Low-Cost, Easy to Use Threshold Based Blood Pressure Measurement Device

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EXECUTIVE SUMMARY

Preeclampsia is a condition characterized by high blood pressure in pregnant women after the 30th week of pregnancy. Preeclampsia causes 50,000 to76,000 deaths worldwide and most of the deaths occur in developing countries due to lack of early diagnosis. Preeclampsia can be diagnosed by blood pressures over 140/90 mmHg and significant levels of protein in urine. A low-cost and easy-to-use threshold based blood pressure measurement device is designed to address the diagnosis problems existent in rural areas. The device is designed to be used by traveling healthcare workers.

A list of user requirements and complementary engineering specifications was generated using interviews with experts in the field, interviews with the medical staff in mentioned regions and QFD charts. Table 1 below summarizes these requirements and engineering specifications.

User Requirements	**Engineering Specifications**
Precision	Measures 140 mmHg -0,+10 mmHg
Inexpensive	< 5 USD
Low number of false alarms	1% false alarms
Long lifetime	> 3 years unit life
Requires no electricity	No electrical power required
Safe to use on patients	No sharp edges, no hazardous materials
Simple Procedure	< 7 steps
Measurements are easy to read	> 4.5 average for likert scale
Adjustable	Circumference range of 9-14 inches
Easy to put on and off	<20 sec with 2 hands
Easy to transport	<24 x 21 x 12 cm^3 , <500 grams
Easy to clean	No parts to disassemble, <1 minutes
Easy to calibrate or requires no calibration	< Once per year
Operates in high humidity	100% RH
Operates in high temperatures	≥40 degrees Celsius

Table 1: User requirements and engineering specifications

Concept ideas were generated using individual and group brainstorming sessions. These ideas were filtered and finalized into a prototype design through Pugh chart analyses and go-no go screenings for both sub-functions and overall design. The prototype design consists of an inflatable cuff with a pressure relief mechanism that notifies the user through an audible signal while releasing air at threshold pressure. The prototype design also uses a fetoscope to listen to Korotkoff sounds.

The prototype was manufactured using parts from a sphygmomanometer pressure cuff and parts machined by lathing, milling and drilling. The process took 14 days. Estimated material cost for the prototype was $70. The bill of materials can be found in Appendix B. Although the completed prototype exhibits threshold based valve opening and sound making characteristics, leakage from the pressure relief valve is an unresolved issue. Other sub systems functioned as predicted during the design process.

A preliminary final concept for large scale manufacturing was also designed. This concept works with the same principles as the prototype design and provides reductions in part cost and size. Although the manufactured prototype was tested for meeting engineering specifications, current leakage problems limit the number of tests. Refinement of the design by further testing and analysis, human subject testing (subject to IRB approval) and mass manufacturing planning are recommended for the future.

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Preeclampsia, Blood Pressure, Threshold Based, Hypertension

ABSTRACT
Preeclampsia is a potentially fatal, pregnancy specific disorder which is characterized by the development of high blood pressure. Preeclampsia affects an estimated 837 million women worldwide and kills 50,000 to76,000 women each year, with most deaths occurring in developing countries due to a lack of blood pressure measuring equipment and trained healthcare workers [1, 2, 3]. The objective of the project is to design a threshold based device for use in rural areas of developing countries which is more inexpensive and requires a simpler procedure than the devices which are currently on the market. A threshold based device has less procedural steps, which facilitates quicker and more efficient early screenings for hypertension and preeclampsia.

INTRODUCTION
Preeclampsia is a potentially fatal condition characterized by hypertension and protein in the urine of pregnant women, usually after the 30th week of pregnancy. Preeclampsia is a pregnancy induced condition, and may develop into eclampsia at any time, which is characterized by seizures that may result in brain damage, coma, or death of mother and infant. Annually, preeclampsia kills 50-76,000 women worldwide, and the majority of the deaths occur in developing countries [2].

The only known cure for preeclampsia is to induce labor, which oftentimes occur prematurely and is dangerous for both the mother and the infant. To prevent preeclampsia from reaching the ultimate stage of eclampsia, treatment from a health clinic should be received immediately when a blood pressure danger threshold has been reached. Preeclampsia is characterized by blood pressures above a 140/90 mmHg (millimeters of mercury), which is when hypertension occurs [2, 3]. The systolic blood pressure, 140 mmHg, is the peak pressure in the arteries, which occurs near the end of the cardiac cycle when the ventricles are contracting [3]. The diastolic blood pressure, 90 mmHg, is the minimum pressure in the arteries, occurring during the beginning of the cardiac cycle when the ventricles are filled with blood [3].

Normal blood pressure is typically less than 120/80 mm Hg [3]. Routine checkups are necessary since there are no physically noticeable symptoms of high blood pressure. Though not intensive, treatments include rest in a hospital bed and care by healthcare workers. However, in the rural areas of developing countries prenatal care is unavailable, and there are no easily accessible resources for healthcare.
Preeclampsia can be detected early by taking periodic blood pressure measurements. It is vital for pregnant women to have access to blood pressure measurements.

Pressure Measurement Devices
The most common technique to measure blood pressure is the auscultatory technique. This method also serves as the standard method for clinical diagnosis [3]. The basic procedure consists of placing a cuff around the

arm just above the elbow. The cuff is inflated to occlude blood flow. Pressure is slowly relieved while the clinician uses a stethoscope to listen for Korotkoff sounds. Korotkoff sounds are the sounds caused by the opening and closing of the arteries, heard during non-invasive blood pressure measurements. The onset of these sounds determines systolic pressure, and the dying out of the sounds determines diastolic pressure. Pressure is measured using a mercury or aneroid sphygmomanometer that is attached to the cuff. This is the most accurate non-invasive way of obtaining blood pressure measurements. This method is fairly accurate when properly administered and widely used, however the equipment is relatively expensive and requires training of the healthcare worker.

In many developing countries, there is a lack of necessary equipment as well as skilled healthcare workers which limits early detection of preeclampsia. Prenatal care is not available to all women, and a day traveling out of the village to a health clinic may pose many problems. The target operator of the device is a healthcare worker and not the expectant mother since she may have little education or experience. The solution should be less expensive than the standard blood pressure measurement equipment. Furthermore, the cost should be moderate so that it is available to all healthcare workers. The device must be easy-to-use for the operator, comfortable for the pregnant women, and durable for rural areas of developing countries.

Several modifications from the common technique should be made for a new device to be used in developing countries. The stethoscope is the most problematic component of taking blood pressure measurements. A decent stethoscope costs approximately $50, which limits its wide distribution in resource limited settings healthcare. The stethoscope requires user training, and also lends itself to observer bias in that the clinician may have to estimate when the first Korotkoff sound was heard and then read the sphygmomanometer [4]. Additionally, in some cultures it may cause cultural controversy. For example, in some cultures, wearing a stethoscope signifies the user is of a doctoral status.

Another modification which should be made is the aneroid sphygmomanometer, which is the gauge from which the user determines the blood pressure readings. This component can also be expensive, ranging from $7 to $100, and requires user training. The purpose of the standard method is to determine the actual blood pressure reading, and the project purpose of a threshold-based method is to determine if the reading is within the regions of hypertension and preeclampsia.

The objective of designing a new product is to determine hypertension accurately with more inexpensive components and simpler procedures than the commonly used auscultatory method aneroid sphygmomanometer with stethoscope.

DESIGN

This section describes the process used to design the prototype.

Design Drivers

The first step in determining the design drivers was to establish a set of customer requirements and corresponding engineering parameters for the device (Table 2). The customer requirements were generated after speaking with the project's mentors and becoming more acquainted with the project purpose. After grasping an understanding of the need for a simpler, more inexpensive blood pressure device to be used to detect preeclampsia, characteristics of a new blood pressure measurement device were defined and pros of current common techniques and devices were taken into consideration.

Customer Requirements	Engineering Specifications
Accuracy	Measures 140 mmHg, -0, +10mmHg
Inexpensive	< 5 USD
Low number of false alarms	1% false alarms
Long lifetime	>3 years unit life
Requires no electricity	No electrical power required
Safe to use on patients	No sharp edges
Simple procedure	<7 steps
Measurements are easy to read	>4.5 average for Likert scale
Adjustable (if necessary)	Circumference range 9-14 in
Easy to put on and off	<20 sec with 2 hands
Easy to transport	<24x21x12 cm^3, <500 grams
Easy to clean	No parts to disassemble, <1 minutes
Easy to calibrate or requires no calibration	<Once a year
Operates in high humidity	100% RH
Operates in high temperatures	≤40˚ Celsius

TABLE 2: Customer Requirements and Engineering Specifications

The design of the device was driven by precision, low number of false alarms, simple procedure and cost requirements. The focus was on designing the threshold based pressure control mechanism to control the pressure applied to the artery and the mechanism to detect Korotkoff sounds. In order to address these focus points, concept generation for each mechanism was conducted separately. Individual concept generation, brainstorming sessions and industry analysis were the main techniques used to generate concepts. Pugh chart analyses and go-no go analyses were conducted to narrow the range of concepts. The selected concepts for applying pressure to the patient's arm and for detecting Korotkoff sounds are presented in Prototype Description section on pg. 6.

Prototype Description

The prototype design was generated using the concepts discussed and eliminating one concept in each category. The design consists of the pressure relief valve, inflatable cuff, and fetoscope concepts to achieve the desired customer requirements.

An inflatable cuff with a bulb pump inflation mechanism is used in the final design. The pressure release screw on the bulb pump is removed, as it is unnecessary for a threshold based design. A removable plastic stopper is attached to the bladder of the cuff in order to allow fast deflation. Pictorial and written instructions are printed on the cuff to guide the user. Figure 1 illustrates the overall design.

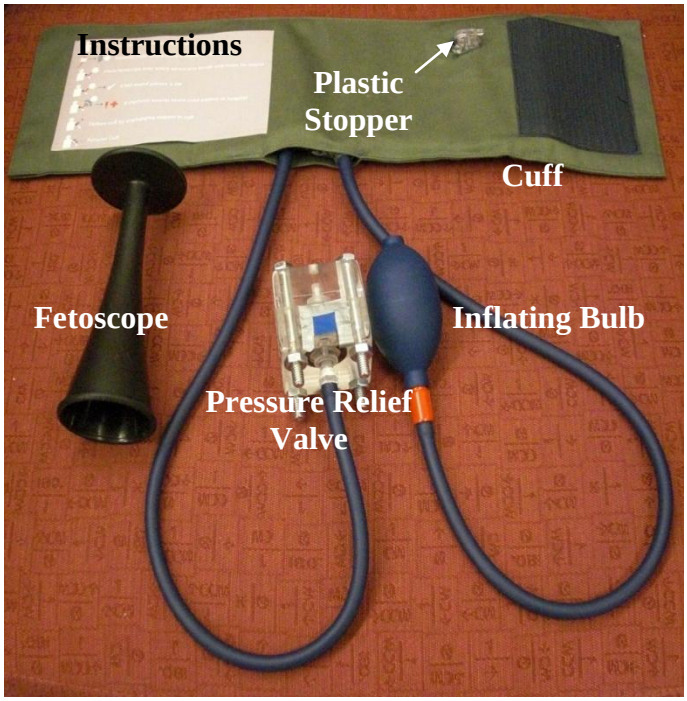

FIGURE 1: Prototype Components

Pressure Relief Valve with Assisted Cuff: The pressure relief valve concept uses a common practice utilized to control high pressure liquids. The pressure relief valve (PRV) consists of a spring loaded piston to trap the air inside the pressure cuff. The piston lifts up to let air out as the pressure in the system rises above a set threshold value. This behavior allows the pressure inside the cuff to stay stable at a preset value regardless of the extra air the user puts into the system. The pressure relief valve has an elastic rubber membrane generates sound. This sound signals the user that the threshold pressure is reached. The main advantages of this approach are the simplicity of the procedure and requiring no electrical power. A detailed illustration of the pressure relief valve can be found in Figure 2.

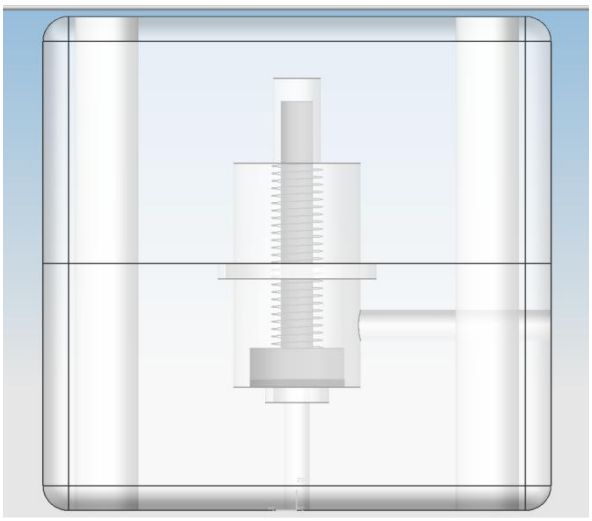

FIGURE 2: Pressure Relief Valve

Fetoscope: The fetoscope concept relies on a currently existing method of manually listening to fetal heartbeats. The fetoscope is a hollow cylinder that is shaped to amplify sounds of the heartbeat. The fetoscope is illustrated in Figure 3.

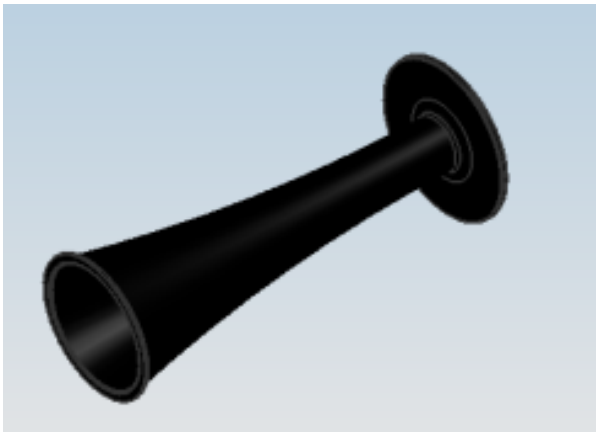

FIGURE 3: Fetoscope

The main advantage of the fetoscope concept is its ability to serve multiple purposes: to listen to Korotkoff sounds while taking blood pressure and to listen to fetal heartbeat during checkups. Other advantages include that it is a low cost, durable mechanism with no moving parts, and is currently used in some rural areas. A disadvantage of the fetoscope is that the user needs training to recognize Korotkoff sounds. However, target users for this device are healthcare workers who have basic training on using a fetoscope.

ENGINEERING ANALYSIS

The design concept was finalized using the engineering analysis. The analysis was conducted on the pressure relief valve, as it was the main mechanism that was designed. The analysis discusses the chamber volume selection, spring selection, piston material and volume selection and the auditory signal mechanism selections.

Spring Specifications

The spring was required to maintain the pressure relief valve in a sealed, closed position at pressures less than 140 mmHg. The spring was also required to allow the valve to remain open at pressures above 140 mmHg and allow substantial air flow. This requirement dictates a low spring constant in order to ensure a large piston displacement when the threshold pressure is exceeded. A force balance analysis of the inlet hole and piston interface of the valve in the closed position served as the starting point for quantifying the spring specifications. The force balance analysis omits the force exerted by the weight of the piston because it is considered to be negligible compared to the other forces.

$$k \leq \frac{A_{piston} P_{inlet}}{\frac{1}{2}(x_{FL} - x_{SL})} \qquad \text{Eq. 1}$$

The spring was selected using the above equation. Using the inlet diameter of 1/8 inches to obtain the effective piston area (A_{piston}) and 140 mmHg threshold cuff pressure as P_{inlet} , simplifies Equation 1 to the following inequality:

$$k(x_{FL} - x_{SL}) \leq 0.066 lbs \qquad \text{Eq. 2}$$

where x_{FL}-x_{SL} is the compressible length and k is the spring constant. A spring with spring constant of 0.09 inch, free length of 0.97 inch and solid length of 0.23 inch was chosen to satisfy this requirement. An inner diameter was selected in order to house a spring guide of standard dimensions. For this spring, the inner diameter was 0.1830 inches and the outer diameter was 0.2030 inches. These diameters also dictate the piston head and shaft selections as discussed in the next section. These values were proven to be invalid after testing was conducted.

