Multi-user Glucose Meter with Insulin Dosage Recommendation

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***Abstract*—Diabetes (Diabetes mellitus) is a metabolic disease that occurs either when the pancreas does not produce enough insulin to regulate blood sugar or when the body itself cannot effectively use the insulin it produces, it leads to increased concentration of glucose in the blood. The most advanced glucose meter module available in the market does not have the capability to create a profile for multiple users and save the test readings they make. In this study, a glucose meter module is modified to effectively store blood glucose reading under a user's profile for blood glucose monitoring purposes. After the reading has been completed, a pop-up window will appear which will show the user the recommended starting dose based on the weight and condition of the user. The accuracy of the device in providing glucose reading is similar to the ones available in the market since the researchers used a commercially available glucose meter modules and innovated it to do additional functions**

***Index Terms*—Blood Sugar; Glucose Meter; Insulin.**

I. INTRODUCTION

Diabetes affects 347 million people worldwide and is one of the leading causes of death and World health organization expects it to increase by 50 % over the next ten years [1]. It is projected that by the year 2030, diabetes will be the seventh leading cause of death among people worldwide [1]. In the Philippines alone, more than 4 million people were recorded to have diabetes. The Department of Health's statistics shows that in 2009, the disease was number 8 out of the ten leading causes of mortality [2].

Being able to monitor blood glucose is essential to a diabetic patient, this made way for the development of glucose meter modules [3]. The most advanced glucose meter modules are the Bayer's Contour Glucose Meter that has the capability to measure blood sugar level and can store up to 2000 data and the Abbott Diabetes Care Freestyle Insulinx can compute for insulin dosage and even transmit data to other devices via wireless connections and can hold up to 3000 data [3]. In addition, there have been reports of glucose meters based for single-handed use with internal strip storage [4], StatStrip based glucose meter [5], protective smartphone case based glucose meter [6] and stretchable glucose meter [7].

However, glucose meter modules with insulin dosage recommendation that are commercially available are incapable of separating and storing data for different users under a single device to test blood sugar level.

The study aims to develop a glucometer with insulin dosage recommendation function for multiple users. Specifically, to test our developed glucometer which measures blood sugar that has multiple user features and compare results with a commercial glucometer. Furthermore, the study will create a program that calculates insulin dosage recommendation.

The glucose meter's basic function and profiling for multiuser features can be used by anyone including non-diabetic patients but insulin dosage recommendation is limited to type 2 diabetic patients who are using Sanofi-Aventus' Lantus Insulin Glargine. The study is limited to Sanofi Diabetes' Dosing and titration options for basal and prandial insulin (Basal insulin dosing options for hospitalized diabetes patients is used a reference in calculating the recommended starting dose). The projected increment /decrement dosage shot units will be based on their sliding scale. Dosing recommendation will be based on the condition of the patient and weight. The options available for 'patient's condition' are Diabetic obese, Diabetic with the risk of hypoglycemia, and Diabetic without other special considerations (without other complications) [8]. The "Normal" selection is the option available for non-insulin diabetic patients who opt to use the device. The study does not cover recommendations for users who are injecting other insulin type other than Sanofi-Aventus' Lantus Insulin Glargine. The device can accommodate multiple users and store a large amount of data. The device is only capable of measuring glucose level and computing recommended insulin dosage based on the provided information (The patient will declare whether he is, normal, obese, with the risk of hypoglycemia and patient without special consideration.

II. METHODOLOGY

The inputs for the system are the diabetic patient's name, weight (kg) and other conditions such as (1) Normal for non-diabetic users; (2) Diabetic with Risk of Hypoglycemia; (3) Diabetic without special considerations (without other complications); and (4) Diabetic Obese. The prototype is composed of three major components: the glucometer (True Result) which will provide the blood sugar reading in mg/dL, Real Time Clock and the Raspberry Pi 1 Model B for the Graphical User Interface of the prototype.

Gambas 3.6.2 would be the software used to program the Graphical User Interface (GUI) of the prototype. The researchers can only use the True Result test strip which will be inserted in the device. A blood sample will then be placed on the test strip when the "Test Strip Ready" shows in the

screen. After the device read the sample, it will give us the Blood Sugar Reading (mg/dL) and the Insulin Dosage Recommended (units) [10]. The conceptual framework of this work is illustrated in Figure 1.

