Blood Pressure Measurement Device for Low-Resource Settings

University of Michigan, College of Engineering
MECHENG 450 Fall 2015

Engineers: Jungsoo Chang
Lauren Kennedy
Caroline Soyars
Si Long (Jenny) Tou

Sponsor: Global Health Design University of Michigan
Professor Kathleen Sienko – University of Michigan Engineering

Mentors: Professor Shanna Daly – University of Michigan Engineering
Professor Turpin – Komfo Anokye Teaching Hospital
Professor Opare-Addo – Komfo Anokye Teaching Hospital
Professor Danso – Komfo Anokye Teaching Hospital
Professor Odoi – Komfo Anokye Teaching Hospital
Dr. Konney – Komfo Anokye Teaching Hospital

Blood Pressure Measurement Device for Low-Resource Settings
Executive Summary

Engineers: Jungsoo Chang, Lauren Kennedy, Caroline Soyars, Si Long (Jenny) Tou
Mentors: Professor. Sienko, Professor Daly — University of Michigan Engineering & Professor Turpin, Professor Danso, Professor Odoi, Professor Opare-Addo, and Dr. Konney, — Komfo Anokye Teaching Hospital

Hypertensive disorders are the leading cause of maternal mortality at Komfo Anokye Teaching Hospital (KATH) in Kumasi, Ghana. These patients with these disorders need their blood pressure monitored to check the stability of their condition however many blood pressure devices for low resource settings do not make this easy to do accurately. This project aims to design a way to assist healthcare providers in measuring the blood pressures of obstetrics patients every 30 minutes or 4 hours according to patients' management plans. The team compiled the device requirements while at KATH and generated many concepts in Ghana and in the US. The drivers for the design were that the device needed to be accurate, affordable, easy to operate, portable, and safe.

The final design is an auscultatory device with a microphone stethoscope and headphones to listen to the Korotkoff sounds, a hand pump for manual inflation, an automatic constant rate deflation facilitated by a solenoid valve, a LCD screen to display the current pressure, a slip-on cuff, an aneroid pressure gauge for calibration, a handle, a storage area, and a rechargeable battery. The current prototype follows the design fairly closely; however the device is not powered by a rechargeable battery and the electrical components are all on a breadboard which prevents a great deal of portability.

Nonetheless, all specification validation testing completed so far on the current prototype has been promising. Three nursing students were able to take measurements using the device that were comparable to the measurements obtained on a aneroid blood pressure gauge. However, more validation needs to be completed to confirm that this device is meeting the requirements before bringing the device in its intended setting for further validation.

The team will continue to work on this design next semester with a focus on increased portability so that the device can be brought to KATH and a focus on improved ease-of-use so that the device is accurate and easy to operate.

Table of Contents

Executive Summary ii

Abstract 4

Introduction 4

Problem Description and Background 5

Our problem definition & need statement 5

Scope of Application: 5

Blood pressure device background 5

Methods of Taking Blood Pressure 6

Blood Pressure in Relation to Gestational Hypertensive Complications 6

Existing Solutions/Benchmarks 7

Validation in Hypertensive Pregnancies 7

Available Cuff Sizes 8

Calibration 8

Durability and Lifetime Cycles 8

Power Source 9

User Requirements and Engineering Specifications 11

Obtaining Requirements 11

Translating User Requirements to Engineering Specifications 11

Scope of the Project 11

Table 2: Sorted user requirements and engineering specifications 12

Detailed Specifications 13

Concept Generation 17

Categories of Concepts Generated 17

Methods of Concept Generation 18

Individual Ideation 18

Brainstorming 18

Functional Decomposition 18

Brainwriting 19

Non-Functional Prototypes 19

Examples of Concepts Generated 19

Feature Specific 19

Holistic Concepts 22

Concept Selection 24
Selection Matrix 25
Challenges in Selection Matrix 25
Top Concepts and Designs from Selection Matrix 25
Mode to Apply Pressure 28
Mode to Release Pressure 28
Display 28
Interpretation Method 29
Attachment Method 29
Power Source 30
Portability 30
Storage and Casing 30
Calibration 30
Refining the Concepts 30
Design Iterations 32
Alpha Design 32
Beta Design 35
Mock-Ups 37
Alpha Design 37
Beta Design 38
Pressure System 40
Electrical System 41
Risk Analysis 41
Final Design 49
Auscultatory Method with Microphone Stethoscope 49
Inflation and Deflation Mechanism 50
Pressure Manifold 50
Display Design 51
Prototype Description 52
Engineering Analysis 54
Design Drivers 54
Accuracy 56
Portability 60

Easy to Use 60
Safe 64
Validation 65
Design Critique 72
Conclusion 74
Acknowledgements 75
Team Biography 76
Bibliography 77
Appendix A: Additional Criteria 77
Appendix B: Gantt Chart 81
Appendix C: QFD 85
Appendix D: Functional Decomposition 86
Appendix E: Selection Matrix – Pugh Chart 88
Appendix F: Generated Concepts from Individual Ideation 92
Appendix G: Group Generated Concepts from Brainwriting 103
Appendix H: Group Generated Concepts 104
Appendix I: Design Review 2 Presentation Summarized Feedback 109
Appendix J: Bill of Materials 110
Appendix K: Design Review 3 Presentation Summarized Feedback 112
Appendix L: Prototype Assembly Plan 113
Appendix M: Arduino Code 120
Appendix N: Design Validation Plan 127
Appendix O: Engineering Design Change Notice 135
Appendix P: Validation Data 139

Abstract

The design team spent eight weeks in the Obstetrics and Gynecology Department at a tertiary referral hospital, Komfo Anokye Teaching Hospital (KATH), in Kumasi, Ghana. During the team's immersion experience at the hospital, the team observed healthcare providers experiencing some difficulties in following obstetrics patients' blood pressure management plans. These difficulties occurred largely because of the high volume of patients in the hospital and the busyness of the wards. The patient's blood pressure measurement strongly influences the patient's treatment especially if she has hypertensive disorders. Hypertensive disorders, mainly preeclampsia and eclampsia, are the second leading cause of maternal mortality worldwide and the leading cause of maternal mortality at KATH. The team identified an opportunity for the development of a blood pressure measurement device to aid the healthcare providers in measuring the patients' blood pressures every 30 minutes or four hours according to their management plans. This project is in collaboration with clinical mentors and advisors at University of Michigan Hospital and Komfo Anokye Teaching Hospital in Kumasi, Ghana.

Introduction

More than 135 million women give birth each year and in 2013, about 289,000 women died of complications during pregnancy or childbirth. Maternal mortality ratios are the highest in sub-Saharan Africa [1].

United Nation's Millennium Development Goal 5 is to improve maternal health and set a target of reducing maternal mortality by 75% by 2015. It also wanted universal access to reproductive health by 2015. However, progress has been too slow to meet these targets [2].

As an effort to continue development in the maternal health field, the team chose to take part in an internship sponsored by Professor Kathleen Sienko to perform maternal health design ethnography in Ghana as part of a collaboration between the Obstetrics and Gynaecology Department at Komfo Anokye Teaching Hospital (KATH) Kumasi, Ghana and the Mechanical Engineering Department at the University of Michigan-Ann Arbor.

The team spent 8 weeks in Kumasi. During the first 4 weeks, the focus was on observing maternal health practices and compiling potential need statements. In collaboration with the project's sponsors, other physicians at KATH and professors at UM, one need statement was chosen to pursue as a project to continue in MECHENG 450.

While in-country, the team also began developing user requirements and engineering specifications. The methods used to elicit feedback for the development user requirements included conducting interviews and introducing sketches and non-functional prototypes with nurses, midwives and doctors of various experience levels.

Problem Description and Background

Our problem definition & need statement

During the team's two month immersion experience at Komfo Anokye Teaching Hospital (KATH) Kumasi Ghana, some difficulties were observed in following obstetrics patients' management plans in a clinical setting due to the demanding workloads of healthcare providers. Such difficulties were especially observed in the A1 High Dependency Unit where patients need to be measured more frequently due to their hypertensive disorders. Based on the observations and interviews, the following need statement was developed:

> *Design a device to assist healthcare providers in measuring the blood pressures of obstetrics patients every 30 minutes, 1 hour, or 4 hours according to patients' management plans in tertiary referral hospitals in low resource settings.*

Scope of Application: Maternal Mortality Overview and relation to hypertensive disorders Prevalence of hypertensive disorders in low and middle income settings (especially KATH)

Approximately 800 women die every day from preventable causes associated with pregnancy and childbirth [2]. Maternal deaths in developing countries account for 99% of all maternal deaths worldwide and more than half of the deaths occur in sub-Saharan Africa [2]. Excluding maternal deaths caused by pre-existing conditions (28%), the top causes for maternal mortality worldwide are severe bleeding mostly after childbirth (27%) and pregnancy induced high blood pressure (14%) [3]. The most common conditions in pregnant women where high blood pressure is a primary indicator are preeclampsia and eclampsia. At Komfo Anokye Teaching Hospital in Kumasi, Ghana, the top cause for maternal mortality is hypertensive disorders, mainly preeclampsia and eclampsia. Eclampsia is the occurrence of grand mal seizures before, during, or after delivery that cannot be contributed to other causes. Warning factors for eclampsia are high blood pressure (>140/90 mmHg) and detectable protein urine levels (>300mg/24 hours), and obstetrics patients with these symptoms are diagnosed with preeclampsia. The mechanics of preeclampsia and eclampsia are not well understood, and currently the ultimate treatment for eclampsia and preeclampsia is delivery of the baby and the placenta [4]. In obstetrics, the desired outcome defined by healthcare professionals is a healthy mother and baby. At KATH, if a preeclamptic patient's state is worsening to an unstable condition, then she has to deliver. Determining the state of a patient's condition is strongly influenced by the patient's blood pressure. Therefore, it is critical that such patient's blood pressure is measured often. At KATH, obstetrics patients with hypertensive disorders are admitted to the A1 High Dependency Unit (HDU). Depending on the A1 HDU patient's observed condition, her blood pressure could be measured half-hourly, hourly, or 4-hourly.

Blood pressure device background

Blood pressure is the measurement of the force exerted by the blood on the wall of the blood vessel. During blood pressure measurement, the patient's brachial artery is occluded and the systolic and diastolic blood pressure measurements are taken based on when the pulse returns to the patient as the occlusion is gradually decreased [5]. During the measurement, the subject must be relaxed with the measurement location at heart level. Blood pressure measurements can be taken by occluding pressure on the patient's upper arm, wrist, thigh, or ankle [6, 7]. Systolic

blood pressure is the force on the arterial walls when the heart is contracting and diastolic is when the heart is relaxed [1]. During blood pressure measurement, pulse of the patient is also taken by the healthcare worker as a part of the vital signs measurement.

Methods of Taking Blood Pressure

Auscultatory and oscillometric are the two main methods to measure clinical blood pressure, and they differ in the way to determine the the systolic and diastolic blood pressure reading [8].

Auscultatory method devices rely on Korotkoff sounds that are taken by a trained healthcare provider. When the artery is partially constricted, sounds are produced by artery vibration due to turbulent blood flow, identified by the name of Korotkoff sounds. The sounds can be picked up by the stethoscope. The 'gold standard' for measuring blood pressure is the mercury sphygmomanometer, which utilizes the auscultatory technique [6]. The mercury sphygmomanometer is universally known to be the most accurate blood pressure measurement device and it is for this reason that most manufacturers recommend that the calibration procedure involves calibrating the device against the mercury sphygmomanometer. International protocols for blood pressure measuring device validation always are in relation to deviation of measurements from the mercury sphygmomanometer method [9-11].

Systolic pressure is classified as the pressure when the first Korotkoff sound (k1) is detected. Determination of diastolic pressure, however, is more controversial, and people argue back and forth between using the muffling sound (k4) or the disappearing of sound (k5) [12].

Devices that use the oscillometric method does not use Korotkoff sounds. Instead, the pressure sensor in the cuff detects oscillation of the artery and transmits the signal to the microprocessor. The microprocessor then picks up the maximum amplitude, which always corresponds to the mean arterial pressure, and applies algorithms to estimate the systolic and diastolic value. There is not a standard or "best" algorithm, and the algorithm used differs from manufacturer to manufacturer. No healthcare provider involvement is required for the determination of blood pressure readings, and thus devices using oscillometric method can be fully automated. Ambulatory devices, which are always attached to the patient and takes blood pressure measurement automatically at regular intervals, also uses the oscillometric method [8, 13].

The auscultatory method has been traditionally preferred for clinical blood pressure measurement for its accuracy. However, in recent years, the reliability of auscultatory devices has been called into question. Mercury is toxic and is not recommended in medical devices. Also, the accuracy of auscultatory devices are subjected to the white coat phenomenon, reaction time, and training level of the healthcare provider [14, 15]. It is also worth noting that previous research has shown that the oscillometric method does not provide accurate reading for patients with preeclampsia due to vascular damage [16]. However, recent clinical trials and validation indicate that an adjustment in the algorithm can improve the accuracy of the oscillometric blood pressure device across the preeclamptic population [17]. For the purpose of the project, a successful device would be one which accuracy is specifically validated on ob/gyn patients.

Blood Pressure in Relation to Gestational Hypertensive Complications

Preeclampsia and other gestational hypertensive disorders currently have no known cure or etiology of the disease. For preeclampsia, the only cure includes delivery of the placenta which

does not guarantee its cure as preeclampsia and eclampsia may be developed after delivery [18]. High blood pressure is one of the symptoms of such gestational complications, and its monitoring is crucial in informing the healthcare providers of the patient's progression with the disorder in order to ensure the health of the mother and the baby.

Existing Solutions/Benchmarks

There are currently two different kinds of devices that are used in KATH. The more commonly used and available device is the Accoson Dekamet mercury sphygmomanometer, which uses the auscultatory method [14]. Safety is the main concern with the mercury sphygmomanometer, as mercury is dangerous to handle and thus not recommended by WHO. In addition, the device depends on the user's skill in the auscultatory method [19]. The other device, Omron BP710CANN, is fully automatic [20]. The problem associated with the device is that battery life is not sufficient for the extensive usage in ob/gyn wards, and healthcare providers expressed during interviews that measurements are inaccurate when low battery. The fundamental reason is that Omron BP710CANN is actually designed for home-use in high-resource settings, instead of in a low-resource clinical setting.

Outside KATH, there are many gaps that exist in the blood pressure device market when considering the devices that available for use in high income settings, low and middle income settings, and in ob/gyn settings. Table 1 provides an accurate depiction of the technical specifications and features of commercialized blood pressure devices.

Validation in Hypertensive Pregnancies

One gap that exists is that most devices are not validated to be used for hypertensive and preeclamptic pregnant women. Of the devices that have been validated across hypertensive and preeclamptic pregnant women, the majority are intended for use in high-resource settings and are therefore too expensive to be used in low and middle income settings. An example of such a device in Table 1 is the OMRON-MIT which is validated across preeclamptic populations yet costs €189. There is currently one device, the Microlife 3AS1-2, that is recommended by the WHO for use in low-resource settings and across preeclamptic patients [19]. Another commonality across many blood pressure devices is that many have been validated across normotensive pregnant populations but do not meet the standard for accuracy in preeclamptic populations [16]. This is most likely attributed to the fact that these devices use the oscillometric method, which without correction, has been shown to be an unreliable method of measuring blood pressure in sub-populations with vascular damage, like women with preeclampsia.

For cases of hypertensive pregnancy, recent studies have shown that auscultatory hybrid sphygmomanometers are more comparable to the gold standard mercury sphygmomanometer than automated, oscillometric methods [21]. However, the market size for this type of blood pressure device is underexplored, as seen in Table 1, since the only device that is recommended for use in low resource settings that also utilizes this method is the Accoson/Greenlight 300. It is important to note, however, that the cost of the Accoson/Greenlight 300 (€ 136) is well over the recommended cost of a device that is intended to be used in low and middle income countries. Another alternative to the mercury sphygmomanometer is a non-toxic column sphygmomanometer which uses an air chamber at one end of the tube and a liquid chamber at the other end. It is currently patented but yet to be commercialized [22].

It is reasonable to assume that most companies favor the development of entirely automatic devices, because users view them as easier to use while eliminating user bias. However, as previously mentioned such devices that are completely automated can oftentimes be inaccurate for cases such as hypertensive pregnancies. For this reason, the development of devices that utilize the auscultatory hybrid sphygmomanometer method should be considered. There is also a patent on integrating the manual device and the electronic device in one single enclosure, allowing the healthcare providers can crosscheck results between the aneroid and the LCD screen where the blood pressure is determined through the oscillometric method [23].

Available Cuff Sizes

With the exception of the Suntech247 ($567 USD), Table 1 shows that all benchmarked blood pressure devices only include one cuff size. Additional cuff sizes are usually available but must be purchased separately. Of the devices that only provide one cuff with the blood pressure device, the Accoson Dekamet Sphygmomanometer is the only device that can accommodate patients over a wider range. However, this device is a mercury-based device and therefore is cause for safety concerns. While there are patented designs for universal blood pressure cuffs, there is yet to be a device that uses a universal cuff that is also recommended for use in low and middle income countries [24]. Because the cuff size is critical to ensure measurement accuracy, there is a need to create a device that has a blood pressure cuff that is both cost effective and accurate across all patient sizes.

Calibration

Another significant gap in the market is that the calibration method for most commercialized devices is complex. While the WHO stipulates that manufacturers should provide a simple methodology to check calibration, almost all devices on the market require the user to send the product back to the manufacturer when calibration is needed [19]. This is the case for both the Omron HEM-SOLAR and Microlife 3AS1-2 as both devices do not provide a calibration method but instead state that the device should be sent back to the manufacturer every two years. Even though both devices are recommended for use in low-resource settings, it is not appropriate that these devices need to be sent away indefinitely in order for them to be calibrated. Most maintenance centers are located in either in the United States or in Europe, which makes calibration in low-resource settings even more difficult. The WHO also recommends that the calibration of blood pressure devices for low resource settings should not require any additional tools or equipment [19]. For devices that do provide instruction on calibration, such as the Suntech247 in Table 1, the standard is that an additional calibration kit needs to be purchased separately. Calibration kits typically include a T or Y-shaped connector to connect to a calibrated pressure reference such as the mercury sphygmomanometer. The lack of simple calibration methods for the blood pressure devices currently on the market reveals the need for devices that can be calibrated in a simple and straightforward way.

Durability and Lifetime Cycles

In addition, it is important to note the discrepancies that exist within the market relating to durability and number of lifetime cycles of existing blood pressure measurement devices. This is particularly important to consider when assessing low cost automatic devices, since such devices are typically targeted for at-home use and therefore are not robust enough to withstand heavy clinical use. For instance, Table 1 shows that the battery life of the Omron BP710CANN (the automatic device that was used at KATH) is 1000 measurements while the cost is around 40

USD. As a comparison, this only a fraction of the WHO recommendation of 10,000-20,000 lifetime cycles and this projected battery life could also only withstand about four days of use in KATH when considering the number of patients on the wards and the frequency at which blood pressure is being monitored for each hypertensive patient. In addition, Table 1 shows that the Omron/Hem-SOLAR, which is WHO recommended for use in low and middle income countries, can only sustain for 280 measurements when operating purely on solar power. The discrepancy between the battery life of blood pressure measurement devices that are used or recommended for use in low resource settings in comparison to the WHO recommendation reveals the need for blood pressure devices that can withstand a greater volume of uses.

Power Source

There is also a gap in the market when considering blood pressure measurement devices that utilize alternative power sources. The most common sources of power for automatic devices (including device used in KATH) are replaceable batteries. All automatic devices that were observed to be used in KATH are also battery powered. While a large amount of measurements can be taken using one set of batteries, the accuracy of devices that use this source of power diminishes after the long-term and frequent usage that occurs when used in a low and middle income clinical environment. In many low and middle income countries, batteries can also be unaffordable or inaccessible. Such limitations to portable energy storage reveal the need to explore other modes of harvesting energy, such as ambient energy from solar loads, wind loads, thermal gradients, or mechanical vibrations in structures [25]. Currently the Omron/HEM-SOLAR is the only device available that is both recommended by the WHO and also uses solar power. However, the device takes 30 hours of continuous charging to be fully charged on a sunny day and 600 hours of continuous charging to be charged if no sunlight is available. This is a substantial limitation when considering the demand for the device in low-resource clinical settings and for this reason it is necessary to consider the development of blood pressure devices that utilize multiple alternative energy sources. One such alternative energy method that has been recently investigated is the harvesting of vibration energy using piezoelectric materials [25]. While such approaches have been shown to provide ample power generation for use in a blood pressure measurement device, there are currently no commercialized devices that use this method.

Table 1: Existing Solutions/ Benchmarks

	Company/ Model	Measurement Method		Clinical Validation for Accuracy				Display	Recommended Calibration Frequency	Power Source	lifetime/ charge	Price	Cuff Sizes	
		Auscultatory	Oscillometric	ESH	BHS	AAMI	Validated in Preeclamptic Population*						Included	Optional Purchase
High Resource Settings	OMRON-MIT [26, 27]		✓	✓		✓	✓	LCD numerical	2 years	4 AAA batteries	300 uses	€ 189	22-32cm	32-42cm
	Suntech247 [26]	✓	✓		✓	✓		LCD numerical	2 years	Rechargeable battery	200 measurements	$567	23-33cm; 31-40cm	17-25cm
Low-Mid Resource Settings	Accoson Dekamet Sphygmomanometer [28]	✓						Mercury column	Not Available	Completely manual		£ 80 - 100	<=42cm	
	Accoson/ Greenlight 300 [29]	✓		✓	✓	✓		LCD aneroid-style	4 years	4 AA batteries	170 hours of continuous use	€ 136	<=34.3cm	<=42cm; <=48.2cm
	MicroLife / 3AS1-2 [30, 31]	✓	✓	✓	✓	✓	✓	LCD numerical	2 years	2 AAA batteries	1000-1500 measurements	€ 20	22-32cm	32-42cm
	Omron/ HEM-SOLAR [32]		✓	✓				LCD numerical	2 years	2 AAA batteries	1500 measurements	€ 25	22-32cm	18-23cm; 33-43cm
										Rechargeable battery (by AC or solar)	280 measurements			
All Settings	Omron BP710CA [33]		✓	✓		✓		LCD numerical		4 AA batteries	1000 measurements	$40	22-32cm	32-42cm
	Diagnostix™ 703 [20]	✓				✓		Aneroid	2 years	Manual	50,000 cycles (completely manual)	$36-60	choose one from the sizes on the right	19-27cm; 23-40cm; 34-50cm

* Only applicable to non-invasive, automated blood pressure device

User Requirements and Engineering Specifications

Obtaining Requirements

The user requirements for the project were developed based on the two month observational period at KATH. Interviews were conducted and sketch and prototype responses were solicited from doctors, midwives, nurses, and technicians. Based on these interviews, benchmark analysis, standards and literature search, and the advice from our sponsor in Michigan, the team developed a preliminary list of user requirements and engineering specifications. The heads of the ob/gyn department at KATH were asked to categorize high, medium, and low priority requirements to understand the priorities of the user requirements. Based on the three in-depth interviews with the heads of the department, the user requirements were ranked.

Translating User Requirements to Engineering Specifications

The user requirements were made into engineering specifications through interviews using sketches with concepts or demonstrations of non-functional prototypes, benchmarking, and standards search. User requirements with vague definitions were further inquired for the team to fully understand what such terms actually meant in terms of engineering specifications. For example, interviewees often stated that they wanted a device that was "easy to use," which had various meanings. Through further interviews, it was determined that "easy to use" encompassed short procedure time, minimal number of steps, readable measurements, and portability. Table 2 below shows the list of user requirements and their respective engineering specifications. The list of user requirements are being continuously modified based on feedback from the stakeholders and findings from literature research. Additional criteria based on the interviews with the KATH stakeholders were included in Appendix I; these were separated into an objective criteria and a luxury criteria. This additional table allows the design to have flexibility in the solution space while keeping in mind the objectives.

Garvin's eight basic dimensions of quality helped in identifying what gaps there may be in the identified user requirements and engineering specifications [34]. The standards of performance, features, reliability, durability, serviceability, and conformance were used to identify the types of the user requirements. This process allowed in seeing what dimension for design quality may be missing in the user requirement.

Scope of the Project

Based on the observations and interviews with the stakeholders, it was identified that the device's main function is to assist healthcare providers when checking patient blood pressure. This defined the scope of the project; the blood pressure device is intended to take discrete measurements and to be used in KATH in addition to other tertiary referral care settings. The blood pressure device, as it takes discrete measurement, will not include any invasive blood pressure measurement methods.

Table 2: Sorted user requirements and engineering specifications

	User Requirements	Engineering Specifications
High	Accurate	The average difference between mercury sphygmomanometer measurements must not exceed a mean difference of ± 5mmHg and standard deviation of 8mmHg for both diastolic and systolic blood pressure measurements. Measuring range of 0-300mmHg Must not exceed ± 3 mmHg for cuff vs. display pressure
	Affordable	Cost ≤ $75 per device
	Short Procedure Time	Time necessary for the entire procedure < 3 minutes
	Appropriate Use	Use in KATH and other tertiary referral care settings for in-patient care Discrete measurements Device allows the nurses and midwives to take blood pressure measurements on time for 40 patients, with 2 to 6 patients needing measurements every 30 minutes and the rest being measured every four hours.
	Durable	Operational temperature between 10-40°C Can be stored at temperatures up to -20 to 60°C (storage) Accurate at up to 85% humidity RH (operational) Can be stored at up to 90% humidity RH (storage) Satisfy the 1 m drop test Satisfy the vibration test Satisfy the markings test for wear ~240 number of cycles per day for lifetime in years >1 years unit life
	Safe	Be able to disengage in <10 seconds Pressure applied should not exceed 300 mmHg Pass the CFR 1500.49 Test for Sharp Edges Hazard numbers for health, flammability, and reactivity should be 0
	Power Source	Primary mode of power can withstand 120 uses per charge cycle
	Accommodates various patient sizes*	Device accommodates 5th to 95th percentile of pregnant women in low-resource areas (when of childbearing age)
	Portable*	Device does not require two hands to carry < 19 cm (width) by x cm by 32 cm (length), < 2.8 kg
Medium	Minimal Steps	No more than two actions simultaneously required of the user during the procedure using mercury sphygmomanometer functional decomposition as reference. < 12 steps (team defined mercury sphygmomanometer steps) including set up and break down (take off and pack) once device is obtained

	Readable Measurements*	3:1 minimum symbol contrast Symbol width-to-height ratio is between 0.5:1-1:1 Strokewidth-to-height ratio is between 1:12-1:5 Spacing between adjacent symbols are separated by at least one strokewidth Spacing between lines of symbols is at least two strokewidths Button diameter is at least 10mm Spacing between buttons is at least 13mm Visual angle is between 10-60
	Easy to calibrate	Calibration time <30 minutes by technician in tertiary referral setting using a Y/ T-tubing calibration method available in-country No more than one calibration necessary per year unless breaking and then need to calibrate it once repaired
	Short Training Time	<15 minutes of instructional period required for users to learn how to use the device
Low	Easy to clean	No additional disassembly from setup or storage mode needed to disinfect the device <30 seconds of cleaning time necessary to clean parts in contact with patient and user, clean with material commonly found in ward (spirit: 83.3% ethanol) using two hands
	Easy to Maintain	All parts are accessible in Ghana All parts can be independently replaced
	Minimal Additional Equipment	No more than 1 additional pieces of equipment required for procedural use

* Additional research required

Detailed Specifications

Accurate: In order to provide proper care and to prescribe appropriate management plan to patients, the blood pressure measurement must be accurate. Patient management plans differ vastly based on the blood pressure differences. Based on the interviews with the doctors, midwives, and nurses, they wanted a device that allows them to measure both the diastolic and systolic blood pressure accurately. Currently, FDA requires that a blood pressure device must pass the Association of the Advancement of Medical Instrumentation (AAMI) SP10 standard to be commercialized and sold legally in the United States. AAMI-SP10 states that in order for a device to be validated, the average difference between the candidate device and the mercury sphygmomanometer measurements must not exceed a mean difference of ± 5 mmHg and standard deviation of 8 mmHg for both diastolic and systolic blood pressure measurements [9]. Other common protocols to validate the accuracy of blood pressure device that may be requested by some customers include the BHS standard and the ESH standard [10, 11]. The accuracy range was set between 0-300 mmHg based on benchmarking and interviews with stakeholders. Interviews with different nurses and midwives at KATH indicated that blood pressures may go up to 270 mmHg for systolic blood pressure. As the occlusion must continue until 30 mmHg above when the brachial artery is occluded, it would be important for the device to be accurate up to 300 mmHg. Additionally, another uniform specification across blood pressure measurement devices is that the display accuracy must not exceed a difference of 3 mmHg from

the cuff. The measurement accuracy standards were derived based on benchmarking of accuracy range of other blood pressure devices currently available on the market [28-31].

Affordable: Affordability is a crucial element in implementing medical devices in low-to- mid resource areas. The calculated cost of less than or equal to $75 per device is based on the following method: $\frac{(Upper\ bound\ of\ current\ device\ price)*(3\ devices\ per\ ward)}{The\ total\ number\ of\ wards\ (5)}$

Interviews with the business manager for the ob/gyn department in KATH revealed that the current device used in the wards costs from $87.50 to $150[1]. In each of the ob/gyn ward, there were three new sphygmomanometers purchased every year. Using this information, the total money allotted to each ward for blood pressure device was calculated. Provided that each ward receives three new devices instead of one current device per year, the $75 was set as an upper limit in order to provide enough devices for each ward. The optimal number of devices per ward was decided to be five devices per ward based on interviews with healthcare providers, which allows each medical team one device per ward. The current head of the ob/gyn department also stated in interviews that he would want a device that is less than $75, with 300 GHC being the upper bound of price.[2]

Short procedure time: Initial interviews with the stakeholders revealed the requirement of the device being "easy to use." Further inquiries revealed short procedure time as a requirement within the easy to use requirement. In the ob/gyn ward in KATH, it was observed that there were between two to six patients that required frequent 30 minute blood pressure measurement in the A1 high dependency unit. In addition, each patient on the ward requires a vital check every four hours. There are maximum 40 patients on the ward that must be checked at this frequency level which is why it is important that the device does not require much time to operate. Based on observations of healthcare providers measuring blood pressure with the current method (mercury sphygmomanometer), an upper bound of three minutes was set for the entire procedure time. In addition, in each ward there is usually one midwife taking the four-hourly measurements even though there are other blood pressure devices available.

Appropriate Use: Appropriate setting and exact intended use for blood pressure devices are crucial for low resource setting device development, as not every device can adequately cater to the needs of this setting. The primary setting and capacity in which these devices would be used would be Komfo Anokye Teaching Hospital, or other similar tertiary referral care settings, where ob/gyn wards each hold a maximum of forty patients. Based on the problem statement and the observations in-country, the intent of this blood pressure is to aid nurses and midwives in taking blood pressure measurements on time for the patients on the ward. Currently observed practice in KATH was a 30-minute interval measurement for patients in HDU (2-6 patients usually) and the rest requiring four-hour interval measurements. In addition, based on the interviews with doctors, midwives, and nurses, it was decided that the blood pressure devices needs to be able to be used across all patients in order for it to be accepted. While the idea to design a continuously monitoring blood pressure device was suggested, the need for an affordable device that can be used across all patients were seen to be more important by the stakeholders.

[1] Calculated by 350-600 GHC given price range with an exchange rate of 1 USD = 4 GHC

[2] Current exchange rate is around 1USD = 4GHC

Durable: Durability is important in conjunction to maintenance and affordability for the device to function well for everyday use in a clinical setting. When benchmarking blood pressure devices currently on the market, it was found that storage temperature and humidity was differentiated from operational temperature and humidity [28-31]. Based on the current blood pressure devices available in the market, the engineering specifications were set similarly to those of devices currently in the market [28-31]. The recommended standard from WHO for low resource setting devices was used for the provided standard [19]. Calculations for the lifetime and years were also done based on KATH observations and interviews. The number of blood pressure measurements per battery life (automatic devices) or per lifetime (manual devices) was calculated based on the number of maximum patients in the ward undergoing the four-hour vitals check management plan. It was calculated that the device would need to sustain around 240 cycles of usage per day in the ward if only one device was being used. Based on this number and the WHO qualification that a device must withstand 10,000-20,000 cycles in the lifetime [19], it was calculated that a device that meets the usage requirements across both sources would be able to last for one year.

Safe: As blood pressure measurement devices are used on patients, the devices must be safe. Safety standards were derived based on ISO standards [35-39]. Surfaces in contact with the patient should not cause any injury or harm to the patient. The device should be able to be quickly disengaged in order to reduce the possibility of injury. The disengagement time was set at 10 seconds, which means that the pressure applied to the patient should be able to be released to zero in 10 seconds. Based on the benchmarking results, current devices in the market did not apply pressure greater than 300 mmHg, so the same protocols were followed. In addition, hazardous materials were decided to not be included on the device for patient safety. Hazardous materials was quantified using National Fire Protection Agency (NFPA) Hazard Diamond. This also takes into consideration the use of mercury blood pressure measurement devices; based on WHO and European Society of Hypertension (ESH) recommendations, devices should not include mercury components for the safety of the user and the patient. In addition, mercury is not environmentally safe to attain [19, 35-39].

Reliable Power Source: In order for the solution to be implemented in a high volume clinical setting, it needs to have a reliable power source. This need was expressed by users as current methods are either entirely mechanical or require replaceable batteries that cannot withstand an adequate amount of uses per battery life. A reliable power source is defined as being a mode of power that is easily accessible to the target setting and can also withstand a long duration of time before a regenerative power source is needed. Because the device needs to withstand around 240 uses per day in order for it to be considered durable, it was determined that the primary mode of power should withstand 120 uses per charge cycle given that there will be at least two devices within the ward.

Accommodates various patient sizes: The device should accommodate to patient's size for accurate pressure readings. Currently used mercury sphygmomanometer in the wards do not accommodate patients of all sizes: the attachment piece on patient is in a form of a cuff on the patient's upper arm. The upper arm has a wide range due to varying patient sizes. Improper fit of the current cuff method can be a source of inaccurate blood pressure readings, leading to over or underestimation of blood pressure. Based on the interviews and prototype presentation with stakeholders in KATH, the overall consensus was that a device that would accommodate women of various sizes would be most ideal. Additional parts of the device catering to different sizes

were seen as unnecessary by the stakeholders. In order to address this user requirement, the device should accommodate pregnant women in the 5th to 95th percentile to allow 90% of potential users receive accurate measurements.

Portable: As these blood pressure measurement devices must be carried from patient to patient, the user should be able to carry the blood pressure measurement device with ease. Based on the interviews and prototype feedback with stakeholders, it was understood that stakeholders did not want a device that requires two hands to carry, as most have additional paperwork or other medical equipment to carry to the patients' bedsides. As the blood pressure measurement devices must be taken to patients' bedsides, devices should be able to fit on patients' beds when the patients are lying down. Many healthcare professionals thought the length of the mercury sphygmomanometer was a good length and couldn't be much longer if they were to hold it in 1 hand. Thus, the maximum length was set to 32 cm. The maximum width was set by the cereal box mock-up. The healthcare professionals responded to it saying that it would be preferable if it wasn't as wide and it was longer. Thus, this width was established as the maximum with at 19cm.

Minimal Steps: The current method used in KATH requires the user to listen with the stethoscope for the Korotkoff sounds while simultaneously controlling the valve to ensure constant deflation and watching the mercury bar and meniscus for measurement. When design feedback was elicited using drawings and prototypes, stakeholders liked designs that required less simultaneous actions. The observed number of steps for the mercury sphygmomanometer was calculated to be twelve steps including the setup and breakdown of the device, so 12 steps was set as an upper bound for number of steps required to measure blood pressure with the device.

Readable measurements: The current method of measurement using the mercury sphygmomanometer requires the user to read the mercury meniscus level, which are indicated with tick marks; during interviews, midwives and nurses expressed difficulty in seeing the meniscus and measurement of the mercury, especially when the patient is lying down. In addition, having to read the meniscus causes the user to estimate and/or round the numbers because the values are user determined. This can lead to over or under-estimation of the patient's actual blood pressure. Readability of measurements in the context of this design will focus on the dimensions of the symbols and buttons that are used on the display, and the spacing between those different features. The readability of the measurements is also based on the visual angle at which the user views the measurements.

Easy to calibrate: Calibration is important in maintaining device accuracy. Based on the interviews with the head of the ob/gyn department and the biomedical engineering department at Komfo Anokye, it was determined that no more than one calibration should be necessary per year unless the device breaks and needs to be calibrated after repair. In addition, the current method of calibration requires that biomedical technicians borrow a calibration kit from an outside source. It was stated that the process of obtaining such equipment takes a long time which prevents blood pressure devices at KATH from being calibrated up to the requested standard. The specifications were set in order to address these concerns, using the current method as the upper limit.

Short Training Time: For the device to be easy to use, one of the component was that the device should require a short training time. Based on interviews with house officers, nurses, and

midwives, the overall consensus was that the current measurement method with the mercury sphygmomanometer required around 15 minutes of instruction time for people to learn. The time required for the current method was set as the upper limit for the engineering specification.

Easy to clean: Just in case the patient is bleeding or has infection possibilities, the device, especially the portion in contact with the patient, should be able to be cleaned with the equipment available in the ward. Due to the busyness of the ob/gyn wards in KATH and to minimize parts from going missing, the engineering specification was set so that no additional disassembly was necessary for cleaning. Interviews from nurses and midwives also provided insight into the maximum time they would be willing to spend in cleaning the device, which was 30 seconds. It was observed that the fluid that was used by midwives, nurses, and doctors to clean equipment contained 83.3% ethanol. For this reason, the design should also be compatible with this cleaning method.

Easy to maintain: In KATH, there was a biomedical engineering department that fixed all the medical equipment. Due to costs and the budget, additional parts for equipment are often difficult to attain if they are not produced in Ghana.

Minimal Additional Equipment: In a large hospital with many patients in one ward such as KATH, it is difficult for healthcare providers to seek out additional equipment for a procedure. When considering the current mercury sphygmomanometer method, midwives and nurses oftentimes have to search for a stethoscope in order to take a patient's blood pressure. In KATH, there is typically only one stethoscope provided on each ward. The need for midwives, nurses and doctors to find a stethoscope ultimately lengthens the overall time it takes to use the device. In order to reduce the amount of time that it takes to look for equipment, it would ideal that the device to not require any additional equipment. However, since the currently accepted standard requires one additional piece of equipment, this is the criteria that needs to be met in order for the device to be used.

Concept Generation

Over one hundred concepts were generated during the scope of this project in attempt to explore the entire solution space before making any selections. Many categories of ideas were generated using many different concept generation techniques.

Categories of Concepts Generated

The team tried to explore the whole space of our need through the generation of diverse concepts so that the team was well-informed of the different design possibilities when making the final design selection. Noninvasive methods for measuring blood pressure were explored as well as invasive methods, such as a pressure sensor that is injected into the blood vessel (Appendix G). The team tried to generate concepts even if they were not as feasible as others, such as the idea that a bacteria could be injected into the patient's artery that would lyse and change color at different pressures (Appendix G). Concepts also varied in their level of automation, type of inflation, type of deflation, method for portability, method for measuring pressure, method for power supply, way to detect a change in blood flow, and way to obtain the blood pressure measurement among other things. As an example, ideas were generated to obtain the final blood

pressure measurement by having lights flash when the current pressure was at the systolic and diastolic values, by having the user press a button when he or she detected the systolic and diastolic values to freeze needle heads pointing at those values, or by having the reading appear on a screen at the end of the procedure (Appendix G). Probably one of the most notable of areas where the team generated and presented many ideas to clinicians and midwives was portability. Concepts that were presented include devices with suitcase handles, with necklace pieces, and with a handgrip built-into the device (Appendix I).

Methods of Concept Generation

To get diverse concepts, the team used many different methods of concept generation.

Individual Ideation

In Ghana and in Michigan, the team performed individual ideation sessions. Team members encouraged each other to use pieces of paper or sticky notes to draw out ideas. Each individual each spent 30 minutes to an hour generating concepts. The location and time of day in which individuals generated concepts were varied to help with the creativity of ideations. On some occasions, the goal of the individual ideation would be to generate any concepts that came to mind and other times the focus was on specific subfunctions of a device like the pressure application method. After individual ideation, members then came together and shared generated ideas to the rest of the team.

Brainstorming

When sharing the concepts generated during individual ideation, the team organically began brainstorming. One member's idea sparked an idea from another member and each member was in charge of recording her ideas on paper so that there was record of them. Sometimes, the team also tried to synthesize ideas from different members so that there were some complete device concepts with promising features.

Functional Decomposition

Functional decomposition list and diagram (Appendix E) were generated to break up the tasks the device and the users were required to perform. In order to understand the steps required for blood pressure measurement, literature research and observations on the current method were conducted in Ghana. The created functional decomposition was focused on how the noninvasive blood pressure method is done; as previously stated, because the project scope is to design a new device to fit KATH settings, invasive blood pressure methods were deemed inappropriate. The generated functional decomposition was catered more towards identifying the actions the user would perform in contrast to what the device is performing. This direction was taken as it was determined that a blood pressure device required many user inputs, especially for the auscultatory method. Because the oscillometric method and auscultatory method had distinctly different ways of measuring systolic and diastolic blood pressure, it was difficult to group these steps specifically.

The steps and categories in the functional decomposition were geared towards identifying and targeting user requirements. The functional decomposition aided in generating concepts that were not originally thought of during individual ideations. The category of generating pressure

on the patient to occlude blood flow and detecting systolic and diastolic categories were of ultimate focus during concept generation.

Brainwriting

After multiple individual ideation and brainstorming sessions, the team conducted a brainwriting session so that team members could build off of the ideas of each other. This method involved each team member first sketching her own idea, and then passing the sketch to the next team member. The next team member was then tasked with changing one feature on the original design before passing it to the next teammate. This ideation method was successful because it prevented team members from being fixated on their own idea. Concepts generated can be seen in Appendix H.

Non-Functional Prototypes

To facilitate conversation with stakeholders and elicit further information, the team created three non-functional prototypes from three diverse design concepts in Ghana. The three concepts experiment on different ways to achieve required functions for a blood pressure device. The aim of having diverse ideas is to open up the design space, see how stakeholders react and aid on compiling user requirements and engineering specifications. The three non-functional prototypes were made from everyday objects and recycled materials, including water bottles, food packages, stones, toilet paper roll and old t-shirt. Feedbacks from stakeholders regarding interacting with non-functional prototypes are positive, with them describing their experience as "helping in understanding the design" and "fun".

Examples of Concepts Generated

During the concept generation process, there were a wide variety of concepts that were generated. These concepts focused on alterations to different distinct features of a blood pressure measurement device. Different features that were considered include the cuff, blood pressure measurement method, power source, inflation, deflation, display, and calibration. The following designs feature different design ideas based on subfunction. Other ideas integrate a combination of diverse design ideas across these different features into a complete blood pressure device.

Feature Specific

During individual ideation and brainstorming sessions, some generated concepts included blood pressure display methods. Figure 1 and 2 depict examples of the blood pressure display methods. Figure 1 is a method for display and energy source. The display is entirely mechanical and resembles a lotto slot machine. The device includes a mechanical inflation component which occurs when the user pulls on a cord, similar to the manual start-up of a lawn mower. Pulling of cord stimulates an internal gear mechanism that rotates the block numbers of the digital display. Figure 2 shows an incremental change on the existing mercury sphygmomanometer, which incorporates a numerical indicator which detects the level of mmHg. The user can press when the systolic and diastolic occur to have the numerical display show the final reading saved on the digital screen.

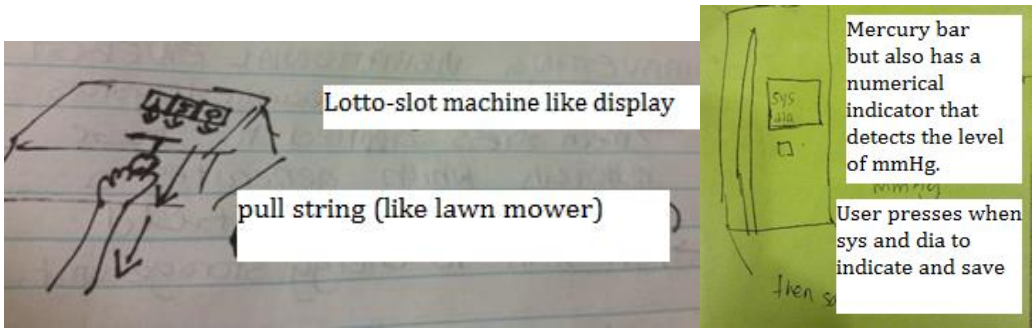


Figure 1 (left): Slot-machine display
Figure 2 (right): Mercury bar with numerical indicator

Figures 3 and 4 depict examples of different cuff concepts. Figure 3 involves an incremental change on the cuff design, with a type of buckle-like backpack adjustable strap theme. The adjustment allows the cuff to fit on various patient upper arm sizes. Figure 4 is inspired by how the airplane emergency vests inflate by pulling on the tabs. The cuff will have two tabs that when the user pulls on them, air will go into the cuff to become the size that will fit the patient. The pressure measurement will be taken from this state.

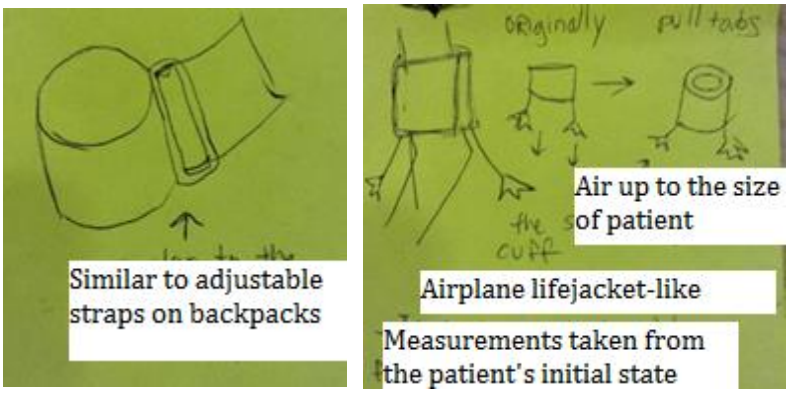
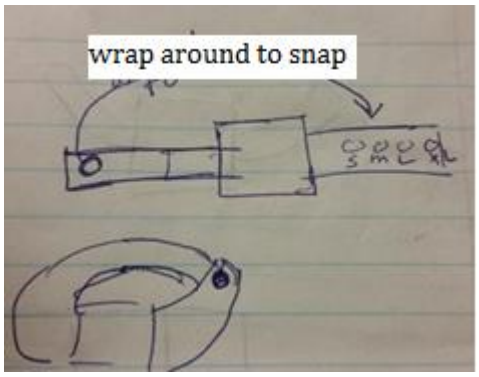


Figure 3 (left): Buckle-like cuff adjustment method
Figure 4 (right): Airplane-vest inspired cuff inflation and adjustability method

Figure 5 and 6 depict concepts of different ways of applying pressure on the patient's brachial artery. Figure 5 is a method to connect a patch attachment to the patient. The attachment method involves straps on either end of the patch with many snap connectors, each one for a different sized patient. For this method, the patch is attached to front of the patient's arm and then the straps are wrapped around the patient's arm and snapped into place. Figure 6 is a proposed method of using a patch as the form of attachment and inflation. The design resembles a plunger, where pressure is applied when plunger is pushed by user into its convex position. Pressure is released by slowing pulling plunger head towards its resting position. Handle of plunger contains a display gauge similar to mercury sphygmomanometer display.



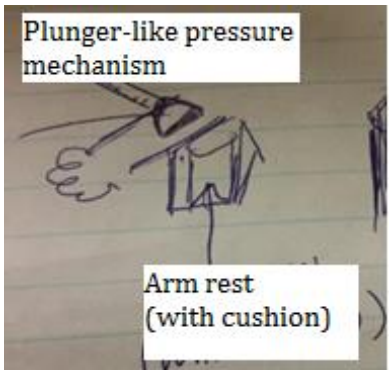
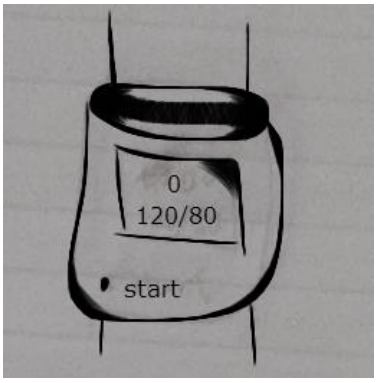


Figure 5 (left): Snap-on pressure attachment method
Figure 6 (right): Plunger pressure application method

Figures 7 and 8 depict universal cuff concepts. Figure 7 is an all-in-one cuff: universal cuff size, hard outer shell and soft inner shell. Once the inner shell inflates to fit the patient's size, the pressure reading will zero automatically. The cuff includes a screen and is fully automatic which means that pressing start button will inflate, deflate, and give final reading on the screen. This is a universal cuff that also has a hard lining for the top inch. Figure 8 is a slip on arm cuff that inflates to patient size with a snug fit. This top inch can be folded over to cut off inflation of the top part of the cuff. This would allow for an adjustable height of the cuff, adding to the adjustability of the cuff.



