DESIGN AND CONSTRUCTION OF A NON-INVASIVE BLOOD GLUCOSE METER

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ABSTRACT

The objectives of this project were to design, construct and evaluate a non-invasive blood glucose meter. Measurement was performed based on the Beer-Lambert principle, whereby photo-electronics were used to derive the relationship between blood glucose concentration and signal voltage. The resulting device is composed of four main parts: 1) input, consisting of an optical sensor for converting light into voltage and contact force circuit for maintaining finger pressure on the sensor; 2) analogue signal conditioning, consisting of a non-inverting AC amplifier and filter circuit; 3) digital signal processing using a microcontroller, involving analogue-to-digital conversion then applying a calibrated equation to obtain the desired measurement, and; 4) a liquid crystal display that presents blood glucose level to the user. Test results demonstrate that this device can measure blood glucose levels with a mean absolute percentage error of 5.12%.

Keywords: Non-Invasive Blood Glucose Meter, Diabetes.

1. INTRODUCTION

The Diabetes Association of Thailand has reported that the incidence of diabetic patients in Thailand increases every year, predominantly in age range of 60 to 69 years. Approximately 15.9% of men and 21.9% of women in this age range are diagnosed with diabetes.[1] Patients often suffer from complications arising from diabetes, such as chronic kidney disease, foot problem, eye damage, heart attack, and peripheral neuropathy [2-4]. Blood glucose monitoring is essential for managing diabetes. Patients are required to measure their blood glucose concentration and receive treatment to maintain their levels within the normal range. Testing blood glucose levels once a month, or once every 3 to 4 months, may not be sufficient for patients to plan dietary adjustments or schedule the most effective time(s) for daily insulin injections [5]. It is therefore necessary for patients to self-test their blood to manage their condition. Using available self-test devices, patients are sometimes required to draw blood 2 to 3 times per a day to prevent complications that can arise from eating too much sugar.

Performing multiple blood glucose measurements per day allows the doctor to adjust the nutrition and treatment plan for their patients. This results in better treatment responses and improves overall patient health [6, 7]. However, drawing blood several times a day causes repeat discomfort and sometimes pain, which can deter some patients from measuring their blood glucose as required. Some patients may also suffer from needle phobia [8] or have other conditions that can complicate things. The most profound disadvantage with using conventional (invasive) blood sampling techniques for diabetic patients is that their wound healing is typically compromised, presenting greater risk of infection and related complications [9]. In addition, blood collection can be complicated, generally requiring trained medical personnel. Hence, some patients are not able to know their blood glucose levels as they should; providing the motivation for developing a more convenient, non-invasive blood glucose meter.

In a previous study, we investigated non-invasive blood glucose sensing technology based on the Beer-Lambert principle. We found that 950 nm light is absorbed by glucose, and employed this physical relationship to develop a prototype non-invasive blood glucose meter using a reflective optical sensor. The relationship between blood glucose level and output voltage was found to be inversely proportional [10].

The present study builds upon this research, aiming to complete the design, construction, and evaluation of a non-invasive blood glucose meter. This is a monitoring device that diabetic patients can use to measure their blood glucose levels by themselves, conveniently and without discomfort. Near-infrared light (950 nm) is used to measure blood glucose concentration from the fingertip with a reflective optical sensor. The principle of infrared light absorption (Beer-Lambert law) was used to plot the relationship between blood glucose concentration and digital output, providing a standard calibration curve from which a fitted equation was derived. This is used to convert input signal voltage into blood glucose level, which is displayed to the user on an LCD.

2. BASIC CONCEPT

The basic concepts employed in this research based on the Beer-Lambert principle and photo-electronics that are described in two sections: 1) design and construction, and 2) evaluation of the non-invasive blood glucose meter. The first section includes the design of analogue electronic circuits for signal amplification and filtering, and digital signal processing algorithm. The second

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section covers testing of integrated circuits, device calibration, functional testing and accuracy testing.

3. PROTOTYPE DESIGN

The design of this non-invasive blood glucose meter can be split into four main parts: 1) signal detection, consisting of a reflective optical sensor and contact pressure confirmation circuit; 2) analogue signal conditioning, including a non-inverting amplification and filtering circuit, 3) digital signal processing, performing analogue-to-digital conversion and transforming measurement voltage into blood glucose level, and; 4) display using an LCD screen. The block diagram in Figure 1 illustrates these four main components of the device design.

