# Device Proposal for Continuous, Non-Invasive Blood Pressure Monitoring

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## Abstract

Hypertension is a major risk factor for numerous conditions such as coronary artery disease and stroke causing an estimated 10.4 million deaths in 2019. Standard blood pressure (BP) measurements are obtained using a cuff that measures the blood pressure in that moment. Newer methods include the usage of 24 hour ambulatory monitors with cuffs that oscillate every 30 minutes during the day and every hour at night. These methods provide only discrete measurements that miss BP variations. A continuous monitor would detect variations as well as allow for typical daily activity resulting in a more accurate outlook at a patient's daily BP. Using a micropressure sensor, we attempted to create a continuous non-invasive BP monitor. The micropressure sensor was modified, and filled with gel. To measure the correlation between a standard BP cuff and our device, the seated participant wore the device on the wrist. After the peaks and troughs of the pressure waves were captured, the BP cuff was used immediately after. The peaks and troughs of the wave were used with the measurement from the standard cuff to attempt to predict systolic and diastolic pressure. There was a statistically significant relationship between the diastolic pressure and trough values, but the relationship between peaks and systolic pressure was not statistically significant. This correlation would be patient specific due to varying arterial stiffnesses. Next steps would include creating a simple way to calibrate the device for each patient and putting the device in the proposed wearable form.

## Introduction

Blood pressure is the force exerted on the arterial walls by blood as it is being pumped. During systole, or when the heart contracts, the typical pressure is 120 mm Hg; during diastole, or when the heart fills, the typical pressure is 80 mm Hg. This amount of pressure in the arteries allows for efficient flow of oxygen from the blood to the body without damage to the arteries. Blood pressure is influenced by genetic and lifestyle factors such as eating habits, exercise habits, and family history of hypertension. Blood pressure is regulated by various factors including the baroreceptor reflex, the renin-angiotensin system, and the release of aldosterone[1]. Additionally, BP is also regulated by an individual’s circadian rhythms as BP fluctuates from one minute to another within a 24 hour period[1].

Observational studies have shown that individuals who maintain arterial pressures at the low end of the healthy range have considerably better long-term cardiovascular health[1] .However, when individuals consistently exceed the healthy range for blood pressure, it is diagnosed as chronic high blood pressure, or hypertension. Hypertension is defined as having a systolic blood pressure consistently over 140 mm Hg and the diastolic blood pressure is consistently over 90 mm Hg[2]. Hypertension typically does not initially present any symptoms, so as a result, half of all people with hypertension are not aware that they have it[2]. The symptoms typically associated with hypertension are the result of damage done to other systems in the body due to the untreated worsening condition. Continually untreated hypertension is a major risk factor for stroke, coronary artery disease, heart failure, atrial fibrillation, peripheral arterial disease, vision loss, chronic kidney disease, and dementia[2]. Approximately 95% of hypertension cases have lifestyle and genetic factors as the cause such as an excess intake of salt, physical inactivity, and excess body weight[2].

Complications from hypertension cause millions of deaths per year. It was estimated in 2019 that 10.4 million deaths globally, 19% of all deaths in 2019, had high blood pressure as a contributing factor[2]. Hypertension prevalence varies significantly due to gender and age. Hypertension affects adult men more than adult women with 50.8% of adult men having hypertension compared to 44.6% of adult women having hypertension[3]. Additionally, for both men and women there was an observed positive correlation between increased prevalence of hypertension and increased age. There was a statistical difference between men and women aged 18-39 (30.0% of men and 16.4% of women) and aged 40-59 (55.9% of men and 49.0% of women)[3]. The prevalence of hypertension also varies across regions, socioeconomic groups, and race. The World Health Organization (WHO) has identified the locations with the highest and lowest prevalence of hypertension within the area to be the WHO African region at 27% and the WHO Region of the Americas at 18%[4]. Additionally, the prevalence of hypertension has nearly doubled since 1975, largely in low- and middle-income countries, with an estimated 594 million adults having hypertension in 1975 and 1.13 billion in 2015[4]. In the US, hypertension affects Black Americans the most with 41.8% of Black Americans having hypertension compared to 23.5% of Hispanic Americans having hypertension[5].

