A $5 Smart Blood Pressure System

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Abstract

The burden of hypertension-related illness is greatest in low-resource settings. Barriers to its treatment include limited access to accurate Blood Pressure (BP) monitors, data on variation of BP readings over time, and training on how and when to take reliable BP readings. We developed an affordable smartphone-based BP monitor that records the pressure signal from a standard manually-inflated armband cuff, through a small low-power circuit board. The values can be stored in the smartphone or sent to a web-based electronic medical record system. The accuracy of the device was assessed by comparing the estimated BP values against the values obtained from two reference Omron devices collected from 40 healthy subjects using an in-house protocol. Over 80% of the resulting estimates were within 5 mmHg from the reference systolic and diastolic BP, and within 5 beats/min from the reference heart rate values. These preliminary results demonstrate that our affordable BP monitor can produce accurate estimates.

1 Introduction

There is a great demand in developing countries for systems that assist in the accurate diagnosis of hypertension, because this condition precedes a range of other health problems. For example, elevated BP is an important (and modifiable) risk factor for coronary artery damage, heart attack, and stroke. It is also responsible for other conditions such as pre-eclampsia and other cardiovascular diseases [1]. The burden of hypertension-related illness is greatest in low-resource settings. In 2000, of the estimated 972 million people with hypertension worldwide, 639 million (66%) were living in developing countries. Kearney et al. [2] projected that by 2025 the number of adult individuals with hypertension in developing nations will reach 1.15 billion, corresponding to almost three-quarters of the global hypertension population. While high-income groups can access services and products that protect them (by proper management) from this risk factor, lower-income groups cannot typically afford such access, and medical care often involves costly journeys for these groups (both in time and money) [3].

Smartphones are becoming ubiquitous world-wide and may revolutionise primary healthcare in resource-constrained settings. We developed an affordable, open-source, smartphone-based BP monitor that allows a minimally-trained person to collect high-quality medical data at the point of care. The clinical data may then be reliably transmitted (even in the case of high-latency network connection [7]) and stored by a web-based system that manages the electronic medical record of patients (such as the OpenMRS), which makes these records accessible via a standard internet browser (including those in the smartphone).
2 Affordable Blood Pressure Monitor

Given the increasing availability and processing power of smartphones, we developed a semi-automatic smartphone-based BP monitor that records the pressure signal from a standard manually-inflated armband cuff, through a small low-power circuit board [8]. It acts as a simple USB peripheral to phones (see Fig. 1). This approach brings a number of advantages: (i) it shifts a significant percentage of the cost of a stand-alone medical device into the already available mobile device; (ii) the peripheral draws power from the mobile device, which avoids the use of external batteries; and (iii) the visual display and resources of mobile devices can be easily leveraged in order to guide the user throughout the data collection process.

The peripheral contains the necessary electronic components to sample and transmit the pressure signal from a traditional arm-based inflatable cuff to a smartphone, where all the signal processing is performed. An earlier version of this device was presented in [8]. The electronics comprise an absolute pressure sensor (Freescale MPXV5050GP), a band-pass active filter with cutoff frequencies of 1 Hz and 19 Hz with x10 amplification, and an ARM-based USB microcontroller (Freescale MK20DN128VFM5). The latter samples both the base pressure signal and the filtered/amplified signal at 250 Hz, at 16-bit resolution. The signals collected and transmitted to the smartphone by our BP monitor enable the computation of physiological variables such as systolic and diastolic BP values, mean arterial pressure, and heart rate.

3 Materials and Methods

3.1 Data Collection

For the analysis described in this paper, we acquired data from a group of 40 healthy subjects (median age 26, range 21-44 years old; 14 females), who underwent 6 consecutive left-arm BP measurements: 3 measurements at rest, followed by 3 measurements while squeezing a ball with the right hand. In both sessions, one of the three measurements was taken using our non-invasive BP device, from which we extracted the pressure signal, which was preceded and followed by a BP measurement using a commercially available BP device (the clinically-validated “M2 Basic” model, Omron, UK). Also, continuous single-lead ECG (256 Hz) and respiration impedance-plethysmogram (using two bands that encircle the chest and abdomen, 256 Hz) signals were also collected during each measurement (using the Visi-3 Digital Sleep System, Stowood Scientific Instruments Ltd., UK). The subjects were asked to sit upright and to perform normal breathing at their own natural rate during all measurements.

3.2 Data Pre-processing

A total of 78 pressure signals containing reliable recordings of BP measurements from the 40 subjects were selected for the analysis (2 recordings were deemed to be of bad quality due to missing data). ECG, respiration, and BP recordings were manually synchronised by two research assistants acting independently, who labelled the beginning and end of all continuous recordings according to the duration of the correspondent pressure signal. Data processing and statistical analysis was performed using MATLAB (Mathworks, USA).