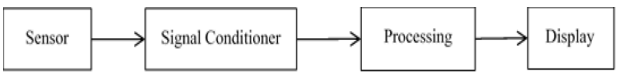

Figure 1 Design block diagram

3.1 Signal Acquisition

3.1.1 Sensor

The TCRT1000 reflective optical sensor operating at a wavelength of 950 nm was used to detect blood glucose. This sensor consists of a near-infrared LED as a light transmitter, paired with a phototransistor receiver. From the TCRT1000 datasheet [11], V_{CC} = 9 V is the DC power supply voltage, V_F = 1.25 V is the forward voltage drop across the LED, I_F = 50 mA is the forward current, I_C = 1 mA is the collector current, and $V_{CE(SAT)}$ = 0.3 V is the voltage between the collector and emitter terminals. In the sensor circuit, a 9 V DC power source was used and two resistors (R_1 and R_2) were selected to limit the current flowing through the photoelectric elements. Resistor R_1 = 155 Ω was connected to prevent damaging the LED. Resistor R_2 = 8.7 kΩ was used to prevent damaging the phototransistor.

3.1.2 Pressing status circuit

A pressing status circuit was included in this design to control the force applied by the fingertip making contact with the sensor. In the case of excessive force being applied to the sensor, blood circulation around the fingertip can be abnormal; potentially causing the signal from detector circuit to be inaccurate. Conversely, insufficient pressure will lead to noisy and unreliable input signal. It is therefore desirable that continuous equal force is applied to the sensor in order to acquire a more reliable signal with the phototransistor.

In this design, the pressing status circuit incorporated a combined red-green-blue LED and an SPDT micro-switch. However, only two of the available colours (red and green) were used to indicate contact pressure status. The micro-switch was used to determine the operating status of the sensor circuit by opening or closing a set of switching contacts. Important components of the micro switch are a pin plunger, hinge, movable spring, contacts and terminal section. Pressing the pin plunger closes the switch, while releasing it opens the switch.

The red and green LEDs were connected to separate contacts of the micro-switch; used to indicate non-contact and contact, respectively. Here, the micro-switch acts as a bridge between the DC power source, pressing status circuit, and the sensor circuit. When the suitable force pressed on the sensor, the circuit is in status NO (Normally Open) so that the sensor circuit is working and the green LED will be brightness. But if the unsuitable force pressed on the sensor, the circuit is in status NC (Normally Close) so that the sensor circuit does not work and the red LED lamp will be brightness instead. The schematic diagram of the sensor circuit connected with the pressing status circuit is shown in Figure 2.

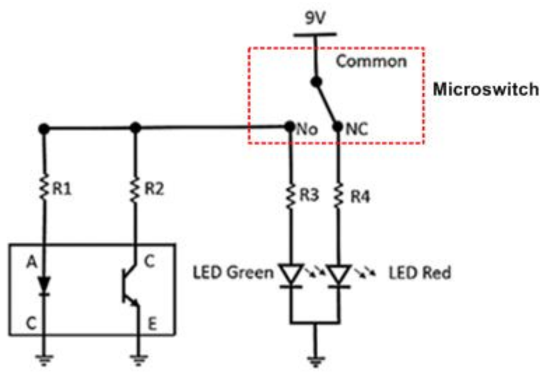

Figure 2 Sensor and press status circuit schematic

From the datasheet of the tri-colour LED, its forward bias voltage and current were 2.4 V and 30 mA, respectively [12]. A 9 V DC source (V_{CC}) powered the circuit, and resistors R_3 and R_4 were connected to limit current, thereby preventing damage to the red and green LEDs, respectively. Resistances R_3 and R_4 were calculated as per equation (1).

$$R = \frac{V_{CC} - V_F}{I_F} \tag{1}$$

$$R_3 = R_4 = \frac{9 - 2.4}{0.03} = 200\ \Omega$$

Therefore, R_3 = R_4 = 220 Ω in the pressing status circuit design.

