A Health-Shirt using e-Textile Materials for the Continuous Monitoring of Arterial Blood Pressure

CHAN, Chun Hung

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摘要

近年來,穿戴式傳感器軀域網絡(BSN)在長期及連續性測量使用者身體 狀況方面的應用漸趨普遍。BSN 更配合移動醫療保健(m-Health)為使用者提 供一個無時間、地點限制的實時診治。BSN 的研究已經開始商品化進程, 利用電子織物製造出可供人類日常使用的"穿戴式底板"。

本論文旨在研發一件"健康衫"(簡稱 h-Shirt) 。該 h-Shirt 可提供長時間 連續的生理參數(如血壓及其變化率),用戶還可以按照個人需要加上不同的 傳感器、測量不同的參數。本文通過十人騎車實驗以 finometer 為參照下驗 証了本作品對血壓測量的準確度,本作品收縮壓和舒張壓的標準差分別為 11.29mHg 及 7.15mmHg。因此,實驗結果証明了 h-Shirt 有能力用於日常 生活中為使用者提供長期及無間斷的血壓數據。

h-Shirt 的血壓測量基於脈搏波傳輸時間(PTT)原理。相比目前市場上的 血壓計測量方法,PTT 測量法是一種能提供無袖帶、無創損的連續血壓測量 方法,測量時需要採集用戶的心電(ECG)和光電容積描記(PPG)信號為計算 參數。在本作品準確度測試中發現有個別用戶沒有在 h-Shirt 上測出良好心 電信號。因此,本論文又在 100 名用戶上對該線路進行了測試,發現其中 6 人雖然 PPG 信號有清晰可見,但卻未能在 30 秒內測出血壓,據此,通過

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進一步的詳細分析,本文再對 h-Shirt 上的心電系統進行改良,並且加入生物信道(bio-channel),將用戶手指上的 PPG 信號以無線方法經皮膚傳送至 h-Shirt 袖口上的處理器中,從而減少了電線,美化了外觀並降低了對用者 日常生活的影響。總而言之,h-Shirt 配合本實驗室的前期工作和數據,將 發展為一個能結合連續測量及治療於一身的方案—衛士"WISSH"。

Abstract

Wearable body sensor networks (BSN) that allow long-term and continuous monitoring of users' activities and health conditions have a multitude of applications in mobile health (m-Health). The BSN reported before comprised of wearable medical devices and a networking platform, which used electronic textiles (e-textile) as a "wearable motherboard".

This research proposes a health-Shirt (h-Shirt) using e-textile materials for long-term and continuous monitoring of physiological parameters, including arterial blood pressure (BP) and blood pressure variability (BPV) by a cuffless approach. Continuous BP measurements using the h-Shirt were tested on 20 subjects. It is found that the h-Shirt could estimate systolic BP (SBP) and diastolic BP (DBP) within 10.64mmHg and 7.13mmHg of the references respectively. The results show that the design works reasonably well and has the potential to be used for BP measurements in an individual's daily life.

The BP measured by this shirt is based on pulse transit time (PTT). Comparing with conventional BP measurement principles, the PTT approach is not only a cuffless and noninvasive technique, but also provides an opportunity for continuous monitoring of BP. To estimate BP with PTT, the users' electrocardiogram (ECG) and photoplethysmogram (PPG) are captured. During the experiment, some of the users have difficulties on capturing clear ECG by our circuit. To confirm this observation, the ECG circuit was tested on 100 peoples. Out of the 100 subjects, 6 of them were failed to obtain a clear R-peak. The ECG filter was modified and increase the reliability. Moreover, bio-channel is tested on h-Shirt, PPG peak signal is transmitted to h-Shirt processing unit through skin. To sum up, a convertible and universal health-suit is combined with the previous work in JCBME, Wearable Intelligent Sensors and Systems for e-Health (WISSH) is formed, it is a full solution to include both monitoring functions and bio-feedback mechanisms for real-time health management.

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Chapter 1 Introduction

Early as 1996, Dr. S. Jayaraman and his colleagues announced the first "Smart shirt" in the world [1]. In the last ten years, many researchers developed their own e-textile garment to capture varies physiological parameters such as electrocardiogram (ECG), heart rate, respiration, arterial oxygen saturation (SaO₂), etc [1-11]. However, one of the important parameters is missing – blood pressure (BP).

1.1 The Difficulties

According to the recent studies [12-14], the pattern of blood pressure over 24 hours may be a sensitive indicator of diseases. In this point of view, the current monitoring devices or garments do not fit such application as all the commercial BP measuring appliances measure BP at a specific time, which is also a limitation of the current BP meter. Lifeshirt from VivoMetrics is the only e-textile garment provides the function of blood pressure measurement. When blood pressure is measured, an arm cuff is connected with Lifeshirt, It functions like a domestic automatic BP measuring machine, where a snapshot of BP is captured. A catheter has to be inserted into blood vessel if continuous BP is needed. Moreover, the pumping and releasing action of cuff greatly affect the user's daily activity. In a nutshell, a non-invasive continuous and long term blood pressure monitoring is failed to demonstrate by the current BP monitoring machine or e-textile garments.

1.2 The Solution

In this project a non-invasive continuous BP measurement method is realized in a shirt, named as health-shirt (h-Shirt). e-Textile material is used as electrodes and electric wires in h-Shirt. Electrocardiogram (ECG) and photoplethysmogram (PPG) capture from h-Shirt are used to calculate pulse transit time (PTT). PTT determines the pulse wave velocity (PWV) that proportional to arterial BP of the user. Once the users wear the h-Shirt, a continuous BP reading appeared. BP is recorded and analyzed by an accessory which has paired with h-Shirt. A wearable intelligent sensors and system for e-health (WISSH) is formed. Other than measuring and monitoring BP, WISSH provides treatment according to BP or blood pressure variability (BPV) of the user. Treatment can be in the form of musical therapy or electro-acupuncture. Furthermore, to reduce the numbers of wires tie around the users, electrical signal pulses transmit though skin was used to replace some of the wired or wireless communication channels in h-Shirt.

1.3 Goal of the Present Work

After a brief summary of the modern e-textile garment and continuous BP measurement technology, the objectives of this thesis are:

- To integrate continuous BP monitoring in e-textile garment.
- To evaluate BP monitoring by h-Shirt.
- To develop a hybrid body sensor network (h-BSN) for blood pressure measurement.
- To realize physiological parameters transmission through skin and muscles.

Chapter 2

Background and Methodology

2.1 Hypertension Situation and Problems Around

the World

Hypertension, also called high blood pressure, is one of the most common chronic diseases around the world. It is also a silent killer, since sufferer usually cannot feel and see it in the normal situation. In 2000, the estimated total number of adults with hypertension was 972 million; 333 million in economically developed countries and 639 million in economically developing countries, Figure 1 and 2 show the hypertensive number and percentage of some representative countries or areas. Moreover, the number of adults with hypertension in 2025 was predicted to increase by about 60% to a total of 1.56 billion around the world [15].

China is the country with the greatest number of hypertensives. The report estimated that more than 160 million people are suffering from this illness in China [15]. Compared with 1991, the prevalence of hypertension increased by 31% with more than 70 million new hypertension patients since 1991. Hypertension can be treated by using drug efficiently, however the population awareness rate of hypertension in China was only 30.2%, the treatment rate was 24.7% and the rate of under-control was 6.1%; compared with the Figures of 26.6%, 12.2% and 2.9% respectively in 1991, although there has been an improvement, the awareness is far from adequate.

2.1.1 Blood Pressure Variability (BPV)

Other than Hypertension, several investigations [12-14, 16-19] have shown the pattern of blood pressure over a 24-hour period may be a sensitive indicator of disease, it can be used to predict the outcome and end-organ damage accurately. However, in the market, none of the BP meter provides such measurement, it is due to the limitation of the traditional BP meter measuring algorithm. To solve this problem, a cuff-less, non-invasive and continuous BP measurement technique are required for 24-hour non-interrupt BP monitoring.

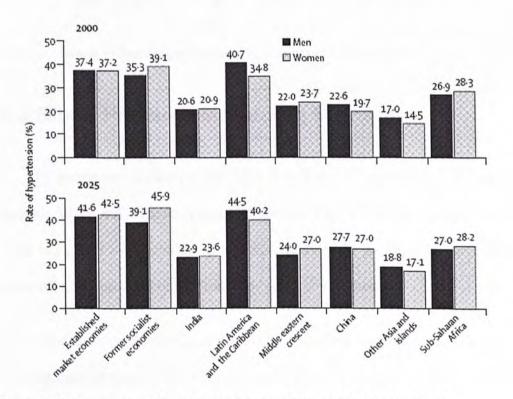


Figure 1 - The comparison of hypertension rate around the world at 2000 and 2025

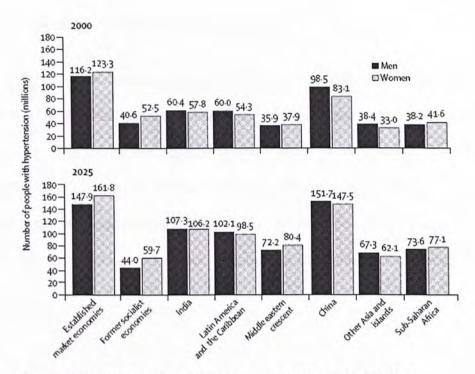


Figure 2 - Number of hypertension subject around the world at 2000 and 2025

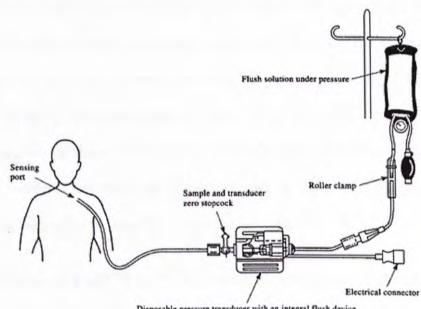
2.2 Blood Pressure Measuring Methods

To determine whether people suffer from hyper or hypotension, BP meter is needed. There are different types and models available in the market, each of them have their own advantages and disadvantage. In this session, the working principal and limitation of traditional BP meter are discussed.

BP measuring method can be divided into two main aspects – direct and indirect measurements [20]. Normally direct BP measurement is only used in the hospital especially during surgery. It is the method which requires to insert a catheter into blood vessel. All the domestic and clinical use BP meters are in the category of indirect measurement, they are free of catheter but all of them include a cuff. An air pumping cuff have to place at either wrist or arm position when function.

2.2.1 Traditional Blood Pressure Meters

Direct measurement can be divided into two categories according to the location of the sensor element. The most common method for directly measuring pressure is to couple the vascular pressure to an external sensor element via a liquid coupling catheter. In the second general category, the liquid coupling is eliminated by incorporating the sensor into the trip of a catheter that is placed in the vascular system. The device is known as an intravascular pressure sensor [20].



Disposable pressure transducer with an integral flush device

Figure 3 - A catheter couples a flush solution (heparinized saline) through a disposable pressure sensor with an integral flush device to the sensing port.

The three-way stopcock is used to take blood samples and zero the pressure sensor.

Indirect measurement is often called non-invasive measurement because the body is not entered in the process. The most commonly used indirect methods are auscultation and oscillometry. The parameters measured by these methods include the systolic blood pressure (SBP), which is the highest value of pressure occurring when the heart contracts and ejects blood to the arteries, and the diastolic blood pressure (DBP) represents the lowest value occurring between the ejections of blood from the heart. The pulse pressure (PP) is the difference between SP and DP, i.e. PP = SP - DP. The period from the end of one heart contractions to the end of the next is called the cardiac cycle, which can be calculated by the integrating the blood pressure waveform overtime.

2.2.2 Limitation of Commercial Blood Pressure Meters

Although these automatic BP meters can provide objective BP readings, most of them, like the conventional mercury sphygmomanometer, incorporate the use of a cuff in their working principles. They could just provide snapshots of BP as mentioned before. In addition, size of cuff dominate the accuracy, it must not be too small since overestimation of BP by using an inappropriately small cuff has been well documented [21]. Thus, the reduction of size, cost and power consumption in these devices become difficult and limit. Moreover, oppilating artery increases the workload of the heart and causes circulatory interference at the measurement site. Therefore, they are not preferred to be used frequently.

2.2.3 Pulse-Transit-Time (PTT) Based Blood Pressure Measuring Watch

In the last few years, Joint Research Center for Biomedical Engineering (JCBME) in The Chinese University of Hong Kong has researched on a cuff-less BP measuring approach. Some characteristic points on users' electrocardiogram (ECG) and photoplethysmogram (PPG) were located. Pulse-transit-time (PPT) is the time difference between these points and representing the pulse wave velocity. There are many papers research on how to relay the pulse wave velocity with arterial blood pressure. After the equations were built, a watch was designed together with Jetfly technology. Users could wear the watch and put a finger on the other hand to the surface of the watch, BP reading will appear after a few seconds.

2.3 Wearable Body Sensors Network / System

Wearable body sensor network or system is one of the medical devices that can provide a convenient, secure and long term monitoring. The term "wearable" means the devices can either be dressed up or appeared as a form of garment. In a nutshell, the development of wearable systems speed up as it can provide advantages over the traditional medical devices. Wearable devices provide a room for:

- Monitoring patients over extensive periods of time.
- Asses the daily body condition of the subject at home or outdoor.
- Gather physiological data by using an ambulatory system.

The parameters and physiological data recorded from wearable devices will further periodically uploaded to a database server via a wireless LAN or a cradle that allow internet connection. The data sets recorded using these systems are then processed to detect events predictive of possible worsening of the patient's clinical situation or they are explored to assess the impact of clinical intervention [22].

