

## Development of an Automatic Blood Pressure Device based on Korotkoff Sounds

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### **Abstract**

*In this study, we develop a Korotkoff sound based automatic blood pressure measurement device including sensor, hardware, and analysis algorithm. PVDF-based sensor pattern was developed to function as a vibration sensor to detect of Korotkoff sounds, and the film's output was connected to an impedance-matching circuit. An algorithm for determining starting and ending points of the Korotkoff sounds was established, and clinical data from subjects were acquired and analyzed to find the relationship between the values obtained by the auscultatory method and from the developed device. The results from 86 out of 90 systolic measurements and 84 out of 90 diastolic measurements indicate that the developed device pass the validation criteria of the international protocol. Correlation coefficients for the values obtained by the auscultatory method and from the developed device were 0.982 and 0.980 for systolic and diastolic blood pressure, respectively. Blood pressure measurements based on Korotkoff sound signals obtained by using the developed PVDF film-based sensor module are accurate and highly correlated with measurements obtained by the traditional auscultatory method.*

**Keywords:** *Blood pressure measurement, Korotkoff sounds, PVDF film, Auscultatory method.*

### **1. Introduction**

Blood pressure, a pressure exerted by blood upon the wall of blood vessels, is an essential vital sign for monitoring cardiovascular function [1]. Blood circulation delivers oxygen and energy to the body, and it needs a certain amount of pressure to sufficiently supply blood to the organs [2]. Blood pressure values change depending on an individual's vascular condition and is controlled by nervous and endocrine systems. Normal resting systolic and diastolic blood pressure ranges in adults are approximately 90–120 mmHg and 60–80 mmHg, respectively [3-5]. Hypertensive patients have blood pressures continuously above 140 mmHg and 90 mmHg for systolic and diastolic pressures, respectively. Long-term high blood pressure is a major factor in cardiovascular disease, stroke, and chronic kidney disease [6]. In order to control hypertension, several approaches are recommended including changing diet, increasing exercise, stopping smoking, and taking medicine. Among those, the most effective manner of hypertension management is taking a precise drug dosage based on the individual's blood pressure [7]. Measurement of blood pressure is very important for diagnosing hypertension, and there are several measurement methods in clinic use [8].

Direct measurement of blood pressure can be achieved by inserting a liquid-filled catheter in an artery. Blood pressure is transmitted via the catheter liquid to the sensor. That method produces the most accurate arterial blood pressure and is regularly employed in emergency and intensive care units for continuous blood pressure monitoring. However, it requires a patient's artery to be cannulated, which means that method may be inappropriate due to the possibility of damage to the patient's vascular system [9, 10].

A standard indirect method for measuring blood pressure is the auscultatory method. An occlusive cuff placed on the upper arm is inflated to a pressure level above the estimated systolic pressure and then the occlusive cuff pressure is slowly released. When systolic pressure becomes higher than cuff pressure, the blood starts to flow in the brachial artery and generates Korotkoff sounds, which can be heard through a stethoscope on the distal side of the brachial artery. The sphygmomanometer pressures observed at the first and last Korotkoff sounds indicate systolic and diastolic pressures, respectively. However, the auscultatory method has measurement errors associated with the observer, thus accurate measurement of blood pressure requires a well-trained observer [11-13].

A third approach, the oscillometric method, is common in currently available automatic blood pressure monitoring devices. It is based on detecting the maximum of the pulse amplitude. The pressure that leads to this maximum is taken as the mean arterial pressure. When the oscillometric cuff pressure is decreased, the arterial pulse appears due to the arterial pulsations under the cuff. Pulse amplitude increases to a maximum at the mean arterial pressure and then decreases with further cuff deflation. The maximum amplitude algorithm is one of the popular methods for estimating blood pressure from pulse amplitude. The systolic pressure is taken as the pressure above the mean at which the pulse amplitude is a constant (from 0.45 to 0.73) times the maximum, and the diastolic pressure is taken as the pressure below the mean at which the pulse magnitude is a constant (from 0.69 to 0.85) times the maximum. However, automatic blood pressure measurement devices provide various outcomes due to their use of different oscillometric algorithms [14-17].

