram

Gathered data will be stored in the Raspberry Pi through a micro SD card. The Raspberry Pi will not only store and process the data gathered but also interprets the data that will be shown in the LCD Screen. The device created uses the light emitted by the NIR LED penetrating the skin which would produce the light reflectance that would be transmitted by the photodiode and then converted into wavelength. The wavelength would then be correlated with the invasive glucometer test results to see if there would be a significant relationship between the data.

C. Graphical User Interface

Shown in Figure 3 is the scanning panel where the user can see the scanned glucose level and status of their blood glucose. The user can set the time of interval in each scan where the device would automatically scan the user's blood glucose, but the time allowed would be a minimum of 2 hours due to the standard process of taking the blood sugar level after eating. Glucose level will show the glucose count of the user which is based on the standard used by the researchers, ISO 15197:2013 and the status or classification of the glucose level would be seen in the status bar. The blood sugar status or classification can be defined as normal, prediabetic, and diabetic.

Fig. 3 Scanning Panel/Home Panel

Different buttons can be seen in the Home or Scanning Panel, the start button is used to start the scanning process and the first scan would be the initial data. To end the scanning process stop button is present. The user can delete all the data they wish to delete by simply clicking the Clear Data button. Graph button allows the user to view the Graph Panel, shown in Figure 4, where the graphical interpretation of all the data made for the current time duration of the scan.

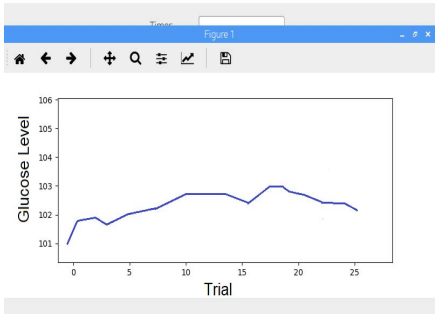

Fig. 4 Graph Panel

In the graph, the user would be able to see the line graph representation of the Glucose Level (y-axis) vs. Trials (x-axis), where the user in the test increase their glucose count as each test is done giving a straight line leaning upwards. The view button allows the user to view the history of all scans made on a certain day.

In Figure 5, the historical record of a certain day is listed. This feature allows the user to pick on a day within the calendar shown. The recorded scans made on that day would be listed on the right-hand side of the panel by simply clicking the pick button. If the user wishes to exit the application the close button will terminate the program immediately.

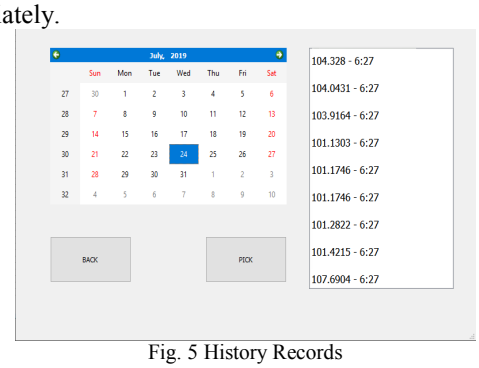

Fig. 5 History Records

III. Testing and Results

The researcher conducted tests from different patients both diabetic and non-diabetic ones. Each patient tested are made sure to have eaten two hours before they went under the two tests, first using the commercial glucometer and second is using the non-invasive glucometer.

The commercial invasive glucometer used in verifying the results of the study is a digital device with the following specifications, the measurement range of 20 – 600 mg/dL, automatic coding method, sample volume of 0.5 µL, data management 7 – 30 days average, and memory capability of 300 memory with date and time. The patient's fingertip is first cleansed using alcohol, then pricked by the lancet. Once a good drop of blood comes out of the patient's finger it is then put into the strip attached to the glucometer device that would then process and show the result of how much the patient's glucose count is. Once the first test is done, the researchers would then proceed to the second test using the non-invasive device. In using the non-invasive device, the patients only need to put the device on their forearm and then press the "start" button shown on the screen. The reading would then be shown on the screen for both the level and the status of the patients' blood. In every test made the researchers list the data gathered which is shown in Table II.

The results of the test conducted by the researchers are all based under the standard, set by ISO 15197:2013. Data shown in Table II were gathered and each column on the table represents different data. Data gathered from the patients using both the commercial and Non-Invasive device can be found in the second and fourth column of the table.

The allowed difference that the non-invasive device is created by the researchers could be found in the third column. These values are the allowed difference in result the device created by the researchers could have from the commercial glucometer. The fifth column shows the difference in the market's glucometer and the non-invasive device have, whereas 97.14%, 68 out of 70 tests, of the test made fell under the +/- 20% accepted value set by ISO 15197:2013 stating that a minimum of 95% of the tests done should fall under the +/- 20% accepted value [19].

Figure 6 shows the pie chart of the collected data given in Table II. As shown in the chat approximately 97% of the test done using the non-invasive device passed the standard while 3% of the test failed.

$$S_{x_D} = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}(X_{Di} - \overline{X_D})^2} \quad (1)$$