The "Wearable Intelligent Sensors and System for E-health (WISSH)" in this paper is based on an e-textile contained h-Shirt, sensors and peripheral that can be connected with. Shirt was chose in the project because clothing is probably the only element that is "always there" (and, thus, pervasive) and in complete harmony with the individual (at least in a civilized society). Also, textiles provide the ultimate flexibility in system design by virtue of the broad range of fibers, yarns, fabrics, and manufacturing techniques that can be deployed to create products for desired end-use applications. Moreover, fabrics provide "large" surface areas that may be needed for "hosting" the large numbers of sensors and processors that might be needed for deployment over large terrains, e.g., a battlefield. The opportunities to build in redundancies for fault tolerance make textiles an "ideal" platform for information processing [23].

2.4 Current Status of e-Textile Garment

Several prototypes of wearable functional device have been proposed in the last few years. Most of them take the approach of attaching conventional off-the-shelf electrical/electronic devices and components to clothes, such as microcontrollers, LEDs, optical fibers, piezoelectric transducers, etc. [24-35]. Table 1 summarized the state-of-the-art in garments incorporating e-textile. These garments are capable of measuring multiple parameters for detecting body motions, such as leg movements [2], and monitoring physiological signals, e.g. electrocardiogram (ECG) [3-5] and respiration [6].

This approach has been led by the well-established high performances of readily available conventional electronics. Furthermore, the consolidated textile technology for the integration of woven metallic yarns into clothes [33,34] has encouraged their use as a suitable means of connection, data communication, and power transfer [37] for chip packages sewn into textiles.

In the following session, there are some reprehensive projects proposed by

several research groups, representing the most relevant contributions to the e-textile field, taking into account the degree of device integration, the resulting wearability, and demonstrated performances.

At the end of the 1990s, Georgia Institute of Technology (Atlanta, GA) has proposed the Wearable Motherboard [26, 38-41]. It consists of a wearable fabric (e.g., a shirt) embedded with metal fibers, working as a data bus, and woven optical fibers. The system is conceived to work as a motherboard structure, where off-the-shelf devices can be reversibly attached. The last developed versions permit plugging in diverse conventional sensors used to monitor several signs, such as heart rate, respiration rate, electrocardiogram (ECG), pulse oximetry, and skin temperature [1, 26, 42]. This system is under commercial development in the form of a product called SmartShirt (Fig. 4) by the company Sensatex [43].

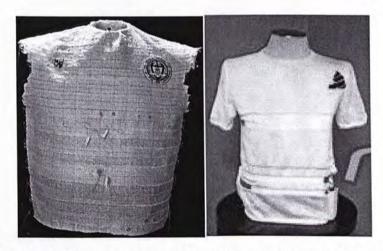


Figure 4 - An outlook of Georgia tech. wearable motherboard - SmartShirt [11, 43]

The use of optical fibers in fabrics as strain/stress sensors has been proposed by Drexel University (Philadelphia, PA) [44, 45]. This technology consists of the integration of multimode optical fibers in a preferably nonwoven textile substrate, in order to facilitate the embedding [45]. Deformations of the fibers induced by mechanical stresses exerted on the fabric alter the fiber boundary conditions and modify the internal propagation of optical signals. In particular, the occurring modal coupling produces a detectable modulation of the modal power distribution [44, 45].

Vivometrics Inc. produces the so-called LifeShirt [46] (Fig.5), consisting of a Lycra vest endowed with sensors detecting respiration, ECG, posture, and movement [47, 48]. Monitoring of respiratory activity and postural changes is performed by means of sinusoidally shaped electrical wires, sewn into the garment. A high-frequency current flowing through the wires generates a magnetic field, used to measure the self-inductance of the wire coils, which varies according to the deformation of the supporting structure [48].

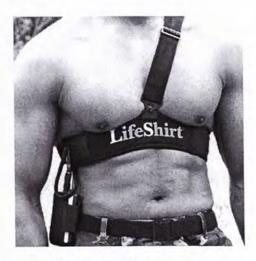


Figure 5 - LifeShirt developed by Vivometrics [46]

The VTAMN project (Vêtement de Télé Assistance Médicale Nomade -Undercloth for Nomad Medical Tele Assistance) aims at measuring the activities and physiological parameters of subjects in their daily life with the use of an original set up of sensors networked in a garment, distributed algorithms, and with the possibility of launching alarms through a cell-phone and to rescue the person after a localization with a worn GPS. Four ECG surface electrodes, the coil of a pneumograph, 2 temperature sensors with their embedded electronics, the fall detection module, wirings and interconnections busses are directly integrated into the garment. The main electronic board, the GSM and GPS modules, the batteries, the ECG electronics were placed on the belt.



Figure 6 - Sensorized T-shirt developed within the VTAM project [49]

ETH of Zürich, Switzerland, has proposed smart textiles embedding electrodes for functional electrical stimulation (FES), capable of providing electrically induced muscular contractions in patients affected by neuromuscular disorders [50]. Electrodes are fabricated by using an embroidery technique for the integration into a textile substrate of conducting yarns, consisting of silver coated fibers [50].

Interdepartmental Research Centre (University of Pisa), Smartex [51] and UTEC (Umana Tecnologia) (Fig. 7) proposed a completely flexible device embedded into truly wearable smart textiles. Sensorized garments capable of monitoring body kinematic variables, such as position and movement of articulation segments, and physiological activities, such as respiration, ECG, and electromyogram. Sensors are fabricated on a Lycra/cotton textile by masked smearing of the conducting mixture. The same polymer/conductor composite is also used as material for the tracks of connection between sensors and an acquisition electronic unit, avoiding the stiffness of conventional metal wires.



Figure 7 - Sensorized shirt developed by Smartex, Interdepartmental Research Centre and UTEC

2.4.1 Blood Pressure Measurement in e-Textile Garment

According to table 1, life-shirt is the only e-textile garment which can provide BP information of the users. Even BP could be measured, a conventional cuff had to be plugged. The user is asked to carry a commercial BP meter anytime and everywhere, which is very inconvenient and bulky. In order to solve the problem, BP in h-Shirt was estimated by pulse-transit-time (PTT) of the user, only the ECG and PPG of the user are needed, both of these signal is captured independent of the air-inflating cuff, blood flow of the subject's arm will not be occlude within the whole process. It is a non-invasive, cuffless and continuous blood pressure estimation method.

TABLE 1: COMPARISON OF STATE-OF-THE-ART E-TEXTILE GARMENTS FOR HEALTHCARE	ATE-OF-THE-ART E-TEX	TILE GARMENTS FOR]	HEALTHCARE	
Selected Measured Parameters	BP Measurement?	Using Other Gadgets / Wear?	Display Method	Connected to Network?
Heart rate, ECG, SpO ₂ , temperature, respiration	No	No	Wireless transmission to off-site	Yes
BP, SpO ₂ , EEG, EOG, body temperature, leg movements, etc.	A peripheral Is needed	No	Displayed on a peripheral	No
Core temperature, respiration, impedance pneumogram, etc.	No	No	Computer display	Yes (GSM)
ECG, pneumogram and temperature	No	No	Computer display Bluetooth	Yes (GSM)
ECG	No	Mobile / PDA	transmission to mobile or PDA	Yes
Sweat relative quantity, pH infection detection, and SPO ₂	No	No	N/A	N/A
ECG, EMG, SpO ₂ , temperature, heat flux, galvanic skin response, etc.	No	Glasses	Computer display	Yes (Wi-Fi)

2.5 Wearable Intelligent Sensors and System for

e-Health (WISSH)

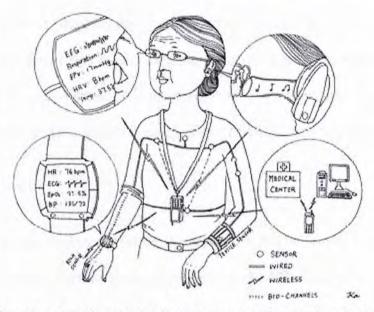


Figure 8 - An illustration of the Wearable Intelligent Sensors and Systems for e-Health (WISSH) with the h-Shirt.

(Artwork: courtesy of Ms. Joey K.Y. Leung, The Chinese University of Hong Kong)

WISSH is a system that presented by Joint Research Center for Biomedical Engineering in 2006 [52]. WISSH combines monitoring, display, treatment and alarming functions. Users wear the h-Shirt and connect wired or wirelessly to the processing unit(s), health condition is determined by the physiological parameters that captured from h-Shirt. Other than parameters capturing, WISSH is the first one suggested to apply biological feedback path that provide treatment function. In this thesis, Responses of 16 hypertensive patient to music did by our group was reviewed. It shows that MP3 included WISSH can be used as treatment or BP control.

2.5.1 Monitoring, Connection and Display

BP and BPV are the parameters that implemented in h-Shirt. These raw signals

would direct into a central processor of h-Shirt, in the first version of this project, connections between sensors and processing units were connected by e-textile, it was a way of wiring technique. Afterward, some wires were replaced by zigbee modules to perform a wireless networking and increase the security level. In the last version, skin-transmission is implemented, characteristic points of PPG are electrically stimulated from finger tips to wrist through skin, as a result, a hybrid body sensor network (hBSN) was formed. All the results were encoded and transmit to varies personal belongings, they could be watch, glass, MP3, PDA or mobile phone.

2.5.2 Treatment

Many clinical findings indicate that certain types of music can reduce blood pressure (BP) under various medical conditions [53-57]. Therefore, BP controlling MP3 is implemented into WISSH. In the experiment did by our laboratory before, BP responses of hypertensive patients was investigated. It was focused on how could music help hypertensive to lower their BP if they listen to the selected music daily. Fifteen subjects from an elderly home participated in the study. Eight of them had initial systolic BP (SBP) higher than 140 mmHg. They listened to the selected music for 25 minutes per day for 4 weeks. BP was measured twice a week by a registered nurse with a sphygmomanometer during the 4-week study period and after the completion of the study. Three subjects, including one with initial SBP higher than 140 mmHg, dropped during the experiment due to changes of medical conditions or personal reasons. After 4 weeks, the average decrease in SBP and diastolic BP (DBP) was 11.8 mmHg (p=0.008) and 4.7 mmHg (p=0.218) (n=12), respectively. For the subgroup of subjects with initial SBP higher than 140 mmHg, the average decrease in SBP and DBP was 19.9 mmHg (p<0.001) and 8.5 mmHg (p=0.087) (n=7), respectively [58]. The results demonstrated that WISSH provided an alternative

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method to reduce high SBP and the responses of hypertensive patients to music depend on the baseline BP.

2.5.3 Alarming

As we mentioned before, h-Shirt could communicate with a PDA or mobile phone, medical doctors could keep checking the condition of his patient if the PDA or mobile phone connected to internet with WAP that has been developed in our laboratory [59]. It utilizes WAP devices as mobile access terminals for general inquiry and patient-monitoring services. Authorized users can browse the patients' general data, monitored blood pressure (BP), and electrocardiogram (ECG) on WAP devices in store-and-forward mode. The applications, written in wireless markup language (WML), WMLScript, and Perl, resided in a content server. A MySQL relational database system was set up to store the BP readings, ECG data, patient records, clinic and hospital information, and doctors' appointments with patients. A wireless ECG subsystem was built for recording ambulatory ECG in an indoor environment and for storing ECG data into the database. The system shows how WISSH can be feasible in remote patient-monitoring and patient data retrieval.

Chapter 3

A h-Shirt to Non-invasive, Continuous Monitoring of Arterial Blood Pressure

The importance of developing wearable medical devices for measuring BP continuously monitoring have been described in Chapter 2. In this chapter, the internal construction and accuracy of h-Shirt will show. The objectives of this chapter are as follows:

- To show the construction of h-Shirt.
- To describe the choice of materials.
- To test the h-Shirt accuracy of h-Shirt in measuring BP under both dynamic and static states.

3.1 Design and Inner Structure of h-Shirt

The outlook of h-Shirt is show in Figure 9. It includes at least one shirt and one peripheral device, the peripheral could be any personal belongings such as mobile phone, PDA, MP3 In this session, a watch was chosen to calculate and display BP as watch is a peripherals that commonly wear when in reality. This display was replaced by a h-Shirt-controlled MP3 player in the later stage.

As we mentioned in Chapter 2, there are many advantages of using e-textile for developing wearable devices to capture 24 hours continuous physiology parameters or signals. However, e-textile material is non-solderable to the printed-circuit-board (PCB), it is impossible to link them by soldering. Fasten snap button is one of the possible solution to act as the joints. It is detachable, solderable and conductive. The watch and PPG sensor can be detached when washing h-Shirt. Figure 9 shows the reverse side of the watch, six male side of fasten snap buttons (three for ECG and three for PPG) were soldered to the corresponding input inside the watch with wires,. Afterward, all six buttons were pasted to the back of the watch by an electrical insulate paste (Loctite 315 and 7386, Eire).

ECG is captured from the two wrists, with reference to an electrode seamed on the forearm to avoid artifact induced by respiration and heartbeat. Figure 10 shows the location of the electrodes. In short, Lead I ECG is captured. The potential of the three capturing points are directed into the watch to amplify and filter. A photo reflective sensor (Waitrony RS-05FS, Hong Kong) is mounted on a PCB to capture PPG from fingertips. Male side fasten snap buttons are also soldered on the PCB copper pads for connection and signal transmission. All conducting electrodes and wires are made of e-textile materials (FlecTron Conductive Fabrics, Less EMF Inc., USA). Cotton clothes is used to shield the e-textile material when it is acted as signal transmitting wires.