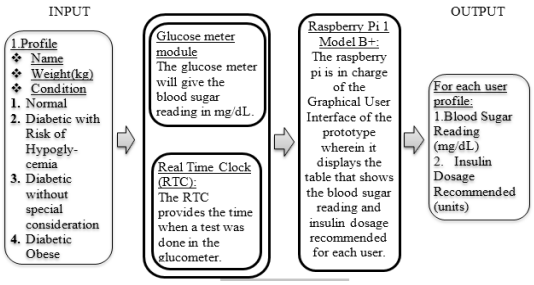

Figure1: Conceptual Framework

A. *Research about glucose meter modules and choose one*

The researchers used Nipro's TrueResult glucose meter module to develop. Thus, the purchased Nipro's True Result glucose meter module was dismantled and modified for the application of this work. The module requires no coding, can store 500 tests in its memory and other key features, making it ideal for further development too.

B. *Analyze the glucose meter module's (True Result) LCD*

The first thing that was done is to know the signals generated by the glucose meter to its LCD so that the signals can be analyzed with each pin having connecting wires.With the aid of PicKit 3 and a voltage supply of 3V, an alternating square wave was read with 10ms per pulse or 20ms period which has 50Hz frequency and 50% duty cycle for each pin. Based on the logic analyzer, it was found out that Pins 7-10 are the selectors who have multiplex signals. Pins 1 and 25 are grounded and pins 2-6 and 11-24 are the signals that turn on the specific segments of the LCD. The LCD will only turn on when the bit (1-15) is high prior to the trigger and the bit (1-15) is low when the trigger (A, B, C, D) is high. A PWM generator was connected to the glucometer's LCD with a pull-down resistor to emulate the glucose meter module's behavior concerning the signals it sends to the LCD. The signal generator was used to make a square wave to run the glucose meter module and having each signal pins (Pins 2-6 and 11-25) in a pull-down manner for the signal to be reset to 0. Since a square wave was generated by the signal, an inverter IC was used to create an inverted signal for the signal pins in order to turn on the segments in the LCD. With these, we were able to determine which pin pair will activate the segments in the LCD. At first all the segments in the LCD are lit. By continuously testing for which Selector Pins and Signal Pins are assigned for the insert test strip, and the multi-segment displays (blood sugar reading values), a character map was made.

C. *Integration of glucose meter module's LCD and RTC with the Raspberry Pi*

Raspbian Wheezy is the OS or Image file we downloaded onto the SD card that also has the programming software that we used, the Gambas 3.6.2.After setting up the Raspberry Pi, we integrated the glucometer's LCD and the RTC to the GPIO pins of the raspberry pi as shown in Figure 2. Using Gamba's inputs, we collected the data that the glucometer provides to the LCD when it turns on. Then, we acquired the states of the segments in the LCD when the selector pins A, B, C and D were in an "on" state. Then, codes and running codes were assigned to every significant data segment to every LCD pins needed to read the blood sugar reading. After the codes were assigned, we programmed the Graphical User Interface (GUI) for the user's profile and for it to be able to get the Blood Sugar Reading from the Glucose meter's LCD and program the Insulin Sliding Scale for the Insulin Dosage Recommendation of our device. The schematic of the prototype is shown in Figure 3.

(a) (b)

Figure 2: (a) Glucometer's LCD integrated to Raspberry Pi, (b) GPIO of the Raspberry Pi

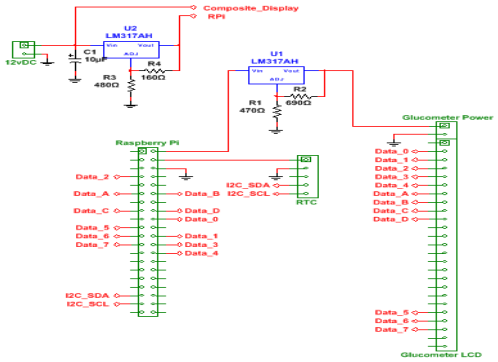

Figure 3: Multi-User Glucose Meter with Insulin Dosage Recommendation Circuit Connection

D. *Implementation*

The program and GUI were created in raspberry pi via Gambas version 3.6.2. In order to assure that the two devices will produce reliable results, glucose solution was used to both devices before proceeding to an actual blood test, the sugar reading should match or at least very close in value. Figure 4 shows Prototype vs Glucose Meter Glucose Solution Reading.