Although the standard blood pressure measurement is based on listening for Korotkoff sounds, there are no automatic devices that use Korotkoff sounds due to cost and difficulties in sensor application. There was a first attempt to develop a Korotkoff sound based device, however, it needs further development for the sensor packaging and improvement for an algorithm [18]. The aim of this study was to develop an accurate automatic blood pressure measurement device which utilizes Korotkoff sounds to determine systolic and diastolic blood pressures. The study includes the development of a vibration sensor using a polyvinylidene fluoride (PVDF) film and the necessary impedance-matching circuit. As well as an algorithm for determining the starting and ending points of the Korotkoff sounds was established. Clinical data were acquired from the developed device and were analyzed to demonstrate the device's accuracy and reliability.

## **2. Methods**

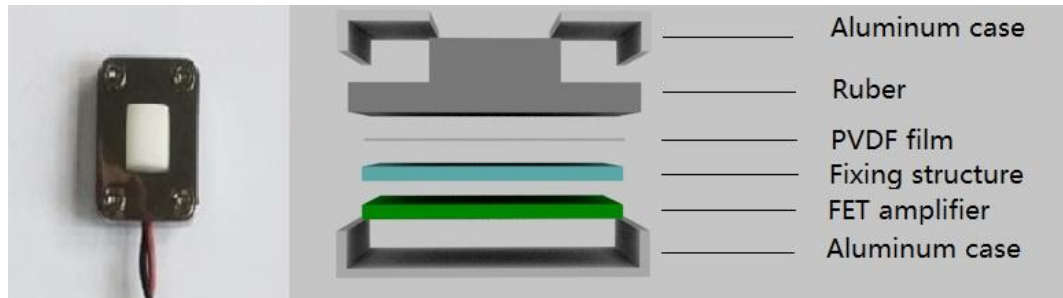
The purpose of this study was to develop an accurate automatic blood pressure device that determines blood pressure values based on Korotkoff sounds. First, a PVDF-based sensor pattern was developed to function as a vibration sensor for the detection of Korotkoff sounds. Second, the film's output was connected to an impedance-matching circuit. Third, an algorithm for determining starting and ending points of the Korotkoff sounds was established, and, finally, clinical data from subjects wearing the device were acquired and analyzed.

### **2.1 Sensing module**

PVDF film, which is a flexible and lightweight plastic, has a wide frequency range ( $10^{-3}$ – $10^8$  Hz) and can be 9–100  $\mu\text{m}$  thick. PVDF film generates an electrical charge when mechanically deformed, and conversely, its dimensions change when coupled to an electrical field. The dominant frequency components of Korotkoff sounds are less than 500Hz [19], and the goal of PVDF film design was to cover the Korotkoff sound frequency range. Figure 1 shows the developed sensing module and a schematic diagram of its construction. Dimensions of the developed sensing module are  $20 \times 15 \times 5$  mm, a size that can be effectively placed atop the brachial artery and under an occlusive cuff for blood pressure measurement. As shown in the schematic, PVDF film was placed on rubber by using an adhesive for fixation. A field effect transistor amplifier was embedded to couple with the film for impedance matching with the film output. All sensor

materials were housed in an aluminum case to prevent interference from ambient noise and to protect the PVDF film.

A pressure sensor (MS1451, Measurement Specialties, USA) was connected to the cuff tube to measure cuff pressure .

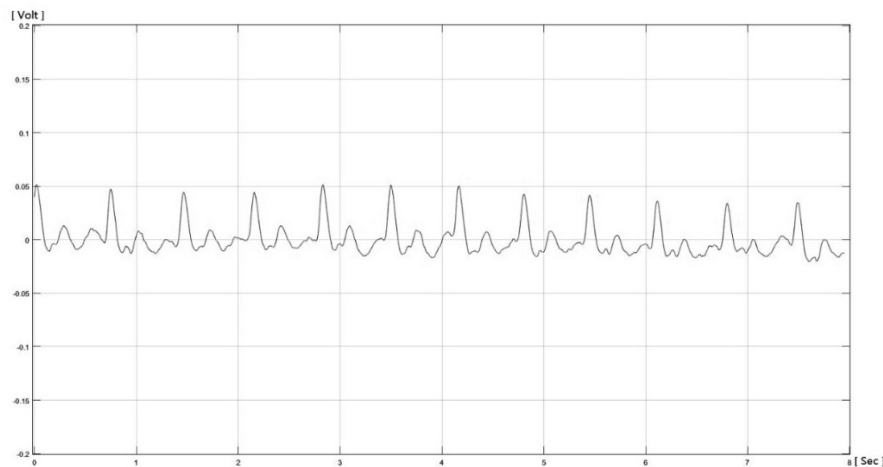


**Figure 1. Sensing module (left) and schematic diagram of sensing module (right)**

## 2.2 Hardware design

The sensing module was placed on the brachial artery, and the pressure sensor was coupled to the open end of the cuff's bladder tube. The outputs of two sensors, PVDF film and pressure sensor, were connected to a hardware circuit, which included high- and low-pass filters and a 60 Hz notch filter.