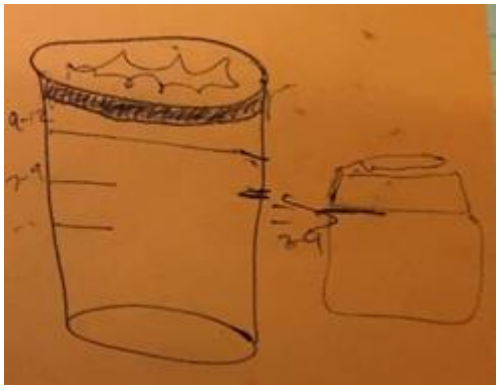
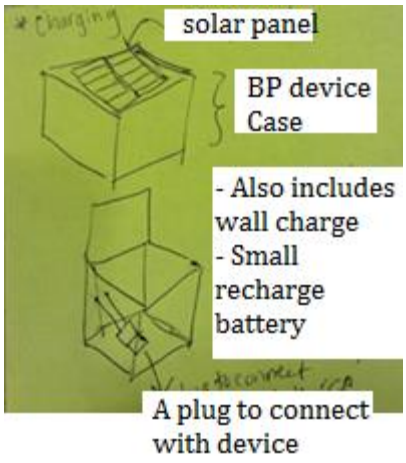


Figure 7 (left): All-in-one universal cuff
Figure 8 (right): Fold-down adjustable universal cuff

Figures 9 and 10 are methods of charging the device. Figure 9 is a solar charging method for the blood pressure device. The solar panel is on top of the blood pressure device case. Inside the blood pressure device is a rechargeable battery which is charged when plugged into the battery reservoir charged by the solar panel. While the device is being used, the case can be left in the sun to be charged and the device can be plugged in the case to charge it. Figure 10 is a way to harvest vibrational energy, similar to a vibraphone percussion instrument. Design consists of a wooden sphere and block that are connected by metal. User applies force with palm to wooden sphere, which makes contact with wooden block and causes vibration. The vibration of the block can somehow be harnessed and converted into a power source.



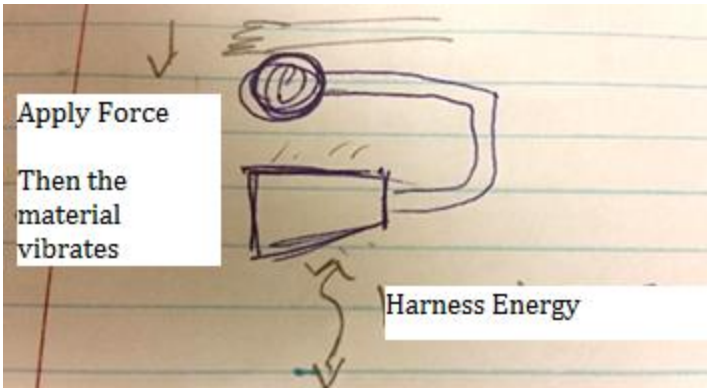


Figure 9 (left): Solar panel power source
Figure 10 (right): Vibrational energy source

Holistic Concepts

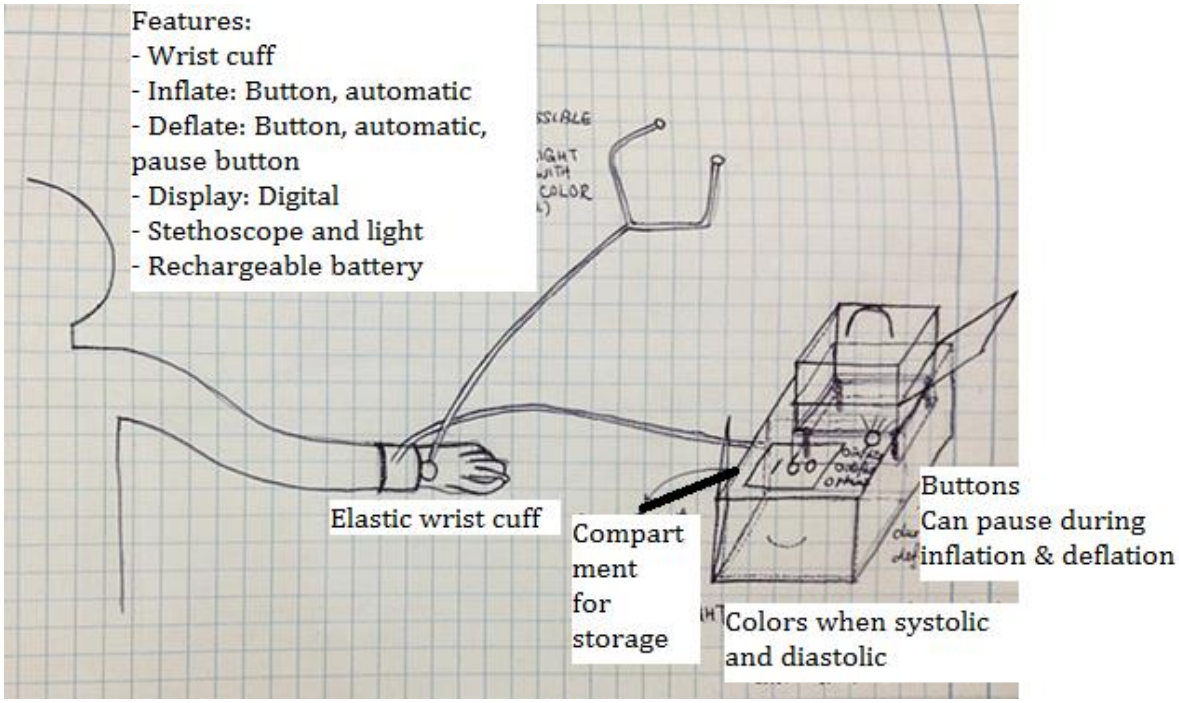


Figure 11: Sketch of a weight mechanism blood pressure device

Figure 12: Non-functional prototype of a weight mechanism blood pressure device

Figure 11 and 12 show the sketch and non-functional prototype of a design that uses a weight to apply pressure. The user only needs to press an inflate button to prompt the lowering of the weight which then compresses a spring or cushion to inflate the cuff. When the user is ready to begin deflation, he or she can press the pause button in order to put on the stethoscope. The user uses a stethoscope placed at the wrist to listen to the Korotkoff sounds. The user can then begin the deflation by pressing the deflate button. The deflate button causes the weight to rise which removes pressure from the cuff. As the pressure deflates, the device uses the oscillometric method to indicate the systolic and diastolic readings via a flashing light and digital display of the reading. The attachment method is an elastic wrist band. The design also contains a compartment for storage of the wrist cuff. The weight is mounted on the platform as shown above and can be stored in this configuration. The power source for the design is a rechargeable battery.

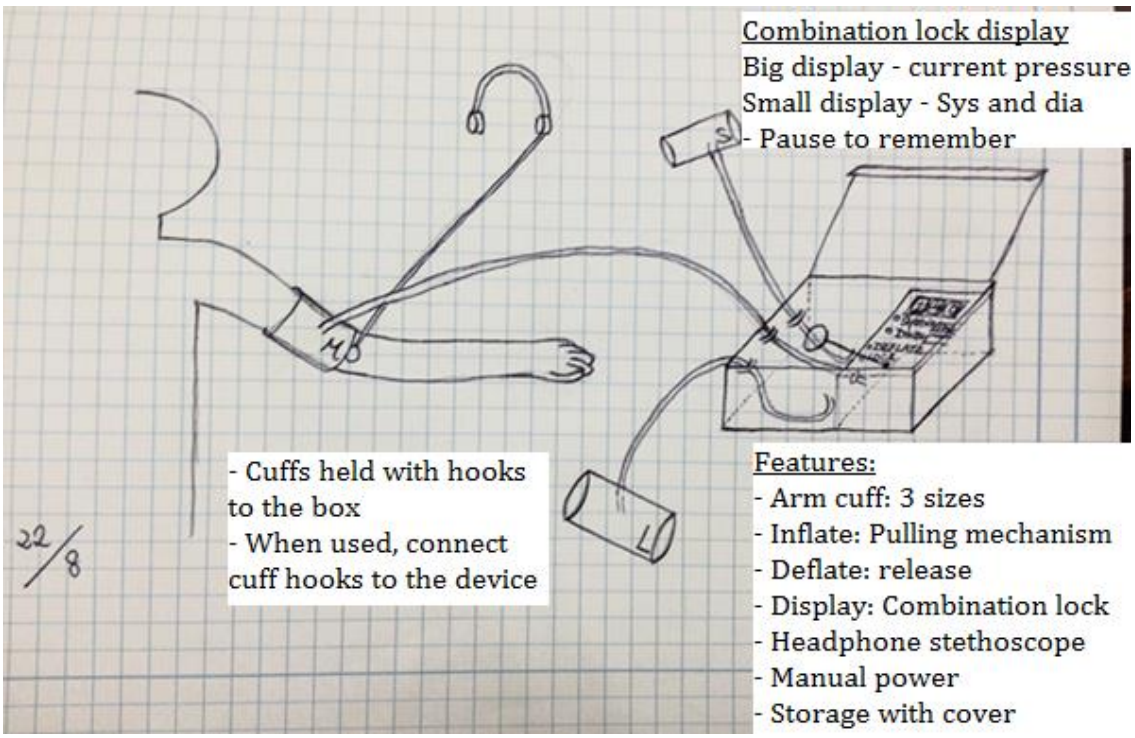


Figure 13: Sketch of boxed mechanical blood pressure device

Device casing

Parts stored in the casing

Figure 14: Non-functional prototype of boxed mechanical blood pressure device

Figure 13 and 14 are the sketch and non-functional prototype of a device design that is entirely mechanical and does not require a power source. The display of the device resembles a combination lock. The user inflates the cuff by pulling on a cord that has sufficient tension so that when the user pulls the cord 2-3 times, enough power is provided to move the combination lock display and inflate the cuff. The device has a pause button that the user can press once the pressure has reached the desired maximum level. The user then uses an over-the-ear stethoscope to listen to the Korotkoff sounds, and again presses the pause button to initiate the retraction of the cord which deflates the cuff. The user can store the systolic and diastolic values by pressing a pin that will lock the values into place on the two smaller combination lock screens on the display. The device has three different cuffs that can be attached to the device. The tubes of the cuffs are attached to the inside of the box so that they cannot be removed. All components can be stored within the device and completely covered. The device also has a handle.

Concept Selection

One success of this group's concept generation was that the team was not fixated on just one idea, and thus going into the concept selection phase, there was no definite selection already unofficially chosen.

Selection Matrix

To choose a top design, a selection matrix was created in order to identify the gaps in the generated concepts and to justify the selection of the concept. With many types of concepts generated, a handful of functional candidates were combined into overall designs. These were designs 8-15 (Appendix I, Figures 13-15). These designs were then analyzed through a Pugh chart. The Pugh chart was used to compare and rank the competing designs in a quantitative fashion, with ratings based on the user requirements and engineering specifications. The ranking was divided into a high, medium, and low importance ranking system with the high of weight 10, medium of weight 7, and low of weight 5. The rating was decided based on the corresponding high, medium, and low priority of the user requirements, shown in Table 2. A scale of 1-3 was also used for rating each design, with 1 indicating that the design did not meet the criteria very well or did not improve the current method and 3 indicating that the design met the engineering specifications and improved the current method used in KATH. This Pugh chart is shown in Appendix F. Design 8-10 were created in-country during the immersion in KATH and had been used to elicit feedback about user requirements and engineering specifications. Design 11-15 were created by the members using the favorite design concepts that were either previously presented or newly conceived. The designs were presented by each member then discussed and scored on the Pugh chart according to the team's evaluation. After the designs were all scored, the overall scores were taken by applying their weights. The highest scoring designs were evaluated based on why it scored high based on our standards, and this led to a discussion regarding the best concepts among the designs. The Pugh chart also helped the team identify the areas the design was not targeting, such as calibration and durability.

Challenges in Selection Matrix

The Pugh chart required the prediction on how the designs would function, which required the estimation of their functions. Although a Pugh chart allowed a quantitative method of viewing the top concepts and designs, individuals felt that the top concepts were already implicitly known amongst the members. In the end, the Pugh chart did not seem to be very additive in the overall discussion of top concepts, as it seemed to be a step backwards from what the team had accomplished in Ghana and had learned through discussion during team meetings.

For example, the feasibility components had the highest weight of 10. The included feasibility components were financial, temporal, and technical, evaluated and estimated based on best of the team's abilities. However, these weights also seemed to hinder and affect the overall score of the designs in the end. Based on the team's gut-check of the weighting outcome, individuals felt that the score didn't reflect the team's ideas and favored designs the team was not comfortable with pursuing. When these weights were not incorporated in the final score, the outcome of the weights matched the team's intrinsic prediction in the weights. This difference in outcome with and without the feasibility component seemed to be dependent on how the team perceived the temporal and technical feasibility.

Top Concepts and Designs from Selection Matrix

The use of the selection matrix revealed that Designs 11, 13, and 15 (Figures 15, 16, and 17 respectively) were the top generated concepts. Because the designs in the selection matrix

reflected an integration of concepts that were generated for individual subcomponents, the team decided to compare the top designs to one another by focusing on the different subcomponents within each design. The team compared the features that corresponded to each subcomponent category for the top three designs. Through this mode of analysis, the advantages and disadvantages of each design were revealed. This mode of analysis aided in the development of the final design concept.

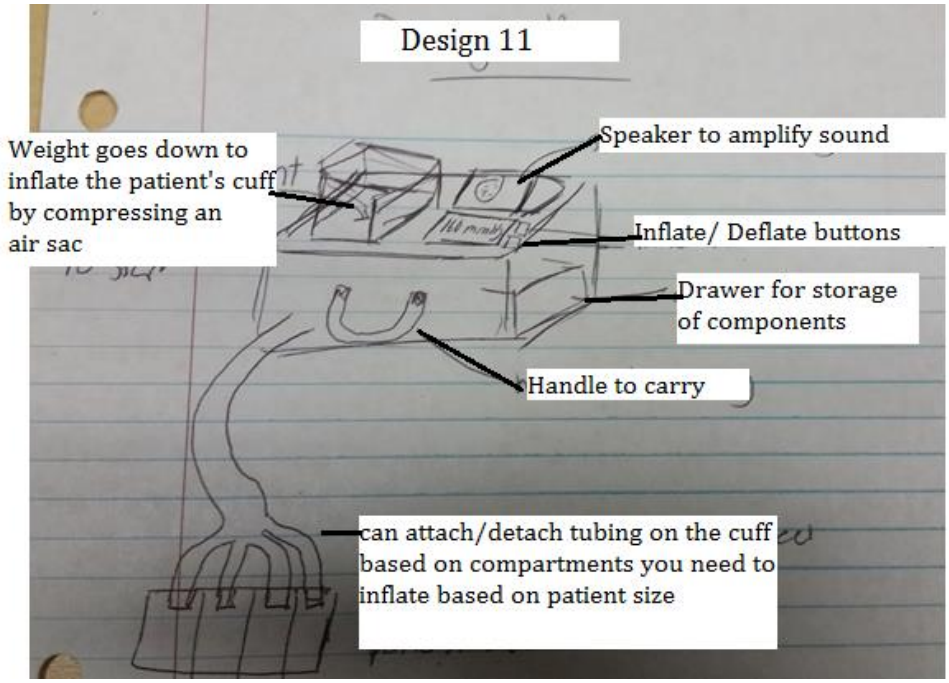


Figure 15: Top Ranked Design 11

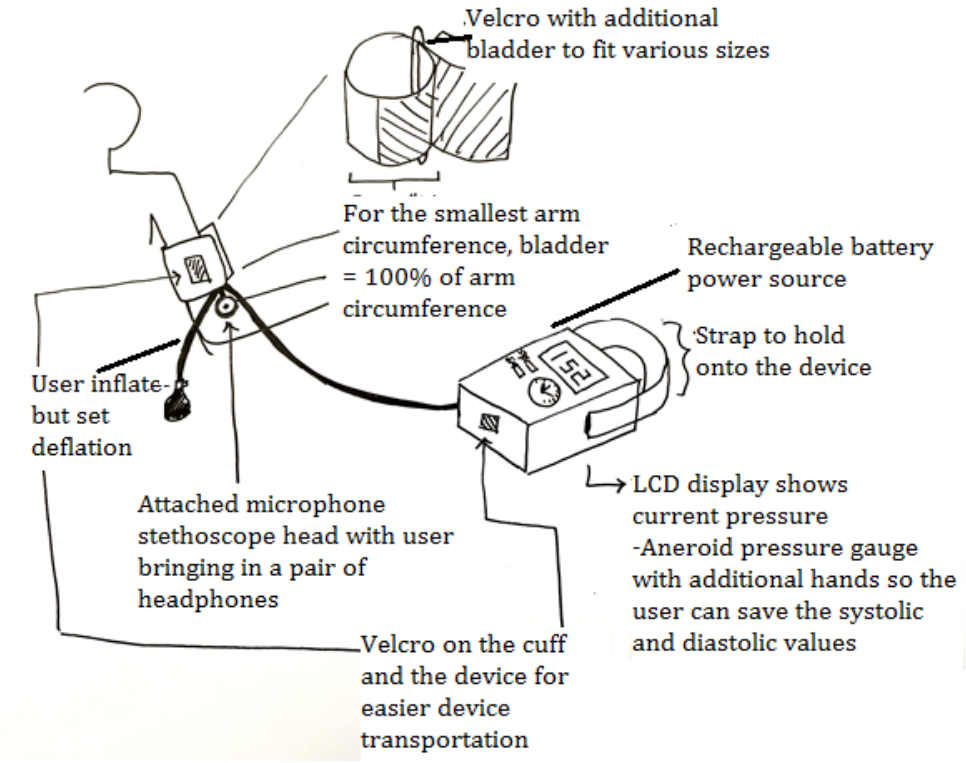


Figure 16: Top Ranked Design 13

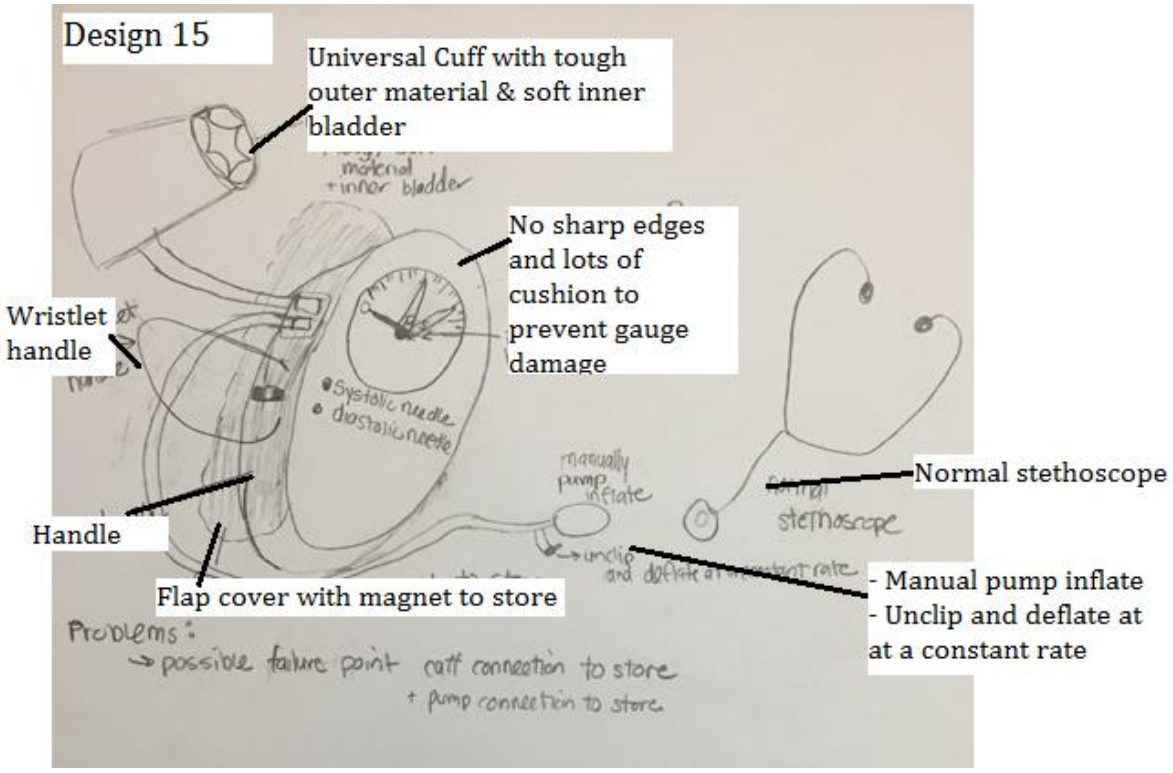


Figure 17: Top Ranked Design 15

Mode to Apply Pressure

Design 11 uses a weight to apply pressure. The weight could be advantageous as it does not require the user to continuously add pressure manually. However, a possible disadvantage to this idea is that the weight might need to be very heavy in order for the device to apply the desired pressure. Because the device needs to be portable so that healthcare providers can bring the device to the bedsides of patients, this would be a significant disadvantage to this design idea. This inflation mechanism is automatic and requires a power source. While automatic inflation is favorable because the user perceives this feature as easier to use, a disadvantage to this method is that it requires significantly more power. In contrast, both Design 13 and 15 use the traditional hand pump which is an entirely mechanical method to apply pressure. This mode of applying pressure is advantageous because it requires no power source. However, a disadvantage of a manual inflation method is that users find the process of manual inflation to be cumbersome and time consuming.

Mode to Release Pressure

The mode of releasing pressure for the top three designs is either manual or automatic. Design 11 uses an automatic mechanism that involves lifting the weight that was previously used to apply pressure in order to release pressure from the cuff. The use of an automatic pressure release method is also favorable because it requires significantly less power to perform this function compared to an automatic inflation method. Design 13 releases pressure through a valve opening that will allow for pressure to be released at a set rate. Design 15 uses a pop off clip to release pressure from the cuff at a constant rate. These manual methods of releasing pressure is advantageous because it does not require the user to constantly adjust the diameter of the release valve in order to maintain a constant deflation rate. This means that the user can focus his or her attention on listening to the Korotkoff sounds while maintaining the recommended deflation rate of 3 mmHg/s. However, the feasibility of this was unclear.

Display

Both Design 11 and Design 13 use an LCD display to show current pressure. The use of an LCD display is advantageous when considering the target setting for this device. Interviews with users revealed that they found this mode of numerical display to be more readable than the current method of reading the mercury manometer bar. This is because the LCD display gives a specific measurement value on the screen, while the current method requires the user to differentiate between graduated line markings.

Design 15 uses a standard aneroid sphygmomanometer display. The display also has three needles that indicate current pressure, systolic pressure, and diastolic pressure. The two buttons on the display are used to freeze the latter two needles at the systolic and diastolic blood pressure values. The ability for the device to record the systolic and diastolic values is an advantage because observations of the current method which uses a graduated mercury column revealed that health care providers estimate the measurement readings once they reach the end of the procedure. The ability to record the blood pressure measurement value might also alleviate the discrepancies in the readings of graduated line markings with the current method. However, this method might still be disadvantageous because the number values for each graduated line marking have to be read from tickmarks. This ultimately means that the final values recorded by user are subject to his or her arbitrary interpretation of these line markings.

Interpretation Method

All three of the top design concepts utilize the auscultatory method. This method was expressed by users as being disadvantageous because it requires the user to listen for and interpret the Korotkoff sounds. Although this method of determining blood pressure requires the user to perform more steps than would be needed when using the oscillometric method, this method has been proven to be much more accurate for use in hypertensive, pregnant populations. Therefore, it has been determined that the auscultatory method is more advantageous for the population that is being targeted for this project.

Design 11 uses an electronic stethoscope to amplify sound. The sound is amplified through a speaker that is mounted to the body of the device, which then allows the user to interpret the sound to determine the patient's blood pressure with the auscultatory method. The use of an electronic stethoscope is an advantageous feature because users expressed that the traditional stethoscopes that are used are uncomfortable and can cause ear infections. One possible disadvantage from using this method of interpretation is that it might sometimes be difficult for healthcare providers to hear the Korotkoff sounds from the speaker when the ward is loud and busy. This mode of interpretation is also disadvantageous because it is expensive and requires a substantial amount of power.

Design 13 uses a microphone stethoscope head that is attached to the cuff. The user has the option to plug in earphones to listen to the Korotkoff sounds. This method is advantageous because users find earphones used to listen to music as more comfortable than a traditional stethoscope. However, one disadvantage to this design is that the microphone components are not easily accessible in the target setting and therefore cannot be easily replaced.

Design 15 uses a normal stethoscope. The interpretation method for both Design 13 and 15 are disadvantageous because users expressed the need for a device that does not require additional equipment. Currently, the stethoscopes that are needed to perform the current blood pressure measurement method are oftentimes misplaced. The interpretation method for both Design 13 and 15 do not address this problem.

Attachment Method

The attachment methods for the three top designs are intended to be adaptable to patient size. This feature is an advantage because the cuff currently used in the target setting is too small for obese patients. The poor fitting of the current cuff for these populations compromises the accuracy of the blood pressure readings. The attachment method for Design 11 does not circumnavigate the entire arm and is segmented into different compartments that can be filled with air. The compartments that are unused during the inflation can be folded over and velcroed to inflated compartments. Each segment has a tube that can be attached so that the pressure generated from the weight mechanism can be uniformly applied across the desired area. A foreseeable disadvantage to this idea is that it would increase procedure time as it requires the user to hook up the tubes that are needed for every patient. Design 13 is adjusted to a patient's size with a clip that is meant to cut off airflow from the excess length of the cuff that is not wrapped around the patient, with a slip-on method similar to the current cuff of many oscillometric blood pressure devices. The attachment method for Design 15 is a cuff that has a tough outer material and inner inflatable bladder to fit the arm. One advantage to all of the

designs is that they do not require the user to wrap the cuff around the patient's arm, which was a step that was often described as being cumbersome by users.

Power Source

The three top designs from the concept selection matrix all use a rechargeable battery that can be charged by a wall cord as the primary power source. The use of this form of rechargeable battery is advantageous in the target setting as access to working power outlets is not an issue. However, a disadvantage to using this form of power source is that it would not be appropriate for areas where access to power outlets is low. While Designs 13 and 15 only use a wall plug for power, Design 11 also has the option to recharge the LCD screen with a solar panel. Incorporating an alternative power source into the device is an advantage because it makes the device more feasible for use in settings where outlet power sources are scarce.

Portability

Each of the top three designs incorporated a feature that is intended to make the device portable. Design 11 has a handle, Design 13 has a velcro strap to allow for holding of the device as well as to allow for attachment of the cuff to the device during transport, and Design 15 has a wristlet strap. All of these features were perceived as advantageous by the users as they expressed that the device needs to be able to be transported using only one hand in order for it to be easy to carry to patient bedsides.

Storage and Casing

Design 11 and 13 do not include any additional features that aim to make the device stowable and covered. Design 15 has a flap to cover the display interface that is secured with a magnet and a storage case that resembles a metal lunch box. Incorporating such features into the device was expressed by users as advantageous because it helps to keep the device clean. Users also said that a device with an all-encompassing case would be perceived to have greater value and would therefore be better maintained.

Calibration

Design 13 is the only design from the top three designs that includes a calibration feature. The device has an aneroid pressure gauge display in addition to the LCD screen. In the event that the device breaks or the user suspects that the LCD screen is inaccurate, the user can simply connect the aneroid gauge with a T-connector that is included with the device and compare between the outputted values of the LCD and aneroid displays. This method of calibration is advantageous as it does not require the user to have any additional calibration equipment. In addition, because this calibration method is embedded into the device itself, it could potentially be used by not only technicians but also nurses, midwives and physicians.

Refining the Concepts

After selecting the top concepts identified from the designs, these concepts were then brought to the professionals in the field for consultations regarding their feasibility in manufacturing. The team had consultations with Michael Deninger, Josh Bishop-Moser, and Grant Kruger to discuss what methods could be possible and how to prototype such methods. Consultations with these individuals helped guide the team towards refining the top concepts and narrowing the focus for the MECHENG 450 class as they had backgrounds in medical innovations and MECHENG 450 design.

During these meetings, the top concepts and the non-functional prototypes were brought and presented to get feedback on how to achieve these concepts. They provided information on how to achieve engineering analysis for the different concepts. Based on this meeting outcome, some of the previous concepts were reevaluated. Some of the discussed concepts included the weight-pressure application method, universal cuff, microphone stethoscope, manual deflation method, and LCD screen sensitive to aneroid display method.

The pressure application method in which the weight would compress a reservoir of air was discussed. Both of these individuals expressed concern regarding the weight required to exert a maximum of 300 mmHg on the patient. Suggestions on how to test this in terms of engineering analysis were discussed and will be done during engineering analysis.

Discussion with Michael Deninger about the universal cuff shed light on how much analysis and work would be required to design and manufacture a universal blood pressure cuff that would accommodate patients within childbearing age in 5th to 95th percentile. He stated that in order to accommodate virtually all patient sizes, there would be a need to switch the air application valves with separate compartments or a large outer hardshell cuff. As the project's focus is on the actual device for measuring blood pressure, it was decided that due to the constraints of the MECHENG 450 class, the manufacturing of the device would not focus on the universal blood pressure cuff.

Microphone stethoscope was a top concept, but the team wanted to manufacture a stethoscope that would allow the microphone to be embedded without a computer or some type of processor. During the conversations, the team was informed of previous projects in BME 450 that have worked on electronic stethoscopes. It was also brought to the attention that there have been a lot of resistance from medical culture to electronic stethoscopes as doctors were concerned for the possibility of sound distortion during the amplification of sound. However, having heard from the midwives and nurses about the pain that the stethoscopes cause and the cumbersome nature of having to acquire a stethoscope, it is important for the team to consider alternative options to the current stethoscopes. In addition, the doctors in the target setting never mentioned any bad medical cultural view about microphone stethoscopes. The team discussed this concept further with mentors at KATH and University of Michigan hospital. The mentors said that moving forward with this design concept was fine as long as it was only amplifying the sound and not trying to interpret it.

Different methods of how to mechanically set the deflation rate were also suggested by the consultants. Josh informed the team of a servomotor that could go on top of the valve to adjust the rate of the deflation by mechanically turning the valve opening to let 3 mmHg of air out per second. This was adopted into the team's top design.

Lastly, the attachment method and detection of pressure changes with LCD were discussed. The team was given information and resources about pressure gauges and sensors available in the market, and some other MECHENG 450 projects from previous years that had incorporated this component. Based on these consultations, it was decided that the final design would have a LCD screen to display the current pressure in the cuff, with an aneroid pressure gauge that could be easily attached to the device.

Design Iterations

Once the team identified the strengths and weaknesses of the subcomponent features in the top three designs and then consulted with design consultants about the feasibility of specific subcomponent ideas, the top chosen design was developed. The top chosen design captures the best subcomponent concepts from the top three designs in the concept selection matrix. Additionally, the top chosen concept also reflects modifications to particular subcomponents that were recommended by design consultants. The desires of the end user were also considered at this stage of the concept selection process in order to ensure that the selected subcomponent features were appropriate for use in the targeted setting. The team also considered which design ideas were novel and not currently seen in any commercialized blood pressure devices.

Alpha Design

The initially developed alpha design uses the auscultatory method (Figures 18, 19). Figure 18 demonstrates the connection of the pressure system within the device. The figure shows the ball valve that would regulate the airflow to the pressure gauge connection. Figure 19 diagrams the actual device and in-depth drawings different components of the device, such as the universal cuff and the lunch-box storage design. The functionality of each part of the device is explained in detail below.

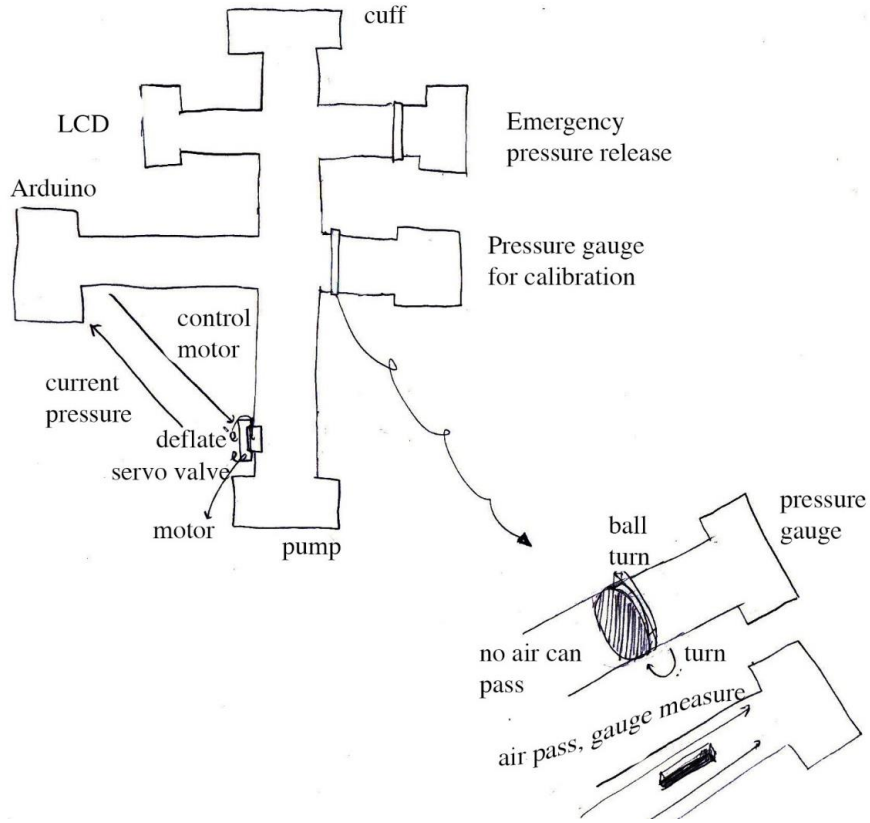


Figure 18: Diagram of how the pressure system is connected

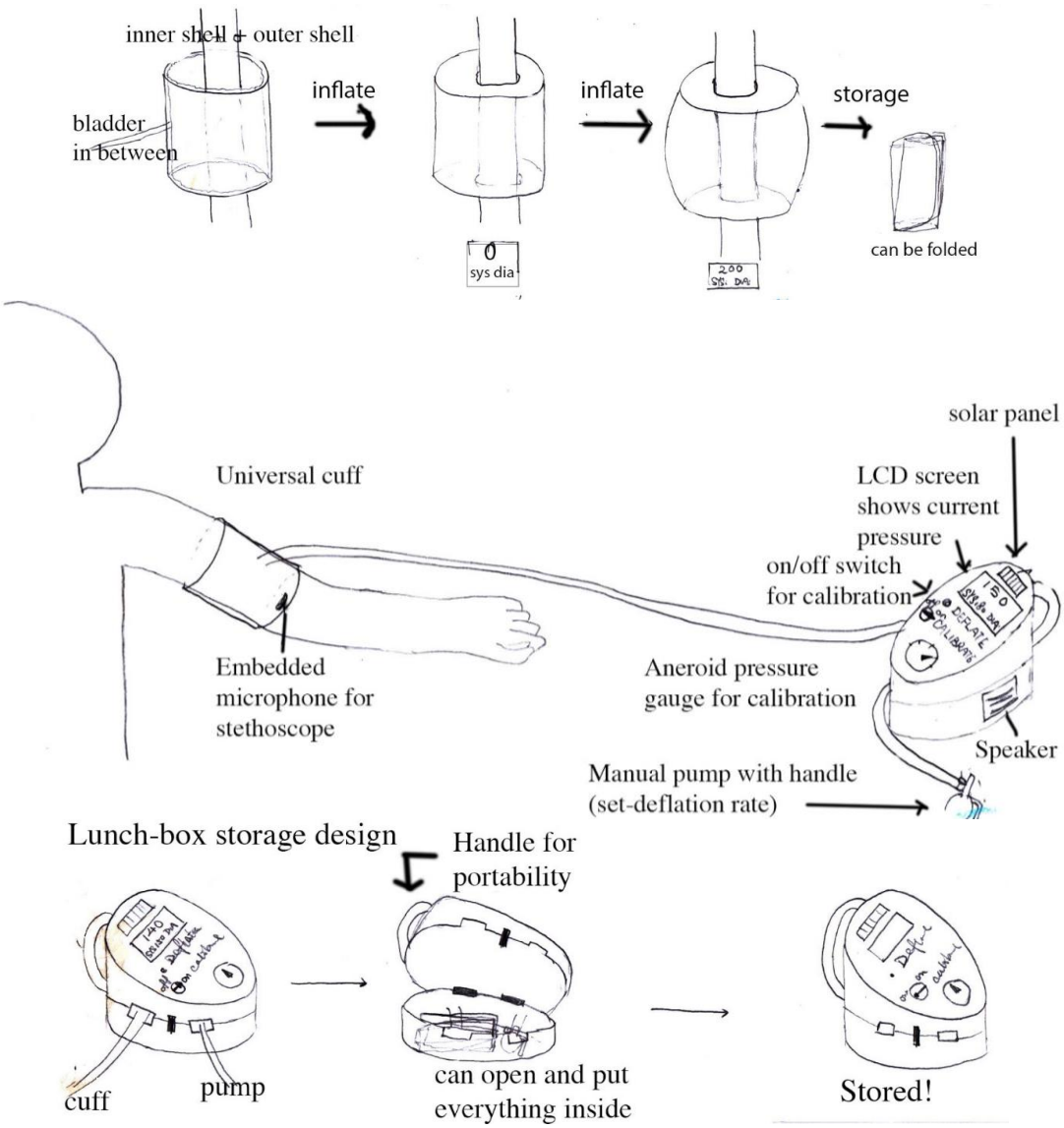


Figure 19: Top chosen design with in-depth cuff and storage method explanation

The use of auscultatory method is supported by the concept selection matrix; all three of the top concepts utilized this method. The auscultatory method is chosen over the oscillometric method not only because this is the method that physicians find to be the most accurate, but also because it would be very difficult to develop an algorithm that would make the oscillometric method accurate for hypertensive patients. For this reason, it has been decided that the best way to improve the level of patient care for hypertensive patients would be to create a device that improves the current auscultatory method.

The top two chosen concepts for the top design with regards to the mode of interpretation of the Korotkoff sounds are the microphone stethoscope and the traditional stethoscope. While the microphone stethoscope is the more preferred method by users because it does not require the stethoscope to be placed in the ear, there are concerns within the team about the cost, durability, needed power supply, and replaceability of parts for this method. The traditional stethoscope method has also being considered, as this method is already available in the target setting and

thus would allow for the device to be easily integrated into the current system. While the use of the traditional stethoscope with the device would allow for easy integration into the target setting, it does not improve upon the method that is currently used in the target setting. The design in figure 19 incorporates a microphone stethoscope with the speaker of the sound on the top of the device.

There are two top chosen concepts for the mechanical inflation method for the top chosen design. The first method that is being considered is the idea from Design 11 that involves the use of a weight to apply pressure. While this method would require less effort by the user to operate and would therefore be preferred, it is still uncertain whether this design would be feasible when considering that the device also needs to be light enough for the user to carry to patient bedsides. The second top chosen concept for inflation is also a mechanical method and resembles the current hand pump. While the users expressed that they would prefer a device that has an automatic inflation method, it was decided that this part of the procedure should remain mechanical in order to reduce the amount of power needed to operate the device. This is important because the device needs to be used for the largest possible number of uses per battery life. A pump inflation method is chosen over other manual inflation methods because users expressed preference in the pump inflation as it was familiar to them. Furthermore, by leaving the hand pump in the device it can potentially be used completely manually if necessary. The top chosen concept for this subcomponent aims to ergonomically improve the current pumping mechanism which is disliked by users because it requires a large amount of physical exertion.

The alpha design has an automatic deflation feature. The chosen concept uses a motor that is attached to the current valve adjustment method. While the some of the top designs utilize manual deflation methods which scored well in the concept selection matrix, it was discovered during design consultations that the concepts that were generated could not be entirely manual. From these consultations, the idea to motorize the current valve opening mechanism was developed. The top chosen concept for deflation involves a mechanism where the deflation rate is programmed so that the valve circumference will be adjusted in order to maintain the desired deflation rate of 3 mmHg. This mode of deflation is chosen because it not only utilizes the current deflation method but also automates the deflation process so that it does not require user control. It is important for this step to not require user control because the auscultatory method requires the user to listen for the Korotkoff sounds. The device also has an additional deflation valve that can be used to manually deflate the device so that the device can still be used in the event that a power source is unavailable.

Additionally, the device includes an LCD display that displays the current pressure in order to improve the readability of the measurement and reduce the likelihood of user estimation. The concept selection matrix revealed that the use of an LCD screen as a display is the preferred method, which ultimately captures the feedback that was elicited from users. When considering the novelty of this feature outside the scope of the targeted setting, it is important to note that there are currently no auscultatory blood pressure measurement devices that use a digital LCD display for the readings on the market. Because the top chosen design utilizes an automatic deflation method, the LCD display for the design must have a low power indicator.

The alpha design also includes an aneroid sphygmomanometer that can be connected to the device with a one-way ball valve (Figure 18). The valve can be opened when calibration of the LCD screen method is desired. This feature of the device is not only a need in the targeted

hospital setting, but is also seen as a way to address the current gap which is that there are currently no blood pressure devices available that incorporate a calibration system into the blood pressure device itself.

The power source for the alpha design includes a wall plug and solar option. The solar panel is intended to alleviate the amount of power required for the entire device by powering the LCD screen. Another reason that the solar panel was incorporated into the final design is so that the LCD can still be charged via an alternative energy source if a wall plug source is not available. Because there is an option for the deflation method to be manual and for the LCD screen to be powered by an alternative energy source, the device can be used in areas that have limited sources of power. The wall plug is the primary rechargeable power source for the top chosen design as the target setting has readily available wall outlets.

The alpha design has a handle in order to make the device easy to carry. These features were heavily favored by both design experts and users when asked how to best make the device easy to carry from bedside to bedside.

The alpha design also has a storage area for the cuff and inflation components underneath the display panel. This storage area can be opened and latched shut. This feature is included in the design as it helps to maintain the cleanliness of the device components. Additionally, because the users in the current setting find it difficult to promptly acquire the additional equipment that is needed for the current method, this storage feature aims to help ensure that all device components are always in the same place.

Beta Design

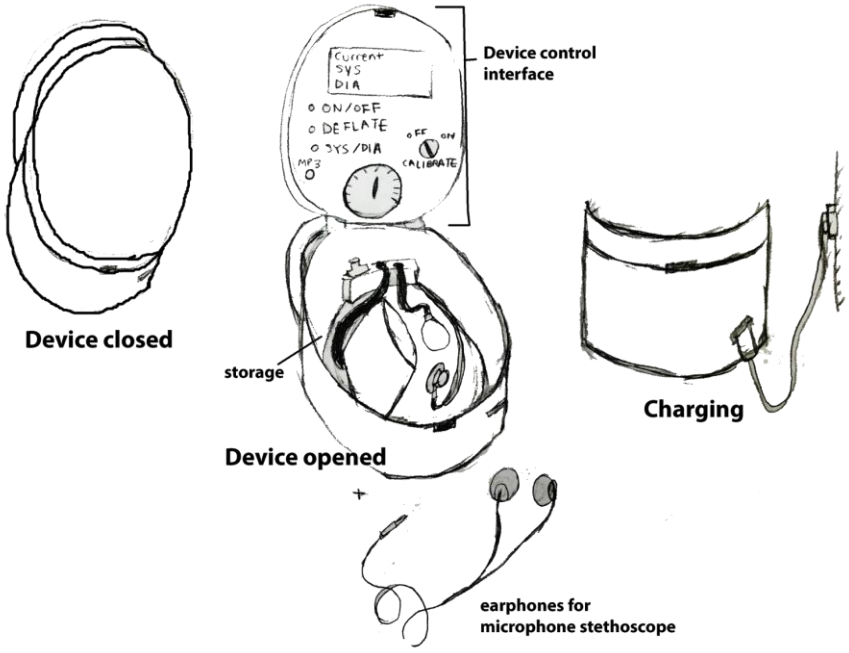


Figure 20: Beta design depicted closed, opened, and charging

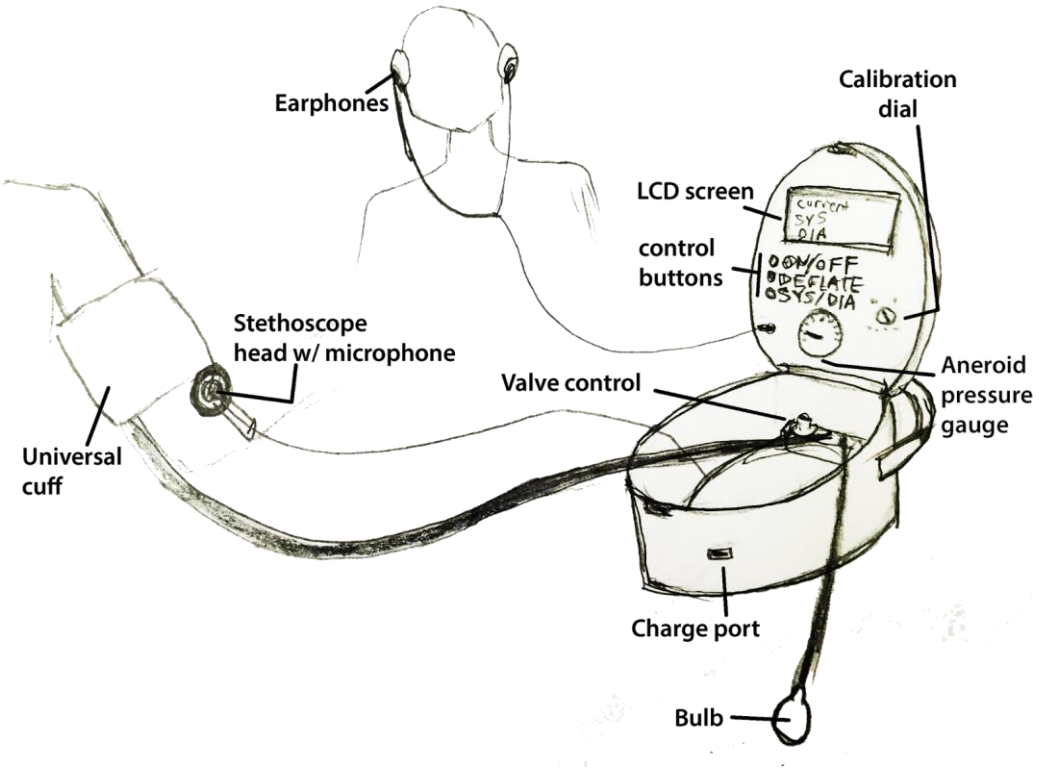


Figure 21: Overall schematics of the beta design

Figures 20 and 21 depict the second drawings of the design, which includes revisions that were made following consultations with doctors from both the University of Michigan and Komfo Anokye Teaching Hospital. First, the listening method for the device was changed from a speaker embedded into the device to an auxiliary jack that is compatible with audio headphones. The device will come with a set of over ear headphones as this type of headphones requires minimal cleaning and reduces the risk of infection. This revision was made after considering the noise in the wards and the fact that an additional amplifier would be needed to amplify the Korotkoff sounds through a speaker. In addition, using this method gives the user the option of bringing his or her own headphones to use with the device. The device also includes a knob to adjust the volume so that that is emitted into the headphones.

In addition, it was decided that the display will not be on the outside of the top face of the device as seen in the alpha design, but will instead be on the inward-facing side of this surface. The beta design has a hinge mechanism that allows the display to be flipped up to a 90 degree angle with respect to the base of the device when the device is in use. One reason that contributed to this decision was that this configuration minimizes the exposure of the display to the surroundings when the device is not being used. Another reason that accounts for this change is that with the display on the alpha design, there would need to be hole for the cuff and air pump tubing on a specific side of the device. This could potentially restrict the healthcare provider when using the device as the tubing may need to be wrapped around the device's perimeter in order for the device to be accessible to the patient. The beta design aims to mitigate this issue because the device lid is no longer closed while in use.