Piston Specifications

The piston was required to cover and seal the inlet hole of the pressure relief valve in the closed position, as well as, serve as a sturdy guide for the spring. This was to be completed while keeping the mass of the piston low so that it would not interfere with the spring force.

Furthermore, the piston had to be smooth to minimize static friction.

Equation 3 below was used to minimize the weight of the piston by constraining the density of the material of which it would be manufactured. The force of the spring applied after 5% compression was set as the limiting force. The criterion dictates that the density, ρ_{piston}, be less than 0.190 lb/in^3.

$$\rho_{piston} < \frac{0.05(kx_{FL})}{V_{piston}} \qquad \text{Eq. 3}$$

The material selected was acetal copolymer. Analysis of acetal copolymer in CES Selector Version 5.1.0 showed that it had a density of 0.05 lbs/inch^3, price of $1.50/lb, and a compressive modulus of 0.45×10^6 psi. It is known for its uses in gears and bearings. Both of these applications require good surface finishes and high strengths.

Further analysis of the material selection using the criterion given in Eq. 3 and previously discussed spring selection shows that the material selection is suitable. A density of 0.05 lbs/inch^3 satisfies this criterion.

Auditory Signal Mechanism

The function of the auditory signal mechanism is to notify the user while air is released from the system. It has to generate audible output with low airflow rate. A clearly audible was defined as 45 dB using a SPL chart [6].

A research on airflow sound mechanisms showed that mechanisms based on Karman Vortex Shedding were suitable candidates for the device [6]. The whistle, wire and membrane based mechanisms were experimented with as the output characteristics of the valve could not be calculated be due to aforementioned reasons. The experimentation resulted with the membrane based mechanism as mentioned in the design section.

RESULTS

The following sections reports the results from preliminary validation of the prototype threshold based blood pressure measurement deceive.

Current Pressure Relief Valve Accuracy and Precision

The accuracy and precision of the pressure relief valve was assessed using an aneroid sphygmomanometer. The valve opens to relieve air pressures of 280 mmHg or greater and drifts to a holding pressure of approximately 100 mmHg. The pressure decreased at a minimum rate of 3-5 mmHg per second. Twenty-five trials were conducted with maximum pressures before the valve opened ranging from 120-300 mmHg. The pressures at which the valve settled ranged from 0-160 mmHg. The maximum and minimum times to achievement of a final pressure after the valve opened were determined to be 30 seconds and 5 seconds, respectively.

Validation of Ease of Use

The blood pressure measurement cuff was found to have a maximum time to place on and off the arm of a patient of 8 seconds. The act of applying and removing the blood pressure cuff consisted only of fastening the cuff to the arm in the correct orientation and location, opening the plastic stopper, and removing the cuff. After 5 preliminary trials, the number of steps in the procedure for measuring blood pressure using the prototype was determined to be 6 steps. The 6 steps are given below:

(1) Place cuff around arm and adjust to fit
(2) Squeeze bulb until a noise is heard from the PRV
(3) Place fetoscope over artery at arm bend and listen
(4) If light rhythmic tapping sound is heard send patient to hospital. If not, then the patient is fine
(5) Deflate cuff by unplugging stopper on cuff
(6) Remove cuff

Validation of how easy the measurements are to read consisted of two evaluations. The first was how easy it was to hear the auditory alert mechanism of the pressure relief valve to determine when a pressure was achieved. The second was how easy it was to hear the Korotkoff sounds through the fetoscope. The datums for these 2 tests were the aneroid sphygmomanometer and stethoscope, respectively. More tests need to be conducted to further assess how easy measurements are to read and understand.

Cost and Lifetime

Total prototyping cost was $70. Fabrication of the blood pressure cuff accounted for approximately 69% of the total cost, of which the outer shell and bladder accounted for 62% and 38%, respectively. Manufacture of the pressure relief valve was 15% of the total cost, for parts only. The acrylic cube used to create the body of the valve was 84% of the total cost of the valve.

CES Selector Version 5.1.0 was used estimate the cost of manufacturing a smaller pressure relief valve that

could be attached to the blood pressure cuff. Assuming an injection molding process with a production run of 20,000 units, the unit cost for the proposed final design was determined to be between $5 and $6.

Assessment of Fetoscope

Preliminary tests have shown that it is possible to hear Korotkoff sounds using a fetoscope in a relatively quiet environment. Further testing is needed to determine audibility of Korotkoff sounds in noisier environments.

DISCUSSION

The pressure relief valve, the main component of the device, is not working as expected. Therefore, not meeting the engineering specification set for precision and accuracy. There is a leakage from the valve causing the air pressure to decrease and not maintain the set threshold pressure. The reason for the valve working improperly is due to lack of sealing in the chamber. In addition, a different spring is needed to displace a smaller distance in order for the valve to release excess air slightly above 140 mmHg +10 mmHg and maintain at 140 mmHg until the total pressure is released through the plastic stopper.

The fetoscope was taken into consideration because it is a medical instrument that is more accessible than a stethoscope in these rural areas, as well as, less expensive. Testing determined that the fetoscope could be used to listen to Korotkoff sounds in place of the stethoscope.

The procedure for using the device was validated to be easy to use. The procedure steps of the threshold based device are less than that of the standard, non electrical way of measuring blood pressure with a sphygmomanometer. The new threshold device procedure eliminates slowly opening the relief valve located on the inflating bulb, observing the sphygmomanometer for the measurements of blood pressure, and listening to the Korotkoff sounds with the stethoscope, all at the same time. In addition, the device eliminates the confusion of the relief valve on the inflating bulb being opened or closed. The new procedure is overall easier to follow and implement and meets our engineering specification of having equal or less than seven procedural steps.

The mass manufacturing cost of the final design of the blood pressure device does not meet the required engineering specification. However, the manufacturing cost is still lower than the lowest cost of blood pressure measuring devices found on the current market.

CONCLUSION

The low-cost easy to use threshold based blood pressure measurement device has been designed to detect preeclampsia early in pregnant women. The design is to make it easier to use and more cost efficient than the current blood pressure measurement devices and procedures to benefit rural area settings. However, further design modifications are needed in order for the pressure relief valve to work properly.

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APPENDICES

Appendix A: Final Report

INTRODUCTION

The purpose of this project is to design and manufacture a low-tech, easy-to-use, threshold based blood measurement device which will aid in monitoring the health of pregnant mothers in rural areas of developing countries such as Ghana. The project sponsor is the University of Michigan's Center for Global Health, and the project mentors are Dr. Frank Anderson, Professor of Obstetrics and Gynecology, Dr. Cosmas Van de Ven, Professor of Obstetrics and of Obstetrics and Gynecology, and Professor Kathleen Sienko.

Although there are many health issues related to pregnancy, the project focus is on early detection of preeclampsia. Internationally, preeclampsia causes 50,000 to 76,000 deaths per year [32]. Preeclampsia is a pregnancy induced condition, which is characterized by hypertension and high protein levels in the urine. Most cases of preeclampsia develop after the 30^{th} week of pregnancy. The only known cure for preeclampsia is to prematurely induce labor, which could be fatal for both the mother and infant. Preeclampsia can lead to eclampsia, a more serious illness, which is characterized by seizures, and can result in a coma, brain damage, and possibly death. To prevent preeclampsia from reaching the ultimate stage, treatment from a health clinic should be received immediately after a blood pressure danger threshold has been reached. The team is defining a danger threshold to be above 140/90 mm Hg (millimeters of mercury), when hypertension occurs [19]. Normal blood pressure is usually less than 120/80 mm Hg [19]. Routine checkups are necessary since there are no physically noticeable symptoms of high blood pressure. Temporary treatments for hypertension include rest in a hospital bed and care by health care workers.

Preeclampsia can be detected early by blood pressure measurements when a systolic blood pressure of 140 mmHg has been exceeded, and usually can be resolved easily with adequate health care. However, in developing countries such as Ghana, there is a lack of accurate, easy to use blood pressure measurement devices, compounded by an absence of trained healthcare workers that can operate the devices in the proper manner [36]. These factors ultimately lead to a failure to identify hypertension, and preeclampsia [36]. Since blood pressure measurement devices and the knowledge of techniques and procedures are limited, hypertension is not easily identified. In addition, there are not enough trained healthcare workers to operate such devices [36]. In Ghana, the current practice involves a traveling nurse or midwife, who may occasionally arrive to a village with the traditional arm cuff and pressure gauge to measure blood pressure. Some pregnant women in rural areas may also visit antenatal clinics at larger District Hospitals, where blood pressure measurements can be taken.

In the United States, the most common practice of blood pressure measurement involves the use of a sphygmomanometer. The method is non-invasive (without penetrating the skin or artery) and sufficiently accurate. To measure the blood pressure, the patient's upper arm must first be compressed using an inflatable cuff that is inflated using a hand pump. A pressure gauge is

connected to the cuff and displays the pressure in the cuff. The healthcare worker applies a pressure of approximately 160 mmHg and places the stethoscope on the patient's forearm. The healthcare worker begins deflating the cuff through a valve, while simultaneously listening for Korotkoff sounds through the stethoscope. Korotkoff sounds are the sounds caused by the opening and closing of the arteries. The pressure at the time when the sounds are first audible and are loudest in magnitude is the systolic pressure. The blood pressure varies between systolic and diastolic pressures for each heartbeat. Systolic pressure is the peak pressure in the arteries, which occurs near the end of the cardiac cycle when the ventricles are contracting [8].

However, the objective of the project is to create a device that is low cost and low tech, and has a simpler procedure. Since prenatal care is neither available nor convenient in most rural areas, healthcare workers should be able to access these low-tech and low-maintenance devices easily for a low cost. The final product will be readily accessible to the pregnant women in Ghanaian villages through healthcare workers, and will be easy to use by people from various educational backgrounds and environments. The dangers and consequences that pregnant women and people in rural villages are too serious to ignore, and with this product an aid will be provided to people of all environments in receiving health care.

BACKGROUND

Maternal Mortality

Although "virtually eliminated" from the developed world, maternal mortality is a risk faced by millions of women in developing countries. Africa has the highest maternal mortality ratio in the world with 235,000 maternal deaths per year [2]. Fifty percent of the maternal deaths worldwide occur in sub-Saharan Africa [21]. Hypertensive diseases of pregnancy (preeclampsia being the most common type) are the most frequent cause of obstetric death. Other causes include ectopic pregnancy, complications of anesthesia, and amniotic fluid embolism. Lack of prenatal care, small number of health care providers, limited care provider ability to recognize danger signs, limited access to transportation, insufficient acceptability/availability of modern health care and low quality of emergency obstetric care make preeclampsia prevalent among killers in Africa. There are also non-healthcare related issues that explain why the expectant mothers do not receive the proper amount of health care. Some of these issues are the value of women in society, education level of women, and political status of an area [2].

Health Care System

Development of design requirements for this project necessitates an understanding of the education level of the user (the healthcare worker) and the cultural environment in which the device will be used.

In Ghana, the pilot region of the project, health care is structured in a three tier system that is made up of Level A, the community level; Level B, the local council subareas level; and Level C, the district hospitals. Level A is made up of health care centers managed by village healthcare workers who provide basic health care and pregnancy management. Level B is comprised of health care centers and posts, which are staffed with a medical assistant, midwife, and community nurses. Healthcare staff at Level B serve the people living within 8 Km of these centers. They travel to communities or villages to supervise level A workers, to diagnose and to

treat simple cases or to refer patients to the higher level C centers, district hospitals where fully trained doctors are located [15].
District hospitals may be located far away from rural communities. This creates a transportation barrier to health care needed by rural community members. To mitigate the transportation and other health care barriers in rural area, the Community-based Health Planning and Service (CHPS) initiative was implemented in 1999 [29]. CHPS guides national health reforms that organize volunteerism, resources and cultural institutions for supporting community-based primary health care and includes the assistance of CHPS health care workers. CHPS workers are resident nurses who are trained and have four years of field experimentation and demonstration by the Ghana Ministry of Health and the Navrongo Health Research Center's Community Health and Family Planning Project that travel on motorbikes to rural districts to provide primary health care and family planning services [28]. During their community visit, CHPS workers may recommend that a patient travel to a district hospital to receive treatment. Travel from the community to the district hospital may take days [11].

The three tier system of healthcare is also based on education levels. The education of CHPS workers and other healthcare workers under the third tier, such as community health nurses and midwives, is given by training, workshops, seminars, courses, fellow health worker mentors, and communications with the ministry of health.

A CHPS worker travels to villages as far as 30 minutes driving distance away to perform checkups with the permission of the village's sub chief. CHPS workers are not equipped with blood pressure measuring devices, due to the fact that stethoscopes and other equipment are too expensive to obtain for every worker [36]. According to our interviews with Joseph Perosky, a former ME 450 student who spent the past summer in Ghana, the only things that CHPS workers bring to the villages are contained in a small box, consisting of examination gloves or special antibiotics for certain patients. The CHPS worker screens the patient (not a diagnostic testing) and prescribes a visit to a health clinic for further examination if necessary. A typical CHPS worker checks 10-30 people per day, pregnant women being their biggest concern. A large number of women do not go to clinics for prenatal care since it takes up to a half an hour on a motorbike just to get their blood pressure measured. Expectant mothers and others who may have hypertension view clinical visits as a burden.

Current Blood Pressure Measurement Techniques and Benchmarking

A list of blood pressure measurement methods was compiled by an online research. Each discovered method was further researched to obtain information pertaining to the procedure, advantages, limitations, and approximate cost. The detailed information was gathered from technical and medical journals. A table summarizing our preliminary findings on blood pressure measurement techniques can be found in Appendix E.

The most common technique is the auscultatory technique, adopted by the American Heart Association for clinical diagnosis. The basic procedure consists of placing a cuff around the arm just above the elbow. The cuff is inflated to occlude blood flow. Pressure is slowly relieved while the clinician uses a stethoscope to listen for Korotkoff sounds. The onset of these sounds determines systolic pressure, and the dying out of the sounds determines diastolic pressure.

The pressure is measured using a mercury or aneroid sphygmomanometer that is attached to the cuff. This is the most accurate noninvasive way of measuring blood pressure. Three factors limit the accuracy of the measurements: appropriate cuff size, auditory acuity of the user, and the anatomy of the patient. This method also lends itself to observer bias in that the clinician may have to estimate when the first Korotkoff sound was heard [36]. The cuff with an aneroid sphygmomanometer can cost $7 to over $100 and a descent stethoscope costs around $50.

The second most commonplace blood pressure measurement technique is the oscillatory technique. Like the auscultatory technique, the oscillatory technique also uses a pressure cuff to apply pressure and occlude blood flow. However, sensors in or around the cuff detect changes in pressure through oscillations of the arterial wall as blood flows. The blood flow in the artery causes the arterial wall to pulsate, which causes minuscule oscillations in the pressure applied by the cuff. A sensor detects these oscillations and algorithms are used to convert the signals into readings of systolic and diastolic pressure. Many electronic home use blood pressure measurement devices use this technique or are hybrids with the auscultatory technique [19]. This method is good for patient use and is moderately accurate. However, it uses sensors and electronics, and may not be the most feasible method. A wide range of these devices are available costing anywhere from $20 to $2500.

The palpatory technique is currently being researched as an effective means of measuring blood pressure. A pressure cuff is used to apply pressure to the brachial artery in the upper arm. Instead of listening for Korotkoff sounds like in the techniques mentioned above, the clinician feels the wrist for a palpable pulse. This is a less accurate means of obtaining systolic blood pressure since the blood may be flowing in the artery before a pulse is felt. There is no current procedure for obtaining diastolic pressure from this technique. However, this method eliminates the need for electronics or a separate listening device. The product cost is primarily a function of the cost of the pressure cuff ($7 to $100) [36].