When the sensing module is placed on the brachial artery, not only Korotkoff sounds but also unwanted pulse wave signals are detected simultaneously. Figure 2 shows the pulse waves detected from the PVDF sensor before cuff inflation. Since the pulse wave signals were regarded as noise during detection of Korotkoff sounds, they should be removed completely.



**Figure 2. Pulse waves before cuff inflation and without a signal filter**

To remove the unwanted pulse wave signals, several filters with different cutoff frequencies were tested to determine their capacity to remove pulse wave signals but keep Korotkoff sounds. Since the main frequency component of the pulse waveform was lower than 8 Hz, a 4th order high-pass filter with cutoffs of 15, 25, and 35 Hz were designed and tested. Figure 3 shows the output of the sensing module after applying the different filters.

Figure 3(a) shows the pulse waves with a 4th order 15 Hz high-pass filter before cuff inflation. The figure shows the pulse wave signals that could be removed by applying a higher cutoff frequency high-pass filter. Figure 3(b) shows the result after applying the 4th order 25 Hz high-pass filter during deflation. The pulse wave signals were reduced significantly, however, pulse signals were still apparent during cuff deflation. Finally, a 4th order 35 Hz high-pass filter

was applied, and the Korotkoff sounds were clearly detected and pulse waves were absent (Figure 3(c)). Thus, the hardware for acquiring Korotkoff sounds was composed of a 4th order 35 Hz high-pass filter and a 2nd order 500 Hz low-pass filter, along with a 2nd order 30 Hz low-pass filter to acquire cuff pressure.

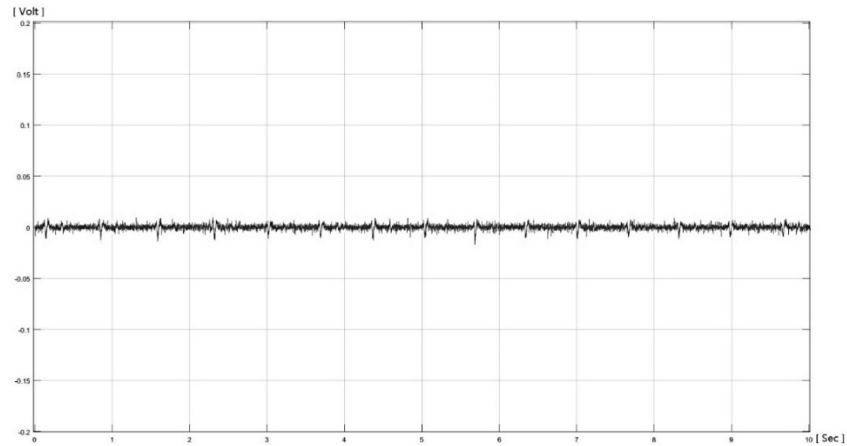


Figure 3(a). Output of sensing module with a 4th order 15Hz high-pass filter before cuff inflation

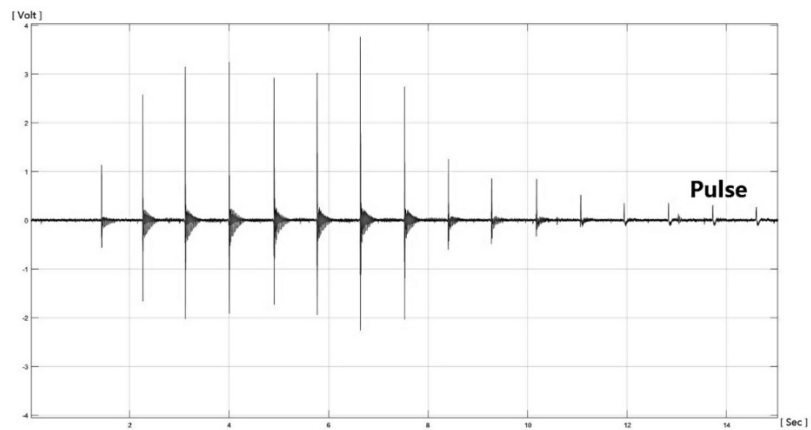


Figure 3(b). Output of sensing module with a 4th order 25Hz high-pass filter during cuff deflation