The beta design no longer has a solar panel because the solar panels were not adding enough energy support for it to be a worthwhile cost. The design also now includes a button on the display that allows the user to record the systolic and diastolic values. In addition, the device has a pressure cap that serves as a safety release valve in the event that the pressure is inflated to a dangerously high level.

The final key decision that was made when constructing the beta design was that the team will not focus on the universal cuff feature of the device. While there is a significant need for a universal blood pressure cuff, the team has decided that it is not feasible to construct a proof-of-concept solution for this problem this semester in addition to the blood pressure measurement device itself. The team recommends that future project teams consider the development of a blood pressure cuff that accommodates all patient sizes as a project topic.

Mock-Ups

Alpha Design

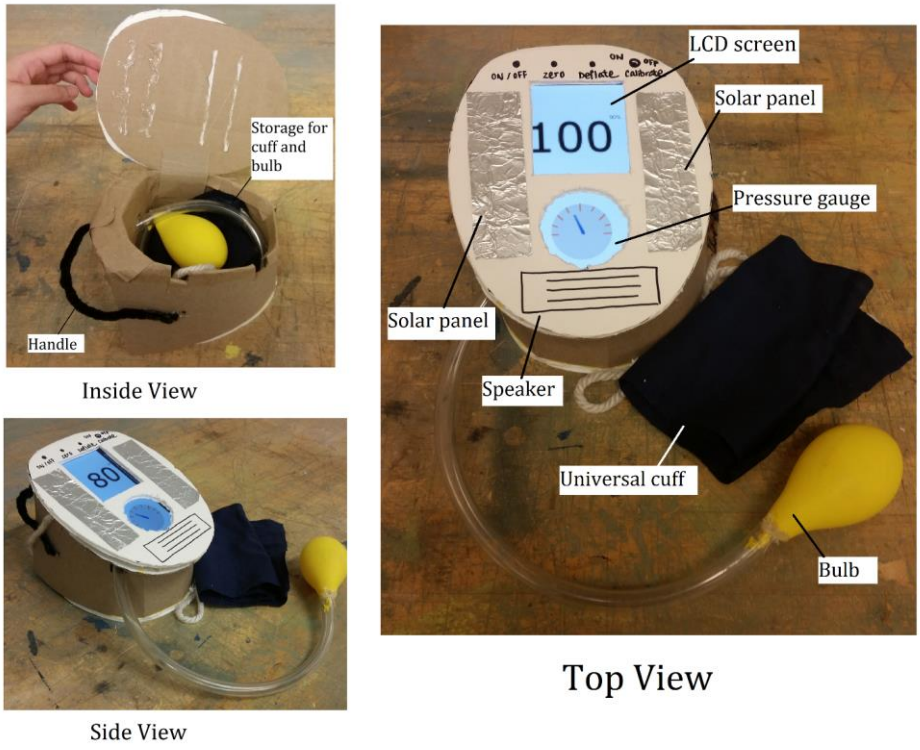


Figure 22: Top, inside, and side view of the mockup

Figure 22 depicts the initial mock-up of the chosen design. This mockup was made out of foam, cardboard, a balloon, cloth, wood, and an iPhone to mimic a LCD screen. This mockup was created to get a better understanding of how the different features in the design would piece together in an actual device.

One thing that was learned from building the mock-up was that the upper cover part of the device could not be bulky nor heavy. Originally, the dimension of the upper part of the device

was bigger to accommodate the microprocessor Arduino, the circuits, the LCD screen, the pressure gauge and other components. However, the first prototype was not stable because the upper part was heavier than the lower part. Based on the experience, the team changed the design so that the electronic component are housed in the lower section of the device.

Building the mock-up also gave the team the opportunity to consider user interaction with the device. The team realized that it might be inconvenient for users to reach the buttons if they were on the surface of the device, as the device is usually put on patient's bed when used while the user stands at bedside. The team brainstormed alternative for locations of the buttons, for example, on the hand pump. After a thorough discussion, the team decided to keep the buttons on the device due to the risk of damage and the difficulty to maintain if they were on the hand pump.

Beta Design

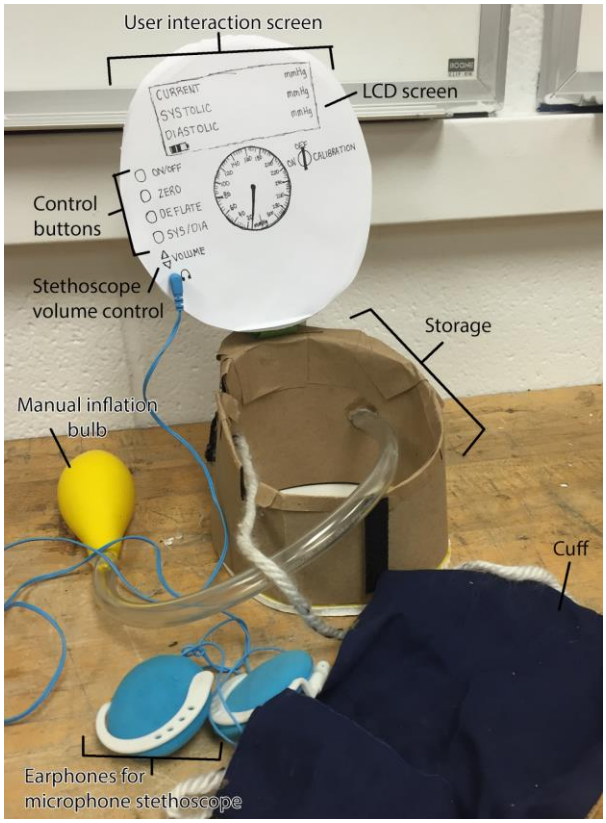


Figure 23: Left - Beta Design Mock-up

After revisions were made to the design as a result of engineering analysis, a mock-up was made of the beta design. Similar manufacturing methods and materials were used for the construction of this mock-up as the alpha design. One notable change to this mock-up is that it has an audio jack for the user to insert headphones into the device instead of a speaker. A volume adjustment mechanism was added to the display so that the user can adjust the volume of the Korotkoff sounds inside the headphones. The solar panels from the alpha design were also removed. In addition, the aneroid gauge was moved to a more central location on the display to provide

maximum cushioning in order to minimize damage. A symbol indicating the battery life of the device was also added to the LCD screen. Finally, the orientation of the top panel with the display was adjusted so that side with the LCD screen closes shut when not in use.

From the process of building the beta design mock-up, it was realized that device itself will need to be larger in order for it to provide storage for the stethoscope and cuff. In addition, the thickness of the top panel may need to be thicker in order to accommodate the dimensions of the parts that have been ordered. Finally, it was realized that more attention needs to be given to the hinge mechanism that props the display upright at a 90 degree angle when in use. This is because the current mock-up does not include any type of support that keeps the screen upright.

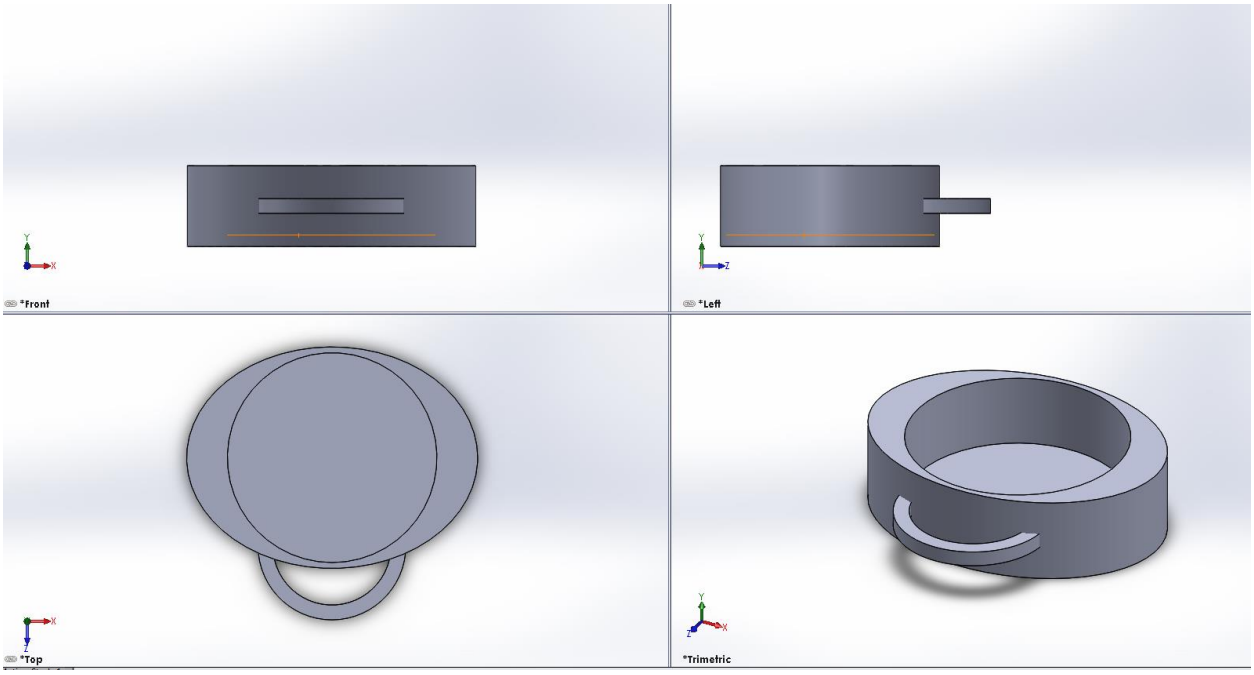


Figure 24: CAD model of device casing.

To develop a functional, proof-of-concept prototype, parts of the device were purchased. The purchased categories include: cuff, hand pump, pressure connection system, pressure sensor, sound system, motor, display, and microcontroller systems. The schematics of the pressure connection is illustrated in Figure 25. The purchased parts and their details are included in Appendix J. As the arm cuff is not a design focus for design within MECHENG 450, a durable nylon cuff was used. In order to test the different types of hand pumps and the most “easy to use”, various types of bulbs were bought to measure the amount of air exerted based on the number of pumps.

Pressure System

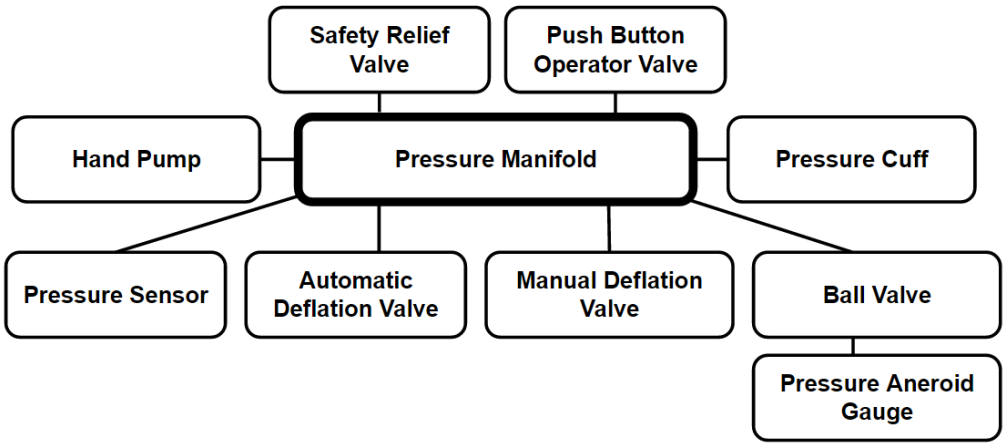


Figure 25: Diagram of the Pressure Distribution System

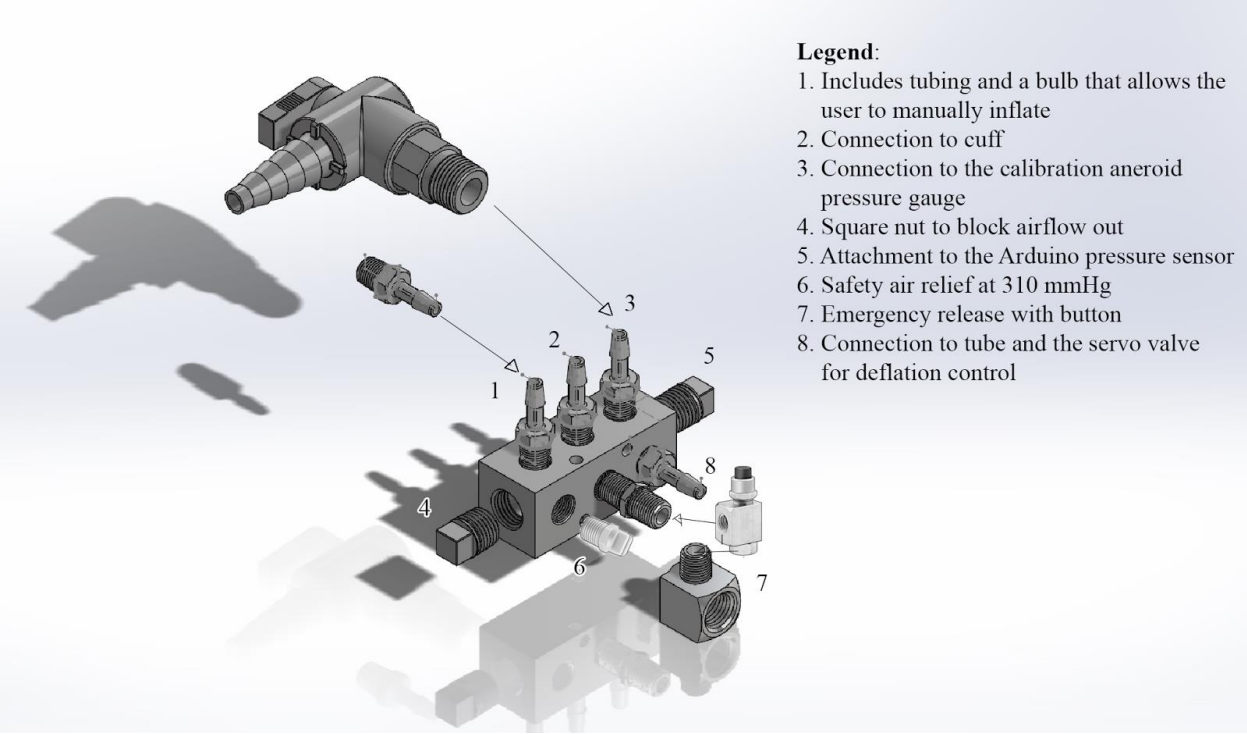


Figure 26: CAD model of the pressure manifold attachments. Excludes tubing and accessories

The pressure connection system consists of a six outlet and two inlet manifold that connects to a pressure sensor. This manifold was chosen over a connection system with t-tubes to reduce the number of manufactured parts as the manifold allows for standardization of the parts. One identified problem for the parts is that Ghana receives many of its manufactured parts from European countries and also uses the metrics system. As the parts sold in America do not have standards that match the metrics, it was important to choose parts and measurements that were also available in Ghana. Therefore a ⅛ NPT outlet and ¼ NPT inlet were chosen on the manifold, given that the NPT standards are available in metrics system. The rubber tubing bought for proof-of-concept is 3/16 inches for inner diameter and ⅜ inches on the outer diameter, which would not be manufactured in Ghana. Based on manufacturer and available item

inventories analysis, adapters for different diameter tubing to the manifold and other pressure components should be easily accessible. Therefore the current straight polyethylene barbed tube fitting for connection between the tubing and other parts would not be 3/16 inch tubing to ⅛ NPT male but replaced by a different inner diameter dimension based on the purchased tube.

Electrical System

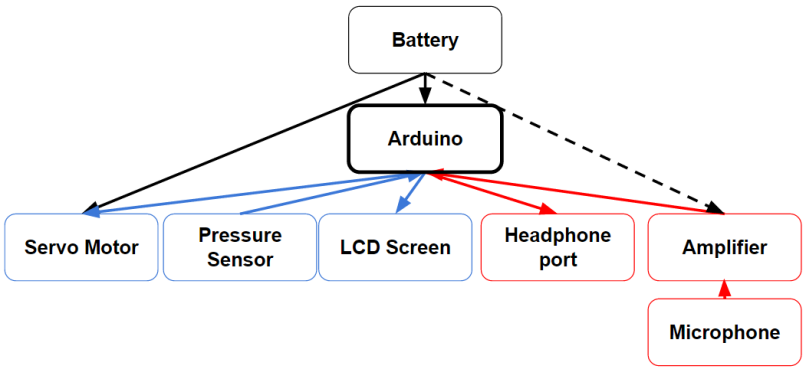


Figure 27: Diagram of the Electrical System

The electrical system is controlled by the microcontroller Arduino. There are two pathways, including the microphone to amplifier to Arduino to headphone pathway, and the pressure sensor to Arduino to LCD screen and servo motor pathway. The first pathway is used to pick up Korotkoff sounds of the patient from the stethoscope and output the data in the over-ear headphone. The second pathway is to send real-time pressure to the Arduino, so that the LCD screen can display the number, and the rotating rate and direction of the servo motor can be adjusted accordingly in response to the current pressure to achieve a constant deflation rate. The Arduino and the servo motor have to be connected directly to the battery to be powered. The amplifier should be able to be driven by the Arduino output voltage and current according to the specification sheet. However, the team considers the possibility of directly connecting the battery to the amplifier until empirical testing is performed to confirm that the Arduino can drive the amplifier.

Risk Analysis

Both a Failure Modes Effects Analysis (FMEA) and Risk Analysis were conducted to identify the hazards associated with the products and the related tasks. The analysis required an identification of potentially hazardous situations which allowed the team to reevaluate some of the steps involved in the blood pressure measurement method and the device. Tables 3 and 4 are Risk Analysis and FMEA respectively.

Table 3: Risk Analysis

Hazard	Hazardous Situation	Likelihood	Impact	Level	Technical Performance	Schedule	Cost	Action to minimize hazard
Pressure harming patient	When the pressure applied is over the limit for patient safety or the device malfunctions and cuff does not deflate to 0mmHg within the procedure time, the circulation is cut off from the arm and this can have longterm consequences for the patient.	Medium	Minor/ severe based on the situation	1	Significant reduction in the technical performance of the device because it cannot deflate the cuff without mechanical user input.	Program critical path affected. Slip <1 month.	Minimal impact	Design will include a pressure release valve that releases air once the presure is above 350mmHg. The device will also have an emergency release valve they can mechanically operate. Furthermore, the device will have a method for user powered and controlled deflation.
Parts (tubes) melting in the sun	It is possible that when the device is out in the sun, the tubes may melt which makes them unusable and unsafe if the melted material is hazardous	Low/Medium	Minor	2	Significant reduction in technical performance as the tubes are integral pressure distribution across the device	New material has to be identified, slip <1 week.	Budget increase or unit cost increase. <1% increase in budget.	Ensure the material used for the tubing is not hazardous to humans and has a high operating temperature
Valve overheating	Motor is overloaded mechanically or electrically	Low	Moderate	3	Significant reduction in the automated deflation function of the device, but blood pressure measurements can still be completed by using manual deflation option.	New material has to be identified, slip <1 week.	Budget increase or unit cost increase. <5% increase in budget.	Use a valve that can handle the load; design a reasonable circuit that output a voltage and current to the motor that is within safe operating range.
Battery overheating	It is possible that the battery could catch on fire	Low	High	2	The device would no longer be able to operate	New battery would have to be ordered, other components may also be negatively affected <1 week	Budget increase or unit cost increase. <15% increase in budget.	Encase the battery separately from the rest of the device
Battery breaks/leaks	Battery acid could harmfully affect the skin.	Low	Moderate	2	The device would no longer be able to operate	New battery would have to be ordered, other components may also be negatively affected <1 week	Budget increase or unit cost increase. <15% increase in budget.	Encase the battery separately from the rest of the device
Material used harmful to patients and user (lead, latex, other allergetics)	Material used may cause reaction of patient and/ or user.	Low	Moderate	1	Minimal or no technical performance	Minimal or no impact	Minimal or no impact	Research common materials that are hazardous or allergenic.

Device gets bodily fluid spilled on it	It is possible to get patient's or user's bodily fluid onto the device. This can be hazardous if the spilled bodilu fluid can transmit diseases.	Medium	Moderate	1	Minimal or no technical performance	Minimal or no impact	Minimal or no impact	Ensure that the device can be cleaned by the equipment commonly found in the ward
Overpressurization of tubing and other device components	When using the device, the device could have too much pressure exerted its components, such as the tubing or the bulb.	Low	Moderate	2	Moderate degradation in technical performance, depending on the consequence of overpressurization.	New material has to be identified, slip <1 week	Budget increase or unit cost increase. <5% of budget increase	Select components of the device that would not be easily damaged with overpressurization & select sensitive pressure sensors & ensure the pressure application and division has no leaks. There will also be a pressurization cap that will open once the pressure sensor detects a pressure above 350 mmHg, which releases the pressure in the device.
Display Panel Breaking Off	It is possible that when the device is under heavy damage or use, the device panel could break off and harm the user or the patient.	Low	Moderate	2	Significant degradation in technical performance as the device cannot measure blood pressure anymore	Panel would have to be replaced and stronger panel material would have to be identified, slip <3 weeks	Budget increase or unit cost increase. <5% of budget increase	The device panel is now designed to be inside of the casing, with the hinge of the screen protected, similar to the hinge of the laptop.
User could be cut/scraped from sharp device components	A user or patient could be cut from the device if it falls or if they brush by it quickly.	Low/Medium	Minor	1	Minimal or no technical performance change	Minimal or no impact	Minimal or no impact	Design a device with few sharp edges that could puncuture the skin.
User could be cut/scraped from LCD screen cracking	User could be harmed by sharp and broken parts of screen	Low	Minor	2	Significant degradation in technical performance as the device cannot measure blood pressure anymore	New screen has to be ordered	Budget increase or unit cost increase. <10% of budget increase	Put a screen protector over the LCD screen.
The tubes connecting the device leaks or breaks off	After heavy usage or heavy wear on the tubes, they could break off or have leaks	Medium	Moderate	2	Significant degradation in technical performance as the tubes are integral in the device success	New material has to be identified, tubes have to be replaced, slip <1 week	Budget increase or unit cost increase. <5% of budget increase	Ensure that the material selected for the tubing has high wear resistance, is resistant to and abrasion, and can be replaced in Ghana
The device closing harms the user or patient	It is possible that the user or the patient could have some body part that is pinched or cut by the closing of the device	Low/ Medium	Moderate	1	Minimal or no technical performance	Minimal or no impact	Minimal or no impact	Ensure there are no sharp edges and the closing process does not exert too much force
The pressure ball system dividing the aneroid pressure gauge and LCD screen breaks	The user does not have the mechanical power to deflate the cuff in under 10 seconds with one swift motion.	Low	Moderate	2	Significant degradation in technical performance as the emergency features are integral for the device to be safe to use	Program critical path affected. Slip <1 month.	Minimal or no impact	Ensure that there is minimal ways for the valve to break. There will also be other methods to deflate it including a mechanical deflate option and a pressure valve for when the pressure reaches over that critical 350mmHg value.

Table 4: FMEA

Item	Function	Potetial Failure Mode	Potential Effects of Failure Mode	Severity of Effect/ class?	Potential Causes of Failure	Occur within a year	current design controls	Detection	RPN (Risk Priority Number)	Recommended Action
Pressure System Manifold	This manifold allows all the pressure components to be connected together. There will be the LCD screen, calibration mechanism, and deflation mechanisms attached to this manifold.	Air Leakage	Wrong measurements between the LCD and aneroid pressure gauge. Wrong calibration.	6	The connection of the tubing is not secure.	2	Choosing a strong material that will not create air leakage, and using seal-tight holds on the parts that attach to the manifold.	2	24	Secure tubing parts with lock-tight tapes or paints when screwing the pressure components.
Tube Connectors	Connects tubings and other pressure components of different diameters	Melting	The tubes and other pressure components will not be attached to another and may result in leaking. This will result in wrong reading and leaking of air during measurement.	6	Tubing or the device is left out in the sun or other hot locations	1	Choosing a material that can withstand high temperatures	3	18	Research different material properties of tubes connectors and their operating temperatures in addition to Kumasi weather
		Ripping	The tubes and other pressure components will not be attached to another and may result in leaking. This will result in wrong reading and leaking of air during measurement.	6	When the connectors are overused or moved around with great force, the tube connectors may rip.	2	Choosing a plastic material that can withstand high forces and extensive uses.	2	24	Research different material properties of the tube connectors and choose one that can withstand high stress.
Pressure sensor	Detect the real-time pressure in cuff and transmit the signal to arduino to enable display and feed to control of deflation rate	Loss of sensitivity	Over/under-determine pressure or no signal picked up at all	8	high temperature, number of uses, overpressurization (exceeds 300mmHg)	3	Secure the pressure sensor in a protected housing, use pressure sensor from a reliable manufacturer	3	72	Secure the pressure sensor in a protected housing, use pressure sensor from a reliable manufacturer
		Air leaking between the pressure sensor and the connection	Over/under-determine pressure or no signal picked up at all	8	Faulty connection possible due to rough usage or overusage	2	The connection of the pressure sensor the tubing is secured tightly with correct sizing tube connector and zip-ties	2	32	Secure the connection between the pressure sensor and the rest of the tube using a type of lock-tight between the pressure sensor and the tube.
Headphone Port	Amplify the Korotkoff sounds so that they are easier to hear for the user	Amplification of noise buries Korotkoff sounds	The amplification cannot be used and a stethoscope has to be used	6	The environment is noisy. The connection between the microphone and speaker is faulty. The microphone is not registering the desired sounds.	3	Using headphones for the amplification method and not an open speaker to the room and the volume can be adjusted.	3	54	Speak with physicians about the microhone amplification and as part of engineering analysis test out a microphone with a stethoscope piece to see how to best

										amplifiy the desired sound to the user
Solenoid Valve	Opens and closes the valve opening based on the feedback loop of the pressure system to keep the constant deflation rate of 3 mmHg/s	Vibrations	Inaccurate positioning, damage to mechanical parts	6	Misaligned gears or foreign debris inside motor	2	Use metal gears, seal the motor	3	36	Use a solenoid valve from reliable manufacturer and seal the motor
		Valve opening failures	Solenoid valve not opening and closing in the desired rate	6	Mechanical overload or thermal load	2	Keep the load below service factor, keep voltage and current in operating range	1	12	
		Encoder output or position count faults	Valve not working at desired speed and/or direction	6	Pressure sensor in cuff failure or pressure sensor failure or bugs in program	2	Test and make sure microcontroller program works, use reliable pressure sensors	1	12	
		Position sensor failures	The microcontroller does not receive correct current position and thus miscalculates the rate at which the valves should open	6	Mechanical wear or overheating	2	Use reliable sensors	3	36	
		Overheating	Breakdown of both mechanical and electrical parts	6	Blockages within valvess or increased environmental temperature or heat generated by nearby machines	2	Seal the valve; consider valve temperature range when determine overall temperature range, ensure no overheating in other components	2	24	
		Electrical surge or overcurrent	Short circuit, damage to electrical parts	8	Fault from connecting machines, i.e. from microcontroller	2	Add surge protection to the motor, and a circuit design that would not lead to overcurrent	1	16	
		Dirt	Inaccurate positioning	6	Valve not fully covered	1	Seal the valve	3	18	
Housing	To encase the device to keep all the parts together and protect the device. The housing also includes the LCD screen on top of the casing	Overheats	The device would overheat and may not work due to high temperatures	7	The device is left out in places with high temperature or in direct sunlight for long period of time	2	Test and validate the material used for the housing	2	28	Research material properties of plastics and electrical components and their operating temperatures in addition to Kumasi weather and the amount of sunlight provided.
		Cracks or breaks	The components within the housing would be vulnerable to damage, and the pressure sensor and other parts related to the LCD screen may not function, depending on the severity of the damage. In addition, the aneroid pressure can be broken and not	8	The device falls or is used with extreme force, causing wear	4	The shape of the device is round to allow the distribution of force when the device falls. In addition, there will be a lot of cushioning around the aneroid pressure gauge. Lastly, the device will be made of materials that	1	32	Research different methods of casing and force distribution to decrease the possibility of breaking during use.

			measure the correct pressures, which is important for calibration. Could harm the patient.				withstand the durability tests, such as 1 m drop test and the dust resistance test.			
		Electric short	The electric short may harm the patient or the user and the device would not function if not powered correctly	8	Circuit modified unintentionally	2	Test to ensure that the parts with wiring would not move within the device casing.	2	32	Ensure that the circuit components cannot be modified unintentionally, even after extensive uses and falls.
Inflate/deflate tubing	The tubing connects the patient's cuff with the pump bulb	Ripping and tearing	There will be a leak when applying pressure onto the cuff or during calibration process, so accurate pressure readings will not be possible as the pressure will continuously be leaking out.	8	It is possible that when the device is out in the sun, the tubes may melt which makes them unusable and unsafe if the melted material is hazardous	2	The pressure tubing will be made of material that is tough but also easy to replace in-country. There is a casing to hold all the tubing during transportation and device storage	1	16	Ensure that the material selected for the tubing has high wear resistance, is resistant to and abrasion, and can be replaced in Ghana. Ensure that the actions required of the user while using the device does not exert force enough to rip the tubing.
		Melting	The melted tubing will not allow the pressure to be measured curretly because the shape of the tubing is deformed. The melted rubber may be hazardous.	7	It is possible that when the device is out in the sun, the tubes may melt which makes them unusable and unsafe if the melted material is hazardous	1	The tubing will be stored within the casing while being transported or being stored, so it will not be put in direct sunlight	3	21	Ensure the material used for the tubing is not hazardous to humans and has a high operating temperature
LCD screen	To display the blood pressure reading	Stuck or dead pixels	Risk of misreading measurement	3	Continuous use of screen over an extended period of time	4	high number of total pixels	2	24	Use a program that exercises the crystals, Tap/rub/press stuck or dead pixels
		Physical burn-in of display	Risk of misreading measurement	3	Continuous use of screen over an extended period of time	4	Off button for LCD so that it can be turned off	2	24	Turn off screen for an extended period of time so that screen can be equilibriated to its baseline "off" state
Battery	Provides power to arduino, deflation motor, and LCD screen	Battery acid leakage	Irritate skin of user, leak toxic substances into environment, explosion, loss of device function	9	Corrosion	1	Seperate casing for the battery	4	36	Dispose of battery and properly clean up the leaked battery acid.
		Overheating	Explosion, fire, loss of device function	9	Overuse	1	Separate casing for the battery	1	9	Refrain from use for an extended duration
Hand pump	To apply pressure to the cuff and occlude blood flow in order to	Air Leakage	More effort required to apply desired amount of pressure to patient's artery	4	Overuse or overagressive use of pump	3	Choice of a durable material that can withstand pressure applied by hand squeezing action	3	36	Seal spot of leakage or replace hand pump

	obtain blood pressure reading									
Microphone	To detect and convert the korotkoff sounds to electric signals.	Does not pick up Korotkoff sounds	The amplification cannot be used and a stethoscope has to be used	6	The environment is noisy. The connection between the microphone and the battery is faulty. The microphone is not registering the desired sounds because of the microphone broke, is not sensitive enough, or is placed in the wrong location by the designer or user.	3	The microphone will be placed in a stethoscope piece to help with the durability and the proper location of the device to pick up the sound. We are also concious of the microsphone manufacture when making a purchase	3	54	Speak with physicians about the microhone amplification and as part of engienering analysis test out a microphone with a stethoscope piece to see how to best amplifiy the desired sound.
Microphone amplifier	To increase the sounds picked up by the microphone to allow the output to the user's earphones	Voltage failure and does not amplify the microphone enough	The Korotkoff sounds cannot be listened to by the user through the earphones	3	The amplifier may become damaged within the microcontroller or the voltage input into the microphone amplifier is not adequate	2	The voltage input and output to the amplifier will be calculated to fit both of the amplifier, microphone, and volume output settings	2	12	Ensure that there would not be a circuit short into the microphone amplifier and that all parts connected are well soldered.
Emergency Release Button	To act as an user operated pressure release valve for when the pressure needs to be deflated to 0 within 10 seconds.	Cannot be pushed to release pressure	The user does not have the mechanical power to deflate the cuff in under 10 seconds with one swift motion and the patient has a large amount of pressure on their arm, which would harm the patient	10	The button is misshapen or broken so that it cannot be pressed	2	There will also be other methods to deflate it including a mechanical deflate option and a pressure valve for when the pressure reaches over that critical 350mmHg value.	2	40	Ensure that there is minimal ways for the valve to break.
		Leaks air out of the button	The overall pressure system will not be kept constant and the leaking will result in wrong reading and leaking of air during measurement.	6	The connection between the manifold and the emergency release button are not tight	2	The button and the valve connection will be connected as tight as possible with a tight-lock type of tape/ glue.	2	24	Ensure there are limited ways for the emergency valve connection to loosen its connection from the manifold

The highest risk identified from the risk analysis was at the level of 3 related to the hazard of the solenoid valve overheating. This hazard can occur when the solenoid valve is overloaded mechanically or electronically. The solenoid valve is an integral component of the device as it controls the automatic deflation rate. If the valve malfunctions, this will lead to the significant reduction in the automated deflation function of the device as it determines the flow rate of air out of the device. In addition, as the design also incorporates a manual hand pump, the user can still use the device to measure blood pressure. However, when failure occurs, it is predicted that a new valve would have to be identified with possible budget or unit cost increase. To combat the possibility of this failure, the solenoid valve used for design is a continuous model, which allows for the continuous use of the valve without overheating. In addition, the team predicts that the valve having to control the constant deflation rate of 3 mmHg/s would require minimal work. Lastly, the circuit will output a voltage and current into the solenoid valve within its operating range, as it is connected to a relay. Lastly, the solenoid valve will also be carefully chosen based on the engineering specifications provided by the manufacturer.

Based on the FMEA, the highest risk priority number was 72, which is a failure related to the pressure sensor. The pressure sensor detects and reports the real-time pressure in cuff and transmits the pressure sensed as a signal to the Arduino to enable the LCD display and the constant deflation rate. The constant deflation rate depends on the pressure sensor to ensure a rate of 3 mmHg/s. It is important for this pressure sensor to work correctly for accuracy in blood pressure readings, which is a top priority design driver. Based on the team's analysis, it is possible for the pressure sensor to lose sensitivity or become damaged, which can lead to an over/underestimation of the pressure or no pressure detection at all. Accuracy of the blood pressure measurement will affect the patient management plans, which would affect the health of both the mother and the child. Possible causes of failure can be due to high temperature, extensive use, and high pressures. These possible causes of failure may occur frequently. The target setting for the device is Kumasi, Ghana, which faces temperatures above 40 C; it is possible for the device to be in direct sunlight or left in areas with high temperatures. In addition, the wards must monitor the hypertensive pregnant patients often, which means the devices would be used extensively. Because of the potential for inaccuracies, a pressure relief button has been incorporated into the design so that if the pressure is too high it can be released quickly by the operator. Furthermore, the safety relief valve will open if the pressure goes above 300 mmHg. Also, the pressure gauge used for calibration can also give the user evidence that the pressure sensor is failing if there are discrepancies between the 2 pressure readings. The current controls for this failure is to secure the pressure sensor in a protective housing so the high temperature and extensive use would not wear down the sensor as much. In addition, the pressure sensor will be bought from a reliable manufacturer; the specifications of the sensor bought will be researched thoroughly to ensure durability, maintainability, and accuracy.

The overall risk associated with all parts of the design are at acceptable levels. However, it will be important for the team to continue reducing these risks for all of the items to meet the reasonable RPN threshold of 30.

Final Design

The final design incorporates components from both the alpha and beta design, but with a couple of changes (Figure 28). Overall, the final design utilizes the auscultatory method as its measurement method with calibration capability, LCD display, constant automatic deflation, and adjustable arm cuff. The use of the auscultatory method is supported by the microphone stethoscope. The LCD screen will display the current pressure and also incorporate a memory feature to allow the user to mark when they hear systolic and diastolic. The calibration method incorporates an embedded aneroid pressure gauge. The device is intended to be opened during use, with the cuff, stethoscope, earphones, and bulb to be stored within the device. The design features a handle on the back for device transport between bedsides.

The design is also able to be used without any battery when using the embedded calibration gauge as the mechanism to display pressure, the inflation and deflation done manually with the bulb, and the auscultatory method carried out by a stethoscope.

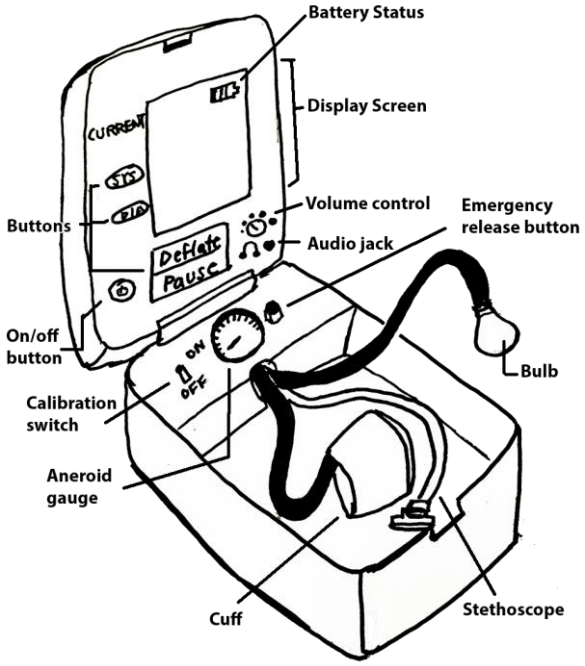


Figure 28: Final Design

Auscultatory Method with Microphone Stethoscope

The final design features a stethoscope head that will be placed on the patient's brachial artery once the cuff is on the patient. This stethoscope will be attached to the microphone on the end of its tube, which will amplify the sound and output to an audio jack. The design will include a set of earphones, but any standard earphones will fit into the audio jack. The volume output is adjustable through the earphones, which was added to take into account the noise level within the wards. Microphone stethoscope was also validated to be accepted within the medical culture after correspondence between the U of M ob/gyn doctors and KATH healthcare providers.

Maintaining the stethoscope head decreases the cost, while increasing durability, and replaceability of parts, which is important for the design's target setting.

Inflation and Deflation Mechanism

The top designs have consistently allowed manual inflation, which is a desired feature in consideration of the device power usage. As the design allows for manual usage without any battery, it requires a hand pump. Because inflation is already manual, there is no need for additional components for the device's use without battery. In addition, the user-controlled will reduce the risk of error of the healthcare provider from over-inflating the blood pressure cuff, as the hand pump will make the over-inflation more difficult.

According to recommendations for blood pressure measurements, it is important to maintain a low deflation rate around 3 mmHg/s to allow the filling of the brachial arteries after its occlusion. Any deflation slower or faster would result in a distorted Korotkoff sounds due to rapid or stunted blood filling into the arteries. Therefore the mode of deflation is automatic at a set deflation rate. The final design's mode of deflation has changed from previous design, as it now incorporates a solenoid valve as opposed to using a servomotor to control the valve opening circumference. The servomotor deflation mechanism was abandoned after considering the manufacturability of servomotors within Ghana or nearby countries. Not only is the servomotor not as common, it also requires a 3D printed component for mounting it on the device, which requires specially manufactured parts. A solenoid valve, on the other hand, can be incorporated within the electrical housing and can be more easily replaced.

The solenoid valve is to open and close depending on the change in pressure detected by the microcontroller. The team would like to use proportional-integral-derivative (PID) controller along with pulse width modulation (PWD) to maintain a constant deflation rate.

Pressure Manifold

As shown in Figure 29, the calibration mechanism and emergency pressure release valve are all mounted within a closed mount; this mount will encase a pressure manifold, which will hold all components that require a distribution of pressure. Previously, the pressure system was intended to be connected using t-tube connectors. However, due to the number of components to the device and after consideration of manufacturability, the t-tubes were switched for a system pressure manifold, to which all pressure components would connect.

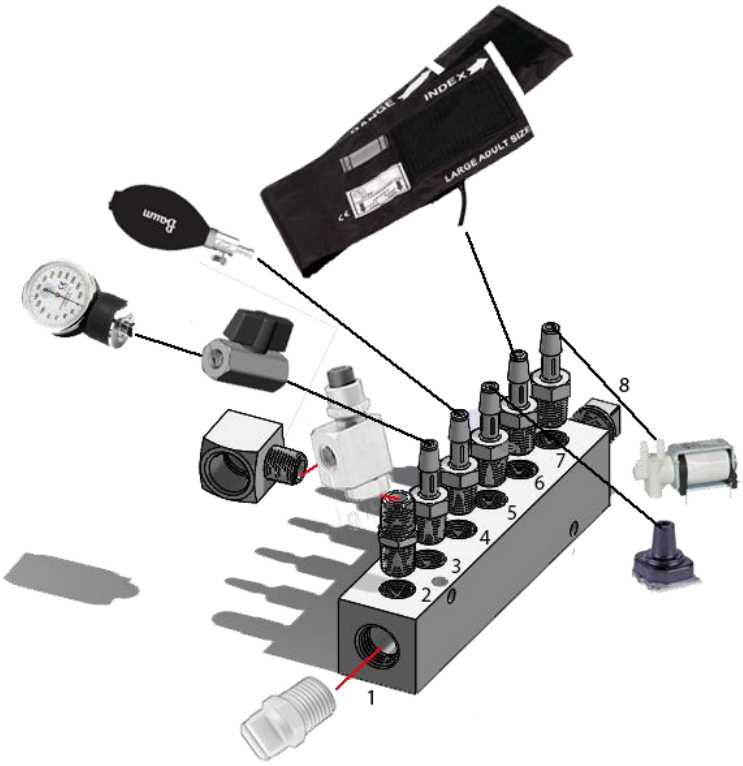


Figure 29: Pressure Manifold Connection Diagram

The pressure manifold is intended to have all of its outlets on one face for manufacturability and storage of the pressure components within the device. The components that require the pressure sensor or any type of pressure application will be attached on this pressure manifold. This manifold will be stored within the device within the aneroid sphygmomanometer mount, as shown in Figure 28.

Display Design

The final design includes the LCD display that shows the current pressure in addition to marking the user determined systolic and diastolic values. This numerical display is intended to improve the readability of the measurement and reduce user estimation of the blood pressure readings. The user will have the option to press systolic and diastolic buttons when he or she hears the Korotkoff sounds, and these values will be featured on the LCD display so the user would not forget the values at which the blood pressure sounds were detected. This pressure display is novel within the field, as there are currently no auscultatory blood pressure measurement devices with the digital LCD display with marking of systolic and diastolic values. The display also features a separate deflate and pause button to allow the user to deflate and pause the deflation whenever desired. The orientation of the LCD screen and buttons of the final display design is based on the display design of the automatic device that is currently used in the target setting. The ideal sizing and spacing of the buttons was determined based on studies conducted by the military and the U.S Department of Transportation.

In addition, the display will show the battery status, which was deemed important from the stakeholders in Ghana. Healthcare providers expressed that it would be important to know when

the device is low on battery so they would know when to change the battery or charge the device if need be. This battery status will be depicted in the right hand corner of the LCD screen.

The final design also features the aneroid sphygmomanometer that can be connected with the rest of the pressure system with a ball valve. The valve can be opened during calibration of the LCD screen. The embedded pressure gauge can also be used for use when the device has no battery. The ball valve will be embedded in the device as a calibration switch within the pressure manifold so the user would connect the pressure gauge whenever desired.

The final design's user interface has also been modified from the previous designs. Now there are two surfaces with buttons on them. The top face which opens has the features utilized during regular use of the device like the LCD screen, the deflate button, the systolic and diastolic buttons, the audio jack, the volume control button, and the power button. This top will be connected to the rest of the device via a friction hinge so that the screen can be adjusted by the user to be at the optimal position in various situations. The secondary features on now on a raised platform in the main part of the device. It will be raised to allow for easy access by the user and to distinguish it from the storage space. The emergency relief valve, the switch to activate the pressure gauge, and the pressure gauge are all in this raised area. This change was in part to have the primary buttons on the main face and secondary buttons on the lower face. Furthermore, the emergency relief button is on the lower face because in distress the user should be pushing down on the button. If the button was on the primary face, the user could push the top further backward rather than pushing the button successfully.

Prototype Description

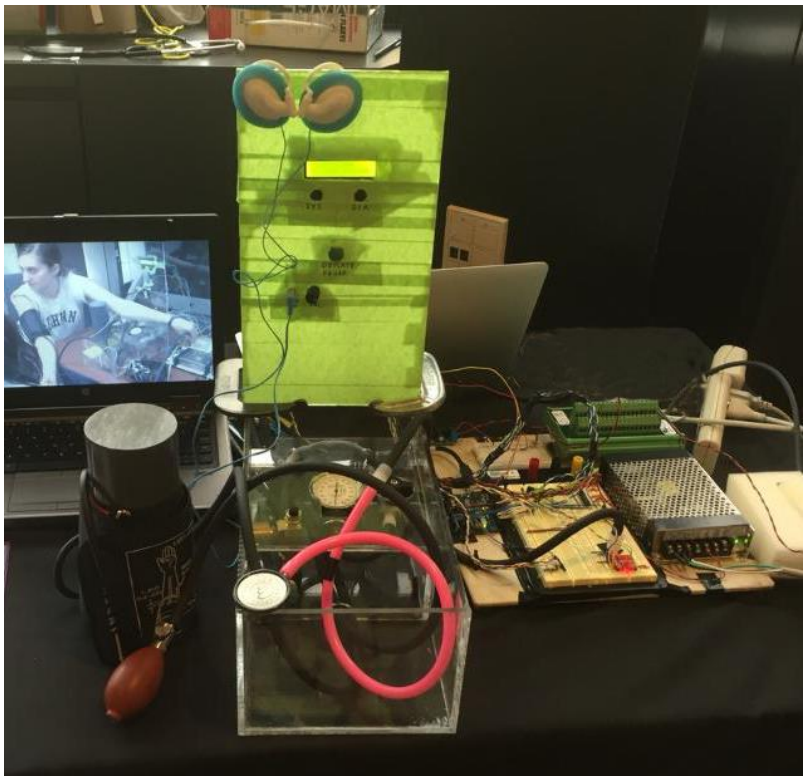


Figure 30: Full prototype (left: with the primary interface, right: without primary interface)

The prototype for the blood pressure device will be functional, but will not have the complete final form of the design. The main function of the prototype will be to ensure that the pressure manifold system, pressure sensors, and microphone stethoscopes are all functional (Figure 30).

The prototype consists of circuits and components connected to the Arduino and the breadboard with connections to the pressure manifold, as shown in **Appendix L Figure 1**. The breadboard will be replaced by a small circuit in the actual design of the device. The pressure manifold is used to keep the pressure constant throughout the device; this connects to the cuff, bulb, pressure sensor, solenoid valve, safety release valve, and emergency release button.

The prototype includes three tactile switches: two to mark the systolic and diastolic, and one tactile switch to deflate the blood pressure cuff. A solenoid valve is used to control the deflation, with inputs for on and off controlled by the Arduino based on an empirically set value. The deflation can be continued and paused with the same button. The solenoid valve was also set to automatically open when the pressure sensor read 40 mmHg, as it is a pressure that would not be possible to detect on a live patient. This value was incorporated to decrease the procedure time.

In addition, the housing is created with laser cut acrylic, which is simpler and less expensive than using a 3D printer or injecting plastic into molds. Figure 30 depicts the CAD drawing of the assembled casing. Though the housing may be less stable and weaker, the prototype will only be used for testing the portability of the device. The current housing is made to fit the pressure manifold and the additional measurement components, including the cuff and the bulb. The housing will be made to hold the small LCD screen for the prototype; the real housing will incorporate a screen that is large enough and will be designed to meet the requirements for readable measurements. Therefore the control system and user interface will have slight differences to accommodate for the prototype. The prototype casing has two interfaces; in-depth explanation of each interface and part is in the assembly plan in Appendix L. The user-interaction interface includes the screen and buttons for control in addition to the audio jack and a volume control for the microphone stethoscope.

