Low-Cost Blood Pressure Monitor Device for Developing Countries

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Abstract. Taking the Blood Pressure (BP) with a traditional sphygmomanometer requires a trained user. In developed countries, patients who need to monitor their BP at home usually acquire an electronic BP device with an automatic inflate/deflate cycle that determines the BP through the oscillometric method. For patients in resource constrained regions automated BP measurement devices are scarce because supply channels are limited and relative costs are high. Consequently, routine screening for and monitoring of hypertension is not common place. In this project we aim to offer an alternative strategy to measure BP and Heart Rate (HR) in developing countries. Given that mobile phones are becoming increasingly available and affordable in these regions, we designed a system that comprises low-cost peripherals with minimal electronics, offloading the main processing to the phone. A simple pressure sensor passes information to the mobile phone and the oscillometric method is used to determine BP and HR. Data are then transmitted to a central medical record to reduce errors in time stamping and information loss.

Keywords: Blood pressure, developing countries, electronic medical records, hypertension, mHealth, resource-constrained healthcare, low-cost devices.

1 Introduction

Globally, hypertension is a major chronic, non-communicable disease and a leading cause of death and disability in economically developing countries [1]. Hypertension, a sustained elevated blood pressure[1] (BP), is a dangerous medical condition that

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* These authors had equal contributions for this paper.

1 A systolic BP consistently above 140mmHg and/or a diastolic BP consistently over 85mmHg, although definitions vary with age, gender, disease factors and measurement location.

K.S. Nikita et al. (Eds.): MobiHealth 2011, LNICST 83, pp. 335–342, 2012.

stresses the heart and promotes vascular weakness and scaring, making blood vessels more prone to rupture [2]. Uncontrolled and untreated hypertension increases the risk of coronary arteries damage, heart attack, stroke, kidney disease, eye damage and is responsible for other conditions such as pre-eclampsia. Most of these problems can be found in developing countries and are a serious economic burden [1,3,4].

Kearney et al. [5] predicted that by 2025 the number of hypertensive adult individuals will approximately be 1.56 billion, 1.15 billion of which are from developing nations [5]. Kearney et al.'s findings also indicate a higher prevalence of hypertension in developed countries (37.3%) than in developing ones (22.9%). However, given the much larger population of developing countries, the absolute number of patients affected by hypertension is considerably larger and is likely to grow [5].

Barriers to the treatment of hypertension include i) lack of detailed data on an individual's BP readings over time, ii) poor infrastructure to deliver medication and information, iii) lack of training in taking reliable BP readings, and iv) lack of financial resources [6,7]. Although manual readings may be suggested to be sufficient, manual recording of data is error-prone and leads to blood pressure overestimation or critical BP-related event misses [8,9]. In particular, lack of data leads to low hypertension awareness rates [10,11] in developing nations and therefore screening for hypertension and the measurement of BP are of critical importance in developing countries.

Nevertheless, current BP electronic devices that enable automatic BP measurements are expensive for the developing countries. In developed countries, one button click, clinically validated electronic BP devices can be found for the upper arm with several features: automatic cuff inflation/deflation cycle, alarm reminders, readings storage, irregular heartbeat or hypertension indication and download of readings to a Personal Computer (PC). These are very useful to monitor BP and heart rate (HR) at home and doctor office visits. Such devices range in price from €20 to €150 depending on the number of features, accuracy of the measurement and quality of the hardware. Therefore they may never be widely available at a reasonable price for the average person in a developing country. However, much of the hardware needed for an automated BP measurement is already in most people's pocket and the extra hardware needed could be manufactured for less than €5. According to the International Telecommunication Union, mobile cellular subscriptions have been increasing significantly over the last decade, particularly in developing countries where the growth is much bigger[12]. Since poor supply-chains are one of the biggest issues in medical device distribution and training, mobile phone offer an enormous potential.

The mobile phone provides the hardware and software required to extract the features from vital signals, calculate and display the results and automatically save them to either a local or remote database. Moreover, it can provide the user with advice on usage, quality and decision support. By off-loading the analysis to a software application running on the phone, software support can be provided without the need for specialist knowledge, thus allowing continual system improvement and optimization for specific communities, such as the hypertense. The mobile platform would also allow for the automatic synchronisation of the BP readings in a remote electronic medical record (EMR). Such data could then be shared with authorized specialists, providing a permanent monitoring service, and an auditing path to improve the system.