Hypertension is currently a significant disease with 48.1% of United States (US) adults affected[3]. As a result, the annual costs associated with hypertension were approximately $219 billion dollars in 2019[6]. Additionally, hypertension contributed and/or caused 658,875 deaths in 2022[6]. Uncontrolled hypertension can over time begin to severely impact the daily lives of patients. Some symptoms of uncontrolled hypertension include debilitating fatigue, cognitive decline, vision disorder, increased pain, and disrupted sleep which can severely impact a patient's ability to effectively function in daily life[7]. As such, early detection is key. It has been shown that healthy lifestyles, healthy environments, and access to detection and treatment that is both affordable and available early on helps save lives and reduce healthcare costs[6].

The traditional use of mercury sphygmomanometers were replaced with automated ‘oscillometric’ blood pressure monitors in the 1970s[8]. Since then, the automated devices have remained largely unchanged with slight variations from company to company and remain the standard device for blood pressure measurement[8]. However, both mercury sphygmomanometers and automated oscillometric blood pressure measuring devices have limitations. It is estimated that sphygmomanometers underestimate systolic blood pressure by an average of 3-4 mmHg and overestimate diastolic blood pressure by an average of 8 mmHg[8]. When automated devices were compared against manual auscultatory measurement, there was an estimated 10-15% error for the automated measuring devices[8]. Many automated blood pressure monitoring devices use fixed-ratio coefficients creating a systemic bias that results in the underestimation of systolic blood pressure as the systolic blood pressure rises[8]. Additionally, the devices cannot accurately account for arterial stiffness resulting in an overestimation for systolic, diastolic, and mean blood pressure readings[8]. These devices measure BP intermittently. As a result, spikes in blood pressure that occur between readings are not captured. Additionally, 24 hour ambulatory monitors limit activity due to device constrictions resulting in an inaccurate snapshot of a patient’s daily blood pressure. However, a continuous monitor would neither miss spikes or limit daily activity allowing for a true measurement of a patient’s daily blood pressure. Therefore, the development of an affordable continuous non-invasive blood pressure monitor that could be used from home would be critical for early and convenient intervention for anyone in need.

Biosensors are a type of non-invasive medical device that can be worn for continuous data collection of biochemical signals[9]. These wearable biosensors are used in many body systems to collect data such as glucose levels and body temperature. Biosensors can be worn in a variety of ways including patches, rings, contact lenses, and even integrated into clothing. Biosensors measure biochemical signals through generating signals that have the same concentration as those in the reaction[10]. The analyte is what is being measured. These analytes are recognized by bioreceptors and the transducers in the bioreceptor converts the concentration of the analyte to a measurable signal[10]. Some key characteristics of a biosensor include selectivity, reproducibility, sensitivity and stability. These characteristics ensure that the correct analyte is collected, the biosensor can generate the same data repeatedly, the biosensor can ignore noise, and the scale of the data collection is correct[10]. One example of a current biosensor is the smart contact lenses for continuous intraocular pressure monitoring[11]. These contacts have a silver nanowire sensor embedded in a silicone elastomer contact lens to allow for comfortable and convenient continuous monitoring[11]. In doing so, the diagnosing and monitoring of glaucoma is vastly improved.

There have also been many prototypes for new models of blood pressure monitors. One example of this is EchoLabs device that uses transmitters to send light and other electromagnetic frequencies into the skin and then measuring the reflected light to analyze blood flow to estimate blood pressure[12]. While this method is meant to focus on accuracy, the raw signal being received has a signal-to-noise ratio of 1 to 100[12]. Additionally, researchers from Tohoku University are experimenting with using ultrasonic sonar to measure blood pressure[12]. Haga developed a sensor that emits a pulse wave from an ultrasonic sensor placed on the skin to detect changes in blood vessel diameter[12]. This technology is promising because it can measure blood pressure from a small, distant target. However, this also results in objects between the sensor and the target inhibiting the reading resulting in considerable noise[12]. In an effort to reduce the signal-to-noise ratio, we are using a different approach than current prototypes by utilizing a micropressure sensor.

In the present study we focus on creating a prototype for a continuous non-invasive blood pressure monitor. We utilized a micropressure sensor to measure arterial pressure over the radial artery during systole and diastole. We wanted to investigate whether a continuous blood pressure reading could be predicted from micropressure sensors as compared to a regular blood pressure cuff.