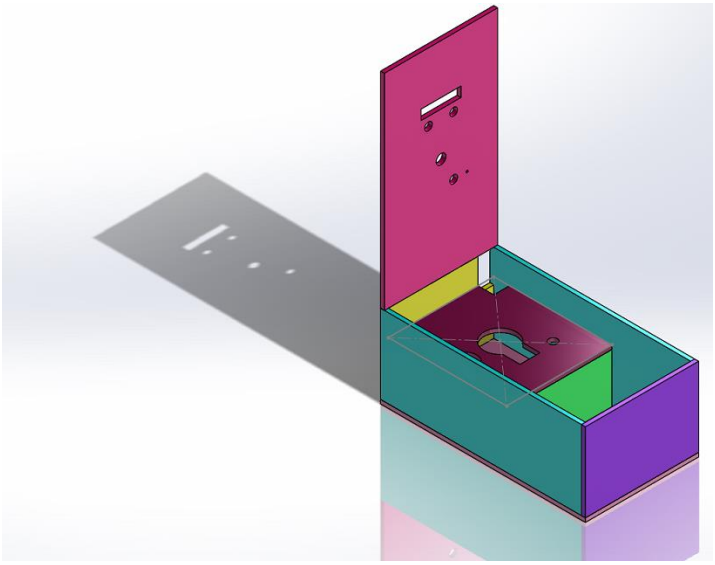


Figure 31: Assembled View of Prototype Casing

The control mechanism is demonstrated through the Arduino, which will be replaced by a small microcontroller in the actual device. The code for the deflation control, button control, and pressure sensor read-in can be found in Appendix M. Some areas that did not translate from the design to the prototype include that PID control was not implemented and thus the solenoid valve was operated with a fuzzy controller. Because the prototype is a proof-of-concept with the connections to the Arduino, the source of power will be only from the Arduino. Therefore the rechargeability of the battery will not be addressed by the prototype during this semester of design.

The prototype Bill of Materials can be found in Appendix J and assembly plan can be found in Appendix L.

Engineering Analysis

In order to be convinced of the design decisions that have been made, the team identified key functions and features of the design and performed engineering analysis. The engineering analysis that was performed serves to justify the acceptable margin of error for different features and functions by performing the simplest possible calculations that also convincingly justify each design decision. The main areas where engineering analysis was conducted include the microphone stethoscope, battery, ability for the device to measure pressure, accuracy, reliable power source, portability, and ease of use.

Design Drivers

Among all the requirements, the team identified five key design drivers for the device: it must be accurate, safe, affordable, portable, and easy to use. All of the identified design drivers are critical for the success of the design. The importance of the design drivers, design driver analysis and validation method of each design driver are described in the following Table 3.

Validating the affordability is another challenge foreseen, as the calculated analysis of finances done in US will not match the market prices in Ghana. As the device also has the engineering specification of being maintained in-country, it would be important for the team to keep in mind the price and the replaceability of each part

Table 5: Key Design Drivers

Driver ID	Description	Importance	Design Driver Analysis	Validation
Portable	Need to design a device that allows the user to carry it easily. Need to determine the size, weight, and holding method for carrying this blood pressure device.	If the device is too big, heavy, bulky, or just difficult to carry in general, the stakeholders would not bother using it. Portability is important because the devices have to be carried between bed to bed or other locations. Because patients have to be regularly monitored, the healthcare provider may be carrying the device for a long period of time. Lastly, the blood pressure devices must also accommodate for patients who are bed-bound.	Conduct an experiment to determine the maximum weight, size shape, and other features that user views as making the device portable	Conduct ergonomic research on what is portable for people to carry; Test of physical prototype with different attachment methods with a focus group
Reliable Power Source	A device needs to be powered in some way whether it be by a user, a battery or other power methods in order for pressure to be applied and released in a specified fashion to find the patient's blood pressure.	The method in which the device is powered is very important to the design because it can restrict the usability of the device; if the device can't or shouldn't be used due to its power source being low or out of power, then it can't help promote the standard of care the hospital wants to achieve.	Calculate the power necessary for one measurement and make sure that the theoretical power given by the power source can match the used until regeneration requirement.	Use the device until the power source is depleted, if not completely mechanical, and count how many measurements were taken over what period of time.
Accurate Blood Pressure Measurement	A device needs to give blood pressure readings that are as close as possible to the actual blood pressure measurement.	Accuracy is important because even a small change in the systolic or diastolic readings can impact the management of a patient. If the device is not as accurate as the current methods, than the device will not be used.	Conduct research to determine the standards for accuracy for blood pressure measurement devices, and the physical mechanisms that are used to obtain accurate readings.	Connect device to a known accurate blood pressure measurement device and compare the difference in the readings.
Affordable	The device needs to be cheap so that it is feasible to purchase in low-resource settings.	The device has to be cost-effective so that the adequate number of devices can be purchased for use in a high-volume clinical environment. There is a set amount of money that goes towards new blood pressure devices each year and this amount cannot be exceeded.	Conduct research to determine how much devices currently cost on the market and what WHO recommends for the price	Conduct an analysis of the finances involved with acquiring the materials and the device parts and manufacturing
Easy to Use	The operation of the device by the user cannot be cumbersome.	The device should be easy to use for the users to use the device. The current method of measuring blood pressure is deemed "cumbersome" by the healthcare providers. Based on the user interviews, for a blood pressure device to be easy to use, it must have short procedure time, requires minimal steps, and minimal additional equipment. In terms of procedure time, the device should enable blood pressure measurement to be taken in a short period of time due to the busyness of the wards and the number of patients in each ward.	Conduct research and benchmark to determine the average procedure time of existing blood pressure devices. Also, time healthcare providers using current blood pressure device in KATH and get current procedure time. Benchmark and conduct research on different types of blood pressure pumps	- Time healthcare providers who have passed training to use the device & Conduct an analysis of the current method of adding pressure to the device and how much force the user should exert.
Safe	The device must be safe to use for both the user and the patient based on the engineering specifications.	Because the device will be used on human subjects, it is crucial for the device to be safe to not harm the patient.	Conduct research based on the types of requirements that must be met for a device to be considered safe.	Conduct empirical testing to ensure that too much pressure is not applied and conduct research to ensure all components of the device are safe on humans.

Accuracy

As the device uses auscultatory method, the accuracy of blood pressure measurement depends on both the machine and the user. This section focuses on the performance of the device in respect of technical specifications for each component.

1. Pressure System
   In our pressure system, air will be running through 3/16 inch inner diameter tubes. These tubes will be connected to a pressure manifold to all other tubing. Although there will be viscous and frictional losses, as there are in all fluid systems, the frictional losses will be negligible due to the low viscosity of air and the negligible size of the associated boundary layers. This system can be thought of as a semi-closed system where air enters through an inlet to fill the allotted volume, where the internal pressure increases in proportion to the amount of air entering.

   Pressure waves travel quickly -- approaching the speed of sound in the fluid because sound, in fact, is a pressure wave. Thus, for the time scales present in the blood pressure measurement process, each pump of the bulb can be considered to distribute the air pressure throughout the system instantaneously. It is not completely instantaneous because of the small volume of air in the tube. According to fluid dynamics and Le Chatelier's Principle, any pressure difference in a connected system generates pressure gradient that drives air to flow from high-pressure areas to low-pressure areas until equilibrium is reached [40]. For fluid to flow, there must be a pressure difference, but since pressure waves move so fast the pressure differences equilibrates very quickly. As the design assumes that the time to restore equilibrium after a change in pressure is negligible, and that the pressure throughout the entire system is uniform at any given time point, it follows that the pressure sensor can be located anywhere in the system, and the measurement of the sensor is equivalent to the pressure in any other part of the tubing.

   By Pascal's Principle states that pressure is transmitted undiminished in an enclosed static fluid. Thus, when there is no inflating or deflating occurring like in between pumps of the hand bulb, the pressure should be uniform everywhere in the system. Because the cuff has a larger area and the same pressure as the rest of the system, it will exert a larger force on the patient's arm then the force exerted in the tubes.

   In addition, a constant deflation rate at 3mmHg/second is important to get an accurate measurement. To ensure accuracy as well as ease to use, an automatic constant deflation is implemented in the design. See Engineering Analysis- Easy to Use for details.

2. Pressure Sensor
   The overall accuracy of the device is highly dependent on the accuracy of the pressure sensor. Full-scale span (FSS) is defined as the output voltage at the maximum pressure minus the voltage at minimum pressure [41]. As it is a fraction of supply voltage, there is always a trade-off between power conservation and accuracy. The margin of error of a sensor is typically defined as a certain percentage of FSS. Therefore, the range of measurable pressures and input voltage are critical in determining accuracy. All pressure sensor candidates for the device have to cover the range of 0- 300 mmHg as specified by

engineering specification for measurement range, and the range of an ideal sensor should be close to the measurement range after considering safety factor.

The sensitivity of a sensor is a combined result of measurement range and full-scale output, and is expressed as the change in output voltage per increment of one unit of pressure. For convention and for the purpose of a blood pressure device, the report uses mV/mmHg as the standard unit. The higher the sensitivity, the more accurate and precise the pressure reading.

Response Time measures the time necessary for the output voltage of the sensor to reflect the change in pressure. The shorter the response time, the more accurate the blood pressure measurement.

The team considered a wide range of sensors and decided that Honeywell Sensing and Control ABPLLNN600MGAA3 will work best for the design. Apart from the criteria discussed above, preference was also given to sensors with analog output due to convenience in connecting to Arduino. The sensor satisfies the engineering specification for accuracy: the accuracy of both sensors is within +-1mmHg [41].

Table 6: Selected specifications of pressure sensor

	Honeywell Sensing and Control ABPLLNN600MGAA3 [41]
Pressure Range	450 mmHg
Operating Voltage	3V
Full-Scale Span (FSS)	0.3V - 2.7V
Accuracy	+- 0.25% of FSS
Sensitivity	5.33mV/mmHg
Response Time	1ms

3. Microphone stethoscope
   As the blood pressure measurement is determined by the user listening to the Korotkoff sounds in the design, it is critical that the microphone chosen is able to pick up the sounds from the stethoscope and broadcast the sounds from the over-ear headphone in real time. The success of this process depends on three main components: the stethoscope, the microphone, and the audio amplifier.

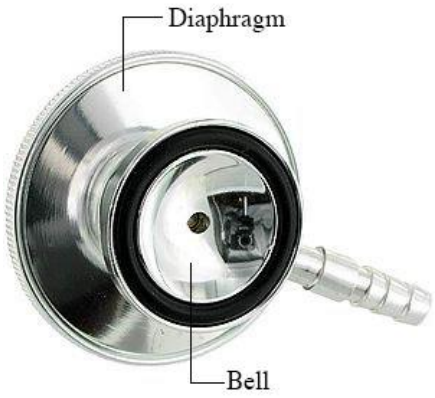


Figure 32 [42]: Labeled parts of a stethoscope head

The stethoscope head is composed of the diaphragm and the bell. The diaphragm is designed to pick up high-frequency sounds and the bell for sounds of low-frequency. Research shows that Korotkoff sounds for blood pressure measurement can be picked up by either side [43].

The microphone stethoscope is built with a stethoscope cut at the tube and secured to the microphone using electrical tape to seal the airway between the microphone and the tubing. Based on the stethoscope and its function, it was crucial to seal the tubing for the sound on the stethoscope head to travel to the microphone.

Figure 33: Set up for the microphone stethoscope. Left- cut stethoscope. Right - Connection to microphone

Figure 34: Overall configuration of the microphone stethoscope modeling

Both the diaphragm and the bell of the stethoscope was used to determine whether a person's heartbeat could be heard through the speaker, though faintly. Both the bell and diaphragm of the stethoscope head were able to pick up noise, but the bell was able to amplify the heartbeat sounds more than the diaphragm. As blood flow beneath the brachial arteries are low-frequency noises, it would be ideal to use the bell side of the stethoscope head for clearer sounds during measurements. However, the amplified sound of the heartbeat was very soft, so high amplification of the sound would be required to pick up the blood flow.

The sound frequency range inside the stethoscope is 20-200Hz [43], which is in relatively low considering humans can hear sounds between 20 and 2000Hz [44]. Low-frequency sounds are more difficult to pick up, and only a small portion of microphones in the market are sensitive enough to pick up such low-frequency sounds. The microphone used is CUI Inc. CMA-6542PF and is an electret condenser. In the proof-of-concept, it has been shown that the microphone is able to pick up the brachial arteries sounds with the stethoscope.

An amplifier breakout board from Sparkfun using the class D amplifier TPA2005DA by Texas Instruments was used. Class D amplifiers are more energy efficient (95%) compared to classA/B amplifiers (50-70%) [45], and is therefore preferred since reliable power source is one of the design drivers. The amplifier provides output that can be directly connected to the headphone jack and used by mono headphones.

Portability

Figure 35: Caroline Soyars assessing maximum weight based on everyday objects

When the team was observing the use of blood pressure measurement devices while in Ghana, it was evident that the device needs to be easily carried throughout the ward in order for it to be used. However, the definition of what makes something portable is ambiguous because there are a variety of factors that altogether contribute to the portability of a device. Because the definition of portability is user-driven, the team decided to conduct portability assessments with the health care providers while in Ghana. These tests consisted of comparing the size, weight, and portability features (such as handles) of different everyday objects that were found on the wards. From these tests, the key qualitative findings were that the device should not exceed 2.8 kg to be considered portable, the width of the device must not exceed the amount of space that is available to place the device on a patient's bed, and that the addition of a handle increases the user's perception of the portability of the device. These findings have continued to be considered throughout the design process. The final device design includes a handle, and the weight and dimension restrictions that were elicited from health care providers have also factored in to the final shape and size of the device. Looking ahead, it will be important to keep the user's perception of portability in mind when selecting materials. Furthermore, the information that was objectively gathered from health care providers in Ghana justifies the design decisions that have been made thus far with respect to portability and will continue to be considered throughout the manufacturing process.

Easy to Use

1. Auto-deflation with solenoid valve
   Research has indicated that a constant deflation rate of 3mmHg/second is critical in obtaining an accurate blood pressure measurement. Meanwhile, the current manual device at KATH requires users to perform three actions— listening, deflating and attending to the mercury column— at the same time, which is cumbersome. Therefore, the team believes that an auto-deflate function will make the blood pressure device more accurate and easier to use, which are two of the key design drivers.

For the deflation of the cuff, the ideal deflation rate and thus the set value of the feedback controller in the system will be 3 mmHg/second. To regulate this rate, a close-loop feedback control system is established. As the real-time information detected by the pressure sensor is pressure (P), while it is deflation rate, which is the derivative of pressure (dP/dt), to be held constant, the set point (duty cycle) of the feedback loop changes according to the current pressure in the system. Deflation rate will be controlled by driving the solenoid with corresponding open or close cycle. Therefore, it is necessary to establish a relationship between pressure in the system and duty cycle of solenoid at dP/dt = -3mmHg/sec. To find out the relationship, empirical testing with the solenoid is needed.

In the test, the duty cycle of solenoid is held constant at a specified value during deflation from 300mmHg to 40mmHg. The team chose 40mmHg as the end point instead of 0mmHg, because the deflation rate curve is logarithmic and it will theoretically never reach 0mmHg. Also, patients can be disengaged from the cuff at 40mmHg without any problem and blood pressure is fairly undetectable below 40 mmHg. The test can be done multiple times with varying values of duty cycle. The result of this empirical test would be a relationship between pressure and time, with multiple curves on the graph, each curve representing a specific duty cycle. Then, the tangent line at -3mmHg/second is found on each curve. Mark the pressure value corresponding to the tangent line. This will provide data points relating pressure in the system and duty cycle of the solenoid for a deflation rate at 3mmHg/sec. With the data points, a best fitting line will be found and thus a relationship between pressure and duty cycle is established.

With the best fitting line that gives setpoint for duty cycle at specific pressures, the first-pass control algorithm will use a ramp function. During the first second of deflation, duty cycle should be held at a set low value, because the flow at start will be very turbulent and hard to characterize, and thus the pressure sensor reading might not best describe how to maintain a constant flow rate. Taken this into account, a time delay can be added to the ramp function, with the first second using a very low duty cycle; afterwards, the function uses the feedback information provided by the pressure sensor, and set the solenoid at corresponding duty cycle using the relationship that has been established. The interval for pressure update should be long enough to allow the solenoid to fully respond in digital control, and also short enough for checking frequently.

The final design has a discrete proportional-integral-derivative (PID) control algorithm. PID will calculate the error value between the actual pressure and the ideal pressure after the actuator, which is the solenoid held in specific duty cycle. The interval for PID error checking will be the same as pressure checking. PID tuning for the parameters will be done with simulation in MATLAB. For the prototype, the team used fuzzy logic controller instead to improve the accuracy of the first-pass set point close-loop controller.

In order to do simulation and auto-tune in MATLAB, a model that describes the pressure system during the deflation phrase has to be built. Using ideal gas law, continuity of fluid, and gas dynamics, the team derived an equation that describes the relationship between deflate rate, current pressure in cuff, and duty cycle of solenoid. Two assumptions are made: gas in the cuff obeys ideal gas law, and volume of the cuff is constant. Note that MPa is used as unit of pressure for convention in combining equations. Final graph in MATLAB uses 1mmHg = 1.33*10-4MPa to translate the result back to mmHg.$PV = NkT$

$$\frac{dP}{dt} = \frac{kT}{V} \cdot \frac{dN}{dt} \quad (1)$$

$$-\frac{dN}{dt} = nAv$$

$$\frac{dP}{dt} = \frac{kT}{V} * (-nAv) \quad (2)$$

$$Q = Av \quad (3)$$

$$(1)(2)(3): -\frac{dP}{dt} = \frac{PQ}{V} \quad (4)$$

P = pressure in cuff (MPa), V = cuff volume (liter), Q = flow rate (liter/minute)
For dry air at valve, minimum pressure ratio b (Pupstream/Pdownstream) for choked flow to occur is 0.528. If (Pdownstream+0.1)/(Pupstream+0.1) > b, the flow will be subsonic flow. In our system, maximum pressure is 300mmHg = 0.04MPa, and pressure after valve is 0mmHg. Because 0.1/0.14 = 0.714 > 0.528, it is always subsonic flow in our deflation system. For subsonic flow:

$$Q = 600C(Pupstream + 0.1)\sqrt{1 - \frac{(\frac{Pdownstream + 0.1}{Pupstream + 0.1} - b)^2}{(1-b)^2}} \times \sqrt{\frac{293}{273 + T}} \quad (5)$$

Because the solenoid valve controls flow rate with different duty cycles, the term Q' = kQ is used to put in equation(4), where k is the duty cycle, Q is flow rate when solenoid duty cycle = 100%, and Q' is the flow rate regulated with the specific k.
Combining equation (4) and (5), the following master equation describes the system during deflation phrase:

$$-\frac{dP}{dt} = \frac{P}{V}600kC(P + 0.1)\sqrt{1 - \frac{(\frac{0.1}{P + 0.1} - b)^2}{(1-b)^2}} \times \sqrt{\frac{293}{273 + T}}$$

Constants: V = cuff volume (liter), C = sonic conductance of the solenoid valve, b = minimum pressure ratio = 0.528, T = temperature (°C)
Variables: P = pressure in cuff (MPa), k = duty cycle of solenoid

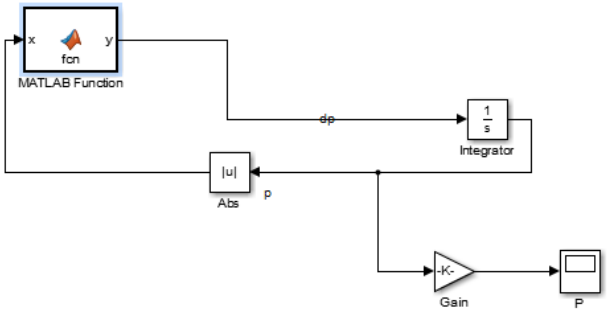


Figure 36: MATLAB block model of the system at deflation phrase

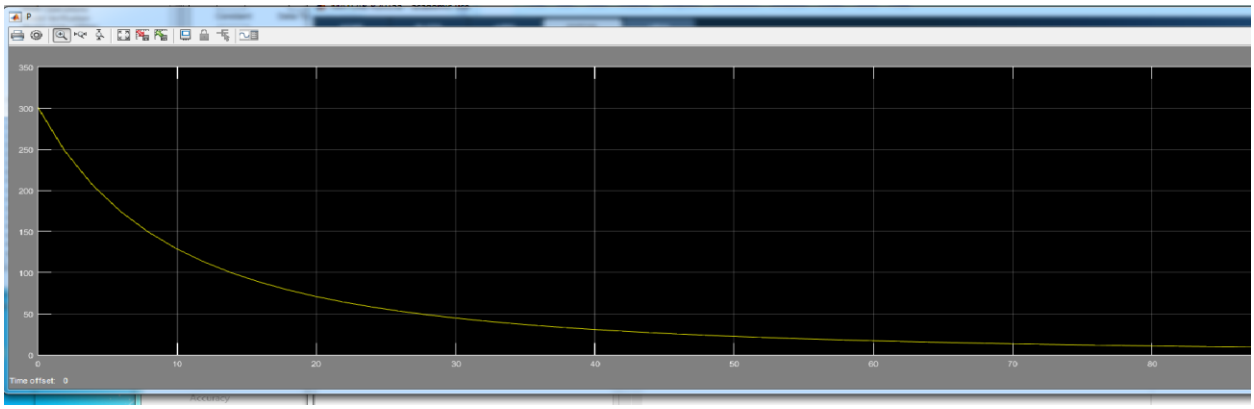


Figure 37: An example of pressure over time at one specific duty cycle

2. User Interface

A comprehensive literature review provided information on associated guidelines for visual performance. Because the use of the device involves user interaction, it is important that the dimensions of the user interface allow the user to navigate the different device features with the greatest possible ease. From the research that was conducted, a couple key quantitative and qualitative insights were obtained. For instance, it was found that in order for a device to be compatible for a wide range of users, it is important for the device to be adjustable. This revealed the importance of designing an interface that can be oriented into different angles to allow users to adjust the screen in order to best cater to their line of vision. Research also revealed that there are uniform standards for the sizing and spacing of alphanumeric symbols. One critical dimension that needs to be determined in order to ensure optimal readability of the symbols is symbol height, which is dependent on the distance from which the user is reading the symbols and the visual angle:

$$height = distance * tan(visual\ angle)$$

The visual angle is the angle at which the user is looking at the interface also impacts the usability. Literature reveals that it is most optimal if the display is oriented such that the user's line of sight is 10-60 degrees below the horizontal, with the most comfortable angle being 15 degrees.

There is also a wide range of literature sources with information on the sizing and spacing of push buttons on a device. Such literature sources stated that for bare hand, fingertip buttons the minimum diameter dimension must be no smaller than 10mm and that the separation between buttons must be no smaller than 13mm [46]. It will be important for the user interface of the final design to align with these standards in order to ensure optimal ease of use. A consistent theme across various research sources also revealed that is important that objects that look the same should act the same. This will be critical when determining how to differentiate between features that are in contact with the user in order to ensure both easy and proper use.

3. Stability of Casing

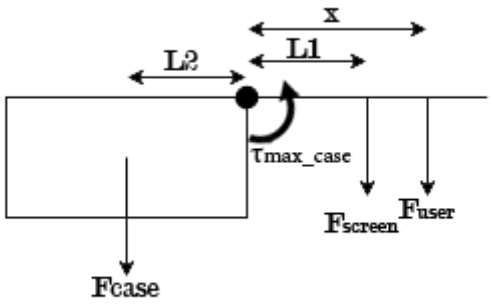


Figure 38: Free body diagram of the casing stability

When considering the ease of use of the device, it is important to ensure that the device will be stable in all possible configurations. Because the selected design has a screen that opens with a friction hinge that allows for 180° of rotation, there will be an opposing torque exerted by the force of the screen and the force that the user exerts on the screen in order to operate the device. Using the definition of torque, one can reach the conclusion that the maximum torque that will be exerted by the screen and the user will be the point at which sin(90°)=0. Figure 36 illustrates the free body diagram of this configuration.

$$\tau = F \times d = F*d*\sin\Theta$$

The point at which sin(90°)=0 is where the opposing torque is maximized given a particular user-generated force F_{user}. When considering the system (Figure 36) to be in equilibrium and the torque at the hinge to be at the maximum torque that can be generated by the hinge to counteract an opposing torque, the force balance can be arranged to solve for F_{user}.

$$\tau_{counterclockwise} = \tau_{clockwise}$$

$$\tau_{case} + \tau_{max\_hinge} = \tau_{screen} + \tau_{user}$$

$$m_{case}gL_2 + \tau_{max\_hinge} = m_{screen}gL_1 + F_{user}x$$

$$F_{user} = (m_{case}gL_2 + \tau_{max\_hinge} - m_{screen}gL_1)/x$$

Where F_{user} represents the force that needs to be applied by a user at a given distance x from the hinge in order to overcome the torque of the hinge and thus cause instability in the system.

Safe

1. Emergency pressure release

One of the important specifications for the device to be safe is that the patient can disengage from the device in less than 10 seconds. This could be translated to achieving a significant decrease in pressure within 10 seconds, to the extent that the cuff can be taken off from the patient. Note that because the deflation is an exponential decay, it is not feasible nor necessary to assume a pressure of 0mmHg before disengagement. From the same simulation in "Engineering Analysis- Easy to Use part 1", also from empirical testing with the push-to-

open release button, the team concluded that the patient can disengage within 10 seconds.

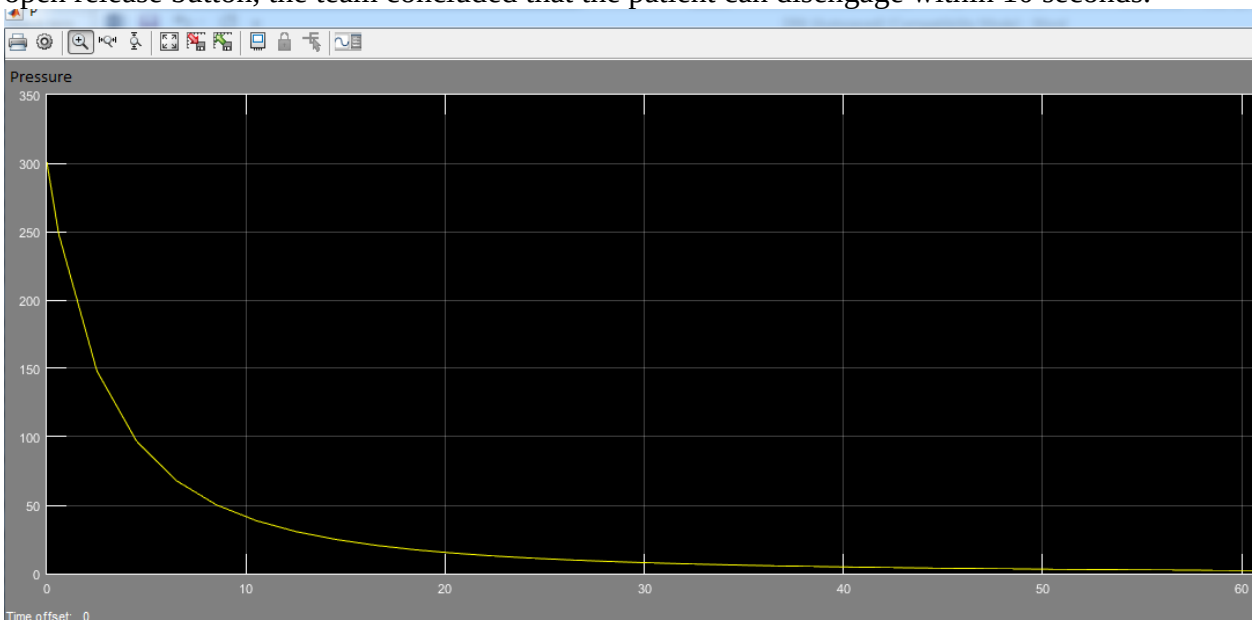


Figure 39: Pressure decreases exponentially during emergency release

Validation

To address whether the prototype for the blood pressure measurement met the user requirements and engineering specifications, it will go through various validation tests to ensure that the prototype satisfies them. Testing will be done for what is possible in the MECHENG 450 scope to determine the success of the prototype. The full validation plan can be found in Appendix N.

Table 7: Validation of User Requirements

	User Requirements	Engineering Specifications	Validation
High	Accurate	The average difference between mercury sphygmomanometer measurements must not exceed a mean difference of ± 5mmHg and standard deviation of 8mmHg for both diastolic and systolic blood pressure measurements. Measuring range of 0-300mmHg Must not exceed ± 3 mmHg for cuff vs. display pressure	Further Validation Needed Yes Cannot Validate
	Affordable	Cost ≤ $75 per device	Further Validation Needed
	Short Procedure Time	Time necessary for the entire procedure < 3 minutes	Further Validation Needed

	Appropriate Use	Use in KATH and other tertiary referral care settings for in-patient care	Cannot Validate
		Discrete measurements	Validated
		Device allows the nurses and midwives to take blood pressure measurements on time for 40 patients, with 2 to 6 patients needing measurements every 30 minutes and the rest being measured every four hours.	Further Validation Needed
	Durable	Operational temperature between 10-40°C	Cannot Validate
		Can be stored at temperatures up to -20 to 60°C (storage)	Cannot Validate
		Accurate at up to 85% humidity RH (operational)	Cannot Validate
		Can be stored at up to 90% humidity RH (storage)	Cannot Validate
		Satisfy the 1 m drop test	Cannot Validate
		Satisfy the vibration test	Cannot Validate
		Satisfy the markings test for wear	Cannot Validate
		~240 number of cycles per day for lifetime in years	Cannot Validate
		>1 years unit life	Cannot Validate
	Safe	Be able to disengage in <10 seconds	Yes
		Pressure applied should not exceed 300 mmHg	Further Validation Needed
		Pass the CFR 1500.49 Test for Sharp Edges	Cannot Validate
		Hazard numbers for health, flammability, and reactivity should be 0	Yes
	Power Source	Primary mode of power can withstand 120 uses per charge cycle	N/A
	Accommodates various patient sizes	Device accommodates 5th to 95th percentile of pregnant women in low-resource areas (when of childbearing age)	N/A
	Portable	Device does not require two hands to carry	Yes
		< 19 cm (width) by 32 cm (length), < 2.8 kg	
Medium	Minimal Steps	No more than two actions simultaneously required of the user during the procedure using mercury sphygmomanometer functional decomposition as reference.	Further Validation Needed
		< 12 steps(team defined mercury sphygmomanometer steps) including set up and break down (take off and pack) once device is obtained	Further Validation Needed
	Readable Measurements	3:1 minimum symbol contrast	N/A
		Symbol width-to-height ratio is between 0.5:1-1:1	N/A
		Strokewidth-to-height ratio is between 1:12-1:5	

		Spacing between adjacent symbols are separated by at least one strokewidth	N/A
		Spacing between lines of symbols is at least two strokewidths	N/A
		Button diameter is at least 10mm	N/A
		Spacing between buttons is at least 13mm	N/A
		Visual angle is between 10-60	N/A
			N/A
	Easy to calibrate	Calibration time <30 minutes by technician in tertiary referral setting using a Y/ T-tubing calibration method available in-country	Yes
		No more than one calibration necessary per year unless breaking and then need to calibrate it once repaired	Cannot Validate
	Short Training Time	<15 minutes of instructional period required for users to learn how to use the device	Further Validation Needed
Low	Easy to clean	No additional disassembly from setup or storage mode needed to disinfect the device	N/A
		<30 seconds of cleaning time necessary to clean parts in contact with patient and user, clean with material commonly found in ward (spirit: 83.3% ethanol) using two hands	N/A
	Easy to Maintain	All parts are accessible in Ghana	Cannot Validate
		All parts can be independently replaced	Yes
	Minimal Additional Equipment	No more than 1 additional pieces of equipment required for procedural use	Further Validation Needed

Cannot Validate means that the specification cannot be validated within the constraints of MECHENG 450. N/A means the design validation is not applicable for the current prototype. Further validation needed means the current data is promising, but the engineering specification cannot be stated as validated.

Accurate

A focus group of three nursing students were invited to measure blood pressure using the prototype and an accurate aneroid sphygmomanometer blood pressure device. Their measurements made when using the aneroid sphygmomanometer and the prototype were compared; the results showed some measurements that were exactly the same systolic and diastolic values for measurements. More validation is necessary, however, as the prototype had little problems while running that deterred from the measurement process. In addition, as many blood pressure measurements were taken on the same individuals, the blood pressures themselves changed throughout the validation process. Nonetheless, the accuracy looks promising.

The embedded aneroid pressure gauge in the device was compared with separate aneroid sphygmomanometer. Measurements were taken with both of the pressure gauges and the

pressure readings were compared for each at 20 mmHg intervals. These interval comparisons showed the prototype's embedded aneroid pressure gauge to have a difference of 2.689 mmHg from the aneroid sphygmomanometer device, with a standard deviation of 0.61 mmHg. As the deviations are less than the engineering specifications, the device aneroid pressure gauge is validated to be accurate.

The pressure sensor output was compared to the embedded aneroid pressure gauge using the pressure comparison as above. The interval comparisons showed the pressure sensor output to have a difference of -1.83 mmHg from the embedded aneroid pressure gauge with a standard deviation of 1.36 mmHg. Therefore the pressure sensor accuracy meets the engineering specifications.

LCD output and pressure sensor screen outputs were comparable and validated to be accurate. The values did not have exactly the same with decimal points because LCD updates at a slower rate than pressure sensor to ensure a good reading by the user.

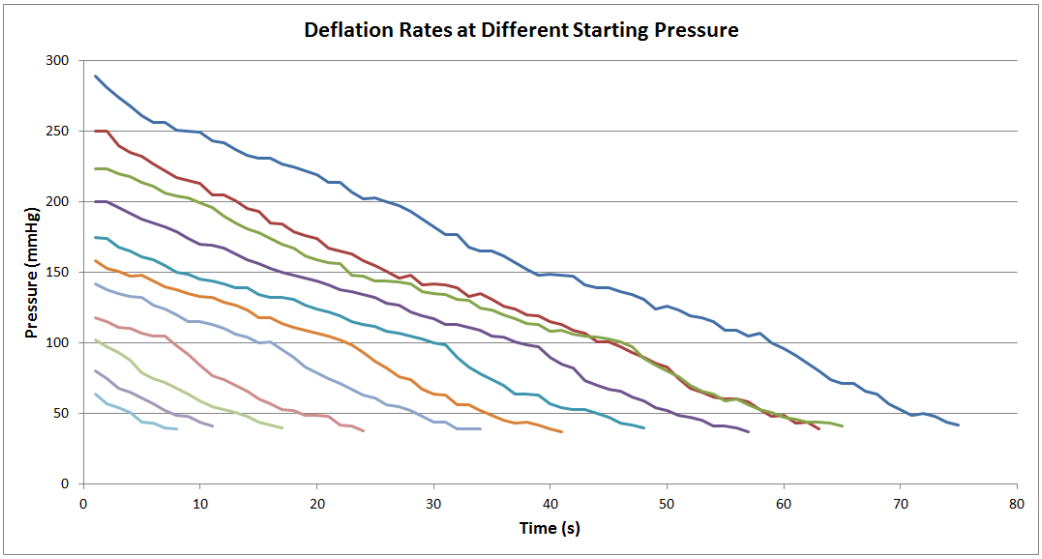


Figure 40: Pressure versus Time Graph for Deflation Rates at Different Starting Pressures

Constant deflation rate was attempted using the solenoid valve and the prototype's current fuzzy control. Figure 40 depicts the graph of pressure and its change over time for different starting pressures. In addition, the dP/dt was taken for each data point, and the average and its standard deviations were evaluated to analyze the deflation rate. The results showed a deflation rate around -3mmHg/s with standard deviations of 1-2 mmHg/s, which leads to an optimum deflation rate for the device.

Table 8: Average and standard deviation of dP/dt with solenoid valve

Start Pressure	Average dP/dt	Standard deviation
289	-3.057862606	±2.33025
250	-3.110390794	±2.370133

223	-2.593063054	±1.768934
200	-2.648100877	±1.438054
175	-2.522996466	±1.780973
158	-2.737920756	±1.76557
142	-2.827492705	±1.656627
118	-2.992741354	±2.10452
102	-3.466218658	±1.572566
80	-3.470404355	±1.420334
64	-3.177207235	±2.229564

The team is not able to validate whether the cuff pressure and display meet the accuracy given in the engineering specifications as a pressure sensor cannot be placed directly within the cuff during this semester.

The pressure sensor is able to measure between the range of 0-450 mmHg according to the part specifications; therefore, the prototype meets this engineering specification.

Affordable

Any of the components purchased for the device were chosen to decrease the overall manufacturing costs without compromising quality; therefore any parts that had extra, unnecessary features were avoided. In addition, how feasible the manufacturing process would be in Ghana was also considered in the design and the choosing of the device components, which also lowered the overall cost of the component. As the prototype does not feature all the components that would be used in the actual device, some of the parts used in the prototype were replaced by parts that would be utilized in the actual design.

There will be a table that has the list of price based on 1000 devices manufactured. As some parts did not feature a specific bulk purchase pricing, estimations for bulk pricing was done based on market price analysis. The trends for the bulk pricing in wholesale sites were taken and graphed with a best-fit log-transform line to acquire the estimation for the bulk-pricing equation.

For parts that were $5, -0.1ln(1000 devices)+original price = bulk price

For parts that were >$5, -0.8ln(1000 devices) + original price = bulk price

After applying this equation and getting the bulk pricing for each component, the device manufacturing price was estimated to be around $130; therefore the prototype currently does not meet the engineering specifications. However, many of the prototype components will not be incorporated in the actual manufactured device. For instance, the bulb and pressure manifold chosen were more expensive options from a site without wholesale options. The team believes the cost for manufacturing can be reduced with additional part cost analysis. Appendix P contains the affordability table.

Short Procedure Time

A focus group of three nurses were observed and timed when using blood pressure measurements using the prototype. The overall average procedure time for the focus group was around 62 seconds, with standard deviation of 21 seconds. The current data shows that the prototype is able to meet the engineering specification for procedure time. However, more validation was deemed necessary before a concrete conclusion was made.

Appropriate Use

The time it would take to measure blood pressure of patients was multiplied to calculate how long it would take to measure six patients. As the estimated average time for measurement is about a minute, it meets the amount of time required to be able to measure blood pressure on time for 40 patients, with 2 to 6 patients needed measurements every 30 minutes and the rest being measured every four hours.

The device takes discrete measurements rather than continuous blood pressure measurement and therefore meets the engineering specifications.

Durable

Durability of the device was not tested, as the prototype manufactured during the semester focused on function rather than form. Therefore the validation methods were not possible as due to constraints of team's budget and time requirement.

Safe

The time to disengage the pressure using the safety relief button required around a second; therefore, the device meets this aspect of the specification.

The device was pumped above 310 mmHg to assess whether the device would disengage when the pressure was reached. The pressure did not decrease, and the safety relief valve was deemed to be broken, as the relief valve is supposed to open when the pressure reaches above 6 psi. Therefore the prototype currently does not meet the engineering specification, but replacement of parts should allow the prototype to function properly.

The guidelines from federal regulations to check sharp edges is not applicable for this prototype, as the parts in contact with the user, including the casing and tubing, were not designed or manufactured to desired design during this semester.

The device does not incorporate any hazardous material and thus meets the specification.

Power Source

The prototype manufactured during this semester did not meet the power source engineering specifications, as the proof-of-concept incorporates batteries and power sources that are not rechargeable.

Accommodates various patient sizes

The prototype manufactured during the semester did not incorporate a new cuff design and therefore did not strive to meet this engineering specification.

Portable

Individuals were observed carrying the laser cut casing. The number of hands and the method people carried the device was noted. As shown in Figure 41, majority of the test subjects used one hand to carry the device.

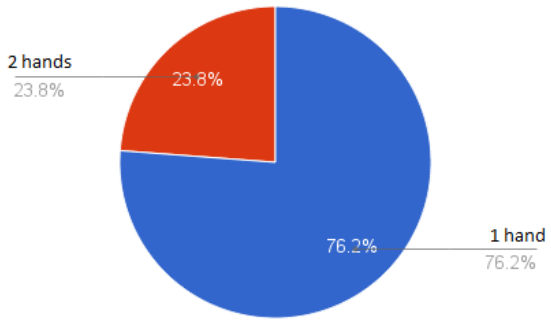


Figure 41: Distribution of Number of Hands used to Carry Device

The prototype currently meets the weight and size specifications, as the device weighs 2.4 kg and is less than the maximum size specification.

Minimal Steps

The focus group of three nursing students were asked for the number of perceived steps, for both the measurement with the aneroid sphygmomanometer and the prototype. The number of perceived steps were 1-2 steps less with the prototype. However, the team deemed the nurse's number of perceived steps to be skewed as the nurses seemed to skip steps during their explanation of each device. Though the data is promising, further validation is necessary.

Readable Measurements

The prototype manufactured and designed during this semester did not use a manufactured LCD screen, but rather a LCD screen for electronic component

Easy to Calibrate

Calibration time was measured with test subjects comparing the LCD pressure and the embedded aneroid gauge pressure. The average time for calibration was measured to be around six minutes, which meets the engineering specification.

The calibration required per year cannot be tested with the prototype due to the time constraints in the semester.

Short Training Time

The engineering specification was based on the interviews with midwives and clinicians at KATH, who stated that it took them around 15 minutes to learn how to measure blood pressure. However, the device is intended to be used by individuals who already know how to measure blood pressure, so the 15 minutes cannot be directly applied as the maximum time required to learn how to use the device. The team timed how long it took for the nurses to understand the directions, and the training time for using the device was measured to be around less than 15 minutes. The instructional time and the practice times were all compared to 15 minutes, with all three nurses learning the device in around 10 minutes. The team decided that more validation would be necessary, but the data shows promise.

Easy to Clean

As the parts designed, assembled, and manufactured during this semester focuses on the function of the device rather than the form, it was not applicable to validate the easy to clean component of the device.

Easy to Maintain

It was not confirmed whether each part would be accessible in Ghana. Therefore the validation test cannot be done for how easy it would be validate this engineering specification.

Everything except the casing was assembled, and therefore, all parts of the device can be independently replaced; the device meets the engineering specification.

Minimal Additional Equipment

The focus group of three nursing students were observed when using the prototype. The team observed that no additional equipment was necessary when they took measurements with the current prototype. As the sample pool is three nurses, further validation is necessary for this specification.

Design Critique

Most of the team will be continuing this project next semester as an independent study. From the validation that was conducted, the device seems like a promising design. From the specifications that could be tested, it was on the right track of meeting those specifications although the sample size of users was not large enough to say anything conclusive. Thus, more validation must be done before more conclusive results are formed.

That being said, one requirement that will not be validated until modifications are made to the device is safe. The safety relief valve needs to be replaced on the current prototype because it does not open at 6 psi and thus that specification is not yet met. It is believed this is due to a faulty valve because it is advertised to release at 6 psi.

The team was encouraged by the fact that the device was able to be operated by nursing students. From these small focus groups, more knowledge was obtained on how to make the device better to use. Firstly, the nurses were so used to using a deflation valve that some of the time they

would open it and then close it again when they remembered that there was a deflation button. Thus, one next step would be to 3-D print a case to slip over the valve so it can be used, but not as instinctively. Secondly, the pressure seemed to take some time to equilibrate in the device and thus the LCD screen would display a pressure that was overshooting the actual pressure. As an example, as the nurse would inflate the cuff the screen would display a measurement of 160 mmHg and so she would stop inflating. Then, in the next 5 seconds the screen would display a dropping pressure to 135 mmHg without the deflation button being pressed. That pressure would hold until the deflation was initiated. From this, it seems like air is not moving as instantaneously as was anticipated. To try and combat this, the team must meet with design consultants to better understand the problem. However, one possible idea is to look into adding air chambers into the pressure system to allow for more air that can flow in the system to low pressure areas. Another issue that air chambers might help fix is that the solenoid operates in a way that causes pulsation like vibrations. These vibrations are felt on the cuff and could interfere with a blood pressure measurement if the cuff was too close to the stethoscope and the stethoscope was picking up the pulsing of the solenoid and not of the artery. Because of this, the team had to advise the nurses to places the cuff in a way that would not touch the stethoscope while taking measurements. The team hopes there is a way to dampen the effects of the pulsating however if this is not possible another valve will have to be used--potentially returning to the earlier servo motor design. Moreover, the microphone stethoscope sometimes gave a lot of background noise and it was realized that when placed in a particular way on the breadboard, it gave no feedback noise. With this in mind, the team is looking into other microphones that would be more durable for this use by not needing to be connected directly into the breadboard. Additionally, problem might helped be addressed by purchasing a new amplifier that can have a higher gain. Finally, the tactile switches used as buttons to deflate as well as record the systolic and diastolic measurements were not as responsive to touch as most everyday devices are. This could be fixed by having buttons that remember their state. Additionally, the team wants to look into the durability of changing the placement of the buttons from the primary interface to being attached to the hand pump. This is because it was observed during the nurses use that nurses were used to holding the hand bulb during deflation, but not touching the screen of the device; it was too far away for them to feel like the buttons were convenient. Thus, the idea is that the wiring of the buttons are extended so that they could be put together with the hand pump in a larger tube for a more durable and easy-to-use design.

When looking into ways to make this device portable so that it could be brought back to KATH, there are multiple modifications that the team wants to make. The most significant of these being the need to convert all the electrical components on the breadboard to a chip. This would take some assistance from outside consultants with electrical backgrounds. Next, the powersource would need to be transitioned to something more portable, probably an initial rechargeable battery. To make this possible, the solenoid would most likely have to be changed for one that needs less current. Additionally, time permitting, a new casing would be manufactured that is not as bulky as the current one and allows for a friction hinge and latch to be attached. Furthermore, the team hopes to revisit the search for a larger LCD screen so that the prototype would be more like the design concept. However, if this isn't possible within the time frame, a mock-up of the desired form of the device will be created so that there is a form and function prototype to receive feedback on. All of this should be done while keeping in mind the cost of the device and what bulk pricing would be.

Although all of these changes are desired, not all of them will be able to be made within the next semester. Thus, priority will be given to aspects that make the device portable enough to travel to Ghana. Thus, the electrical components that might be adjusted before a chip is designed need to be completed early in the semester so that the chip can be designed, manufactured, and implemented. Finally, with the changes that will be made, more validation is necessary to confirm that the changes are improving the design.

Conclusion

This project aims to design a way to assist healthcare providers in measuring the blood pressures of obstetrics patients every 30 minutes or 4 hours according to patients' management plans. The team compiled the device requirements while at KATH and generated many concepts in Ghana and in the US. The driving characteristics of the device are that it needed to be accurate, affordable, easy to operate, portable, and safe. The final design is an auscultatory blood pressure measurement device that incorporates features that allow for the current pressure to display on an LCD screen, an automated constant deflation rate with a solenoid valve, a calibration mechanism using aneroid pressure gauge, and the amplification of Korotkoff sounds through a microphone stethoscope.

The current prototype satisfies almost all validation testing completed so far. Three nursing students were able to take a few readings with the prototype that were comparable in value when compared to when taken on another device. However, more validation needs to be completed to confirm that this device is meeting the requirements.

The team will continue to work on this design next semester with a focus on increased portability so that the device can be brought to KATH and a focus on improved ease-of-use so that the device is accurate and easy to interact with.

Acknowledgements

We would like to extend a special thanks to the many collaborators that we have had during the project. First, thanks to our sponsor and mentors at the University of Michigan Engineering School including Professor Kathleen Sienko and Professor Shanna Daly and at Komfo Anokye Teaching Hospital including Professor C.A.Turpin, Professor K. A. Danso, Professor A. T. Odoi, Professor H. S. Opare-Addo, and Dr. Thomas Okpoti Konney.

Thank you to all of the health professionals at Komfo Anokye Teaching Hospital including Dr. Nana Akua Abruquah, Dr. Adrian Agyen, Dr. Fiifi Asamoah, Dr.Kwaku Adu-Gyamfi, Dr. Francis Diji, Dr. Kwadwo Sarbeng, Dr. Ben Ofosu-Barko, Dr. Stephen Annan, Dr. Anna Abadoo-Brew, Dr. Hanna-Lisa Tetteh, Dr. Joel Duah, Dr. Peggy Ekremet, Dr. Kwaku Gyasi Danso, Dr. Michael Yeboah, Dr. Wisdom Azanu, Dr. David Kupualor, Dr. Collins Oteng, Dr. Nana Yaa Odamea Asare, Dr. Lawrence O. Kusi-Appiah, Dr. Samuel Kwabena Ampong, Dr. Kobina Kwantsin Hagan, Dr. Adwoa Serwaa Pokuaa, Dr. J. H. K. Afedoh, Dr. Fauster Kwawununu, Dr. Owusu Bempah, Dr. Edem D. Darkey, Dr. Yaw Opare Larbi, Dr. Daniel Oppong-Kyekyeku, Dr. Charles O. Mensah, Dr. Edward Anabila Agana, Dr. Alex Asamoah Ankomah, Dr. Gloria Kyem.

