Wearable and Low-stress Ambulatory Blood Pressure Monitoring Technology for Hypertension Diagnosis

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Abstract—We propose a highly wearable, upper-arm type, oscillometric-based blood pressure monitoring technology with low-stress. The low-stress is realized by new developments in the hardware and software design. In the hardware design, conventional armband; cuff, is almost halved in volume thanks to a flexible plastic core and a liquid bag which enhances the fitness and pressure uniformity over the arm. Reduced air bag volume enables smaller motor pump size and battery leading to a thinner, more compact and more wearable unified device. In the software design, a new prediction algorithm enabled to apply less stress (and less pain) on arm of the patient. Proof-of-concept experiments on volunteers show a high accuracy on both technologies. This paper mainly introduces hardware developments. The system is promising for less-painful and less-stressful 24-hour blood pressure monitoring in hypertension managements and related healthcare solutions.

I. INTRODUCTION

Hypertension (HT), high blood pressure (BP) disease, is the most common chronic disease in the world by affecting approximately 30% of the population [1]. However, most of the people are unaware or undiagnosed of the disease. The symptoms of HT are not clear and its progress through the life is usually very silent. It is called as “silent killer”, and if it is not controlled well, it leads to mortal cardio-cerebrovascular diseases such as stroke (brain) and heart attacks [2]. Especially, early morning hypertension and/or sleep hypertension (non-dipper) significantly increases the risks of stroke and heart disease [1-4]. BP in daily life can be monitored by using ambulatory blood pressure monitoring (ABPM) technologies [4]. ABPM can take BP measurements every 15 minutes to 30 minutes. By analyzing the BP change patterns, it is quite possible to improve the diagnosis and the treatment of white-coat hypertension, masked hypertension, sleep hypertension and so on. Conventional ABPM technologies, as shown in Fig. 1 (left), have separated units of blood pressure cuff (inflatable air bag), tube(s), a belt and a logger unit composed of electronic chips, battery and pumps/valves. Even though the current technology is sensitive enough, it has some drawbacks preventing its widespread use in the management of hypertension, leading to less effective healthcare managements and solutions.

The reasons of unpopularity are considered as follows, (1) Conventional ABPM has separated and bulky units (Fig. 1, left), (2) Cuff (or armband) width is big in size (~14 cm), (3) It is not wearable enough (heavy and thick (~3 cm)), (4) It is clearly seen by others and privacy is damaged, and (5) It is stressful and painful due to strong squeeze. This is especially problematic during sleep. People wake up due to pain and complain about it. They usually refrain from next inspection.

In this paper, we propose a wearable, 24 hours, low-stress blood pressure monitor (ABPM) technology such that (1) New ABPM is unified and more comfortable (Fig. 1, right), (2) Cuff width is downsized (almost 20%), (3) It is more wearable (lighter and thinner, almost 50%), (4) It can be worn under the clothing and so privacy is preserved/enhanced, and (5) By a new prediction algorithm, low-stress (weak squeeze) is achieved for the first time to our knowledge. It is less painful and monitoring during sleep is possible. This might enable us new healthcare solutions and business potentials where conventional ABPM technologies were not efficient.

In NEC’s new ABPM technology, there are novel developments in hardware and software design. In the hardware design, system is unified and 50% downsized in volume thanks to a flexible plastic core and a liquid bag, which leads to more compact and wearable device due to less air volume necessity. In the software, new prediction algorithm is introduced such that it measures diastolic BP but predicts the systolic BP with a pressurization value between SBP and DBP. This enabled to apply less stress (less pain) on the upper arm of the patient. In this paper, hardware developments are mainly discussed.