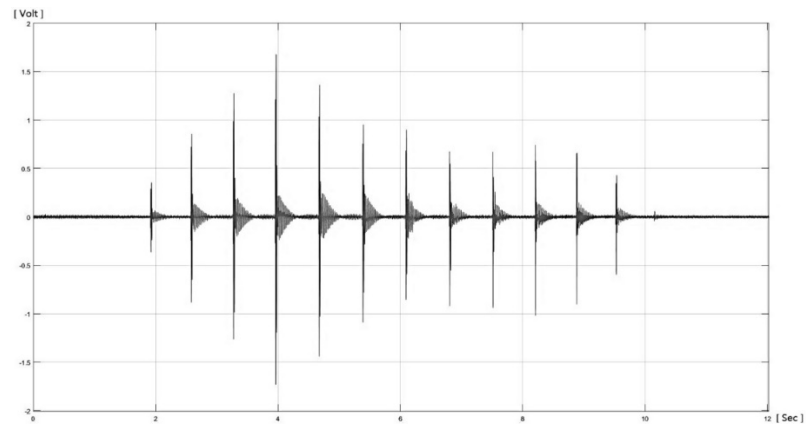
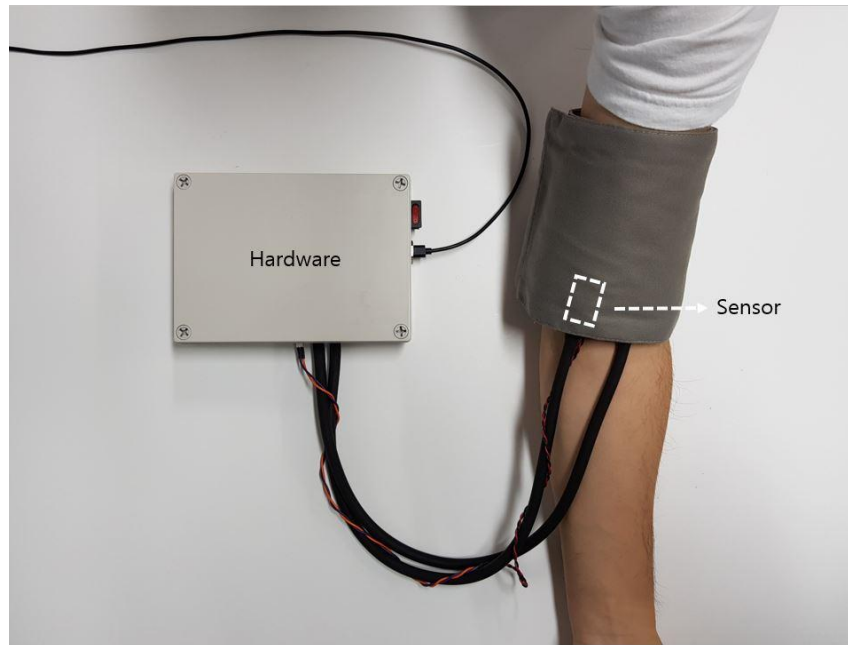


Figure 3(c). Output of sensing module after applying a 4th order 35Hz high-pass filter showing Korotkoff sounds

Figure 4 shows the picture for the developed device including sensor implemented inside the cuff. PVDF film sensor is located inside the cuff as marked in the figure. Hardware includes pump for inflation and deflation of cuff bladder, pressure sensor for measuring applied pressure, and hardware for processing sensor output. Output from the hardware system is connected to the Biopac 150 system (Biopac Systems, Goleta, CA, USA) for data acquisition.

