

Non-Invasive Continuous Blood Pressure Monitor

A Major Qualifying Project (MQP) Report submitted to the Faculty of WORCESTER POLYTECHNIC INSTITUTE in partial fulfillment of the requirements for the Degree of Bachelor of Science in Mechanical Engineering Robotics Engineering Electrical and Computer Engineering

> Submitted By: Asha Karmen-Chan Jim Huang John Winship Sydney Cohen

Submitted to: Professor Yihao Zheng, Department of Mechanical Engineering

> Submission Date: March 24, 2023

This report represents the work of one or more WPI undergraduate students submitted to the faculty as evidence of completion of a degree requirement. WPI routinely publishes these reports on the web without editorial or peer review.

Li	st of Figures	3
List of Tables		
Abstract		
1.	Introduction	6
	1.1 Problem Statement	6
	1.2 Goal Statement	6
	1.3 Objectives	6
	1.4 System Requirements	6
2.	Background	8
	2.1 Methods of Measuring Blood Pressure	8
	2.1.1 Oscillometry	8
	2.1.2 Arterial Catheterization	9
	2.1.3 Volume Clamp Technique	10
	2.1.4 Applanation Tonometry	11
	2.2 Existing Tonometric Devices for Non-invasive Continuous Blood Pressure Monitoring	12
	2.2.1 Automatic Tonometric Devices	12
	2.2.2 Manual Tonometric Devices	13
3.	Methods	14
	3.1 Hardware Design	14
	3.1.1 Pressure Control Mechanism	15
	3.1.1.1 Pumps and Valve	16
	3.1.2 Sensor Box	16
	3.1.3 Pocket Box	18
	3.1.4 Circuit Design	19
	3.2 Equipment Selection Process	20
	3.2.1 Balloon Selection	20
	3.2.2 Air Pump Selection	21
	3.2.3 Tonometry Sensor Selection	22
	3.2.3.1 Sensing Range	23
	3.2.3.2 Resolution	23
	3.2.3.3 Sensing Surface Area	24
	3.2.3.4 Price	24
	3.2.3.5 Ease of Implementation	24
	3.2.4 Sensor Testing and Change	24
	3.3 Software Design	27
	3.3.1 Sensor Signal Filtering	27
	3.3.2 Hold-on Pressure Control Scheme	30
4.	Results	32
	4.1 Final Prototype	32
	4.2 Arduino IDE Update and Best Results	33

4.3 MGH Consultation Results	34	
5. Discussion and Recommendations		
5.1 Recommendations for Hardware	36	
5.2 Recommendations for Software	37	
6. Broader Impact		
6.1 Engineering Ethics & Societal Impact	38	
6.2 Codes and Standards	38	
6.3 Economic Factors	39	
References	40	
Appendix		
Appendix A: Application Code	44	

List of Figures

Fig. 1 C	Commercially available, Omron D-ring cuff [Omron Healthcare, 2019]	09
Fig. 2 In	ntra-arterial catheter (A-line) [American Thoracic Society, 2004]	10
Fig. 3 F	inapres volume clamp [Finapres]	11
Fig. 4 T	The T-Line Tensymeter TL100 [Smzuk et al., 2008]	11
Fig. 5 Au	utomatic applanation tonometry devices.	12
Fig. 6 M	anual applanation tonometry devices.	13
Fig. 7 P	revious Design And Prototype [Zhang et al., 2019]	14
Fig. 8 In	nitial Drawing of Sensing Scheme	15
Fig. 9 P	umps and Valve	16
Fig. 10 T	Subing Connection	16
Fig. 11 S	ensor box, internal view	17
Fig. 12 S	Sensors inside casing.	17
Fig. 13 E	Base chasing with adhesive applied.	18
Fig. 14 P	Pocket Box Inside View	18
Fig. 15 P	Prototype Circuit Schematic	19
Fig. 16 (Circuit Implementation	20
Fig. 17 A	Air pump selection	21
Fig. 18 L	Low-profile Honeywell force sensors	23
Fig. 19 I	nitial Testing of Honeywell Sensor	25
Fig. 20 S	Signal noise observed on sensor output	25
Fig. 21 S	Signal Obtained through Stabilized Sensor Test	26
Fig. 22 N	Noise Observed on Input Signal with no Load applied to sensor	26
Fig. 23 F	Frequency response of initial FIR filter design	28
Fig. 24 F	Filtering results with a running average filter	29
Fig. 25 E	Data sensor output after filtering.	29
Fig. 26 F	Frequency responses of attempted filter designs	30
Fig. 27 I	nflation Pump Control Block	31
Fig. 28 [Deflation Pump Control Block	31
Fig. 29 F	Final Assembly.	32
Fig. 30 F	Filtered Signal with potential visible BP wave	33
Fig. 31 S	Signal measured from FSS005WNSX with ideal signal amplification & filtering	34
Fig. 32 N	Noise observed in system with no sensor attached	35

List of Tables

Table 1. System Requirements**Table 2.** Pumps Testing Results

Abstract

Blood pressure (BP) monitoring is a critical parameter during anesthesia, surgery, and in intensive care units. Continuous BP monitoring provides valuable diagnostic information, but the current gold standard for continuous monitoring is the invasive arterial line (A-line). A-lines can cause discomfort for patients, and increase the risk of severe infection. The goal of this project was to develop novel algorithms and hardware with improved stability to meet the clinical need for noninvasive continuous BP monitoring. We present a proof-of-concept for a continuous non-invasive BP monitor that is mounted on the superficial temporal artery (STA). This design has several advantages, including avoidance of incisional infection, portability, and ease of installation. This report contains mechanical design, circuit design, data analysis, and recommendations for future work.

1. Introduction

1.1 Problem Statement

Continuous blood pressure (BP) is one of the most critical monitoring parameters during anesthesia, surgery, and in intensive care units (ICU). However, the current gold standard technology for BP monitoring, the invasive arterial line (A-line), causes patient suffering (physical pain) and increases the risk of infection, and current noninvasive BP technologies have poor stability.

1.2 Goal Statement

The goal of this project was to develop novel algorithms and hardware with improved stability to meet the clinical need for noninvasive continuous BP monitoring. The design process would prioritize creating an unobtrusive, wearable device, without impairing accurate BP measurements. This device is targeted towards perioperative care, for use in the ICU.

1.3 Objectives

Objectives were outlined at the beginning of the project to guide the design process. For the creation of a noninvasive, continuous BP monitor, the following objectives were established:

- Conduct a literature review on existing BP technologies. Determine gaps in application, accuracy, and continuity of monitoring associated with BP devices.
- Specify design requirements. Consider the needs of the patient and construct associated engineering requirements.
- Specify component performance parameters. Compare and select components to meet predefined parameters.
- Create a serviceable hardware prototype.
- Create a functional prototype with electrical component integration.
- Develop an algorithm that can compute pressure measurements as BP.
- Test the device to verify engineering requirements are met.

1.4 System Requirements

Design requirements were defined to guide the development of the final product. We determined the top ten patient needs, and then created engineering requirements based on the patient needs. The patient needs and associated engineering requirements were based on background research and the experience of professors that specialize in medical device design.

Each patient need is identified by an ID and followed by the associated engineering requirements, respective justifications for the requirement, and priority.

