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eBP: FREQUENT AND COMFORTABLE BLOOD PRESSURE MONITORING FROM INSIDE HUMAN'S EARS

Excerpted from "eBP: A Wearable System For Frequent and Comfortable Blood Pressure Monitoring From User's Ear," from MobiCom 2019, *Proceedings of the 25th Annual ACM International Conference on Mobile Computing and Networking*, with permission.
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Diagnosing hypertension or hemodialysis requires patients to carry a blood pressure (BP) monitoring device for 24 hours. Therefore, wearing the wrist/arm-based BP monitoring device, in this case, has a significant impact on users' daily activities. To address the problem, we developed eBP, an ear-worn device that measures blood pressure from inside the ear. Through the evaluation of 35 subjects, eBP can achieve the average error of 1.8 mmHg for systolic BP and -3.1 mmHg for diastolic BP with the standard deviation error of 7.2 mmHg and 7.9 mmHg, respectively.

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Measuring BP is clinically important for diagnosing severe disease. While high BP can be an expression of heart disease, preeclampsia in pregnancy, chronic kidney disease, sleep apnea, and adrenal and thyroid disorders, low BP indicates the possibility of heart or endocrine problems, dehydration, severe infection, or even blood loss. As well, hemodialysis patients, individuals with undiagnosed white coat hypertension, or undiagnosed masked hypertension, which have a prevalence of 15-30% [1] and 16.8% [2] in the US and organ transplant recipients [3] require frequent BP monitoring for precise assessment. In such cases, BP is measured every 30 minutes for 24 hours [4]. However, commercialized BP monitoring devices are not practical for frequent measuring as they are cumbersome, uncomfortable, and inconvenient, which limits patients in their activities.

Conventional BP measurement techniques (pressure-based arm or wrist cuff) require blood flow to be blocked completely. This leads to discomfort while measuring BP frequently because the constant squeezing of the BP cuff prevents the users from taking a rest. In addition, there have been prior attempts to build a cuff-less, continuous BP monitoring device [5]. Pulse Transit Time [6] technique is the most common method in the continuous BP monitoring system. This method measures the time interval between the peaks of the pulse signal and uses reference peaks from an electrocardiogram (ECG). However, these systems are not accurate due to the low specificity of ECG on BP [7]. Another cuff-less approach tried capturing BP by having the user press on the phone screen [8]. However, the technique requires a user to maintain constant finger pressure to obtain a proper measurement. Other notable cuff-less BP monitoring form-factors include the combination of a built-in smartphone camera and an accelerometer [9] or mounting sensors onto glasses [10]. These approaches significantly improve flexibility, but they may be aesthetically unappealing and highly obtrusive.

In this project, we aim to develop a novel cuff-less wearable system to frequently monitor BP inside the ear called *eBP* (as illustrated in Fig. 1). eBP resolves the issues above with its discreet design, quiet components, and convenient location. However, realizing eBP has the following challenges: (1) In-ear BP monitoring is an unexplored topic in which many of the existing techniques cannot be applied. (2) The mechanism enabling the use of an inflatable balloon to measure BP from inside the ear is non-trivial. When the balloon inflates, the sensor should attach firmly to the ear canal and not slide out. In addition, applying insufficient pressure will result in an inaccurate BP measurement, while applying too much pressure may cause discomfort or hurt the ear canal. (3) The in-ear pulse signals are weak and buried under noises. In addition, the motion artifacts are difficult to remove and can impact BP measurement accuracy. (4) BP measurements are sensitive to the contact quality (i.e., pressure) between sensor and in-ear skin, yet maintaining consistent contact pressure is difficult. Thus, along with introducing the novel concept of in-ear frequent BP monitoring and showing its feasibility as well as comfortability, we propose a blocking-free optical-oscillometric approach to allow the in-ear sensor to measure important parameters in BP measurements (i.e., systolic amplitude and diastolic amplitude). In addition, we devise an algorithm to process and qualify the very noisy pulse signals captured from inside the ear to ensure the high-quality BP measurements. We prototype a device with a custom-built circuit and hardware/software components including (1) a light-based pulse sensor attached to an in-ear inflatable pipe (or balloon), (2) an air pump, a pressure sensor, and a valve controlling module to control the balloon's contact to the in-ear skin for pulse measurement, and (3) a in-ear BP estimation algorithm. The in-ear pipe is slowly inflated by the digital pump to create small pressure on the outer ear canal