3.2 Analogue Signal Conditioning

Signal conditioning is the manipulation of an analogue signal to optimise it for further processing. The signal obtained from the detector circuit is a small voltage concomitant with electromagnetic interference and other sources of noise. It is necessary to improve this signal and prepare it for downstream processing. This can be achieved by performing amplification using a non-inverting AC amplifier, and filtering out the noise with a band-pass filter.

For the non-inverting amplifier circuit, we selected a low-power LM358 op-amp. The input stage of the amplifier was connected to an RC network forming the high-pass portion of the filter. The amplifier output was connected to a low-pass RC network configuration. The schematic design of this analogue signal conditioning circuit is shown in Figure 3.

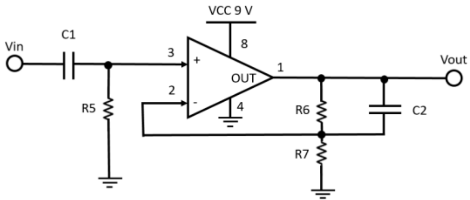

Figure 3 Analogue signal conditioning circuit schematic

The high pass filter circuit allows signal frequencies above its cut-off frequency to travel through without attenuation, while attenuating signals with frequencies lower than its cut-off frequency. This circuit is constructed by connecting a series capacitor followed by a resistor tied ground. The cut-off frequency (f_c) of the high-pass filter circuit was designed to be 0.5 Hz. After selecting a capacitor value of 0.1 µF, R_5 was calculated by equation (2) as follows.

$$R = \frac{1}{2\pi f_c C} \tag{2}$$

$$R_5 = \frac{1}{2\pi \times 0.5 \times 0.1 \times 10^{-6}} = 3\ M\Omega$$

In the design of the non-inverting AC amplifier, we selected appropriate resistor values to amplify the signal from the sensor circuit. This input voltage (V_i) had a peak voltage of 200 mV. In order to derive an output voltage (V_{out}) of 4 V, the amplification rate (A_v) was designed to be 20 as follows: if R_i = R_7 =10 kΩ and R_f = R_6, the resistance R_6 can be calculated by equation (3).

$$A_V = \frac{V_{out}}{V_{in}} = 1 + \frac{R_f}{R_i} \therefore R_f = R_i(A_v - 1) \tag{3}$$

$$R_6 = 10 \times 10^3\,(20 - 1) = 190\ k\Omega$$

The low-pass filter circuit is designed to allow signal frequencies below its f_c to pass, while attenuating signals with frequencies above f_c. This is an RC network with a series resistor and a capacitor tied to ground. To determine the cut-off frequency of this low-pass filter to be 2.5 Hz, the capacitance C_2 was calculated following equation (4).

$$C = \frac{1}{2\pi f_c R} \tag{4}$$

$$C_2 = \frac{1}{2\pi \times 2.5 \times 190 \times 10^3} = 0.33\ \mu F$$

The complete signal acquisition and conditioning circuit includes seven resistors (R_1 = 155 Ω, R_2 = 8.7 kΩ, R_3 = R_4 = 220 Ω, R_5 = 3 MΩ, R_6 = 190 kΩ, and R_7 = 10 kΩ) and the two capacitors (C_1 = 0.1 µF and C_2 = 0.33 µF). The analogue front-end circuit of the non-invasive blood glucose meter is shown in Figure 4.

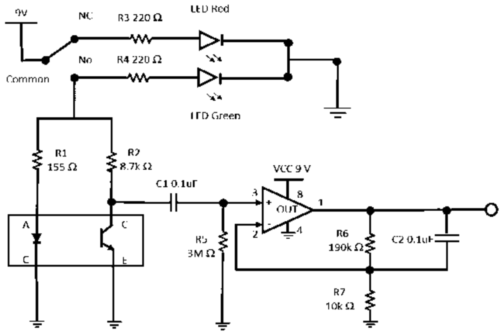

Figure 4 Non-invasive blood glucose meter front-end schematic

3.3 Digital Signal Processing

A commercial microcontroller was used to convert the input signal from analogue to digital before further processing. An Arduino UNO R3 microcontroller was selected for this purpose because it has sufficient resolution to capture the signal, comes in a small form-factor, and has a maximum analogue input voltage requirement of 5 V.