ID	Patient Need	Engineering Requirement(s)	Reasoning	Priority
PND-01	Accurate BP reading when placed approximately on the STA	BP should be measured within the 95/90 confidence reliability interval of a cuff based BP measurement.	Ensures BP measurements are accurate and meet the standard of cuff-based measurements.	1
		95/90 confidence reliability 2 mm of the STA.	Ensures BP can be measured accurately even if not directly on the STA.	1
PND-02	HCP should be able to place device near to the STA	The device should allow for placement within 2 mm of the STA.	Ensures BP can be measured accurately even if not directly on the STA.	1
		The device should have a tool that can aid with placement of the device on the STA.	Increases ease of application for HCP	1
PND-03	Ability to wear device for multiple days	Device should maintain adhesion to the dermis for 3+ days.	Reduces the number of times the device needs to be changed by the HCP.	2
		Device should maintain adhesion with up to 7 N of internal force.	Ensures the device remains adhered while hold-on pressure is applied.	1
		Device should be able to be re-adhered to the patient if adhesion breaks.	Reduces medical waste.	2
PND-04	Ability to wear device without irritation of the dermis	All surfaces of the device that make contact with the dermis should be biocompatible.	Reduces risk of irritation and patient discomfort.	2
PND-05	PND-05 Ability to maintain full range of motion while wearing the device.	Device should maintain adhesion with up to 100 N of external force applied.	Allows patients to move and rest their head without dislodging the device.	2
		All cables extending from the device should be at least 0.4 m.	Limits risk of patient accidentally tugging/dislodging device.	2
		Device hold-on pressure should adjust based on external movement/force.	Ensures BP measurement is not impaired by patient movement.	2
PND-06	Portable power supply	The device should be powered by a battery.	Reduces the number of cables in the system.	2
PND-07	Ability to wear device without visual/hearing impairments	The device should not exceed a size greater than 50 x 30 x 30 mm.	Limits the obtrusiveness of the device.	1

 Table 1. System Requirements

		Device can be placed to avoid the eye socket.	Avoids visual impairment.	1
		Device can be placed to avoid the ear.	Avoids auditory impairment.	1
PND-08	Ability to wear the device on either side of the body.	The device should be able to meet 95/90 confidence reliability on either side of the face.	Allows HCP to place device for patient comfort and minimal interference.	1
PND-09	Frequent BP readings	The device should record at least 10 BP waveforms for every 1 minute interval.	Ensures continuous monitoring of BP.	1
PND-10	Ability to wear device in hospital setting	Device electronics should not cause interference with other hospital electronics.	Interference can cause other hospital devices to record inaccurate measurements.	1
		Device should contain a maximum of two cables.	Limits physical interference with the environment.	2

2. Background

Arterial BP monitoring is critical to perioperative and intensive care medicine. Frequent monitoring of arterial BP is a mandatory practice: BP is subject to inconsistent fluctuations and abnormal BP is linked to poor operative and postoperative outcomes (commonly, myocardial and acute kidney injury) (Saugel & Sessler, 2021). Unfavorable BP can be rapidly treated and managed, hence the necessity of persistent and accurate BP monitoring in perioperative care (Meng et al., 2018).

2.1 Methods of Measuring Blood Pressure

There are two standard ways of monitoring BP in perioperative care: oscillometry and arterial catheterization. Oscillometric collection is performed most frequently because it is non-invasive. Arterial catheterization is used instead of oscillometry for high-risk surgeries and patients with illness that require more precise BP measurements. Despite standard use, oscillometry and arterial catheters have multiple shortcomings when monitoring BP. These shortcomings have prompted research in non-invasive continuous BP monitoring. The two common technologies used in these research, volume clamp and applanation tonometry, are discussed here.

2.1.1 Oscillometry

Oscillometry is the most common method of monitoring blood pressure. Oscillometric measurements are made intermittently and recorded using an inflatable cuff (Fig. 1). The cuff is

wrapped around the arm and inflated to occlude the brachial artery. Pressure is measured inside the cuff during inflation and deflation. The cuff pressure displays small oscillations, which correspond to small changes in blood volume due to pulse. Blood pressure can be measured from the amplitudes of the oscillations and the cuff pressure (Liu et al., 2016). Oscillometric monitoring is primarily limited by accuracy and intermittent readings. Oscillometric measurements are limitedly accurate. They perform effectively for normal BP ranges, but accuracy is impaired for the extreme ends of the BP spectrum (this method frequently overestimates high/low pressures, and fails to detect hyper- and hypotension) (Saugel & Sessler, 2021). Further, the accuracy of oscillometric measurements declines for patients with illnesses that cause cardiovascular irregularities, obese patients (due to poor cuff-width to arm-circumference ratio), and patients that struggle to remain motionless (children) (Roach & Thiele, 2019). The accuracy of measurements is also compromised by the intermittent readings. Because readings typically occur in three to five minute intervals (to allow the artery to recover after deformation), incidences of abnormal BP are more likely to be missed (Roach & Thiele, 2019; Saugel & Sessler, 2021). Additionally, intermittent monitoring does not supply sufficient data to document BP waveform, which limits the amount of information that can be extrapolated from the pressure reading.



Fig. 1 Commercially available, Omron D-ring cuff [OMRON Healthcare, 2023].

2.1.2 Arterial Catheterization

A-line monitoring is the gold standard of blood pressure monitoring (Fig. 2). This method utilizes an invasive transducing procedure for recording BP. The arterial catheter is placed directly into the systemic arteries and connected externally to a pressure sensor (Wheatstone bridge strain gauge) via a stream of saline. Mechanical deformation of the Wheatstone bridge changes the resistivity of the circuit, which is measured in volts. This voltage is converted to

pressure (mmHg) to give a BP measurement (Roach & Thiele, 2019). A-line monitoring has the highest accuracy of all BP monitoring techniques. The primary limitation of A-line monitoring is the invasiveness of the procedure required to place the device. This procedure requires extra time, skilled application, and introduces the risk of nerve damage, hematoma formation, and infection. Complications due to catheterization are rare but severe (Liu et al., 2016; Roach & Thiele, 2019; Saugel & Sessler, 2021).

Limitations in oscillometry and arterial catheterization have created opportunities for a new area of research: non-invasive, continuous BP monitoring. The most common methods for this type of monitoring are volume clamp technique and applanation tonometry. Both methods are able to provide valuable BP waveform information, which can be used to understand stroke volume and cardiac output.



Fig. 2 Intra-arterial catheter (A-line) [American Thoracic Society, 2018].

2.1.3 Volume Clamp Technique

In this technique, BP is measured from the finger using a clamp and a photodiode (Fig. 3). The photodiode continuously measures the diameter of the artery in the finger, and the cuff adjusts to maintain a constant diameter of the artery. Pressure is measured by change in cuff pressure. Multiple studies find that the volume clamp measurements for mean arterial pressure have a 95% confidence interval of A-line measurements (Roach & Thiele, 2019; Karim et al., 2016). However, in comparisons between oscillometry and volume clamp, volume clamp significantly increases the amount of bias in the system. Volume clamp is limited by use of photoplethysmographic (PPG) signals and patient discomfort. PPG signals can be interrupted by conditions that alter the tissues (like skin and fat) and lose accuracy for obese patients and patients with darker skin (Bent et al., 2020; Roach & Thiele, 2019). Disruption of the PPG signal impedes cuff performance, bearing inaccurate results. Cuff inflation can also cause discomfort to the patient, stemming from congestion in the venous return where the cuff is placed. For commercially available volume clamps, like Finapres (pictured), the manufacturer specifies that the cuff needs to alternate between fingers for different intervals of monitoring.



Fig. 3 Finapres volume clamp. [Langewouters, 2022]

2.1.4 Applanation Tonometry

Applanation tonometry uses a tonometer (small transducer) to detect pressure changes in the peripheral arteries (Fig. 4). This method can be performed on peripheral arteries that are on top of bone. The tonometer is used to partially applanate (flatten) the peripheral artery and record a pressure waveform (Meidert & Saugel, 2017). The radial artery is most frequently used for applanation tonometry, but applanation of the superficial temporal artery (STA) has also been studied (Jiang et al., 2020). The location of the STA (on the head) is normotensive, meaning it introduces less variation than the radial artery. In research, applanation tonometry is regarded as accurate, performing within 95% confidence of A-line measurements (Roach & Thiele, 2019). This same level of confidence has been reported for patients with known cardiovascular diseases/histories. Applanation tonometry is currently limited to clinical research. Commercial tonometers (manual and automatic) are available, but not widely adopted in clinical settings. This is partially due to the maturity of measuring algorithms and the frequency of noise artifacts (Roach & Thiele, 2019).



Fig. 4 The T-Line Tensymeter TL100. Automated wrist appliance for measuring BP from the radial artery. [Szmuk et al., 2008]

2.2 Existing Tonometric Devices for Non-invasive Continuous Blood Pressure Monitoring

Commercial devices that are validated for applanation tonometry are limited. Here, devices are considered validated by the FDA and/or the international validation registries SRIDE BP (STRIDE BP, 2023) and Medaval (Medaval Limited, 2023; Picone et al., 2020). These devices can be separated into two categories based on manual and automatic capability.

2.2.1 Automatic Tonometric Devices

Current research (Kim et al., 2021) favors the use of the HEM-9000AI produced by OMRON Healthcare (Fig. 5(a)). This device uses applanation tonometry in conjunction with an oscillometric cuff to record continuous BP measurements. Radial applanation tonometry is performed by placing the wrist on the AI Pulse Wave Measurement Unit. The unit records radial pulse, and then the AI Pulse Wave Sensor Unit (splint) can be positioned on the wrist via palpation. The cuff is used to isolate systolic and diastolic BP, which guides the tonometer in identifying a BP waveform.