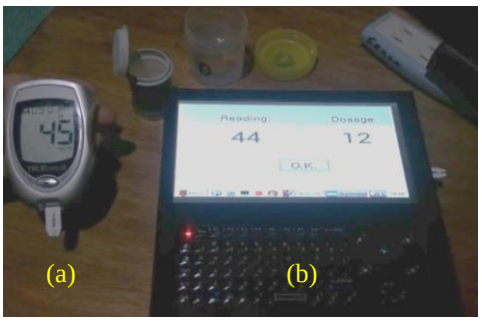

Figure 4: (a) Prototype vs (b) Glucose Meter Glucose Solution Reading

E. *Prototype system flow*

The course of the system as a user navigates the device from start to finish is shown in Figure 5. Once the program

has started, the guest has the option to select his existing profile or to create a new profile. If the guest opts to create a new profile, he will be asked to input his name, weight and condition so that the program can calculate the guest's starting insulin dose. After saving this information in the system, the guest shall set his profile. The monitor will display a "No Strip Found" message indicating that you should insert a test strip. After feeding the device a test strip, it will initialize the strip and once completed, the monitor shall display "Test Strip Ready". The user should provide a sample of his blood to the allotted blood slot on the test strip. The program will process the information and shall display the user's random blood glucose reading onto the monitor. The user may just press "ok" if he wants to conduct another test or just close the program to end the simulation.

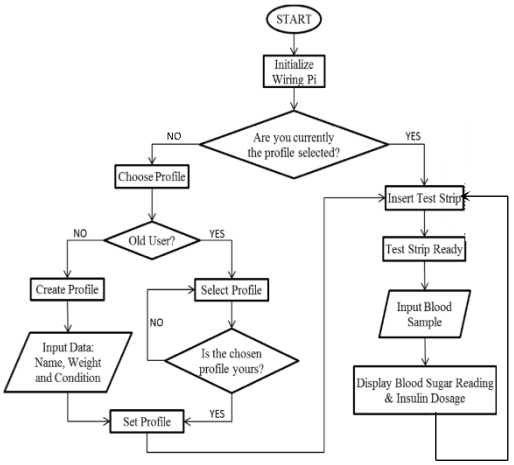

Figure 5: System Flow Chart

F. Research about diabetes and its basis of insulin dosing

There are three general types of diabetic patients based on the abridged prescribing information of Lantus. 1. Diabetic with Risk of Hypoglycemia (such as patients with renal or hepatic dysfunction, elderly, etc), 2. Diabetic without special consideration, and 3.Diabetic Obese. The device will recommend a basal insulin starting dose (0.3, 0.5 and 0.7 units/kg) depending on the patient type and weight. If the patient is a non-diabetic person, there will be no recommended insulin. Identify medical standards used in dosing insulin and know its formula [4]. First step is to compute the starting dose based from the Sanofi Diabetes' Dosing and titration options for basal and prandial insulin (Basal insulin dosing options for hospitalized diabetes patients is used a reference in calculating the recommended starting dose). The next step depends on his blood sugar reading. To compute for the starting dose, we need the diabetic patient's weight to be multiplied to a certain multiplier for each condition in the prototype which is shown in Table 1.

Table 1
Dosing Based on Diabetic Patient Type and Weight

Basal Insulin Dose	mmol/mol
0.3 units/kg	Conditions with the risk of hypoglycemia
0.5 units/kg	Patients without special considerations
0.7 units/kg	Obese

After obtaining the starting dose, increments/decrements will be added / subtracted from the starting dose depending on the blood sugar reading of the user. The formula for the Insulin Dosage Recommended by the prototype would be:

$$A = B + C \tag{1}$$

where A is insulin dosage recommended by the prototype which is the final dose given by the prototype,B is starting dose which is the initial amount of insulin dose to be increment/decrement by the dose change in the sliding scale and C is dose change which is increment/decrement dose change in the starting dose dependent on blood sugar reading

The sliding scale is based on the published Journal of Diabetes Science and Technology, Initiation and Maintenance Phase Minimum Dosing Titration Algorithms shown in Table 2.