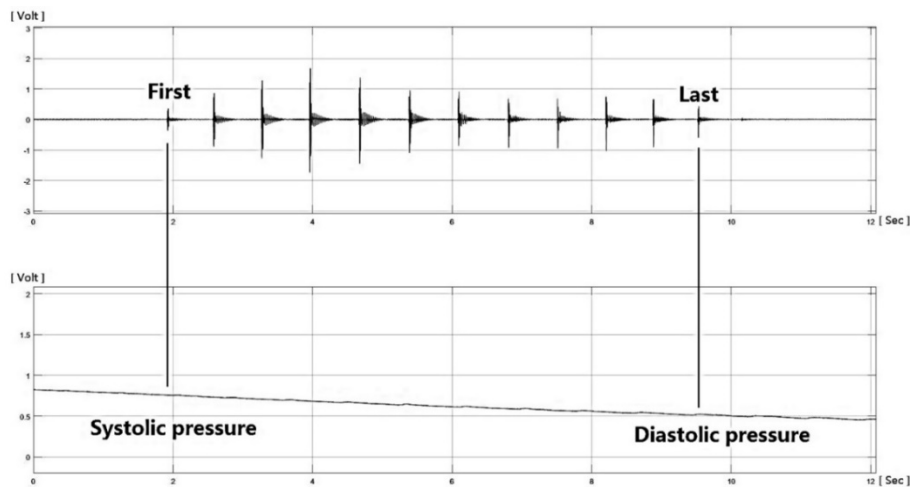


**Figure 4. Developed device including sensor implemented inside the cuff**

### 2.3 Data acquisition and analysis

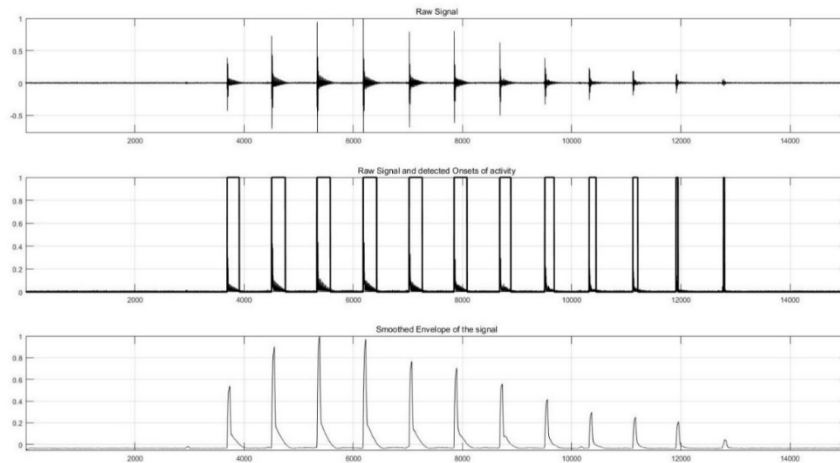
Fifteen subjects participated in this study, and the procedure was performed according to the international validation protocol. Subjects were positioned comfortably for 5 min, after which seven left-arm blood pressure measurements were performed sequentially by using both the developed device and the auscultatory method. Measurement intervals were 30–60 sec (less than 30 sec may cause venous congestion while more than 60 sec may cause increased variability). The 1st, 3rd, 5th, and 7th measurements were obtained by using the auscultatory method, and the 2nd, 4th, and 6th were obtained by using the developed device [20, 21]. A Biopac 150 system was used to collect the data, and differences between two measurement values were used to determine the accuracy of the developed device.

Matlab (MathWorks, Natick, MA, USA) was used to establish an algorithm to extract the first and last Korotkoff sounds. The algorithm needed to establish the first and last detected Korotkoff sound, and those detections had to be matched with the concomitant absolute cuff pressure values in order to determine the blood pressure. Figure 5 shows a series of Korotkoff sounds and a curve of absolute cuff pressure, which are used jointly to determine systolic and diastolic pressures.



**Figure 5. Korotkoff sounds (top) and the corresponding cuff pressure (bottom)**

Figure 6 shows the processing steps involved in extracting the first and last Korotkoff sounds. Raw signals on the top graph in Figure 6 were rectified and smoothed for enveloping to obtain the peak value of the signal. Then, a threshold value, based on the noise level, was set, and the Korotkoff sounds were determined from the signal strength greater than the threshold. Figure 6 shows each peak of the Korotkoff sounds as a box.