Some of the more sophisticated and costlier techniques are the ultrasound technique and the tonometric technique. The ultrasound technique consists of using an ultrasound imaging device to actually see when blood begins to flow in the artery. Tonometry uses an array of transducers, usually placed at the wrist, to measure arterial pulsations and to determine pressure [19]. Both methods require electricity and can be costly. Ultrasounds can cost more than $400, while tonometric devices can cost anywhere from $50 to $300.

SPECIFICATIONS

Customer, or project, requirements were determined using preliminary research and information obtained from expert interviews. The research conducted focused on qualities of the regions of the world that would most likely use the device. Factors such as culture, geography, education level, infrastructure, language barriers, climate, anatomy, and physiology were all taken into account. Interviews conducted with Dr, Kathleen Sienko, Dr, Cosmas Van de Ven, and Dr. Frank Anderson helped paint a vivid picture of the circumstances which necessitate a need for such a device. The appropriate people were then asked to rank the importance of each customer requirement based on their vision of the device, such as local doctors as well as Ghanaian healthcare workers. Each survey taker ranked each customer requirement on a scale of 1 to 10 based on level of importance, with 1 being not important and 10 being necessary.

A larger sample size would have produced more reliable results. The total number of survey responses only totaled to five people. Surveys would be distributed to more users and patients, rather than the designers, however due to the limited resources and time constraint of the project, future investigation was not pursued.

The results of the surveys were then averaged for each customer requirement. The results of the sponsors' surveys were weighted heavier in the averaging than the team's results due to the fact that the sponsors were more knowledgeable of the project and the environment the device was entering. The final averaged results were used to rank the customer requirements from lowest to highest. The survey that was submitted to the mentors can be found in Appendix H. The results of the survey are shown in Table 1 in the executive summary. The following is a list of the customer requirements that were determined and a brief description.

Precision. It is desired that the device precisely measure blood pressure within some allowable error to minimize false positives. The device is intended to measure blood pressure in the last trimester of pregnancy. In the intended region where the blood pressure measurement device is to be utilized it is difficult to travel to a hospital. Patients should not make the trip to the hospital unless absolutely necessary.

The alarm threshold to warn the user of high blood pressure is determined as 140 mmHg systolic pressure as agreed upon by the interviewed doctors and through literature research. The error for this threshold should be -0, +10 mm Hg. Dr. Cosmas Van De Ven of University of Michigan Medical School suggests these error margins to ensure that people with blood pressures lower than 140 mmHg are not sent to hospitals unnecessarily in a resource limited setting.

Inexpensive. The device should be inexpensive. The locations where the device is to be predominantly used will typically be developing countries. The majority of the users will be unable to afford expensive medical equipment. Thus, cost of manufacture and cost of ownership must be low.

Unit cost of less than $5 is a target given to the team by Dr. Frank Anderson, of the University of Michigan Medical School, who travels to Ghana frequently to provide support on public health issues.

Low number of false alarms. Repeated measurements acquired using the blood pressure measuring device must be reliable. Users of the device must have a significant level of confidence in the information obtained using the prescribed procedure.

It was determined that the device should exhibit no more than one false alarm per one hundred tests.

Long lifetime. Current issues with cost, transportation, materials, and usage require the development of a device that is reusable rather than disposable. The device should function over a period of three years, under some basic assumptions.

In terms of lifetime, the device should last longer than three years. This number is assuming that the healthcare worker visits 10-30 pregnant women on a daily basis, and uses the device twice on each visit (according to former ME 450 student Joseph Perosky). Benchmarking of current blood pressure measurement devices also showed that the lifetimes of such devices are typically two to five years [35].

Requires no electricity. Blood pressure measurements should be taken with no electricity. In the regions of the world where this device will be used, electricity is in short supply.

The project mentors have expressed the preference that there should be no electric power source needed to operate the blood pressure measurement device. It is also assumed by the team that with electricity come higher costs. Therefore, in order to keep cost, the second most important requirement, low electric power should be secondary to non-electric power solutions.

Safe to use on patients: The device must be safe for the patient to use on a daily basis. Specifically, hazardous materials, such as mercury, which is used in some sphygmomanometers, should be avoided. In addition, the device should be noninvasive and comfortable for the user.

The device will be placed on a patient's body, so there should be zero sharp edges on the device so as not to injure the patient. The materials use to manufacture the device should be nonhazardous and within the guidelines and standards set forth by the FDA and applicable to similar devices.

Simple Procedure: The sponsors have said that the need is for a solution that emphasizes low technology and low cost. They have stated both implicitly and explicitly that the device should be easy for the healthcare workers to use.

The most common blood pressure measurement is the auscultatory technique which uses a pressure cuff, aneroid sphygmomanometer, and stethoscope to listen for Korotkoff sounds to determine both systolic and diastolic pressure. This technique has been determined to have seven key procedural steps. If the final device designed by the team is less than seven steps then it may be simpler than the widely practiced AHA procedure. Also, recognize that the device being designed will only need to measure systolic pressure, not systolic and diastolic. The team realizes that number of steps may not be enough to classify the device as simple to use and is researching more ways to measure the simplicity of the final procedure.

Measurements are easy to read: Users must be able to understand the output of the device quickly and accurately. A simple indicator, such as a sound or light, would notify the user if their blood pressure is above the predetermined threshold. Digital displays or readouts should be a low priority.

The engineering specification determined to quantify how easy measurements obtained from the device are to read is the Likert scale. A Likert survey is a questionnaire answering how well people agree on a particular claim. The project section will be asked to use the device to obtain a blood pressure measurement and complete a Likert survey that addresses how easy the measurements were to read. The aim is for the average response to the claim that the

measurements were easy to read be greater than 4.5, which corresponds to agree and strongly agree [26].

Adjustable: Due to variations in the size of human anatomy, and the need to impact many lives effectively, the final device should adopt a one size fits most approach, or be adjustable to some degree.

Using anthropometric data of women of childbearing age in Nigeria and body measurement standards compiled by the National Bureau of Standards, a range was determined for the amount of adjustability necessary to cover the majority of intended patients [15,27]. The lower limit was set to an average wrist circumference of approximately 9 inches, while the upper limit of 14 inches was set to the average upper arm circumference for women. Benchmarking of current devices, specifically blood pressure measurement cuffs, was also used to determine this engineering specification.

Easy to put on and off: The device should be easy for clinicians to put on patients and remove. Furthermore, placement of the device on the patient's body should not be overly constrained. Most current blood pressure measurement devices on the market can be operated by a single person with two hands. The team also watched many videos on taking blood pressure, as well as watched a blood pressure measurement being conducted in a clinical setting. Neither initial placement of the present devices, nor removal of the devices took longer than twenty seconds.

Easy to transport. Healthcare workers and users of the device do a considerable amount of travelling on a frequent basis. The device should be small enough so that it can be carried with relative ease, such as by hand or a small tote.

After becoming more acquainted with the Ghanaian healthcare workers' duties and responsibilities, insight was gained on how to get around to various villages and what they take on their visits. Furthermore the engineering specification relating to size constraints was developed. The healthcare worker rode a small motorbike with limited space. However, it appeared to be adequate space and a reasonable means for the worker to carry something of a size on the order of a lunch box. Thus, the dimensions of the blood pressure measurement device have been restricted to be no larger than that of a lunch box (approximately 24 x 21 x 12 cm^3). Similarly, the weight has been restricted to no larger than 500 grams, which is typical for current portable electronic blood pressure measurement devices [18].

Easy to clean. It is advantageous that the clinician be able to take readings of multiple patients on a daily basis; so that, a device which can be cleaned quickly and easily would be best.

A device which can be cleaned without disassembly is easier to clean than one which must be disassembled first. The most obvious being the amount of time required to complete the cleaning process. It is envisioned that the final device could be cleaned by simply wiping it off with a cleaning cloth or rinsed. This should take no longer than a minute.

Easy to calibrate. Lack of technical knowledge and maintaining ease of use means the device should be easily calibrated or require no calibration at all. Some calibration may be needed to

ensure accuracy. However, the procedure for doing so should be sufficient and simple. Furthermore, the frequency of such calibration procedures should be low.

A calibration specification of less than once per year seems reasonable and compares to the recommended calibration protocol for other measurement devices, such as the aneroid sphygmomanometer.

Can withstand high temperatures and high humidity. The climate of the intended region necessitates a device that can withstand high temperature and high humidity. The operating temperature of 40 °C and operating humidity of 100% RH are the historical maximum climate conditions in Ghana.

ALPHA DESIGN

Concept Generation

To capture all the aspects and functions of the blood pressure measurement device, a functional decomposition was created as seen in Figure 1 below.

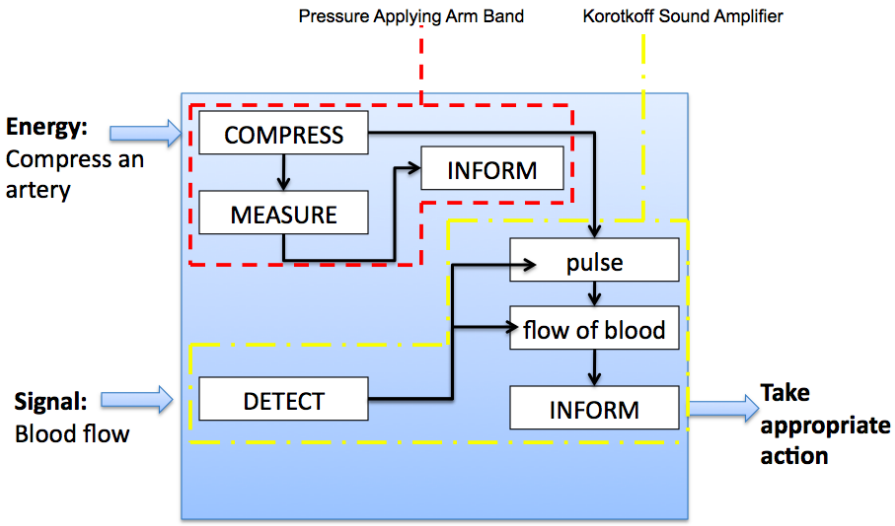


FIGURE 1: Functional Decomposition

The first action is to provide energy into the system, by compressing an artery in the arm. The compression of the artery must be limited to a pressure less than 280 mmHg to ensure the safety of the patient. However, the pressure must be stabilized at 140 mmHg. After the artery is compressed at 140 mmHg, the measurements are taken and should inform the user. The next action is a signal. The signal is the determining factor if the detection of the pulse or blood flow while the blood flow is occluded at the threshold pressure, 140 mmHg. Determining whether the threshold has been reached so that the user can be informed is very important. Once the signal notifies the user, the patient will then take the appropriate action depending on the resulting information. If a red light results, the patient needs to receive immediate health care, and if a green light results, no action is necessary.

To begin the initial brainstorm, our team played "hot potato", where we used a crumpled paper ball, and took turns tossing the ball to each of the four team members. The person in possession of the ball gave one design concept idea, and would toss the ball to someone else. This process continued for twenty minutes, until a list of approximately thirty different ideas was generated. The ideas ranged from devices to procedures, regarding pressure measurements and pulse detection. We then used ten minutes to individually come up with a device design, selecting ideas generated produced from "hot potato". The ideas were shared and discussed in detail. Team members critiqued each design, and afterwards each person spent five minutes fixing their design.

The second concept generating session our team conducted was during class recitation. We explained the project goals and all the functions the device should have. After introducing our task, our peers were divided into teams and given large notepads and markers to draw with. Together, they sketched as many ideas as possible during ten minutes. At the end of the ten minutes, the class converged and everyone posted their notepads on the walls and shared their ideas and answered any questions about their concept. Our team passed out a stack of post-it notes to everyone, and asked them to rank the design concepts based on the following categories: low cost, simple procedure, creative approach, overall design concept, method of reading pulse, and method of applying pressure. The sketches and annotated post-it notes were then collected, which our team kept for design ideas.

After the class discussion, our team conducted a second individual brainstorm session. Since the last individual brainstorm, our team acquired more valuable resources; we combined ideas from the classroom discussion, the CHPS video, and conversation with Joseph Perosky. During this session each member generated two more design concepts. The following brainstorming sessions were held similarly, by using new ideas acquired from our new resources.
In total, our team generated approximately 20 concepts for measuring blood pressure, and the ideas to create them came from many different sources. In addition to the classroom discussion, we obtained a copy of a video detailing the duties of a CHPS worker from Joseph Peroski, who was a former student in ME 450 and spent three weeks in Ghana during the past summer. Joseph was an important resource for our team, since he had firsthand experience in Ghanaian settings and was very informed on their health care. Another source is the existing patents which currently exist; we found many ideas about new ways to measure blood pressure through patent searches. Some of the heavier influences on our concept generation were from our customer requirement, factors involving Ghanaian environments, as well as our mentors' opinions.

Concept Selection
From the 30 concepts generated in two categories, applying pressure concepts and detecting the pulse or Korotkoff sounds, the top five concepts were selected from each category creating a total of ten top concepts. These top ten concepts were selected based on the highest number of customer requirements the concept met in addition to if it would be feasible to manufacture. In order to condense the top ten concepts we evaluated the two concept categories in separate Pugh charts. A Pugh chart is a process used to evaluate multiple options against each other, in relation to a datum. In the pressure Pugh chart, the datum is the standard cuff that is currently used to measure blood pressure. The datum will be compared to the different pressure concepts based on the customer requirements. The pulse and Korotkoff sound Pugh chart datum is a stethoscope

comparing the concepts based on the customer requirements that apply to the pulse and Korotkoff sounds. In both Pugh charts, the datum was set at a reference of 3. If the concept satisfied the customer requirement as the datum it received a score of a 3, however if the concept is better than the datum it received a score greater than 3, 5 being the greatest. If the concept is worse than the datum it received a score less than 3, 1 being the worse. The scores for each concept are summed and then ranked from 1-6, 1 being the best 6 being the worst. The top three ranked concepts from the Pugh chart were selected to undergo further evaluation to determine a concept that combines both the application of pressure and determine the pulse or Korotokoff sound. The evaluation included determining which pulse and Korotkoff sound can be applied to the pressure concepts. It was then decided that the fetoscope concept will be the main focus for the Korotkoff sound concept because it ranked the highest in the Pugh charts, it can be purchased or manufactured, and is being used in Ghana by the CHPS worker to detect fetus heart beat. The worm gear mechanism concept will be our main focus to combine with the fetoscope concept because it also ranked the highest on the Pugh chart, easy accessibility, it will be easy to manufacture.

Top Applying Pressure Concepts

This section will provide a detailed description including the advantages and disadvantages of the top three ranked concepts for applying pressure in the Pugh chart.

Self Inflatable Cuff: The standard cuff will be modified to self inflate to a threshold pressure of 140 mmHg instead of using the current method of using a pump manually. A button will be located on the cuff and once the button is pressed the bladder inside the cuff will inflate to the threshold pressure (Figure 2).n the Pugh chart analysis, the concept met 10 out of 13 customer requirements. However, the concept wasn't ranked as the highest because it was evaluated as an electric concept. Though this concept can be manufactured as electrical or non-electrical, if an electric concept is needed this concept will be the best concept to consider.

The advantages of the this concept are it provides a simple procedure, only implementing four steps and it will be less complex to manufacture since the cuff already exists. The main disadvantage is that the concept is electric. If it is powered by batteries, it is not likely that the batteries will be replaced.