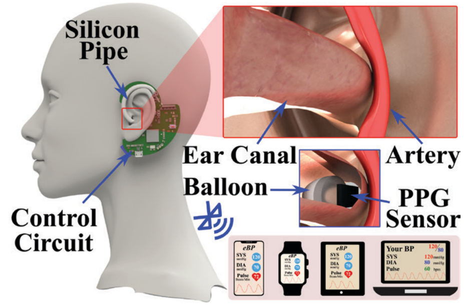

FIGURE 1. In-ear blood-pressure monitoring.

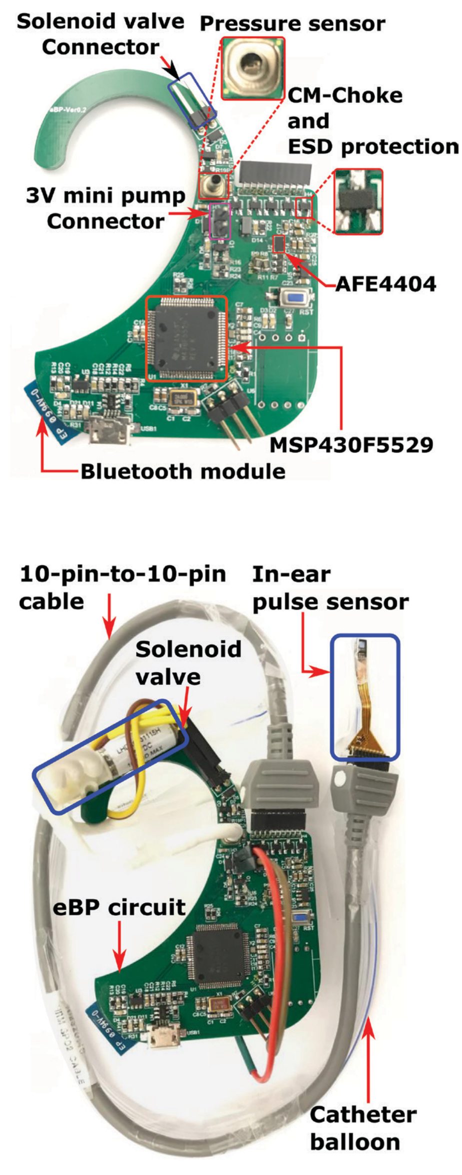

FIGURE 2. eBP prototype.

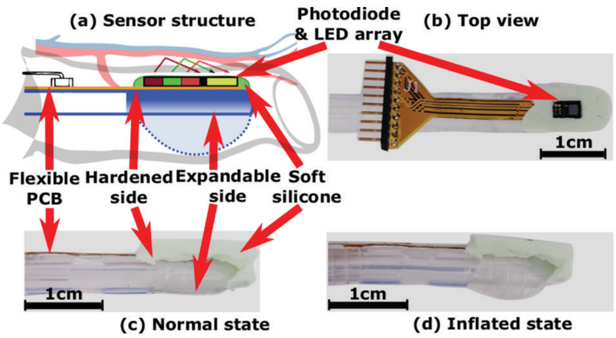

FIGURE 3. In-ear PPG sensor and balloon design.