## Methods

The target population for a pilot study for this device was healthy individuals aged 18 to 35. The device was worn on the inside of the wrist (Figure 1). Subjects wore a wrist band on the non-dominant hand that has two ends attached by velcro. A modified micropressure sensor (Digikey model number MPXV7025GC6U) filled with gel (NuSil model number MED-6342) was pressed above the radial artery. The micropressure sensor was modified by removing the plastic extrusion coming out of the top and the small metal plate separating the inner cavity of the sensor from the plastic extrusion. The NuSil two parts gel was mixed in a 1:1 ratio and poured into the cavity of the sensor until there was a dome of gel. The now filled device was put into a bell jar vacuum until all air bubbles were removed. The gel in the device was cured at 180 degrees fahrenheit for 4 days. Wires were soldered onto the pins on the micropressure sensor

and were connected to an ElegroUno R3 Arduino board. On pins 2, 3 and 4 a wire was wrapped around the pin and attached using solder. In order to avoid frying the chip, the soldering iron was applied about 2 inches away from the desired soldering location so only the wire would be heated. The soldered wire on pin 2 plugged into the 5V pin on the Arduino board. The soldered wire on pin 3 plugged into the ground pin. The soldered wire on pin 3 plugged into the voltage out pin. The board then transmitted data to the Arduino IDE app when the board and a computer were connected. The data was then continuously plotted on the serial plotter. The source of the code was originally from Chat GPT. The code was modified to be more sensitive so that it would be in the correct range of pressure and the print pressure was modified to be in millimeters mercury instead of kilopascals. Additionally, the delay was decreased significantly so a continuous graph with clear waveforms could be seen.

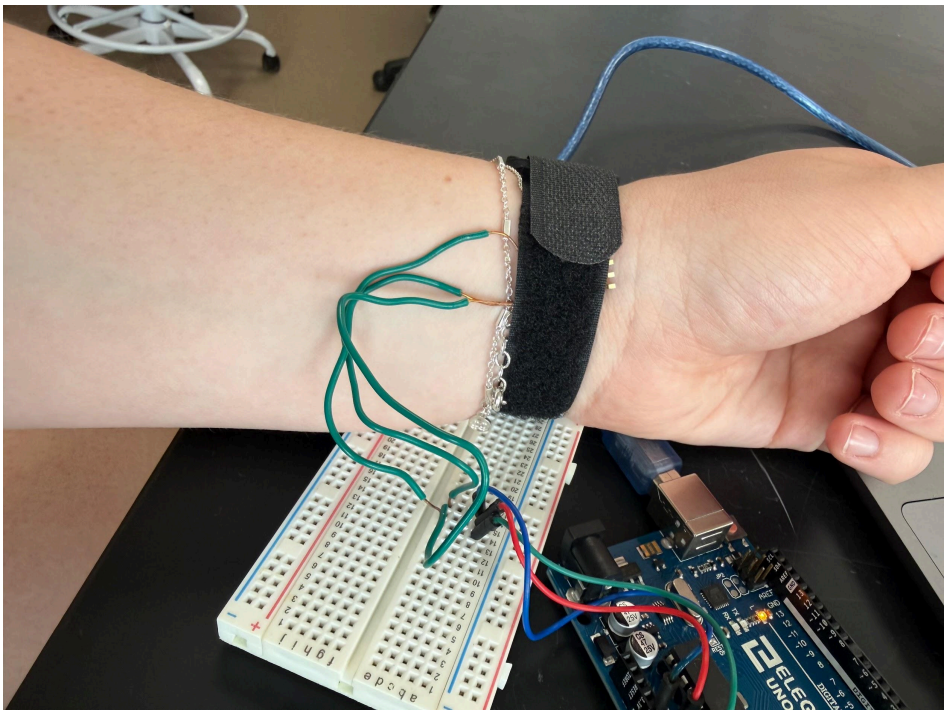

Figure 1. The device attached to the wrist

Procedure:

There was one participant in this pilot study. The patient was seated comfortably with the device on their left wrist. Once at least 10 BP waves were captured, the waves were saved and the researcher put a standard cuff on the participant's arm and measured their BP. The systolic and diastolic pressure were recorded. This was repeated 10 times.

Analysis:

Ten data points from the peaks and troughs of the collected data waves were collected and averaged from each trial. The averaged peak value was compared to the recorded systolic

pressure using a blood pressure cuff and the averaged trough value was compared to the recorded diastolic pressure using a blood pressure cuff for each trial.