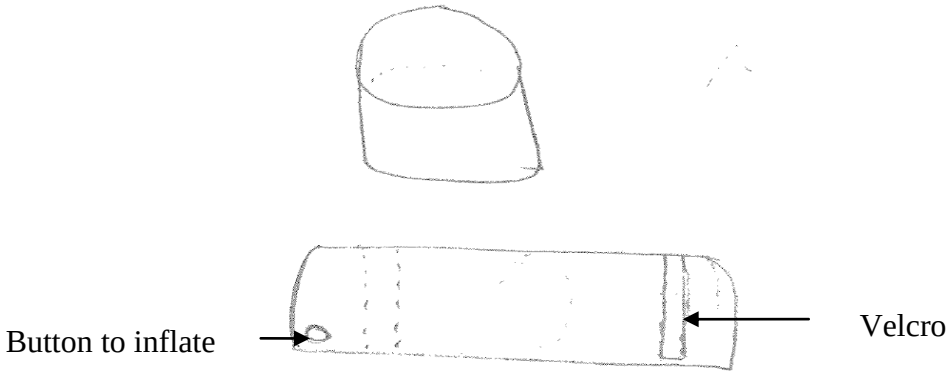


FIGURE 2: Self Inflatable Cuff

Spring Loaded Clamp: The spring loaded clamp applies an amount of pressure by clamping it to the arm where the artery is being blocked. It meets 8 out of 13 customer requirements. Some of the advantages are that it will be easy to purchase or manufacture, inexpensive, and it has a simple procedure with few steps. The disadvantages are that it is less accurate and further research is needed to determine how to apply a threshold pressure.

Cuff with Worm Gear Mechanism: Shown in Figure 3, the worm gear arm band device works almost the same way as the pressure cuff. It wraps around the arm with Velcro bands. However, the Velcro on the outer side is attached to a free moving pad which connects to a gear mechanism through a force gauge. As the worm gear turns, the band tightens around the arm, applying pressure to it.

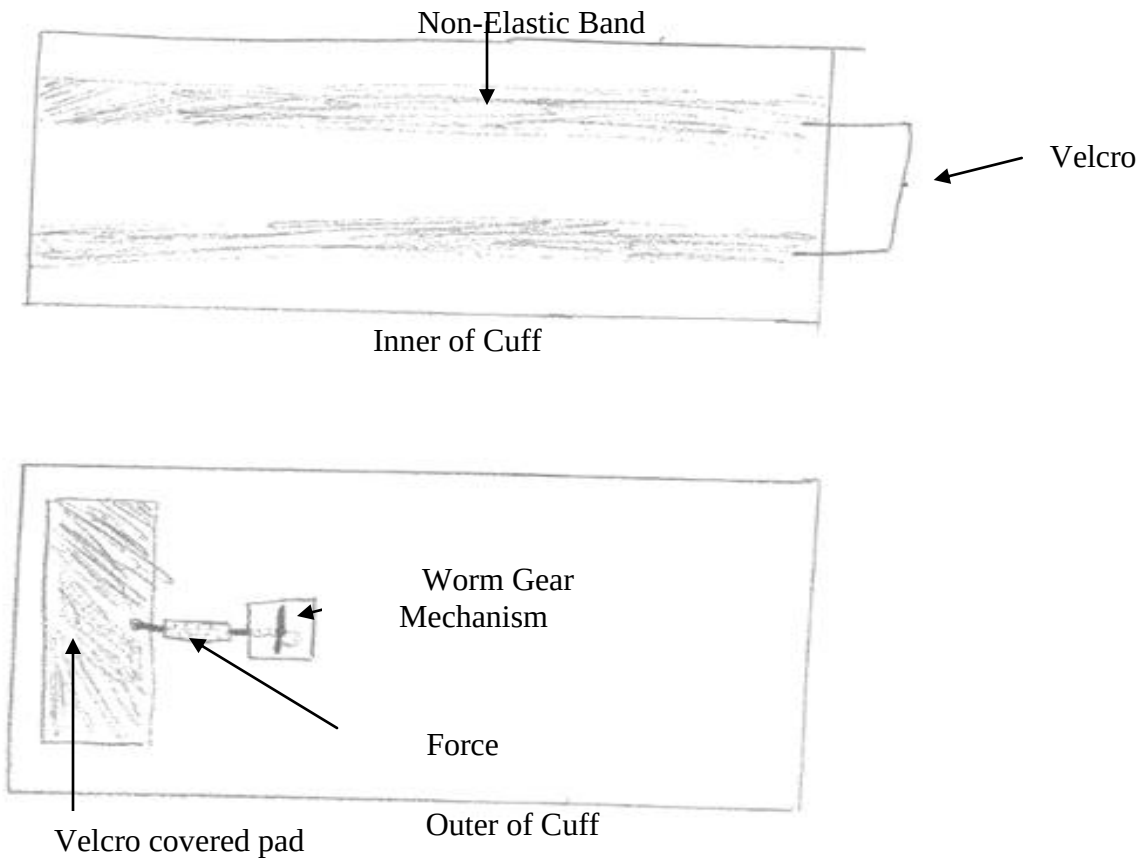


FIGURE 3: Cuff with Worm Gear Mechanism

Top Pulse and Korotkoff Sound Concepts

Fetoscope: A fetoscope is a midwifery tool which is shaped like a funnel and has a flatter, wide end to place on a pregnant woman's stomach and the midwife can place her ear on the other end to listen to the fetal heartbeat [41].

To use this device in terms of Korotkoff sound detector, the flat end can be used similarly on the forearm of the patient to detect blood flow while pressure has been applied to the upper arm. The fetoscope is easier to use, has more uses per unit, inexpensive, and easier to clean and transport than a stethoscope. This device is also more appealing because it is widely used and accessible in developing countries such as Ghana. However the disadvantages of the fetoscope include less accuracy, and pulse readings may be more difficult to understand.

FIGURE 4: Fetoscope [39]

Pulse Amplifier – Drum with Metal Beads: The pulse amplifier is essentially the head of a stethoscope with small metal beads contained on the inside of the convex cavity. When the device is placed over an artery in the forearm, the vibrations caused by the blood flow should be detected, and thus the metal beads will begin to vibrate to create noise. The sound of the vibrating metal beads will be the indicator of a "red light", since blood flow can still be detected in the forearm once the pressure has been applied to the upper arm, and "green light" when there are no audible sounds. This device is inexpensive, easy to put on and take off, and easy to transport and clean. However, this device may not be accurate and the procedure to measure pulse may be more difficult than listening to the Korotkoff sounds using a stethoscope.

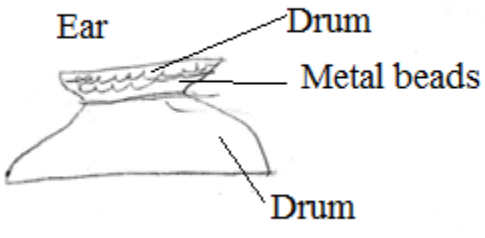


FIGURE 5: Drum with Metal Beads

Stethoscope Head: The stethoscope head can be detached from the earpiece and tubes and used alone to listen for the Korotkoff sounds. The use is similar to the fetoscope, where one end is placed on the skin above the artery and the health care worker will listen to the sounds with his or her ear pressed against the other side of the stethoscope. This design concept is a modified version of our datum. It is less expensive, easy to put on and take off, and easy to clean and transport. The only disadvantage is that it may be more difficult to measure the pulse and have a more difficult procedure.

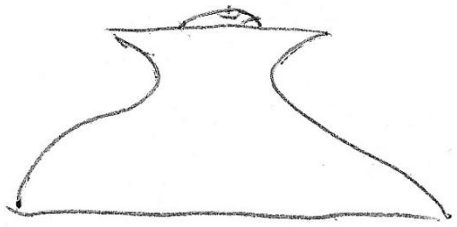


FIGURE 6: Stethoscope Head

Concept Selected

The concept generation and selection processes led to an alpha design concept. The team decided to separate alpha design into two main sections: the device and the procedure. Separation of the device design and procedure design will allow better analysis and improvement of the concept in the future. These sections also have their own subsections according to their functions. The device is made up of two sub devices: a pressure applicator arm band and a listening device to listen to Korotkoff's sounds. The procedure has three parts: set up, listen, and remove. After discussing the device and the procedure, an analysis of the design will be done by benchmarking the design against the customer requirements and engineering specifications.

Device

The device is made up of two sub-devices. The pressure applicator arm band applies pressure to the upper arm in order to constrain blood flow and informs the user about the pressure it is applying. The Korotkoff sound listening device allows user to hear Korotkoff sounds. In other words, it detects the flow of blood and informs user. How these sub-devices fit into the functional decomposition can be seen in Figure 1 (pg. 19).

Pressure Applicator: The pressure applicator is a non-elastic arm band with a tightening mechanism on it. It is wrapped around the patient's arm. Therefore, two sides of this arm band will be referred to as the inner and outer sides. The inner side is defined as the side that is in contact with the patient's arm and the outer side is the side that does not contact the patient's arm when wrapped around the arm. Outer side of the device has 3 major parts attached to it. These parts are:

1- ***Rotational to linear motion converter mechanism***: This mechanism translates rotational motion applied by the user to linear motion. The user applies force by turning a small handle. As this handle turns, the mechanism "pulls" a linear element. The linear element is connected to the force gauge. This mechanism is attached rigidly to the arm band.

A few potential systems for this use are:

a) Rack and pinion gearing: translates rotational pinion motion to linear rack motion (Fig. 7-A)

b) Reel mechanism: winds up a high strength wire around itself to generate linear motion (Fig. 7-B)

c) Worm gear mechanism: Turning worm gear moves a steel band with slits on it. (Fig. 7-C)

A- Rack and Pinion Gear[5]

B- Reel Mechanism[6]

C- Worm gear Mechanism[19]

FIGURE 7: Potential mechanisms for rotational to linear motion converter

2- ***The force gauge***: Force gauge is used to measure the force applied to tighten the band around the patient's arm. The gauge is made up of a spring in a housing that is marked with equivalent forces to the spring's extension distance. Pressure equivalents of force readings will be calculated and the gauge will be marked to show arm pressure instead of the force on the band. One side of the force gauge is connected to the rotational to linear motion converter mechanism while the other side is connected to the Velcro covered pad. This element is not rigidly attached to the elastic band as it is used to transmit motion and thus force between the rotational to linear motion converter mechanism and the Velcro covered pad.

3- ***Velcro covered pad*****:** This element is a flat surface which is covered with Velcro. It is used to attach the Velcro covered stripes in the inner surface of the band to the tightening mechanism mentioned above.

The mechanism on the outer surface functions by accepting input through the knob on the rotational to linear motion converter. The converter generates linear motion and pulls the linkage

element towards itself. The linkage element is attached to the force gauge which is practically a spring in a housing. The spring deflects and applies the same force to the other side. Attached to the other side of the spring is a linkage element which transmits the force to the Velcro covered pad. Figure 8 below summarizes this design.

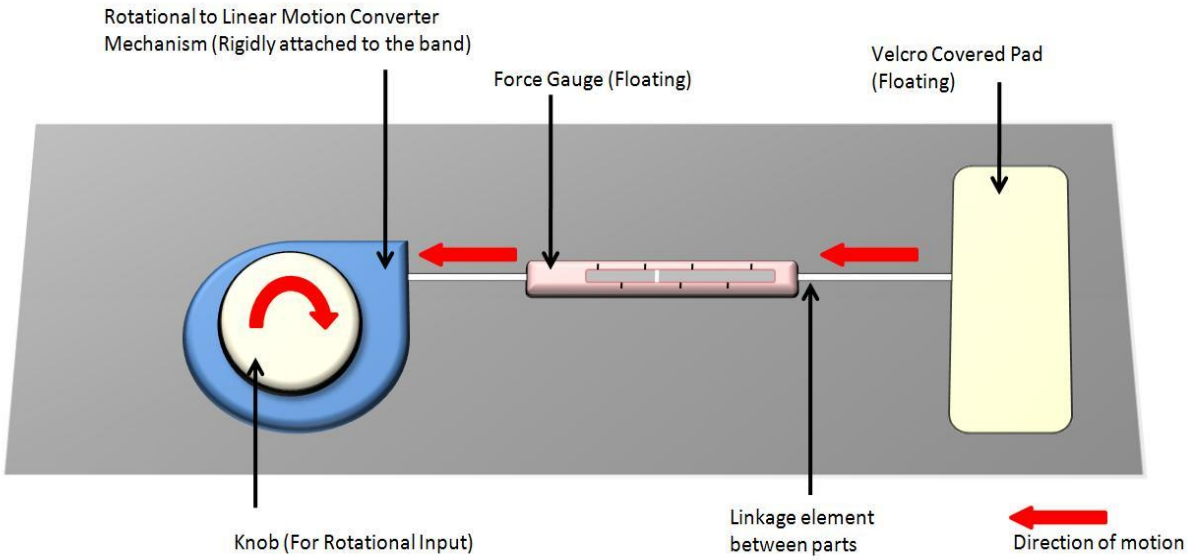


FIGURE 8: Model of the outer surface of the pressure applicator band

Inner side of the arm band has multiple Velcro stripes along the length. These Velcro stripes attach to the Velcro covered pad on the outer surface, creating a closed loop around the arm. The loop gets smaller as the Velcro covered pad on the outer side is "pulled" towards the rotational to linear motion converter. This causes the band to tighten around the arm and generate pressure in the arm. A graphical model of inner surface can be found on next page (Figure 9).

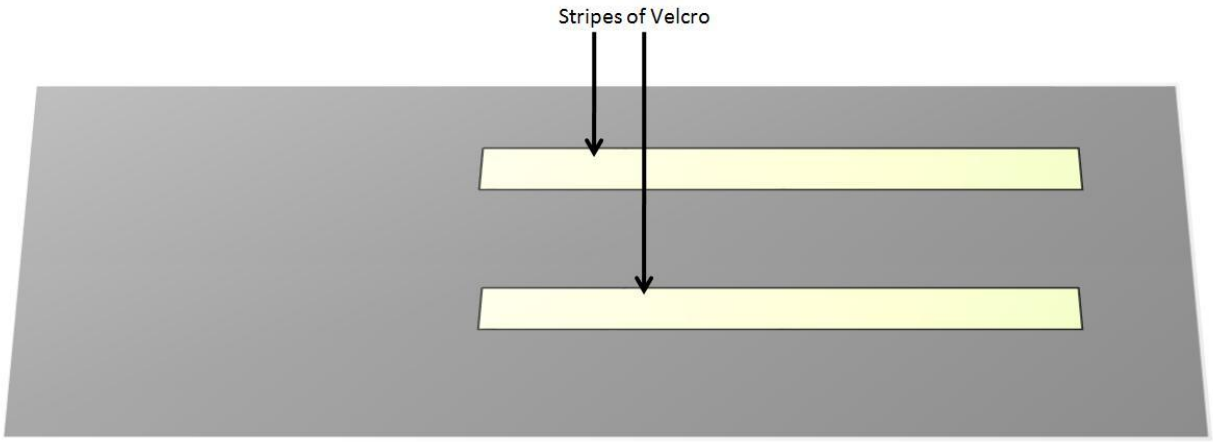


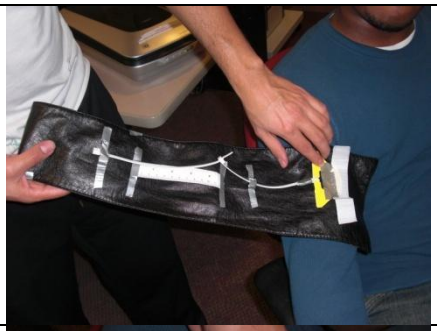
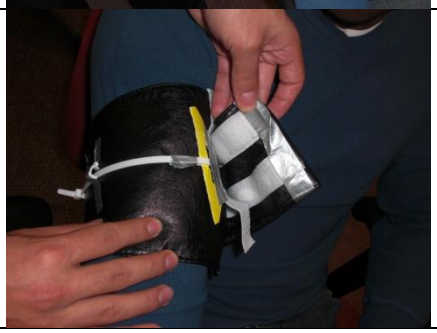
FIGURE 9: Model of the inner surface of the pressure applicator band

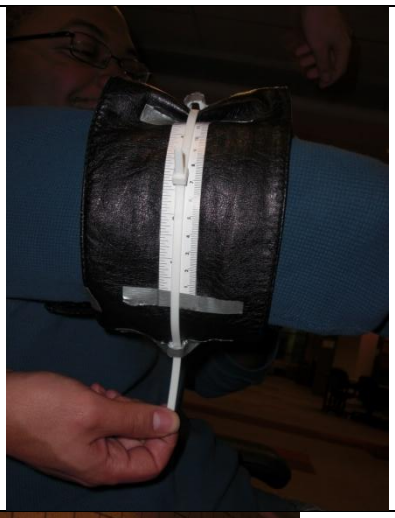
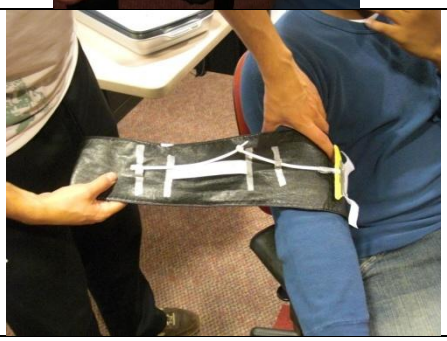
Korotkoff Sound Amplifier: Korotkoff sound amplifier serves to amplify the Korotkoff sounds which occur in the brachial artery when the pressure around the arm is less than the systolic pressure. The device that will serve as the Korotkoff sound amplifier is a fetoscope.