The output from the signal conditioning circuit is an analogue voltage with a peak of 4 V. To transform this voltage level into a measurement of blood glucose concentration, it first has to be converted into a digital signal. This is performed using the inbuilt analogue-to-digital converter inside of the microcontroller. The calibration curve equation is then applied to obtain a value of blood glucose concentration in mg/dL. The digital output is also available for use in software for signal processing Display

The LCD chosen for this device has a screen size capable of fitting two rows of sixteen characters. The microcontroller was used to drive this display. After digital signal processing, the measured value of blood glucose level was displayed on the screen shown in Figure 5.

4 EXPERIMENTS

Experiments of the non-invasive blood glucose meter consisted of testing the integrated circuits, determining the relationship between the concentration of blood glucose levels and digital output, performing a functional test, and testing its accuracy.

4.1 Testing of integrated circuits

The integrated circuits were tested by having a subject place their fingertip on the signal detection element. An oscilloscope (Tektronic, model TDS1002) was used to measure the output voltage signal from the analogue front-end of the device. An example of signals recorded with the oscilloscope is shown in Figure 6.

4.2 Relationship between blood glucose levels and digital output

An equation was derived relating concentration of blood glucose in mg/dL with digital signal level. Measurements were taken from 200 patients during their routine annual check-up at U Thong Hospital, Suphan Buri Province, Thailand. Participation in the study was voluntary and patient data was not identifiable. Subjects fasted for 8 h before testing. Blood glucose levels were measured according to the standard procedure at the hospital. Immediately following the blood test, subjects placed their index fingertip on the non-invasive blood glucose meter in 20 s to record the digital output value. This data was then used to find the relationship between the concentration of blood glucose and digital output by the fitting of an exponential function, as illustrated in Figure 7. These procedures were granted ethical approval by the Committee of U Thong Hospital.

4.3 Functional testing

In order to perform functional testing, blood glucose measurements from the described non-invasive blood glucose meter were compared with published results from oral glucose tolerance testing (OGTT) [10]. In this experiment, five volunteers were instructed to refrain from food for at least 8 h. Following this fasting period, blood glucose level was measured from each subject using our device. The time relative to eating their first meal was recorded. After eating a meal, subjects had their blood glucose levels monitored at 20 min intervals, up until 140 min, using the non-invasive meter. This data is plotted in Figure 8, showing the changes in blood glucose level that occurred over time.

4.4 Accuracy testing

To evaluate the accuracy of the non-invasive blood glucose meter, nine healthy volunteers underwent blood glucose testing with the standard measurement technique at Faculty of Medical Technology, Rangsit University. Their blood glucose levels were also recorded using the non-invasive blood glucose meter. Subjects refrained from food for at least 8 h. Blood was sampled according to the standard method; 5 min afterwards, their blood glucose level was measured three times using the non-invasive blood glucose meter. This data was used to evaluate the mean absolute percentage error of the non-invasive blood glucose meter.

5 RESULTS

The non-invasive blood glucose meter is shown in Figure 5. This device can measure blood glucose level from the fingertip by the principle of absorption of infrared light. Measurements are computed in mg/dL when a finger is placed on the sensor. Readings are then displayed on the LCD screen.

Figure 5 The complete non-invasive blood glucose meter

Evaluation of the non-invasive blood glucose meter was divided into four parts: 1) testing of integrated circuits; 2) finding the equation relating digital signal output with blood glucose level; 3) functional testing, and; 4) accuracy testing. The results from each of these parts are reported below.

5.1 Sensor integrated circuit test

In testing of signal output of integrated sensor in volts by using oscilloscope, it was found that the output signal is in the range not exceeding 5 V, which is designed and determines the size of the maximum output signal. Therefore, the output signal is suitable to the signal processing part. The result was shown in Figure 6.

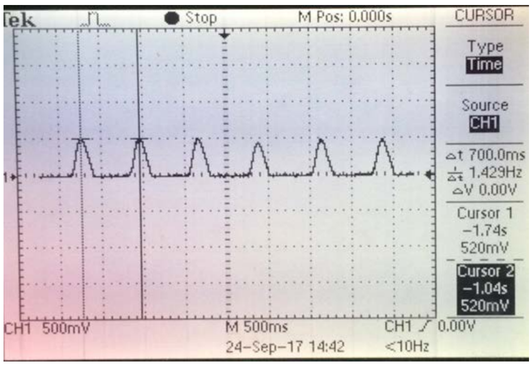

Figure 6 The output signal of the sensor integrated circuit.