## RESULTS

When comparing the average systolic value from each trial with the systolic pressure captured by the BP cuff, there was a parametric relationship with an R^2 value of 0.001 (Figure 2) meaning that only approximately 0.1% of the data was explained by the linear relationship. The p-value was 0.9237 meaning there was a 92.37% chance the relationship was due to chance. When comparing the average diastolic value from each trial with the diastolic pressure captured by the BP cuff, there was a parametric relationship with an R^2 value of 0.457 (Figure 3) meaning that approximately 45.7% of the data was explained by the linear relationship. The p-value was 0.0319 meaning that there was only a 3.19% chance the relationship was due to chance. The negative values recorded by the device seen in Figure 2 and Figure 3 currently do not have any meaning. With further research, the code will be adjusted with an equation for a specific participant's arterial stiffness in order to receive a correlated value that is true to their blood pressure.

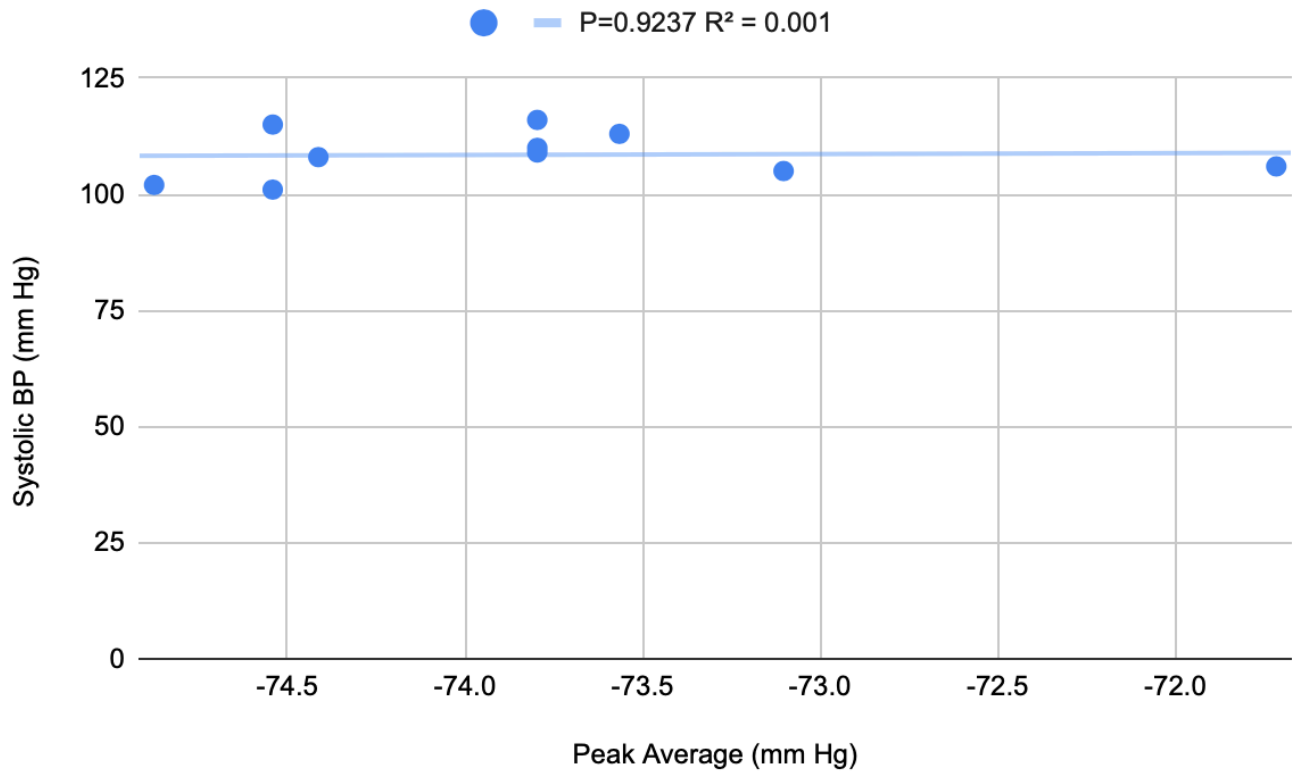


Figure 2. The average peak value of each trial compared against the cuff systolic blood pressure (p=0.9237)

