DESIGN OF A PORTABLE CONTINUOUS SYSTOLIC BLOOD PRESSURE MONITORING KIT WITH BUILT-IN LOW AND HIGH BLOOD PRESSURE EARLY WARNINGS

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by

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LIST OF ABBREVIATIONS

AAMI	Association Advancement of Medical Instrumentation
ABP	Arterial Blood Pressure
AgCl	Argentums Chloride
BP	Blood Pressure
bpm	beats per minute
DBP	Diastolic Plood Pressure
ECG	Electrocardiograph
EEPROM	Electrically Erasable Programmable Read Only Memory
EMFi	Electromechanical film
EMG	Electromyogram
Gnd	Ground
HR	Heart Rate
I/O	Input/Output
LCD	Liquid Crystal Display
LED	Light Emitting Diode
LM	Levenberg-Marquardt
MHR	Maximum Heart Rate
mmHg	millimeters of mercury
MOE	Mean of Error
MSE	Mean Square Error
NN	Neural Network
PPG	Photoplethysmographic

PWTT	Pulse Wave Transit Time
ROM	Read Only Memory
RAM	Random Access Memory
RST	Reset
SA	Sinoatrial
SBP	Systolic Blood Pressure
STD	Standard Deviation

REKABENTUK ALAT PEMANTAUAN TEKANAN DARAH SISTOLIK BERTERUSAN MUDAH ALIH DENGAN SISTEM AMARAN AWAL BAGI TEKANAN DARAH RENDAH DAN TINGGI

ABSTRAK

Kira-kira satu daripada tiga orang dewasa di Amerika Syarikat mempunyai tekanan darah tinggi tetapi tekanan darah tinggi sahaja biasanya tidak mempunyai tanda-tanda. Lazimnya, hipertensi bagi penduduk Malaysia yang berumur 31 tahun keatas adalah lebih daripada 42.6%. Sebahagian besar kes (64%) di negara ini masih tidak dikenalpasti. Hanya 26% daripada pesakit Malaysia mencapai tekanan darah terkawal (<140/90 mmHg). Pada masa kini, ramai orang mempunyai tekanan darah tinggi selama bertahun-tahun tanpa mengetahuinya. Tekanan darah tinggi tidak terkawal boleh menyebabkan strok, serangan jantung, kegagalan jantung atau kegagalan buah pinggang. Perkara inilah yang menyebabkan tekanan darah tinggi dipanggil 'silent killer'. Hanya satu cara untuk mengenalpasti tekanan darah anda iaitu dengan mengukur tekanan darah. Tekanan darah kebiasaannya diukur dengan menggunakan peranti yang dipanggil sphygmomanometer, stetoskop dan manset tekanan darah. Kebanyakkan teknik yang digunakan untuk mengukur tekanan darah secara automatik atau manual adalah tidak bersesuaian untuk mengukur tekanan darah secara berterusan. Objektif kajian ini adalah untuk membangunkan satu alat mudah alih yang boleh mengukur tekanan darah secara berterusan dengan menggunakan sensor electrocardiography (ECG) dan sensor denyut. Dua kaedah telah digunakan untuk mengukur tekanan darah secara berterusan. Kaedah pertama yang telah digunakan untuk mengukur tekanan darah secara berterusan adalah berdasarkan kadar degupan jantung (HR) dan kaedah kedua adalah berdasarkan 'Pulse Wave Transit Time' (PWTT). Kedua-dua kaedah ini dibahagikan kepada dua teknik yang berbeza bagi mengukur tekanan darah sistolik. Teknik-teknik yang telah digunakan untuk merekabentuk hubungan diantara data PWTT/HR dan tekanan darah sistolik adalah model regresi lurus, model regresi tidak lurus dan model rangkaian neural. Model rangkain neural memberi nilai terkecil bagi purata ralat dan ralat sisihan piawai untuk pengukuran tekanan darah berdasarkan PWTT atau HR. Ralat-ralat ini adalah boleh diterima dan agak kecil berbanding ketepatan piawai, yang sepatutnya mempunyai nilai purata ralat 6 mmHg dan ralat sisihan piawai ±10mmHg. Subjek-subjek yang telah terlibat dalam pengujian alat pemantauan tekanan darah ini adalah subjek tekanan darah normal, subjek tekanan darah rendah dan subjek tekanan darah tinggi. Kesemua data telah diambil dalam masa 5 minit untuk setiap subjek dan hasil ujian telah dipantau oleh pakar jantung/doktor atau jururawat. Ketepatan data daripada sistem pemantaun BP berterusan telah disahkan menggunakan sphygmomanometer. Hasil ujian menunjukkan alat sistem BP yang telah dibangunkan ini adalah sesuai digunakan untuk mengukur atau memantau tekanan darah sistolik secara berterusan. Sistem amaran telah dibangunkan di dalam alat pemantaun BP ini. Sistem amaran berfungsi berdasarkan nilai tekanan darah dan tren naik turun nilai tekanan darah sistolik. Sistem amaran ditunjukkan dalam bentuk penggera. Penggera akan aktif apabila nilai tekanan darah sistolik lebih daripada 140mmHg (Tekanan Darah Tinggi) atau kurang daripada 100mmHg (Tekanan Darah Rendah) atau jika tren tekanan darah sistolik meningkat atau menurun lebih daripada 5mmHg untuk setiap 30 saat.