Thank you to the University of Michigan Mechanical Engineering faculty and staff including Amy Hortop, Professor Jeff Stein, Toby Donajkowski, and Dan Hiemstra.

Thank you to our consultants at Insitu including Dr. Josh Bishop-Moser, Dr. Michael Deninger, Dr. Grant Kruger, Ibrahim Mohedas, Jared Miles, Lydia Su, Joshua Perez, and MariaRose Young.

Thank you to these individuals for sharing your time and knowledge: ChonKit Pun, William Creighton, Scott Cooper, and Professor Matthew Reed.
.

Team Biography

Jungsoo Chang

Jungsoo is a junior pursuing her B.S.E. in Biomedical Engineering with a minor in Law, Justice, and Social Change. After graduation, she hopes to attend medical school. She is currently working in University of Michigan breast cancer lab in the Cancer Center as a research assistant focusing on using Boolean signaling to predict signaling pathway in different cell lines of breast cancer. Jungsoo is interested in social justice efforts within global health development and efforts towards precision medicine.

Lauren Kennedy

Lauren is a senior pursuing a major in chemical engineering with minors in Multidisciplinary Design and Community Action and Social Change. She is originally from the greater Boston area and spent her summer as a research assistant for Pamela Silver's Laboratory at Harvard Medical School and in Ghana as part of an internship doing maternal health design ethnography. She is interested in the global health as well as engineering education.

Caroline Soyars

Caroline is a senior studying biomedical engineering. Her academic interests include international development and design of appropriate technologies for low resource settings. Caroline will continue to explore her interests within public health through an internship with the World Health Organization in Geneva, Switzerland this winter semester. She then hopes to work for a couple years within the medical device industry before pursuing a master's degree in public health.

Si Long (Jenny) Tou

Jenny is a senior studying Cognitive Science with a focus on computation. She is interested in research on healthcare technologies using computational, mathematical and statistical tools. During the summer, she was an undergraduate fellow in a Summer Institute in Biostatistics focusing on Big Data and did research on fMRI data processing. She is currently a research assistant in the Direct Brain Interface Laboratory at the University of Michigan working on the effect of parameter choices on feature weights generation and the accuracy of the brain-computer interface. After graduation, Jenny wants to go to graduate school in Machine Learning, and ultimately pursue a career in academia.

Bibliography

[1]WHO, 2014, “10 Facts on Maternal Health,” Geneva, World Health Organization.

[2]WHO, 2014, "Maternal Mortality," Fact sheet N°348, Geneva, World Health Organization.

[3]Say L et al., "Global Causes of Maternal Death: A WHO Systematic Analysis," Lancet. 2014.

[4]Callahan, T. L., and Caughey, A. B., 2013. Obstetrics & Gynecology, Sixth Edition, Blueprints Series, LWW, China.

[5]Westat, Inc., 1989, "National Health and Nutrition Examination Survey III Cycle 2: Pulse and Blood Pressure Procedures for Household Interviewers."

[6]Pickering, T. G. et al., 2005, “Recommendations for Blood Pressure Measurement in Humans and Experimental Animals,” Hypertension, 2005; 45: 142-161, Published online before print December 20, 2004, doi: 10.1161/01.HYP.0000150859.47929.8e.

[7]Nexoe, J., Damsbo, B., Lund, J. O., Munck, A., 2012, *Measurement of blood pressure, ankle blood pressure and calculation of ankle brachial index in general practice*, Family Practice, Volume: 29 Issue: 3, pp345-351.

[8]Ogedegbe, G., Pickering, T., 2010, "Principles and Techniques of Blood Pressure Measurement," Cardiol Clin, 28(4): 571–586.

[9]Association for the Advancement of Medical Instrumentation. American National Standard. Manual, electronic or automated sphygmomanometers ANSI/AAMI SP10-2002. 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598, USA: AAMI; 2003.

[10] O'Brien E, Petrie J, Littler WA, de Swiet M, Padfield PL, Altman D, Bland M, Coats A, Atkins N. The British Hypertension Society Protocol for the evaluation of blood pressure measuring devices. J Hypertens 1993;11(suppl2):S43-S63.

[11] O'Brien E, Pickering T, Asmar R, Myers M, Parati G, Staessen J, Mengden T, Imai Y, Waeber B, Palatini P with the statistical assistance of Atkins N and Gerin W on behalf of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension. International protocol for validation of blood pressure measuring devices in adults. Blood Press Monit 2002;7:3-17.

[12] Duggan, P. M., 1998, "Which Korotkoff sound should be used for the diastolic blood pressure in pregnancy?," Aust N Z J Obstet Gynaecol, 38(2):194-7.

[13] SCENIHR, 2009, "Sphygmomanometers," EUROPA Public Health.

[14] Arabidze, G.G., Petrov, V.V., Staessen, J.A., 1996, "Blood pressure by Korotkoff's auscultatory method: end of an era or bright future?.," Blood Pressure Monit., 1(4):321-327.

[15] Zhu, N., 2008, “A Study of the White-Coat Phenomenon in Patients with Primary Hypertension,” Hypertension Research (2008) 31, 37–41; doi:10.1291/hypres.31.37.

[16] Franx, A., 1997, "Comparison of an auscultatory versus an oscillometric ambulatory blood pressure monitor in normotensive, hypertensive, and preeclamptic pregnancy," Hypertension in pregnancy, Volume: 16 Issue: 2 Pages:187-202.

[17] Reinders, A., Cuckson, A.C., Lee, J. T., Shennan, A. H., 2005, " An accurate automated blood pressure device for use in pregnancy and pre-eclampsia: the Microlife 3BTO-A," BJOG. 2005 Jul;112(7):915-20.

[18] Blois et al., 2015, *Cellular and Molecular Life Sciences*, Volume 72, Issue 1, pp39-50.

[19] WHO, 2005, "Affordable technology: blood pressure measuring devices for low resource settings," Geneva, World Health Organization.

[20] American Diagnostic Corporation, "Diagnostix Aneroids: Pocket, Palm, Clock Type; Use, Care, & Maintenance".

[21] Davis, G. K., Roberts, L. M., Mangos, G. J., Brown, M. A., 2015, "Comparisons of auscultatory hybrid and automated sphygmomanometers with mercury sphygmomanometry in hypertensive and normotensive pregnant women: parallel validation studies," Journal of Hypertension, 33:499–506.

[22] Chen, et al., Non-toxic liquid column sphygmomanometer. QDevice Medical Inc., assignee. Patent US 20060247541 A1. 2 Nov 2006. Web.

[23] Ramsey, M., Integrated manual mechanical and electronic sphygmomanometer within a single enclosure. Ramsey Medical Inc., assignee. Patent US 20060155196 A1. 13 July 2006. Web.

[24] Frick, G., and Lee. T-H., Blood Pressure Monitor Calibrating Device. Microlife Intellectual Property Gmbh, assignee. Patent US 6733462 B1. 11 May 2004. Web.

[25]Bilgen, O., Kenerson, J. G., Akpinar-Elci, M., Hattery, R., Hanson, L. M., 2015, "The Search for High-Impact Diagnostic and Management Tools for Low- and Middle-Income Countries: A Self-Powered Low-Cost Blood Pressure Measurement Device Powered by a Solid-State Vibration Energy Harvester," J Clin Hypertens (Green-wich), 17:644–650.

[26] Intelli sense, "Digital Automatic Blood Pressure Monitor Model MIT Elite," 2012, IM-HEM-7300-WE7-03-05/2012.

[27] Golara, M., Benedict A., Jones, C., Randhawa, M., Poston, L., Shennan, A. H., 2002, "Inflationary oscillometry provides accurate measurement of blood pressure in pre-eclampsia," BJOG: an International Journal of Obstetrics and Gynaecology October 2002, Vol. 109, pp. 1143–1147.

[28] AC Cossor & Son (Surgical) Ltd, 2003, Web. 20 Sep 2015. http://accoson.com/accosson_products_0125.htm

[29] "Accoson Greenlight 300 Sphygmomanometer," AC Cossor and Son (Surgical) Ltd, 2004, Web. 20 Sep 2015. http://www.greenlight300.com/index.htm

[30] Microlife, "Microlife BP 3AS1-2".

[31] ANSI, & AAMI. (2012). Medical electrical equipment - part 1: General requirements for basic safety and essential performance. Association for the Advancement of Medical Instrumentation, ES60601-1

[32] Omron, "Solar Charging Manual Inflation Blood Pressure Monitor Model HEM-SOLAR," IM-HEM-4500-SOLE-01-03/09.

[33] Omron, "Omron BP710CANN Instruction Manual".

[34] Garvin, D. A., Harvard Business Review. November-December 1987, pp.101-9

[35] ANSI, & AAMI. (2012). Medical electrical equipment - part 1: General requirements for basic safety and essential performance. Association for the Advancement of Medical Instrumentation, ES60601-1

[36] ANSI, AAMI, & ISO. (2005). Medical devices - guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices. Association for the Advancement of Medical Instrumentation, TIR16142

[37] ANSI, AAMI, & ISO. (2007). Non-invasive sphygmomanometers - part 1: Requirements and test methods for non-automated measurement type. American National Standard, 81060-1

[38] ANSI, AAMI, & ISO. (2009). Human factors engineering - design of medical devices. American National Standards Institute, HE75

[39] ANSI, AAMI, & ISO. (2009). Non-invasive sphygmomanometers - part 2: Clinical validation of automated measurement type. American National Standard, 81060-2

[40] Clark, J., "Le Chatelier's rincipple," 2002, Web. http:// http://www.chemguide.co.uk/physical/equilibria/lechatelier.html

[41] Freescale Semiconductor, "Integrated Silicon Pressure Sensor On-Chip Signal Conditioned, Temperature Compensated and Calibrated," 03/2010.

[42] Dual Head Stethoscope 300B, Xump. Web. Accessed 23 Oct 2015. http://www.xump.com/Images/Products/Dual-Head-Stethoscope-300B.jp

[43] Telehealth Technology, "Eletronic Stethoscopes- Technology Overview," Web. http:// http://telehealthtechnology.org/toolkits/electronic-stethoscopes/about-electronic-stethoscopes/technology-overview

[44] Cutnell, J. D., Johnson K. W., *Physics*. 4th ed. New York: Wiley, 1998:466.

[45] Allan R., "Sound check: Silicon MEMS Microphones Ready To Make Lots of Noise," Design, Feb 26 2009.

[46] Department of Defense Design Criteria Standard Human Engineering, MIL-STD-1472G, 11 Jan 2012.

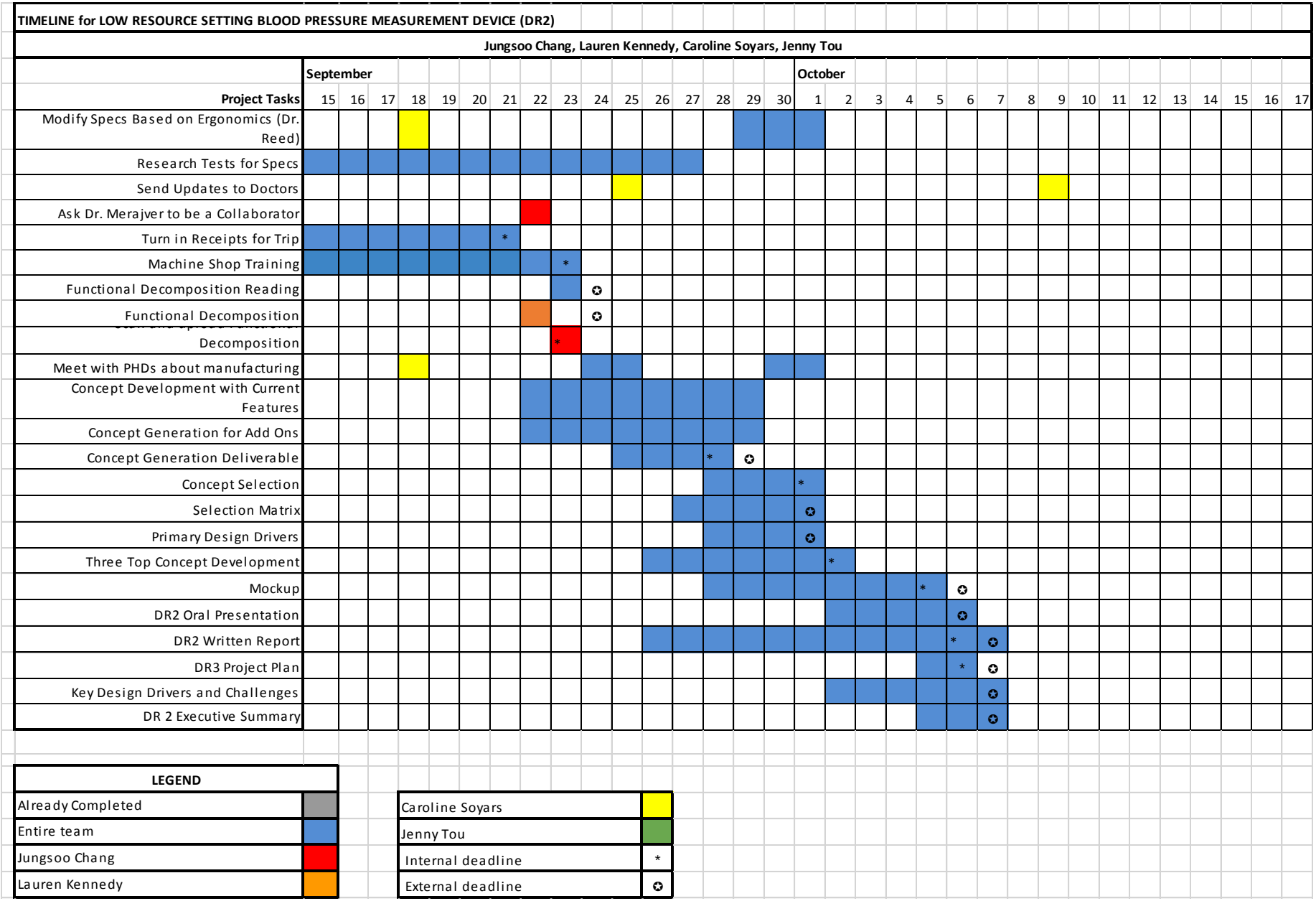
Appendix A: Additional Criteria

Objectives
Ability to measure pulse
Consideration of set-up and break-down time
Accessibility of equipment needed for use and calibration
Minimal situations for estimation of reading by user
Casing
Power Source
Minimal Discomfort to User and Patient

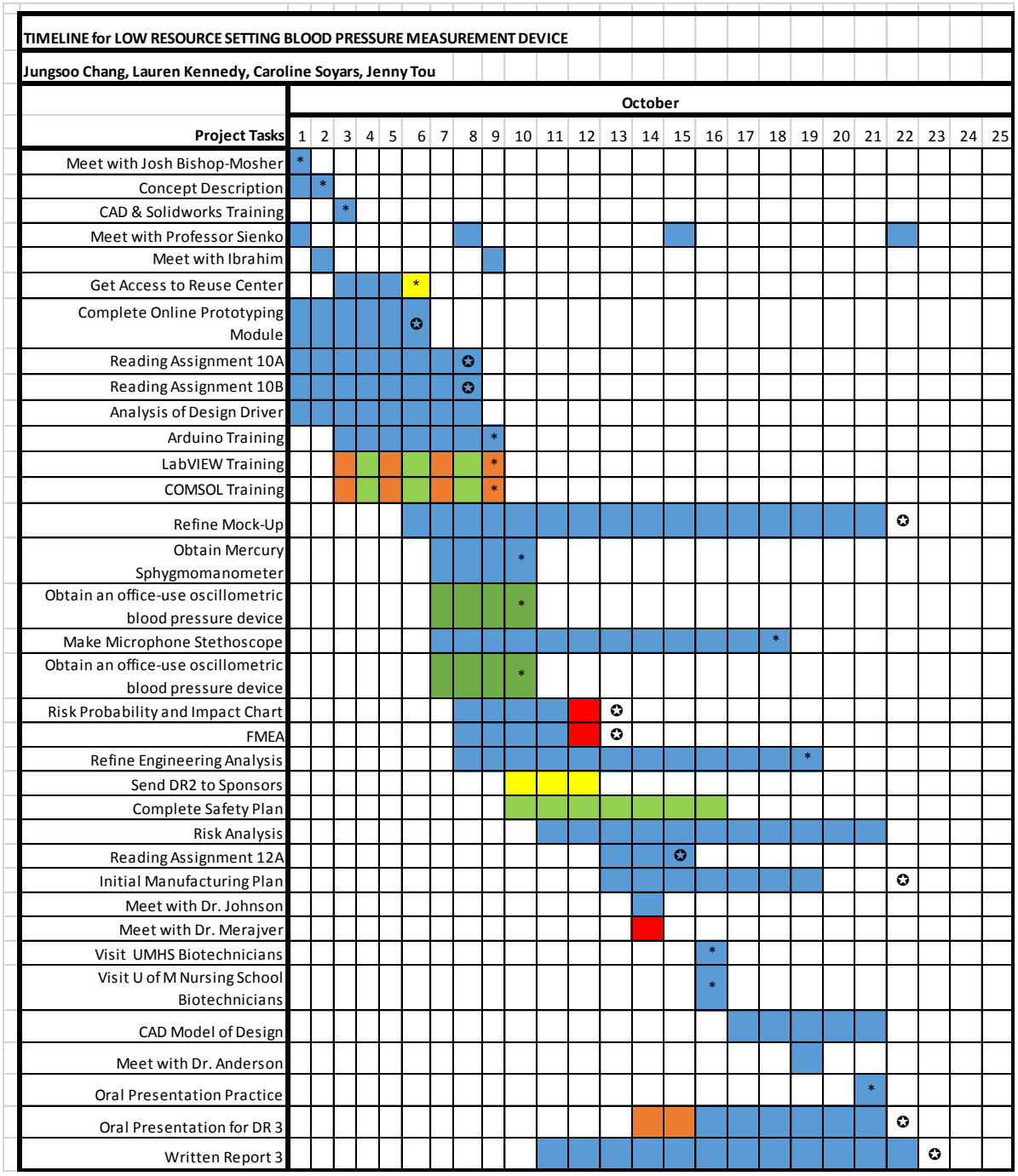
Luxury
Ability for User to do other tasks during the measurement procedure
Option for user to calibrate the device

Appendix B: Gantt Chart

DR 1 and DR 2

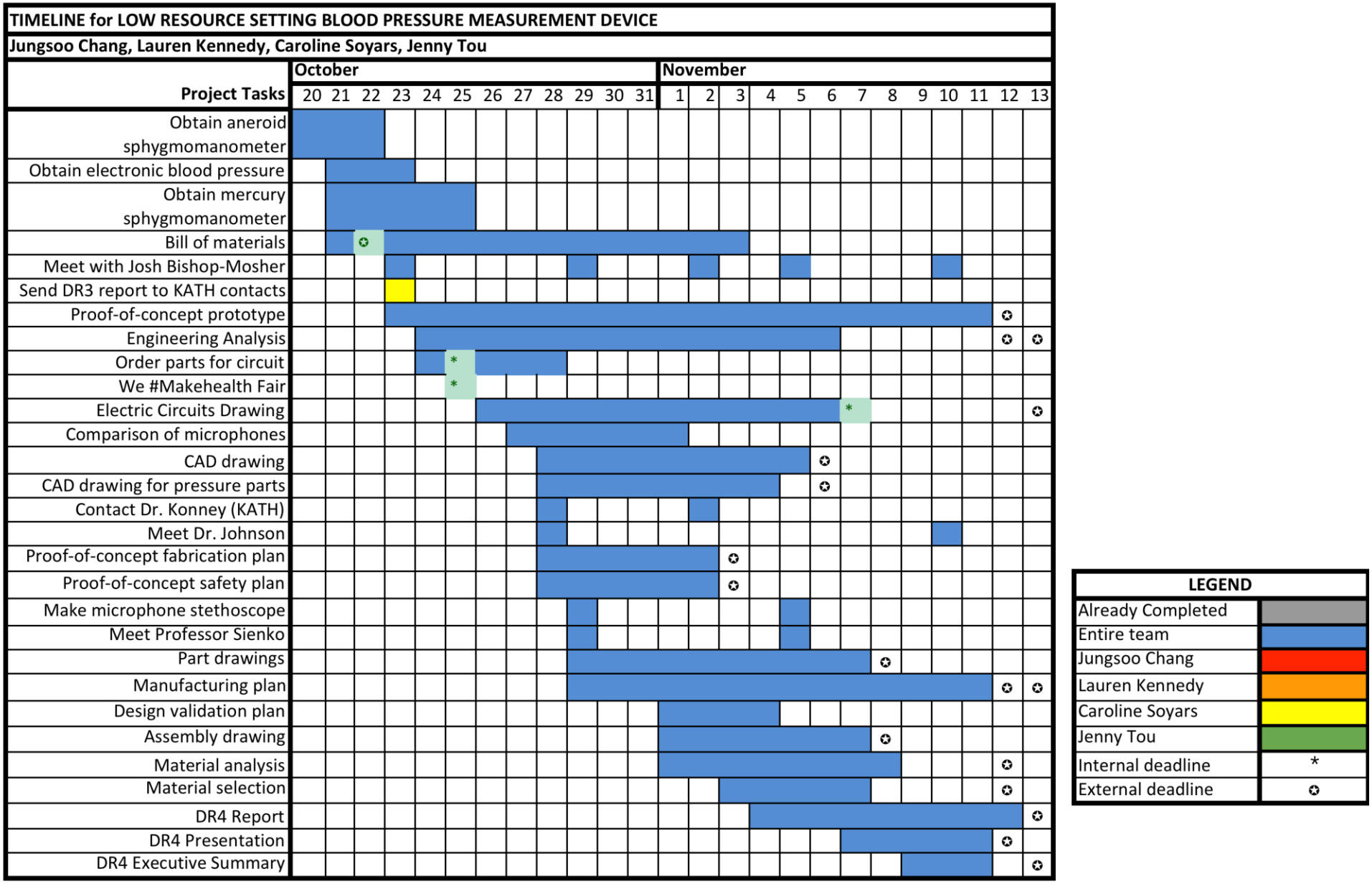


Gantt Chart for DR3

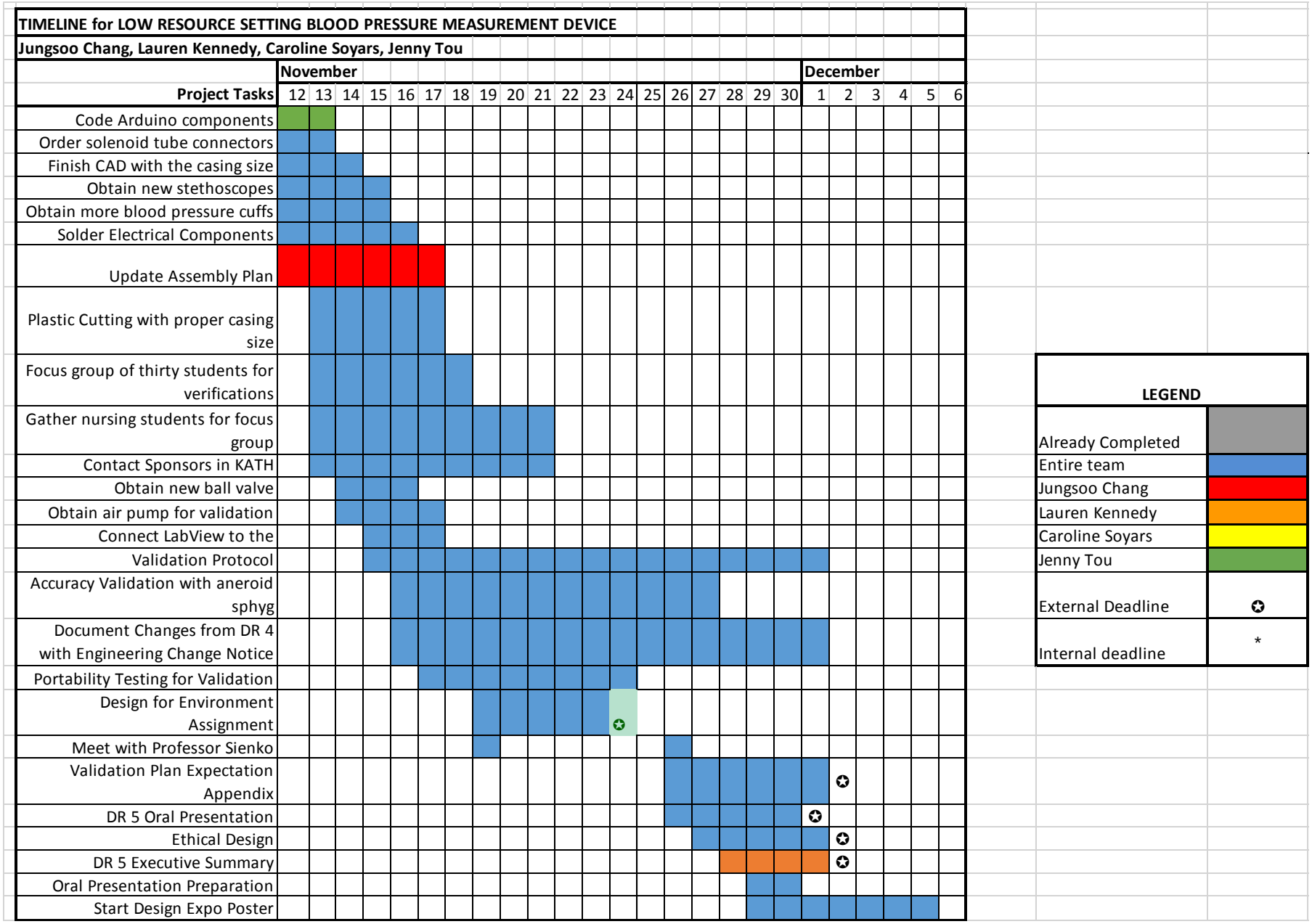


LEGEND	
Already Completed	
Entire team	
Jungsoo Chang	
Lauren Kennedy	
Caroline Soyars	
Jenny Tou	
Internal deadline	*
External deadline	✪

Gantt Chart for DR4



Gantt Chart for DR5



Appendix C: QFD

	Accurate Measurements	Affordable	Procedure Time for Each Discrete Measurements	Teaching and Mastering Technique Time	Minimal steps	Minimal Additional Equipment	Readable Measurements	Adaptable to Various Patient Sizes	Easy to Calibrate	Durable	Device Safety	Portable	Easy to Clean	Casing	Minimal Discomfort to User	Able to regenerate power
Accurate	x															x
Cheap		x														
Easy to Use			x	x	x	x	x		x						x	
Fits all Patients								x								
Safe											x					
Durable									x	x						
Easy to carry												x				
Exposure to infection &bodily fluid													x	x		
Valued by User	x													x		
Cumbersome			x		x	x	x	x								
Low battery																x
Outputs systolic and diastolic measurements	x															

Appendix D: Functional Decomposition

Level 1

1. Maintain accurate device conditions
   1.1 Allow proper assembly of device components
   1.2 Calibrate

2. Distance is established so that within range for device use on patient
   2.1 Transport device to patient and/or patient to device
   2.2 Prepare patient for attachment/ensure proper positioning of patient for use
   2.3 Ensure proper position of device for use

3. Attach specified/appropriate component to patient
   3.1 Locate desired artery for occlusion
   3.2 Place component to patient
   3.3 Secure on patient

4. Apply pressure to occlude blood flow
   4.1 Incrementally increase pressure applied to artery
   4.2 Regularly check status of blood flow (not upstream) when point of pressure is applied

5. Detect when blood flow is occluded

6. Apply some more (20-30mmHg) pressure
   6.1 Incrementally increase pressure applied to artery

7. Release pressure uniformly across attachment component
   7.1 Release at constant rate

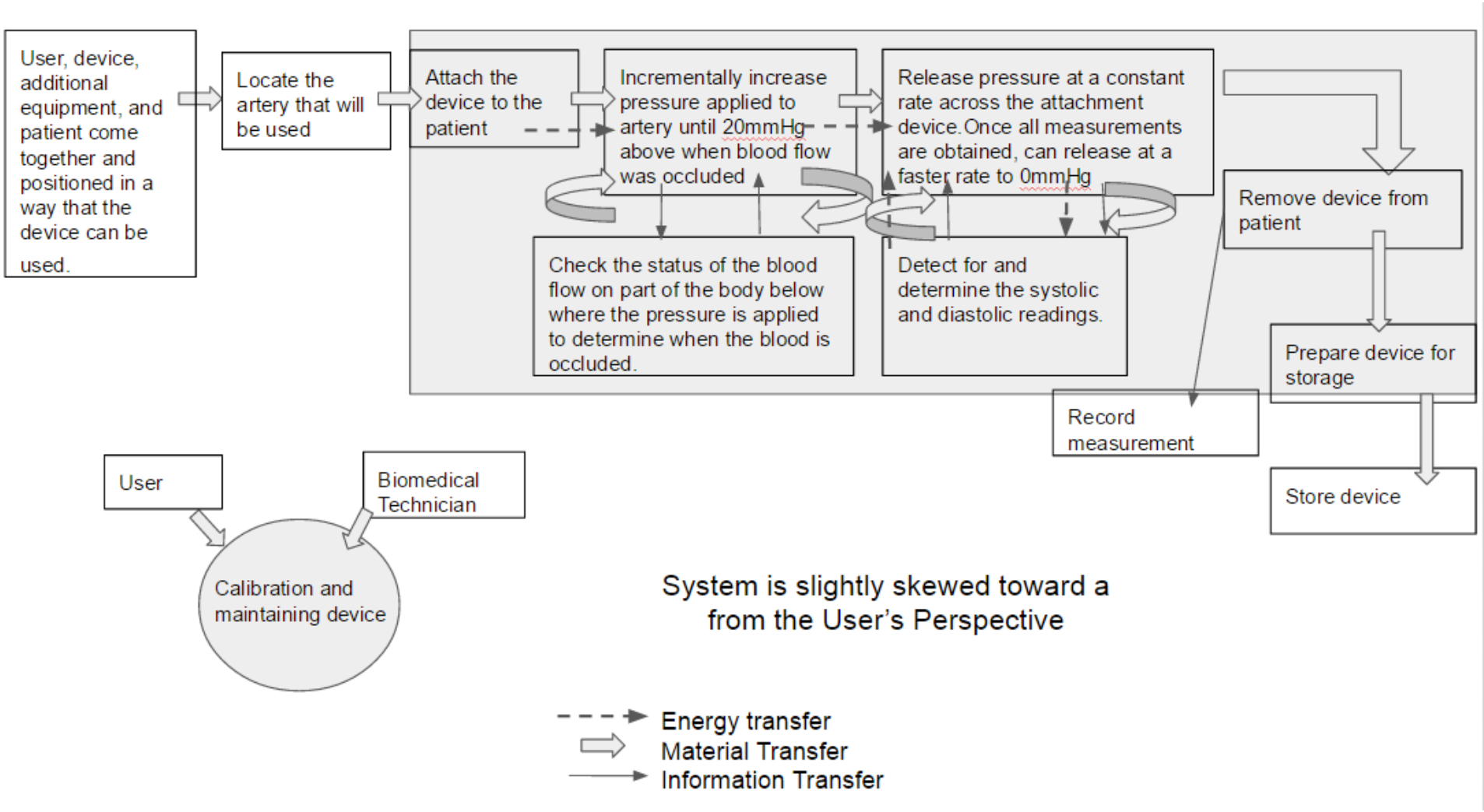
8. While releasing, determine systolic
   8.1 If using auscultatory method: 1st appearance of faint repetitive tapping sounds that gradually increase in intensity for at least two consecutive beats.*
   8.2 If oscillatory, use mean arterial pressure sensory detection to calculate systolic

9. Continue releasing pressure, determine diastolic
   9.1 If using auscultatory method: distinct abrupt muffling of sounds (before is crisp) when becomes soft and blowing in quality
   9.2 If oscillatory, use mean arterial pressure to calculate diastolic

10. Release pressure until component attached to patient can be removed from patient
    10.1 Assess when attachment is able to be removed safely

11. Remove from patient
    11.1 Detach device from patient

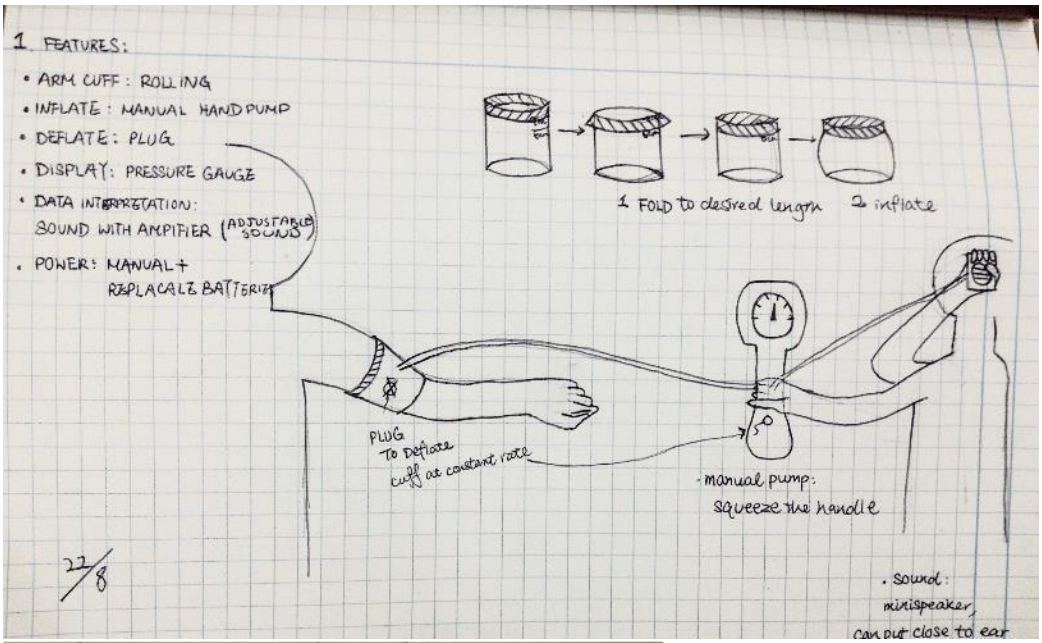
12. Store device
    12.1 Record/make note of measurement obtained
    12.2 Consolidate parts to store
    12.3 Store


User, device, additional equipment, and patient come together and positioned in a way that the device can be used.
Locate the artery that will be used
Attach the device to the patient
Incrementally increase pressure applied to artery until 20mmHg above when blood flow was occluded
Release pressure at a constant rate across the attachment device. Once all measurements are obtained, can release at a faster rate to 0mmHg
Remove device from patient
Check the status of the blood flow on part of the body below where the pressure is applied to determine when the blood is occluded.
Detect for and determine the systolic and diastolic readings.
Prepare device for storage
Record measurement
Store device
User
Biomedical Technician
Calibration and maintaining device
System is slightly skewed toward a from the User's Perspective
Energy transfer
Material Transfer
Information Transfer

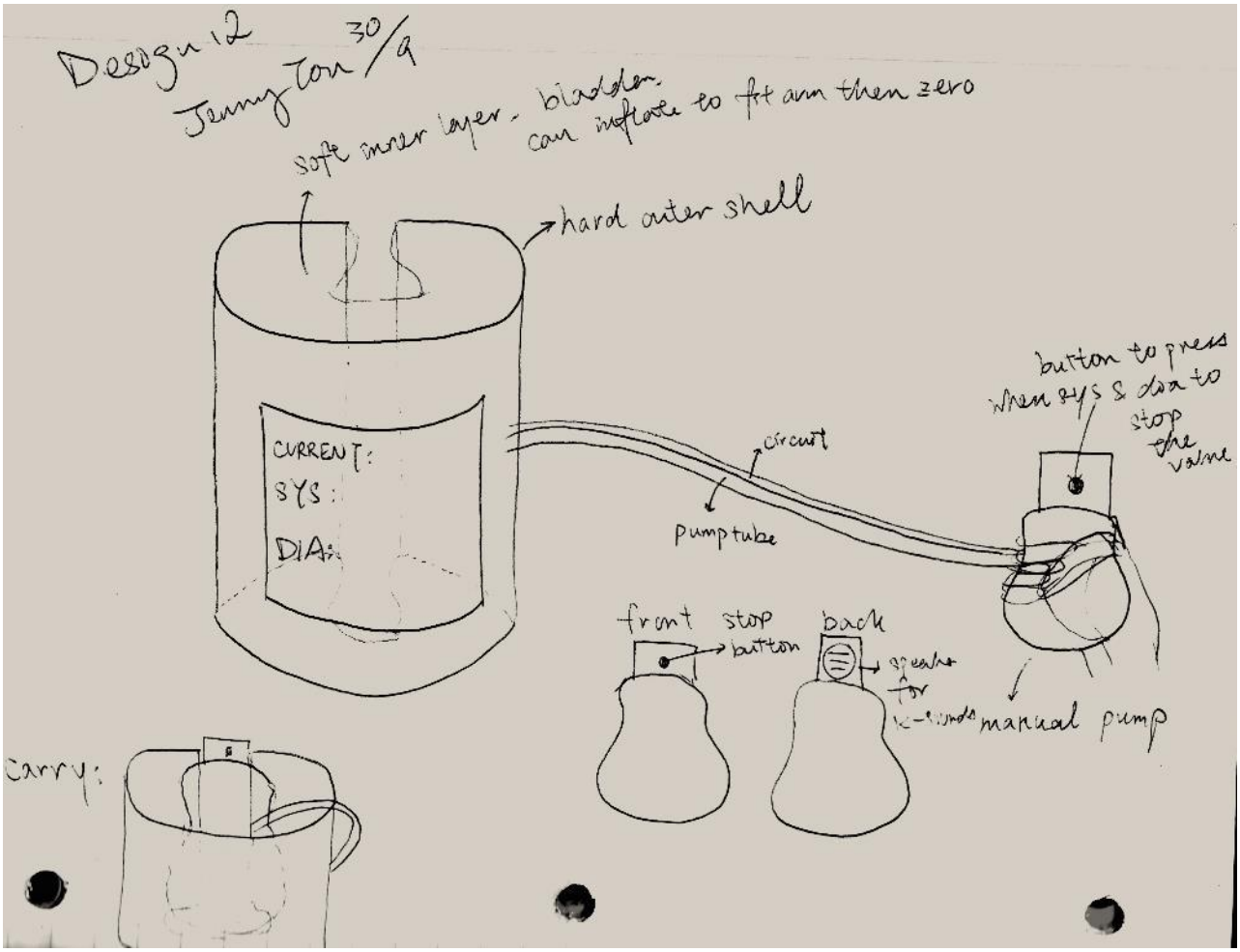
Appendix E: Selection Matrix – Pugh Chart

Requirements\/ Concept>	Weight of requirement	**Design 8**	**Design 9**	**Design 10**	**Design 11**	**Design 12**	**Design 13**	**Design 14**	**Design 15**
Accurate	10	2	1	3	3	3	3	3	2
Affordable	10	2	1	1	2	2	1	1	3
Short Procedure Time	10	2	3	1	2	2	2	3	1
Durable	10	1	1	1	1	1	1	1	2
Safe	10	3	3	3	3	3	3	3	3
Power Source Regeneration	10	2	2	3	3	3	3	3	3
Accommodates Various Patient Sizes	10	3	3	3	3	3	3	3	3
Minimal Step	7	2	3	1	2	2	2	2	1
Readable Measurements	7	1	2	3	3	3	3	3	2
Easy to Calibrate	7	1	1	1	1	1	1	1	1
Portable	7	1	1	2	1	2	2	1	2
Easy to Maintain	5	2	1	2	2	1	2	1	3
Minimal Additional Equipment	5	3	3	3	3	3	1	3	1
Financial Feasibility	10	2	1	2	2	1	2	1	3
Temporal Feasibility	10	2	1	1	2	1	2	2	2
Technical Feasibility	10	2	1	2	1	1	2	1	3
TOTAL		270	239	274	294	276	291	279	312
	without the feasibility components	210	209	224	244	246	231	239	232

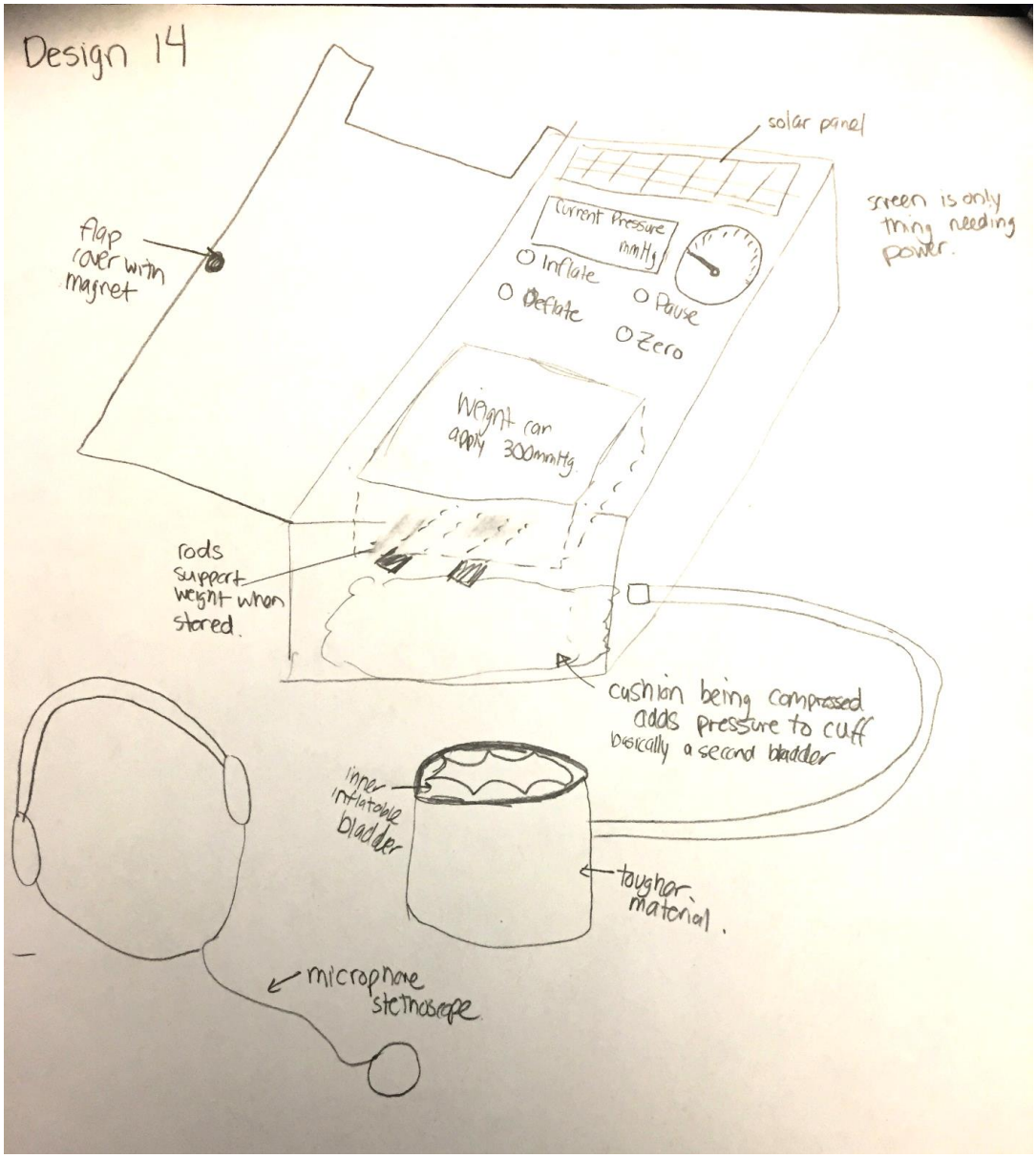
Designs used for Pugh Chart (Designs 9, 10, 11, 13, and 15 can be seen in Figures 11-15, respectively)



Design 8: The device is handheld. The device has a bulb on the grip so that the user can grip the device while also manually inflating the cuff. The deflation mechanism is a plug that can be pulled on the handle to deflate the cuff at a constant rate. The cuff for this device is universal. It has a hard outer shell and soft inner shell to accommodate all patient sizes, and can also be folded down to adjust the length of the cuff. The design has a digital display that gives the current pressure readings. Instead of a stethoscope, there is a speaker that amplifies the Korotkoff sounds is a separate component that can be placed at the ear.

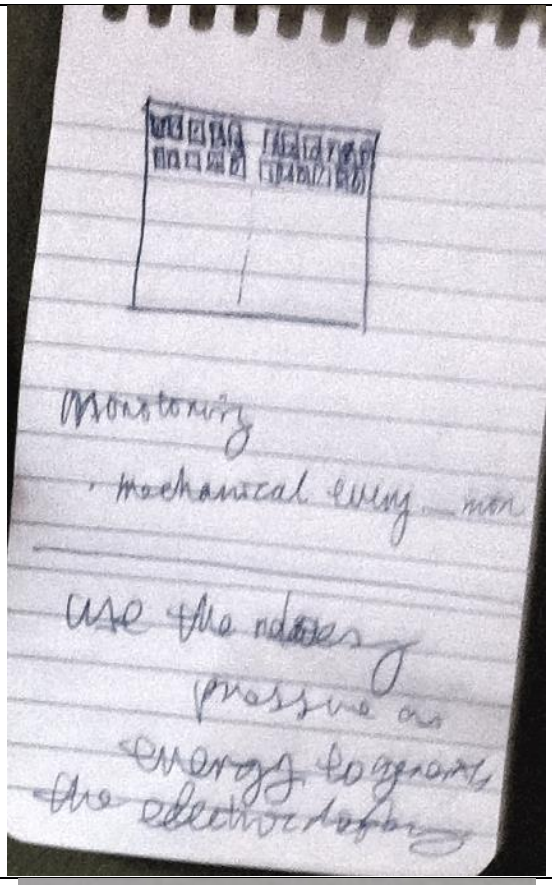
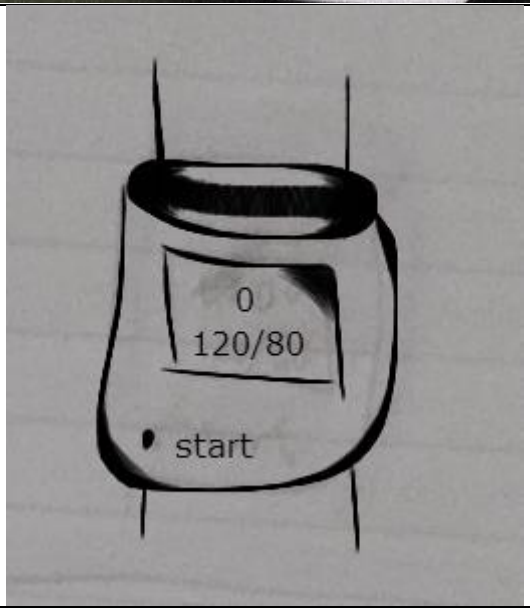


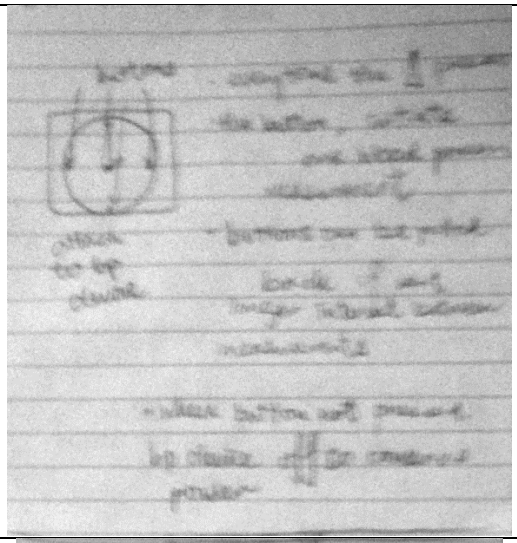
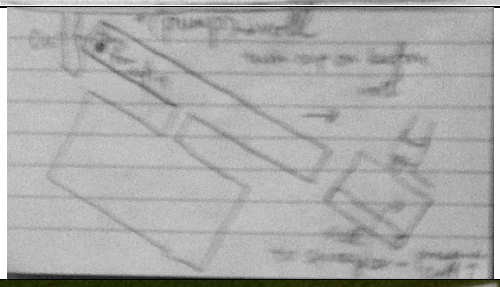
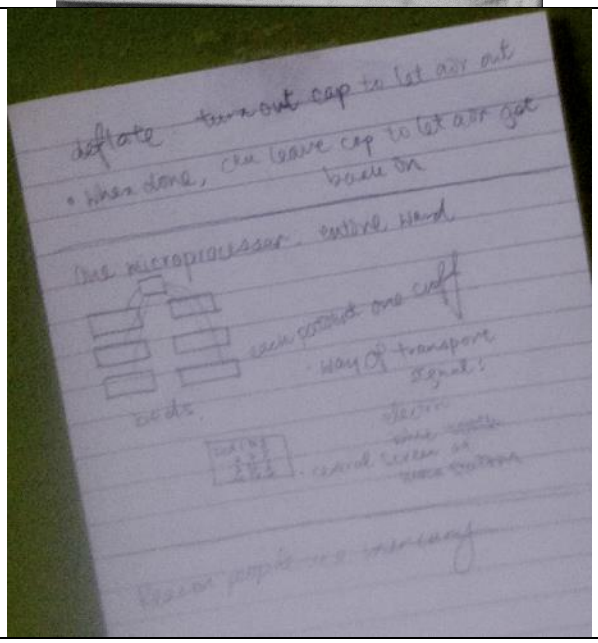
Design 12: Manual pump, auto-deflate, listening method via speaker, numerical value on LCD screen. Universal cuff with hard outer shell and soft inner shell. Size is very big and can fit most patients as required by spec, then user inflates the bladder between the hard and soft layers until the cuff fits the patient and the system will automatically set the value to 0. a “clip on” cuff rather than “slide on”. Microphone attached to inner layer of cuff, signal transmits to manual hand pump+ speaker combination. User listens to sound via speaker and volume can be adjusted. The button behind the speaker, first press to start deflate, second press to record systolic value when hear first K-sound, third press to record diastolic value when hear last K-sound. Looking at current pressure when locking values is not necessary. Screen is on cuff. When carry around, the hand pump and speaker combination can be put and secured in cuff.