Previous studies also evaluate the cuffless T-Line system developed by Tensys Medical, Inc, which is now obsolete (Fig. 5(b)). The T-Line system measures BP via a wrist splint. A tonometry sensor is encased in the splint, and two motors are used to position the sensor for optimal reading position. The T-Line system functioned without the need for an oscillometric cuff, and performed similarly to invasive arterial measurements (Szmuk et al., 2008). Like other applanation tonometry devices, the T-Line was prone to picking up noise artifacts that interfered with signal (Meidert & Saugel, 2021). Because of this interference, Saugel et al. (2012) concluded that the T-Line system could not be used as a standalone device due to high limits of agreement.



Fig. 5 Automatic applanation tonometry devices. (a) HEM-9000AI by OMRON Healthcare [Medaval], and (b) The T-Line TL-200 System (Obsolete) by Tensys Medical Inc. [Medaval].

2.2.2 Manual Tonometric Devices

Manual tonometric devices are well established in research on operative BP monitoring. Manual tonometric devices require an operator to constantly probe the device on the artery. Here, the manual devices discussed are designed for use on the radial artery. Manual radial artery tonometry can easily be taught to an operator, and can provide less discomfort for the patient (Nelson et al., 2010).

The SphygmoCor (developed by AtCor Medical) appears most frequently in literature about manual tonometric devices (Fig. 6(a)). This device is the only non-invasive continuous device cleared by the U.S. Food and Drug Administration to evaluate central aortic pressure waveform. The SphygmoCor uses a probe to palpate the wrist for a BP waveform. This probe is used in conjunction with an electrocardiogram (ECG), which guides the probe waveform by isolating heartbeats to assess pulse transit time (Butlin & Qasem, 2016; Pereira et al., 2015). This basic apparatus is sold as the SphygmoCor CvMS. Like the aforementioned tonometry devices, the SphygmoCor CvMS has a history of issues with noise and interference which can make calibration difficult (Salvi et al., 2015). A cuff-based version of the SphygmoCor is also available (SphygmoCor XCEL) which utilizes a cuff to help obtain the BP waveform (Butlin & Qasem, 2016). Multiple studies demonstrate the accuracy of the device, but the monitoring technique is limited for operative care. Because the SphygmoCor is a manual device, an operator is needed to manipulate the device during usage. This requires extra space in the operating room, and constant access to the patient's wrist.

Other manual tonometric devices available commercially include the PulsePen (DiaTecne) (Fig. 6(b)) and the Compilor (Colson). Both devices also require use of an ECG to record BP waveform (Pereira et al., 2015). The general appearance and procedure for use of these devices are similar to the SphygmoCor, and are of comparable accuracy, but they are less frequently cited than the SphygmoCor (Stea et al., 2014).





(a)

(b)

3. Methods

Development of the final prototype was separated into three categories: hardware, electrical, and software. A rough design of the device hardware was prototyped while electrical components were selected and tested. After electrical component selection was finalized, hardware designs were updated to incorporate specific component features. Software was developed for a complete functional prototype. Initial testing of the prototype demonstrated proof of concept for the design, but noise and interference were prominent in sensor readings. Software development was revised with the goal of reducing noise in the system.

3.1 Hardware Design

This project is intended to develop a non-invasive blood pressure measurement device for use with ICU patients. The main requirements are:

- 1. Small size and lightweight.
- 2. Easy and fast in installation.
- 3. No damage and serious discomfort to the user.

To achieve the above requirements, we studied past products as Figure 7 shows and articles and drew inspiration from them to come up with our design.



Fig. 7 Previous Design And Prototype [Zhang et al., 2019]

Fig. 6 Manual applanation tonometry devices.(**a**) SphygmoCor CvMS by AtCor [Medaval] and (**b**) the PulsePen by DiaTecne [Medaval]

In order to reduce the weight of the patient wearing the device to improve comfort, we decided to divide our device into two parts, sensor box and pocket box. In the sensor box, there are two sensors and a balloon. The sensor box is affixed to the target position on the patient's face by an adhesive patch which is light, small and relatively stable. The initial drawing is shown in Figure 8.



Fig. 8 Initial Drawing of Sensing Scheme

The pocket box combines every other circuit component, including two pumps, an Arduino Micro microcontroller, and the breadboard used to construct the circuit. This box should be able to be carried in the patient's pocket or placed on the table. Considering the possible noise from the pump, and the weight of the whole equipment, we found the distributed design to be more reasonable.

3.1.1 Pressure Control Mechanism

One of the difficulties of this project is to apply a stable pressure to the sensor to reduce the error due to the different hold-on pressure. In previous studies and designs, there was no real mechanism to regulate hold-on pressure. They mostly rely on the elasticity of the material and manual devices for small, unspecified quantitative adjustments. However, this project is extremely sensitive to pressure. All readings, calculations are closely related to pressure. In addition, according to Dr. Zhang's experience of the BP monitor on the wrist, the motion of muscle is a big issue in their project. The force from muscle will cause 10 times error, since the force from pulse is in a small range. To solve this issue, we decided on a mechanism to secure the stability of hold-on pressure. This design includes a balloon to generate the pressure which also can absorb some pressure from muscle in theory, two pumps, a valve, a reference sensor to determine the current hold-on pressure and tubing. The balloon would be installed above the sensors. All electronics are connected to an Arduino board to control.

3.1.1.1 Pumps and Valve

Air pumps are commonly utilized in blood pressure (BP) monitors. In the current market, the most common design is a combination of a pump and a valve. However, in our study, we opted to implement a design that utilizes two separate pumps, one for inflation and one for deflation, in order to achieve more precise control. The main difference between our design and the commonly used design is that our design creates a closed loop. With the conventional design, the amount of air released through the valve is non-linear and influenced by the pressure. As a result, when the pressure reaches a certain threshold, the valve releases air at a decreasing rate, and the amount of release becomes unknown. This, coupled with the fact that the sensor experiences a delay, can result in an over-release of air, leading to inadequate pressure. In contrast, our design does not face this problem, as the power of the pump is essentially fixed, resulting in a relatively linear input and output. This makes the implementation of our control system more straightforward, as we are able to input and output the desired amount of air. Our test results indicate that this design is easy to control and has significant potential. We did not encounter any unexpected problems during the implementation process. Figure 9 shows the pumps and valve used in our design. Since the diameters of the valve and pump are similar, we used heat shrink and super glue to address this issue, as shown in Figure 10. Further recommendations are presented in the Discussion of this paper.



Fig. 9 Pumps and Valve



Fig. 10 Tubing Connection

3.1.2 Sensor Box

The sensor box is the component that is placed on the patient's head and consists of two sensors and a balloon. As a result of changing the sensor during the research and development process, there have been slight alterations to the size and holes of the casing. Figure 11 displays the interior of the balloon. The two sensors are installed vertically in parallel, as illustrated in Figure 12 in order to ensure the tips of the two sensors are as close as possible. To achieve this, we even modified the wiring design. The BP reading sensor is activated using button one, while the top sensor serves as the reference sensor for hold-on control. Since the application of heat shrink could damage the balloon during the manufacturing process, we wrapped a thin layer of foam around the bottom of the balloon to isolate the heat. We then secured it with a zip tie and finally sealed it with heat shrink to ensure a tight seal. This manufacturing method is the most efficient and produces the smallest size.

As previously stated, the adhesive would be applied to the base. After the base has been affixed to the patient's face, the sensor would be positioned in the base. To assist in locating the artery, we designed a guide tool as depicted in Figure 13. Users can make a mark before installation. The sensor button view is illustrated in Figure 13. The base would hold the upper part of the sensor box around 1.3mm away from the skin. This design allows the sensor tips to be in close proximity to the skin without applying pressure at the initial position. Additionally, it avoids contact between the body of the sensor and the skin, which could result in calculation errors. The base and bottom of the sensor box are made of TPU. The bottom plate that holds the sensor is particularly noteworthy, being 0.5mm thick. TPU allows for minor deformation, and once the hold-on pressure is applied, the sensor tips are pushed into the skin. The soft base better conforms to the patient's face. We attempted to minimize disruptive factors and simplify the contact surface of the sensor with the skin when conducting force analysis.