DESIGN OF A PORTABLE CONTINUOUS SYSTOLIC BLOOD PRESSURE MONITORING KIT WITH BUILT-IN LOW AND HIGH BLOOD PRESSURE EARLY WARNINGS

ABSTRACT

About one in three adults in the United States have high blood pressure but high blood pressure itself usually has no symptoms. The prevalence of hypertension in Malaysians aged 30 years and above was 42.6%. The majority of cases (64%) in this country remain undiagnosed. Only 26% of Malaysian patients achieved blood pressure control (<140/90 mmHg). Now days, many people have high blood pressure for years without knowing it. Uncontrolled high blood pressure can lead to stroke, heart attack, heart failure or kidney failure. This is why high blood pressure is often called the "silent killer." The only way to tell if you have high blood pressure is to have your blood pressure checked. Blood pressure is often measured using a device called a sphygmomanometer, a stethoscope and a blood pressure cuff. Almost all the existing manual or automatic measuring techniques of blood pressure are based on this principle, which is not convenient for continuous monitoring of blood pressure. The objective of this study is to develop a portable continuous blood pressure monitoring system using an electrocardiography (ECG) sensor and a pulse sensor. Two methods were used to measure blood pressure continuously. The first method measures blood pressure continuously based on Heart Rate (HR) and the second method is based on Pulse Wave Transit Time (PWTT). Both methods were separately implemented for different techniques to measure systolic blood pressure (SBP). The techniques that were used to model the relationship between the PWTT or HR data to systolic blood pressure are linear regression model, non- linear regression model and neural network model. Neural network model gave the smallest value of mean of error and standard deviation of error for measuring blood pressure based on PWTT or HR. These errors are acceptable and relatively small compared to the standard accuracy, which should have a minimum mean of error value of 6 mmHg with a standard deviation of error of ±10mmHg. The subjects that were involved in portable BP monitoring kit testing are normal blood pressure subjects, low blood pressure subjects and high blood pressure subjects. All the data were taken about five minutes for each subject and the results were monitored by medical cardiologist/doctor or nurses. The accuracy of the SBP data from portable continuous BP monitoring kit was validated using sphygmomanometer. The results indicate that the developed portable BP system is adequate to be used for monitoring or measuring systolic blood pressure continuously. Warning system was developed in this portable BP monitoring kit. The warning system is generated based on blood pressure value and trend of increasing or decreasing of systolic blood pressure values. The warning is given in form of alarm. The alarm will be "on" when the systolic blood pressure value goes more than 140mmHg (High Blood Pressure) or less than 100mmHg (Low Blood Pressure) or if the SBP increasing or decreasing trend in more than 5mmHg for each 30 seconds.

CHAPTER 1

INTRODUCTION

1.1 Introduction

In fact, nearly one in three United State adults has high blood pressure, but because there are no symptoms, nearly one-third of these people do not know they have it (American Heart Association, 2008). The prevalence of hypertension in Malaysians aged 30 years and above was 42.6%. The majority of cases (64%) in the country remain undiagnosed. Only 26% of Malaysian patients achieved blood pressure control (<140/90 mmHg) (Ministry of Health, 2008). Now days, many people have high blood pressure for years without knowing it. Uncontrolled high blood pressure can lead to stroke, heart attack, heart failure or kidney failure. This is why high blood pressure is often called the "silent killer." The only way to tell if you have high blood pressure is to have your blood pressure (BP) checked.

Arterial blood pressure is most accurately measured invasively by placing a cannula into a blood vessel and connecting it to an electronic pressure transducer. This invasive technique is regularly employed in intensive care medicine, anesthesiology and for research purposes. However, it is associated (rarely) with complications such as thrombosis, infection, and bleeding.

The non-invasive auscultatory and oscillometric measurements are simpler and quicker, require less expertise in fitting, have no complications, and are less unpleasant and painful for the patient. In addition, the methods are less accurate and have small systematic differences in numerical results. These methods actually measure the pressure of an inflated cuff at the points where it just occludes blood flow, and where it just permits unrestricted flow. These are the methods commonly used for routine examinations and monitoring. Nevertheless, the accuracy of these devices has not yet reached the necessary level, since only some of them are clinically validated and most have a questionable accuracy (O’Brien, 2001).