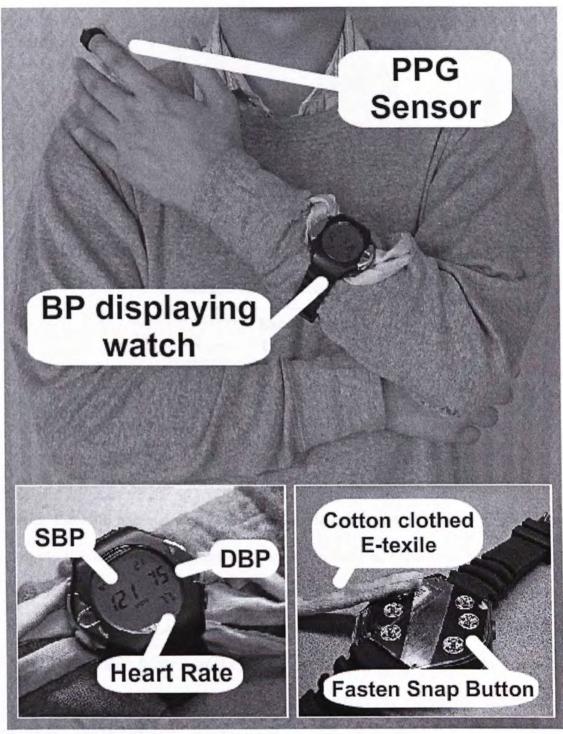


Figure 9 - Outlook of h-Shirt:

BP reading on the façade of displaying watch (lower left), Reverses side of the watch showing the connections to PPG and ECG. (lower right)

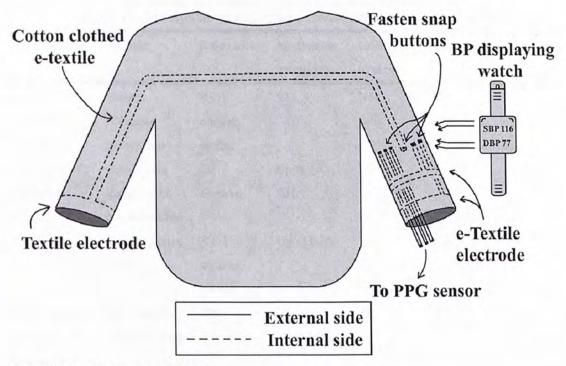


Figure 10 - Inner structure of h-Shirt

3.1.1 Choose of e-Textile Material

Conductive e-textile material played a main role in constructing h-Shirt in this thesis. E-textile material acts as ECG capturing electrodes and conducting wires in h-Shirt, the material used must be highly conductive, washable, stretchable and non-irritating. Table 2 summarizes the specifications of some common conductive textile that could be bought in the market with those provided sufficient specification. Stretch conduction fabric from Less EMF Inc. is currently used in h-Shirt. It is the only conductive material which satisfied all requirements aforementioned, i.e. it is machine washable, highly stretchable, non-irritating and with low resistance (<10hm per sq.).

Manufacturer	Material	Resistance	Application frequency	Irritation to skin?	Washable?	Stretchable?
Laird	Copper	< 0.1	NM	NM	No	NM
Technology	Polyester	ohm/sq.				
	Nonwoven	inches				
EMF -	Conductive	10 ⁹	Up to 10	No	Yes	NM
Naturashield	inside, with	Ohm/sq	GHz			
Fabric	cotton outside					
FlecTron	Copper plated	< 0.1	Up to GHz	No	No *	No
	nylon	ohm/sq. inches				
EMF - Stainless	Pure surgical	NM	15 dB at	No	Yes	Yes
steel mesh	stainless Steel		1900 MHz			
shielding fabric						
EMF - Nickel	Polyester	< 0.1	Up to 18	Not for	NM	NM
Mesh Fabric	mesh with	Ohm/sq	GHz and	direct skin		
	Cu-Ni		beyond	contact		
EX-STATIC™	87%polyester,	10 ⁵ ohms	NM	NM	No **	NM
	13% carbon	per square,				
	fibers					
EMF -	Stretchy silver	<5	33 dB at 1	NM	NM	Yes
See-Through	coated sheer	Ohms/sq	GHz			
conduction fabric	nylon weave					
EMF- Siliver	Silver coated	<0.5	>60dB until	NM	Yes	NM
mesh fabric		Ohm/sq	3GHz			
ZELT	Tin/Copper	<0.1	Up to 1 GHz	No	Yes	No
FABRIC	coated nylon	ohm/sq				
	fabric					
EMF-Microwav	carbon fibers	~3 Ohms	Microwave	Yes	NM	47 N/15mm
e absorbing sheet		per square	absorber			
EMF - Stretch	Silver plated	<1 ohm/sq.	NM	No	Yes	Yes
conduction fabric	Nylon and					
	Dorlastan					

TABLE 2: COMPARISON OF COMMON CONDUCTIVE TEXTILE AVAILABLE IN MARKET***

* Material will tarnish with exposure to liquids and skin oils

** Conductivity will hold up to 50 or more low heat washings

*** 1) Only material with specification is shown. 2) Information was summarized from [60-62].

NM: Not mentioned

3.1.2 Design of ECG Circuit

The wrist watch used for processing signals and displaying BP was designed together by our laboratory and one of our sponsoring company, Jetfly Technology Ltd. The company improved the watch design in terms of size and cost for manufacture. The final design is confidential. In the following sessions, ECG and PPG circuits are the version that before implementing as the watch, the parameters are basically same as the final product.

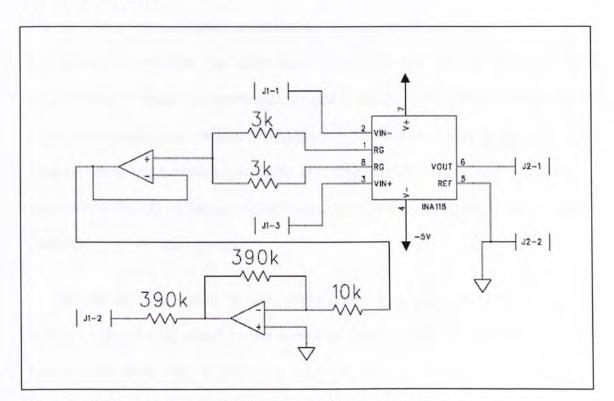


Figure 11 - ECG differential input circuit together with driven-right-leg circuit.

Figure 11 shows the input part of the ECG circuit. A precision, low power instrumentation amplifier (INA 118, Burr-Brown) was used. It is constructed to provide three main functions:

- To calculate the potential difference between left finger and right finger;
- To pre-amplify the differential ECG signal; and

 To reject common mode noise and avoid electric shock by using a Driven-right-leg circuit

The ECG captured by the watch reflex Einthoven lead I ECG. Einthoven limb lead I (standard leads I) is defined as left limb potential minus the potential records from right limb. It is below 1mV [20], the signal have to gain for more than 1000 times to analyze, the voltage supply in the later stage ranged form +5V to -5V, 5mV of DC offset voltage already cause the filter and gain in the later stage completely saturate. In the instrumentation amplifier, the common-mode gain is much lower than the differential amplifier that constructed by op-amps and lumped circuit. In the circuit shown in Figure 12, common-mode gain is caused by mismatches in the values of the equally-numbered resistors and by the non-zero common mode gains of the two input op-amps. Instrumentation amplifier obtaining very closely matched resistors is a significant difficulty in fabricating these circuits, as is optimizing the common mode performance of the input op-amps.

Driven-right-leg circuit is also implemented in h-Shirt, the common mode voltage on the body is sensed by two averaging resistors, inverted, amplified, and fed back to the human body. It provides a reference point on patient that normally is at ground potential. Generally, it is made to an electrode on the patient's right leg, however, in the h-Shirt it is put on the right arm of the user. The experiment on session 3.4 showed that this action did not effect on the ECG waveform in our application. The circuit can also provide some electric safety. If an abnormally high voltage appears between the patient and ground as a result of electric leakage or other cause, the auxiliary op amp in Figure 11 saturates. This effectively ungrounds the patient, because the amplifier can no longer drive the right arm of the user.

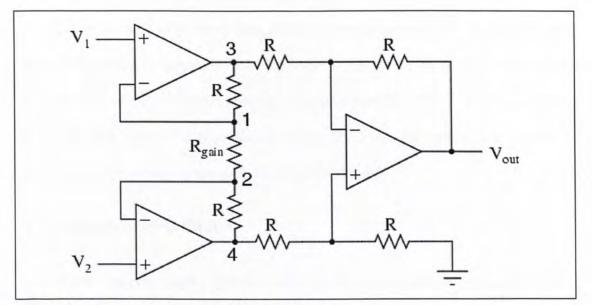


Figure 12 - Basic structure of instrumentation amplifier

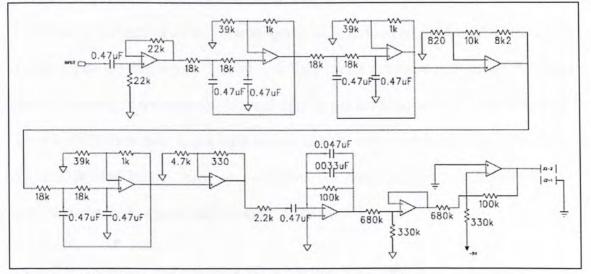


Figure 13 - ECG filters and gain used in the prototype of the wrist watch

The filtering range of ECG signal is determined by application. The clinical bandwidth (12-lead ECG) is 0.05-100Hz. For monitoring applications (such as for intensive care patients), the bandwidth is restricted to 0.5-50 Hz. In monitoring applications, rhythm analysis (or rhythm disturbances, i.e. arrhythmias) is principally of interest rather than subtle morphological changes in the ECG waveforms. Thus, the restricted bandwidth attenuates the higher frequency noise caused by muscle contractions (electromyographic or EMG noise) and the lower frequency noise caused by motion of the electrodes (baseline charges).

In this thesis, pulse-transit-time (PTT) is used to estimate BP. In the ECG, only R-peak is needed to calculate PTT. The target of the circuit is to filter out a distinct R-peak. 99% of QRS complex power is concentrate within 0-33Hz, more than 50% of power is in 8-16Hz. The filter shows in Figure 13 was the circuit that we used to capture the user's ECG, it results 6-18Hz bandwidth [63].

3.1.3 Design of PPG Circuit

Photoplethysmography (PPG) is a noninvasive technique for measuring volume changes in a specific body segment conducted by optical means [64]. The PPG probe in h-Shirt is composed of an infrared light source and infrared detector, which are to be placed on the finger tips. The infrared light source scattered from inside the tissue and is detected by the detector. Infrared light of 940nm from a GaAs LED (Everlight, IR11-21C/TR8) is used as the light source. A NPN silicon phototransistor (Everlight, PT11-21B/L41/TR8) is used as a detector for receiving the reflected light. The phototransistor has a peak wavelength of 940nm.

When blood is ejected from the heart into the tissue, a surge of blood pumps through the vascular system, expanding the capillaries in the finger, and changing the amount of light returning to the phototransistor. The resistance of the phototransistor changes as a function of the amount of light falling on it resulting in a change in the electrical current flowing through the detector circuit. In this way, the dynamic activity of the vasculature is converted into an electrical signal, which is the source of the PPG signal. Figure 14 illustrates the probe for measuring the PPG signals.

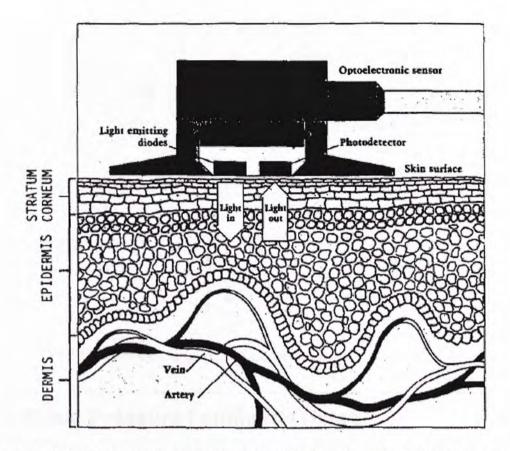


Figure 14 - Principal of measuring photoplethysmographic signal illustrating the optical sensor and the different layers of skin [65].

The PPG signal (caused by blood flow) from the detector is amplified with band-pass filters. The PPG signal is finally sent to the computer for recording and analysis. The cut-off frequency of a high-pass filter is 0.5Hz and that of a low-pass filter is 16Hz, because the most important frequency spectrum of the PPG signal is between 0.5-16Hz [65-66]. The interference due to the 50Hz from power-lines and other occasionally high-frequency noise at the input is reduced. The filter effectively allows the passage of the PPG signal. Figure 15 demonstrated the schematic circuit of the PPG device.

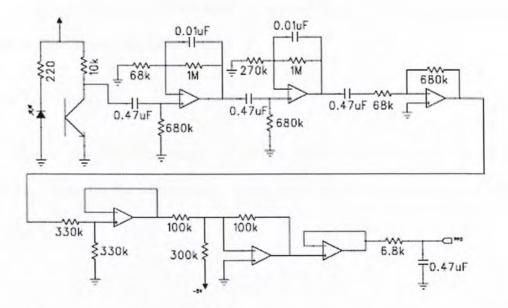


Figure 15 - PPG filters with infrared photodiode and phototransistor

3.2 Blood Pressure Estimation Using

Pulse-Transit-Time Algorithm

3.2.1 Principal

In this section, the BP estimating algorithm used in h-Shirt will be described. ECG-PPG interval is used as a parameter to estimate the values of blood pressure without using a cuff. The interval consists of pulse transit time (PTT), where PTT is defined as the time an arterial pulse takes to travel between two points along the same artery. The clinical application of the PTT to detect the change in respiratory effort and sleep apnea is commonly used [67-68]. In addition, PTT is also employed to assess the stiffness of the artery [69], which is closely related to BP.