Fig. 11 Sensor box, internal view.

Fig. 12 Sensors inside casing.



Fig. 13 Base chasing with adhesive applied. The left hole is marked for sampling on the artery.

3.1.3 Pocket Box

The Pocket Box was originally designed to integrate the electronics and appliances needed to reduce the weight of the devices that patients need to carry on their heads. Since we used Arduino and pumps, we divided the pocket box into two layers to separate the circuit board and the pump. The inside view is shown as Figure 14.



Fig.14 Pocket Box Inside View

3.1.4 Circuit Design



Fig. 15 Prototype Circuit Schematic.

The circuit consists of 2 primary subcircuits (Figure 15). The first subcircuit is for sensor input. The sensors used are represented in schematics as a wheatstone bridge, with the outputs passed into the analog input channels of our Arduino. The second subcircuit is the pump control circuit. The Pump Control Valve, Inflation Pump, and Deflation Pump are all connected in parallel to the voltage supply of the arduino. They are then connected in series with a WeiMeet Model RFP30N06LE N-Channel MOSFET. Each MOSFET acts as a switch in the circuit, creating a path to ground for the given branch of the circuit and allowing current to flow. The gate of each MOSFET is tied to a digital output pin on the arduino, which controls the state of the MOSFET and allows for independent control of each pump/valve. The benefits and drawbacks of this circuit design are discussed in our results and analysis.

The circuit design was tested with various microcontrollers. An implementation of the circuit with an Arduino Micro is shown in Figure 16.



Fig. 16 Circuit Implementation.

3.2 Equipment Selection Process

For the engineering process, a range of materials and electronics were tested and selected to better meet the design requirements and to keep costs within our budget. In this section, we analyze our selection process from multiple perspectives.

3.2.1 Balloon Selection

The initial hardware design incorporated a balloon into the device casing. The balloon was implemented to apply constant pressure of the tonometric sensors to the dermis. Incorporation of a balloon and pump system allowed for controlled hold-on pressure, in parallel with inflation and deflation of the balloon. We determined that the balloon selected for the device needed to fit within device casing, be biocompatible, and compliant. We evaluated three material options for balloons: a thin latex balloon (6.7 in x 2.09 in), a tough white latex finger cot (size small, 2.5 in), and an airtight fabric that could be heat sealed (Seattle Fabrics). Initial prototyping with all three options indicated the latex finger cot was the most viable option for the functional prototype. The finger cot was biocompatible (commercial product for medical use), easily fit within the hardware, and remained compliant for the degree of inflation required. The thin latex balloon was too large to function within the prototype and modification of the balloon resulted in loss of structural quality and airtightness. The airtight fabric was unsuitable for a small balloon and biocompatibility of the material could not be verified. In later stage prototyping, the finger cot was fitted to thin PVC tubing and sealed using foam, a zip tie, and heat shrink. This arrangement comprised the balloon that was later inserted into the device casing (Fig. 11).

3.2.2 Air Pump Selection

In order to meet the purpose of miniaturizing the entire device, we decided to use the smallest possible pumps to meet our needs. We ended up purchasing 5 different models from a variety retailers, for a total of 19 pumps (Fig. 17(a). The different models and dimensions are shown (Fig. 17(b-f)). Further, we have tested all models of pumps and the results are shown in the Table 2 below, with nomenclature determined by known model and profile characteristics. For the arrangement of the subsequent design, we deliberately selected a pump with both input and output ports. Based on the test results, we chose the 370 Medium Circular Pump (370 pump below), although the JSB1523018 Mini Water Pump is a great choice. The 370 Medium Circular Pump can withstand the higher pressure and offers a larger pressure range. All pumps are DC pumps. The working voltage is between 3.7V to 5V. We did extra testing for the 370 pumps. The deadband for this model is 0.95V. In principle it can satisfy fairly precise control.

b)



a)







C)





Fig. 17. Air pump selection. **a)** Representative image of all model pumps purchased. **b)** SC0801X Micro Water Pump. **c)** JSB1523018 Mini Water Pump. **d)** 310A Small Circular Pump. **e)** 370 Medium Circular Pump. **f)** 520 Large Circular Pump.

f)

Mode	Air Pressure In (mmHg)	Observations
520 Large Circular Pump	195	Fast
SC0801X Micro Water Pump	N/A	Failed to inflate
310A Small Circular Pump	28	Very slow
370 Medium Circular Pump	220+	Fastest
JSB1523018 Mini Water Pump	113	Medium speed

3.2.3 Tonometry Sensor Selection

When selecting a sensor to use in our design, we first set out to define a set of requirements for our sensor. The criteria considered were sensing range, resolution, sensor surface area, price, and ease of implementation into our system. We searched three online retailers to try to find sensors to meet our requirements. These retailers were DigiKey Electronics, Mouser Electronics, and RS (Formerly known as Allied Electronics).

Two sensors stood out to us after searching for sensors meeting our requirements on these retailers' websites. The Honeywell FSS005WNSX and the Honeywell FSG005WNPB met our technical requirements. The Honeywell FSS005WNSX Sensor is the same one used by the team

researching the previous phase of the project, so our criteria were determined roughly around the known values of this sensor. Two sensors are shown in Figure 18.



Fig. 18 Low-profile Honeywell force sensors. On the left **a**), Honeywell FS005WNSX Tonometry Sensor [DigiKey] and on the right **b**), Honeywell FSG005WNPB Tonometry Sensor [DigiKey].

After narrowing down our search to these two sensors, we began comparing them to determine which fit our criteria best.

3.2.3.1 Sensing Range

The input range of our sensor was one of our critical criteria for selecting a sensor. We needed to ensure that the sensor we used was able to handle the full range of pressure expected from normal operation of our device. We selected our desired sensing range to be 0-5 Newtons, based on the advice given to us by the team working on the previous phase of the project. This range allows for a substantial amount of pressure to be applied to the sensor by the surface of the skin without exceeding the overforce rating of the sensor.

Both the Honeywell FSS005WNSX and the Honeywell FSG005WNPB had the same sensing range of 0-5N, so no advantage was discerned between the two in this area. Both sensors were available with higher force ranges, but these higher ranges came at the cost of the next criteria, resolution.

3.2.3.2 Resolution

The sensor resolution, or measurement resolution, of a sensor is defined as the smallest incremental change in the input that can be recognized, and thus causes a change in the output. This is an important aspect of our sensor, as a poor resolution would prevent a valid signal from being acquired. Our research could not reveal a definitive value for the resolution of the FSS005WNSX, but the FSG005WNPB stated on the datasheet that it was capable of a resolution of down to 0.0098N. This provides 512 discrete values possible within our sensing range, which is only half the resolution of the Analog to Digital Converter in the Arduino Micro. Because of

the lack of information about the resolution of the FSS005WNSX, we were unable to use this criterion to decide between the sensors.

3.2.3.3 Sensing Surface Area

In order to facilitate clean signal acquisition, we wanted to make sure that the contact area of our sensor with the skin was large enough to cover the entirety of the STA.

The actuator of the FSS005WNSX is a hemisphere with a radius of 1 mm. The actuator protrudes from the surface of the sensor body by 0.375mm. In contrast, the actuator of the FSG005WNPB is a flat circular plunger with a radius of 2mm. The actuator protrudes from the surface of the sensor body by 1.33mm.

We determined that the increased surface area of the FSG005WNPB and the flat sensing surface would be better at sensing a signal when pressed against the STA. In addition, the increased height of the sensor surface above the body allows for higher tolerance when constructing our device's casing.

3.2.3.4 Price

Price was one of the most important factors in selecting a sensor. With a total budget for our project of \$1000, we quickly decided that we needed to prioritize the price of our sensor. The FSS005WNSX was \$125 from all retailers we looked at, and the FSG005WNPB was \$187. The lower price of the FSS005WNSX, especially when considering that we would have to purchase at least 2 of the chosen sensors for our final design, made it a stronger option.

3.2.3.5 Ease of Implementation

A difficult criterion to quantify was the ease of implementing each sensor into our system. The FSS005WNSX had a strong advantage in that the previous team used this sensor for their research, meaning we knew it worked as intended. Since both options we considered were close in most of the categories we considered, we decided to go with the FSS005WNSX for our initial purchase.