3.3 Estimation of Physiological Variables

Systolic and diastolic BP values were estimated from the pressure and oscillometric waveforms (Fig. 2) using the oscillometric method, which is the most widely used method in com-
mercial BP monitors [9]. The oscillation waveform from one representative measurement is shown in the figure. Note the resemblance of this mobile-acquired signal to a typical oscillometric cuff measurement.

The pressure in the cuff that corresponds to the point of maximum oscillation is typically deemed to be the mean arterial pressure [9]. The values of systolic and diastolic BP are subsequently estimated from this waveform, using an envelope-based approach: a ratio is obtained dividing the amplitude of the oscillations by the maximum value of the amplitude of the envelope. The ratios before (to the left of) the maximum amplitude are compared to a pre-determined reference ratio to estimate the systolic BP. The ratios after (to the right of) the maximum amplitude are compared to another reference ratio to estimate the diastolic BP. Different ratios are typically used by researchers and manufacturers [9].

Beat detection using the oscillation waveform was performed using a signal segmentation algorithm that marks the peaks of each beat. For that, the mean value was removed from the signal, and the resultant signal was differentiated using a five-point digital differentiator. The energy of the differentiated signal was then determined and finally a threshold-based detection algorithm (using $T = 0.005$) was applied to detect the most significant local maxima of the signal. A fifth-order polynomial interpolation of the detected beat maxima was applied to determine the envelope of the waveform; finally, systolic and diastolic BP values were estimated using reference ratios of 0.56 and 0.76 to the left and right of the maximum value of the envelope, respectively.

The heart rate was calculated from the frequency spectrum of the oscillation waveform, which was generated using the fast Fourier transform (FFT), using a window size of 64 seconds. The FFT component with the highest magnitude, within physiologically acceptable limits (0.5 Hz and 3 Hz), was taken to correspond to the heart rate.

3.4 Performance Evaluation

The accuracy of the device was assessed by comparing the estimated BP values with the average values from the reference Omron devices; i.e., the average value of the BP measurements that preceded and followed each measurement performed with our device. The reference heart rate values were obtained from the ECG recordings (acquired simultaneously with the BP measurement). The Pan-Tompkins QRS detection algorithm [10] was used to determine the time between consecutive beats in the ECG, and thus to determine the average heart rate for each record, by taking the average of the inverse of the beat-to-beat intervals for the entire record.

The performance of our BP monitor was assessed using the mean absolute error (MAE) in the correspondent units, $\text{MAE} = \frac{1}{n} \sum_{i=1}^{n} | \hat{y}_i - y_{ref,i} |$, where $n$ is the number of recordings considered, and $\hat{y}_i$ and $y_{ref,i}$ are the estimated and reference values for recording $i$, respectively.

4 Results and Discussion

Figure 3 shows the change in the physiological variables between the two sessions undertaken by each patient (rest vs “activity”). The rationale for this was to produce a change in the physiology of the subjects to test the performance of the algorithm during a “stress” situation. We observe that both systolic and diastolic BP values increased significantly ($p < 0.01$, Wilcoxon-Mann-Whitney test) during the activity session.

The accuracy of the estimated BP and heart rate values is shown in Fig. 4. 80% and 90% of the estimates were within 5 mmHg of the reference systolic and diastolic BP, respectively. 89% of the heart rate estimates were within 5 beats/min of the reference values. Also, we observe that the difference between the estimated values of the reference devices was not noticeably different from the difference between those of our BP monitor and reference devices (within the same session).

Table 1 shows the overall MAE for the different vital signs.
Table 1: Mean absolute error for each vital sign estimated using the blood pressure monitor. The reference estimated population median and interquartile range (IQR) values are also shown.

<table>
<thead>
<tr>
<th>Vital Sign</th>
<th>Median (IQR)</th>
<th>Estimate</th>
<th>MAE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic BP</td>
<td>120.2 (13.8)</td>
<td>119.8 (16.0)</td>
<td>3.57</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>73.7 (16.0)</td>
<td>73.1 (13.0)</td>
<td>2.45</td>
</tr>
<tr>
<td>Heart Rate</td>
<td>76.7 (15.8)</td>
<td>77.2 (18.2)</td>
<td>0.75</td>
</tr>
</tbody>
</table>

extracted from our BP monitor compared to the gold standard reference values. We observe that a good agreement between the estimated values for the BP and heart rate was found, with a mean absolute difference of less than 5 mmHg and 3 beats/min, respectively.

These preliminary results suggest that our BP monitor can produce accurate estimates. We intend to obtain regulatory approval for the device so it may be incorporated in an m-Health system that can be used at the primary care environment, especially mobile clinics in resource-poor settings. As pointed out by OpenQRS [11], assuring the quality, reliability, and safety (“QRS”) of medical devices brings other challenges. When products follow established guidelines, such as obtaining FDA approval or a CE mark, the products price typically increases, making it often unaffordable for the originally-intended low income market. Our plan is to “crowdsource” the validation of the device in its target markets. This could be enabled by using open-source tools and standards to develop and monitor the use of the device to assure its QRS in an affordable way.

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References