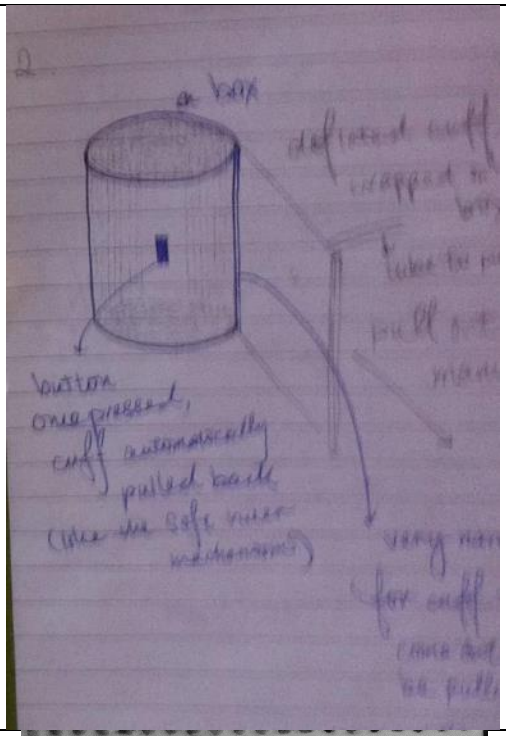
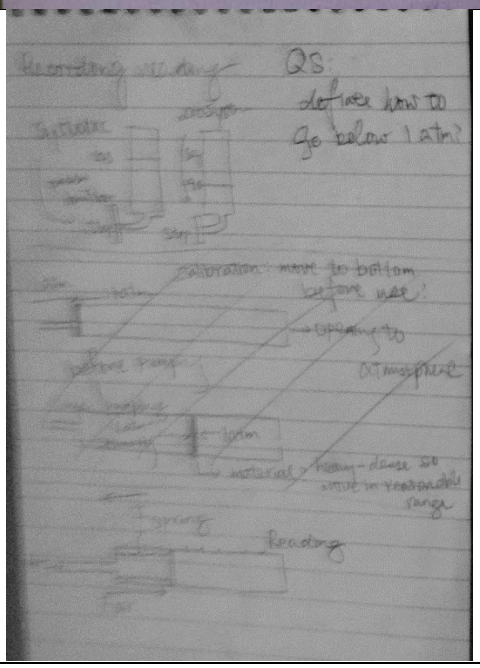


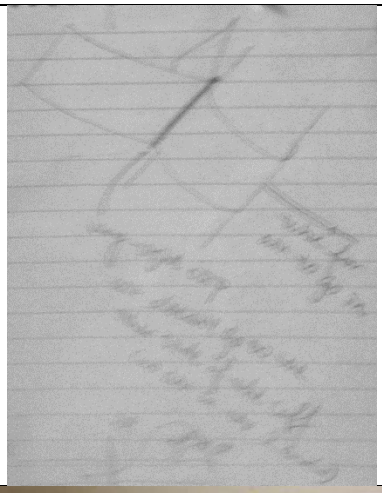
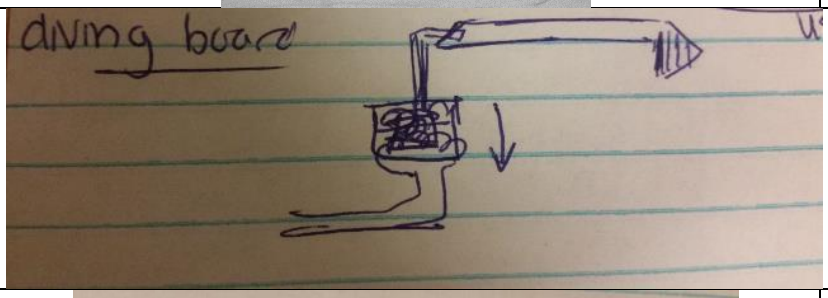
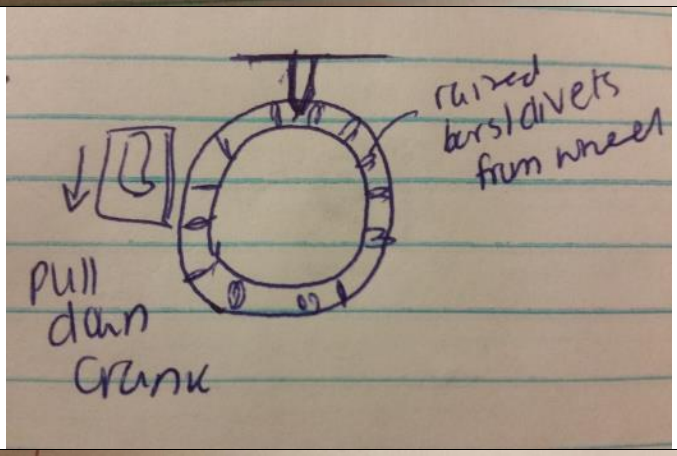
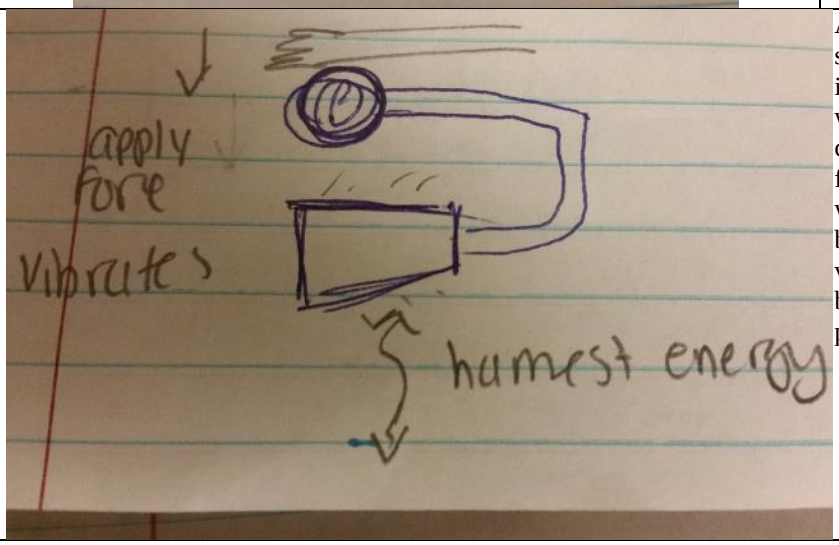
Design 14: Microphone stethoscope, LCD screen with current pressure, use a weight to inflate and deflate. Has a clip to clip weight above compression mechanism for storage. Rechargeable batteries with solar panel, but option to charge in outlet. Universal cuff with inflatable bladder to fit arm. 4 buttons: Inflate, deflate, pause, zero out pressure gauge so can pump bladder to fit patient. Also flap over with magnet to cover screen and cuff can be placed over screen before close device. Somehow, a pressure gauge also on the display panel with the buttons, LCD screen and solar panel. Solar panel placed so not covered by cover.

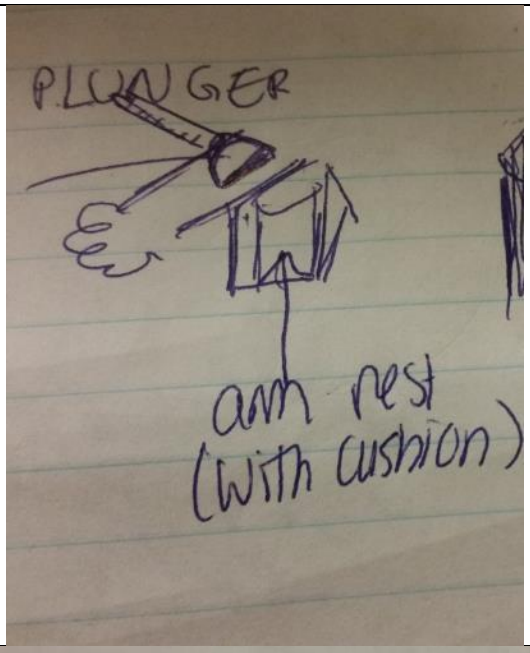
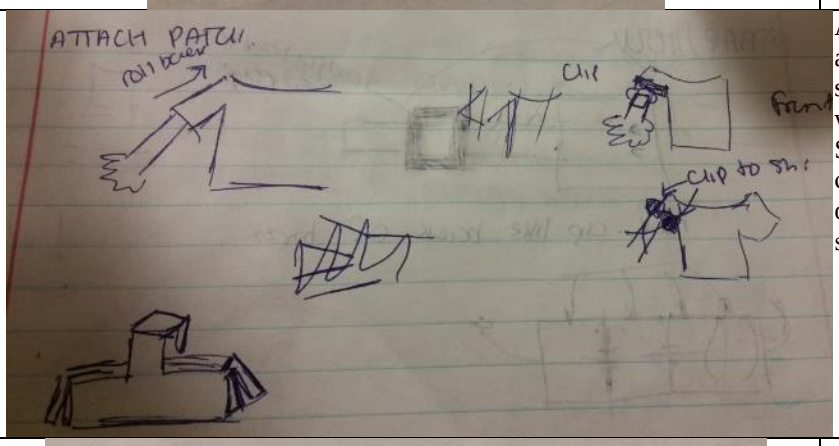
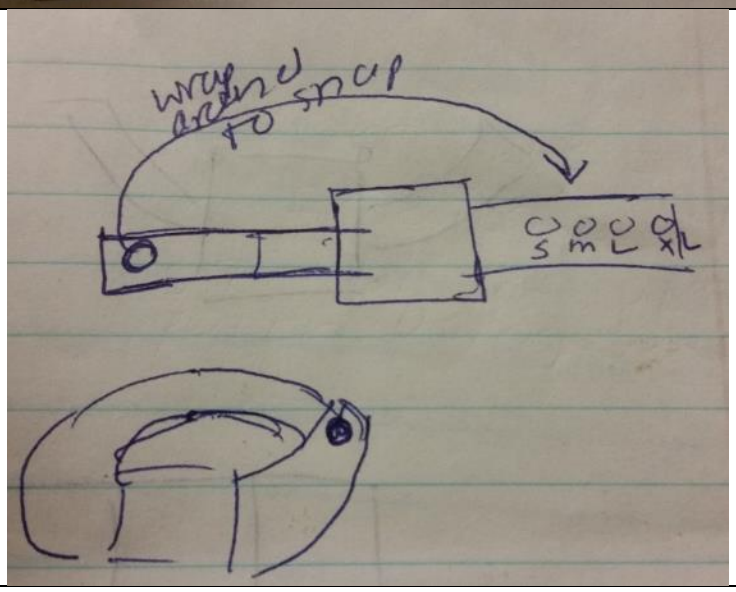
Appendix F: Generated Concepts from Individual Ideation

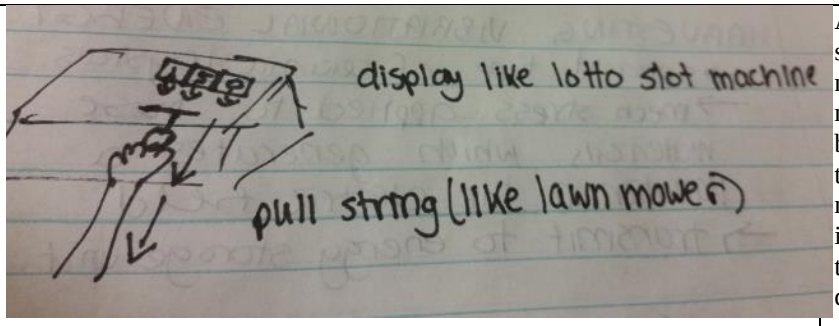
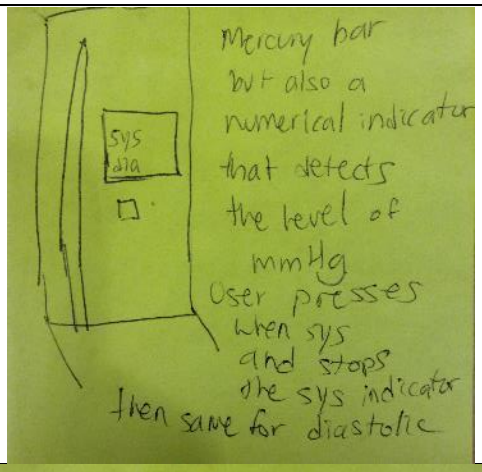
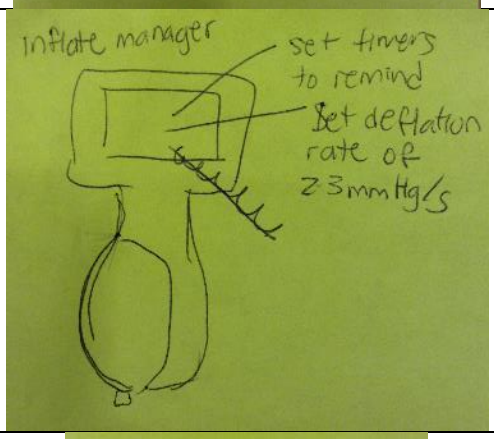
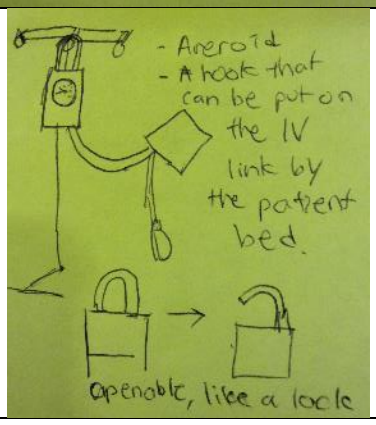
Type	Concept Picture	Description
Record/memory		The design is for monitoring patients. User can choose on the device which patient they are taking the measurement, and the result will be stored in the device. The way of display memory is some mechanical rolling numbers. When user wants to record the measurements to patient's history, he/she chooses the patient on the device, then the last 6 measurement numbers roll automatically at the bottom of the device. Then user can use it like a stamp, and stamp the readings on patient's history. The power to roll the numbers would be using the air that is released from cuff.
cuff		All-in-one cuff: universal cuff size, hard outer shell and soft inner shell. Once air in inner shell fits patient's size, reading will zero automatically. Screen on cuff. Fully automatic, press start button, will inflate, deflate, and give final reading on the screen.

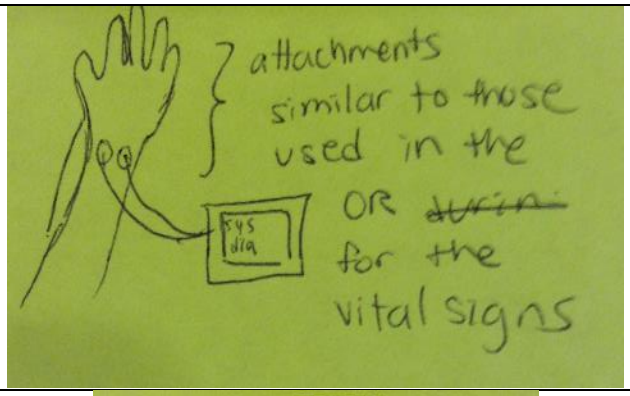
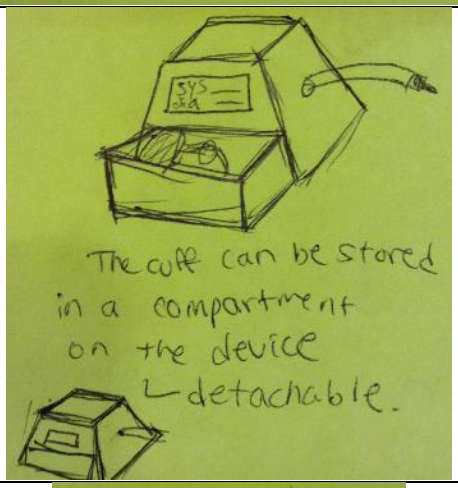
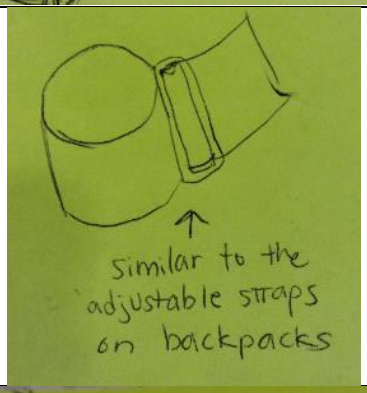
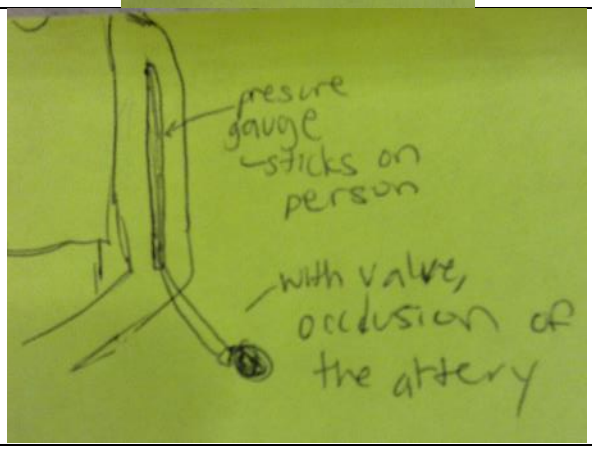
Continuous monitoring		This design is for contiuous monitoring. The way to initiate a measurement at desired frequency is to connect the "start" button with a clock. There are sensors at each 15 minutes on the face of the clock, depending on patient's management plan, user can turn on/off the sensors. When arm of clock hit sensor, a bp measure is initiated. Numbers are stored in the device.
Cuff inflation		The idea comes from sandwich bags. When sandwich bags are rolled, volumn decreases and the air got squeezed. Connect a sandwich bag thing to cuff, air in sandwich bag will be enough to inflate cuff to desired pressure, so instead of pumping, user rolls the baggy thing.
Cuff on patient		Somehow leave the cuff on patients, and all cuff are connected to one single processor. Ways to transmit signal was not specified, was thinking electric wires or bluetooth. There is a screen control all the cuffs at nurses' station. Nurses can initiate bp measurements on any patients with cuff on at station and do not need to walk to patients.

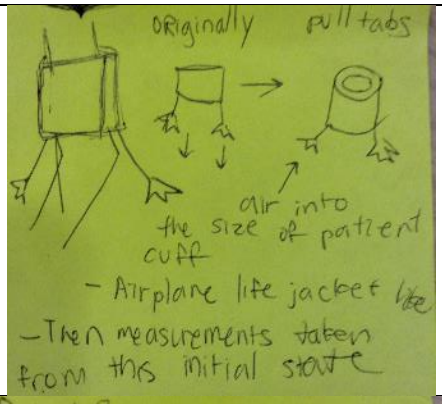
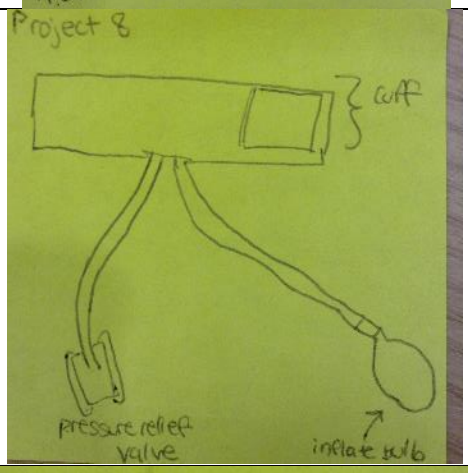
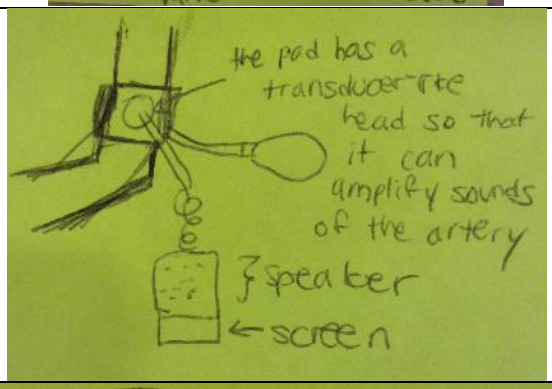
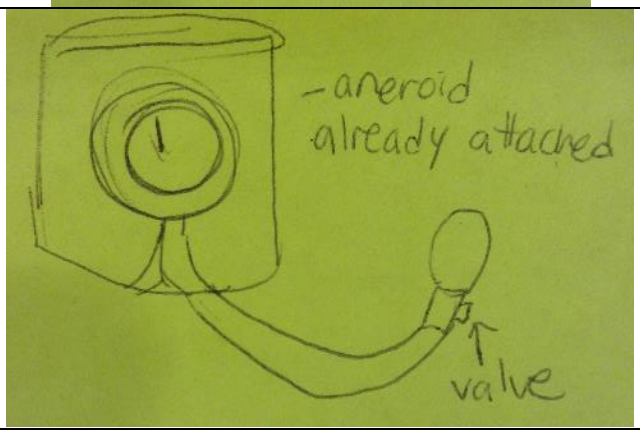
Cuff		Cuff in a soft-ruler shell. Can pull out cuff till desired length to wrap around patient's arm. There is a button, once pressed, the cuff will go back into the shell automatically, so user does not need to roll/fold cuff after usage.
Display Method		Was thinking a way to hold the mercuy at sys and dia, so user can read the numbers afterwards, instead of having to listen, look at value, and deflate at the same time. This design has two mercury columns. User hits a button when hear first and last k-sound (sys and dia), when button first hit, the tube connected cuff and first mercury column will be closed, so value will be held there. When second hit, the other column stops, which is the dia readng.

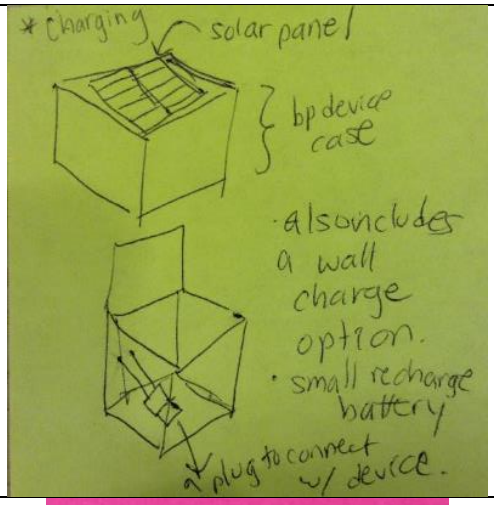
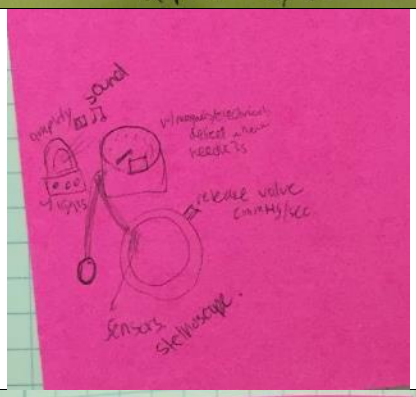
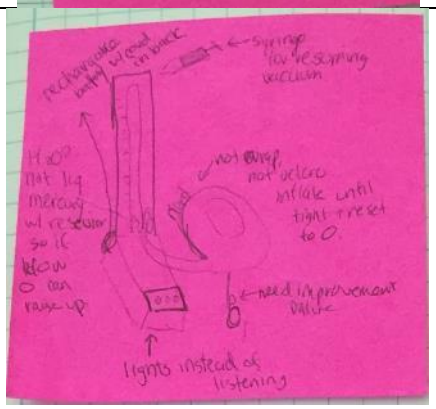
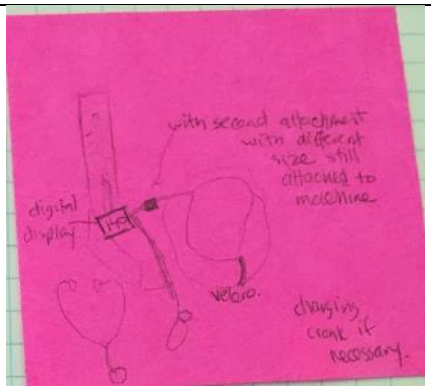
cuff		Universal cuff idea: add a clip and make the cuff a slide in-and-out design. Clip is tight and strong enough that air will not go to the 2 arms of cuff after the clip.
Power Source		A way to harvest vibrational energy that is similar to a diving board. User applies a force in downward direction with a handle, releases hand, which creates vibration of board that can then be harnessed for energy.
Power Source		A way to harvest vibrational energy that is similar to a game show wheel. Design consists of a wheel that has pegs sticking out around its circumference. Some sort of tab is overlaying the top of the wheel. When a user pulls down a crank, the wheel spins which causes the pegs to collide with the tab and cause it to vibrate. Vibration of tab can somehow be converted into energy.
Power Source		A way to harvest vibrational energy, similar to a vibraphone percussion instrument. Design consists of a wooden sphere and block that are connected by metal. User applies force with palm to wooden sphere, which makes contact with wooden block and causes vibration. The vibration of the block can somehow be harnessed and converted into a power source.

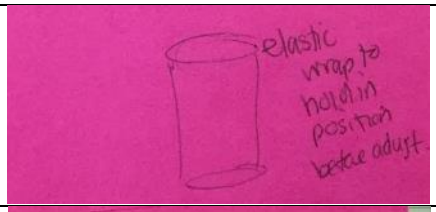
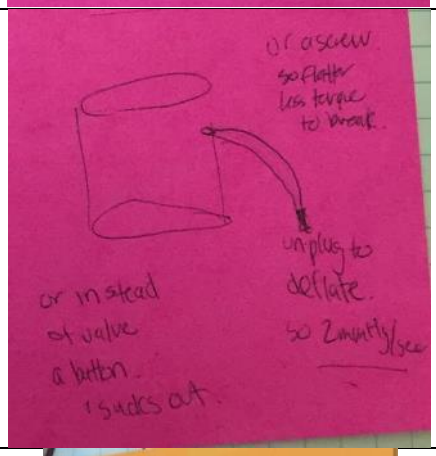
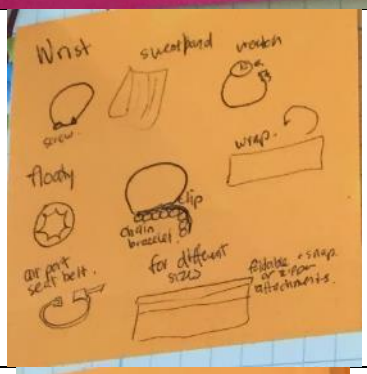
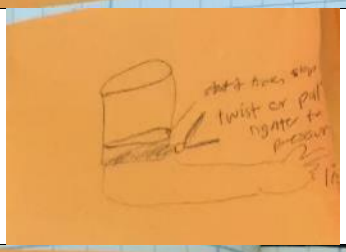
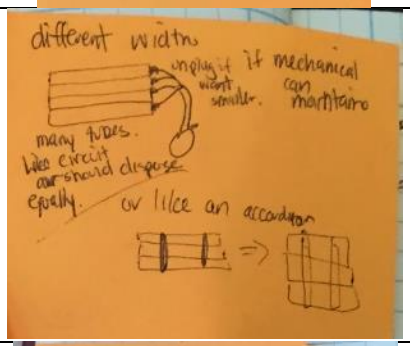
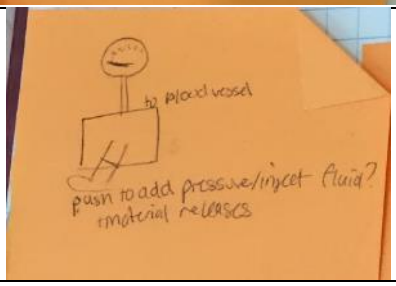
Attachment Method & Pressure application		A proposed method of using a patch as the form of attachment and inflation. The design resembles a plunger, where pressure is applied when plunger is pushed by user into its convex position. Pressure is released by slowing pulling plunger head towards its resting position. Handle of plunger contains a display gauge similar to mercury sphygmomanometer display.
Attachment Method		A method to connect a patch attachment to patient. Patch has two straps connected on either of its ends which have a clip connected to them. Straps are wrapped around the back of the patient's arm and cross each other. Clips are then attached to the sleeve of the patient's clothing.
Attachment Method		A method to connect a patch attachment to the patient. The attachment method involves straps on either end of the patch with many snap connectors, each one for a different sized patient. For this method, the patch is attached to front of the patient's arm and then the straps are wrapped around the patient's arm and snapped into place.

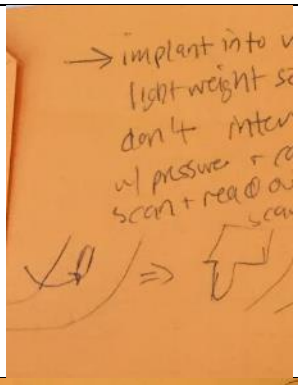
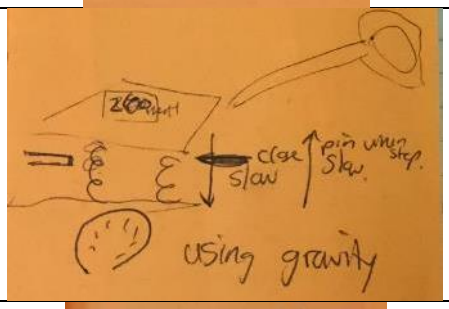
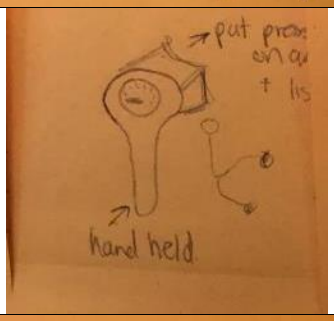
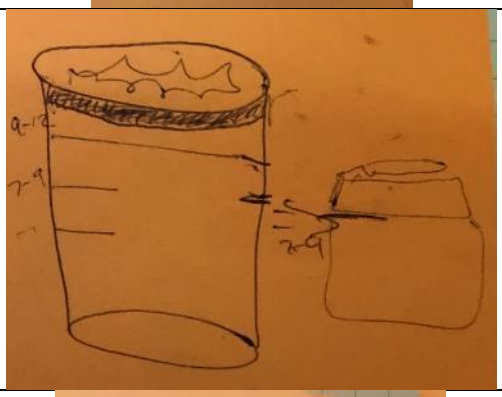
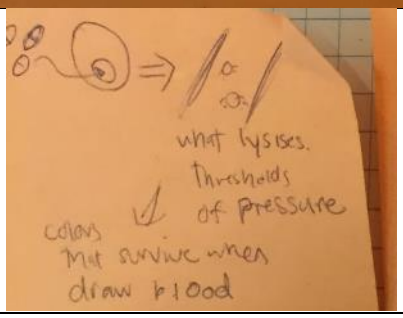
Display Method & Power Source		A method for display and energy source. The display is entirely mechanical and resembles a lotto slot machine. Mechanical inflation occurs by patient pulling on a cord, similar to the manual start-up of a lawn mower. Pulling of cord stimulates an internal gear mechanism that rotates the block numbers of the digital display.
Display Method		An incremental change on the existing mercury sphygmomanometer, which incorporates a numerical indicator which detects the level of mmHg. The user can press when the sys and dia occur to have the numerical display show the final reading saved on the digital screen.
Pressure Application		An incremental design improvement on the current bulb method for putting air in the blood pressure cuff. There is a timer to remind the nurses and midwives when to next take the patients' measurements. Set deflation rate at 2-3 mmHg/s, but user must inflate the bulb.
Portable Methods		Change in portability method with a type of handle on the aneroid sphygmomanometer device that allows the user to hang the device on the IV hook that are usually next to the patients' beds. The handle can be opened, similar to a lock.

Attachment Methods & Pressure Application		Attachment of the device on the patients wrist, with two circle dots that detect the blood flow from the veins in the patients' wrist. The systolic and diastolic values are based on the pressure under the veins. Pressure is applied on the patients' wrist to stop blood flow, and the slow release allows the detection of the blood pressure.
Casing		The cuff can be detached from the device. Oscillometric measurement method. There is a compartment on the bottom of the device with a drawer that allows the user to store the cuff inside of the device.
Cuff		An incremental change on the cuff design, with a type of buckle-like backpack adjustable strap theme. The adjustment allows the cuff to fit on various patient upper arm sizes.
Pressure Application		A type of pressure gauge stick to go on the patients' brachial artery location. Instead of having the cuff, a pressure patch to occlude the artery so that there is no need for the fitting on the patient. A type of pump was suggested to apply the pressure that would be on the pressure patch. The patch is disposable and can be left on the patient after the measurement for repeated use on one patient.

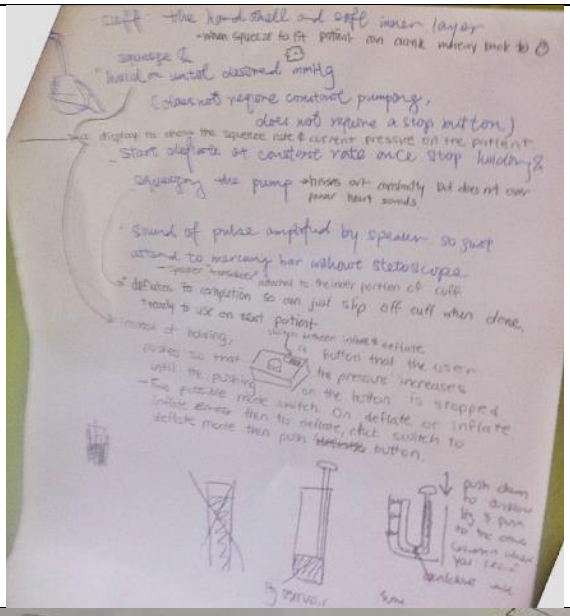
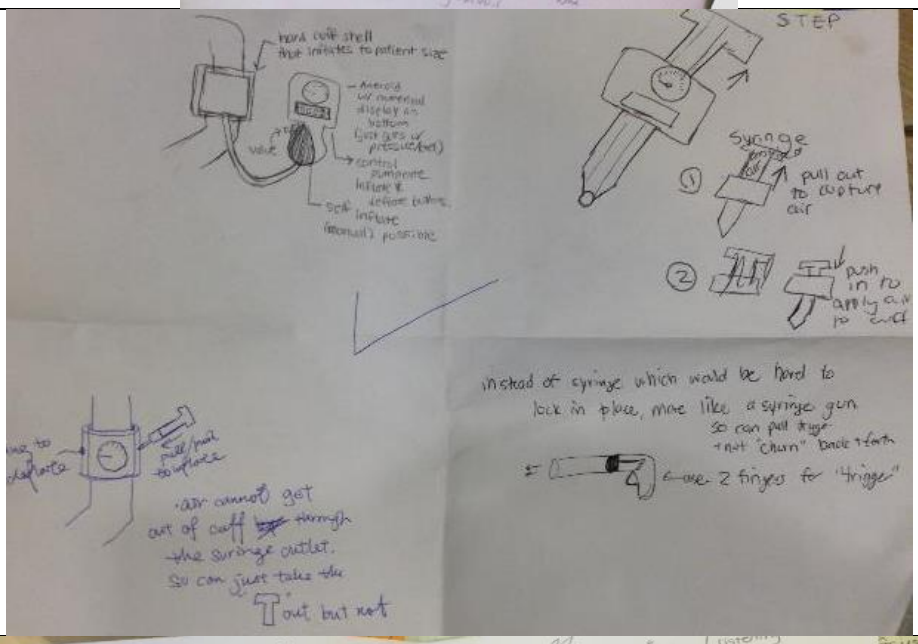
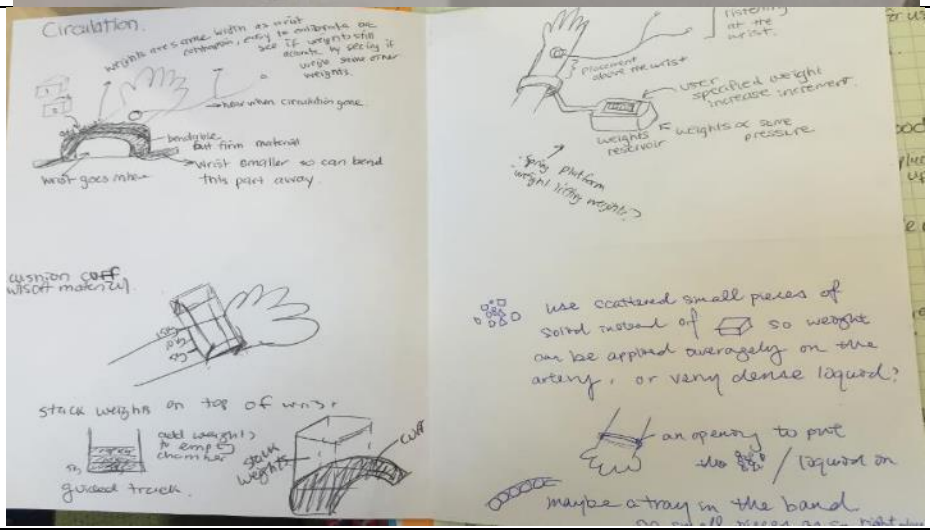
Cuff		Inspired by how the airplane emergency vests inflate by pulling on the tabs. The cuff will have two tabs that when the user pulls on them, air will go into the cuff to become the size that will fit the patient. The pressure measurement will be taken from this state. Kind of a universal cuff method.
Overall device		From a previous MECHENG 450 project. A blood pressure threshold indicator. A cuff to occlude the patient's brachial artery and a pressure relief valve to indicate if the patients' blood pressure is above a certain amount (such as the suggested threshold for preeclampsia for pregnant women)
Listening Method, cuff		A blood pressure cuff with a microphone/ pad with transducer-like head so that the blood pressure sounds can be amplified. There is a speaker, similar to the fetoscope (ultrasound method)
Display Method		An incremental change to the existing blood pressure. Aneroid blood pressure device with the aneroid pressure gauge already attached on the blood pressure measurement cuff. The user needs to carry only the blood pressure cuff and the pressure bulb when going to measure blood pressure on the patient.

Power source		A solar charging method for the blood pressure device. The solar panel on top of the blood pressure device case. Inside the blood pressure device is a rechargeable battery which is charged when plugged into the battery reservoir charged by the solar panel. While the device is being used, the case can be left in the sun to be charged and the device can be plugged in the case to charge it.
Overall		This complete device has an aneroid pressure gauge, a hand pump, and a universal cuff that has a release valve on it. It also has a microphone stethoscope source in the cuff that transmits the sound to a speaker that sits on a table.
Overall		This complete device was like a mercury sphygmomanometer to keep some familiarity to the device, but a different, more environmentally friendly fluid. To help ensure a vacuum This device would not use a stethoscope; lights are used to signal the systolic and diastolic measurements. The inflation and deflation methods are the same as the mercury sphygmomanometer--a hand pump and a valve. This device has a rechargeable battery that can be plugged into the wall. The cuff is an inflatable bladder where it comes as 1 circular piece and the user inflates the cuff to fit the patient and then zeros the device.
Overall		This device is a mercury sphygmomanometer with many cuffs attached so the user could select the most appropriate cuff and use a velcro to secure it. This device would use a digital current pressure display which is recharged with a small hand crank; the mercury column is still available for times when the screen does not have power. The other components like inflate and deflate method remain the same as the mercury sphygmomanometer.

Cuff		This cuff is a universal cuff where the inner bladder would be inflated to the desired fit. In addition, it has an elastic bands at the top and bottom of the cylinder so that it stays in place as the user is adjusting the fit.
Cuff deflation		This cuff as a deflation string attached to the cuff, in which the user would pull to deflate it and then need to replace it after use.
Attachment Methods		This shows generated concepts for how a device could attach to a wrist. There were clasp, wrap, and snap methods among other ideas.
Cuff		This is a cuff where you twist and pull the cuff tighter to add pressure to the arm and occlude the blood flow.
Cuff		This cuff is adjustable by unplugging different subparts of the bladder to choose the best size for the patient. It could also have cords to shorten the height of the bladder to also better fit the user.
Overall		On this device instead of having a cuff, it would have a pressure pad which is pushed on the arm and a syringe is used to add pressure on the vessel. A pressure gauge would be attached to the pressure pad and a stethoscope was used to listen to the blood flow.

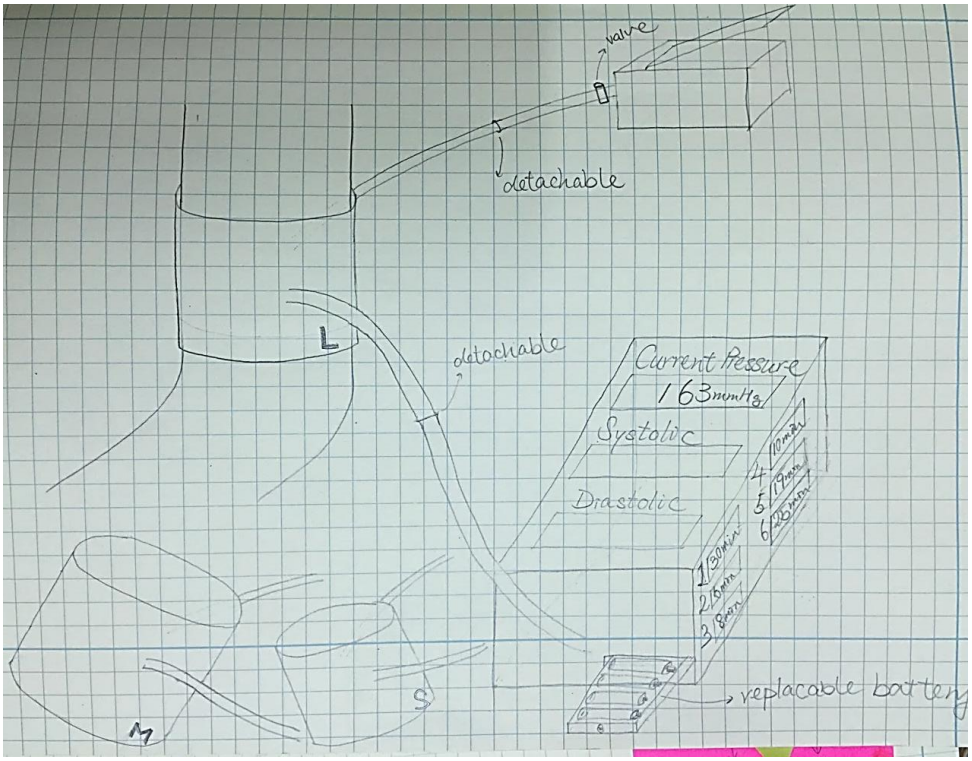
Overall & Invasive		This device is an invasive method in which the pressure gauge sensor would be inserted into the blood vessel and a machine would pick up the electric signals.
Overall		This device uses a weight to compress springs assisted with a pin to guide the weight to increase the pressure on the cuff and then a pin that raises the weight to deflate at a constant rate. This device also has a LCD screen.
Overall		This device is handheld and the pressure pad is set up to be in contact with a patient and a motor pushes the pad into the patient increasing the pressure and the gauge is in the head of the pressure pad. A stethoscope still needs to be used for this method.
Cuff		This is a universal cuff that also has a hard lining for the top inch. This is a slip on arm cuff that inflates to patient size with a snug fit. This top inch can be folded over to cut off inflation of the top part of the cuff. This would allow for an adjustable height of the cuff. This would add to the adjustability of the cuff.
Overall & Invasive		This is an invasive method where bacteria is injected the blood vessel. At a certain pressure, the different bacteria would lyse at different pressures and change the color of the blood. By the color of the blood, the user could distinguish in what range is the blood pressure.

Appendix G: Group Generated Concepts from Brainwriting

Drawing	Description
	Incremental change to current mercury sphy. The new pump has enough compression power that, user just needs to squeeze once and would be enough to pump up the cuff. User keeps holding the squeeze until blood flow is occluded, then once let go of the squeezing, the cuff will deflate automatically at constant rate. If want to inflate again during/after the process, just squeeze the pump again anytime. Sound amplfier instead of stethoscope. Still uses mercury column.
	Four concepts generated after a session of brainwriting. The left-hand corner blood pressure device involves hard cuff shell with soft inner lining, a cuff that inflates to fit the patient's size. The pressure gauge is aneroid with a hand held pump with controlled deflation rate. The upper right hand corner incorporates a syringe method to insert pressure on the patient. The left hand corner took the first two ideas with a plug to deflate and an aneroid display. The right hand corner device involves a pressure gun.
	This is a team brainwriting example for a way to add pressure to the cuff by adding physical weight to the device's contact point on the patient to cut off circulation. This went from adding brick like weights to the wrist, to adding the weight to a weight platform, to stacking weight to a chamber attached to a wrist, and finally to adding bead-likes weights to a bracelet.