In this paper we present and pre-validate a low-cost easy-to-use BP monitor device for developing countries running on a mobile phone through the use of a typical cuff. The solution evades the presence of trained personnel to take BP measurements, and allows for medical data storage, avoiding human mistakes such as transcription errors.

2 Methods

In the device described in this paper, the manometer is removed from a traditional sphygmomanometer and its air tube is connected to a pressure sensor integrated in a low-cost hardware. The cuff and tubing taken from the traditional sphygmomanometer costs around €3 and is widely available in many settings. It is also easily replaced by comparable materials. The hardware is connected to a mobile phone using an USB cable so that power is supplied from the phone, no wireless transmission chips are needed (which would quadruple the system cost) and data pairing between the hardware and the phone is instant, secure and trivial. Pumping is performed manually so that there is no significant power drain, or heavy pumps. The application in the mobile phone allows the user to measure BP and HR and then save it to the device database and synchronize it with the patient EMR.

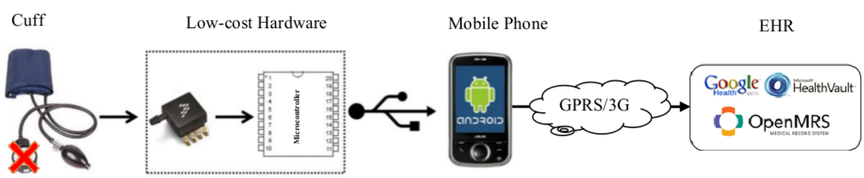

Fig. 1. Overview of the system. Note that the manometer is removed as the phone now calculates the pressure from the output of the pressure transducer.

2.1 Low-Cost Hardware

To minimise the size and cost of the device, the peripheral hardware contains just enough elements to transmit the pressure signal to a mobile phone for the digital signal processing. The final circuit board is shown in Fig. 2.

As is common for electronic BP devices, the air pressure in the inflatable cuff is converted into an analogue electric signal by a pressure sensor (located on the top of Fig. 2). The transducer used in the device presented in this work is the MPXV5050GP from Freescale Semiconductors [13], an on-chip integrated and temperature-compensated pressure sensor. The analogue output signal from the sensor is sampled at 100Hz with a 10-bit resolution (0.29 mmHg per bit) using a PIC18F14K50 from Microchip [14]. The data containing discrete pressure values is sent to the mobile phone through USB, made simple by the USB 2.0 module integrated in the chosen microcontroller. In order to communicate with the peripheral, the mobile phone must support the USB 'On-the-Go' supplement of the USB 2.0 standard, which allows the phone to act as a USB Host to the external device. Furthermore, when using this feature, the peripheral can be powered from the mobile phone.

The resulting peripheral device is a 39x30mm PCB potted inside a small PVC box (recycled from a typical confectionary box at no cost), with a connector for the cuff air tube and a single full size female USB socket. Since most smart phones come with a USB cable of varying connector sizes at one end, which fit the phone, and a full size male USB cable at the other, choosing a female USB socket for this board means that no extra cables need to be purchased.

2.2 Cuff Pressure Signal Processing

The oscillometric method has been widely used in BP monitoring [15-20]. In our algorithm, the source signal is initially pre-filtered using a 5 point median filter to reduce the noise and possible motion artefacts from the signal. A 6^{th} order Butterworth band-pass filter with cut-off frequencies of 0.5 and 5 Hz is then applied in order to obtain the oscillation waveform. This allows the determination of the mean arterial pressure (MAP), systolic BP (SBP) and diastolic BP (DBP) by using a height-based approach [15-17]. Ratios of 50% and 70% out of the maximum amplitude (MAP) were chosen for the SBP and DBP respectively [15]. HR is calculated from the frequency component with highest magnitude of the frequency spectrum generated via Fast Fourier Transform (FFT) of the oscillation waveform.

All signal processing routines were firstly written in MATLAB, and then ported to the Java version compliant with the Dalvik Virtual Machine [21] for Android.