3.2.4 Sensor Testing and Change

When we received the FSS005WNSX sensor, we began work on testing and characterizing the sensor. It very quickly became clear that the surface mount connection required for the sensor made it very difficult to prototype with. When attempting to solder the first sensor, the size of the sensor and the pins made it difficult to get a clean connection to wires. To resolve this, we took a small prototyping board and soldered a sensor onto it. This made it easier to wire the sensor but increased the effective area of the assembly. We connected the sensor to an Arduino Mega microcontroller, and constructed a simple circuit to illuminate an LED when force was applied to the sensor. The testing status is shown in Figure 19.



Fig. 19 Initial Testing of Honeywell Sensor.

The sensor successfully gave a force reading, which was captured through Arduino's Serial Plotter. When viewing the waveform produced by the sensor reading, we noticed a significant amount of signal noise obscuring the reading (Fig. 20).



Fig. 20 Signal noise observed on sensor output.

This noise would prove to be persistent throughout our initial testing of the sensor. We believed this issue to be a result of damage to the sensor, possibly due to overheating during soldering or excessive force applied to the sensor during shipping or our initial handling of the sensor. We ordered another sensor of the same model to verify this theory.

The second sensor proved to have the same issues with noise as the first sensor. In an attempt to isolate the source of the noise, we conducted a test where we stabilized the sensor

using a table mounted vice and applied pressure with a finger. This test was intended to remove the possibility of noise resulting from movement of the sensor and any resulting disturbances.

With this setup, we were able to obtain a roughly periodic waveform resembling the pulse through the finger (Fig. 21)



Fig. 21 Signal Obtained through Stabilized Sensor Test

The signal obtained through this test still had a high level of noise, but represented the first signs of a significant signal. The noise in the sensor with no pressure applied was found to have a peak-to-peak amplitude of 5mV, roughly twice the minimum resolution of the sensor. The noise appeared to be non-periodic, though some repeating patterns were observed (Figure 22).



Fig. 22 Noise Observed on Input Signal with no Load applied to sensor.

The limited resolution of the sensor made it difficult to determine the exact magnitude of the noise. To test the effect of the noise on acquisition of a blood pressure signal, we attempted to place the sensor on the radial artery of one researcher. The heart rate of the test subject was monitored through a fitness tracker attached to the left wrist, while the sensor was affixed to the radial artery using a Velcro strap. The test subject performed several plyometric exercises to elevate their heart rate, and the signal output was observed in real time. The mean value of the signal obtained was raised due to the hold-on pressure applied by the Velcro strap, but the amplitude of the signal remained unchanged, and no pulse waveform was observed. The noise on the signal remained consistent through a range of heart rates between 50 bpm and 150 bpm. The test was repeated with the sensor affixed to various positions on the wrist of the test subject to try to obtain the strongest signal possible. All test runs resulted in the signal noise obfuscating any signal we acquired, making the results unreadable.

After concluding these tests, we reached out to our advisor and researchers in the previous phase of the project, who had used the FSS005WNSX sensor in their research, for advice. We were advised that the sensor exhibited similar issues with noise in previous research, and that it was difficult to filter out. We were advised to look into purchasing a different sensor, which would potentially provide a better reading. From our previous research into sensors, we knew that the FSG005WNPB would be a good choice for our design, and purchased 2 sensors for testing.

Upon receiving the new sensors, we began testing them in the same way as we had done for the FSS005WNSX sensors. Initial tests quickly showed that the new sensors also displayed a significant amount of noise. Without the time or budget to attempt to research new sensors, we began to try to filter the input signal to remove the noise. The details and development of our filtering process are discussed in the next section.

3.3 Software Design

This section discusses the two major components of software development throughout our research. Section 3.3.1 discusses the process we followed in attempting to filter out the noise in our sensor data and isolate a valid blood pressure signal. Section 3.3.2 discusses the development of a control system for the pressure control system we developed.

3.3.1 Sensor Signal Filtering

Cursory research and discussion with our advisors and other researchers revealed that the signal we were looking to isolate has a relatively low frequency of 1-4 Hz. The human heart beats at various frequencies depending on a variety of biological and environmental factors, but should rarely exceed values of 200bpm. This corresponds to a frequency of less than 4Hz. Although the noise we observed was not entirely periodic, it occurred at a much higher frequency than the signal we were looking to isolate. To isolate the lower frequencies in our signal, we designed and implemented a low-pass finite impulse response (FIR) filter. The first filter we used had a pass band from 0-10Hz, with an attenuation of -40dB in the stop band (Fig. 23).



Fig. 23 Frequency response of initial FIR filter design. The horizontal axis represents frequency in Hz. The vertical axis represents filter gain in decibels.

The designed filter has 21 coefficients. The filter coefficients are:

[-0.02010411882885732, -0.05842798004352509, -0.061178403647821976, -0.010939393385338943, 0.05125096443534972. 0.033220867678947885, -0.05655276971833928, -0.08565500737264514, 0.0633795996605449, 0.31085440365663597, 0.4344309124179415. 0.31085440365663597, 0.0633795996605449. -0.08565500737264514, -0.05655276971833928, 0.033220867678947885, 0.05125096443534972, -0.010939393385338943, -0.061178403647821976, -0.05842798004352509, -0.02010411882885732]

In addition to the low-pass filter, which was intended to filter noise on the signal of the data sensor, we implemented a simple running-average filter to eliminate noise on the auxiliary hold-on sensor. Since this sensor was primarily intended to give a reading of the average hold-on pressure exerted by our device on the skin, we used a strong averaging filter to eliminate any small signal from the reading of the hold-on sensor. The reading before is shown in blue, and the reading after filter is shown in red as Figure 24. The results are significantly better.



Fig. 24 Filtering results with a running average filter. (*Note: the blue line is the raw value of the sensor data, while the orange line shows the data after passing through the running average filter.*)

A test of the running average filter with a filter length of 8 showed promising results, and was able to largely diminish the effect of noise on reading the average hold-on pressure. After verifying that our running average filter was sufficient to dampen the noise on the hold-on sensor, we began testing our low-pass filter's ability to filter out noise on the data sensor. We redid the experiments we had done previously without any filtering, and observed the live graph of the results (Fig. 25).



Fig. 25 Data sensor output after filtering. (Note: Sensor was placed on the radial artery of subject with heart rate of 100 BPM)

Our tests revealed that the filter we had chosen was unsuccessful at filtering out the noise on our signal. We repeated these tests once more, this time attempting to get a signal from the STA. Neither set of tests gave us anything resembling a blood pressure waveform, and noise was consistently present throughout all tests.

We attempted several different filter designs, each with modifications to passband and stopband frequencies, filter length, sampling frequency, and stopband attenuation. Frequency



response graphs for several of the attempted filter designs are shown in Figure 26.

Fig. 26 Frequency responses of attempted filter designs. Sampling frequencies of 50 Hz and 100 Hz were designed and tested for.

None of the filter designs we attempted gave any significant results. Each signal was overshadowed by noise despite testing a wide range of filter parameters.

3.3.2 Hold-on Pressure Control Scheme

A simple Arduino script was written to control the inflation and deflation of the balloon exerting force on the back of the sensors in our sensor box. The script adjusts the air pressure in the balloon based on the value read from the hold-on sensor. If the hold-on pressure is below the lower threshold value for clean signal acquisition, the pump control valve is switched off, allowing air to flow from the inflation pump into the balloon. The inflation pump is then run at a duty cycle of 50% for 100ms before checking the value of hold-on pressure. The code is shown below in Figure 27.

```
if (holdOnSensor_filteredVal <= holdOnPressure_SPLow)
//If hold on pressure is below defined setpoint, begin inflation
{
    digitalWrite(pumpControlValve, LOW); //Divert valve to allow inflation
    if (digitalRead(pumpControlValve) == 0) digitalWrite(inflationPump,HIGH);
//Only inflate if valve is in proper position
    delay(50); //Inflate for 50ms
    digitalWrite(inflationPump,LOW);
    delay(50); //Duty cycle low
  }
  else digitalWrite(inflationPump, LOW);</pre>
```

Fig. 27 Inflation Pump Control Block

If the hold-on pressure is above the upper threshold, the pump control valve is switched on, and the deflation pump runs with the same 50% duty cycle for 100ms (Fig. 28).

```
if (holdOnSensor_filteredVal >= holdOnPressure_SPHigh)
//If hold on pressure is above defined setpoint, begin deflation
{
    digitalWrite(pumpControlValve, HIGH); //Divert valve to allow deflation
    if (digitalRead(pumpControlValve) == 1) digitalWrite(deflationPump,HIGH);
//Only deflate if valve is in proper position.
    delay(50); //Deflate for 15ms
    digitalWrite(deflationPump,LOW);
    delay(50);
  }
  else digitalWrite(deflationPump,LOW);
```

Fig. 28 Deflation Pump Control Block

While the hold-on pressure is between the upper and lower threshold, it is deemed sufficient for signal acquisition, and neither pump is enabled.