Table 2
Insulin Dose Adjustment Algorithm

Insulin glargine		
Plasma equivalent glucose values		
mg/dl	mmol/liter	Dose change
<80	<4.4	-2 units
80 - 100	4.4-5.5	0
101-120	5.6-6.7	+2 units
121-140	6.8-7.8	+4 units
141-160	7.9-8.9	+6 units
>160	>8.9	+8 units

III. RESULT AND DISCUSSION

To establish the accuracy of the blood glucose reading provided by the prototype, we have used several glucose control solutions of different known concentration as the prototype and the glucose meter module specimen. The Prototype vs. Glucose Meter Module using Glucose Concentration accuracy is 97.26% and the data summary is shown in Figure 6.

Meanwhile, to check the accuracy of the provided insulin (glargine) recommended dose of the device based on the condition of each user (multi conditions), it was actually tested by diabetic patients that uses the specific insulin and the result is further compared to the glucose meter module reading and the doctor's recommended insulin dose. Each patient has a different condition such as (1) Normal for non-diabetic users; (2) Diabetic with Risk of Hypoglycemia; (3) Diabetic without special consideration (without other complications); and (4) Diabetic Obese. The overall accuracy of the Prototype vs. Glucose Meter Module using Blood Sample is 96.97% while it's accuracy in recommending insulin is 89.00% as shown in the result summary in Figure 7. The accuracy calculation was adapted based on the method shown in the study done by Zhu [11] and the formula can be referred to the study by Zhu [11] and it will not be discussed here.

A sample T-test was done based on H_o(null hypothesis): There is no difference in the blood sugar reading provided by the glucose meter modules and the prototype. For Patient A data is done and the module prescribed insulin dosage and the data from the prototype has no critical difference. It confirms no statistical difference in the blood sugar reading of a glucose meter module and the prototype. Summary found in Table 3.The t-stat value was utilized as the t-statistic is the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error.

TRIALS	PATIENT	WEIGHT	CONDITION	GLUCOSE SOLN (mg/dl)	GLUCOSE SOLN READING USING GLUCOSE METER MODULE (mg/dl)	GLUCOSE SOLN READING USING PROTOTYPE (mg/dl)	% ERROR OF PROTOTYPE IN MEASURING BLOOD SUGAR READING	AVE ACCURACY
1	A	60	ROH	<80	65	67	3.0769	96.7639
7	B	120	ROH	<80	73	71	2.7397	97.0972
13	C	180	ROH	<80	69	72	4.3478	97.4919
19	D	60	NORMAL	<80	70	68	2.8571	97.4286
25	E	120	NORMAL	<80	67	63	5.9701	97.2187
31	F	180	NORMAL	<80	63	65	3.1746	97.6919
37	G	60	OBESE	<80	64	66	3.125	97.1655
43	H	120	OBESE	<80	64	67	4.6875	97.7512
49	I	180	OBESE	<80	73	69	5.4795	96.7861
			OVERALL ACCURACY OF PROTOTYPE IN MEASURING THE GLUCOSE CONCENTRATION					97.2661

Figure 6: Prototype vs. Glucose Meter Module using Glucose Concentration results

PATIENT	WEIGHT	HEIGHT	CONDITION	BLOOD SUGAR READING (mg/dL) MODULE	BLOOD SUGAR READING (mg/dL) PROTOTYPE	%ERROR BLOOD SUGAR READING	Average Accuracy (Prototype)	INSULIN DOSAGE RECOMMENDED in units/mL DOCTOR's PRESCRIBED	INSULIN DOSAGE RECOMMENDED in units/mL PROTOTYPE	%ERROR INSULIN DOSAGE RECOMMENDATION (Prototype)	Average Accuracy, Recommended Insulin Dose (Prototype)	PROTOTYPE STARTING DOSE (units/mL)	PROTOTYPE INCREMENT	PROTOTYPE INSULIN DOSAGE RECOMMENDED in (units/mL)
A	49	5'1"	Diabetic w/ risk of hypoglycemia	101	99	1.98	97.89	15	14	6.67	93.33	14	0	14
B	55	5'	Diabetic w/o special consideration	84	87	3.57	97.07	25	27	8.00	88.80	27	0	27
C	66	5'2"	Diabetic Obese	104	100	3.85	96.65	42	46	9.52	87.71	46	0	46
D	56	4'10"	Normal (Diabetic w/o special consideration)	90	93	3.33	96.28	26	28	7.69	86.15	28	0	28
OVERALL ACCURACY OF PROTOTYPE IN MEASURING BLOOD SUGAR							96.97	OVERALL ACCURACY OF IN RECOMMENDING INSULIN			89.00			