**Figure 6. Determination of systolic and diastolic pressure based on Korotkoff sounds and cuff pressure. (a) raw Korotkoff sounds, (b) square wave indicates detection of Korotkoff sound after rectification, and (c) determination of Korotkoff sounds above the preset threshold**

### 3. Results and Discussion

The purpose of this study was to develop an accurate blood pressure measurement device based on the detection of Korotkoff sounds. In order to detect Korotkoff sounds, a sensing module using PVDF film was developed, and a pressure sensor was connected to an occlusive cuff to obtain an absolute pressure value. The associated hardware was designed to obtain clear and accurate Korotkoff sounds and absolute pressure values. An algorithm was established for extracting first and last Korotkoff sounds to determine systolic and diastolic pressures.

Figure 7 shows the output from the device's sensors; the top graph shows the Korotkoff sounds from the PVDF film, the middle graph shows the cuff pressure during deflation, and the bottom graph shows the pulse signal from the brachial artery.

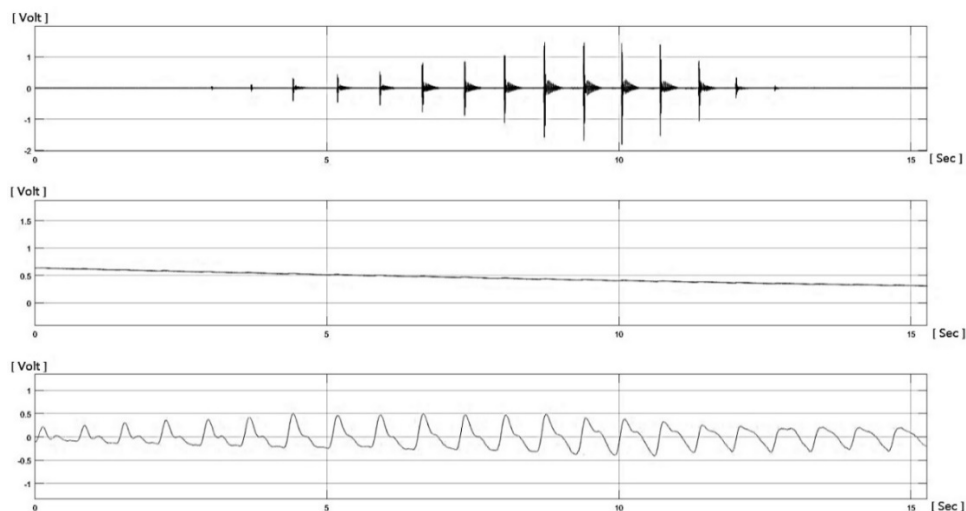


Figure 7. Top, Korotkoff sounds; middle, cuff pressure; bottom, pulse waves

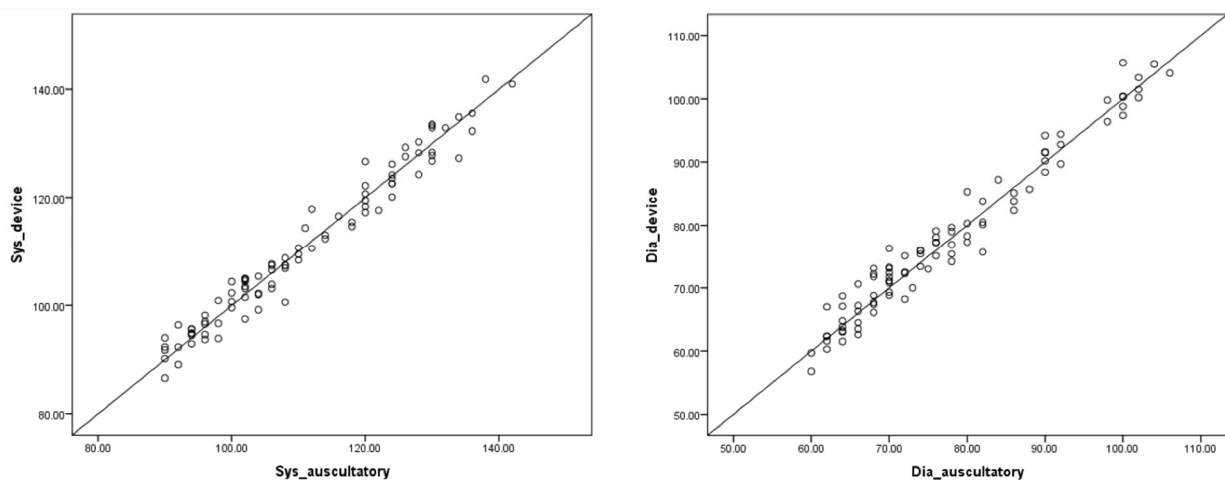
Table 1. Mean and standard deviations of blood pressures obtained by the auscultatory method and from the developed device for 10 subjects