Conventional separated-unit ABPM

NEC single-unit ABPM (Under development)

![Figure 1. Comparison of separated-unit conventional ABPM and NEC’s single-unit, downsized & wearable ABPM with a smartphone application.](image)

II. CONCEPT

Conventional BP monitors have an armband which is called as cuff. The cuff contains an air bag whose size is 12 cm by 24 cm designed for a standard adult (22-32 cm upper arm size). Including the textile cover, the width of the cuff approaches to 14 cm; which is very large and uncomfortable. There were different studies to decrease the width of the cuff,
but it concluded that decreasing the cuff width caused over-estimation of blood pressure readings, and the size of the cuffs remain unchanged for decades [5]. The reason of this is probably related to cuff-edge problems explained in Fig. 2. When the width of cuff is decreased, loss of contact area with the arm increases and effective squeezing area decreases. The system forces itself to occlude the artery underlying and pressure inside the cuff increases, which leads to over-estimation. Conventional cuffs have a parabolic pressure profile on the body portion when it is pressurized. In order to investigate this, an experiment is conducted on a commercial cuff positioned between 2 clamping plates. Flexible and flat force (pressure) sensor is placed along the width of cuff. In another experiment, a liquid (water) bag bigger than the air bag of the cuff to reduce contact loss at the edges is placed on the cuff and the system is clamped between plates again. The experimental results are shown in Fig. 3. Accordingly, the conventional cuff suffers from pressure loss at the edges. Pressure profile decreases almost 50% at the edges which corresponds approximately 30% of the cuff width. This corresponds to 3 to 4 cm. When a liquid bag is utilized to improve the compliance, the recovery of the pressure profile at the edges is clear and the pressure profile approaches to a uniform profile as proposed in Fig. 2.

As explained in Fig. 2, proposed cuff is composed of a plastic core (poly-ethylene, 1 mm thick), a liquid bag (poly-ethylene, 0.1 mm thick) and a downsized air bag (poly-urethane, 0.2 mm thick). The air bag is preferable in double cuff format (i.e. air bag + sensing bag) where its higher accuracy compared auscultatory measurements was already shown [6] in standard cuffs. The core in the proposed cuff is flexible but hard enough to limit the squeezing direction towards body portion, which leads to reduced cuff-edge problems (i.e. enhanced contact area at the edges). Liquid bag improves compliance towards the body-portion. The size of the air bag is reduced more than half (less than 140 ml where commercial cuff volume is less than 300 ml), and therefore the total width of the cuff is reduced too. Instead of a liquid, a jelly structure is applicable as well. Actually, due to hydraulic and gravitational influences, it is better to use viscous liquids or jelly structures to eliminate adverse effects. On the basis of the structure, a core width of 10 cm (and 21 cm in length in average) and a liquid bag (filled with ultrasonic gel named Neo ProjellyT) bigger than air bag but smaller than the core are utilized. The device is designed for a standard adult whose upper arm circumference is between 23 cm to 32 cm.

IV. PROOF-OF-CONCEPT EXPERIMENTS

The proposed cuff structure is experimentally tested on 16 individuals with 3 consecutive BP readings, which counts 48 readings. (The study protocol was approved by the ethic committee of Yokohama City University, School of Medicine.) During the tests, a commercial, upper arm type, oscillometric BP monitor, which measures BP during uprisings of pressure, is utilized. The same commercial BP monitors (with the same main unit containing the same algorithm) are set to both arms of the subjects (Fig. 4), and inter-arm blood pressure differences are ignored. The subjects sit on a chair and both arms are put on a table. Right arm is selected as reference, and prototype is put on the left arm and connected to the BP monitor with a tube. All subjects are adults with the information as follows; average age is 40.3±8.7 years old, average arm size is 27.3±2.4 cm and average BMI is 24.1±4.5 kg/m², respectively. The average can be accepted as a standard adult.

Five different BP cuffs are tested (Fig. 5 & Fig. 6). A is commercial cuff with 13.5 cm in width, B is a commercial cuff for kids with a 6 cm width, C is a prototype-air bag with 8cm in width, D is the prototype cuff where plastic core is attached to C, E is the proposed cuff where a liquid bag is placed between plastic core and air bag. The liquid bag is bigger than the air bag but smaller than the plastic core. BP readings are measured in millimeter mercury (mmHg) of the proposed cuff using a fluidic set-up (Fig. 2, [6]). Systolic BP (SBP) and diastolic BP (DBP) values are checked for medical standards. If the error; difference between reference and prototype value, is within 5 mmHg, it is accepted as within standards [4, 7]. In the case of medical accuracy, at least 85 subjects with 3 readings (255 reading in total) are necessary [7]. But, in these tests, we evaluated the accuracy on 16 subjects and the results (SBP & DBP) are shown in Fig. 6 for those subjects only. (Medical standard of accuracy is ±5.0±8.0 mmHg, mean ± standard deviation [7].)