Figure 7: Prototype vs. Glucose Meter Module using Blood Sample

Table 3
Patient A: Diabetic Risk of Hypoglycemia

Items	Module	Prototype
Mean	102.2	101.2
Variance	68.7	69.7
Observations	5	5
PooledVariance	69.2	
Hypothesized Mean Difference	0	
df	8	
t Stat	0.19007148	
P(T<=t) one-tail	0.426993741	
t Critical one-tail	1.859548038	
P(T<=t) two-tail	0.853987482	
t Critical two-tail	2.306004135	

Table 4
Patient B: Normal

Items	Module	Prototype
Mean	98.4	97.6
Variance	133.3	117.8
Observations	5	5
PooledVariance	125.55	
Hypothesized Mean Difference	0	
df	8	
t Stat	0.112889002	
P(T<=t) one-tail	0.456449971	
t Critical one-tail	1.859548038	
P(T<=t) two-tail	0.912899942	
t Critical two-tail	2.306004135	

Thus based on the results in Table 3, shows that we cannot reject null hypothesis because t Stat is less than t Critical one-tail (0.1901<1.8595). Blood sugar reading results in module and prototype for patient A who is a diabetic risk of hypoglycemia shows no difference. Table 4 shows the results for Patient B,normal. Based on Table 4, shows that we cannot reject null hypothesis because t Stat is less than t Critical one-tail (0.1129<1.8595). Blood sugar reading results in module and prototype for patient B who is normal shows no difference.

Table 5 shows the results for Patient C , Diabetic Obese. Based on the results in Table 5, it shows that it cant reject null hypothesis because t Stat is less than t critical one-tail (0<1.8595). Blood sugar reading results in module and prototype for patient C who is obese diabetic shows no difference.

Table 6 shows the results for Patient D, Diabetic without special consideration. Based on the results in Table 6, it shows that it does reject null hypothesis because t Stat is less than t critical one-tail (-0.0904<1.8595). Blood sugar reading results in module and prototype for patient D who is diabetic without special consideration shows no difference.

Table 5
Patient C: Diabetic Obese

Items	Module	Prototype
Mean	107	107
Variance	147.5	176.5
Observations	5	5
PooledVariance	162	
Hypothesized Mean Difference	0	
df	8	
t Stat	0	
P(T<=t) one-tail	0.5	
t Critical one-tail	1.859548038	
P(T<=t) two-tail	1	
t Critical two-tail	2.306004135	

Table 6
Patient D: Diabetic without Special Consideration

Items	Module	Prototype
Mean	109.2	109.6
Variance	32.7	65.3
Observations	5	5
PooledVariance	49	
Hypothesized Mean Difference	0	
df	8	
t Stat	-0.09035079	
P(T<=t) one-tail	0.465114825	
t Critical one-tail	1.859548038	
P(T<=t) two-tail	0.930229651	
t Critical two-tail	2.306004135	

IV. CONCLUSION

The researchers were successful in enhancing a glucose meter module by adding user profiling and insulin dosage recommendation functions. Under each profile, user information such as name, weight, condition, blood sugar reading can be saved to a user profile. The device is 97.26% accurate in comparison to the prototype and the module. The device does recommend the starting dose of a user, which is dependent on the patient's blood sugar reading and weight. Any adjustment in the dosing titration shall follow Lantus outpatient dosing recommendations. Several trials were made for each patient type namely (1) Diabetic with risk of hypoglycemia; (2) Diabetic obese; (3) Diabetic without special considerations/complications; (4) Normal (non-diabetic); The overall accuracy of the prototype vs. Glucose Meter Module using Blood Sample is 96.97% while it's accuracy in recommending insulin is 89.00%. T-test two-sample assuming equal variance confirms that the means of the doctor's prescribed insulin dosage and the data given by the prototype has no statistical difference. T-test also confirms no statistical difference in the blood sugar reading of a glucose meter module and the prototype. Moreover, users can create their own profile without mixing their information with other user.

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