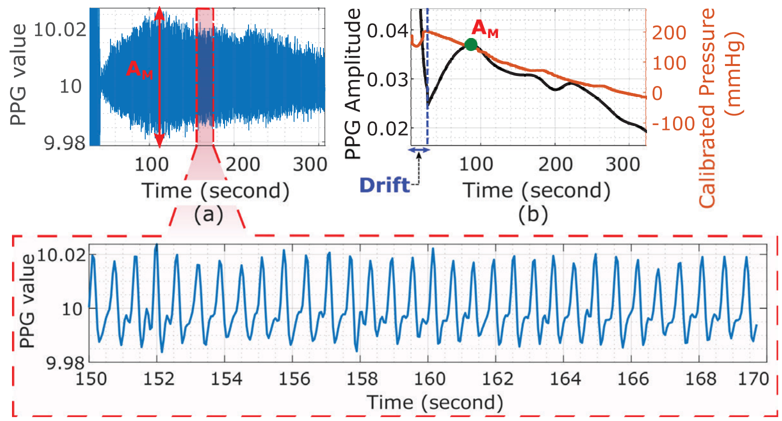

FIGURE 4. In-ear PPG signal (a) with corresponding amplitude and pressure (b).

until the diastolic and the systolic value are estimated. The study of this prototype on 35 users verifies the performance of eBP on par with an FDA-approved BP measurement device (KonQuest KBP-2704A).

These promising results not only show the feasibility of an in-ear blood monitoring concept but also open up the possibility of making current gold standard cuff-based BP measurement more comfortable. With the continued trend of incorporating biometric monitoring into devices that are worn on a daily basis, there would be minimal behavioral changes required on the part of the wearer to benefit from eBP. As ear-worn devices are becoming increasingly popular, eBP could potentially be integrated into a headphone or hearing aid. Our BP calculation algorithm can be applied to make existing cuff devices more comfortable. In addition, the use of a medical balloon to deliver a sensor into the ear can widely benefit other applications; for example, it can improve the contact points and the conductivity of electrodes for the in-ear sensing area.

CORE HARDWARE COMPONENTS

The in-ear BP measuring module consists of: (1) a PPG sensor, (2) an air balloon, and (3) an air pump and a valve controller to control the balloon having good contact with the in-ear skin.

Since the human ear canal can be as small as 2.4mm in diameter, both the LED and photodiode of a PPG sensor need to be miniaturized to fit the ear canal. PPG sensing requires tight contact points between the sensors and the skin for accurate measurement. However, keeping the sensor in contact with the skin at all times might generate discomfort to the user for long-term use. To overcome this challenge, the sensor is designed to be flexible and operates as an in-ear balloon to only contact the human skin tightly when conducting PPG measurements. Specifically, we mount the PPG sensor on top of a small catheter balloon [11] that can be pumped up or vented out via a precise controller module to ensure the consistency of the contact force for maintaining high-quality PPG measurements. The module includes a digital pressure sensor for measuring the contact force, a mini air pump, a solenoid valve for filling and venting the air, and a network of soft silicon pipes connecting them. Furthermore, the circuit for the PPG sensor needs to flexibly deform and stay attached stably on one side of the balloon as the balloon inflates and deflates.

We design our in-ear sensor by integrating a PPG sensor with the balloon of a Foley catheter made by Poiesis Medical [11]. The catheter is created from 100% medical silicone so it can be safely and comfortably inserted inside the body. We found that the SFH7050 PPG sensor from OSRAM is the best fit for the small size of the ear canal. The sensor is driven by a specialized analog front end IC (AFE4404) from TI. To ensure high-fidelity signals, a common-mode (CM) choke coil is used as an analog low-pass filter before the input of the AFE. The analog signal is sampled and digitized with a sampling rate of 320 Hz. The PPG sensor is soldered onto a thin layer (0.1 mm) of flexible PCB. The whole sensing device is then integrated on top of the balloon catheter by using a thin layer of liquid silicone gel. Our in-ear balloon is hardened by curing the thin layer of liquid silicone gel at 80˚C for 1 hour, so it will only expand on one side.

Manufacturing a disposable in-ear balloon sensor, including a catheter balloon and the SFH7050 sensor, costs approximately $19.81, which is cheaper than a disposable BP handcuff [12]. The cost can even be reduced further through optimization and large-scale production.