Traditionally, two peripheral pulse detectors are used to measure the PTT, however they are easily interfered by motion artifact and the measured time interval is indistinctive [70]. Thus, the time difference between the occurrence of R-peak on the

ECG signal and that peak of PPG signal in the same cardiac cycle is employed instead of the time delay of two pulses [71].

3.2.2 Equations

The Moens-Korteweg model is used to develop BP estimating equations in h-Shirt. To sum up, the relationship between pulse velocity and pressure in a tube can be simplified to:

$$\Delta P \propto c^2 \left(\frac{\Delta V}{V}\right) \dots (3.1)$$

Where V is the initial volume of the artery, ΔV is the change in volume resulting in the pressure pulse ΔP , and c is the pulse wave velocity. According to the result, the approximate relationship between pulse transit time and blood pressure can be expressed as below, which was adopted in [72].

$$BP = \frac{A}{PTT^2} + B \dots (3.2)$$

Where A and B are subject dependent constants, which are determined by individual calibration for SBP and DBP separately. All the BP readings measured in h-Shirt are based on equation 3.2. The constant B in the equation equals to 75 for SBP and 45 for DBP.

$$SBP = \frac{A}{PTT^2} + 75$$
(3.3)
 $DBP = \frac{C}{PTT^2} + 45$ (3.4)

3.2.3 Calibration

To calibrate the individual parameters in equation 3.3 and 3.4, a traditional cuff

BP meter will be used. Reading from the cuff-BP meter and PTT from h-Shirt was substituted into the equations, variable A and C are calculated. Afterward, these two values are substitute into the equations, so that BP can depend on PTT alone.

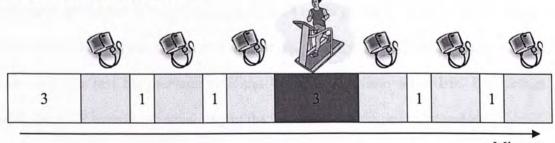
3.3 Performance Tests on h-Shirt

3.3.1 Test I: BP Measurement Accuracy

In this experiment, accuracy of h-Shirt will be compared with automatic BP meter before and after exercise.

3.3.2 Test I: Procedure and Protocol

To test the proposed h-Shirt design, 10 volunteers were recruited. The subjects were asked to put on the h-Shirt with the watch. BPs were simultaneously recorded using the h-Shirt and an automatic BP meter (Omron HEM907, Japan), which was used as the reference. The first set of BP measurements was used to calibrate the watch. Within 10 minutes after calibration, another two datasets were recorded while the subjects were at rest. The subjects were then directed to run on a motorized treadmill (Model C956, Precor, USA) at a moderate speed for 3 minutes. After exercise, 3 datasets were recorded.



Minutes

Figure 16 - Time-line of Test I on h-Shirt

3.3.3 Test I - Results

Figure 17 shows a typical signal recorded immediately after exercise. The QRS complex of the ECG and peak of PPG signal can easily be seen and processed by the wrist watch.

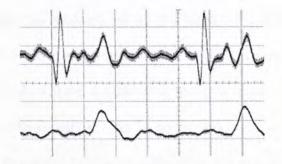


Figure 17 - Typical ECG (above) and PPG (below) captured from a subject wearing the h-Shirt after exercise.

From the data analysis, it is found that the h-Shirt could estimate systolic BP (SBP) and diastolic BP (DBP) within -5.3 ± 10.1 mmHg and 2.0 ± 8.4 mmHg of the references respectively. The results show that the design works reasonably well and has the potential to be used for BP measurements in an individual's daily life.

3.3.4 Test II: Continuality BP Estimation Performance

In this session, the continuous BP estimating ability was examined. As we have mentioned in Chapter 2, the BP pattern over 24 hours or the BPV can be an indicator of disease. To enable this function in h-Shirt, the long term estimation ability has to be guaranteed. To test the performance and bring h-Shirt into daily life, the h-Shirt beat-to-beat BP estimating reliability in the following conditions were tested:

- 1. In the resting state;
- 2. During exercise; and

3. Post-exercise.

3.3.5 Test II – Experiment Procedure and Protocol

To compare the beat-to-beat or beats-to-beasts BP non-invasively, finometer (Finapres Medical Systems, Finometer model-1, Netherland) is the only choice. It is a non-invasive instrument to measure BP on the finger of a human. In the finometer, brachial artery pressure wave is reconstructed in waveform and level. For this purpose patented methods and algorithms are included, using an upper arm cuff return-to-flow systolic pressure determination, to substantially reduce inaccuracies. The reconstruction procedures run fully automatically as the default setting of Finometer, the details of finometer are provided on Appendix.



Figure 18 - Outlook of Finometer

In the beginning of the experiment, both the finometer and h-Shirt had to be calibrated for estimating BP accurately. Finometer was calibrated with its own cuff and pump automatically once entering calibration mode. At the other side, h-Shirt was calibrated by an automatic BP meter (Omron, HEM907, Japan). When calibrating the h-Shirt, ECG and PPG from h-Shirt were captured for a minute, the automatic BP machine reading was recorded simultaneously within the minute.

After all the calibrating processes compete, 15 minutes of biological signals were captured, including SBP, DBP, ECG, PPG and finger pressure information. Within

the 15 minutes signal, subjects were asked to ride on a bicycle ergometer for 5 minutes. Two more automatic meter readings were captured before the cycling and at the end of the experiment. The timing and details of the experiment were summarized in Figure 19.

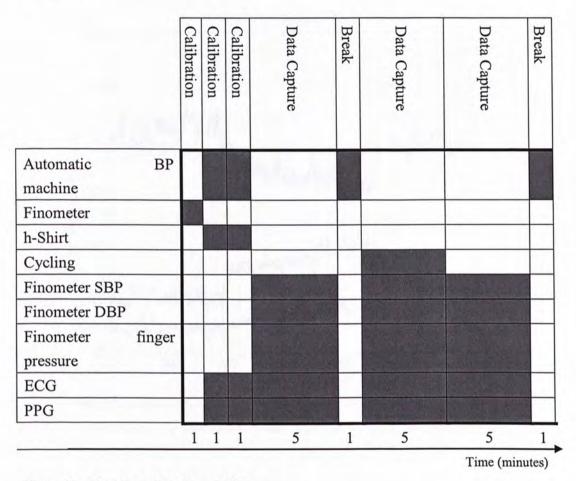


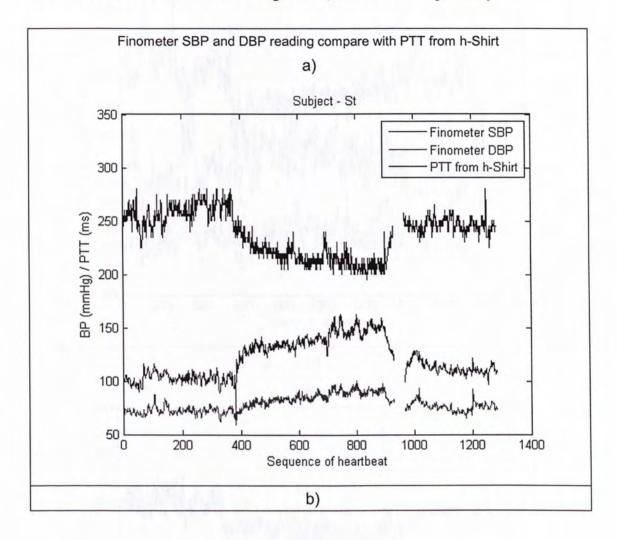
Figure 19 - Time-line of Test II on h-Shirt

3.3.6 Test II – Experiment Result

After the experiment, the recorded data of the 20 subjects were put into computer for analysis. Matlab version R2006a was used to calculate errors, standard deviations or correlations of the captured signals. The overall least-mean-square error of the SBP and DBP refer to finometer is 10.64mmHg and 7.13mmHg respectively.

The beat-to-beat PTT from h-Shirt and the corresponding BP readings from

finometer were plotted. In terms of correlation between PTT and BP, the best, typical and the worse case were shown in Figure 20a, 20b and 20c respectively.



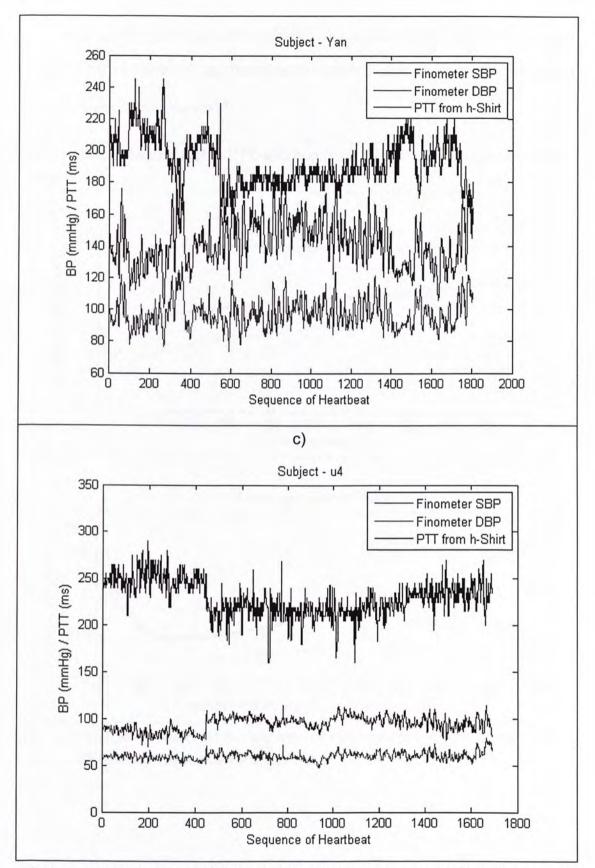


Figure 20 - Comparison between PTT from h-Shirt and BP from finometer with a)best, b)mean, c)worst correlation.

Beats-to-beats BP is also one of the concerns in this paper. The following graphs show how the h-Shirt PTT and finometer BP correlate each other when the number of averaging points was increased.

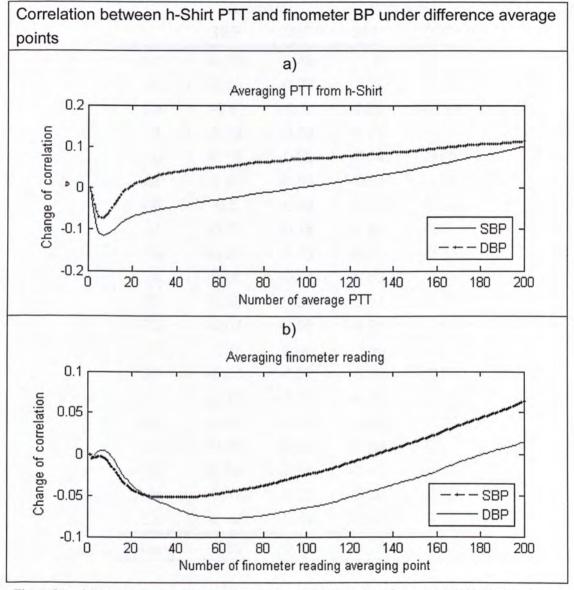


Figure 21 - a) Beats-to-beats h-Shirt PTT correlates with beat-to-beat finometer BP. b) Beats-to-beats finometer BP correlates with beat-to-beat h-Shirt PTT.

	: TEST II CO Beat-to-t		7 pts ave		
	correlate with		correlate with		
Subject	finon	neter	finon	neter	
	SBP	DBP	SBP	DBP	
Lc	-0.76	-0.49	-0.8	-0.52	
Jo	-0.66	-0.25	-0.74	-0.27	
Ca	-0.6	-0.6	-0.76	-0.68	
Di	-0.72	-0.48	-0.78	-0.53	
Gu	-0.75	-0.62	-0.84	-0.69	
St	-0.82	-0.66	-0.87	-0.71	
Mf	-0.5	-0.42	-0.64	-0.50	
u4	-0.55	-0.18	-0.80	-0.34	
Xu	-0.56	-0.23	-0.75	-0.36	
Ya	-0.64	-0.41	-0.72	-0.46	
Zb	-0.58	-0.30	-0.61	-0.36	
P2	-0.67	-0.56	-0.74	-0.63	
S2	-0.6	-0.45	-0.64	-0.54	
G2	-0.75	-0.62	-0.81	-0.70	
On	-0.73	-0.31	-0.80	-0.36	
Fu	-0.56	-0.32	-0.66	-0.38	
Zi	-0.78	-0.46	-0.82	-0.50	
Yp	-0.52	-0.34	-0.60	-0.38	
Yb	-0.62	-0.28	-0.69	-0.32	
Cc	-0.77	-0.44	-0.85	-0.63	
Mean	-0.66	-0.42	-0.75	-0.49	

Table 3 shows the detail correlation information of each subject.

h-Shirt PPT was converted into BP in the computer. In this part, BP was calculated by equation 3.3 and 3.4.

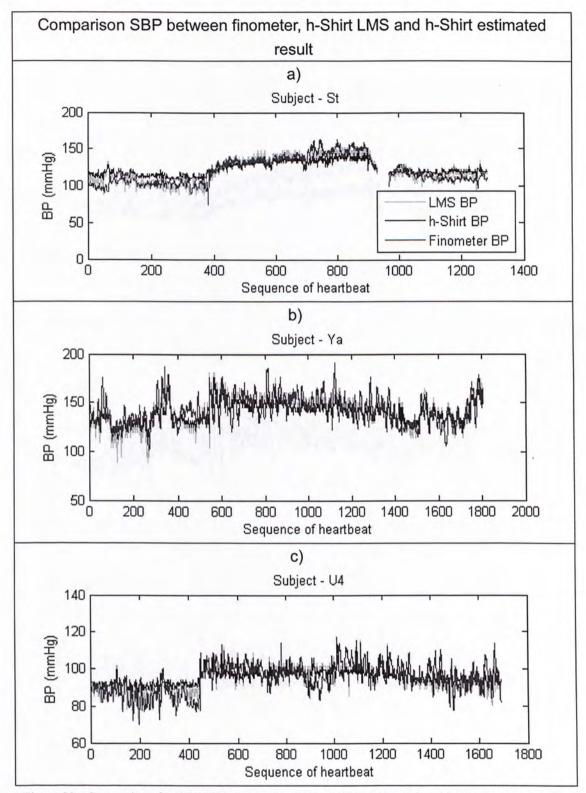


Figure 22 - Comparison for the SBP between finometer, h-Shirt estimated and least-mean-square of three typical subjects.