A fetoscope works by focusing vibrations (sound) emitted from inside the body on user's ear. This allows a certain level of amplification. The fetoscope will be used when the pressure of 140 mmHg is applied to the upper arm. The receiving end is placed on the brachial artery. The hearing end is placed by user's ear. It amplifies the Korotkoff sounds and makes them audible to the user if they exist. Figure 9 shows the type of fetoscope which will be used.

FIGURE 10: A Fetoscope with Labels

Procedure

Step	Picture
Wrap the band around the upper arm. (Outer surface shown in the picture)	
Attach Velcro inside the cuff to the Velcro covered pads at the outer side.	

Tighten by turning the knob until tension gauge shows 140mmHg. (The picture shows manually tensioned arm band instead of by turning the knob on rotational to linear motion converting mechanism)	
Listen to Korotkoff sounds with the fetoscope.	
Loosen the rotation to linear motion converter and remove the arm band by detaching the Velcro surfaces.	

Satisfaction of Customer Requirements

An early stage analysis of the proposed alpha design is done to understand which customer requirements the design satisfies, which ones it is most likely to satisfy and which ones may be hard to satisfy by the design.

Customer Requirement	Engineering Specification	How Alpha Design Satisfies the Requirement
Requires no electricity	No electrical power required	Requires no electrical power
Safe to use on patients	No sharp edges	No sharp edges
Simple procedure	<7 Steps	5 steps
Adjustable	Circumference range 15-45 cm	Circumference variable
Easy to clean	No parts to disassemble, <1 minute cleaning time	No parts to disassemble, inside surface of the band has a plain surface. Fetoscope has a plain patient contact surface

TABLE 1: Customer requirements satisfied by the alpha design

Customer requirements shown in Table 1 are satisfied by the alpha design. Requiring no electricity, having no sharp edges and a procedure of 6 steps are clearly seen in sections above. Adjustability of the band is satisfied by having only one non flexible part (rotary to linear motion converter) that needs to be rigidly attached to the band. Other parts are either all floating or flexible and thus do not affect the loop radius of the band. Even the rotary to linear motion converter can be attached to the band at a single point if radius requirements dictate. The device takes less than one minute to clean as the only parts to be cleaned are the inner side of the band and the receiving end of the fetoscope. Inner side of the band is a flat surface. The Velcro on this side is made of fabric and has no teeth (the female part), thus doesn't collect unwanted particles. The fetoscope end is also a flat surface which can be wiped easily.

Table 2 on the next page lists the customer requirements that are most likely to be satisfied by the alpha design. The column on the right justifies the reasoning behind each selection.

Customer Requirement	Engineering Specification	Why Alpha Design is Likely to Satisfy the Requirement
Easy to put on and off	<20 seconds with 2 hands	Although alpha design is relatively easy to put on and off with Velcro stripes, this engineering specification cannot be justified without actually manufacturing the product
Easy to transport	<24 x 21 x 12 cm^3 and < 500 grams	Alpha design is almost certain to weigh less than 500 grams but volume and exact weight cannot be determined at this stage as the material selection and selection of some mechanisms isn't complete.
Easy to calibrate or requires no calibration	< Once per year	The tension force gauge is made up of a spring and housing and is not expected to loose calibration unless the spring constant changes with time and use. In case it is found out to be changing with time, an easy calibration screw can be added to the mechanism. Fetoscope has no parts to calibrate
Operates in high humidity	Operates in 100% RH	No electronic parts or very small and very precise metal parts are expected to be used in the arm band. No metal part touches patient body and this gives the team freedom to use various anti corrosive coatings. Fetoscope can be made of non-metallic materials.
Operates in high temperatures	>/= 40 degrees Celsius	No electronic parts or battery in the design. A correction factor for tension readings can be incorporated incase high temperatures have a dramatic effect on spring constant.

TABLE 2: Customer requirements that are likely to be satisfied by the alpha design.

Table 3 lists the customer requirements that may or may not be satisfied by the product. Either the design is at an early stage to determine if it fulfills these requirements or the fulfillment of requirements cannot be predicted with certainty until the final prototype is built and tested.

Customer Requirement	Engineering Specification	Why Satisfaction of the Requirement Cannot be Determined
Precise	Measures 140 mmHg -0 +10 mmHg	Precision of the tension gauge cannot be determined at this stage in design
Low number of false alarms	1% false alarms	Cannot be determined without field testing
Long lifetime	>3 years unit life	Although lifetime of some materials can be obtained, lifetime of the overall product cannot be determined without actual testing
Measurements are easy to read	>4.5 on Likert scale	Cannot be obtained without testing of the actual product
Inexpensive	<5 USD	Cannot be determined at this stage in design. All material and fabrication method selections has to be made.

TABLE 3: Customer requirements which may or may not be satisfied by the alpha design

BETA DESIGN

Beta Design Concept Generation

The alpha design did not meet the easy to use, precision, and easy to read measurements customer requirements. Thus, brainstorming and generating concepts for an improved beta design was initiated.

The main problem with the alpha design was the application of pressure, not the detection of blood flow. The overall functional decomposition of the device remained unchanged from the alpha design. However, the team decided to revisit ideas for ways of applying pressure that better fulfilled the previously listed customer requirements. Also, more focus was placed on ease of use, whereas initially the team was focused heavily on low cost approaches. This change in thought process opened the door for an electrical device. The team then met and brainstormed devices again. This time, brainstorming was specifically centered on making the device as easy to use as possible, regardless of whether it was electrical or mechanical. Appendix I contains sketches of ideas which emerged from this brainstorming session.

After collectively and individually brainstorming and discussing possible methods of applying pressure, the team ultimately decided that inflation of a cuff was optimal. In other words, inflation was deemed the easiest, safest, and most precise means of applying pressure to the arm. The entire design process started again with these ideas in mind. Patent searches were revisited and the team discovered a patent outlining the creation of a blood pressure cuff that used pressure relief vents to hold and alleviate pressure [31]. The patent detailed the use of two pressure relief vents one for indicating the maximum diastolic pressure and the other for indicating the systolic pressure. Moreover, the patent specified that the pressure relief vents presented auditory or visual cues once the maximum pressure of the vent was reached. It was

agreed that this was a good concept and that a threshold based device would only require one such pressure relief mechanism. The team came together and brainstormed a final mechanical idea based upon using a pressure relief valve to alleviate pressure in excess of 140 mmHg in an inflatable cuff. The final brainstormed mechanical concept is shown below in Figure 6.

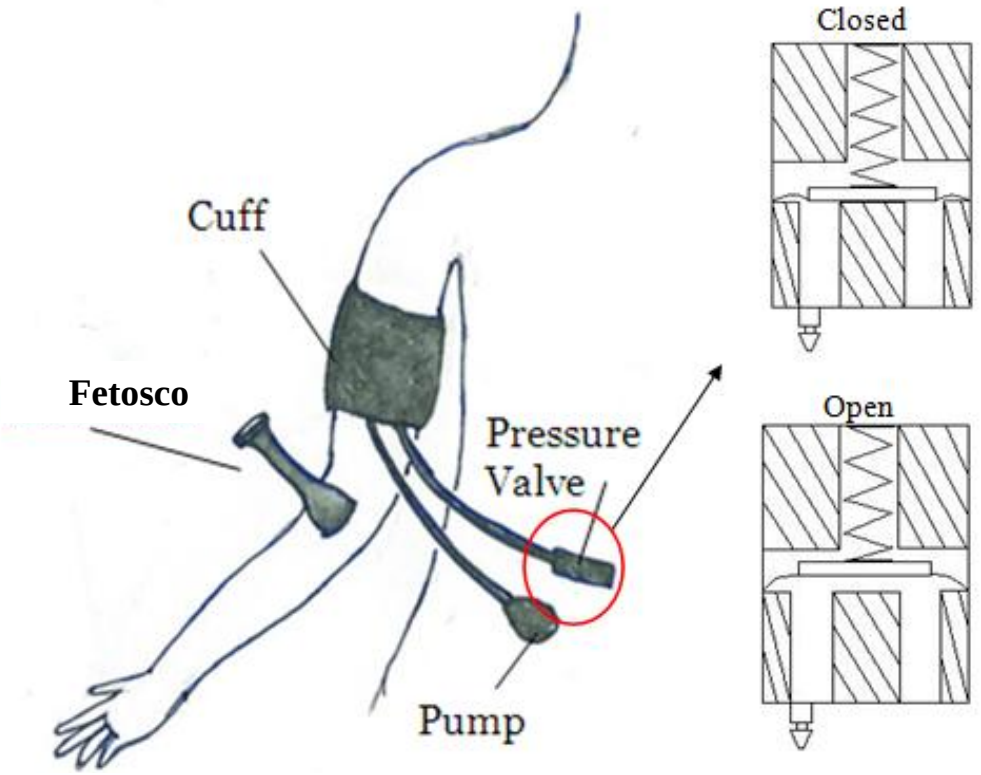


FIGURE 11: Final Brainstormed Mechanical Concept

To fulfill the easy-to-use criteria, an electronic concept was devised to minimize the number of steps needed to operate the device. Through brainstorming sessions, an electronic design consisting of only one piece of equipment to apply pressure and collect pulse information was developed. The cuff would extend from the upper arm (above the elbow) to the lower arm (below the elbow). The upper part of the cuff would house a bladder inside, and the bladder would be inflated by hand using a hand pump, until a pressure of 140 mmHg was detected. After the pressure had been detected and held, a small LED light would flash to notify the user that the pulse is being detected on the lower section of the cuff. A small pulse detector would be embedded below the elbow, and if pulse cannot be detected through the sensor then a green LED light would be displayed to notify the patient that she does not have hypertension. If a pulse was detected, a red LED light would be displayed to notify the patient that her blood pressure is dangerously high and she needs to seek medical attention immediately. After the detection procedures are completed, pressure can be relieved through the cuff by manual deflation, using a plastic stopper or similar device.

With instructor John Baker's guidance, a feasible electrical system was created, which could be assembled using low cost, off the shelf components. This device concept was still targeted

towards the health workers as the main operators of the device. However, this device concept could easily be used by the patient herself. After slipping the cuff through her own arm, the patient would need to inflate the cuff until the light comes on, and the electronics would collect the data and display easy-to-read results.

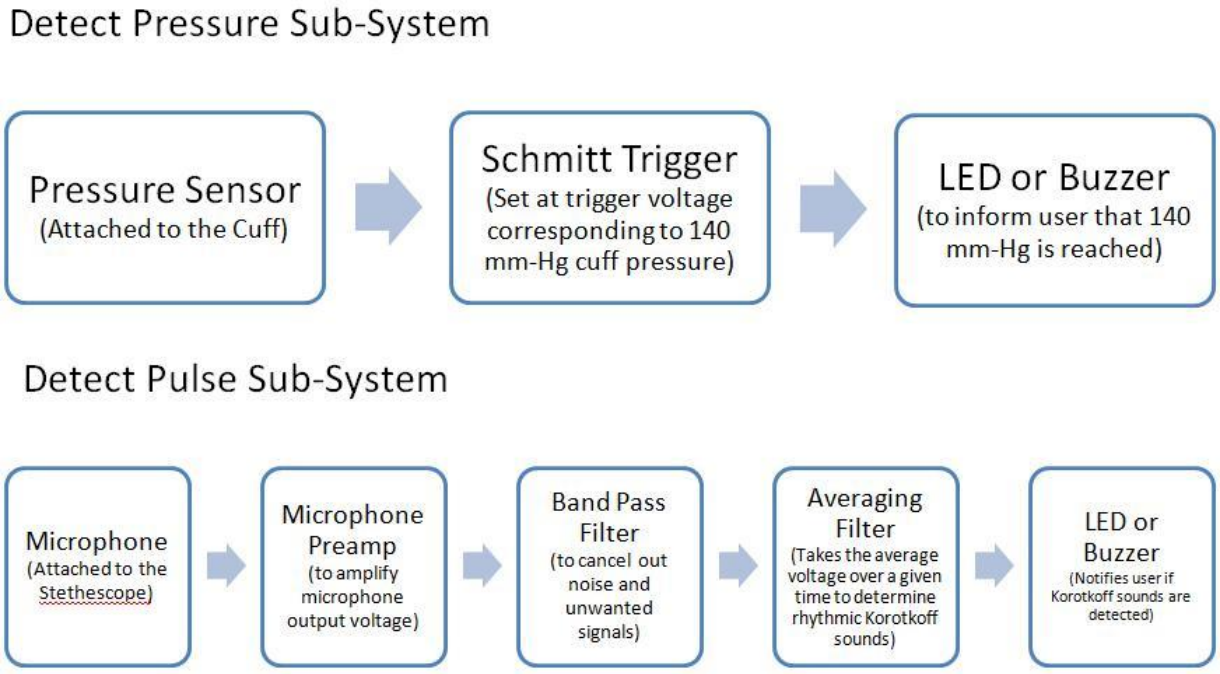


FIGURE 12: Final Brainstormed Electronic Design Concept

Accordingly, the team began the concept selection process with the aforementioned concepts and detailed mechanical and electrical threshold based blood pressure measurement devices. Worth restating is the fact that the beta design concept generation process focused on developing a new way of applying pressure. The fetoscope aspect of the alpha design was not altered. After conducting several experiments on team members and Professor Sienko, it was determined that the Korotkoff sounds were clearly audible through the fetoscope when placed on the arm surface just distal to the standard blood pressure cuff. The Korotkoff sounds detection method remained the same for the beta design.

Beta Design Selected as Prototype

The pressure relief valve is connected to a signaling mechanism which notifies the user when a pressure of 140 mmHg has been reached. It was agreed upon that it would either be a visual or auditory signal. BP team members then considered and discussed feasible ways to connect the pressure relief valve to the signal. Ideas for visual signal included an inflatable balloon and a spinning fan. Ideas for auditory signals included a whistle, bell, or a kazoo.

To relieve the pressure in the inflatable bladder within the cuff, concepts were analyzed through a roundtable discussion and through conversations with Professor Sienko. Currently, plans are moving forward with a rubber stopper that impinges the bladder of the cuff, which is opened to release air in the cuff. More information on this approach is provided later in this report.

The beta design has been selected as the prototype for the threshold based blood pressure measurement device. Figure 13 below is a computer generated model of the proposed prototype.

Again, the main components are the blood pressure cuff, the fetoscope, the hand pump, and the pressure relief valve.