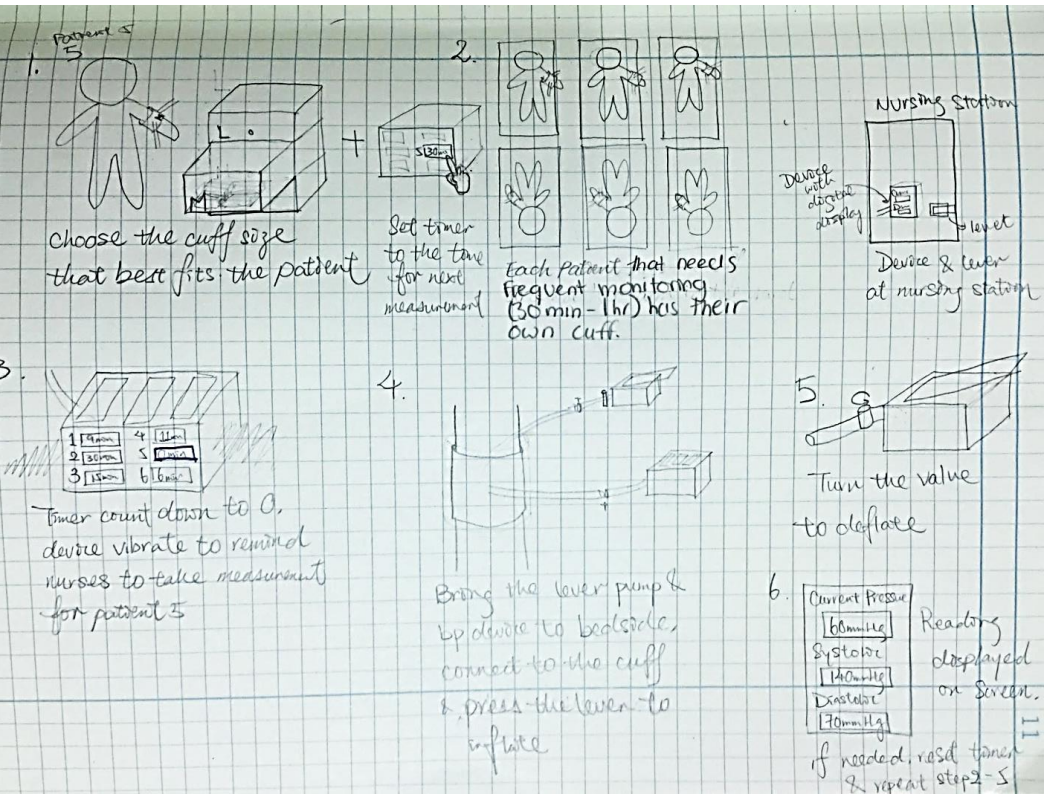
Appendix H: Group Generated Concepts

Design 1



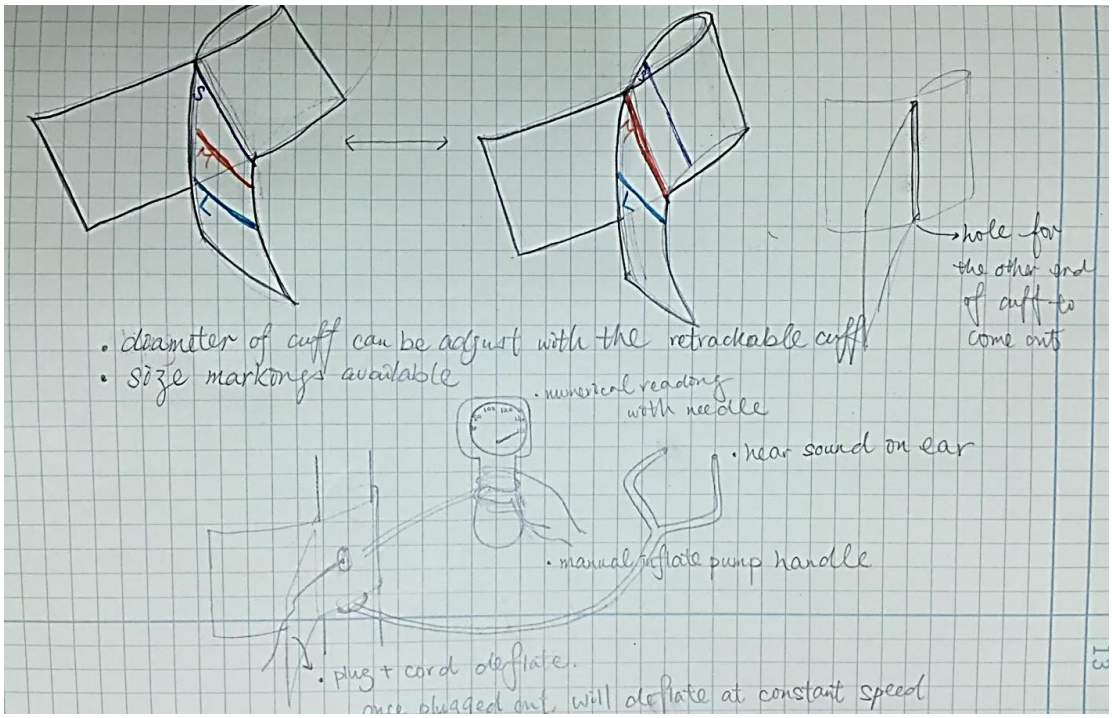
The design is automatic with a digital display of current pressure, systolic pressure, and diastolic pressure. Design can store up to six previous blood pressure readings. The device has a mechanical inflation with a hand pedal mechanism and a valve that can be turned to deflate automatically at a constant rate. The design has three different cuffs that can be attached and removed to the device to accommodate patients with different arm sizes. The device is powered by a replaceable battery. The design also has an alert system so that the user can be notified when it is time to for the next blood pressure to be taken.

Design 1 Supplement Diagram



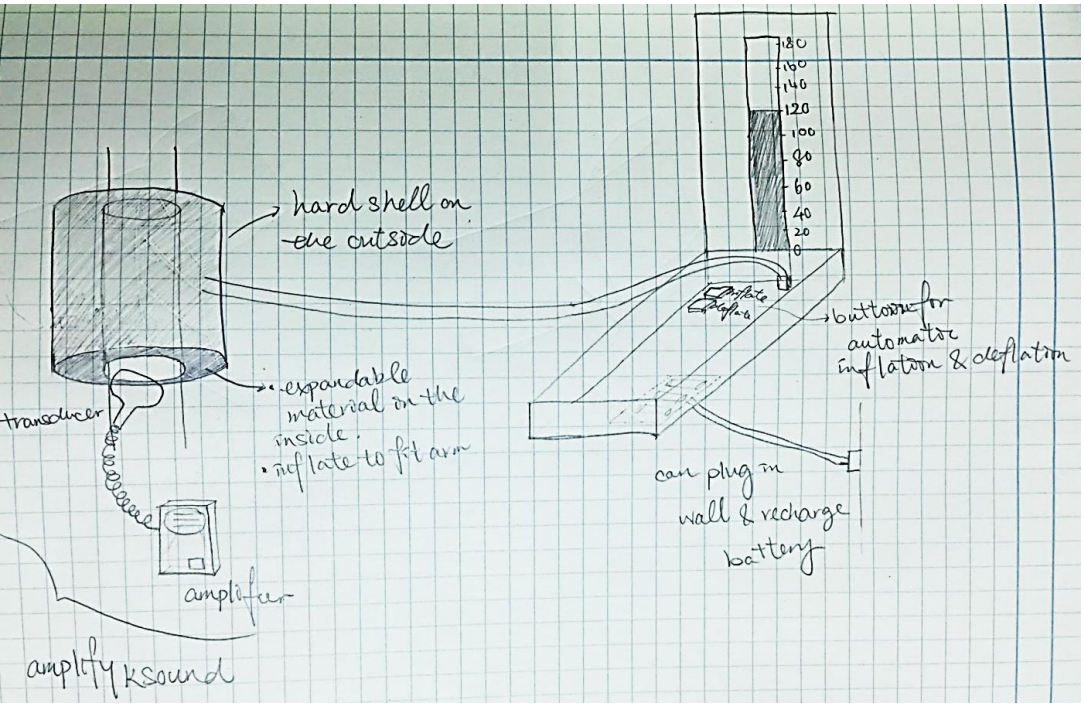
The design is intended to allow for cuffs to remain attached to patients that need to be monitored at 30 minute intervals. This eliminates the need for the user to have to attach the cuff every time the blood pressure needs to be taken for these patients.

Design 2



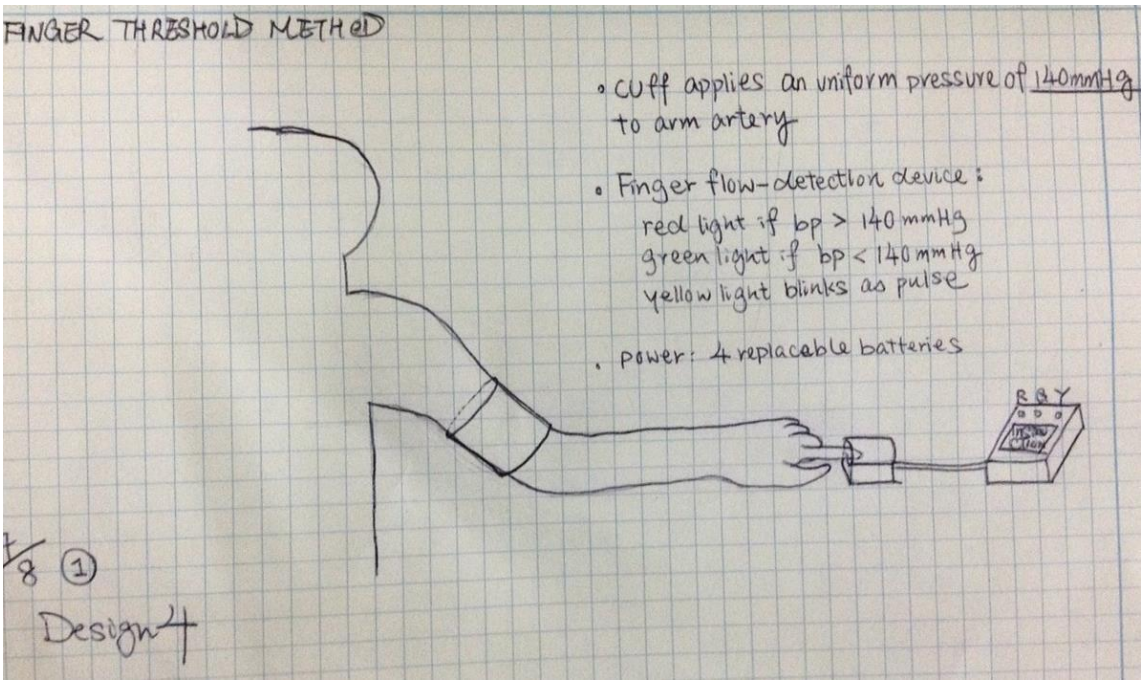
The design is handheld and has the manual pumping bulb embedded into the grip of the device. The device has an aneroid display. The cuff has a plug that upon pulling will deflate the cuff at a constant rate. The user needs a stethoscope in order to listen to the points of systolic and diastolic pressure. The cuff is a universal cuff that wraps around the upper arm. The cuff has slit to slide the other end of the cuff through and a clip that can be locked into place at different patient sizes. The clip prevents air from being added into the excess cuff strap.

Design 3



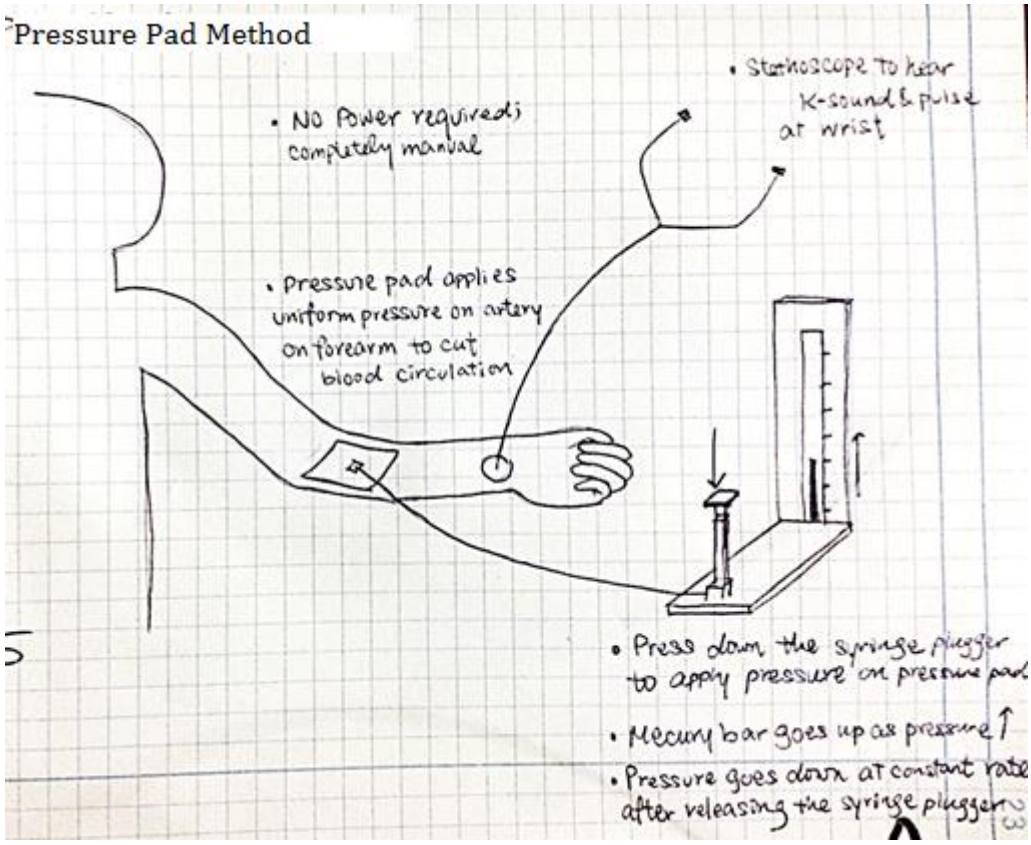
The device display resembles the mercury sphygmomanometer, but a fluid other than mercury is used. The device has a manual inflation and deflation which can be initiated by the user with a button. The design uses a universal cuff which has a hard outer shell and a soft inner shell that can be inflated to the patient's arm size. Once cuff is inflated to the patient's arm size, the device can zero the pressure to begin the blood pressure measurement procedure. The power source for the device is a rechargeable battery. The design uses an electronic transducer that amplifies the sound with a speaker.

Design 4



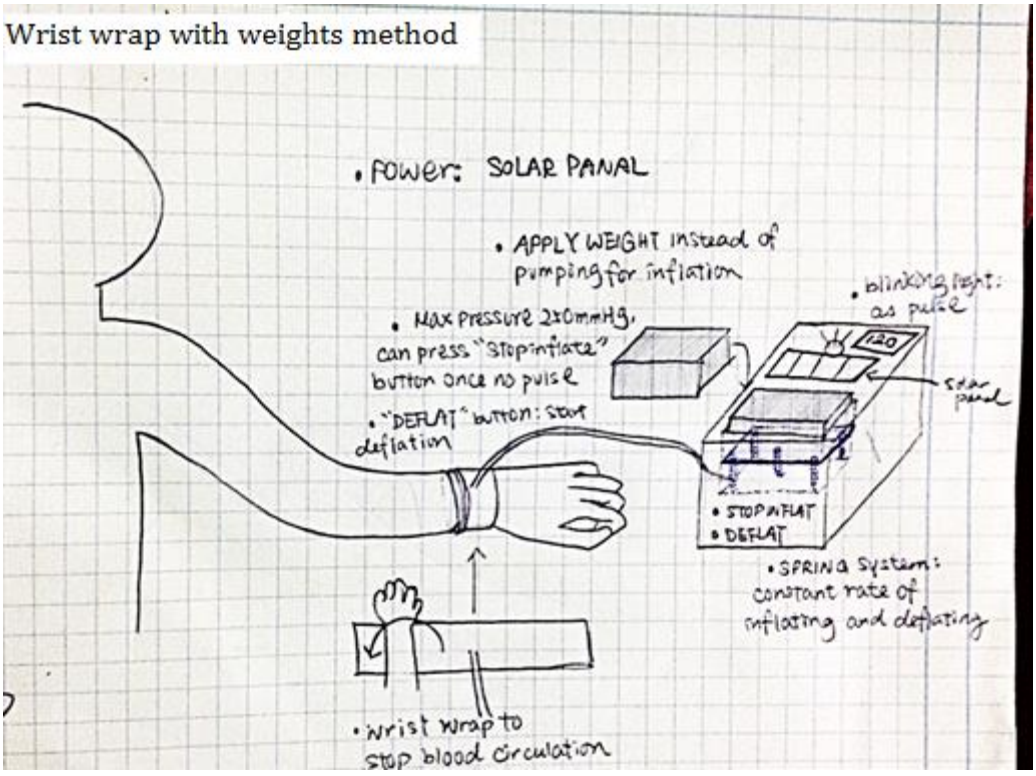
The design is from a previous MECHENG 450 project that was based on blood pressure. The design is a finger-based threshold method. The device displays a red light if the blood pressure is greater than 140mmHg and a green light if the blood pressure is less than 140mmHg. The device is powered by four replaceable batteries.

Design 5



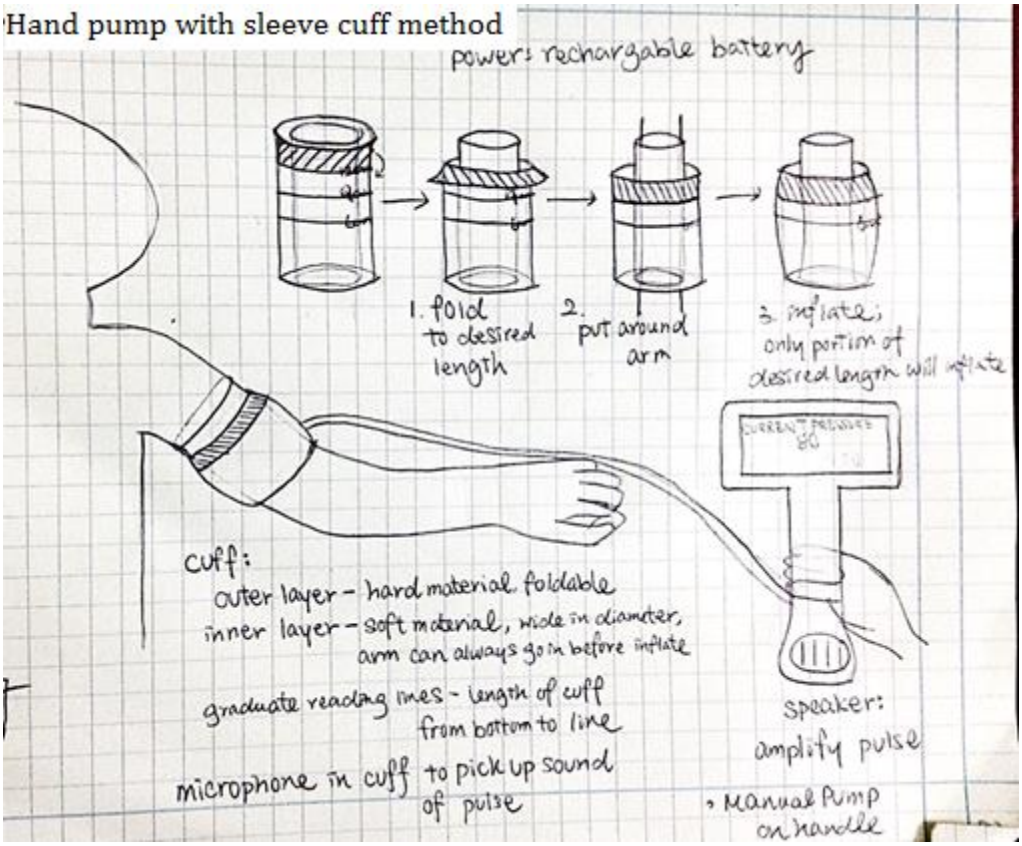
The design has a mercury sphygmomanometer display. The design has a syringe plunger that is pressed down by the user to inflate a patch that is placed over the brachial artery. Once the max pressure is applied, the user can stop pressing down on plunger and plunger will automatically rise which will deflate the patch. The device requires a stethoscope to obtain the systolic and diastolic readings via the auscultatory method. The user listens to the Korotkoff sounds at the wrist. The device does not require a power source.

Design 6



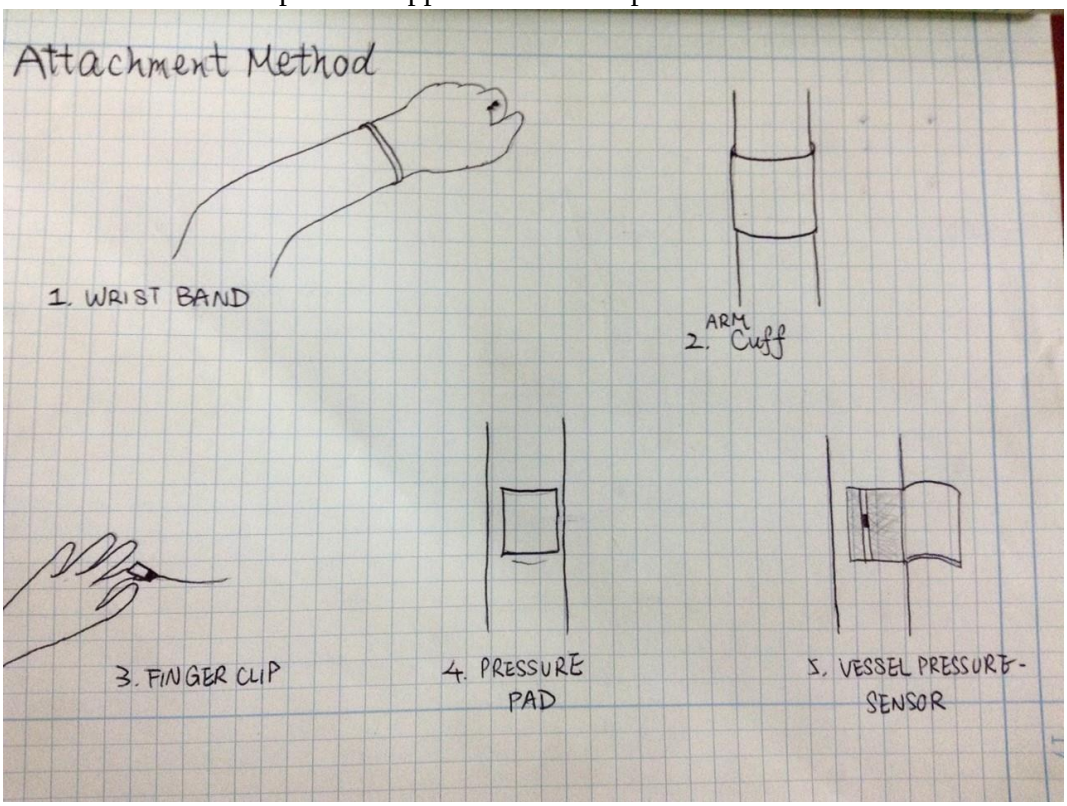
The device uses a weight and spring system to apply pressure to mechanically inflate, and only requires the user to press a button to prompt inflation. The weight can apply a maximum of 300mmHg to accommodate patients with high blood pressure levels. The device deflates automatically when the user presses the deflate button. The design consists of a digital display that provides the current blood pressure reading. The device uses the oscillometric method to detect blood pressure, and the systolic and diastolic readings are indicated by a flashing light. The pressure is applied to a cuff that is wrapped around the wrist. The power source of the device is a solar panel.

Design 7

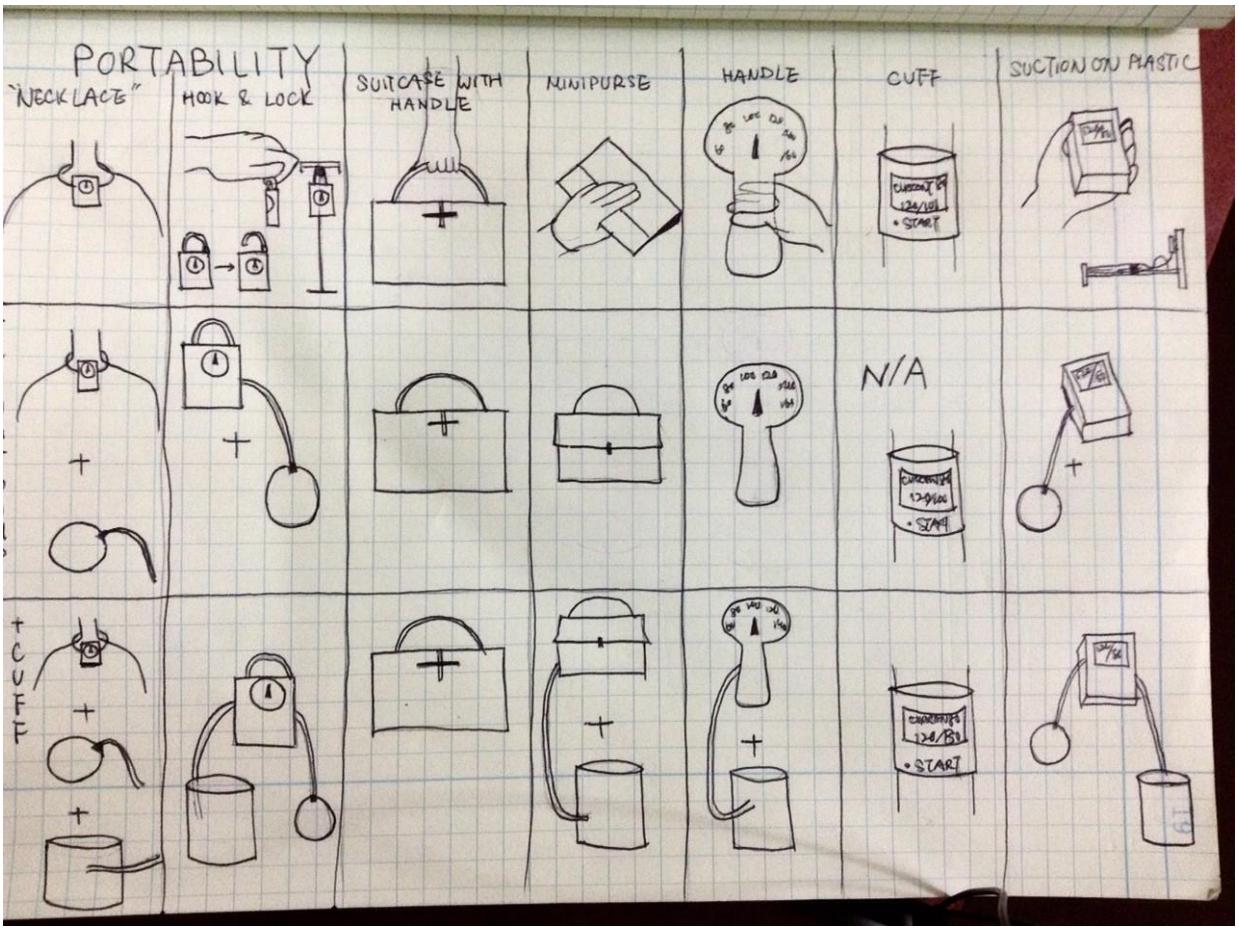


The device is handheld. The device has a bulb on the grip so that the user can grip the device while also manually inflating the cuff. The deflation mechanism is also manual. The grip also has a speaker embedded into the device so that the user can listen to the Korotkoff sounds without a stethoscope. The cuff for this device is universal. It has a hard outer shell and soft inner shell to accommodate all patient sizes, and can also be folded down to adjust the length of the cuff. The design has a digital display that gives the current pressure readings.

Different methods of pressure application on the patient



Different methods of portability



Appendix I: Design Review 2 Presentation Summarized Feedback

As part of the project, the team presented much of the material in this written report to an audience of other MECHENG 450 students and a MECHENG professor.

During the presentation, students wrote comments to the team about aspects they liked, aspects they didn't, and questions they had. The comments and questions have been compiled and summarized below.

Presentation Feedback:

- Team is knowledgeable about their problem and chosen concept
- Could have used mockup more to demonstrate key parts of the design
- Well-prepared slides and mockup
- Good, brief recap of your background
- No labeling of concept drawings
- Practice voice cadence and tone of presenting
- Reduce text on slides
- Clearly showed the priority of our user requirements
- Presenter looked at slides multiple slides
- Functional decomposition should be more structured
- Engineering specifications were wordy
- Possibly highlight benchmarked devices to make the space clearer for our audience

Design Feedback:

- Will the sun required for the solar panel melt the tubes?
- Solar panel power calculations were based on outside conditions
- How many days in Ghana are covered with clouds? How strong is the solar intensity inside?
- Would the solar panels on the device limit the storage options?
- Is there too much technology here? Sounds very expensive
- Why are there speakers on this device but not machines in the US?
- The more complicated the circuitry the more you sacrifice durability and portability
- Liked the latch for storage

From this presentation feedback, it was deduced that there needs to be more background information for an audience who is seeing the project for the first time specifically about other devices in the market. In regards to the design, it seems that to convince the audience of the importance of a solar panel in the device more engineering analysis must be done.

Appendix J: Bill of Materials

Category	Subcategory	Item	Main Specifications	Manufacturer	Part Number	Amount	Unit Cost	Total Cost
Cuff	Arm Cuff	Adult Size	11.8"-16.5"	Veridian	15921	1	15	15
Pump	Hand Pump	Latex Free Bulb	Unspecified	W.A.Baum	1890NL	1	21.98	21.98
Pressure Connection System	Ball Valve	Miniature Chrome-Plated Brass Ball Valve	1/8" BSPP Female X 1/8" BSPP Female	McMaster	8156K11	1	8.58	8.58
	Deflation Valve	Air-Flo Control Valve	5/32" Tube ID	W.A.Baum	N/A	2	0	0
	Connector	2 inlets 6 outlets Anodized Aluminum Manifold	Inlets 1/4 NPT, outlets 1/8 NPT	McMaster	5469K151	1	19.33	19.33
		Straight Polyethylene Barbed Tube Fitting	3/16" Tube ID X 1/8 NPT Male	McMaster	2808K26	10	0.605	6.05
			3/16" Tube ID X 1/4 NPT Male	McMaster	2808K37	10	0.605	6.05
		Clear Polycarbonate Barbed Tube Fitting	3/16" Tube ID X 3/32" Tube ID	McMaster	5117K57	10	0.794	7.94
		Durable Nylon Tight-Seal Barbed Tube Fitting	3/16" Tube ID X 1/8 NPT Male	McMaster	5463K11	10	0.703	7.03
		90 Degree Threaded Pipe Fitting	1/8 Male X 1/4 Female	McMaster	50785K916	1	5.04	5.04
		Brass Hex Nipple	1/8 NPT Male	McMaster	5485K217	1	2.09	2.09
		Tube to tube reducing straight connector	3/16" to 1/8"	McMaster	5117K59	10	0.827	8.27
	Tube	Durable Rubber Tubing	3/16" ID, 3/8" OD, 10ft Length	McMaster	51225K25	2	6.5	13
		Durable Santoprene Rubber Tubing	1/8" ID, 1/4"OD, 25ft length	Mcmaster	51225K22	1	7.75	7.75
	Blockage	Square-Head Plug	1/4 NPT Male	McMaster	44605K222	2	0.18	0.36
			1/8 NPT Male	McMaster	44605K221	6	0.12	0.72

	Pressure upper bound control	PVDF Relief Valve	1/4 NPT Male	McMaster	4277T52	1	19.89	19.89
	Emergency release	Push-Button Valve	1/8 NPT Female	McMaster	6790T42	1	18.48	18.48
	Pressure Gauge	Aneroid	0-300 mmHg	Prestige Medical	70-OB	1	19.07	19.07
Pressure Sensor	Pressure Sensor	Sensor	600 mBar Max	Honeywell Sensing and Control	ABPLLNN600MGAA3	1	15.41	15.41
Microphone Stethoscope	Stethoscope	Clinical Lite Stethoscope	Unspecified	Prestige Medical	121-HPK	1	11.45	11.45
	Microphone	Electret Condenser	Sensitivity - 42dB ±3dB @ 94dB SPL, 20Hz - 20 kHz	CUI Inc.	CMA-6542PF	1	1.18	1.18
	Amplifier	Mono Audio Class D, Analog output	1.4W @ 8Ohms, 2.5-5.5V supply, RoHS Compliant	Sparkfun	RB-Spa-684	1	7.95	7.95
	Potentiometer	Log potentiometer	10K OHM, 1/20W power rating	Panasonic Electronic Components	EVU-F2LFL3D14	1	0.9	0.9
	Knob	Knob	.50" DIA, 6mm Shaft	Kilo International	OEJL-50-4-7	1	5.36	5.36
Deflation	Solenoid	12VDC normally closed	12V, 100mA	American Science & Surplus	NA	1	3.75	3.75
Display	LCD Screen	LCD Screen for Arduino	16 characters X 2 lines	Arrela	1602	1	8.99	8.99
Button	Tactile switch	SWITCH TACT SPST-NO 0.025A 50V	12.4mm diameter, 14.4mm height	E-Switch	320.02E11.08BLK	2	2.18	4.36
	Tactile switch	SWITCH TACT SPST-NO 0.025A 50V	15.88mm diameter, 15.3mm height	E-Switch	320.02E11.09GRN	1	2.58	2.58
Micro Controller	Arduino	Arduino UNO	5V, 8-bit	Arduino	UNO	3	0	0

Total Cost for Proof of Concept Before Tax:	233.84

Appendix K: Design Review 3 Presentation Summarized Feedback

As part of the project, the team presented much of the material in this written report of design review 3 to an audience of other MECHENG 450 students and faculty.

During the presentation, students wrote feedback to the team about how they interpreted the project, its progress, and questions they had. The comments and questions have been compiled and summarized below.

It was suggested by the team's sponsor that the device has some way to capture and possibly record the sound waves detected from the microphone so that they can be analyzed and possible listened to again. It was also recommended by the team's sponsor that the team learn how to take blood pressure measurements, look into research on the font and style of the user interface, as well as potentially use a friction hinge for the device.

The team was also asked about the background noise the microphone and the overall accuracy of the device.

The written feedback asked a lot about the technical analysis that was completed and wanted to see equations. Because of this, people were unsure of the electrical and pressure systems.

From this presentation feedback, it was deduced that more research needs to be done in the user interface of the device as well as further work has to be put into the microphone stethoscope analysis.

From the written feedback, the team learned that the audience wanted more technical analysis with equations to further assure them of the team's progress. More analysis was completed and energy calculations were done, but because these things were not given numerically, the audience was not convinced.

Appendix L: Prototype Assembly Plan

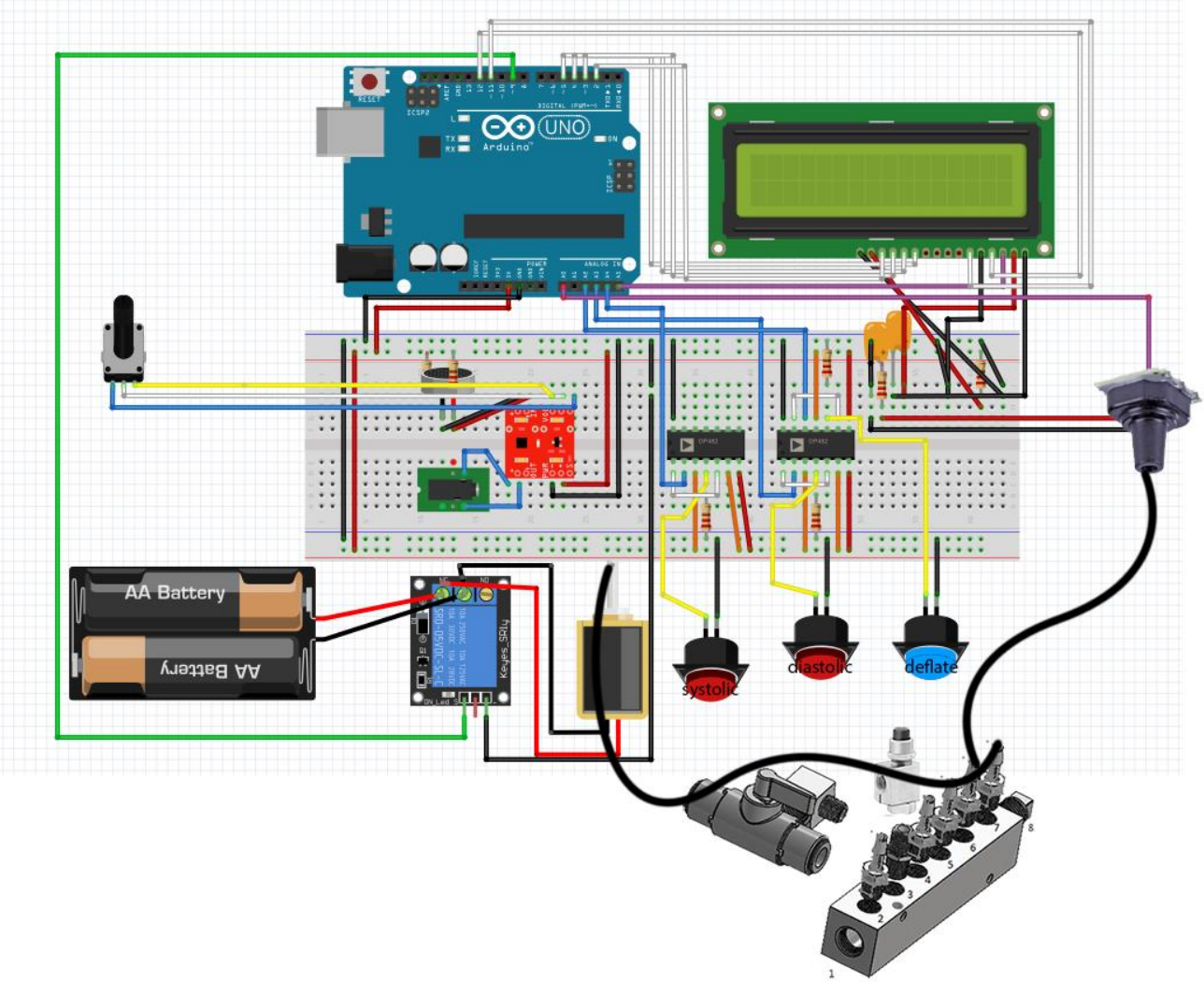


Figure 1: Electrical Components and Pressure Manifold Connection

Electrical components and connections:

Depicted system is not to scale. The black lines indicate tubing connections to the pressure manifold system. The battery, relay, and solenoid valves were not depicted by its exact models.

1) The Arduino UNO connects through a USB port into a computer for the proof-of-concept prototype manufacturing. This connection to the computer will power both the breadboard and the Arduino UNO.

2) The LCD connects to both the Arduino and the breadboard, using the described LCD connection to the Arduino from the LCD spec sheet.

    a) LCD will be programmed to display a total of two lines with sixteen characters for each line.

    b) LCD will attach to the breadboard with 0.1 headpins soldered onto the pin slots.

    c) LCD wires to the circuit board as such:

        1. Following pins connected from the LCD:

(1) LCD VSS to ground

(2) LCD VDD to +5V

(3) LCD Vo pin to Arduino analogue pin A5

(4) LCD RS pin to Arduino digital pin 12

(5) LCD RW pin to ground

(6) LCD Enable pin to Arduino digital pin 11

(7) LCD D4 pin to Arduino digital pin 5

(8) LCD D5 pin to Arduino digital pin 4

(9) LCD D6 pin to Arduino digital pin 3

(10) LCD D7 pin to Arduino digital pin 2

2. A 150 ohm resistor is wired for the powering of the display backlight by connecting to pin 15 (LCD A pin) and wiring pin 16 to ground.

3) Three buttons are wired as the digital inputs to the circuit to allow the user to press them when the measurement pressures are detected or when deflation is desired. Two buttons are the same; one will be for systolic and the other for diastolic. The third button will be used for deflation/ pause purposes.

a) Two Flip-flop model HD74LS74A are placed in the middle of the breadboard. Each flip-flop can accommodate two buttons. The following represent the pin configuration:

1. "Clear" and "Present" ports connected to positive
2. Qnot connected to D
3.
4.
5. VCC to positive, GND to negative
6. Q connected to the Arduino analog pin A2 for deflation, A3 for diastolic, and A4 for systolic
7. "Clock" port connected to one leg of button, then a 2.7k resistor to ground

b) The other leg of the button to positive

4) The Honeywell ABPLLNN600MGAA3 pressure sensor will be an input to the Arduino to read in the pressure as a voltage to the Arduino. This voltage is translated as mmHg into the LCD screen. The pressure sensor is soldered onto the breadboard. A tube from the pressure manifold attaches to the pressure sensor through tube adaptors (3/16 inch to 3/32 inch). This overall system gauges the pressure from the flow rate of the manifold.

a) The pressure sensor will be soldered on for connection to the breadboard, as the pressure sensor is leadless.

b) 1k ohms resistor

c) Pressure sensor pin 3 to Arduino analog pin 0

5) The CUI Inc. CMA-6542PF electret condenser microphone is connected to the input +/- on the SparkFun Mono Audio Amp Breakout - TPA2005D1 amplifier, which connects to the breadboard. The microphone inputs to the amplifier, with the microphone receiving its signals from the end of the stethoscope. The output of the amplifier is to the audio jack, which has an on-ear headphone connection. Gain will be adjusted in the system using capacitors and resistors. The volume will also be controlled through the amplifier using a potentiometer.

   a) The amplifier will attached to the breadboard with 0.1 headpins soldered onto its pin slots.

   b) 8.2k resistor between power and microphone

6) A miniature solenoid valve to the relay which will provide enough voltage and current to the solenoid valve for deflation control. The relay connects to the arduino UNO, which is connected to the solenoid valve. The solenoid valve connects to the pressure manifold by a tube in order to release the air within the manifold. Solenoid valve is connected to the manifold tubes with tube adaptors. The information for the solenoid valve opening and closing relays from the pressure sensor. The solenoid valve connects to the Arduino UNO to receive the pressure change, which changes the deflation rate through the solenoid valve.

   a) A 12 V battery connects to the relay to provide 1.2 Watts for the solenoid.

      1. 15 V battery is connected as a power source to a mini breadboard. Given the resistors can only handle 0.5 Watts, the total resistance was deemed to be 450 ohms. 90 ohms resistors were connected in series to induce a voltage drop to power the relay. 360 ohms resistor was then grounded in series.

   b) The solenoid connects to the pressure manifold with a ⅛ inch tubing that connects with a ⅛ inch to 3/16 inch tubing connector.

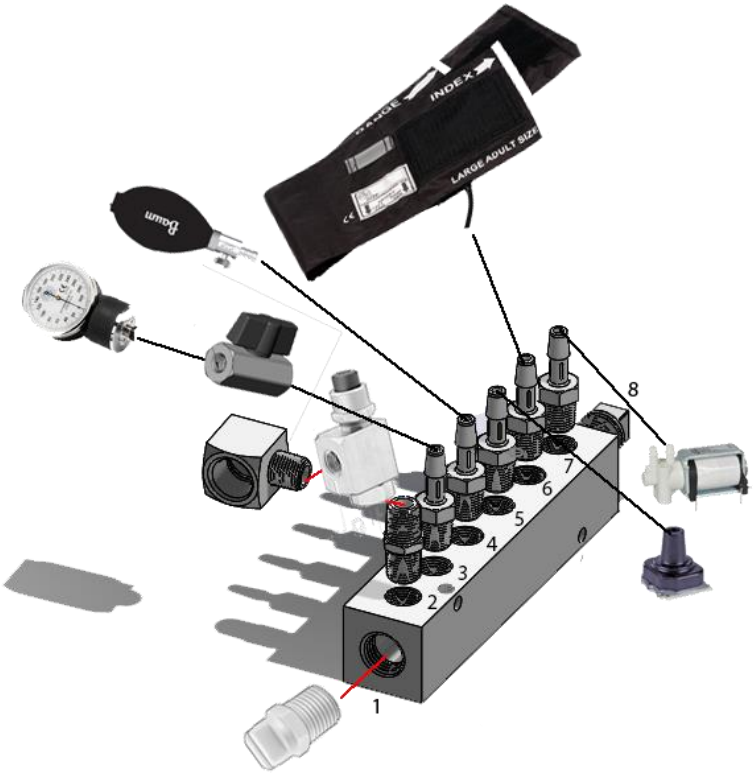


Figure 2: Pressure Manifold Connection

Pressure system

This system is not to scale because some part could not be modeled in CAD. There is a pressure manifold (McMaster 5469K151) with 8 holes, 6 outlets on one side to connect all of the pressure system parts. All parts that having tubing and then the component will have a nylon connector screwed into the manifold to connect the tubing to. Loctite or some other thread tape seals all components to the manifold. All the connectors screwed onto the manifold are push-to-connect with the tubing. Figure 2 depicts the overall pressure manifold connection, with black lines indicating connection with 3/16 inner diameter rubber tubing and red lines indicating direction connection to the pressure manifold.

1) The safety relief valve (McMaster 4277T52) is screwed into the manifold at the ¼" inlet hole which evacuates air if the system reaches about 310mmHg (6psi).
2) The push button operator valve (McMaster 4277T51) is screwed into the manifold to allow the operator to release the air of the cuff to 0mmHg within 10 seconds.
3) The manifold connects to a push-to-connect ball valve (McMaster 4796K550) with tubing nylon connectors on both sides of its inlets. The ball valve is connected with tubing to the pressure gauge (Prestige Medical 70-OB) which is also push to connect.
4) Tubing connects to the manifold which connects to the hand pump and manual deflation valve (W.A.Baum 1893NL). The manual deflation valve is made to fit on the outlet hand pump and the valve is push to connect to the tubing.
5) Tubing connects the pressure sensor (Honeywell ABPLLNN600MGAA3) to the manifold. To connect the pressure sensor and the manifold, a 3/32 inch diameter tube is attached to the pressure sensor. A tube adaptor (3/16 inch to 3/32 inch) is connected to the tube and the 3/16 inch black rubber tubing from the pressure manifold.

6) Tubing connects the manifold to the blood pressure cuff (Prestige Medical 70-OB) which is made to order already connected to the tubing.
7) A tube with ⅛ inch inner diameter connects the solenoid valve inlet (ASCO RLB204KP30B) and the manifold. A tube adaptor (3/16 inch to ⅛ inch) is necessary to connect the valve to the tubing.
8) The last inlet hole is screwed closed with a ¼" NPT Male Square-Head Plug (McMaster44605K222).