IN-EAR BP MEASUREMENT

The fundamental difference between measuring BP from inside the ear with other techniques is the complete obstruction of the blood artery in measuring systolic BP (SBP). The oscillometric method demands the artery be blocked entirely in order to capture the SBP. While the cuff-based approach can satisfy the requirement effortlessly by squeezing the cuff around the arm/wrist, the structure of ear-canal only allows the balloon to press on one side of the artery, thus, merely blocking it. This problem poses a significant challenge because the pressure is insufficient for measuring systolic BP. Also, the ear canal's skin is susceptible, which limits the immense pressure. In this section, we introduce a new approach to calculate the systolic pressure without the need for completely obstructing the artery.

To estimate the SBP (P_S) given the pressure of MAP (P_M) and diastole (P_D), we apply the relational equation between MAP, SBP and DBP

$$P_M = \beta P_S + (1 - \beta) P_D \quad (1),$$

where β is the systole ratio of the cardiac cycle. We derive the value of β by calculating the duration of the systolic cycle over the length of the pulse cycle. The method provides an adaptive estimation of β depending on the user-specific pulsatile waveform at the time of measurement.

MAP represents the pulse pressure or the highest PPG amplitude. The precise location depends on the quality of the signal amplitude. To achieve the goal, we strictly enforce that the peak-to-peak amplitude of the PPG signal is only calculated by subtracting the top to bottom. It means only data in the diastolic cycle of the pulse is used to calculate the amplitude. Also, we impose a constraint to remove the falsely detected peaks in the signal amplitude caused by the drifting effect.

According to [13], amplitude rapidly decreases once the pressure passes the MAP and moderately decreases once it reaches the diastole point. In other words, the DBP position occurs at the highest decreasing amplitude. We can formulate this as the minimum of the first derivative amplitude.

PPG signal quantification: Since our proposed algorithm strongly depends on the quality of the PPG signal, we introduce two criteria to omit non-pulsatile data and movement noise from the user and the in-ear sensor probe. Firstly, the Peak Interval Variability (PIV) is calculated as the standard deviation of all peak intervals in the current window to measure the consistency of the signal interval. Secondly, we compute the Entropy variance by calculating the difference between the pulsatile wave with the normal distribution. The entropy S of a signal x is defined as

$$S(x) = \sum_{i=1}^{n} x[i]^2 log_e(x[i]^2)$$

that correlates to the change in signal shape. A chunk of PPG data is clean whenever all pulses have similar entropy.

PERFORMANCE EVALUATION

We conduct an experiment for eBP on 35 subjects alongside an FDA-approved, gold standard, arm-cuff BP measurement device (KonQuest KBP-2704A) (Fig. 5). For assessment, we use the metric that is widely accepted by other BP studies, which consists of bias or mean error μ, a precision

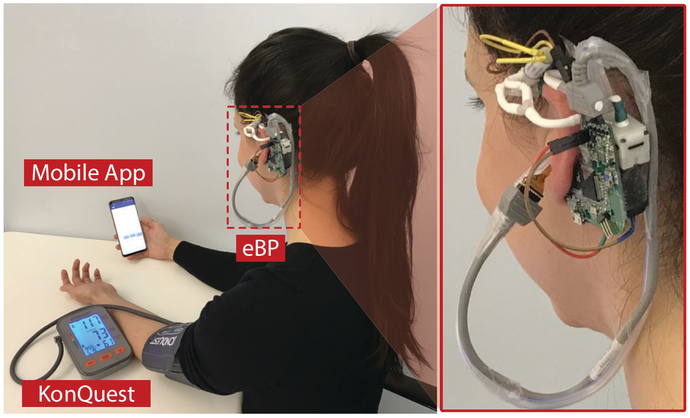

FIGURE 5. Experiment setup to compare eBP with the KonQuest device.