5.2 Determining the relationship between blood glucose level and digital output

Using blood glucose concentration data from a cohort of 200 patients, an equation was derived for converting digital signal output of our device into blood glucose level. This data is plotted in Figure 7, which illustrates the relationship between blood glucose concentration measured using the standard laboratory measurement technique and digital output.

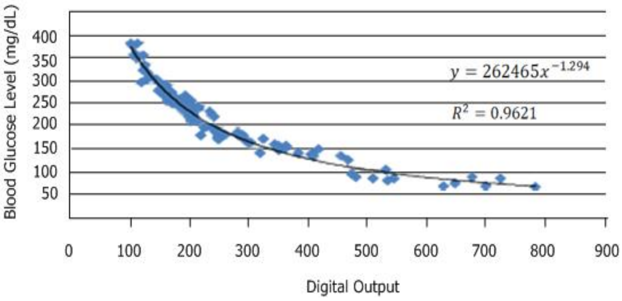

Figure 7 Graph showing the relationship between blood glucose levels and digital output

The graph in Figure 7 exhibits a relationship between blood glucose levels, plotted in the y-axis (mg/dL), compared with digital output plotted in the x-axis. There is an inversely proportional relationship; digital output is low when blood glucose concentration is high, and digital output is high when blood sugar level is low. The range of blood glucose level measurements from the subjects extended from 87 to 377 mg/dL. The line of best fit for this data was found to be an exponential, such that $y = 262465x^{-1.294}$. This calibration curve produced a coefficient of determination (R^2) of 0.9621 over a measurement range of approximately 80 to 350 mg/dL.

5.3 Functional testing

The results from functional testing of the non-invasive glucose meter on five subjects included pre-meal blood glucose levels measured as 89, 84, 110, 103 and 90 mg/dL. Subsequent measurements of their glucose levels at 20 min intervals (up to 140 min) after eating found that their blood glucose concentrations peaked at 60 min post-meal for four of the subjects; equalling 143, 114, 151, and 116 mg/dL. The maximum value of the fifth subject of 177 mg/dL was measured 80 min post-meal. After peaking, the blood glucose levels of each subject decreased towards baseline. These results are plotted in Figure 8. When comparing these graphs obtained from non-invasive blood glucose meter measurements with previously published data from OGTT[13], a similar pattern of increasing and then decreasing blood glucose levels post-meal are observed.

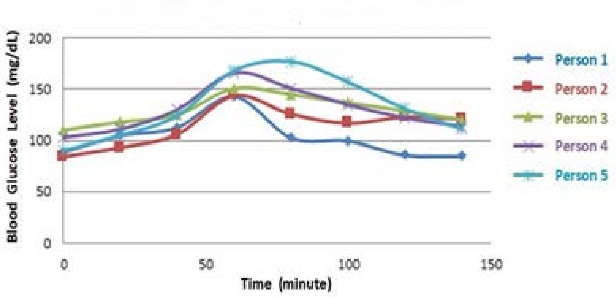

Figure 8 Graph showing the relationship between blood glucose levels of five subjects over time.

5.4 Accuracy testing

To test the accuracy of the non-invasive blood glucose meter, blood glucose level was measured form nine subjects using the standard method. Five minutes afterwards, their blood glucose level was measured three times using the non-invasive blood glucose meter. The results from this experiment and comparison of these measurements are shown in Table 1.

Table 1 Results of accuracy testing of the non-invasive blood glucose meter compared with a standard laboratory measurement technique.

Subject	Blood glucose level from the standard measuring methods (mg/dL)	Blood glucose level from the non-invasive blood glucose (mg/dL)			Average blood glucose level from the non-invasive blood glucose (mg/dL)	Standard Deviation	error (%)
		1	2	3			
1	80.4	97	90	92	93	3.61	15.67
2	90.2	99	85	82	88.6	9.07	1.77
3	133.9	120	108	119	115.6	6.66	13.67
4	92	87	104	95	95.4	8.50	3.7
5	90	98	80	90	89.5	9.02	0.56
6	84.7	85	100	81	88.8	10.02	4.84
7	88.8	107	84	80	90	14.57	1.35
8	82.8	80	82	89	83.5	4.37	0.85
9	91.7	99	86	80	88.3	9.71	3.71
Average Percentage Error (%)							5.12

From the data presented in Table 1, it can be seen that the maximum error of the non-invasive blood glucose meter was 15.67% and the mean absolute percentage error was 5.12% compared with standard laboratory measurements. This is within the standard of glucose measurement device error of ±10% [14].