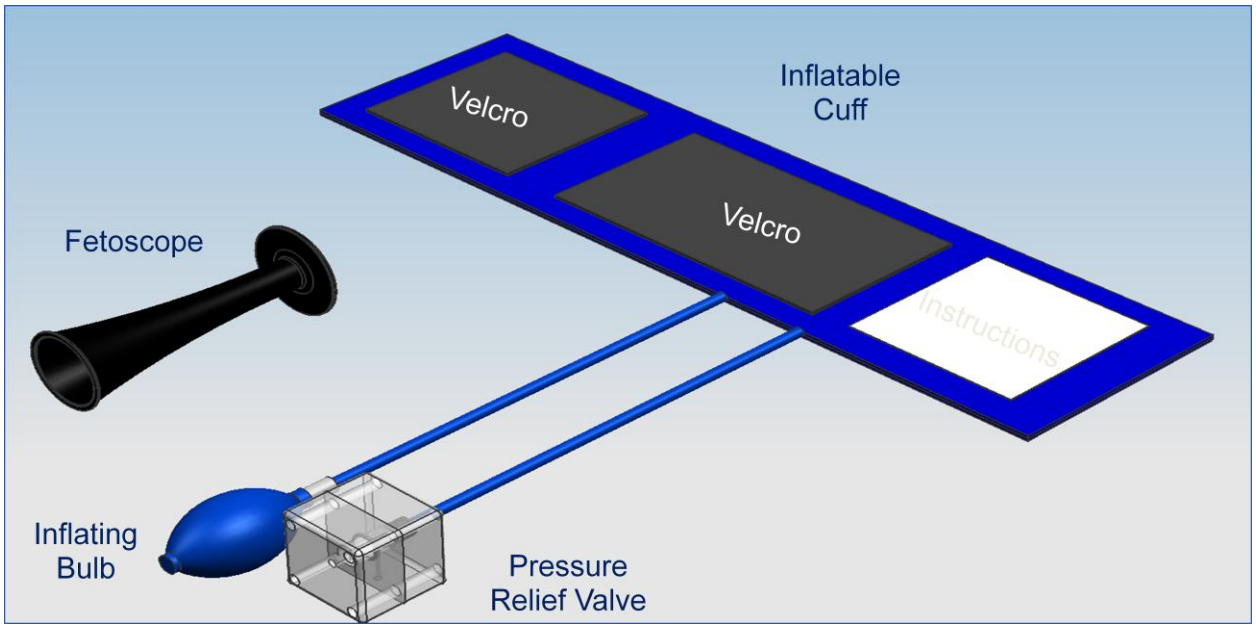


FIGURE 13: Prototype

Blood Pressure Cuff: Initially, the blood pressure cuff used to construct the prototype will be purchased off of the shelf, rather than constructed. The cuff was purchased from CVS pharmacy and cost approximately seventeen dollars. These cuffs offer average performance with great re-configurability. Parts are easily disassembled and reassembled and the prototype can be implemented using this cuff with relative ease.

The purchased cuff is intended for use in the United States and both male and female users. As such, it offers a wide range in arm length adjustability. The cuff fits arms of sizes 5 to 18 inches. The team recognized that this range encompasses the range of expected arm circumference for pregnant women in Ghana and deemed this cuff adequate for the construction of the prototype. However, the team is currently considering fabricating a cuff more specific to the needs of the intended patients, pregnant Ghanaian women. The initial plan is to use a bladder from a purchased cuff, and stitch a smaller cuff which is made specifically with an arm circumference of 9 in. to 14 in. in mind. Ideally, the cuff is to also have area cutouts for the pressure relief valve and the final pressure relief mechanism that will be attached. The team will spend more time benchmarking materials options for the cuff, but the most common material for this application, nylon, will be the most likely candidate. CES will be used to guide the material selection process as well. Nylon offers good durability, weather resistance, and is low in cost.

The cuff purchased from the store is a standard blood pressure measurement cuff and the overall goal of the team is to make a threshold based device. Therefore, the threshold based device will need to be differentiated from the standard blood pressure device. The team mentors have stated that users of the threshold based device should not mistakenly pick up the standard blood

pressure cuff device when using the threshold based device procedure and vice versa. Therefore, an instruction label will be attached to the cuff itself. The method for attaching the instruction label to the prototype cuff will most likely be a laminated sheet attached to the cuff using an adhesive. For the revised prototype which will be displayed at the design expo, the desire is to have the label sewn onto the fabricated cuff or ironed on to the cuff. In the future, the pressure relief valve will protrude from the cuff further helping the user differentiate between our device and the standard cuff.

As stated previously, a standard blood pressure measurement device will be purchased and modified to produce a threshold based blood pressure measuring device. The aneroid gauge and stethoscope head will both be detached from the cuff. These parts will be removed by simply pulling the tube off the ends, which are attached using a friction fit. The stethoscope head which comes attached to the cuff is easily detached by removing the connecting screw.

The tubing of the blood pressure cuff measures approximately 20 inches long. The initial prototype will not alter the length of the tubes, but the prototype presented at the design expo will likely have shorter tubing to the pressure relief valve if the design has the pressure relief valve attached to the cuff. The length of the tube will have little to no effect on the flow characteristics of the bladder and tubing system, or the dynamics of the designed pressure relief valve. This is due to the fact that the entire bladder/tubing system can be thought of as one pressure vessel where the pressure of the entire system is allowed to come to 140 mmHg. The material of the tubing will remain unchanged as well. Therefore, the airflow characteristics at the pressure valve will remain relatively unchanged.

Fetoscope: The prototype will utilize a plastic fetoscope. The fetoscope was purchased from the online auction website, Ebay, rather than manufactured. Manufacturing a fetoscope is unnecessary because the purchase cost is low, fetoscopes are already used by Ghanaian healthcare workers, and the fetoscopes currently available have been shown to successfully detect Korotkoff sounds. We have opted to use the plastic fetoscope, rather than the aluminum fetoscope that was also purchased. The first reason being that the plastic fetoscope is more similar to the one the health workers are accustomed to using. According to Domitilla Debpuur, head nurse at the Sene District Hospital in Ghana, fetoscopes are readily available and are "easily" used by the CHOS, or community health officers. CHOS are given on the job training, as well as, an additional one week training period. The team realizes that the training is for detecting the sound of the fetal heartbeat. Secondly, preliminary testing of comparison between the plastic and aluminum fetoscopes has shown no gains in sound quality through the use of an aluminum fetoscope.

Attaching the fetoscope to the cuff has been discussed within the group. It was concluded that if the fetoscope were attached to the cuff, it may cause confusion to patients and healthcare workers by alluding to the idea that the fetoscope is no longer intended for its primary purpose. In other words, the fetoscope should remain separate from the designed blood pressure cuff to reinforce that it still serves its original function. The team has considered the idea of designing a shorter, similar horn type device that could be attached to the cuff with the sole purpose of listening to Korotkoff sounds. A sketch of such a device is shown below in Figure 14. However,

if the fetoscope validation requirements are met there is no need to incur additional manufacturing costs of the threshold based device by creating another listening mechanism.

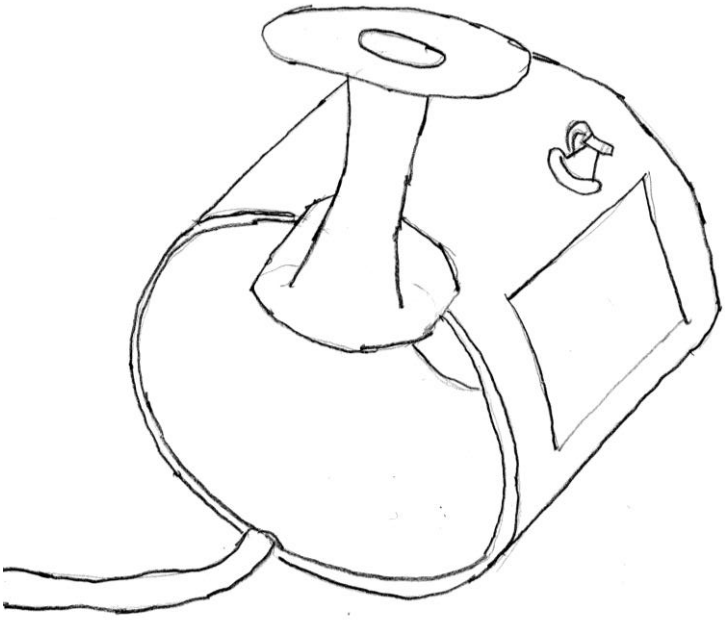
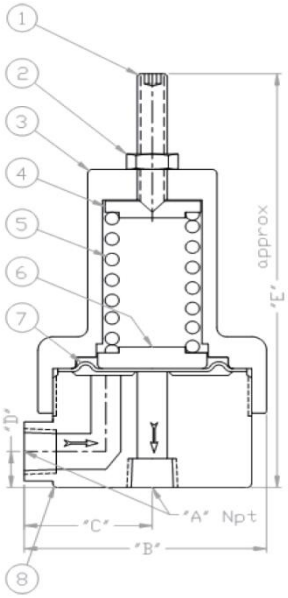


FIGURE 14: Concept Sketch of Blood Pressure Cuff with Miniature Fetoscope Attached

Pressure Relief Valve: The bulk of the engineering analysis went into the design of a pressure relief valve that opened at 140 mmHg. The design of the relief valve went through many variations. Benchmarking of valves showed that costs of applicable valves were from $20 to in excess of $145. The costs of the valves were driven by the cost of expensive valve sealing materials, such as Teflon, and robustness of the valve itself. Adjustable valves were typically for high pressure or steam applications and were more robust than what the device required. Qual Corp offers an in-line pressure relief valve for about twenty dollars with a crack pressure of 130 mmHg. A free sample of this valve was ordered and tested to prove the concept. For the purposes of the prototype, an end of line valve with a maximum pressure of 140 mmHg is required and will be manufactured.

Research and benchmarking of various pressure relief valves provided information on the general layout and workings of typical designs. The most common design consists of a spring, piston, and membrane encased in a valve body as shown in Figure 15. Gas or liquid enters through the inlet hole and pressure is applied to the exposed face of the piston. When the pressure exceeds the force applied by the spring and weight of the piston, the piston head moves upwards and the working fluid escapes through the outlet hole. Once pressure recedes to a level equal or lower than the force of the spring and piston, the valve recloses.



1. Adjusting screw Steel
2. Lock nut Steel & SS
3. Spring chamber Steel & SS
4. Spring pusher Steel & SS
5. Spring Steel & SS
6. Spring Carrier Steel & SS
7. Diaphragm Teflon/ Viton/ Buna
8. *Body 303SS or 316SS

*Body also available in PVC, Monel, Teflon, and Hastelloy (most sizes)

FIGURE 15: Most Common Type of Pressure Relief Valve [38]

The design selected for the prototyped pressure relief valve uses the method outlined above. However, a key difference is the absence of a membrane. After discussions with Dan Johnson, the team agreed that a membrane was not necessary for this application. The membrane used in other manufactured pressure relief valve is mainly for protecting the inner components of the valve from the working fluid. Air will be the input to the prototype relief valve, making the use of a membrane unnecessary.

Initially, the intent was to seal the valve using epoxy or glue. However, after interviews with Marv Cressey in the ME450 machine shop the design was altered to include the use of o-rings to seal the connection between the piston face and inlet hole, as well as, the halves of the valve body. This construction allows the valve to be opened in order to adjust the force of the spring and prevent air leaks.

Pressure Notification Mechanism: The selection of the trial an error mechanism that will be attached to the prototype will be a trial and error process. Once the team has developed a working pressure valve and can better describe the characteristics of the outlet airflow, different auditory and visual mechanisms will be mated to the valve. These devices will consist of whistles, recorders, balloons, and fans. Interviews with Professors Karl Grosh and David Dowling, at the University of Michigan, about acoustic devices persuaded the team to do trial and error testing, rather than extensive engineering parameter analysis. Both agree that this is the best approach and that the calculations required to quantitatively design an acoustic device are extremely complex. However, each professor has stated that should the team ascertain more properties of the outlet airflow, such as the pressure and flow rate, and decides to use a whistle, a rough approximation to expected sound frequencies can be made using Helmholtz resonator equations.

DESIGN

The prototype was not a full scale of the final design. Therefore, the final design is not the same as the prototype and will have different sizes and materials. The following section will describe the prototype design, the final design, and the difference between the prototype and final design. Furthermore, the description of how the final design can be validated through the prototyping.

Prototype

The prototype consists of an inflatable cuff, inflating bulb, pressure relief valve, pressure relief stopper, fetoscope, and two rubber tubing (Figure 16).

Inflatable Cuff: The cuff was constructed from an olive green cotton material. The current arm cuff in practice is constructed from nylon and is usual a blue or black color. The Cotton is an ideal material to use for the cuff because it is less expensive than nylon, durable, lightweight, and comfortable for the skin contact on the patient. The olive green color will distinct the threshold based cuff from the original cuff so healthcare workers will not mistake the two.

The cuff consists of a bladder inside and instructions on the outer surface. The bladder has two rubber tubes to connect to the pressure relief valve and the inflating bulb. The printed instructions on the outer surface of the cuff demonstrate how to operate the device. The instructions of are pictorial descriptions as well as a word description in English.

The length of the cuff is 16 inches, since the maximum arm circumference length of women in the target demographics is approximately 14 inches [15, 27]. The 2 extra inches provides enough space on the cuff to attach and secure Velcro straps, which are sewn onto the cuff. The width of the cuff measures 5.375 inches, which is based on a typical blood pressure cuff for the arm. This cuff size allows comfortable use for the patient, and also low volume and low weight so that it is compact enough for the health care worker to travel with.

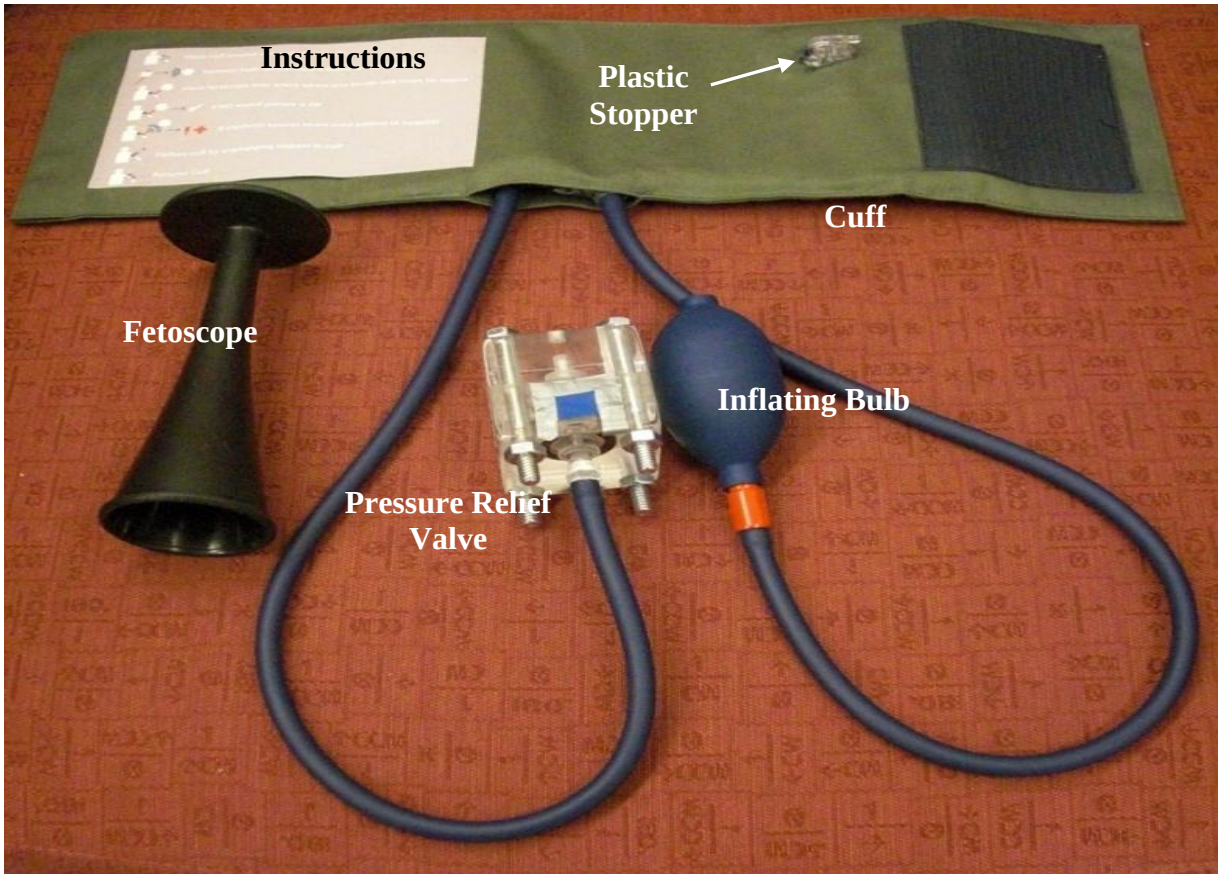


FIGURE 16: Prototype

Inflating Bulb: The inflating bulb is a modification of the bulb from a standard cuff. The standard bulb consists of a valve to open and close to release or hold air pressure (Figure 17). It is sometimes difficult to determine if the valve is closed, therefore, a user can attempt to inflate but will the cuff will not inflate. To eliminate the difficulty, as the valve was closed, the knob of the valve was removed from the inflating bulb for the prototype to ensure that bulb operates one way. Therefore, the air only flows from the bulb to the cuff, and the cuff cannot be deflated unless the user unplugs the stopper directly from the cuff. The bulb is constructed from soft rubber. The tubing is also made of rubber. The tubing has diameter of approximately 3.15 inch, and the length form the bulb to the cuff is approximately 1.5 feet, which a distance is slightly less than an arm's length away from the patient. This distance is comfortable for both the health care worker to operate and the patient to maintain comfortable space. The bulb will fit into the palm of the health care worker, so that it is easy to apply force into the pump to inflate the cuff. The approximate length of the bulb is 3.25 inches and a diameter of 1.5 inches.