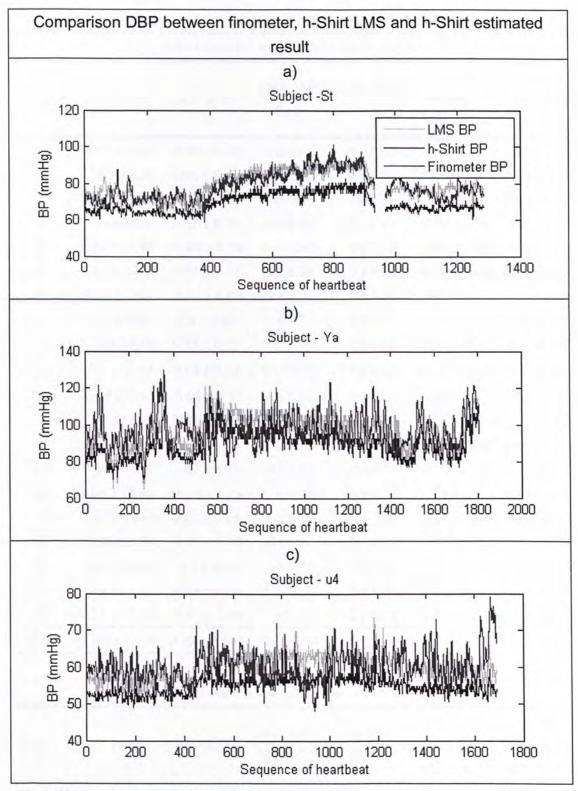
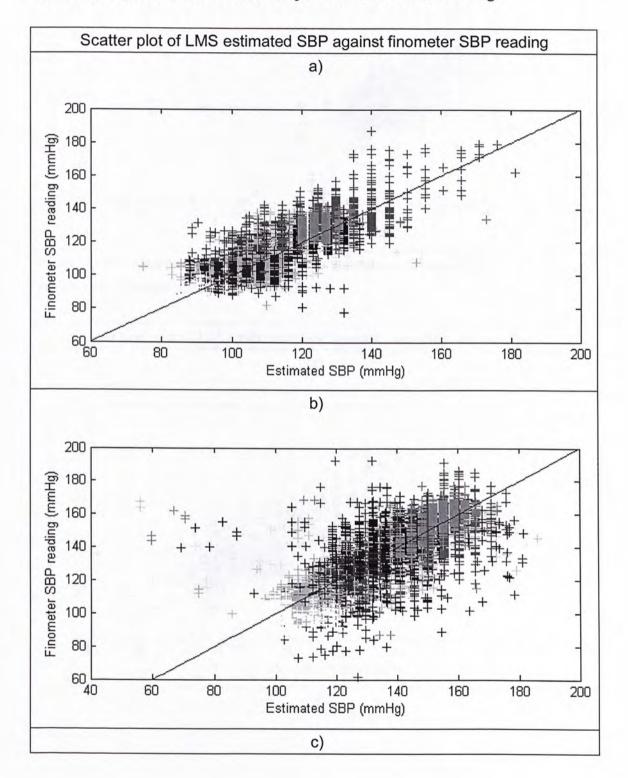


Figure 23 - Comparison DBP between finometer, h-Shirt estimated and least-mean-square of three typical subjects.

Subject	SBP Error	DBP Error	LMS SBP Error	LMS DBP Error	7 points averaged SBP Error	7 points averaged DBP Error
Lc	-6.97 ± 9.33	-6.66 ± 9.38	0 ± 8.51	0 ± 6.63	-6.84 ± 8.7	-6.6 ± 9.02
Jo	7.38 ± 14.25	8.68 ± 9.13	0 ± 15.35	0 ± 8.89	7.67 ± 13.71	8.84 ± 8.74
Ca	20.61 ± 12.15	16.8 ± 4.64	0 ± 13.55	0 ± 5.4	20.8 ± 12.07	16.89 ± 4.71
Di	0.05 ± 7.84	3.52 ± 6.97	0 ± 8.14	0 ± 7.11	0.22 ± 6.99	3.61 ± 6.49
Gu	2.54 ± 11.43	16.29 ± 6.29	0 ± 12.22	0 ± 7.17	2.73 ± 11.53	16.36 ± 6.55
St	-2.27 ± 10.83	9.84 ± 5.29	0 ± 8.38	0 ± 5.97	-2.14 ± 10.74	9.91 ± 5.2
Mf	-9.92 ± 7.66	-5.61 ± 6.09	0 ± 8.74	0 ± 7.12	-9.77 ± 7.57	-5.5 ± 6.08
u4	-0.93 ± 6.69	5.9 ± 4.46	0 ± 7.17	0 ± 5.47	-0.77 ± 6.65	5.93 ± 4.36
Xu	1.74 ± 11.79	6.58 ± 6.85	0 ± 13.78	0 ± 6.86	2.06 ± 11.41	6.78 ± 6.36
Ya	2.71 ± 11.47	8.53 ± 9.04	0 ± 13.17	0 ± 9.22	2.78 ± 12.23	8.59 ± 9.28
Zb	-6.97 ± 9.33	-6.66 ± 9.38	0 ± 8.51	0 ± 6.63	-6.84 ± 8.7	-6.6 ± 9.02
P2	7.38 ± 14.25	8.68 ± 9.13	0 ± 15.35	0 ± 8.89	7.67 ± 13.71	8.84 ± 8.74
S2	20.61 ± 12.15	16.8 ± 4.64	0 ± 13.55	0 ± 5.4	20.8 ± 12.07	16.89 ± 4.71
G2	0.05 ± 7.84	3.52 ± 6.97	0 ± 8.14	0 ± 7.11	0.22 ± 6.99	3.61 ± 6.49
On	2.54 ± 11.43	16.29 ± 6.29	0 ± 12.22	0 ± 7.17	2.73 ± 11.53	16.36 ± 6.55
Fu	-2.27 ± 10.83	9.84 ± 5.29	0 ± 8.38	0 ± 5.97	-2.14 ± 10.74	9.91 ± 5.2
Zi	-9.92 ± 7.66	-5.61 ± 6.09	0 ± 8.74	0 ± 7.12	-9.77 ± 7.57	-5.5 ± 6.08
Yp	-0.93 ± 6.69	5.9 ± 4.46	0 ± 7.17	0 ± 5.47	-0.77 ± 6.65	5.93 ± 4.36
Yb	1.74 ± 11.79	6.58 ± 6.85	0 ± 13.78	0 ± 6.86	2.06 ± 11.41	6.78 ± 6.36
Cc	2.71 ± 11.47	8.53 ± 9.04	0 ± 13.17	0 ± 9.22	2.78 ± 12.23	8.59 ± 9.28
Mean	-2.49 ± 13.34	3.03 ± 12.87	0 ± 10.64	0 ± 7.13	-0.24 ± 13.05	5.18 ± 11.31

The overall	estimated	errors	are shown	in t	he fo	llowing	two table	es.

Subject	SBP Error	DBP Error	LMS SBP Error	LMS DBP Error	7 points averaged SBP Error	7 points averaged DBP Error
		Session 1	Pre-exercise p	eriod (5 minut	es)	
Mean	-2.22±10.54	6.56±9.66	0±8.95	0±5.94	-2.17±10.61	6.61±9.66
		Session	2 Dynamic per	riod (5 minutes	5)	
Mean	-1.99±15.87	-0.7±14.32	0±12.72	0±7.98	-1.72±15.31	-0.5±13.92
		Session 3 F	Post-exercise	period (5 minu	tes)	
Mean	-3.35±12.3	4.15±12.53	0±9.3	0±6.99	-3.2±12.34	4.2±12.49



The performance could also be shown by scatter plots. Here are the plots showing least-mean-square BP from h-Shirt compare with finometer BP reading.

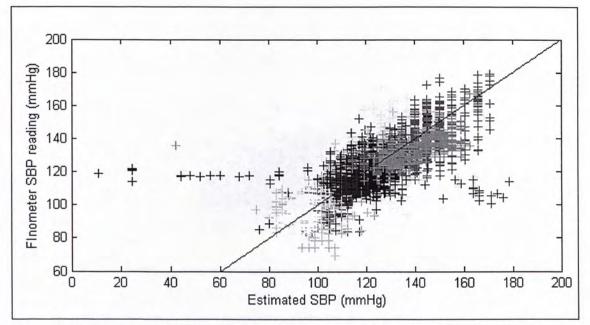
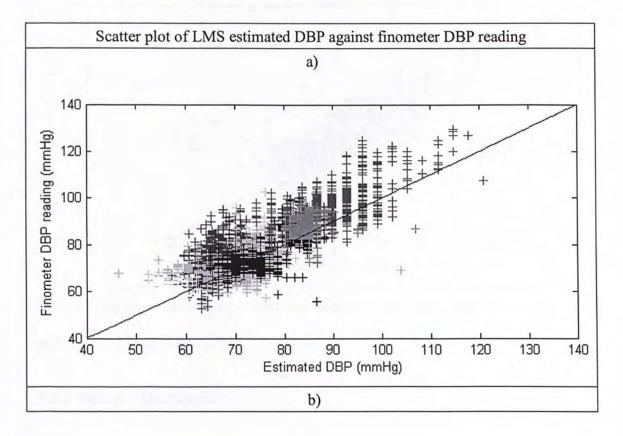


Figure 24 - The scatter plot showing the SBP estimate performance in three sessions, they are a) pre-exercise, b) dynamic and c) post-exercise period



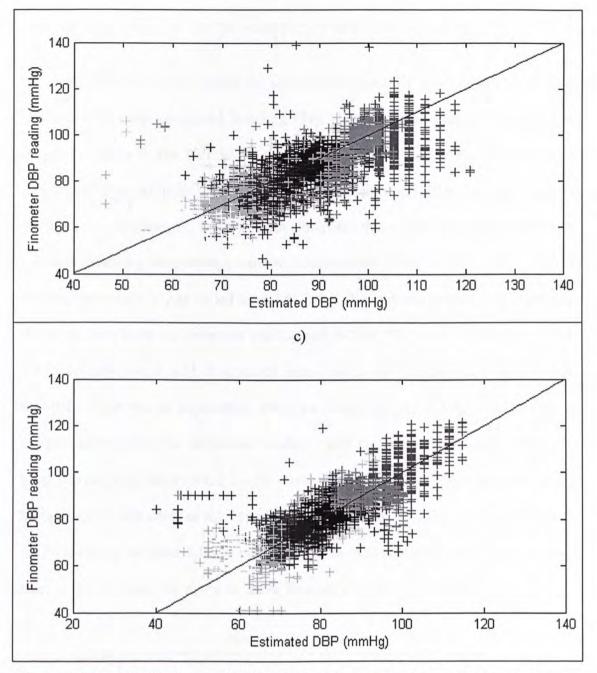


Figure 25 - The scatter plot showing the DBP estimate performance in three sessions, they are a) pre-exercise, b) dynamic and c) post-exercise period

3.3.7 Test II – Discussion

The correlation between PTT and BP plays a main role in the accuracy of h-Shirt. According to Table 3, the PTT to SBP and DBP mean correlation of 20 subjects are -0.66 and -0.42 respectively. This result is compatible to a similar test done by Marie *et al.* in 1984 [73]. The BP raised by mild exercise such as handgrips

exercise. Finally they got -0.57 to -0.89 for SBP and -0.1 to -0.63 for DBP.

In 2003 Katz *et al.* studied the relation between PTT and respiration effort in children with sleep-disordered breading [74]. He found that there is a regular low frequency ripple in the PTT of all the subjects, the ripples are synchronized with esophageal pressure which measured by a 6-french water-filled catheter (Corpak Medsystems, Wheling, IL, U.S.A.). Eliot eliminated this respiratory variation by using a 4-second moving time average window in advanced CODAS software. The width of moving time window was varied from 1 to 200 PTT in my experiment, it is found that the correlation between finometer reading and h-Shirt PTT reach a maximum when 7-PTT windows were used. It increased from -0.66 to -0.77 for SBP and -0.43 to -0.51 for DBP. There was no explanation about the window length in Katz's report. One of the possible reasons for difference window width is the age and status of subjects, Eliot's experiment subjects are 2 - 16 years old children, their respiration rate would be higher than the adult in my experiment [99]. Moreover, exercise was included in my experiment whether Eliot's experiment data was captured when subjects were slept, these two factors may cause the difference between two window width.

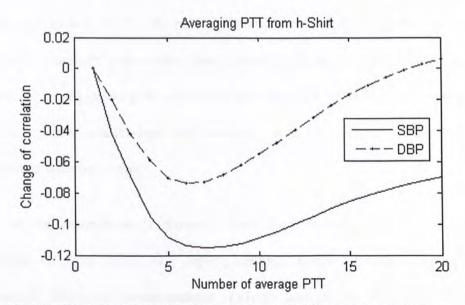


Figure 26 - The BP to PTT correlation change form 1 to 20 PTT averaging windows.