6 DISCUSSION

In the design and construction of the described non-invasive blood glucose meters we used a reflective optical sensor (TCRT1000) for converting 950 nm light into voltage. The amount of light absorbance by constituents in the blood is used to infer the concentration of blood glucose. A contact force circuit was used to confirm when a finger is placed on the sensor. Signal conditioning was performed with a non-inverting AC amplifier circuit. Analogue to digital conversion and transformation of digital signal into a blood glucose measurement was achieved using an Arduino UNO R3 microcontroller. An LCD was then used to display blood glucose levels to the user in mg/dL.

When testing integrated circuits, the analogue output signal range did not exceed 5 V (0 to 4 V). This was found to be suitable for further signal processing using the microcontroller.

Blood glucose concentration measured using the standard medical procedure and digital signal level obtained from the non-invasive device clearly showed an inverse relationship. This was used to derive an equation for converting digital signal level into blood glucose concentration. The equation of this relationship between blood glucose level (in mg/dL) and digital output was $y = 262465x^{-1.294}$, which produced a coefficient of determination equal to 0.9621.

The trend of blood glucose level changes measured after eating using the non-invasive blood glucose meter is in agreement with observations from OGTT [13]. Blood glucose level was found to slowly increase until approximately 60 min post-meal before reaching its maximum value. This happens because the body needs time to convert carbohydrates into blood glucose; a process that typically takes 1 hr after eating a meal. The measured blood glucose levels then steadily descend towards the baseline. The data plotted in Figure 8 represent typical glucose tolerance curves for healthy persons during standard OGTT.

When testing the accuracy of the non-invasive blood glucose meter compared with values obtained from standard measuring methods in the laboratory, the mean absolute percentage error was found to be 5.12%. The three measurements taken from each subject using the non-invasive device showed some variability. This was deemed to be due to inconsistent levels of force applied to the sensor, resulting in variable measurements. The average of three measurements taken using the non-invasive blood glucose meter was found to minimise the error compared with standard laboratory test results.

The data collected for device calibration constrain the accuracy of measurements for blood glucose levels less than 80 mg/dL or more than 300 mg/dL. The number of samples in this range was very few, therefore affecting the calibrated equation to convert digital signal into blood glucose level.

The comparison between this technique with the other non-invasive methods such as a non-invasive blood glucose measurement by urine testing found that non-invasive blood glucose measurement by urine testing is easy to perform but the blood sugar level must be higher than 180 mg/dL to be able to detect blood sugar in this way[15]. And when this technique compared with a blood glucose monitoring with a breath-analyzer that is the monitoring acetone concentrations in breath found that there are limitations in the measurement of blood glucose in patients who smoke and the device remains expensive and non-portable[16]. Therefore, this technique is more advantage in more comfortable and convenient for a daily use by patients.

Future work will aim to improve the force controlling aspect of the sensor to maintain constant force while measurements are taken. Furthermore, the model for calculating blood glucose levels may be modified using the average pulse rate to obtain more reliable and stable readings; other factors including age, sex, and body-mass index may also be incorporated to improve model accuracy.

7 CONCLUSION

This paper has presented the design and construction of a non-invasive blood glucose meter that relies on the photoelectric (Beer-Lambert) principle of light absorption by glucose in the bloodstream. The device incorporates signal detection with a 950 nm reflective optical sensor (TCRT1000) and pressing status circuit, analogue signal conditioning circuit with an LM358 (low-power) op-amp, digital signal processing using a microcontroller (Arduino UNO R3), and display using LCD screen. This design can measure blood glucose levels from the fingertip in 20 s in the range 80-300 mg/dL and display the measured value on the screen, suitable for non-invasive blood glucose monitoring by diabetes patients. When compared with blood glucose measured using the standard laboratory method, this device was evaluated to have a mean absolute percentage error of 5.12%.

8 ACKNOWLEDGMENT

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