2.3 Software Architecture

The main requirements for the software are: i) the interface must be easy-to-use and guide the user to take high quality BP measurements; ii) the application must support different languages, especially those spoken in developing countries; and iii) the device must save BP measurements to a local database to provide review capabilities, and to a remote system to allow the back-up of data, device-independence, and sharing with a healthcare providers.

The main elements of our system are: 1) the *help page* has pictograms that allow the user to learn easily how to interact with the device and take the BP in a proper way even if they are partially literate; 2) the *measure page* guides the user during the measure and shows his BP at the end of recording; 3) the *measure list page* shows the list of measurements saved by the user and also provides a way to synchronise them with a specific EMR; 4) the *measure view page* displays the information of a specific measure as well as a field to attach useful notes to the data; and 5) the database contains all the saved measurement information. Finally, the application allows the user to save the entire signal to a file in the mobile phone. This information can then be synchronised with a database of BP signals to improve signal processing strategies.

2.4 Prototype

Fig. 2 shows the experimental setup of the mobile BP measure device. The manometer is removed from a traditional sphygmomanometer and its tube connected to the pressure sensor on the PCB. The latter is encased in a free confectionary enclosure and connected to the mobile phone using a standard USB cable.

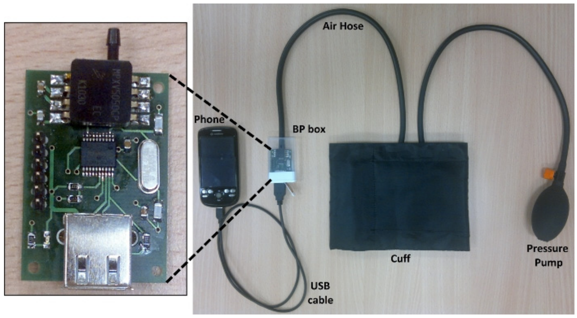

Fig. 2. Experimental setup of the mobile BP measure device. Note that the sphygmomanometer is not used. The cuff and pump were purchased with the sphygmomanometer for less than $10.

The application was implemented using Android 2.2 Software Development Kit (SDK) on an Android device that supported USB host mode. The application comprises 5 pages: *main page*, *help page*, *measure page*, *measure view page* and *measure list page*, that were implemented as Activity classes from the Android SDK [22]. To guide the BP measurement, the *measure page* has a chart that renders the real time pressure values coming from the cuff while the measure is being taken, suggesting that the user to pump until a pressure of 200 mmHg (or another defined limit based on historical or user-selected values) is reached and stop pumping. The device is then allowed to slowly deflate. The application also identifies if the deflation was too fast to extract the oscillations from the recording. In such a case the application requests the user to repeat the measurement with a slower deflation rate. Otherwise, after the pressure drops to 30 mmHg the measurement stops, the SBP, DBP and HR are determined from the processed pressure recording and the result is shown to the user. The user can then save the measurement to the database and also create a CSV file with all the information used to derive the measurement (for debugging and development). This file is only created on the mobile phone if the micro SD card is available with sufficient free space. The application has been translated to 7 different languages. The application, and PCB design are open-source and available in the project website [23].

3 Results and Validation

The prototype was used in 5 different healthy volunteers (1 female, mean age 25.0, range 24-27 years, 1 Hispanic, 3 Caucasian and 1 Afro-European) to measure SBP, DBP and HR. The automatic Boots Arm Cuff BP Monitor 5690447 (The Boots Company PLC, Nottingham, England), which is well known CE marked device, was used in order to pre-validate the BP and HR measurements.

Three measurements with both devices were taken for each subject in the following conditions: i) after lying down for 5 minutes; ii) after running for 5 minutes and iii) after inserting the right hand in a bucket of ice water for 1 minute. These measures try to simulate daily events like, a person at rest, a person after physical activity and a person undergoing a stressful condition, respectively. The measurements were performed on the left arm with the subject sitting down with the cuff at the same height as the heart, except for the first condition where the subject remained lay down. A 5-minute period was given between the readings from the two devices.

The percent difference (mean ± standard deviation) between our device and the Boots device were compared for each individual over all three types of tests and all individuals for each type of test, and the mean percent differences for all individuals over all readings were 14.5 ± 9.8 %, 5.0 ± 5.3 % and 8.1 ± 6.9 % for SBP, DBP and HR, respectively.