Due to our inability to acquire a clean signal throughout development, we were unable to identify a proper window of hold-on pressure that yielded the best signal, so the threshold values are not well defined. These values are easily adjustable in the code and are declared as top-level variables to allow for quick adjustments to be made. All tests conducted showed that this control scheme was able to maintain hold-on pressure between the specified values.

4. Results

4.1 Final Prototype

From the hardware level, we completed our design. It is a functional design. Although it still has improvement in size, layout, we believe it is enough to prove our concept. The sensor box, pocket box, fully assembled product, and the functional prototype are shown in Figure 29. Considering the cost and time issues, most of the casing parts are made by PLA 3D printing. In the state of use, the wearer does not feel discomfort and the device does not fall out in a small range of motion.



a)







Fig. 29 Final Assembly.

a) sensor box, b) pocket box, c) fully assembled system, d) assembled system tested on the STA.

4.2 Arduino IDE Update and Best Results

In an attempt to rule out all possibilities of software bugs, we updated the version of the Arduino IDE we were using from Version 1.8.13 to version 2.0.4. The updated version of the software brought several changes to the tools available to us, and showed some slightly improved results to our filtering attempts (Fig. 30).



Fig. 30. Filtered Signal with potential visible BP wave

We ran the same set of tests as we had with the old software, and our results improved significantly. We were able to see a waveform that closely resembled the blood pressure wave we were looking for. However, we were rarely able to see this signal, and an excessive level of noise still present made it difficult to verify if the signal we were seeing was a valid blood pressure waveform. We reran all previous tests done on the old version of the software, but we were still unable to achieve a clean signal with any consistency.

Due to budgetary constraints, we were unable to continue investigating the issues with signal acquisition. We concluded our research into our signal analysis issues by traveling to the research labs at Massachusetts General Hospital (MGH) to consult with researchers there about the issues we encountered. There, we tested our device with the same filtering and amplification setup as had been successfully used by the previous team of researchers.

4.3 MGH Consultation Results

Our consultation with researchers at MGH helped us to narrow down the possible sources of our issues with getting a clean signal from our sensors. We attempted to install each of our 4 sensors into the data acquisition system (DAQ) used by researchers there. This DAQ performed the same process of signal amplification and filtering used by our predecessors to achieve a clean blood pressure signal. Our tests revealed that the signal noise present in our system remained significant, and continued to obfuscate any reading we tried to get (Fig. 31).



Fig. 31. Signal measured from FSS005WNSX with ideal signal amplification and filtering

While swapping out sensors in between tests, we observed that even with no sensor hooked up to the system, there was still a significant presence of noise. This noise is pictured in Figure 32.



Fig. 32. Noise observed in system with no sensor attached

These tests enabled us to narrow down the list of possible issues with our system. The presence of noise when plugging our sensing circuit into an established system with signal amplification and filtering that is known to work with our sensors indicates that the issue lies with the only other difference between our system and the successful prior system: the circuit hardware used. This theory is further supported by the presence of noise in the system with no sensor attached. We observed that the research at MGH was conducted with professional equipment, most notably a dedicated DAQ and shielded signal cables. In contrast, our circuit was constructed with hobby equipment, with cheap arduino jumper cables and a breadboard for circuit construction. The modularity of these components allowed us to prototype quickly and cheaply, but seems to have severely compromised the integrity of our signal.

The noise in our system likely results from a few significant components. The quality of the wires we used to connect our sensor to our circuit was poor, and seemed to introduce enough noise alone to obfuscate our signal completely. In addition to this, we believe that passing the signal through various prototyping boards (in the case of the FSS005WNSX surface mounted sensor) and a breadboard introduces compounding noise for each stage of hardware between the sensor and the analog input pins of the arduino. The remaining hardware in the circuits, specifically the air pumps, also serve as a potential source of noise, due to the pumps being wired in the same circuit as the sensors.

Due to budgetary constraints, we were unable to test these theories to affirm our suspicions. Details of how we recommend future research proceed to avoid the issues we encountered are outlined in chapter 5.

5. Discussion and Recommendations

The issues we encountered in development of our prototype revealed many insights to us about the challenges of conducting biomedical research, and the resources and experience necessary to make such research successful. At several stages in our development, we found ourselves adopting a trial-and-error approach to identifying the source of the issues we faced in development. This method proved to be time consuming and costly, which left us unable to concretely identify or resolve the issues with the resources available to us. For most of our team, this project was our first foray into biomedical research. Our lack of experience in the field contributed heavily to our inability to determine a more systematic approach to development.

Further, we were hindered in our research by a lack of literature produced by previous researchers. The lack of literature combined with the difficulty of scheduling consultations with more experienced researchers ultimately made it challenging to determine the best way to approach issues in development. Our consultation with researchers at MGH revealed that a number of the prominent issues we experienced in our research were identical to issues encountered by previous researchers. The lack of documentation from previous researchers limited our ability to understand the issues we could expect, or the nature of the signal we were looking for.

Although we were unable to overcome the issues we encountered in signal acquisition, prior research indicates that with the correct equipment, our design could see substantial success. We believe that by documenting the issues we encountered, future researchers will be able to use our research as a launching point, and will enable them to avoid encountering the same issues as we did, and will further ensure that they are able to more quickly and reliably solve those issues if they are encountered.

5.1 Recommendations for Hardware

Future development should prioritize high-quality hardware designed for biomedical research applications. Shielded components and wires would go a long way towards removing the effect of noise from the signal. Access to a dedicated Analog DAQ would enable more precise filtering and amplification of the signal to improve signal integrity. Isolation of the sensing circuit and the pump circuit would prevent any potential noise caused by the pumps. The cheapest way to get a significant improvement would be to design and make all circuits on PCB boards. Implementing the design on a dedicated PCB can also reduce the size of the pocket box. We strongly suggest using surface-mount components to reduce the height overall and avoid broken pins.

In the further design, we suggest implementing Bluetooth capability to communicate with Arduino and battery for power supply. It would make the device more flexible and wireless. Unstable wires made trouble during our R&D process.

Regarding balloon selection, we found a waterproof fabric from a company called "Seattle Fabric." It was also used for soft robots in the Robotics Lab. However, it needs a heated press to seal the edge, which is the equipment we do not have. This kind of fabric is strong and can be easily shaped into a rectangle. We suggest trying to use it as an alternative balloon.

Regarding the pumps, we are using the model that is overqualified. We did not have enough time to test the working range we needed. As we stated above, the JSB1523018 Mini Water Pump might be a good option to try. However, the pressure it can provide is much lower than the 370 medium pumps. Besides, the tubing for the pumps and valve should be 2.2 to 3 mm in diameter. The tubing we have is 1.8 mm, 3.2 mm, and 4.8 mm.

Regarding the sensor, we consider the working range of our sensor to be good enough. However, the geometric design of the sensor tips could be improved. We were trying to find some sensors with flat tips so we would not have to worry about force analysis calculation. If the gap between the tip and the main body can be bigger, it would be better to avoid the body of the sensor touching the skin and causing the wrong force model in force analysis.

5.2 Recommendations for Software

Due to the issues encountered with signal acquisition, it is difficult to determine the effectiveness of the signal acquisition technique chosen. Further analysis on proper hardware is necessary for future development.

The pump control software seemed to operate within our expectations, but finer control of hold-on pressure might be achieved with more refined techniques. One method is a proportional-integral-derivative (PID) controller, which allows for continuously modulated control of a process variable, such as hold-on pressure. We did not research alternate pump control schemes at depth, due to the roadblocks in our design process. We recommend future teams investigate the available methods for this type of process control.

6. Broader Impact

The broader impact of our device was considered with respect to societal impact, medical device standards, and economic factors. We suggest that if commercialized, our device would have a monumental and validated effect on improving BP-related health outcomes.