TABLE 6: HEART RATE AND BREATHING RATE IN DIFFERENCE AGE GROUP [99]						
Age Group	Heart rate	Breathing rate	No. of heart beat in a breathing cycle			
8 or above	60 - 100	16 – 20	~ 4-6			
1 to 8 years old	80 - 120	20 - 30	~ 4			
Below 1	120 - 140	36 - 40	~ 3			

There are three sessions in the experiment, the least-mean-square error of the h-Shirt compare to finometer is 8.95mmHg before exercise, 12.72mmHg during exercise was recorded and return back to 9.3mmHg in the recovery period. To sum up, the overall SBP and DBP least-mean-square error of the h-Shirt compare to finometer are 10.64mmHg and 7.13mmHg respectively. The result is comparable to the test we did in the test I (BP watch test). In this experiment, finometer which is widely used in research and tilt laboratories [75, 76] was chosen to be the reference. Studies on its accuracy have suggested little systematic bias versus intra-arterial pressure but substantial variability. Inconsistency between studies, as relating to magnitude, direction and variance of bias, has been described in validation studies versus direct intra-arterial blood pressure. However, in combined data from 20 published studies, the average (SD) Finapres systolic bias was 2.2 (12.4) mmHg and the Finapres diastolic bias was 20.3 (7.9) mmHg [77-80]. As a result, the performance of h-Shirt can both closer or even worse than finometer when compare to the traditional BP meter. It is misleading to conclude the accuracy of h-Shirt by using the listed finometer error result alone, all the result in this experiment were the bias when compared with finometer.

In the experiment II protocol, there were two procedures for automatic BP machine (Omron HEM 907, Japan) readings before and after the dynamic test. Although they were instantaneous readings comparison, the bias of h-Shirt was

smaller than finometer both before and after exercise (Figure 27 and 28). Further more, according to the tests did by JCBME and Massachusetts institute of Technology before [81-83], the PTT based BP estimating algorithm compare with conventional cuff BP meter reach 0.6 ± 9.8 mmHg and 0.9 ± 5.6 mmHg for SBP and DBP respectively. Combine the automatic BP machine, continuous finometer readings and the pervious works, it is possible to say that h-Shirt is more accuracy then finometer when compared with traditional BP measuring instrument. Before the actual conclusion, more comparisons have to perform, for example, catheter could be inserted in the blood vessel, however, it is danger when dynamic exercise is included, some handgrip exercises is suggested[73].

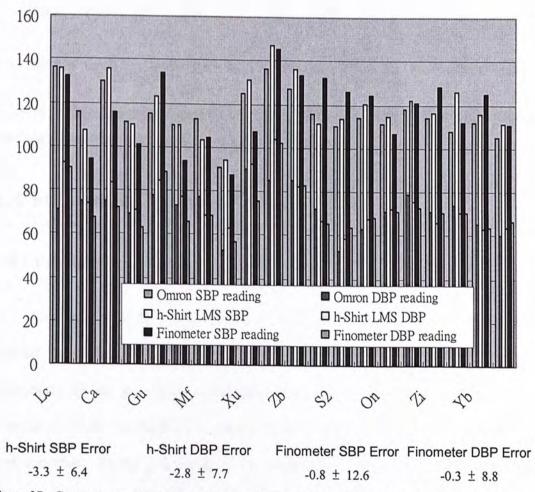
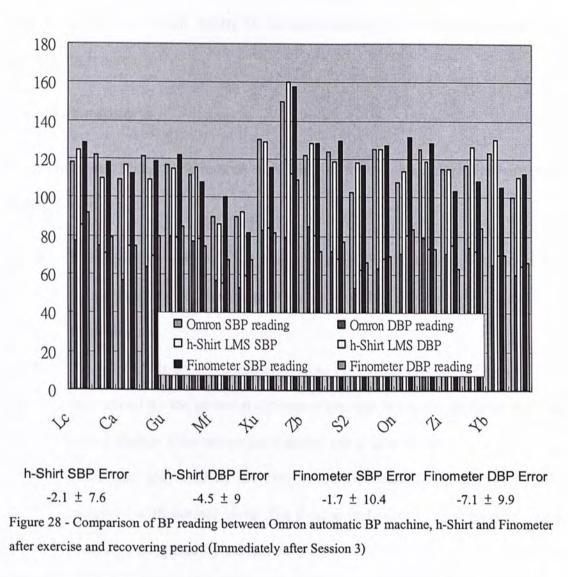


Figure 27 - Comparison of BP reading between Omron automatic BP machine, h-Shirt and Finometer before exercise (Immediately after Session 1)



3.4 Follow-up Tests on ECG Circuit

3.4.1 Problems

After the test in the last session, the h-Shirt continuous BP monitoring reliability proved. However during the experiment, some of the users have difficulties on estimating BP on the watch. Afterward, ECG and PPG of those failed users were studied; it found that the ECG R-peak of those subjects could not be recognized easily and accurately by the processor. In the meanwhile, one of our cooperate company Colusa Ltd. indicated that two of their employees failed to capture a clear ECG with their BP meter. As a result, totally 16 subjects were studied with the assumptions in the coming session.

3.4.2 Assumptions

To infer and find out the reasons of failure, the following assumptions were made before the experiment.

- The impedance (skin/contact/tissue impedance) from heart to finger-tips was higher than the normal range, This may weaken the electrical signal from measuring site.
- The wrist to finger-tips impedance from the two arms were unbalance. ECG was formed by the potential difference between left and right fingers, it may looked strange if the transmitting media was greatly varies.
- The signal generated by the heart muscle of those failed users was small compared with normal users. The R-peak and other ECG properties cannot be easily recognized by the software.
- The user's ECG frequency response did not match the designed one (6-18Hz). QRS complex could be suppressed or enhanced by the designed filter, unstable filtering caused reduction of signal-to-noise ratio.
- The ECG captured from finger tips were difference to the standard position (wrists and right leg).

3.4.3 Experiment Protocol and Setup

Base on the assumptions in the last session, a series of tests were performed to direct again those suggestions.

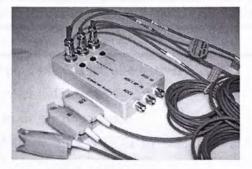


Figure 29 - BP testing system developed by JCBME

90 subjects from different departments were tested on a BP meter. Out of the 90 subjects, 6 of them were failed to estimate BP within one minute. Together with the 2 failed subjects from Colisa Ltd. and 8 control subjects totally 16 were recruited for further study. Table 1 summary the test content. To ignore the effect due to area variation of the electrodes, 9 dry stainless steel electrodes with same shape and surface area (10mm x 15mm) were attached on fingers, wrists, elbows and legs (position shows on Figure 30) with different combination were used for ECG capturing or skin-impedance measurement. ECG captured from wrist watch prototype circuit, frequency testing filters or standard ECG machine (Auto-Med Inc. Model 7400 physiological recorder) were digitize through windaq (DATAQ instrument, DI720). Each data set were 20 seconds continuous ECG, all data were stored in a computer for analysis.

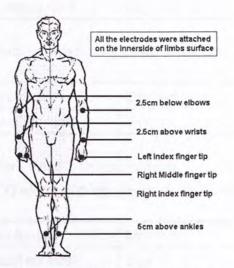


Figure 30 - Electrodes position of ECG circuit follow up experiment

No.	Experimental content	No. of sets
1.	BP device ECG and path impedance alternatively	3 sets
2.	Left and right hand potential refer to WCT	1 set
3.	Left and right wrist to finger impedance	1 set
4.	Lead I, Lead II and three fingers ECG by standard machine	1 set
5.	Capturing ECG with different filters (6-18Hz, 4-18Hz, 8-18Hz, 4-33Hz and 8-33Hz) simultaneously.	1 set

The experiment procedures were divided into two parts. First part of the experiment studied the relationship between ECG magnitude and skin impedance, ECG from standard machine would also be captured in this part. In part two, ECG performance on filters with difference bandwidth were studied. The following tables describe the details of the experiment, measuring position, content and electrode status were listed for each part.

Part 1:

1. Record the ECG with wrist watch prototype circuit (20sec.).

Position	Electrode	Dry/wet	Remarks	
Finger tips	Stainless steel	Dry		

2. Estimate the skin + contact impedance of the user (20sec.).

Position	Electrode	Dry/wet	Remarks	
Finger tips	Stainless steel	Dry	Method 1	

3. Repeat procedure 1 and 2 two more times.

4. Record the ECG with right-leg-driven electrode on right leg (20sec.).

Position	Electrode	Dry/wet	Remarks
fingers and DR	L Stainless steel	Dry	
on right leg			

5. Record the ECG by wrist electrodes and right-leg-driven electrode on right-leg (20sec.).

Position	Electrode	Dry/wet	Remarks
Wrist and DRL on	Stainless steel	Dry	
right leg	11	1944	

6. Record the left hand potential (10sec.).

Position			Electrode	Dry/wet	Remarks
Finger ti left-leg	ips	and	Stainless steel	Dry	

7. Measure the left hand skin impedance.

Position		Electrode	Dry/wet	Remarks	
Finger tips left-leg	and	Stainless steel	Dry	Method 2	

8. Record the right hand potential (10sec.).

Position			Electrode	Dry/wet	Remarks
Finger	tips	and	Stainless steel	Dry	
left-leg					

9. Measure the right hand skin impedance.

Position		Electrode	Dry/wet	Remarks
Finger tip left-leg	s and	Stainless steel	Dry	Method 2

10. Change the INA118 into INA116 and record the ECG (20sec.).

Position	Electrode	Dry/wet	Remarks	
Finger tips	Stainless steel	Dry		

11. Add jel to all the electrodes.

12. Repeat procedure 3 with wet electrode.

Position	Electrode	Dry/wet	Remarks	
----------	-----------	---------	---------	--

Finger tips	Stainless steel	Wet	

13. Change the driven-right-leg current and record the signal change (20sec.).

Position	Electrode	Dry/wet	Remarks	
Finger tips	Stainless steel	Wet		

14. Measure the Lead II ECG by BP meter. (20sec.)

Position	Electrode	Dry/wet	Remarks	
Finger tips and left	Stainless steel	Wet		
leg				

15. Record ECG waveform with wet electrodes (3 fingers) by standard ECG machine.

Position	Electrode	Dry/wet	Remarks	
Finger tips	Stainless steel	Wet		

16. Repeat procedure 15 by standard Lead I ECG positions (20sec.).

Position	Electrode	Dry/wet	Remarks	
Std. lead I	Stainless steel	Wet		

17. Repeat procedure 15 by standard Lead II ECG positions (20sec.).

Position	Electrode	Dry/wet	Remarks	
Std. lead II	Stainless steel	Wet		

Part two:

1. Record ECG waveform with the old BP circuit (20sec.).

Position	Electrode	Dry/wet	Remarks	
Finger tips	Stainless steel	Wet		

Measure the ECG with the following filter simultaneously with wet electrode for 20 seconds.

2. 8-18Hz filter.

3. 4-18Hz filter.
 4. 8-35Hz filter.
 5. 4-35Hz filter.

3.4.4 Experiment Results

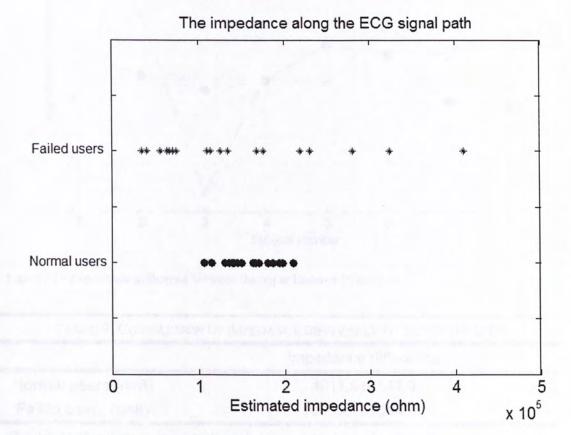


Figure 31 - ECG path impedance of 16 subjects

TABLE 8: C	OMPARISON OF	ESTIMATED IMPEDANCE ALC	ONG THE BP DEVICE ECC
		CAPTURING PATH	
		Normal users (n = 8)	Failed users (n = 8)
Estimated	impedance	157988 ± 32688	146645 ± 98576
(ohm)			
Range (ohm)		105900 - 210000	34380 - 410000

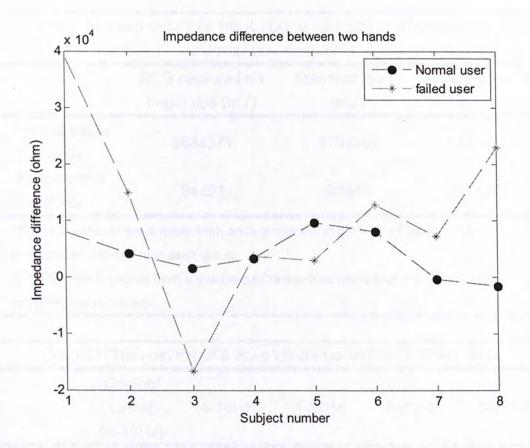


Figure 32 - Impedance difference between the upper limbs of 16 subjects

	IMPEDANCE DIFFERENCE OF THE TWO HANDS
Impedance difference	
Normal users (n=8)	4011.9±4147.9
Failed users (n=8)	10755.5±16143.0

The values shown are a mean from each group and in form of

n = number of subjects in each group.

	CAPTURE CON	FIGURATION	
	ECG captured on finger tips (mV)	Standard lead I (mV)	Standard lead II (mV)
Normal users (n=8)	353±371	370±352	682±497
Failed users (n=8)	94±51	95±46	357±266

TABLE 10: COMPARISON OF THE R-PEAK MAGNITUDE IN DIFFERENCE ECG

The values shown are a mean from each group and in the form of mean ± SD.

n = number of subjects in each group.