	Systolic pressure				Diastolic pressure			
	Auscultatory		Device		Auscultatory		Device	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
1	120	4.19	117.9	3.43	91	1.09	91.1	2.19
2	127.3	2.73	126.1	2.17	81.5	4.33	79.9	3.00
3	117	3.28	115.5	3.96	78.3	2.94	77.5	2.26
4	92.2	2.52	91.0	2.68	63	2.09	61.53	2.77
5	132.7	3.44	131.2	3.16	101	2.75	100.9	3.90
6	103.3	1.63	103.41	3.03	74.6	1.63	75.1	2.00
7	92.3	2.33	93.7	2.18	68	1.78	68.9	3.56
8	106	3.09	104.9	3.65	66	2.5	66.9	3.36
9	111	4.69	111.4	6.16	86.6	3.26	87.9	4.06
10	97	3.03	98.25	3.71	63.3	2.06	64.4	3.15
11	99.3	2.06	100.2	4.38	71.1	2.04	71.2	1.83
12	134.3	4.8	136.1	4.18	101	2.09	101.2	2.14
13	98	3.79	98.3	3.30	70	1.26	71.8	3.11
14	123.3	2.73	125.1	3.48	78.6	2.73	78.8	3.62
15	107.5	2.34	107.6	4.26	67.5	4.37	68.4	5.21

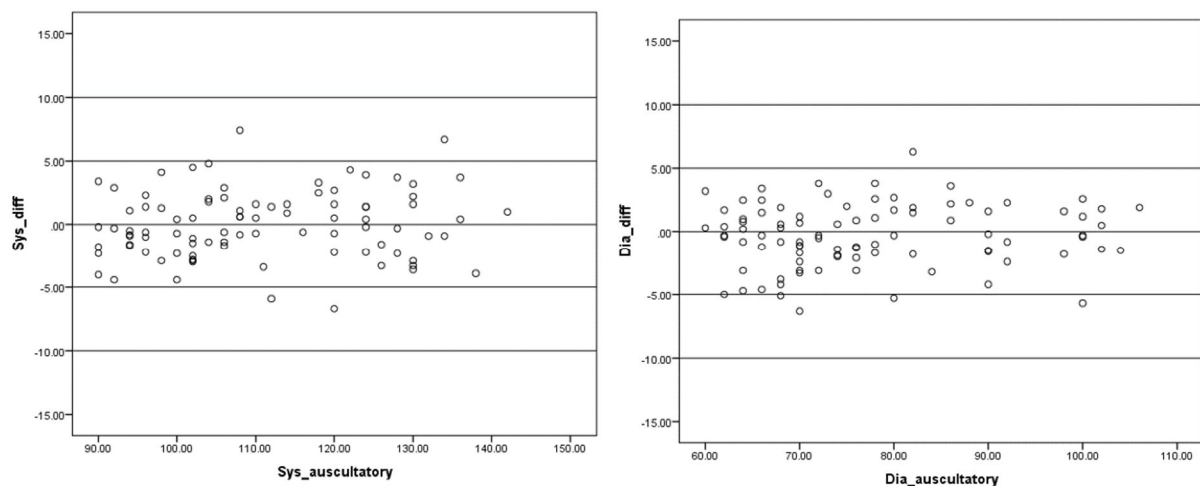
Table 1 shows the blood pressures and standard deviation values for each of the ten subjects. Standard deviations of the measurements from the developed device were 2.17–6.16 mmHg and 1.09–5.21 mmHg for systolic and diastolic pressures, respectively. The standard deviations were greater than 5 mmHg in subjects 11 and 13. Such standard

deviations can be expected in a series of seven sequential measurements; regardless, most standard deviations were under 5 mmHg and would qualify as valid under the international validation protocol.