Two numbers are used to describe blood pressure, which are systolic blood pressure and diastolic blood pressure. Blood pressure is often measured using a device called a sphygmomanometer, a stethoscope, and a blood pressure cuff (Webster, 1998; Sola, 2007). The cuff is placed around the upper arm and filled with air. This tightening effect is used to stop the blood from flowing through the brachial artery of the arm. The stethoscope is placed over the artery in front of the elbow and the pressure in the cuff is slowly released. No sound is heard until the cuff pressure falls below the systolic pressure in the artery, at this point, a pulse is heard. As the cuff pressure continues to fall slowly, the pulse continues, first becoming louder, then dull and muffled. The cuff pressure at the point at which the first sounds are heard, is defined as the systolic blood pressure (SBP). The cuff pressure at the point at which the sounds stop, is defined as the diastolic blood pressure. A doctor would quote patients blood pressure as the value of the systolic pressure over the value of the diastolic pressure.

1.2 Continuous Blood Pressure Measurement

In recent years there has been increasing interest in wearable health monitoring devices, both in research and in industry. These devices are particularly important to the world's increasingly aging population, whose health has to be assessed regularly or monitored continuously in daily life (Tr¨oster, 2005). Blood pressure has been an important physiological parameter. However, no fully satisfactory ambulant sensor exists up to now for long-term and continuous monitoring (Hereyan, 2007; Berner, 2008). Those devices that utilized an occlusive cuff are not fully wearable and unobtrusive. Therefore, it is clear that new techniques for monitoring the blood pressure without the use of cuff are needed.

Teng and Zhang (2003) published the paper of Continuous and Noninvasive Estimation of Arterial Blood Pressure (ABP) using a Photoplethysmographic (PPG) Approach. Their study examines the relationships between arterial blood pressure and certain features of the photoplethysmographic signals obtained from l5 healthy subjects. Width of 1/2 pulse amplitude, width of 2/3 pulse amplitude, systolic upstroke time and diastolic time of the pulse were selected as features of the PPG signals. It was found that the diastolic time has higher correlation with systolic blood pressure and diastolic blood pressure than other features. The estimated results using diastolic time are better than the results using systolic upstroke time. The preliminary results indicate that it is possible to use the photoplethysmography only for cuffless and continuous estimation of arterial blood pressure.

Kerola et al. (1997) proposed a method to measure blood pressure continuously, which used an arm cuff with two electromechanical film (EMFi) sensors under it. The delay change between signals from these sensors was to be measured by the cross-correlation method. Later on, Sorvoja and Myllylä (2005) proposed a method, where an EMFi sensor is used to sense radial artery pulsations and a cuff is placed around the upper arm to occlude the brachial artery.

Blood pressure determination was based on either pulse amplitude change or pulse wave transit time (PWTT) change.

Teng & Zhang (2003) published a paper describing a method for noninvasive and cuffless blood pressure measurements on 15 young, healthy subjects. They used photoplethysmograph (PPG) sensor and electrocardiograph (ECG) sensor to measure blood pressure values. To provide reference measurements, they used an oscillometric BP-8800 device manufactured by Colin, Ltd. Measurements, taken at three different stages: rest, step-climbing exercise and recovery from the exercise, indicated the mean of error is (7.3 ± 0.2) mmHg for systolic and (4.4 ± 0.2) mmHg for diastolic blood pressure. A year later, Hung et al. (2004) reported a wireless measurement concept using Bluetooth for telecommunication from a PPG sensor to a mobile phone, PC or PDA device. The achieved mean of error is (8.6 ± 1.8) mmHg for systolic and (6.3 ± 0.5) mmHg for diastolic blood pressure. This study proved that the proposed technique (PWTT) is suitable for measuring blood pressure of healthy subjects.

Poon & Zhang (2005) extended the measurements to include the subjects aged 28 to 86 years, which included hypertensive subjects. These measurements were conducted over an average period of 6.4 weeks. They collected about one thousand pairs of systolic and diastolic blood pressure values. Reference results were provided by the average of results measured by a nurse using the auscultatory method and results obtained using two clinically approved automated blood pressure meters (BP-8800 Colin, Ltd and HEM-907, Omron, Ltd). Poon & Zhang reached the value of (9.8 ± 1.6) mmHg for systolic and (6.6 ± 1.9) mmHg for diastolic blood pressure. The results obtained in this study indicated that the value of diastolic blood pressure and systolic blood pressure are suitable for cuffless measuring blood pressure.

Berner (2008) designed CNAP™ Monitor 500, it performs continuous noninvasive blood pressure monitoring. The unit can be used in conjunction with other monitoring systems or alone as a self contained, battery powered unit. CNAP™ traces blood pressure changes through the patented CNAP™ cuff at the fingers. However, until recently only invasive methods provided quality information to the clinician. CNAP™ provides reliable blood pressure monitoring comparable to invasive techniques and adds valuable information about fluid responsiveness of the patient non-invasively.

1.3 Objectives of Research

The main objective of this study is to develop a portable continuous blood pressure monitoring kit with built-in low and high blood pressure early warnings. The specific objectives of this research are mentioned as below:

- To identify the parameters that are used to measure blood pressure.
- To formulate and validate the mathematical models between the affecting parameters and systolic blood pressure.
- To develop a portable and low cost blood pressure monitoring kit based on the selected mathematical model.
- To develop the high and low blood pressure early warnings function. The warning system is generated based on blood pressure value and trend of increasing or decreasing of systolic blood pressure values.