All ECG were captured from a standard ECG machine (Auto-Med Inc. Model 7400 physiological recorder)

Marca	Original circuit (6-18Hz)	4-18Hz	4-33Hz	8-33Hz	8-18Hz
Normal users (n=8) Failed	0.69±0.38	0.65±0.36	0.71±0.39	0.80±0.43	0.73±0.40
users (n=8)	0.34±0.25	0.24±0.21	0.35±0.25	0.47±0.32	0.30±0.26

The values shown are a mean from each group and in form of mean ± SD.

n = number of subjects in each group.

TABLE 12: COMPARISON OF ECG STRENGTH				
	R-peak magnitude difference between ECG captured on finger tips	R-peak magnitude differend between standard lead I an		
	and lead I (mV)	lead II (mV)		
Group A	16±69	312±454		
Group B	2±12	262±233		

The values shown are a mean from each group and in the form of mean ± SD.

n = number of subjects in each group.

All ECG were captured from a standard ECG machine (Auto-Med Inc. Model 7400 physiological recorder)

3.4.5 Discussion

The ECG path impedance was estimated by Geddes's method [69], it is the way that estimates path impedance according to a specific physiological signal. In his paper, he simplified the model of ECG path and he found that it could be approximate proportional to a pure resistance. As a result, a large variable resistor was added between the two input electrodes of the ECG circuit. ECG magnitude was recorded before adding the resistor, afterward, reducing the resistance gently until the signal magnitude remained half. The resistor value at that moment indicated the path impedance.

There are five assumptions listed above, in this part, each of the assumptions will be discussed individually. The first Prospect assumed that the failure was caused by unusual high impedance along the ECG path (i.e. from heart to upper limb). Table 1 showed that the path impedance of those normal users were concentrated between 106k to 210kohm. However, for those 8 failed subjects, their path impedance ranged from 34k to 410kohm. Two of the failed subjects had extremely high impedance compared with the other 14 subjects. In this point of view, this assumption is agreed, since the failure of other subjects may due to other factors.

Assumption 2 pointed out that the failure may due to unbalance of limbs impedance. According to Figure 31, all the subjects in the control group have the impedance difference within 10kohm. Nevertheless, half of the subjects in the failed subject group bias more that 10kohm, one of them bias 40kohm. Assumption 2 was also agreed.

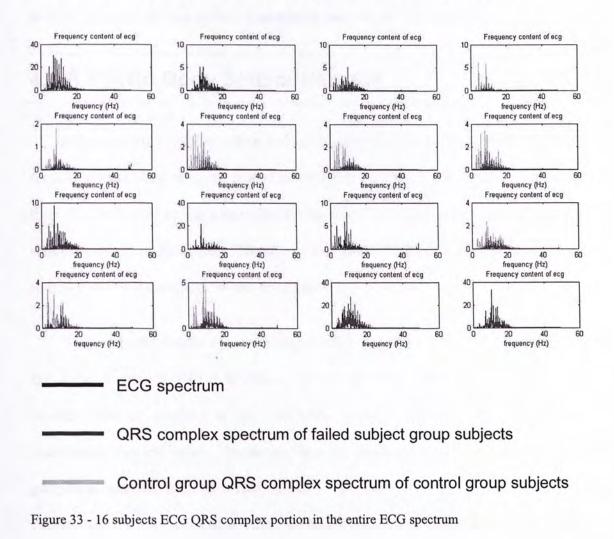
In Assumption 3, the magnitude of ECG in the failed subjects was assumed to be smaller than the control group. The ECG R-peak magnitude captured from a standard ECG machine (Auto-Med Inc. Model 7400 physiological recorder) was listed in table 4. It showed that the R-peak of failed subject group in both lead I and lead II were generally smaller than the control group. As a result, assumption 3 is also agreed.

Figure 33 shows the entire ECG spectrum compared with the corresponding QRS complex spectrum in the standard ECG machine of all the 16 subjects. In the figure, for those subjects in the control group, their QRS complex dominated the ECG spectrum, 87% of ECG spectrum power belong to the part of QRS complex. For the failed subject's group, their QRS complex consumed only 55% of the whole ECG spectrum power. In the h-Shirt, only QRS complex is used in the BP estimation algorithm, in this point of view, the respond of those users should considerate when designing the filter.

The ECG filter range in h-Shirt was designed to 6-18Hz. As we mentioned before, more than 50% of QRS complex power was concentrated in this region. Table 3 presented that the portion of R-peak within the whole ECG spectrum increased from 69% to 80% for control group and from 34% to 47% for failed subject group if the h-Shirt ECG passband broadened to 8-33Hz. To sum up, the current ECG filter may not fit to all users, the filter was suggested that to be broadened. The assumption 4 is agreed.

The last assumption concerned the measuring position as the testing module captured ECG on fingers tips, nonetheless all the standard measuring positions were on forearm, leg and trunk part of body. In the experiment, ECG was captured on both fingers and standard position with the same machine and electrodes. The result indicated that there were not significant difference between the two measuring position in both magnitude and waveform. Assumption 5 is the only failed prospect after the experimental proved.

The experimental result showed that there may be more than one factor causing the difficulties on capturing ECG on those failed users. Unexpected high ECG path impedance or unbalanced limb impedance may also one of the reasons. However, all the subjects show a better performance when the filter bandwidth width broaden, it was because the ECG over filtered when the h-Shirt was first designed. Other than changing the filter range, an auto gain filter or algorithm is suggested to implement in the later version of h-Shirt in order to solve problem of weak signal subjects.



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Chapter 4: Hybrid Body Sensor Network in h-Shirt

In the h-Shirt, we propose using multiple modes of communication, including communication via wired, wireless and/or biological channels (bio-channels) of the human body, to network the various sensors, i.e. the idea of hybrid body sensor network (h-BSN). In this chapter, preliminary results show that h-BSN is potentially useful for monitoring BP over extensive periods of time and the idea can be extended to other applications that employ multiple on-body or in-body sensors.

4.1 A Hybrid Body Sensor Network

Patients who need long-term and continuous collection of medical data often require several sensors to be placed at their different body locations. Most of the time, data collected by the sensors have to be fused together before a medical decision or a diagnosis can be made. Therefore, it is useful to setup a body sensor network (BSN) to allow the sensors to communicate with each others.

Two common modes of connecting sensors together are the wiring and wireless (i.e. radio frequency, RF) techniques. In respect of the wiring technique, the recent development of conductive and washable e-textile material [84] is extremely convenient and effective. However, this technique is unsuitable for connecting peripheral sensors, such as a ring sensor. Therefore, a frequently used method to connect them is by means of wireless RF techniques [64]. Both these techniques are very useful in setting up a BSN, but, if only these techniques are employed, a readily available conductor which is unique to BSN is being neglected. And, the conductor is the human body where the sensors are placed.

JCBME have previously shown that it is possible to use the biological channels (bio-channels) of the human body to secure sensor communication via wireless channel [85]. In this paper, I will discuss another usage of bio-channels, which is to transmit medical data. It is proposed that depending on the application, one or more modes of communication should be used to connect various sensors, i.e. the concept of hybrid BSN (h-BSN).

4.2 Biological Channel Used in h-Shirt

University of Hong Kong).

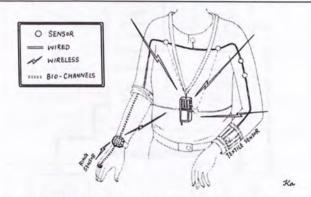


Figure 34 - An illustration of a hybrid body sensor network that uses wired, wireless and biological channels for communication (Artwork: modified based on an illustration of WISSH by Ms. Joey K.Y. Leung, The Chinese

Fig. 1 illustrates the h-BSN idea for continuous and long-term measurement of arterial BP. As previously described [3], e-textile material was used in h-Shirt for collecting ECG. An infra-red optical sensor embedded in a finger ring was used to collect PPG from the subject. Instead of using wiring or wireless (i.e. RF) techniques to connect the ring sensor to the h-Shirt, intra-body communication through a bio-channel was used. Fig. 2 shows how the ring sensor is connected to

the h-Shirt via a bio-channel.

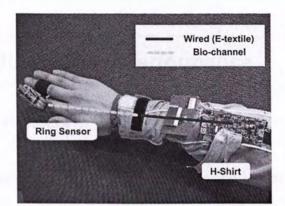


Figure 35 - Connection of the h-Shirt and the ring sensor via a bio-channel.

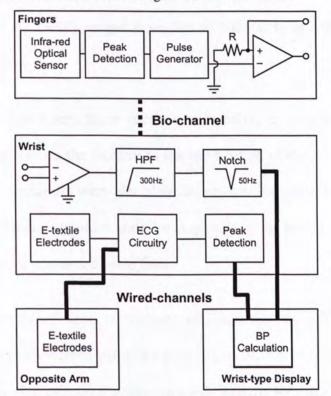


Figure 36 - A block diagram describing the setup of the hybrid body sensor network for the long-term monitoring of blood pressure.

Fig. 3 shows the block diagram of the developed system that uses the proposed h-BSN to connect the h-Shirt and ring sensor. Specifically, whenever the ring sensor detected a volumetric pulse in the PPG, it would generate a square pulse of 1ms duration. Since the human body is a conductor, the pulse could be picked up by electrodes connected to a differential amplifier (INA118, Texas Instrument) placed on the wrist of the same arm. Together with the timing of the R peak of ECG, PTT

could be determined and thus, BP could be estimated.

4.3 Tests of Bio-channel Performance

4.3.1 Experiment Protocol

Two experiments were conducted to evaluate the system. Total 13 volunteers (aged 20-30 yrs. old, 8 male, 5 female) were recruited in each experiment, the subjects' systolic BP (SBP) ranged from 128 to 102mmHg and diastolic BP (DBP) from 85 to 53mmHg.

In the first experiment, three subjects were asked to wear the ring sensor and electrodes were placed on the forearm to test the strength of the pulse received via the bio-channel. The electrodes were placed on the wrist of the subject and moved in 1cm interval towards his/her shoulder until the amplitude of the received pulse was of the same order of magnitude as the noise floor.

In the second experiment, 10 subjects were asked to put on the h-Shirt and ring sensor, which were connected using the proposed h-BSN shown in Fig. 2. BPs were simultaneous recorded using our system and an automatic BP meter (Omron HEM907, Japan), which is used as the reference. The first set of measurements was used to calibrate the PTT-based estimation approach. Three other datasets were collected subsequently for testing the system. The subjects were allowed to rest for 1 min. in between each measurement.

4.3.2 Results

From the first experiment, the noise floor of the receiving module was found to

be approximately 290±140mV. Fig. 4 plots the amplitude of the received pulse against the distance of the electrodes from the wrist.

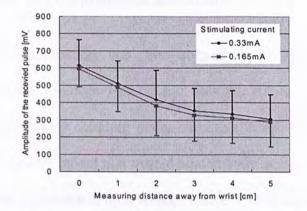


Figure 37 - Amplitude of the received pulse as a function of measuring distance away from wrist. The gain of the receiver is 33.

From the second experiment, it is found that when the subjects were at rest and the measurements were made within 15 min. after calibration, the system that connects the h-Shirt and the ring sensor using h-BSN could estimate SBP and DBP within -0.63 ± 3.13 mmHg and 1.10 ± 2.75 mmHg of the references respectively.

4.4 Discussion and Conclusion

The results of this experiment showed that the strength of the received pulse decreased proportionately to the distance of the electrodes from the source. Within 5 cm from the wrist (i.e. approximately 19 cm from the stimulating source), the received signal can be distinguishably identified from the noise floor. Further studies could be made to examine whether increasing the frequency of the input pulse could increase the transmission distance via bio-channels as other studies suggested [86, 87]. Nevertheless, the results of the study already suggest that if the electrodes for receiving pulses are placed close to the wrist of the h-Shirt, the bio-channel functions reasonably well and can be potentially used to replace wiring or RF techniques for transmitting the timing of the arrival of the volumetric pulse at the peripheral. This is extremely useful for our application, where the timing information of the ECG and PPG are both needed in order to estimate arterial BP.

Intra-body communication was first suggested by Zimmerman [88], who demonstrated how electronic devices on and near the human body could exchange information by capacitively coupling micro-currents through the body. Hachisuka *et al.* [87] suggested another model that treated human body as a guide to high frequency electromagnetic waves generated by a voltage source. Our design uses a relatively low frequency square pulse generated by a current source as the input signal. There are several advantages using a current source over a voltage source. When skin heat up and skin resistance deceases with time due to current passing through, using a voltage source will result in an increase in power dissipation but the same phenomenon will decrease power dissipation if a current source is used [89]. A current source could also force the stimulating strength within a safety range to prevent any harmful condition [90]. In addition, the circuit path of a current source is not complete until the device is loaded, thus loosen connection can easily be detected [90].

Safety of electrical stimulation via bio-channels is a great concern in this study. According to the AAMI safety standard on transcutaneous electrical nerve stimulators [91], the maximum output current of the stimulus generator shall not exceed 10mA and charge per pulse must be lower than $(20+28t)\mu$ C into a 500-ohm load, where *t* is the pulse width of stimulus in ms. In other words, for a 1ms square pulse, the allowable charge per pulse is 48 μ C. For our design, the maximum current and charge that could be drawn from the stimulator is 0.33mA and 0.33 μ C per pulse, which satisfy the safety standard suggested by AAMI [91]. Compared to wireless RF techniques, the advantages of bio-channels are their low power consumption and provide a more secured pathway for transmission. At the same time, they do not require an external connection as in the case of wiring techniques. On the other hand, wireless techniques can be used as another mode of communication when the subject is present in a crowded environment, where communication via bio-channels could be difficult. Wireless communication could also be used in parallel with bio-channels to increase the security level of the transmission [92]. We therefore conclude that the connection in BSN should not be limited to one technique – wired, wireless RF or bio-channel. Rather, depending on the application, one or more techniques could be used within a network, and thus, forming a h-BSN. We have shown in this study that a h-BSN can potentially be used to monitor BP and BPV over extensive periods of time. The same idea can be applied to other applications that required multiple sensors to be placed on or inside the human body.