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**Figure 2.** Cuff-edge contact problems in a conventional cuff and parabolic pressure profile are shown. At the edges, contact of the cuff towards the body portion is lost. A plastic core; limiting the direction of squeezing, and a liquid bag; improving fitness and pressure uniformity, reduce cuff-edge contact problems. Those provided downsized air bag leading to smaller pump and battery, which contributed to unification and compactness. As shown in inset of real images, 50-60% reduction of air volume from 240 to 130 ml is expected. Air bag width is reduced from 12 to 8 cm, air bag length is reduced from 24 to 16.5 cm as shown in inset.

**Figure 3.** Experimental pressure profile of a conventional cuff tested between 2 clamping plates with a flat force (pressure) sensor is shown. It suffers from loss of pressure at the edges (i.e. a parabolic profile). But, when a liquid bag is placed on the cuff, insufficient pressure at the edges are almost eliminated (i.e. a uniform profile). Curves are fitting.
In cuff A (12x24 cm<sup>2</sup> air bag), 80% of the readings were within standards. Even though 2 similar BP were used, 20% of the readings were out of standards. Those could be due to non-simultaneous operation time, irregularities of the placements of the cuff, or inter-arm blood pressure differences. Cuff B is a commercial cuff for kids, and its width is 6 cm (6x17 cm<sup>2</sup> air bag). 11% of the readings were within standards and the results were highly overestimated as expected [5].

(Cuff B: SBP: 15.4±8.8 mmHg, DSP: 12.2±6.5 mmHg, Fig. 6) Keeping the length at 17 cm, 8 cm-wide cuff C (8x17 cm<sup>2</sup> air bag) is tested too. As expected, the accuracy increased to 44%. However, it is still out of standards due to high mean shift and big deviations (Cuff C: SBP: 6.1±8.4 mmHg, DSP: 5.2±5.9 mmHg, Fig. 6). When the plastic core is introduced in cuff D (Core/8x17 cm<sup>2</sup> air bag), the accuracy is improved significantly, 77% is achieved. The plastic core is very effective to improve the pressure profile of the smaller air bag and BP readings are within standards. (Cuff D; SBP: 3.8±6.1 mmHg, DSP: 1.4±2.8 mmHg, Fig. 6) In the proposed Cuff E (Core/Liquid-bag/8x17 cm<sup>2</sup> air bag), a liquid bag is introduced between the plastic core and the air bag and it reached an accuracy of 84%. It is even better than commercial ones, but with a smaller size and air volume. Furthermore, cuff E readings are less deviated, more stable and more balanced than cuff D, and liquid bag is very effective to improve the compliance of the cuff to the body portion. (Proposed cuff E; SBP: -0.8±4.5 mmHg, DSP: 0.6±3.0 mmHg, Fig. 6) Bland-Altman plot of the proposed prototype shown in Fig. 7 indicates that most of the errors are within 10mmHg and concentrated around 0, which is very promising.

Proposed hardware structure has almost 50% less air volume than that of commercial counterparts (from 300 ml to 140 ml, in the worst case), but its accuracy is similar to them. The downsizing is achieved by keeping the standards. On the basis of the experiments, a prototype is fabricated (Fig. 8). It is smaller compared to conventional BP monitors, and just a single-unit. It is 11cm in width with textile cover and its air volume necessity is less than the half of the commercial ones. It is less than 250 grams, and as thin as 1.5 cm. The fabricated cuff can be worn under clothing and privacy is preserved. The device can be manipulated by a smart-phone application with different information options to monitor such as sport activities, lunch, medication time and so on. When compared with conventional technologies, it is clearly more user-friendly, more compact and more wearable (Fig. 9). The system is currently under investigation for further modifications and clinical trials.

Figure 4. Experimental view is shown. Arm-to-arm difference in blood pressure is ignored. A commercial BP monitor main unit is connected to the prototype on the left arm using a fluidic set-up, and another BP monitor main unit is connected to a commercial and conventional cuff on the right arm. Right arm is selected as reference. Reference cuff width is 13.5 cm.