6.1 Engineering Ethics & Societal Impact

The importance of BP monitoring extends beyond perioperative care. Blood pressure is a crucial physiological index that can be used to help identify (risk of) disease and augment disease outcomes (Meng et al., 2018; Roach & Thiele, 2019). In this project, we upheld fundamental engineering principles by using our knowledge to improve human welfare in the area of BP monitoring. The device we developed can be used to redefine BP monitoring in clinical (non-perioperative) and ambulatory environments. Misdiagnosis of BP-related diseases is often missed during routine physicals due to intermittent BP measurement technique and phenomena such as white coat- and masked hypertension (Franklin et al., 2013). The commercialization of a small, wearable BP monitor creates greater opportunity for ambulatory BP regulation. With ambulatory monitoring, patients are less likely to experience phenomena like masked hypertension because they are familiar with their environment (Franklin et al., 2015). The introduction of continuous ambulatory monitoring is critical because it provides healthcare providers with more information about patients BP waveform, and their cardiac health.

6.2 Codes and Standards

ISO and FDA standards were referenced in the development of the device prototype, and design control was enforced to ensure the product met users' needs. Our final deliverable demonstrated proof of concept, classifying the project within an early R&D stage. Future iterations of this project will need to more rigorously consider design control and medical device standards for commercial applications. We consulted ISO medical device standards 14971 (Risk Management), 10993 (Biocompatibility), 62304 (Medical Device Software), and 13485 (Quality Management Systems) during our device development (International Organization for Standardization, 2006, 2016, 2018, 2019). Material selections were informed by ISO 10993 and hardware designs were guided by ISO 14971. Electrical components and software development did not conform to ISO standards 14971 and 62304, respectively. These standards were considered beyond the scope of this project due to the early R&D stage and budget restrictions. Beyond the basic ISO standards, we reviewed ISO 18615:2020 which detailed standards for electric radial pulse tonometric devices (we noted that this did not include tonometric devices on the STA) (International Organization for Standardization, 2020).

If this device were to reach the market in the United States, it would be designated as a Class II device (special controls) because BP monitoring (designated for clinical use) needs to meet specific performance standards (U.S. Food and Drug Administration, 2023). Approval for this device could be sought via a 510(k) pathway, which would advocate for device approval based on previous tonometric devices that passed FDA approval (Zuckerman, 2015).

6.3 Economic Factors

Arterial catheterization is the only procedure that allows for continuous BP monitoring in perioperative care. A-line insertion requires an A-line kit (necessary equipment to assemble the system), a healthcare provider trained in A-line insertion, and operating room time. Each requirement for the insertion increases the cost of the procedure (Froehler et al., 2018; Mitchell et al., 2012; Valdez et al., 2018;). The average cost of placing a radial A-line is \$774.70 USD, but this price can increase if there are complications during insertion that necessitate additional catheters and/or additional operating room time (Froehler et al., 2018; Mitchell et al., 2012). The device we developed for this project costs approximately \$450 USD to produce. The tonometric sensors account for the significant cost of the device, priced at approximately \$200 USD per sensor. The material costs for our device are notably higher than the equipment cost for an A-line, but the overall total is lower due to lack of operating and application costs. For this project the cost of the device was not a significant factor in device design (we justified that a low risk, non-invasive continuous device would be a higher priority than an inexpensive device) and we theorize that the same device could likely be produced for a lower cost. Moreover, we specify that our BP monitor should last at least three days on the patient, but the hardware and electrical components are designed for long term use. The tonometric sensors can be used repeatedly, and the hardware design allows for the removal of the adhesive casing and the reapplication of the device.

References

- ATS Patient Education Series. (2004). Arterial Catheterization. American Thoracic Society. https://www.thoracic.org/patients/patient-resources/resources/arterial-catheterization.pdf
- Franklin, S. S., O'Brien, E., Thijs, L., Asayama, K., & Staessen, J. A. (2015). Masked hypertension. *Hypertension*, 65(1), 16-20. https://doi.org/10.1161/hypertensionaha.114.04522
- Franklin, S. S., Thijs, L., Hansen, T. W., O'Brien, E., & Staessen, J. A. (2013). White-coat hypertension. *Hypertension*, 62(6), 982-987. https://doi.org/10.1161/hypertensionaha.113.01275
- Froehler, M. T., Chitale, R., Magarik, J. A., & Fusco, M. R. (2018). Comparison of a pressure-sensing sheath and radial arterial line for intraoperative blood pressure monitoring in neurointerventional procedures. *Journal of NeuroInterventional Surgery*, *10*(8), 784-787. https://doi.org/10.1136/neurintsurg-2018-013769
- Gotzmann, M., Hogeweg, M., Seibert, F. S., Rohn, B. J., Bergbauer, M., Babel, N., Bauer, F., Mügge, A., & Westhoff, T. H. (2020). Accuracy of fully automated oscillometric central aortic blood pressure measurement techniques. *Journal of Hypertension*, 38(2), 235–242. https://doi.org/10.1097/hjh.00000000002237
- 6. International Organization for Standardization. (2006). *Medical device software Software life cycle processes*. (ISO Standards No. IEC 62304:2006). https://www.iso.org/standard/38421.html
- International Organization for Standardization. (2016). Medical devices Quality management systems — Requirements for regulatory purposes. (ISO Standards No. 13485:2016). https://www.iso.org/standard/59752.html
- International Organization for Standardization. (2018). *Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process*. (ISO Standards No. 10993-1:2018). https://www.iso.org/standard/68936.html
- International Organization for Standardization. (2019). Medical devices Application of risk management to medical devices. (ISO Standards No. 14971:2019). https://www.iso.org/standard/72704.html
- International Organization for Standardization. (2020). *Traditional Chinese medicine General requirements of electric radial pulse tonometric devices*. (ISO Standards No. 18615:2020). https://www.iso.org/standard/71491.html

- 11. Jiang, Z., Zhang, Z., Fu, Z., Shi, Y., Strangman, G., & Zhang, Q. (2020). Noninvasive continuous blood pressure monitoring via superficial temporal artery tonometry. *engrXiv*. https://doi.org/10.31224/osf.io/xvb5p
- 12. Langewouters, G. (2022, January 21). Why to choose the volume clamp method for cNIBP over other methods. *Finapres*. https://www.finapres.com/blog-7/
- 13. Tensys T-Line TL-200 Medaval. (n.d.). Www.medaval.ie. Retrieved March 24, 2023, from https://www.medaval.ie/resources/EN/devices/Tensys-T-Line-TL-200.php
- 14. Meidert, A. S., & Saugel, B. (2018). Techniques for non-invasive monitoring of arterial blood pressure. Frontiers in medicine, 4, 231.
- Meng, L., Yu, W., Wang, T., Zhang, L., Heerdt, P. M., & Gelb, A. W. (2018). Blood pressure targets in perioperative care. *Hypertension*, 72(4), 806-817. https://doi.org/10.1161/hypertensionaha.118.11688
- Mitchell, M. D., Hong, J. A., Lee, B. Y., Umscheid, C. A., Bartsch, S. M., & Don, C. W. (2012). Systematic review and cost–benefit analysis of radial artery access for coronary angiography and intervention. *Circulation: Cardiovascular Quality and Outcomes*, 5(4), 454-462. <u>https://doi.org/10.1161/circoutcomes.112.965269</u>
- Nelson, M. R., Stepanek, J., Cevette, M., Covalciuc, M., Hurst, R. T., & Tajik, A. J. (2010). Noninvasive measurement of central vascular pressures with arterial tonometry: clinical revival of the pulse pressure waveform?. Mayo Clinic proceedings, 85(5), 460–472. https://doi.org/10.4065/mcp.2009.0336
- 18. OMRON Healthcare. (2019, April 30). *OMRON D-ring small blood pressure cuff*. https://omronhealthcare.com/products/small-d-ring-cuff-hemcs24b/
- Pereira, T., Correia, C., & Cardoso, J. (2015). Novel Methods for Pulse Wave Velocity Measurement. Journal of medical and biological engineering, 35(5), 555–565. https://doi.org/10.1007/s40846-015-0086-8
- Picone, D. S., Padwal, R., Campbell, N. R., Boutouyrie, P., Brady, T. M., Olsen, M. H., Delles, C., Lombardi, C., Mahmud, A., Meng, Y., Mokwatsi, G. G., Ordunez, P., Phan, H. T., Pucci, G., Schutte, A. E., Sung, K., Zhang, X., & Sharman, J. E. (2020). How to check whether a blood pressure monitor has been properly validated for accuracy. *The Journal of Clinical Hypertension*, *22*(12), 2167-2174. https://doi.org/10.1111/jch.14065
- Roach, J. K., & Thiele, R. H. (2019). Perioperative blood pressure monitoring. *Best Practice & Research Clinical Anaesthesiology*, 33(2), 127-138. https://doi.org/10.1016/j.bpa.2019.05.001