Chapter 5: Conclusion and Suggestions for Future Works

5.1 Conclusion

This thesis was carried out to present the development of a health monitoring garment – h-Shirt. h-Shirt can be used in WISSH to monitor human health, provide treatment remotely. It solves the major problems in noninvasive and cuffless BP estimation: 1) a continuous BP estimation in daily life is realized; and 2) during estimation, both of the hands are freed. The thesis is composed of four parts: 1) structure of h-Shirt; 2) BP estimation accuracy of h-Shirt; 3) tests and amendments on h-Shirt's ECG circuit; and 4) hybrid body sensor network in a renovated h-Shirt. The contributions of thesis in each of four parts are summarized as follows:

5.1.1 Structure of h-Shirt

There are two versions of h-Shirt presented in this thesis. The first one is used to test BP estimation accuracy; the second one is the revised version which combines of wired, wireless (radio frequency) and bio-channel in h-Shirt. e-Textile materials are used as the ECG sensing electrode and conducting wires from sensing site to processing unit. The joints between processing unit and conducting e-textile are fasten-snap buttons, it makes the processing unit become removable and h-Shirt becomes washable. In the updated version of h-Shirt, a communication channel is added – bio-channel. It is exploited to replace the wired communication between PPG

sensor and processing unit, in the meanwhile a low power consumption is maintained.

5.1.2 Blood Pressure Estimating Ability of h-Shirt

The BP estimating ability is reported in two directions. Snapshots of BP reading by h-Shirt were compared with commercial automatic BP meter before and after exercise. The differences between the estimated and reference BP were -5.3±10.1mmHg for SBP and 2.0±8.4mmHg for DBP. Afterward, the continuous BP estimating accuracy was studied. Subjects were asked to wear h-Shirt during the whole experiment period. The beat-to-beat BPs were compared with finometer before, during and after exercise. The overall SBP and DBP bias were 11.29mmHg and 7.15mmHg respectively. Both results show that the design works reasonably well and has the potential to be used for BP measurements in an individual's daily life.

5.1.3 Tests and Amendments on h-Shirt ECG Circuit

After the accuracy test, it was found that some users failed to capture a distinct R-peak in h-Shirt. Limbs and ECG path impedance were estimated for 12 subjects to figure out the reason, while ECG circuit was studied to find solution. The results showed that some of the failed users may due to the unexpected high or unbalanced path impedance. Moreover, their R-peak magnitude in standard ECG machine is generally smaller than the control group but independent to the measuring positing that we tested. Finally, the filter was suggested to rebuild with a wider passband in order to increase the signal-to-noise ratio.

5.1.4 Hybrid Body Sensor Network in h-Shirt

In this part, difference communication modes were integrated into h-Shirt: 1)

wired by conducting wires or e-textile material, 2) radio frequency wireless communication and 3) bio-channel communication through skin. There are many data communication channels in h-Shirt, difference communication modes were chosen according to applications. For example, the wired PPG channel was replaced by bio-channel in the revised version of h-Shirt. The reason of choosing bio-channel is because it can maintain the advantage of wired communication (i.e. zero time delay and low power consumption) but wirelessly. In short, it combines the advantage of wired and wireless mode. Throughout the experiment, the resting BP estimation errors of the revised h-Shirt are -0.63 ± 3.13 mmHg and 1.1 ± 2.75 mmHg for SBP and DBP respectively. Moreover, within 5 cm from the wrist (i.e. approximately 19 cm from the stimulating source), the received signal can be distinguishably identified from the noise floor. In a nutshell, a body sensor network is performed in h-Shirt.

5.2 Suggestions for Future Work

5.2.1 Further Development of Bio-channel Biological Model

h-BSN was developed in the latest version of h-Shirt. Bio-channel is used to transmit PPG information. The principal is similar to the explanation from K. Koshiji [93], who claims that wireless transmission through human body treats the media as a waveguide. A high-frequency electromagnetic wave generated by a terminal propagates through the body and is received by another terminal. However, the biological model is not yet confirm. Further experiments are needed for developing a bio-model to study whether the signal is transmitting through skin surface or by deep tissues in order to improve performance and simplify the circuit.

5.2.2 Positioning and Motion Sensing with h-Shirt

h-Shirt was highly recommended to use in elderly home and hospital. The zigbee in h-Shirt can be modified into position sensing modules. Elderly home can easily locates the position of all subjects by using a computer. The computer will notice the operator if the user stays in place for a long time or the subject enters some restriction areas. Other than positioning, motion sensing is one of the parameter that implemented in the health garment provided by other research centers [103]. h-Shirt is also suggested to add accelerometers, however, the application is difference to others. It is suggested to add air bag into h-Shirt, once the falling action is detected, the air bag is pumped to prevent the elderly hurts.

5.2.3 Implementation of Updated Advance Technology into h-Shirt

In chapter three, the outlook and internal construction of h-Shirt were shown. It consisted of a shirt, e-textile wires, a watch or central processing PCB. In order to enhance the outlook and practicability of h-Shirt, the components are suggested to fabricate directly on the textile. Recent advances in microelectronics have enabled the manufacturing of integrated electronic circuits with millions of logic switching elements per square millimeter of silicon. Since the of these devices are in the micrometer regime and the typical dimensions in textile and garment technologies are in the order of several millimeters, a novel technology for the electrical interconnects has been developed (if has been developed, it should not be placed in the future work direction).

The h-Shirt calibration is currently carried out using a commercial automatic BP meter. In order to improve the convenient of calibration, a number of researchers [94-97] including JCBME have started to develop some new approaches for cuff-less

calibration. Hydrostatic calibration is one of the published one which is potentially apply in the reality. The calibration require users perform difference posture, without any externally applied forces, the transmural BP at each point along the artery differ from the BP at the heart by a hydrostatic pressure. Thus, pressure in the artery becomes a linear function of the distance away from the heart and the time need for the pulse to travel through a small segment does not only depend on BP but also on its height above heart level. As a result, if pairs of artery position and PTT were captured, the subject dependence parameters in the equation 3.3 and 3.4 can be eliminated, actual BP can be obtained.

Appendix: Non-invasive BP Measuring Device – Finometer

Volume Clamp

Finometer (Finapres Medical Systems, Finometer model-1, Netherland) [104] is base on volume-clamp method which was first introduced by Czech physiologist Prof. J Peñáz in 1967. With this method, finger arterial pressure is measured using a finger cuff and an inflatable bladder in combination with an infrared plethysmograph, which consists of an infrared light source and detector.

The infrared light is absorbed by the blood, and the pulsation of arterial diameter during a heart beat causes a pulsation in the light detector signal.

The first step in this method is determining the proper unloaded diameter of the finger arteries, the point at which finger cuff pressure and intra-arterial pressure are equal and at which the transmural pressure across the finger arterial walls is zero. Then the arteries are clamped (kept at this unloaded diameter) by varying the pressure of the finger cuff inflatable bladder using the fast cuff pressure control system.

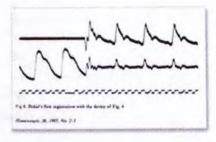


Figure 38 - Volume-clamp methodology Downloaded from http://www.finapres.com

A servo-controller system usually defines a target value or setpoint and a measured value that is compared with this setpoint. In the servo-controller the setpoint is the signal of the plethysmograph (unloaded diameter of the arteries) that must be clamped. The measured value comes from the light detector. The amplified difference between the setpoint and measured value, "the error signal," is used to control a fast pneumatic proportional valve in the frontend unit. This proportional valve modulates the air pressure generated by the air compressor, thus causing changes in the finger cuff pressure in parallel with intra-arterial pressure in the finger so as to dynamically unload the arterial walls in the finger. The cuff pressure thus provides an indirect measure of intra-arterial pressure.

Physiocal

Defining the correct unloaded diameter of a finger artery is crucial for the accuracy of the measurement. Changes in hematocrit, stress and the tone of smooth muscle in the arterial wall will affect the unloaded diameter. Therefore, the unloaded diameter is usually not constant during a measurement and must be verified at intervals. Periods of constant cuff pressure are used to adjust the correct unloaded diameter of the finger artery based on the signal from the plethysmograph in the finger cuff.

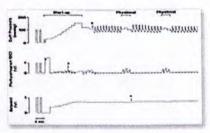


Figure 39 - Physiocal methodology Downloaded from http://www.finapres.com

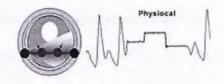


Figure 40 - Physiocal mechanism Downloaded from http://www.finapres.com

The Physiocal (abbreviation for Physiologic Calibration) algorithm in Portapres® and Finometer®, developed by the Dutch physicist Prof. KH Wesseling, not only uses the amplitude, but also interprets the shape of the plethysmograph signal during periods of constant cuff pressure. By analyzing the plethysmograph signal at two or more pressure levels, the Physiocal algorithm, explores part of the pressure-diameter relation and is able to track the unloaded diameter of a finger artery, even if smooth muscle tone changes. The periodic interruption of a finger blood pressure measurement, with constant cuff pressure levels, is further referred to as "Physiocal".

Physiocal is the automatic algorithm that calibrates the finger arterial size at which finger cuff air pressure equals finger arterial blood pressure. Physiocal is built into Portapres and Finometer and users can determine whether they wish to use the Physiocal algorithm or switch it off during tests in which uninterrupted data-collection is required.

Brachial Artery Pressure Reconstruction

There is a delay of several dozen milliseconds between finger blood pressure pulsations and intra-brachial pulsations since the former travel further. In addition, their levels are generally lower and the waveforms appear more distorted, mainly due to reflections and pressure gradients. To correct the distortion in finger pressure relative to brachial artery pressure, a frequency dependent filter can be used to restore the waveform at the brachial level. This brachial artery pressure reconstruction technique allows clinicians and researchers to obtain the brachial arterial pressure if they wish to perform a more precise measurement at the heart level. Waveform filtering is done in realtime.

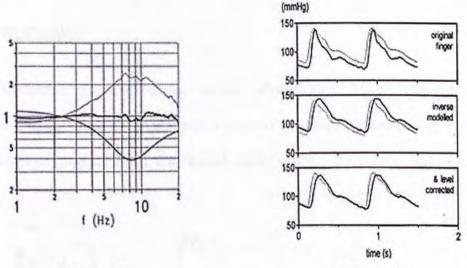


Figure 41

Figure 42

Figure 41 - The transfer function from brachial to finger resonates at about 8Hz (thin top trace). This causes oscillatory distortions of the finger wave. Distortions can be removed by a digital filter that has an anti-resonance at 8Hz (bottom trace). The two transfer functions compensate each other almost perfectly to produce a desirably flat overall transfer function (thick trace) Figure 42 - Brachial reconstruct model

Downloaded from http://www.finapres.com

Return to flow calibration

Return-to-flow calibration is an individual upper arm cuff systolic calibration which can provide much higher accuracy of a measurement.

For this purpose, an arm cuff is wrapped around the same arm as the finger cuff and the operator can set the computer system to automatically inflate and deflate the arm cuff. When arm cuff pressure is supra-systolic, no pulsations can be sensed in the finger.

The first slight pulsation that passes under the arm cuff signals return to flow. It is sensed in the finger and detected by the software. The arm cuff pressure is read at that instant and the reconstructed brachial pressure is defined by this individual amount, thus improving bias and precision substantially.

MODELFLOW®

Modelflow is a model-based method and algorithm used to compute the aortic flow waveform from an arterial blood pressure pulsation by simulating a nonlinear, self-adaptive (three-element Windkessel) model of the aortic input impedance.

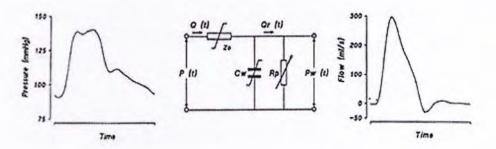


Figure 43 - Diagram of modelling flow from measurements of arterial pressure. Left panel: Left panel: non-invasive pressure as input to the model for one heartbeat.

Middle panel: three-element model of the aortic input impedance used to compute flow from pressure. Zo characteristic impdance of the proximal aorta; Cw 'Windkessel' compliance of the arterial system; Rp, total systemic peripheral resistance. The Zo and Cw elements have non-linear, pressure-dependent properties indicated by the stylized \int symbol. The peripheral resistance element, Rp, varies with time as symbolized by the arrow. P(t), arterial pressure waveform; Q(t) blood flow as a function of time; Pw(t) Windkessel pressure.

Right panel: the computed output of the model, i.e. aortic flow as a function of time. Downloaded from http://www.finapres.com

The three-element model is well known in the field of physiology for its ability to compute stroke volume. Aortic characteristic impedance and Windkessel compliance depend nonlinearly on arterial pressure, and peripheral resistance adapts to changes in mean flow. The degree of nonlinearity depends strongly on the subject's gender, age, height and weight. Stroke volume is computed by taking the area under the flow pulse in systole. Cardiac output is the product of stroke volume and heart rate. Total systemic peripheral resistance equals the sum of the aortic characteristic impedance Zo and peripheral resistance Rp.

Modelflow provides close tracking of changes in cardiac stroke volume and output and is integrated in the BeatScope® software. The combination of Modelflow with advanced signal and pattern recognition techniques in BeatScope enables the computation of many cardiovascular parameters using an arterial pressure waveform as the sole input.

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