4 Conclusion and Discussion

A low-cost and open source BP monitor has been developed to function as a mHealth device for developing countries (see [23]). The preliminary data showed a good agreement between the values of SBP, DBP and HR measured with a known device, with an average error of less than 20%, which is within the accuracy levels of the Boots device itself. A standard inflatable cuff and an inexpensive peripheral make use of the processing power in mobile phones to digitally process the pressure signal and compute the BP and HR values using the oscillometric method. The software developed for Android powered devices allows the user to keep records of the measurements in their mobile phone and/or upload them to EMR systems using the connectivity provided by the phone. Such an implementation would serve as an efficient platform for sampling and analysing BP data from large populations. This could subsequently be used to monitor treatments and in epidemiological studies.

Further work includes completing the validation of the device on larger populations, software improvements to support different cuff sizes and integration with other applications such as SANA Mobile [24]. Calibration for different age groups hypertensive patients is also required, since standard oscillometric methods are known to lead to clinical error through under- and over-estimation of blood pressure [25-28]. We also hope to include warnings and guidelines for bradycardia, tachycardia, hypertension, hypotension and arrhythmia, as well as integration with other decision support tools such as cardiovascular risk indicators. However, we do not envision this system as a replacement for trained medical oversight at this stage. Therefore, integration with a medical record system shared or supported by a medically-trained worker will be important.

Earlier in this paper we noted that barriers to the treatment of hypertension, and in fact healthcare delivery in general, include i) lack of detailed temporal data ii) poor infrastructure, iii) lack of training, and iv) lack of financial resources. The first of these barriers can be addressed by frequent measurement-taking (if a suitable device is available), and transmission of the data to a central medical record. This is only likely to happen if the individual or a close care-giver is able to take readings. Poor infrastructure can be addressed by using existing supply channels, such as Coca Cola's delivery trucks, or a more decentralised approach such as that taken by mobile phone companies. Training can be addressed by adding user-feedback and intelligent processing into the device. Our system addresses all these problems (and solutions).

An obvious criticism remains, in that Android only runs on smart phones, which are not widely available in developing countries. However, Android represents the best choice of development platform for several reasons. First, Android is constantly being ported to cheaper devices with the price point dropping from several hundred dollars to under one hundred dollars in just a couple of years. Over the last year, Android adoption has increase 886%, with the closest competitor, the iPhone, increasing only by 86% [29]. Moreover, in contrast to the iPhone, Android's gains have been largely in developing countries.

Android, being adopted by Google, has followed its philosophy of cloud data storage and analysis. An individual's data medical record can be stored in the cloud, and ported across several devices and shared with several users. Even when phone sharing is common, Android allows you to authenticate a single device with several accounts. Finally, we should note that our BP system is initially aimed at healthcare workers, where deployment of the phone is essentially a low overhead compared to the rest of the clinical trial. By the time the system has been proved to be efficacious (or not), the price point for Android phones is highly likely to have tumbled even further.

Our code is basically vanilla Java and/or C, which means that cross-platform portability is technically simple. The issue lies purely in the way the manufacturers decide to lock down the hardware. Unfortunately most phone OS's do not allow good low level interaction with peripheral sensors or devices. In particular, true USB host capacity is currently only available for mobile phones under Android (and on a limited number of iOS devices). In general there has been a move towards using Bluetooth for medical devices to interface with phones which is partly driven by the lack of USB hosting on phones. However, Bluetooth is more expensive, requires more energy, drops packets, and can be easily 'sniffed' raising privacy concerns. USB tethering increases data quality and privacy, allows delivery of power in an efficient manner and prevents the phone from being plugged into the mains during medical device use, thereby enhancing isolation. Of course, if the low cost pressure sensor is integrated into the phone, these issues are mute.

The final point to consider is how to deploy the non-phone hardware. Although the cuff, pump and tubing in a typical manual device cost about €3, and are easily replaced by local equipment, the electronics are not. It is therefore our intention to make the electronics available either as built-in systems for phones or as a low-cost add-on for the phone available through the same supply channels for phone accessories such as the charger, USB cables and batteries.

Acknowledgments. CA, JSD, MAFP and MDS acknowledge the support of the RCUK Digital Economy Programme grant number EP/G036861/1. The authors thank Catarina Figueiras (MD) for supporting the validation process.

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