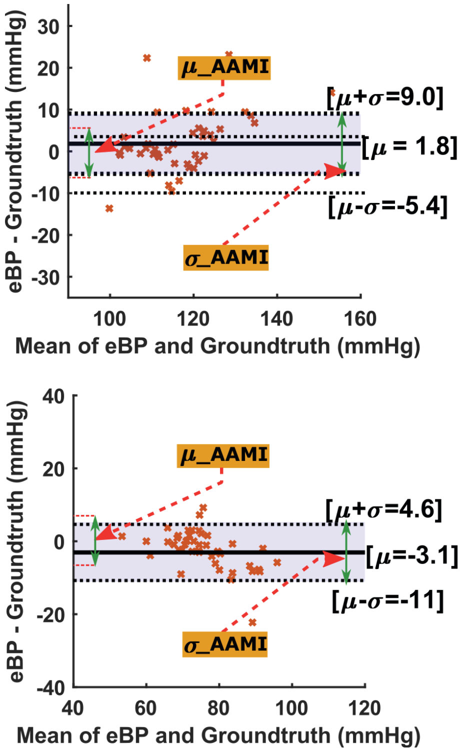

FIGURE 6. Bland-Altman plot comparing eBP's measurements and groundtruth.

or standard deviation (SD) σ error, and the Pearson correlation coefficient ρ. We select five participants' data for calibration using a polynomial regression model.

Fig. 6 shows the Bland-Altman diagram that describes the average error between eBP and the ground-truth. Consequently, the mean and SD error of SBP and DBP are 1.8 mmHg and 3.1 mmHg, which is within the Association for the Advancement of Medical Instrumentation's (AAMI) requirement (μ_{AAMI} <5 mmHg) [14]. In addition, our SD error for SBP and DBP also satisfy the criteria where σ_{AAMI} <8 mmHg [14]. On the other hand, the Pearson correlation coefficients correlation of the SBP and DBP are 0.81/1.0 and 0.76/1.0 DBP, respectively. The results show that our system's measurement is highly correlated to that of the FDA approved device.

REMAINING CHALLENGES AND FUTURE IMPROVEMENT

Through the in-lab experiments, the eBP has demonstrated its ability to measure BP from inside the ear, but there is still plenty of room for improvement. The following paragraphs enlist several important factors that, in our opinion, can significantly improve system performance as well as user comforts.

Optimizing the balloon design: Our current off-the-shelf medical balloon shape does not respond linearly to pressure changes. The balloon also has a high level of stiffness and thus demands a strong pressure to break the equilibrium point. In addition, unlike the cuff, the elasticity of the balloon quickly recoils to its original state at the onset of deflation. Therefore, it inserts a large amount of pressure into the pressure sensor that sometimes overwhelms the device. As a result, improving the linearity of the balloon's material is our priority. The new material should satisfy the linearity property while being comfortable, but still complying with the safety requirements as the current catheter balloon does.

Safety control and sensor placement: So far, we configure a safety threshold for the pressure and use a low power DC pump to protect users. However, this solution only prevents the air from pumping into the balloon continuously. We also need a mechanism for supervising the eBP placement to ensure that users do not place it too deep inside their ear which could injure the tympanic membrane. In addition, a better tragus-mounting mechanism is required to keep the sensor stable inside the ear. We will need to evaluate the signal quality of different sensor placement locations and obtain the cleanest signal by utilizing SNR, PIV, and entropy variance.

Hardware optimization: We aim to optimize the design of eBP prototype by miniaturizing the main circuit, i.e. using smaller components, reducing power consumption, and leveraging on-chip processing data. We aim to eliminate the wireless streaming by off-loading signal processing to the microcontroller and taking advantage of the dedicated DSP core. On-chip processing requires less power consumption, smaller battery usage and hence reduces the size and weight of the device.

SUMMARY

In this article, we presented eBP, a new method to capture BP from inside the ear. We proposed the in-ear BP model that requires no constant parameters, by observing the behavior of pulse amplitude. We also introduced a technique to customize an off-the-shelf catheter as the in-ear pulse pressure sensor. The promising results from our evaluation not only show the feasibility of an in-ear blood monitoring concept but also open up the possibility of making current gold standard cuff-based BP measurement more comfortable. ■

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