$$t = \frac{\overline{X_D}}{\frac{S_D}{\sqrt{n}}} \quad (2)$$

$$H_0 : t \leq 3.46 \quad (3)$$

$$H_1 : t > 3.46 \quad (4)$$

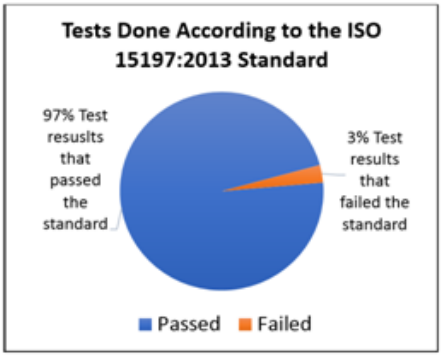

Fig. 6 Pie Chart for Test Results of Non-invasive Glucometer

TABLE II. BLOOD GLUCOSE DATA AND RESULTS

Patient	Commercial Glucometer	Allowed Difference	Non-Invasive Glucometer	Actual Difference
1	153	+/- 30.6	156	3
2	119	+/- 23.8	115	-4
3	111	+/- 22.2	110	-1
4	99	+/- 19.8	116	17
5	120	+/- 24	116	-4
6	86	+/- 17.2	99	13
7	158	+/- 31.6	158	0
8	98	+/- 19.6	114	16
9	125	+/- 25	130	5
10	103	+/- 20.6	105	2
11	94	+/- 18.8	100	6
12	68	+/- 13.6	84	16
13	157	+/- 31.4	157	0
14	201	+/- 40.2	205	4
15	97	+/- 19.4	100	3
16	89	+/- 17.8	102	13
17	138	+/- 27.6	152	14
18	90	+/- 18	107	17
19	85	+/- 17	101	16
20	185	+/- 37	221	36
21	90	+/- 18	107	17
22	88	+/- 17.6	88	0
23	94	+/- 18.8	111	17
24	79	+/- 15.8	93	14
25	157	+/- 31.4	158	1
26	91	+/- 18.2	91	0
27	168	+/- 33.6	175	7
28	195	+/- 39	188	-7
29	152	+/- 30.4	63	11
30	110	+/- 22	129	19
31	107	+/- 21.4	124	17
32	185	+/- 37	186	1
33	169	+/- 33.8	180	11
34	88	+/- 17.6	101	13
35	168	+/- 33.6	184	16
36	241	+/- 48.2	238	-3
37	106	+/- 21.2	103	-3
38	146	+/- 29.2	156	10
39	96	+/- 19.2	94	-2
40	97	+/- 19.4	111	14
41	164	+/- 32.8	159	-5
42	93	+/- 18.6	96	3
43	131	+/- 26.2	131	0
44	98	+/- 19.6	96	-2
45	86	+/- 17.2	99	13
46	89	+/- 17.8	101	12
47	104	+/- 20.8	114	10
48	112	+/- 22.4	115	3
49	130	+/- 26	122	-8
50	117	+/- 23.4	125	8
51	89	+/- 17.8	98	9
52	83	+/- 16.6	97	14
53	97	+/- 19.4	99	2
54	83	+/- 16.6	86	3
55	210	+/- 42	212	2
56	101	+/- 20.2	104	3
57	117	+/- 23.4	118	1
58	68	+/- 13.6	80	12
59	97	+/- 19.4	99	2
60	145	+/- 29	135	-10
61	97	+/- 19.4	109	12
62	143	+/- 28.6	157	14
63	128	+/- 25.6	131	3
64	89	+/- 17.8	101	12
65	91	+/- 18.2	94	3
66	76	+/- 15.2	99	23
67	170	+/- 34	165	-5
68	89	+/- 17.8	98	9
69	93	+/- 18.6	101	8
70	76	+/- 15.2	92	16

Tests made under the use of commercial glucometer is under the second column which is tested using the conventional way of taking blood glucose measurement, pricking the fingers and applying a drop of blood on to the strip that is to be inserted in the glucometer device. The fourth column is the tests done by using the non-invasive device created by the researchers. Using (1) the researchers were able to come up with the result shown in the fourth column. The researchers used the raw data, light reflectance to see the relationship between the glucometer and the non-invasive device.

To further see the statistical significance between the data gathered from the commercial and non-invasive glucometer the researchers used Paired T-test. On the test done by the researchers used the suggested P-value, Probability that is equal to 0.0016, whereby conventional criteria, this difference suggests and considered to be very statistically significant. Using (2), the value of t is equal to -3.2871. The critical value for the test made using the data in Table II, a commercial and non-invasive glucometer is equal to 3.46. Since the absolute value of t is less than the critical value, the test states that the data is gathered from the commercial and non-invasive glucometer, are very significant with each other and is not significantly different in their data giving 95% confidence, which is in the range of the allowed successful tests set by ISO 15197:2013.

The null hypothesis, H_0, states that the value of t should be less than or equal to the accepted critical value of 3.46 for the data from commercial glucometer and non-invasive glucometer be accepted as significantly the same with each other. The alternative hypothesis, H_1, on the other hand, states that if the t value is greater than the accepted critical value, the data from the commercial glucometer and non-invasive glucometer are different from each other giving a low confidence percentage in accuracy. Based on the results of the t-test made, the value of t is less than the accepted critical value and the data from both glucometers are significantly similar to each other.

IV. CONCLUSION AND FUTURE WORKS

The device created by the researchers can measure the blood glucose level of a patient accurately. The NIR sensor used was correctly calibrated and integrated with the Raspberry Pi, the algorithm placed inside the Raspberry Pi microcontroller used by the researchers is working properly together with the NIR LED and Photodiode. The data gathered by the user were successfully stored in the memory file created inside the Raspberry Pi with the micro SD card.

Based on the following data collected 97.14% of the test made, which is 68 out of 70 tests were able to meet the acceptable range set by ISO 15197:2013 where at least 95% of the results should fall under the acceptable range of +/- 20% of the results coming from the commercially available glucometer. Based on the results of the hypothesis test, the null hypothesis is accepted which means that there is no significant difference between the data from the commercial glucometer and the non-invasive glucometer.

For future works, the researchers recommend that in improving the data results a better controller should be used so that using other kinds of algorithm wouldn't be a problem. The researchers also recommend combining or testing different spectroscopy method in measuring blood glucose to increase precision and accuracy of the device created. Improving the size of the device is advised so that the device would be more convenience and portable. The user interfaces for multiple users that can save each data is also recommended to improve the features of the device.

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