FIGURE 17: Inflating Bulb with Valve[41]

Pressure Relief Valve: The pressure relief valve consists of a valve body, a load spring, and a piston. Valve body encapsulates the spring and piston. The inlet and outlet holes are machined in the valve body. The piston is made up of a piston head and a shaft, which also functions as a guide for the spring. Major parts of the pressure relief valve are in Table XX and all other parts are located in Appendix B.

PART	MANUFACTURER	PART NO.
CLEAR CAST ACRYLIC CUBE, 2" SQUARE	MCMASTER	8680K28
1/4" STEEL HEX BOLTS, 2 1/2" LONG	CARPENTER BROS.	N/A
1/4" WING NUT	CARPENTER BROS.	N/A
SOFT BUNA-N O-RING, AS568A DASH NUMBER 009	MCMASTER	4061T114
SQUARE BUNA-N O-RING, AS568A DASH NUMBER 209	MCMASTER	4061T231
ACETAL COPOLYMER ROD, 1/8" DIAMETER, WHITE	MCMASTER	8497K171
ACETAL COPOLYMER ROD, 3/8" DIAMETER, WHITE	MCMASTER	8497K11
COMPRESSION SPRING	CENTURY SPRING	A-14
CLEAR POLYCARBONATE SNGL-BARBED TUBE FITTING, ADAPTER FOR 3/16" TUBE ID X 1/16" NPT MALE PIPE	MCMASTER	5117K89

TABLE 4: Valve Part List

Valve Body: The valve body is made up of an acrylic block of 2 × 2 × 2 inch. However, after fabricating the valve dimensions were 1.94 x 1.87 x 1.94 inch. Inside the valve body a chamber of 3/8 inch diameter and 3/16 inch diameter where the piston and the spring are placed as shown in Figure 18. The valve body also consists of an inlet and outlet diameter of 0.1 inches. Two o-rings were placed around the inlet hole of the valve body to better seal from leakage. To hold the acrylic block together fours screws and bolts were used. A swedglock is placed in the inlet to connect the rubber tubing which is connected to the bladder. A piece of rubber is placed over the outlet hole to create a sound when the excess air pressure is being released.

Load Spring: This spring has a free length of 0.28 inch, a spring constant of 0.24 lbs/inch, solid length of 0.07 inch, inner diameter of 0.187 inch and outer diameter of 0.203 inch. Compressed length of the spring at the force experienced by the piston at 140 mm-Hg cuff pressure is 0.176 inch.

Piston: The piston is made up of a piston head and a shaft, which also functions as a guide for the spring. The piston is made out of acetal copolymer. The piston head has 1/8 inch thickness and a diameter of 3/8 inch. The shaft has a length of 1 inch and a diameter of 1/8 inch.

Fetoscope: The fetoscope is of plastic material with dimensions of height 14.3 cm with a diameter of 5.6 cm.

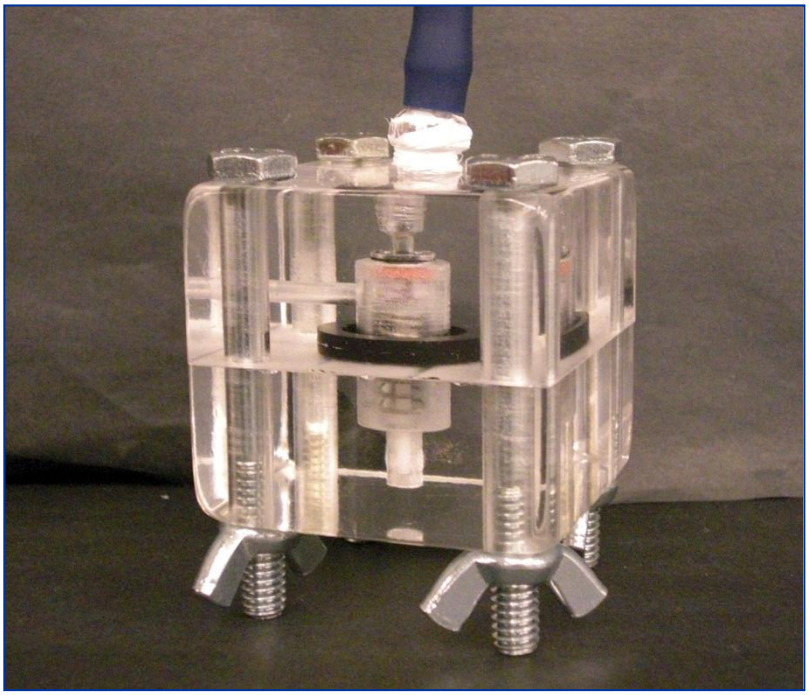


FIGURE 18: Prototype Pressure Relief

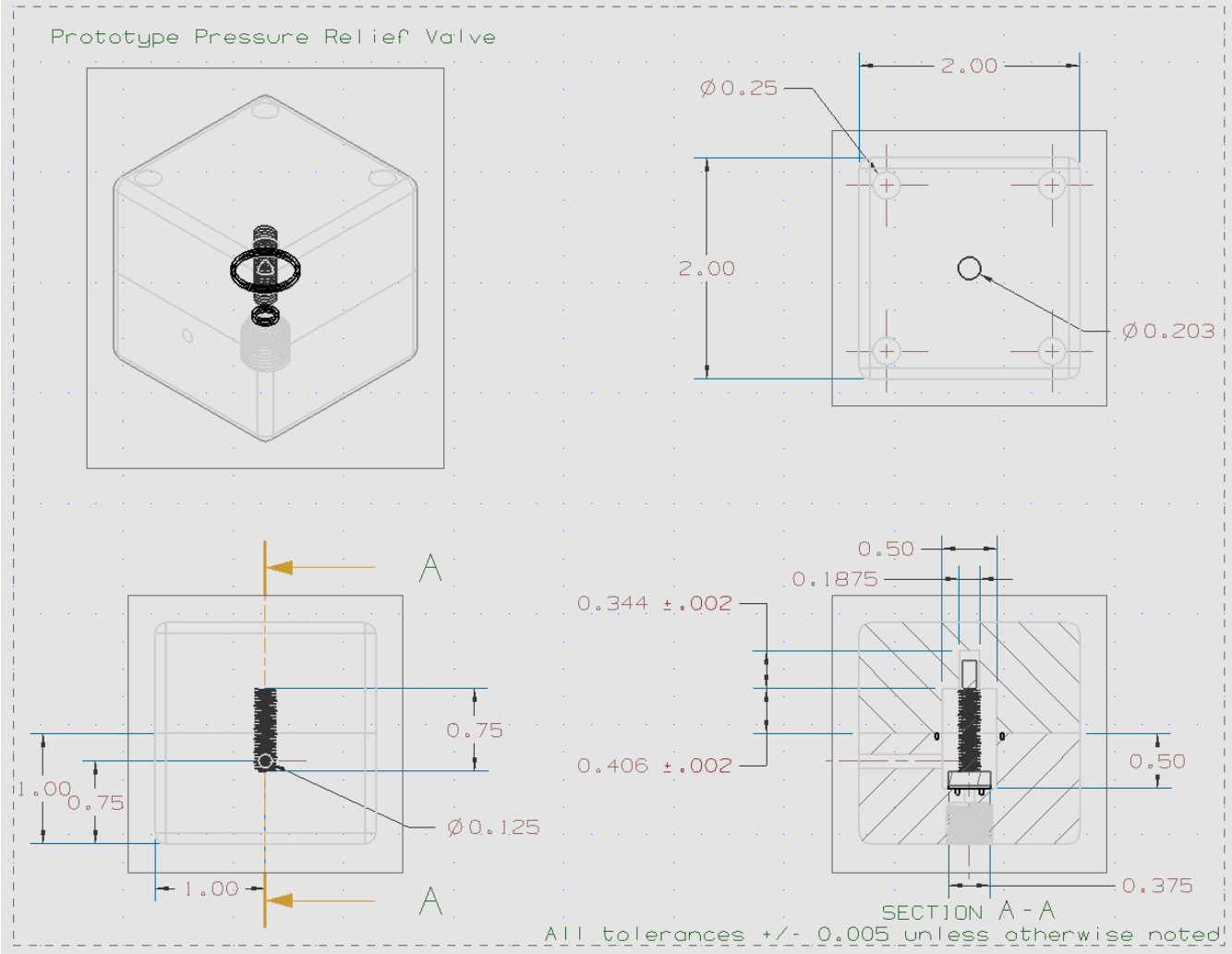


FIGURE 19: Pressure Relief Valve Dimensions

Pressure Release: In place of using the inflating bulb to release air pressure a plastic stopper was embedded to the bladder for deflation. When the plastic stopper is plugged into a soft plastic hole, a vacuum is created to maintain pressure in the cuff. When the plastic stopper is open, it will release the pressure entirely. It may be desirable for the health care worker to deflate the cuff after Korotkoff sounds have been diagnosed when the cuff can be compressed for storage. The radius of the stopper measures approximately 1 inch in diameter and 0.75 inch in height.

Final Design

The final design will resemble the prototype design in many ways. It will rely on the same engineering principles and some of the mechanisms will be the same as the prototype with small variations. For each element that will be modified from the prototype for the final design will be explained in the following section and can be referenced to the CAD drawing in Figure 20.

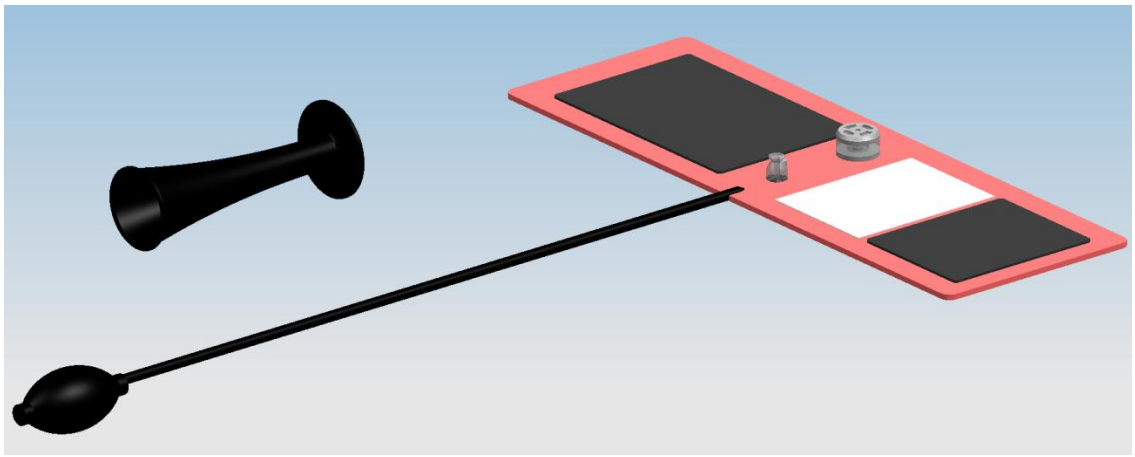


FIGURE 20: Final Design CAD Drawing

Inflating Bulb: A rubber bulb will be manufactured instead of modifying a standard bulb. The manufactured bulb will include a one way valve without an adjustable knob.

Pressure Relief Valve and Notification Mechanism: Instead of the pressure relief valve being attached to the bladder of the cuff through a rubber tube, the valve will be located on the bladder directly. Therefore, only one rubber tubing will be used to connect the inflating bulb. In addition, the pressure relief valve will be combined with a notification mechanism instead of placing a piece of rubber over the outlet. A whistle mechanism provides the ceiling to the pressure relief valve chamber. Outlet air passes through the spring and released to the whistle mechanism through a hole at the top of the chamber. Figure 21 shows the valve body and the ceiling design. A whistle mechanism will be attached to the ceiling.

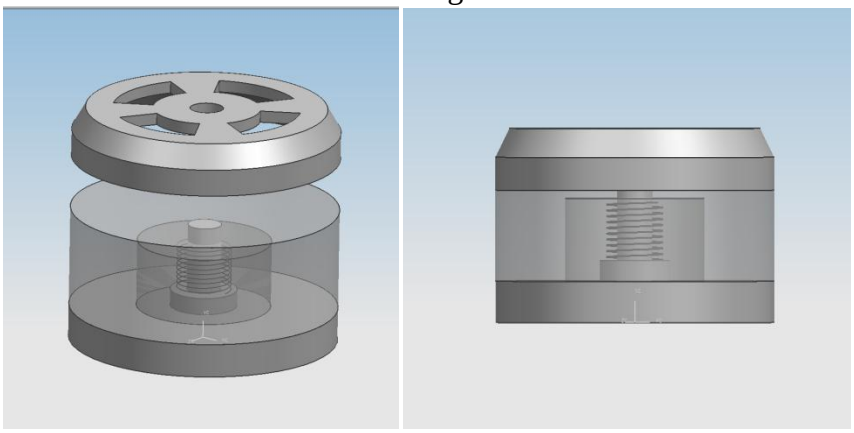


FIGURE 21: Pressure Relief and Notification Mechanism Design

Valve Body: The dimensions of the valve body will decrease to a height of 0.587 inch and diameter of 1 inch. The size also depends on the available springs that satisfy the criteria set by Equation 11. However, by having smaller dimensions the valve can be placed directly on the bladder of the cuff to make handling easier. In addition, a screw will be placed above the

chamber in order to adjust the force on the spring in case threshold based pressure needs to be changed. By adding the screw will eliminate for disassembling the device to fine tune the spring for different pressure values. Figure xxx

Piston: The piston and the valve body will be made of either polypropylene (PP) or polyvinylchloride (PVC).