Components in the center 2 outlet holes should be screwed in first, then others are screwed in from the center to outwards

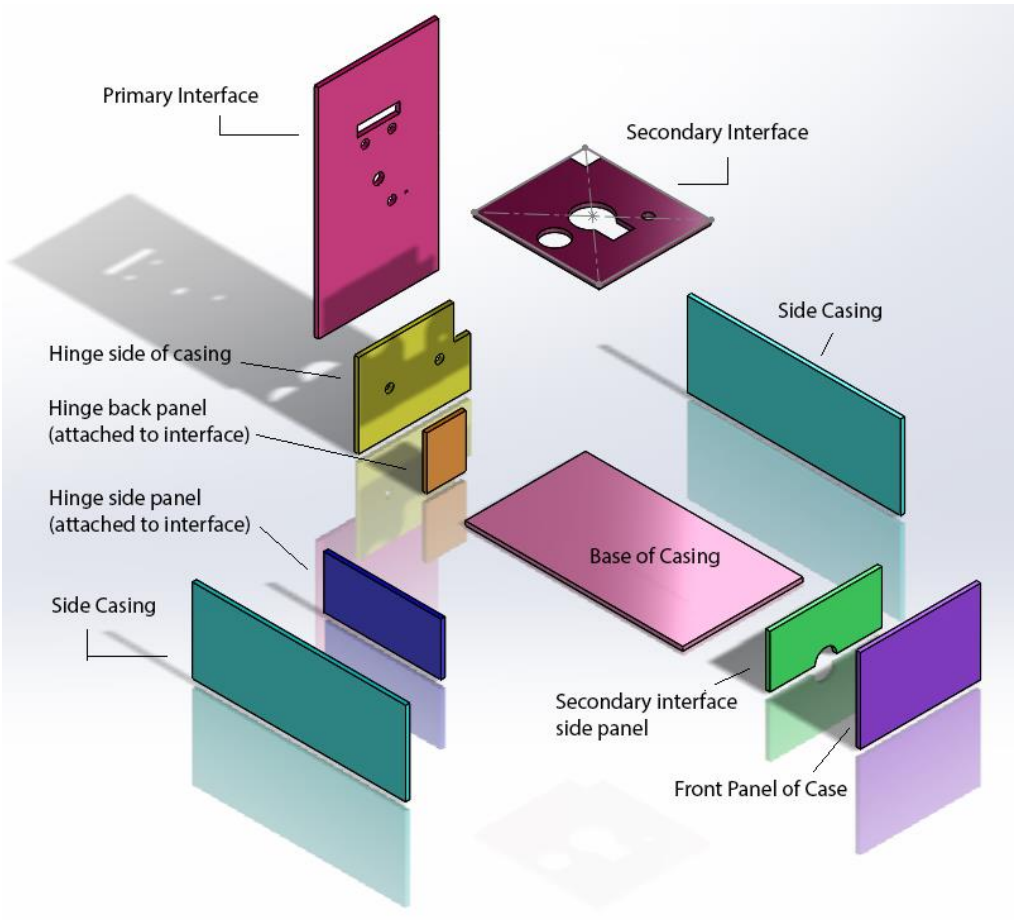


Figure 3: Labeled Exploded View of Casing

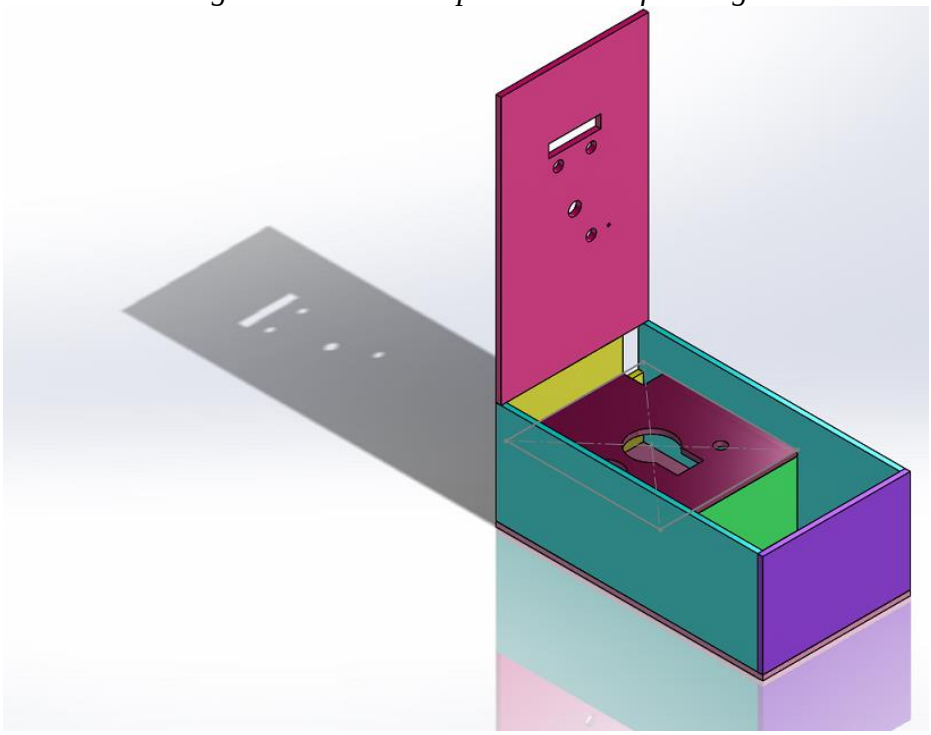


Figure 4: Assembled View of the Casing

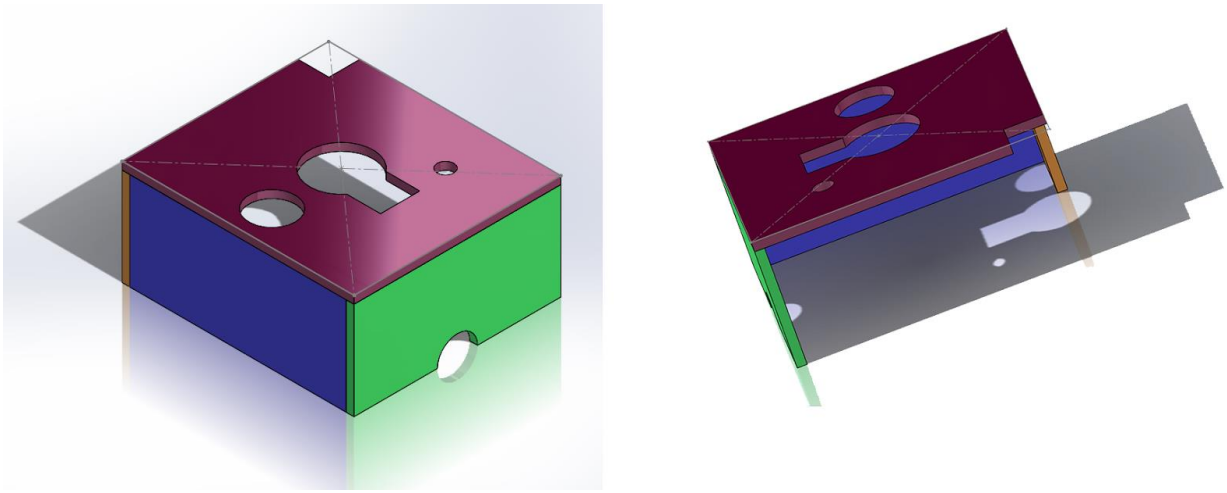


Figure 5: Two Views of Secondary Interface

Casing

1) The drawings of the different faces are created in SolidWorks. There are 9 different types of faces, one of which is duplicated. Figure 3 and 4 depict the exploded and assembled view respectively of the whole case while figure 5 depicts the isolated secondary interface.
   a) Primary interface (1)
   b) Secondary interface (1)
   c) Side casing (2)
   d) Base of casing (1)
   e) Front panel of case (1)
   f) Hinge side of casing (1)
   g) Hinge side panel attached to interface (1)
   h) Hinge back panel attached to interface (1)
   i) Secondary interface side panel (1)
2) Upon completion of faces, the parts are assembled in SolidWorks.
3) The small boxes are created to place at bottom corners of casing to increase surface area for when parts are cut and need to be attached.
4) All parts are laser cut on ¼" acrylic following the instructions outlined in the laser cutting operating document on Ctools.
5) Glue faces together using dichloromethane. There are two groups of faces that are attached to each other with dicholoromethane.
   a) Side casing, base of casing, front panel of case, and hinge side of casing will be attached together.
   b) Secondary interface, hinge side panel attached to interface, hinge back panel attached to interface, and secondary interface side panel will then be glued together.
6) Velcro is added to the hinge side panel and hinge back panel that are attached to interface.
7) Ribbon is threaded through the respective holes on the hinge side of casing face.
8) Primary interface is attached to the rest of the faces with a friction hinge. The lid with the user interface will be laser cut out of acrylic.

Appendix M: Arduino Code

```
#include <LiquidCrystal.h>
#include "math.h"

int sysPin = A4;
int diaPin = A3;
int deflatePin = A2;
int sysState, diaState, preSysState, preDiaState, deflateState, preDeflateState;
int interval = 265;

double pressureSum = 0;
int count = 0;
double currentPressure = 0;
double prePressure = 0;
double currentPressure2 = 0;
double prePressure2 = 0;
int solenoidPin = 9;
int pressureSensorPin = A0;
double pressureSensorValue = 0;
const double inputVoltage = 3.1;
LiquidCrystal lcd(12, 11, 5, 4, 3, 2);
bool deflate = false;
bool openn = false;
int dp = 0;
unsigned long timer;

int get_dp() {
  prePressure2 = currentPressure2;
  currentPressure2 = getCurrentPressure(pressureSensorValue);
  int real_rate = round((prePressure2 - currentPressure2)/interval*1000.0);
  if (currentPressure2 < 120) {
    if (real_rate <= 4 ) return 0;
  else if (real_rate <= 5) return 1;
    else if (real_rate <= 6) return 2;
  else return 3;
  }
  else if (currentPressure2 < 200) {
  if (real_rate <= 4 ) return 0;
  else if (real_rate <= 6) return 1;
  else return 2;
  }
  else {
  if (real_rate <= 4 ) return 0;
  else return 1;
  }
}

void pressureSensorThread() {
  pressureSensorValue = (analogRead(pressureSensorPin)) * ( 5.0 / 1024);
  if (deflate) {
      count = count + 1;
      currentPressure = getCurrentPressure(pressureSensorValue);
      pressureSum = pressureSum + currentPressure;
      if (count == 4) {
          three_digit_display(round(pressureSum/4),'p');
          Serial.print(millis());
          Serial.print(' ');
          Serial.print(round(pressureSum/4));
          Serial.print('\n');
      }
```

```
  }
  else {
    currentPressure = getCurrentPressure(pressureSensorValue);
    three_digit_display(round(currentPressure),'p');
  timer = millis()/1000.0;
  Serial.print("Time: ");
  Serial.print(timer); //In s
  Serial.print(" Pressure: ");
  Serial.print(getCurrentPressure(pressureSensorValue));
  //Serial.print(" Voltage: ");
  //Serial.print(pressureSensorValue);
  }
    sysState = analogRead(sysPin);
 if (abs(sysState - preSysState)>100) {
     three_digit_display(getCurrentPressure(pressureSensorValue),'s');
     preSysState = sysState;
     Serial.print("SYS");
  }
  diaState = analogRead(diaPin);
 if (abs(diaState - preDiaState) > 100) {
     three_digit_display(getCurrentPressure(pressureSensorValue),'d');
     preDiaState = diaState;
     Serial.print("DIA");
  }
}

void three_digit_display(int currentPressure, char mode) {
  if (mode == 'p'){
  lcd.setCursor(8, 0);
  }
  if (mode == 's') {
    lcd.setCursor(4, 1);
  }
  if (mode == 'd') {
    lcd.setCursor(12, 1);
  }
  if (currentPressure < 10) {
    lcd.print(0);
    lcd.print(0);
    lcd.print(currentPressure);
  }
  else if (currentPressure < 100) {
    lcd.print(0);
    lcd.print(currentPressure);
  }
  else {
    lcd.print(currentPressure);
  }
}

void printdata() {
  pressureSensorThread();
  //timer = millis();
  //Serial.print("Time: ");
  //Serial.print(timer); //In s
  //Serial.print(" Pressure: ");
  //Serial.print(getCurrentPressure(pressureSensorValue));
  //Serial.print('\n');
}

double getCurrentPressure(const double &voltage)
{
```

```
  double value=(voltage - inputVoltage * 0.1) / (inputVoltage * 0.8) * 450.037;
  if(value<0) return 0;
  else return value;
}

void setup() {
  // put your setup code here, to run once:
  pinMode(solenoidPin, OUTPUT);
  digitalWrite(solenoidPin,LOW);
    // connect to computer console
  Serial.begin(9600);
  //set analog reference
  analogReference(DEFAULT);
  //LCD
  lcd.begin(16, 2); //set up the LCD's number of columns and rows
  lcd.display();  //turn on LCD
  //button
  pinMode(sysPin, INPUT);
  pinMode(diaPin, INPUT);
  pinMode(deflatePin, INPUT);
  preSysState = analogRead(sysPin);
  preDiaState = analogRead(diaPin);
  preDeflateState = analogRead(deflatePin);
  sysState = analogRead(sysPin);
  diaState = analogRead(diaPin);
  deflateState = analogRead(deflatePin);
  //end button
  lcd.print("CURRENT:"); //first line
  lcd.setCursor(0, 1); //cursor at beginning of second row SYS position
  lcd.print("SYS:");
  lcd.setCursor(8, 1); //cursor at DIA position
  lcd.print("DIA:");
  pinMode(pressureSensorPin, INPUT); //pressure sensor
}


void loop() {
  pressureSensorThread();
  deflateState = analogRead(deflatePin);
  if (abs(deflateState - preDeflateState) > 100) {
    preDeflateState = deflateState;
    if (deflate)
    {
      deflate = false;
      Serial.print("closed");
      Serial.print('\n');
    }
    else if (!deflate && !openn) {
      deflate = true;
      Serial.print("opened");
      Serial.print('\n');
    }
    else if (openn) {
      openn = false;
      deflate = false;
      digitalWrite(solenoidPin, LOW);
      Serial.print("closed");
      Serial.print('\n');
    }
  }
   //-----------set DUTY CYCLE----------
if ((getCurrentPressure(pressureSensorValue) < 40) && deflate){
```

```
  deflate = false;
  openn = true;
}
if (deflate) {
//0ms
  int dp;
  pressureSum = 0;
  count = 0;
  if (currentPressure < 85) {
    delay(interval);
    printdata();
    digitalWrite(solenoidPin,HIGH);
    dp = get_dp();
    delay(16 - dp);
    digitalWrite(solenoidPin,LOW);
    delay(interval);
    printdata();
 //280ms
    digitalWrite(solenoidPin,HIGH);
    dp = get_dp();
    delay(16 - dp);
    digitalWrite(solenoidPin,LOW);
    delay(interval);
    printdata();
 //560ms
    digitalWrite(solenoidPin,HIGH);
    dp = get_dp();
    delay(16 - dp);
    digitalWrite(solenoidPin,LOW);
    delay(interval);
    printdata();
 //840ms
    digitalWrite(solenoidPin,HIGH);
    dp = get_dp();
    delay(16 - dp);
    digitalWrite(solenoidPin,LOW);
 //870ms
  }
  else if (currentPressure < 100) {
    delay(interval);
    printdata();
    digitalWrite(solenoidPin,HIGH);
    dp = get_dp();
    delay(15 - dp);
    digitalWrite(solenoidPin,LOW);
    delay(interval);
    printdata();
 //280ms
    digitalWrite(solenoidPin,HIGH);
    dp = get_dp();
    delay(15 - dp);
    digitalWrite(solenoidPin,LOW);
    delay(interval);
    printdata();
 //560ms
    digitalWrite(solenoidPin,HIGH);
    dp = get_dp();
    delay(15 - dp);
    digitalWrite(solenoidPin,LOW);
    delay(interval);
    printdata();
 //840ms
```

```
    digitalWrite(solenoidPin,HIGH);
    dp = get_dp();
    delay(15 - dp);
    digitalWrite(solenoidPin,LOW);
  //870ms
   }
 /* else if (currentPressure < 130) {
    delay(interval);
    printdata();
    digitalWrite(solenoidPin,HIGH);
    dp = get_dp();
   //  Serial.print(dp);
   //  Serial.print('\n');
    delay(13 - dp);
    digitalWrite(solenoidPin,LOW);
    delay(interval);
    printdata();
  //280ms
    digitalWrite(solenoidPin,HIGH);
    dp = get_dp();
   //  Serial.print(dp);
   //  Serial.print('\n');
    delay(13 - dp);
    digitalWrite(solenoidPin,LOW);
    delay(interval);
    printdata();
  //560ms
    digitalWrite(solenoidPin,HIGH);
    dp = get_dp();
   //  Serial.print(dp);
    // Serial.print('\n');
    delay(13 - dp);
    digitalWrite(solenoidPin,LOW);
    delay(interval);
    printdata();
  //840ms
    digitalWrite(solenoidPin,HIGH);
    dp = get_dp();
   //  Serial.print(dp);
   //  Serial.print('\n');
    delay(13 - dp);
    digitalWrite(solenoidPin,LOW);
  //870ms
   }*/
   else if (currentPressure < 130) {
    delay(interval);
    printdata();
    digitalWrite(solenoidPin,HIGH);
        dp = get_dp();
    delay(13 - dp);
    digitalWrite(solenoidPin,LOW);
    delay(interval);
    printdata();
    delay(interval);
    printdata();
  //560ms
    digitalWrite(solenoidPin,HIGH);
        dp = get_dp();
    delay(13 - dp);
    digitalWrite(solenoidPin,LOW);
    delay(interval);
    printdata();
```

```
//840ms
 }
 else if (currentPressure < 200) {
   delay(interval);
   printdata();
   digitalWrite(solenoidPin,HIGH);
      dp = get_dp();
   delay(11 - dp);
   digitalWrite(solenoidPin,LOW);
   delay(interval);
   printdata();
   delay(interval);
   printdata();
//560ms
   digitalWrite(solenoidPin,HIGH);
      dp = get_dp();
   delay(11 - dp);
   digitalWrite(solenoidPin,LOW);
   delay(interval);
   printdata();
//840ms
 }
   else if (currentPressure < 220) {
   delay(interval);
   printdata();
   digitalWrite(solenoidPin,HIGH);
      dp = get_dp();
   delay(9 - dp);
   digitalWrite(solenoidPin,LOW);
   delay(interval);
   printdata();
   delay(interval);
   printdata();
//560ms
   digitalWrite(solenoidPin,HIGH);
      dp = get_dp();
   delay(9 - dp);
   digitalWrite(solenoidPin,LOW);
   delay(interval);
   printdata();
//840ms
 }
   else  {
   delay(interval);
   printdata();
   digitalWrite(solenoidPin,HIGH);
      dp = get_dp();
   delay(8 - dp);
   digitalWrite(solenoidPin,LOW);
   delay(interval);
   printdata();
   delay(interval);
   printdata();
//560ms
   digitalWrite(solenoidPin,HIGH);
      dp = get_dp();
   delay(8 - dp);
   digitalWrite(solenoidPin,LOW);
   delay(265);
   printdata();
//840ms
 }
```

```
}
else if (openn) {
  if (currentPressure > 0) {
  digitalWrite(solenoidPin,HIGH);
  }
  else {
    digitalWrite(solenoidPin,LOW);
    openn = false;
    Serial.print("closed");
    Serial.print('\n');
  }
  delay(800);
}
else delay(800);
}
```

Appendix N: Design Validation Plan

As the design for the device this semester does not incorporate a universal cuff design, the user requirement and engineering specifications for accommodating various patient sizes will not be included in the validation plan.

As a general note, the team is striving to have a n=30 so the assumption can be made that the data is normally distributed. From there, the average and standard deviation can be calculated.

1) Accurate:

    a) The average difference between mercury sphygmomanometer measurement must not exceed a mean difference of ± 5mmHg and S.D of 8mmHg.

    Due to the required IRB for human subject testing, it is not feasible to validate the device on ob/gyn patients this semester. The team sees the best alternative to be performing preliminary testing within the team using the proof-of-concept device.

    Mercury sphygmomanometer is the "gold standard" for blood pressure measurement, and it is usually the point of reference when validating accuracy of a blood pressure device. The team plans to acquire a mercury sphygmomanometer and connect it with the pressure system of the proof-of-concept. If a mercury sphygmomanometer cannot be acquired within this semester, an aneroid pressure gauge that is regarded as a calibration device will be used as a proxy.

    The first test to validate accuracy will be to compare the embedded aneroid gauge on the device with the acquired aneroid pressure gauge. This will be done by connecting the two devices, inflating the cuff up to 300 mmHg, comparing the blood pressure readings at 20 mmHg intervals. The readings on both devices will be recorded compared.

    Then, the output of the pressure sensor will be compared to the embedded aneroid pressure gauge. The same procedure that was used to compare the embedded aneroid gauge and the acquired aneroid pressure gauge will be used for this validation procedure.

    After the accuracy of the pressure sensor is confirmed, the same pressure data will be used to determine the accuracy of the LCD screen readings. Arduino output on a computer monitor will be compared to what the LCD screen says for 20 mmHg intervals from 0 to 300 mmHg.

    The next test for the pressure system aims to test the constant deflation rate of the automatic deflation valve and the accuracy of the LCD screen during constant deflation. For constant deflation rate, pressure data from the pressure sensor transmitted through the Arduino will be recorded in a software on a laptop. A graph will be created to show the relation of pressure data (in mmHg) and time (second). It can be seen whether the deflation rate is constant at 3 mmHg/second on the graph, which is the desired deflation rate.

    Once the accuracy of the pressure system components are confirmed separately, a group of nursing students will be recruited to take blood pressure measurements.

The purpose of the first test is to validate the accuracy of the outputted measurements on the LCD screen and the embedded aneroid calibration gauge. The team has invited four nursing students (test administrator) to perform the test. Both arms of the four team members (subject) will be used for blood pressure measurements, and thus, each nursing student will do the test 8 times in total. For each arm, the nursing student will take the systolic and diastolic blood pressure measurements twice: once with the device and once with the separate aneroid device. When taking the systolic and diastolic blood pressure measurements with the device, the nurse will record the values displayed on the LCD screen and the embedded aneroid gauge. The nurse will not utilize the systolic and diastolic buttons for this procedure, but will instead be asked to remember the obtained values at the end of the procedure. The test administrator will use the ball pump and the manual deflation valve. The user will also use a traditional stethoscope for this validation procedure. Then, the measurements from both the LCD and aneroid display of the device will be compared to the acquired aneroid device.

The last part of the test aims to test the accuracy of the microphone stethoscope. The microphone stethoscope amplifier will be connected directly to the computer and there will be a real-time sound wave graph generated. The program will be designed so that whenever the mouse is clicked, that particular time point is recorded. A traditional stethoscope will be placed on the subject's brachial artery near the elbow. During deflation, the test administrator will also listen through the traditional stethoscope, and click when he or she hears systolic and diastolic. The waves from the graph from the microphone stethoscope method will be compared to the listening result. The systolic blood pressure can be when the amplitude of the sound curve is greater than 4 standard deviations from the occlusion, and the diastolic point will be when the sound curve is qualitatively similar to the occlusion.

b) must not exceed +/- 3 mmHg for cuff vs. display pressure

A pressure sensor will be placed in the tube that directly connects the cuff for the purpose of validation. The cuff pressure sensor will be connected to a computer to display cuff pressure. The cuff pressure reading is compared to the display pressure reading from the LCD screen. The pressure will be compared at an interval of 20 mmHg increase in pressure.

c) Measuring range of 0-300mmHg

The accuracy of the pressure sensor shall determine the measuring range of the device. The spec of the pressure sensor shall be compared to calculate its accuracy range.

2) Affordable

a) Cost ≤ $75 per device

The cost of bulk purchase (around 1000) for the device parts will be calculated and compared to the maximum cost of $75.

3) Short procedure time (discrete measurements) with use

a) Time necessary for the entire procedure < 3 minutes

A focus group with four nursing students at U of M will be created and they shall be provided with instruction on how to use the proof-of-concept and how long it takes them to take blood pressure measurements will be assessed. All healthcare workers are required to know how to take blood pressures using the auscultatory method, so the users should be familiar with the techniques involved with using the device. In addition, the time it requires for each identified step will be measured to identify the rate limiting step of the device.

Validation method for the actual device: A focus group with midwives, doctors, and consultants at Komfo Anokye Teaching Hospital, with the focus on midwives and nurses, will be created. This focus group shall be provided with instructions on how to use the device and how long it takes them to actually measure the blood pressure will be assessed. The procedure time and the time specified in the engineering specifications will be compared.

4) Short training time

a) Instructional period < 15 minutes

A focus group made up of general population (n= 30 sample population) shall be created, how long it takes these individuals to use the device will be assessed. This test will be done without using Korotkoff sounds, as general population would not know auscultatory blood pressure measurement methods. The device components and each function will be taught, and it shall be measured how long it takes them to understand how to use the device, including the calibration method. The median time can be taken as a rough estimate of how long it may take to teach the healthcare professionals in Ghana how to use the device.

5) Minimal steps

a) No more than two actions simultaneously required of the user during the procedure using mercury sphyg functional decomposition as reference

b) < 12 steps (team defined mercury sphygmomanometer steps) including set up and break down (take off and pack) once device is obtained

A focus group of four nursing students will be observed using the device and the team shall count the number of steps it takes the focus group when making measurements. Furthermore, the observer should be aware of how many actions were completed at the same time. Next, this observation shall be repeated with the aneroid blood pressure device or the mercury sphygmomanometer. Then the focus group will be asked to walk the observer through the procedure of both devices and count the steps together and how many steps are done individually.

For the actual device, the healthcare providers at KATH will be observed during measurements.

6) Minimal Additional Equipment

   a) No more than 1 additional pieces of equipment required for procedural use

      The focus group of nursing students will be assessed again during this validation. During the healthcare provider's use of the device, the observer shall count how many outside pieces of equipment he or she needed to use the device. For the current device, four nursing students will complete this task whereas for the actual test we would use more healthcare providers at KATH.

7) Readable Measurements

   a) 3:1 minimum symbol contrast
      The contrast between the blood pressure measurement readings and the background of LCD screen will be determined by calculating the contrast ratio, which is defined as the ratio of the difference between character and background luminance.

   b) Symbol width-to-height ratio is between .5:1-1:1

   c) Strokewidth-to-height ratio is between 1:12-1:5

   d) Spacing between adjacent symbols are separated by at least one strokewidth

   e) Spacing between lines of symbols is at least two strokewidths

      The dimensions of the symbols on the LCD screen will be determined by conducting precise measurements of different number combinations.

      Due to the constraints of the MECHENG 450 semester and funding, the prototype will not be able to be used to validate this specification.

8) Easy to Calibrate

   a) Calibration time <30 minutes by technician in tertiary referral setting-checking numbers

      Focus group comprised of students (n= 30 students) will be assessed on the time it takes for them to calibrate the device using the connection to the pressure gauge. The time it takes them to calibrate can be taken as the upper limit of how long it would take a technician in KATH. Calibration entails the measurements to be taken simultaneously with the aneroid sphygmomanometer gauge and the prototype and going up 20 mmHg each time and compare the measurements. Because calibration is a new type of activity for the students, there will be three practice rounds before actually measuring how long it takes the students to calibrate the device.

   b) No more than one calibration necessary per year unless breaking and then need to calibrate it once repaired

      Calibration will be based on how accurate and well-calibrated the LCD screen is and how durable the pressure sensor is. The acquired LCD screen and the pressure sensor's specification sheets shall be referred to get the maximum time before calibration would be required.

1) Durable

   a) Accurate at up to 10-40C (operational)

   b) Can be stored up to -20 - 55 C (storage)

   c) Accurate at up to 85% humidity RH (operational)

   d) Can be stored < 90% humidity RH (storage)

      The most ideal validation test for these specifications would be to assess the maintenance of functionality during both operation and storage at different temperatures and humidities using controlled environmental chambers. There are many companies in Michigan that provide environmental testing services. However, it is most likely that such validation methods will not remain within the constraints of the team's budget and time requirement.

      A feasible method of testing would be to use the temperatures and humidities of different environments, such as room temperature or freezing. Temperatures would be recorded with a conventional thermometer and humidity would be recorded with a hygrometer. However, the team will not conduct such tests on the proof-of-concept prototypes as there is not a large quantity of the prototype available. If a large number of devices were available, it would be important for the duration of the test to be over a short period of time, possibly the target procedure time. Tests for storage temperatures will need to extend over multiple hours.

      The operational temperatures, storage temperatures, and humidity specifications for each part shall be researched so that it can be validated that each part falls within the desired range.

   e) Satisfy the 1 m drop test

      If a large quantity of the device was available, a conventional drop test would be performed to ensure that the device is durable. The team would use constrained drop testing, which is the most common. The device would be considered to pass this 1m drop test if there was no damage to the device that prevented full performance of the device.

   f) Satisfy the vibration test

      Validation method for the actual device: Intended for validation of motor-driven equipment. Perform test on servo motor to valve coupling system.

   g) Satisfy the markings test for wear

   h) ~240 number of cycles per day for lifetime in years

      An air pump will be purchased (or find one in the Mechatronics lab) and the Arduino shall be configured so that it will repeat a simulated cycle of inflation by the air pump and then automatic deflation. An important time that would need to be kept in mind for this test would be the average length of time that passes in order to acquire an accurate

BP measurement for the following patient. This would dictate the period of rest between each cycle during this validation test.

i) > 1 years unit life

This test cannot feasibly be performed this semester. This test would be validated by assessing the function of the device across a period of one year when the device is being used for the desired number of cycles per day.

10) Safe

a) Be able to disengage in 10 seconds

A test group with students (n = 30 students) will be gathered to show users the method of disengaging the device. The users will then perform this procedure on a test subject, such as a member from the design team. It will be important to consider the amount of stress that the healthcare provider would experience in this type of simulated setting versus a real-time situation.

b) Pressure applied should not exceed 310 mmHg

A teammate shall attempt to pump a blood pressure greater than 310 mmHg on a PVC pipe in order to reduce risk to the user. At the point in which the device reaches 310 mmHg, it will be recorded whether the 6psi safety relief valve is activated.

c) Pass the CFR 1500.49 Test for Sharp Edges

The guidelines from federal regulations to ensure that all components of the device pass the CFR1500.49 Test for Sharp Edges shall be utilized for device part comparisons.

d) Hazard numbers for health, flammability, and reactivity should be 0

Look at specifications for device components to confirm that all hazard numbers for the materials that are used are zero.

11) Portable

a) Device does not require two hands to carry

b) < 19 cm (width) by x cm by 32 cm, < 2.8 kg

Thirty individuals (excluding the team members) will be observed carrying the 3-d printed casing. The number of hands used to carry the device will be observed. It shall be crucial for the other individuals to not see how the other individuals have carried the device.

For the current device, the CAD drawing will be used to determine the dimensions of the casing. Finally, the mass of the casing will be calculated based on the weight with the actual materials and this mass shall be assessed for portability requirement. .

12) Easy to clean

a) No additional disassembly from setup or storage mode needed to disinfect

b) <30 seconds of cleaning time necessary to clean parts in contact with patient and user, clean with material commonly found in ward (spirit: 83.3% ethanol)

   Individuals (n= 30 students) shall be provided with cotton balls with alcohol and shall be timed on the length it takes them to clean the device. The locations that requires cleaning will be determined by the individuals in the study. It shall also be observed if the individual disassembled the device to clean in the way they saw fit. The team will also cross check the reactivity of the device and ethanol. With the final device, this would be done at KATH once the supplies were obtained.

13) Easy to maintain

a) All parts are accessible in Ghana

b) All parts can be independently replaced

   The contacts in Ghana shall be contacted about the currently available parts in Ghana. Based on the available parts, the design for the target setting will be focused on metric measurements.

14) Able to follow all patient management plans*** Appropriate use

a) Use in KATH and other tertiary referral care settings in in-patient with maximum 40 patient occupancy

b) Discrete measurements

c) Device allows the nurses and midwives to take blood pressure measurements on time for 40 patients, with 2 to 6 patients needing measurements every 30 minutes and the rest being measured every four hours.

   The average procedure time, based off of the focus group measurements, will be multiplied by six (patients on half-hourly blood pressure management plans.) This time will be used to check if the device requires less than or equal to 30 minutes to take the necessary measurements. The result from the product will be subtracted from 4 hours; the difference can be assessed as the remaining available time to carry out the 4-hourly measurements. The average procedure time can be multiplied by (40 - 6) (patients on 4-hourly blood pressure management plans), and it shall be checked to assess whether the result is less than or equal to the available time for 4-hourly measurements.

15) Power source

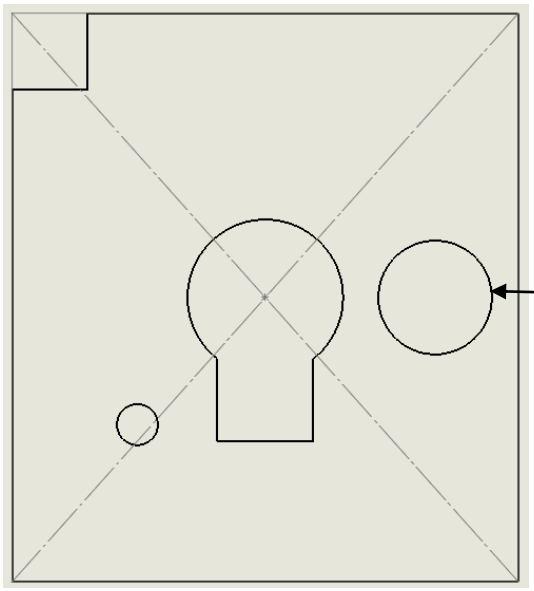
a) When continuously plugged in, the device can be used for x hours. When using a replaceable battery, the device can be used for x hours per replacement cycle. When using a rechargeable battery, the device can be used for x hours per replacement cycle.

   Due to the constraints with time and budget during MECHENG 450, the power source for the proof-of-concept will incorporate batteries connected in series, which will not be

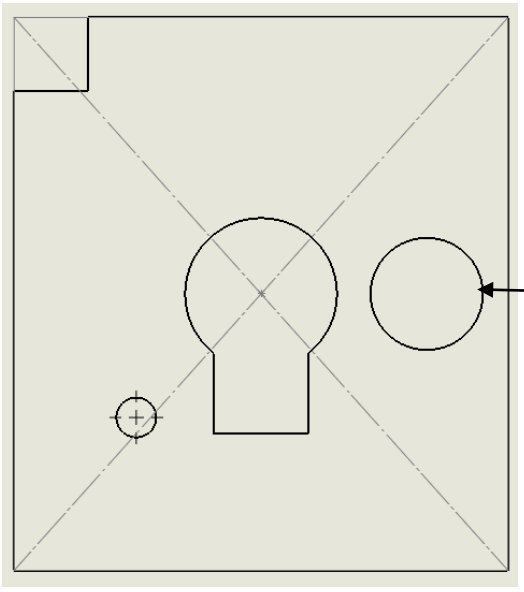
rechargeable. The actual design incorporates a rechargeable battery, which will not be achieved during this semester and therefore would not be able to valida

Appendix O: Engineering Design Change Notice

WAS:



IS:

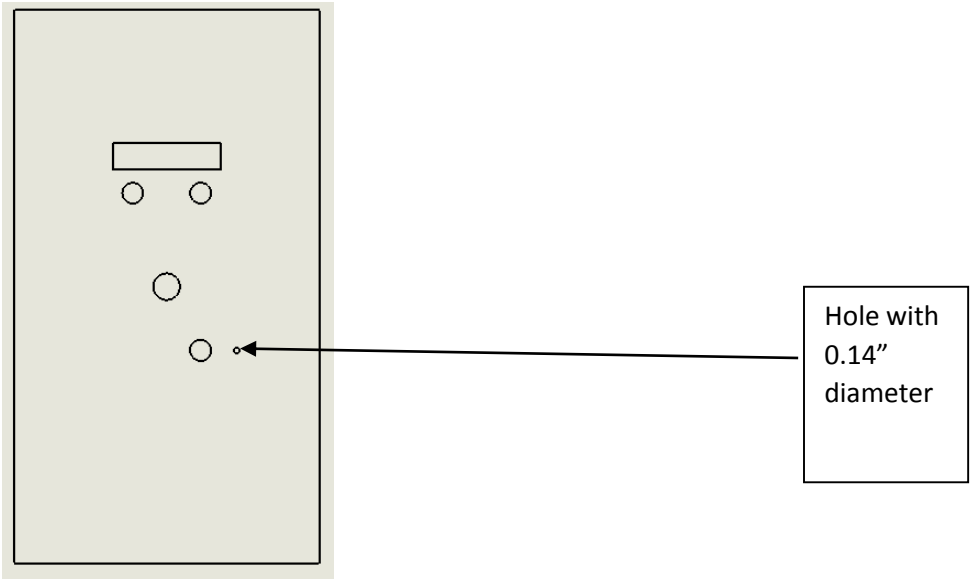


Notes:

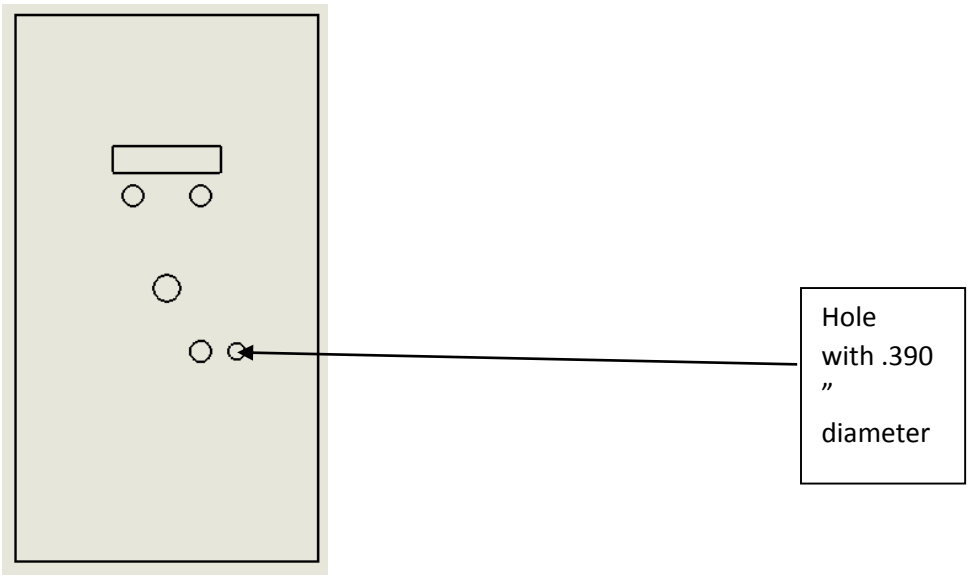
Needed to change the size of the rightmost hole on secondary interface panel to allow complete rotation of the ball valve.

ME 450 Team 7	
Project: Blood Pressure Device for Low Resource Settings	
Ref Drawing: Secondary Interface	
Engineer: C. Soyars and L. Kennedy	11/23/2015

WAS:



IS:



Notes:

Needed to drill the audio jack hole in order to increase diameter so that the audio jack would fit through the opening.

ME 450 Team 7	
Project: Blood Pressure Device for Low Resource Settings	
Ref Drawing: Primary Interface	
Engineer: C. Soyars and L. Kennedy	11/23/2015

WAS:

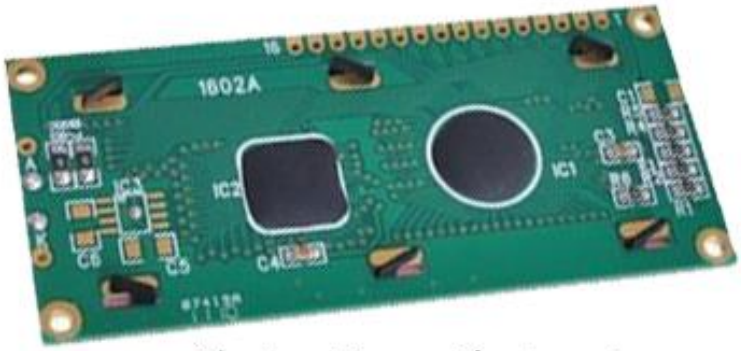


Photo: Esum Electronic

IS:

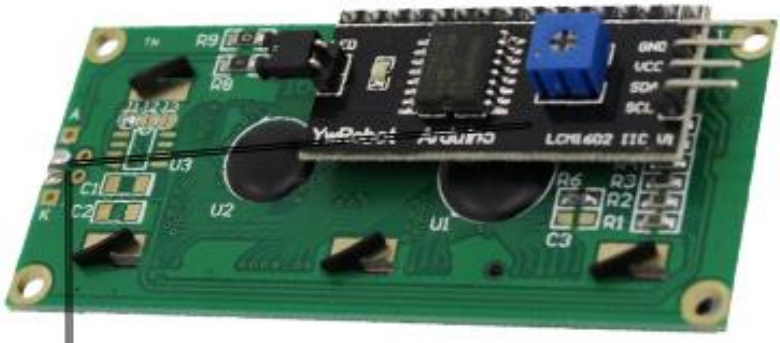


Photo: Arrela

Potentiometer to adjust contrast in new LCD screen

New LCD screen is acquired because old one is faulty and gives random behavior

ME450 Team 7	
Project: Blood Pressure Device for Low Resource Settings	
Ref Drawing: LCD Screen	
Engineer: J. Chang and S.L. Tou	12/02/2015
Mgmt./Sponsor: K. Sienko	

WAS:

5V

Photo: ASCO

IS:

12V

Photo: American Science & Surplus

New solenoid is acquired because old one broke and is too long in response time.

ME450 Team 7	
Project: Blood Pressure Device for Low Resource Settings	
Ref: Solenoid Valve	
Engineer: J. Chang and S.L. Tou	12/02/2015
Mgmt./Sponsor: K. Sienko	

Appendix P: Validation Data

Accuracy Data:

Table: Nurse 1 Accuracy Test

Person	Arm used	Device	Stethoscope Type	Deflate Type	BP	Time (s)
Caroline	Left	Aneroid	Stethoscope	Manual	130/68	56.76
	Right	Aneroid	Stethoscope	Manual	128/66	53.45
	Right	Device + stethoscope + manual deflate	Stethoscope	Manual	125/73	36.27
	Left	Device + manual deflate + stethoscope	Stethoscope	Manual	130/71	36.27
Jungsoo	Left	Aneroid	Stethoscope	Manual	112/78	60
	Right	Aneroid	Stethoscope	Manual	112/78	40.5
Lauren	Left	Aneroid	Stethoscope	Manual	108/70	50.15
	Right	Aneroid	Stethoscope	Manual	110/68	49.89
	Right	Device + manual deflate + microphone stethoscope	Microphone	Manual	101/75	166.45
	Right	Device + manual deflate + stethoscope	Stethoscope	Manual	111/52	29.53
	Right	Device + manual deflate + microphone stethoscope	Microphone	Manual	117/63	56.69
	Right	Device + manual deflate + stethoscope	Stethoscope	Manual	112/68	40.25
Jenny	Left	Aneroid	Stethoscope	Manual	108/72	27.04
	Right	Aneroid	Stethoscope	Manual	108/72	77.13
	Right	Device + manual deflate + stethoscope	Stethoscope	Manual	108/62	88.01
	Left	Device + manual deflate + stethoscope	Stethoscope	Manual	114/70	41
	Right	Device + manual deflate + stethoscope	Stethoscope	Manual	113/62	56.59
	Right	Device + manual deflate + microphone stethoscope	Microphone	Manual	106/64	52.72
	Right	Device + gauge + stethoscope	Stethoscope	Manual	108/76	47.62
					average time	59.21818182
					standard deviation	38.91528641

Table: Nurse 2 Accuracy Test

Person	Arm used	Device	Stethoscope Type	Deflate Type	BP	Time (s)
Jungsoo	Right	Device + automatic deflate + microphone stethoscope	microphone	Solenoid valve	108/7?	3 minutes (practice round)
	Right	Device + automatic deflate + microphone stethoscope	microphone	Solenoid valve	108/74	73.97
	Left	Aneroid	Stethoscope	Manual	108/66	76
	Right	Aneroid	Stethoscope	Manual	108/64	70
Jenny	Left	Aneroid	Stethoscope	Manual	112/64	78
	Right	Aneroid	Stethoscope	Manual	112/64	64
Caroline	Left	Aneroid	Stethoscope	Manual	122/74	63
	Right	Aneroid	Stethoscope	Manual	122/74	45
	Right	Device + automatic deflate + microphone stethoscope	microphone	Solenoid valve	118/66	60
	Left	Device + automatic deflate + microphone stethoscope	microphone	Solenoid valve	117/65	81
	Left	Device + automatic deflate + stethoscope	Stethoscope	Solenoid valve	118/68	64
	Right	Device + automatic deflate + stethoscope	Stethoscope	Solenoid valve	116/67	70.28
Lauren	Left	Device + automatic deflate + microphone stethoscope	microphone	Solenoid valve	105/59	
	Right	Device + automatic deflate + microphone stethoscope	microphone	Solenoid valve	102/48	76
	Left	Device + automatic deflate + stethoscope	Stethoscope	Solenoid valve	94/49	60
	Right	Device + automatic deflate + stethoscope	Stethoscope	Solenoid valve	103/57	63
	Left	Device + gauge+ LCD + manual deflate + normal stethoscope	Stethoscope	Manual	110/60	53
	Right	Device + gauge+ LCD + manual deflate + normal stethoscope	Stethoscope	Manual	108/64	67
					average time	66.03111111
					standard deviation	8.648046664

Table: Nurse 3 Accuracy Test

Person	Arm used	Device	Stethoscope Type	Deflate Type	BP	Time (s)
Lauren	Right	Aneroid	Stethoscope	Manual	108/66	51.46
	Left	Aneroid	Stethoscope	Manual	108/64	34.73
	Right	Device + microphone + automatic deflate	Microphone	Solenoid valve	108/66	90
	Right	Device + microphone + automatic deflate	Stethoscope	Solenoid valve	98/60	60
	Right	Device + stethoscope + manual deflate	Stethoscope	Manual	83/55	49
Caroline	Right	Aneroid	Stethoscope	Manual	114/76	49.01
	Left	Aneroid	Stethoscope	Manual	112/72	32.42
Jungsoo	Right	Aneroid	Stethoscope	Manual	88/62	40
	Left	Aneroid	Stethoscope	Manual	88/62	37.15
	Right	Device + stethoscope + automatic deflate	Stethoscope	Solenoid valve	96/63	53.27
	Left	Device + stethoscope + manual deflate	Stethoscope	Manual	97/57	
	Right	Device + stethoscope + manual deflate	Stethoscope	Manual	98/60	58
Jenny	Left	Aneroid	Stethoscope	Manual	92/62	40
	Right	Aneroid	Stethoscope	Manual	102/66	42
					average time	62.054
					standard deviation	16.19566547

Table: Pressure Sensor to Calibrated Device

Pressure of calibrated device (mmHg)	Pressure Sensor 1	Pressure Sensor 2	Pressure Sensor 3	AVERAGE	Pressure of calibrated-average per trial
0	0	0	0	0	0
20	17	18	23	19.33333333	-0.6666666667
40	39	40	40	39.66666667	-0.3333333333
60	58	59	57	58	-2
80	77	77	75	76.33333333	-3.666666667
100	96	97	99	97.33333333	-2.666666667
120	119	115	117	117	-3
140	140	134	138	137.3333333	-2.666666667
160	160	156	158	158	-2
180	177	177	179	177.6666667	-2.333333333
200	199	195	201	198.3333333	-1.666666667
220	217	217	218	217.3333333	-2.666666667
240	241	241	242	241.3333333	1.333333333
260	257	260	257	258	-2
280	277	281	278	278.6666667	-1.333333333
300	296	298	295	296.3333333	-3.666666667

Affordability Table:

Category	Subcategory	Item	Main Specifications	Manufacturer	Part Number	Amount	Unit Cost	Estimated Bulk Cost
Cuff	Arm Cuff	Adult Size	11.8"-16.5"	Veridian	15921	1	15	9.47
Pump	Hand Pump	Latex Free Bulb	Unspecified	W.A.Baum	1890NL	1	21.98	16.45
Pressure Connection System	Ball Valve	Miniature Chrome-Plated Brass Ball Valve	1/8" BSPP Female X 1/8" BSPP Female	McMaster	8156K11	1	8.58	3.05
	Deflation Valve	Air-Flo Control Valve	5/32" Tube ID	W.A.Baum	N/A	2	0	0.00
	Connector	2 inlets 6 outlets Anodized Aluminum Manifold	Inlets 1/4 NPT, outlets 1/8 NPT	McMaster	5469K151	1	19.33	13.80
		Straight Polyethylene Barbed Tube Fitting	3/16" Tube ID X 1/8 NPT Male	McMaster	2808K26	10	0.605	0.52
			3/16" Tube ID X 1/4 NPT Male	McMaster	2808K37	10	0.605	0.52
		Clear Polycarbonate Barbed Tube Fitting	3/16" Tube ID X 3/32" Tube ID	McMaster	5117K57	10	0.794	2.41
		Durable Nylon Tight-Seal Barbed Tube Fitting	3/16" Tube ID X 1/8 NPT Male	McMaster	5463K11	10	0.703	1.50
		90 Degree Threaded Pipe Fitting	1/8 Male X 1/4 Female	McMaster	50785K916	1	5.04	4.35
		Brass Hex Nipple	1/8 NPT Male	McMaster	5485K217	1	2.09	1.40
		Tube to tube reducing straight connector	3/16" to 1/8"	McMaster	5117K59	10	0.274	2.74
	Tube	Durable Rubber Tubing	3/16" ID, 3/8" OD, 10ft Length	McMaster	51225K25	2	6.5	7.47
		Durable Santoprene Rubber Tubing	1/8" ID, 1/4"OD, 25ft length	Mcmaster	51225K22	1	7.75	2.22
	Blockage	Square-Head Plug	1/4 NPT Male	McMaster	44605K222	2	0.18	0.36
			1/8 NPT Male	McMaster	44605K221	6	0.12	0.72
	Pressure upper bound control	PVDF Relief Valve	1/4 NPT Male	McMaster	4277T52	1	19.89	14.36
	Emergency release	Push-Button Valve	1/8 NPT Female	McMaster	6790T42	1	18.48	12.95
	Pressure Gauge	Aneroid	0-300 mmHg	Prestige Medical	70-OB	1	19.07	13.54
Pressure Sensor	Pressure Sensor	Sensor	600 mBar Max	Honeywell Sensing and Control	ABPLLNN600MGAA3	1	8.82	8.82
	Stethoscope	Clinical Lite Stethoscope	Unspecified	Prestige Medical	121-HPK	1	11.45	5.92

Microphone Stethoscope	Microphone	Electret Condenser	Sensitivity - 42dB ±3dB @ 94dB SPL, 20Hz - 20 kHz	CUI Inc.	CMA-6542PF	1	0.50	0.50
	Amplifier	Mono Audio Class D, Analog output	1.4W @ 8Ohms, 2.5-5.5V supply, RoHS Compliant	Sparkfun	RB-Spa-684	1	7.95	2.42
	Potentiometer	Log potentiometer	10K OHM, 1/20W power rating	Panasonic Electronic Components	EVU-F2LFL3D14	1	0.50	0.50
	Knob	Knob	.50" DIA, 6mm Shaft	Kilo International	OEJL-50-4-7	1	5.36	0.52
Deflation	Solenoid	12VDC normally closed	12V, 100mA	American Science & Surplus	NA	1	3.75	3.75
Display	LCD Screen	LCD Screen for Arduino	16 characters X 2 lines	Arrela	1602	1	8.99	3.46
Button	Tactile switch	SWITCH TACT SPST-NO 0.025A 50V	12.4mm diameter, 14.4mm height	E-Switch	320.02E11.08BLK	2	2.18	3.67
	Tactile switch	SWITCH TACT SPST-NO 0.025A 50V	15.88mm diameter, 15.3mm height	E-Switch	320.02E11.09GRN	1	2.58	1.89
Micro Controller		Micro Controller				1	~1.00	1.00
							Total Cost for Proof of Conce	139.35

Portability Data:

Table: Subjects and the Method of Carrying Device

Subject #	Number of hands used	Method of transportation
1	1	Handle
2	1	Handle
3	1	Handle
4	1	Handle, tucking device under one arm, holding device in one arm like a baby
5	1	Handle
6	1	Handle
7	1	handle
8	1	under arm
9	2	under arm, second arm supporting front
10	2	in front with hands at either end
11	1	under arm
12	2	in front with hands at either end
13	2	in front with hands at either end
14	1	handle
15	1	handle
16	1	handle
17	1	handle
18	1	handle
19	1	handle
20	2	with hands on both ends
21	1	handle