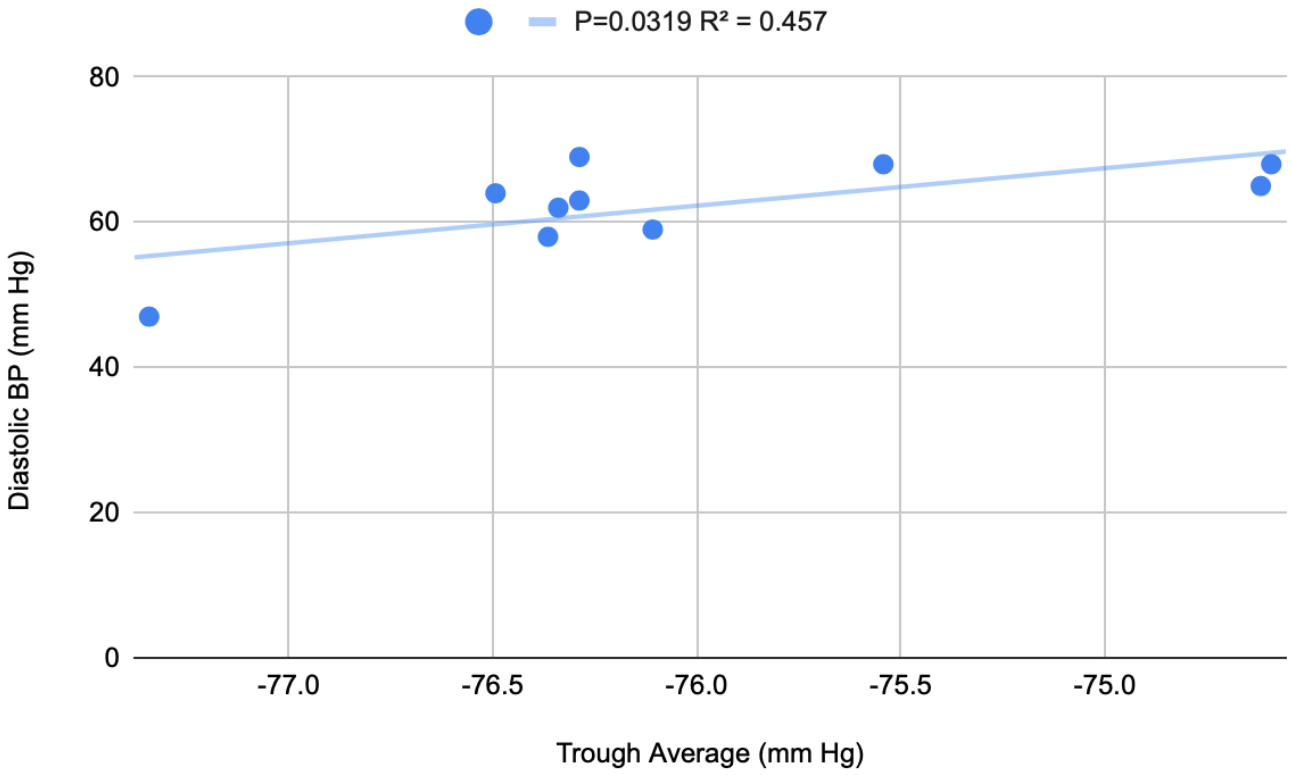


Figure 3. The average trough value of each trial compared against the cuff diastolic blood pressure (p=0.0319)

## DISCUSSION

We attempted to predict systolic and diastolic pressure using the peaks and troughs of the pressure waves. While the systolic pressure had no predictive power, the diastolic pressure was very promising. One possible reason for this may be that the sensitivity value in the code may have been too high and as such, either did not capture the true peaks of the waves or "rounded off" their true peaks. The heightened sensitivity impacts the systolic value because it is higher than the diastolic and may be out of range. Additionally, the true spike is a very brief window whereas the resting window is much longer.

The main limitations to the prototype are that the device has to be connected to a computer currently to record data so it's not truly wearable yet; In addition, the device is not waterproof yet so participants cannot shower with it. The Arduino Uno R3 may not be the most accurate as compared to boards like the Arduino Uno Q. The main limitation to this experiment is that there was only one participant from a healthy population. Additionally, this device was not tested for extended periods of time or during activity.

Possible next steps for this project would be altering the setup so that the data could be acquired using bluetooth instead of being hooked up to a computer. This way the data could be sent to an app for patient and healthcare provider viewing. Additionally, the code would need to

be adjusted to allow for input of data points for each individual patient in order to calibrate the device to each individual's arterial stiffness. The device should also be tested in different conditions such as when the heart is stressed from exercise. Furthermore, the device should be kept inside a 3D printed container with a small extrusion to keep the device in place over the radial artery. This 3D printed CAD modeled container would be strapped on using the velcro strap.

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