Figure 5. Percentage of the results (SBP and DBP) within medical standards in average in 48 trials (16 subjects, 3 times) is shown. Average age is 40.3±8.7 years, average arm size is 27.3±2.4 cm and BMI is 24.1±4.5 kg/m<sup>2</sup>. Standard commercial cuff (A) is 80%, a narrower commercial cuff (B, for kids) is 11% (inaccurate), 8 cm wide air bag (C) is 44% (inaccurate), a plastic core improves the accuracy into medical standard (77%), and proposed cuff containing both a plastic core and a liquid bag enhances the accuracy further (84%).

Figure 6. Statistical analyses of errors for 48 trials are shown for the cuffs of A, B, C, D and E in Fig. 6. A conventional and commercial reference device is evaluated by itself in A. B (cuff for kids) is highly over-estimated and shifts to higher BP values are clear. C is over-estimated. D and E are accurate and within standards. However, E is more balanced and more stable. Medical standard of errors is ±5.0±8.0 mmHg, mean ± standard deviation [7].

Figure 7. Bland-Altman plot of errors of the hand-made prototype is shown. Errors of SBP (-0.8±4.5 mmHg) and DBP (0.6±3.0 mmHg) are within standards for 16 subjects (±5.0±8.0 mmHg [7]).
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Figure 8. Photo of NEC’s single–unit ABPM prototype on a subject (left) is shown. Under the clothing (right), it is not recognizable and privacy is preserved. BP can be monitored on a smart phone with information like medication time or activities. Data analytics are possible. BP monitor width, thickness, and weight are 11 cm, 1.5 cm and less than 250 g, respectively. The system is designed for 30-minute intervals, 24-hour ABPM applications.

![Smart phone & app](image1)
![Smart phone & app](image2)

Figure 9. Comparison of the prototype with some conventional ABPM technologies. It is more compact and wearable. (Est: Estimated.)

![Comparison Chart](image3)

Figure 10. Prediction algorithm with high accuracy is shown. Subject is a standard adult. ABPM is taken every 15 minutes with 12 readings. Stop of the squeezing pressure of the device is reduced almost 40%, from 148 mmHg to 88 mmHg. The stop value of the squeezing pressure is individual dependent and it is between SBP and DBP.

![Pressure Chart](image4)

V. SOFTWARE DESIGN

Algorithm to analyze oscillometric SBP and DBP values and a first-of-its-kind prediction algorithm to determine SBP value when the pressurization bigger than DBP are currently under investigation. Prediction algorithm analyzes the pulse wave and determines some parameters to be used in the prediction of SBP. (Detailed analysis of the algorithm is under consideration for a future publication.) When machine learning is completed, the reading will be done with the help of the prediction algorithm parameters and the stop of the pressurization value (which is normally 40mmHg above SBP) of the conventional BP monitors is reduced to a value between SBP and DBP, which is individual dependent. This capability leads to less stressful or weak squeezing of the cuff and so BP monitoring even at sleep or workplace will be relatively applicable. It is believed that this capability will enable new data analytics and related business potentials. The prediction algorithm is tested in a standard adult (Fig. 10) in a 15-minute ABPM mode. The results are highly accurate (SBP: -1.5±4.6 mmHg, DSP: 0.8±4.6 mmHg) and promising. Almost 40% of the reduction of the stop of the pressurization from 148 mmHg to 88 mmHg is achieved by keeping the accuracy within standards. Low-stress blood pressure monitor capability is confirmed. Especially, sleep hypertension without wake-ups where conventional ABPM suffers and/or workplace hypertension managements in life-style diseases are some potential application areas.

VI. CONCLUSIONS

A new ABPM technology having high accuracy within standards is introduced. The proposed hardware structure composed of a flexible plastic core (limiting the squeezing direction) and a liquid bag (improving compliance) enables to downsize the cuff width. Approximate reduction of 20% in width, 40% in weight, 50% in thickness, 50% in air bag volume, and 40% in stop of pressurization value (whose value ranges between DBP and SBP value) with a novel prediction algorithm are achieved. Those capabilities provided to use smaller pump and battery, which contributed unification and compactness. NEC’s new blood pressure monitoring technology is promising in monitoring of hypertension in daily life with less stress on the patients (especially during sleep and work), which has potentials in data analytics and related business in healthcare. Refinements, modifications and clinical trials for the medical approval of the device are currently under investigation.

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REFERENCES


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