Figure 8 presents regression plots for the values obtained by the auscultatory method and from the developed device. Correlation coefficients were 0.982 and 0.980 for systolic and diastolic blood pressure, respectively. Figure 9 shows the difference values between pressures obtained by using the auscultatory method and the developed device. The horizontal axis is for the blood pressure values for the auscultatory method, and the vertical axis is for the values differences between the auscultatory method and the developed device. Based on the international protocol for the validation of automatic blood pressure monitoring devices, if the differences are within 0–5 mmHg, the device is categorized as group A; accordingly, 6–10 mmHg differences as group B, 11–15 mmHg as group C, and more than 16 mmHg as group D. The results summarized in Figure 9 show that 86 out of 90 systolic measurements (95.5%) and 84 out of 90 diastolic measurements (93.3%) belong to group A, indicating that the developed device passes the validation criteria of the international protocol.



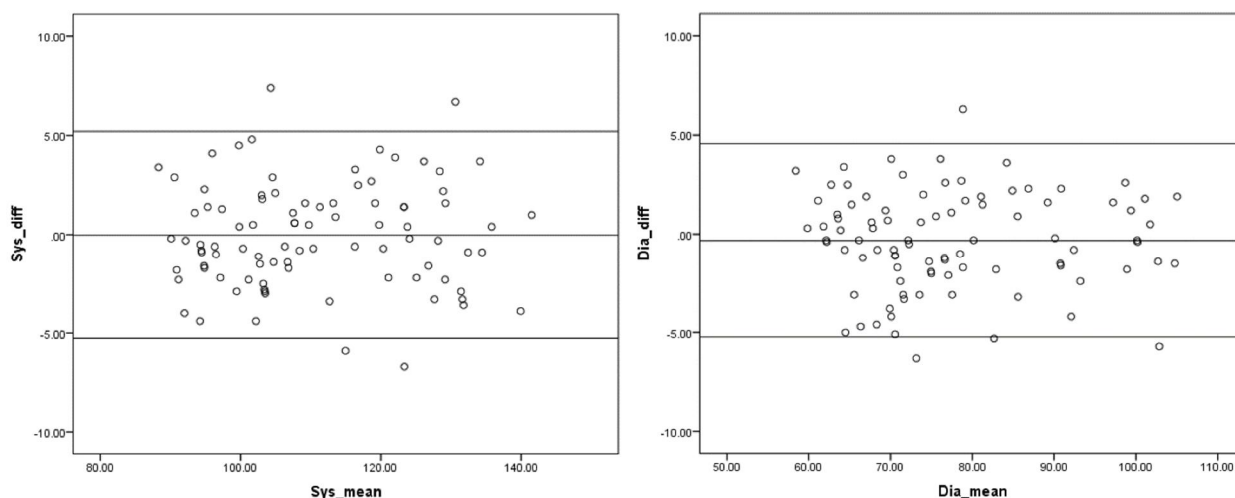
**Figure 8. Correlation between auscultatory method and PVDF device measurements of systolic (left) and diastolic (right) blood pressures**



**Figure 9. Difference values between auscultatory method and developed device for systolic (left) and diastolic (right) pressures**



Figure 10 shows Bland-Altman plots for the blood pressure values from the auscultatory method and the developed device. Horizontal axis presents the mean values from the auscultatory method and the developed device, while the vertical axis presents the differences between the auscultatory method and developed device values. The plots indicate that 95.5% of the measured values were within the upper and lower limit range, showing that the values obtained from the developed device and the auscultatory method were highly correlated.



**Figure 10. Bland-Altman plots device for systolic (left) and diastolic (right) pressures obtained by the auscultatory method and the developed device.**

## 4. Conclusions

The aim of this study was to develop an automatic blood pressure monitoring device based on Korotkoff sound data. A PVDF film-based device was used to detect Korotkoff sounds in the brachial artery. The size of the sensing module was sufficiently small to cover the brachial artery, and the film's boundary condition specification was set to optimum. To acquire clear Korotkoff sounds, accurate signal filtering was added to remove unwanted pulse wave signals, which could cause false detection of the Korotkoff sounds. An appropriate filtering approach was established and tested.

It was concluded that blood pressure measurements based on Korotkoff sound signals obtained by using the developed PVDF film-based sensor module are accurate and highly correlated with measurements obtained by the traditional auscultatory method. Future study will be performed to improve the pressure measurement algorithm and to confirm that the developed device meets the international standard. Once the device is developed for commercial availability, it would help patients measure their blood pressure in daily life accurately and easily and help in the effective management of hypertension.

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