- 22. Salvi, P., Grillo, A., & Parati, G. (2015). Noninvasive estimation of central blood pressure and analysis of pulse waves by applanation tonometry. Hypertension research : official journal of the Japanese Society of Hypertension, 38(10), 646–648. https://doi.org/10.1038/hr.2015.78
- 23. Saugel, B., & Sessler, D. I. (2020). Perioperative blood pressure management. Anesthesiology, 134(2), 250-261. https://doi.org/10.1097/aln.00000000003610
- 24. Szmuk, P., Pivalizza, E., Warters, R. D., Ezri, T., & Gebhard, R. (2008). An evaluation of the T-line® Tensymeter continuous noninvasive blood pressure device during induced hypotension*. *Anaesthesia*, 63(3), 307-312. https://doi.org/10.1111/j.1365-2044.2007.05369.x
- 25. Stea, F., Bozec, E., Millasseau, S., Khettab, H., Boutouyrie, P., & Laurent, S. (2014). Comparison of the Complior Analyse device with Sphygmocor and Complior SP for pulse wave velocity and central pressure assessment. Journal of hypertension, 32(4), 873–880. https://doi.org/10.1097/HJH.0000000000000091
- 26. Stride BP. (2023). *Stride BP*. Principles for device listing. Retrieved March 24, 2023, from https://stridebp.org/about-us/principles-for-device-listing
- 27. Medaval Limited. (2023). *Star-Rating Criteria*. Medaval Star-rating criteria. Retrieved March 24, 2023, from https://medaval.ie/resources/EN/pages/star-rating-criteria.html
- 28. Kim, H., Kim, I. C., Hwang, J., Lee, C. H., Cho, Y. K., Park, H. S., ... & Hur, S. H. (2021). Features and implications of higher systolic central than peripheral blood pressure in patients at very high risk of atherosclerotic cardiovascular disease. Journal of Human Hypertension, 35(11), 994-1002.
- Meidert, A. S., & Saugel, B. (2021). Evaluation of Devices for Measurement of Blood Pressure. Cardiopulmonary Monitoring: Basic Physiology, Tools, and Bedside Management for the Critically Ill, 273-281.
- 30. U.S. Food and Drug Administration. (2023, January 17). Code of Federal Regulations Title 21: Part 870(b) (21CFR870.1120). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=870.1120
- 31. Valdez, R., Drevik, J., Isali, I., Kutikov, A., Sindhani, M., Prunty, M., Calaway, A., Ponsky, L., Bigalli, A. C., & Bukavina, L. (2022). Pd13-07 Cost-effectiveness analysis of arterial catheter insertion on robotic-assisted laparoscopic prostatectomy. *Journal of Urology, 207*(Supplement 5), e253. https://doi.org/10.1097/ju.0=0000000002545.07

- 32. Zhang, Q., Zhang, N., Kang, L., Hu, G., Yan, X., Ding, X., Fu, Q., Zhang, Y.-ting, Zhao, N., Gao, J., & Strangman, G. E. (2019). Technology development for simultaneous wearable monitoring of cerebral hemodynamics and Blood Pressure. *IEEE Journal of Biomedical and Health Informatics*, 23(5), 1952–1963. https://doi.org/10.1109/jbhi.2018.2876087
- 33. Zuckerman, B. D. (2015, May 15). TL200 T-LineS Non-invasive Blood Pressure Monitoring System. Silver Spring, MD; U.S. Food and Drug Administration.

Appendix

Appendix A: Application Code

```
#include <FIR.h>
#define PERIOD 1667 //Define sampling period in microseconds
FIR<float, 15> fir;
                                  //Lowpass Filter for filtering signal on data sensor
FIR<float, 15> running_average;
                                  //Running average filter to eliminate noise on hold-on
sensor.
unsigned long last_us = OL; //Last timestamp in microseconds
//Name input pins
int holdOnSensor pos = A2; //Positive signal of hold-on sensor
int holdOnSensor_neg = A3; //Negative signal of hold-on sensor
int dataSensor pos = A0; //Positive signal of data sensor
int dataSensor_neg = A1; //Negative signal of data sensor
//Name output pins
int pumpControlValve = 3; //Digital pin used to control air valve
int inflationPump = 5; //Digital pin used to control inflation pump
int deflationPump = 6;
                       //Digital pin used to control deflation pump
//Hold on sensor values
double holdOnSensor_valuePos = 0; //Positive input of hold on sensor
double holdOnSensor valueNeg = 0; //Negative input of hold on sensor
double holdOnSensor_valueDiff = 0; //Differential value, true reading
double holdOnSensor valueLast = 0; //Last value of sensor
//Data sensor values
double dataSensor_valuePos = 0; //Positive input of hold on sensor
double dataSensor_valueNeg = 0; //Negative input of hold on sensor
double dataSensor valueDiff = 0; //Differential value, true reading
double dataSensor_valueLast = 0; //Last value of sensor
double holdOnSensor_filteredVal = 0;
double holdOnSensor_rawVal = 0;
double dataSensor filteredVal = 0;
double dataSensor rawVal = 0;
int holdOnPressure_SPLow = 8; //Low threshold for hold-on pressure
int holdOnPressure_SPHigh = 12; //High threshold for hold-on pressure
void setup() {
```

// put your setup code here, to run once:

```
pinMode (holdOnSensor_pos, INPUT);
pinMode (holdOnSensor_neg, INPUT);
pinMode (dataSensor_pos, INPUT);
pinMode (dataSensor_pos, INPUT);
pinMode (inflationPump, OUTPUT);
pinMode (deflationPump, OUTPUT);
pinMode (pumpControlValve, OUTPUT);
```

//Declare low pass filter coefficients

```
last_us += PERIOD;
sample();
}
```

```
}
void sample() {
    holdOnSensor_valuePos = analogRead(holdOnSensor_pos);
    holdOnSensor_valueNeg = analogRead(holdOnSensor_neg);
    holdOnSensor_valueDiff = holdOnSensor_valuePos - holdOnSensor_valueNeg;
    holdOnSensor_rawVal = holdOnSensor_valueDiff;
    dataSensor_valuePos = analogRead(dataSensor_pos);
    dataSensor_valueNeg = analogRead(dataSensor_neg);
```

```
dataSensor_valueDiff = dataSensor_valuePos - dataSensor_valueNeg;
dataSensor_rawVal = dataSensor_valueDiff;
```

```
holdOnSensor_filteredVal = running_average.processReading(holdOnSensor_valueDiff);
dataSensor_filteredVal = fir.processReading(dataSensor_valueDiff);
```

```
if (holdOnSensor_filteredVal <= holdOnPressure_SPLow) //If hold on pressure is below
defined setpoint, begin inflation
```

```
{
    digitalWrite(pumpControlValve, LOW); //Divert valve to allow inflation
    if (digitalRead(pumpControlValve) == 0) digitalWrite(inflationPump,HIGH); //Only inflate
if valve is in proper position
    delay(50); //Inflate for 50ms
```

```
digitalWrite(inflationPump,LOW);
   delay(50); //Duty cycle low
 }
 else digitalWrite(inflationPump, LOW);
 if (holdOnSensor_filteredVal >= holdOnPressure_SPHigh) //If hold on pressure is above
defined setpoint, begin deflation
 {
   digitalWrite(pumpControlValve, HIGH); //Divert valve to allow deflation
   if (digitalRead(pumpControlValve) == 1) digitalWrite(deflationPump,HIGH); //Only deflate
if valve is in proper position.
   delay(50); //Deflate for 15ms
   digitalWrite(deflationPump,LOW);
   delay(50);
 }
 else digitalWrite(deflationPump,LOW);
 Serial.print(dataSensor_rawVal);
 Serial.print(",");
 Serial.print(dataSensor_filteredVal);
 Serial.print(",");
 Serial.print(holdOnSensor rawVal);
 Serial.print(",");
 Serial.println(holdOnSensor filteredVal);
```

```
}
```