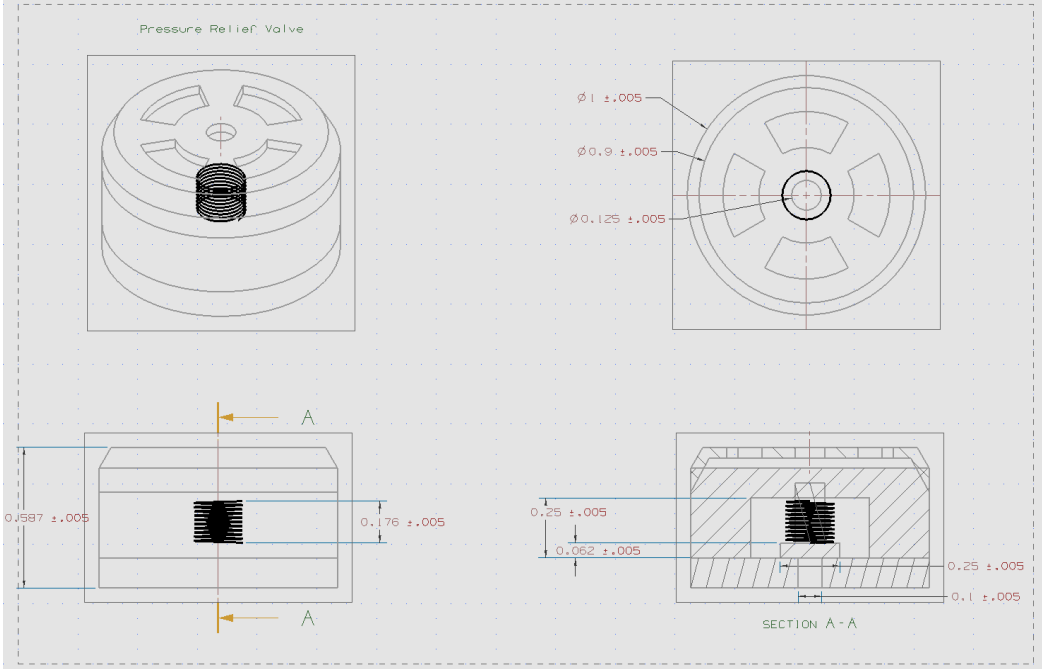


FIGURE 22: Technical Drawing of Pressure Relief and Notification Mechanism

Load Spring: For the smaller valve, a spring with the proper length must be used to ensure that the spring will work properly at 140 mmHg.

Validation: The prototyping will and will not validate the customer requirements for the final design. The prototype will validate if the pressure relief valve is a probable way of measuring pressure at a threshold for the final design. The prototype will also validate the ease of use for the final design because the procedural steps will not change.

The prototype will not validate the unit life and operations in high humidity and temperatures of the final design due to the different material selection for the final design. In addition, the

Since not all customer requirements for the final design can be validated from the prototype, the final design must further go more validation. To ensure that the final design will meet all customer requirements, the device can be validated through testing on voluntarily hypertension patients by nurses.

VALIDATION RESULTS

Subsequent to prototype fabrication, validation testing was conducted to prove that the device functionality and verify that it meets the engineering specifications. However all engineering specifications may not be validated through testing or experimenting. Some engineering specifications will be validated from engineering analysis.

Measures 140 mmHg, -0 mmHg, +10mmHg: A pressure relief valve is used in the blood pressure measurement device to allow only a systolic blood pressure of 140 mmHg of pressure to be applied, which is the determined danger threshold. The lower and upper bounds of error are -0 mmHg and +10 mmHg. These values were translated from customer requirements. Once 140 mmHg is applied the pressure relief valve will release any air to remain at a constant pressure of 140 mmHg. The lower bounds of the error is set at -0 mmHg because 140 is the definite cutoff for sending patients to the hospital. Even if the patient's blood pressure measured 135 mmHg, the healthcare worker would not find necessary to recommend pregnant women to travel great distances if they do not have hypertension. The upper bound of the error is defined to be +10 mmHg, since pressures above 140 are within the hypertensive region. To ensure that the pressure relief valve is working properly, a mercury manometer will be attached in parallel and multiple tests at different orientations will be performed to guarantee that 140 mmHg pressure is being applied and releasing the excessive air pressure above 140 mmHg. A reasonable sample size for valve accuracy testing is 730, the same number for calibration testing since the device will not be in use once the device is functional. The reasons are described more in detail in the Calibrate <1 time per year section.

There may be a small percentage of patients who may develop white coat hypertension, which is a syndrome which patients experience higher blood pressure during blood pressure measurements and may be attributed to anxiety. There is a chance that this may occur, but once the pregnant woman's blood pressure elevates, it will not drop and will then be diagnosed with preeclampsia.

1% False Alarms: A false alarm is defined as when the blood pressure device is working properly at 140 mmHg and the Korotkoff sounds can be heard, the pregnant woman will be diagnosed in the rural clinic as having high blood pressure and possibly preeclampsia. However, after traveling to the hospital to confirm the diagnosis, it is revealed that the blood pressure is below 140mmHg. Thus a false alarm has occurred. False alarms must be as low as l% because it is already inconvenient for pregnant woman to travel to the hospital and too many false alarms can discourage women from traveling to the hospital when it is necessary.

False alarms can be caused from the healthcare worker mistakenly hearing the Korotkoff sounds or the pressure valve is operating at a pressure less than 140 mmHg, which will be validated in a validation test in order to ensure that it will not. To ensure that only 1% of false alarms occur, a mercury manometer will be attached to the device and a stethoscope as well as the fetoscope will be used to hear the Korotkoff sounds. If the Korotkoff sounds are heard in the stethoscope and not in the fetoscope, this is considered as a false alarm. If the Korotkoff sounds cannot be heard in the stethoscope but heard in the fetoscope, this can also be considered as a false alarm in the

validation testing. However if the Korotkoff sounds cannot be heard or can be heard in both the stethoscope and the fetoscope this is not a false alarm.

Results from testing of 25 subjects will be included to validate <1% false alarms. Since it is not feasible to test 100 subjects, given a limiting testing pool, a quarter of 100 will be tested and the information can be extrapolated. Since a 25 people of 100 are tested, then there cannot be any false alarms. Tests will be conducted on subjects after approval has been received from IRB. In addition, the device will be tested numerous times on voluntarily hypertension patients in the Women's Hospital with no official data. Because these patients have hypertension, their blood pressure is greater than 140 mmHg. Their blood pressure will be measured once the pressure relief valve is functional, using the prototype and if the Korotkoff sounds can be heard it validates that the blood pressure measurement device is working properly. However if we cannot hear the Korotkoff sounds then this is may be considered as a false alarm.

7 Step Procedure: To verify to simplicity of the procedure, the new device was limited to a seven-step procedure for operation. The most common method of taking blood pressure measurements, with an aneroid sphygmomanometer and stethoscope, requires at least seven clearly defined steps, and the total steps of operation may even be more due to the vagueness of user judgment. The procedure of the new device involves six steps, which include

(1) Place cuff around arm and adjust to fit
(2) Squeeze bulb until a noise caused by the pressure relief valve is heard at 140 mm Hg
(3) Place fetoscope over brachial artery where arm bends and listen for sound
(4) If no sounds are heard, the patient is not hypertensive. If Korotkoff sounds are heard send patient to hospital
(5) Deflate cuff by unplugging stopper in cuff
(6) Remove cuff.

The aneroid technique with the sphygmomanometer and stethoscope require several more steps, such as the listening of Korotkoff sounds in addition to reading the gauge while releasing pressure in the cuff through a thumb valve. The goal of the threshold-based device fulfills the simplicity requirement since it requires a fewer number steps for operation.

4.5 Avg from Likert Scale for Easy to Read Measurements: A Likert scale was utilized to verify the measurements are easy to comprehend, with an average of 4.5 of easiness. Test subjects will be presented with the threshold-based device, including the fetoscope, and the device procedure was carried through the steps 1 through 3 (mentioned in Simple procedure), and the user will try to listen through the fetoscope for Korotkoff sounds as a notification of whether hypertension is present. The test subjects will then rank the clarity on a scale from 1 to 5, with 1 being very difficult to hear Korotkoff sounds and 5 being Korotkoff sounds were clearly audible through the fetoscope. After the experiment is conducted the averaged results will determine if the engineering specification of easy to read measurements has been satisfied. If the average is above 4.5, the customer requirement has been fulfilled and measurements are easy to understand.

Cuff Circumference Range of 9in-14in: The cuff must be versatile so that all it fits and is able to operate on all pregnant women. The engineering specification, which correlates to adjustability, is a circumference range of 9-14 inches. Research was conducted on the

demographics of Nigerian women, who are similar to the women of Ghana. The range of arm sizes measures 9 to 14 inches. A cuff from the threshold-based device was obtained and strapped around cylinders of different circumferences, including one of 9 inches and 14 inches, by adjusting the Velcro and the cuff was inflated to a pressure of 300 mmHg. For all instances, the Velcro remained secure around the cylinder. The cuff was concluded to be adjustable and operational at different sizes.

Put On and Off with Two Hands in 20 seconds: To validate the ease of handling the cuff, an engineering specification was implemented with the requirement that the user puts on and takes off the cuff from the patient's arm with 2 hands in 20 seconds. This number came from experiments. To validate the ease of the requirement, seven test subjects were given an arm cuff with Velcro fastenings. The test subject was then asked to put the cuff on to another person's arm and secure the cuff so it fit snugly around the arm while the test conductor recorded the time on a stopwatch. The timer was then stopped and restarted when the test subject began to take the cuff off from the patient's arm and unplugged the already deflated cuff, until the cuff was completely removed.

No Electrical Power Required: The engineering specification of no electricity required for function was straightforward and easy to validate. The device is composed of all mechanical components which do not need electrical power for operation. The main component of the device is the pressure relief valve that ensures the right amount of pressure is being applied. The pressure relief valve is mechanically powered and the other components are manually operated.

FABRICATION PLAN

The detailed fabrication plan of the prototype is discussed in this section. First, the blood pressure cuff will be purchased and altered. Next, the pressure relief valve will be machined. Note that in this section dimensions are given without tolerances for clarity. Please refer to Appendix G for drawings detailing dimensions and their associated tolerances.

Blood Pressure Cuff

The blood pressure cuff that will be used to construct the initial prototype has been obtained from CVS pharmacy. The aneroid pressure gage attached to the end of one of the tubes will be removed by pulling the connection apart. The stethoscope head which is attached to the nylon material of the cuff via a standard Phillips screw, will be removed using a screwdriver. Next, a 4" by 4" label of the blood pressure device's instructions will be printed and laminated. The label will be secured to the cuff at the position indicated using hot glue. For the purposes of the prototype the label will be written in English, but the language chosen for the final design will obviously have to be of the chosen region. Additionally, the label will include colorful, easy to understand illustrations to show the proper procedure. A student in the art department has agreed to help the team create this label. As stated previously, the hand pump will not be altered for the initial prototype because research is still being conducted on the best method of relieving the pressure at the end of the procedure. This will conclude alterations to the cuff for the initial prototype.

Figure 23: Picture of fabricated cuff

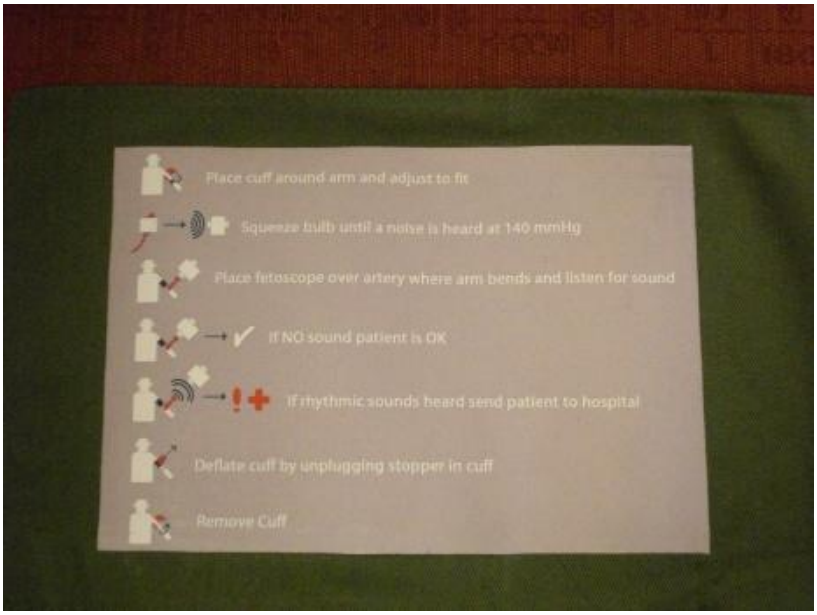


FIGURE 24: Picture of label

Pressure Relief Valve

An overview of the manufacturing process of the pressure relief valve is presented in Table 6. The following is a more in depth account of the method that will be used to fabricate the pressure relief valve of the prototype.

The main body of the pressure relief valve will be made of clear acrylic of dimensions 2”x 2”x 2”. Four 0.25” holes will be drilled through the acrylic cube in the pattern shown in Table 2, page 39. This will be done using a standard drill press. The holes will be reamed, but not threaded so that the valve body may be opened relatively quickly during the testing phase. The 0.25” screws and 0.25” wing nuts serve only to provide enough clamping force to seal the valve body. The acrylic cube will then be cut in half using a band saw. The surfaces of the resultant halves created by the band saw will likely be less flat and less smooth than the uncut surfaces. Therefore, the surfaces that were cast by the manufacture will be the surfaces which form the mating surface for the seal of the valve body.

One half of the acrylic cube is to be machined in the following manor. On the surface parallel to the surface cut by the band saw, a 0.125” wide circular trench, centered at the center of the surface, will be machined. The trench will be 0.125” deep with an inner and outer diameter of 0.5625” and 0.6250”, respectively. A center lathe will be used for this operation. Next, using an end mill, a 0.5” diameter hole, centered at the center of the cube face, will be drilled to a depth of 0.5”. An end mill has been selected to create this feature rather than a drill bit due to the fact that the flatness of the bottom of this hole will serve as the base for the piston in the closed position. To ensure proper sealing by the piston in the closed position it is critical that this surface be as flat and smooth as possible. A 0.125” diameter hole, centered at the center of the previous hole, will be drilled through the remaining thickness of the half of the cube to create the air inlet hole. The hole will be reamed to ensure a smooth surface. The mouth of this hole located on the bottom surface will be widened to 0.375”for a depth of 0.375” using a drill press. This hole will be NPT (National Pipe Thread) to ensure a leak free connection when the tubing adapter is inserted into the valve. Using a center lathe, another o-ring trench, 0.0625” wide and 0.0625” deep, will be drilled around the inlet hole. The inner and outer diameter will be 0.2187” and 0.3437”, respectively. Lastly, this half will be turned over and a 0.242” hole will be drilled and tapped to a depth of 0.375” using a drill press. This hole will be located at the center of the surface and serve as the hole where the tubing connector will be inserted. NPT thread will be used to ensure that there are no air leaks associated with the adapter. Finally, a 0.125” diameter outlet air hole will be drilled to a depth which intersects the 0.5” hole drilled for the piston chamber. The hole is located at the center of any one of the side faces.

The remaining half of the acrylic cube will be machined in the following manner. All operations are performed on the square surface uncut by the band saw and centered at the center of this surface. A 0.5” hole will be drilled to a depth of 0.40625” using an end mill operation. This time a flat bottom surface is needed to support the top of the spring. Next, a 0.1875” inch hole is drilled and reamed to a depth of 0.34375” using a drill press. This hole is the guide for the piston shaft. This will complete fabrication of the body of the pressure relief valve.

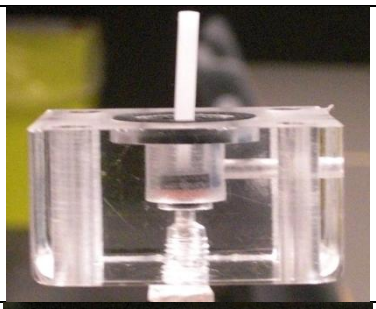
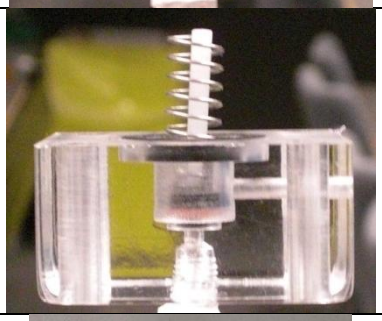
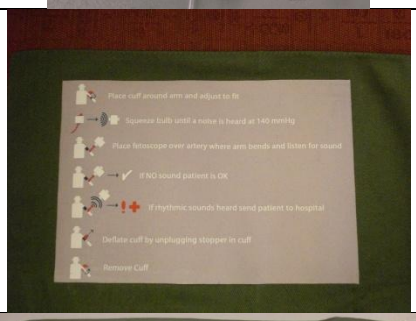
Piston and Spring.
The piston and shaft will be constructed of acetal copolymer rod stock. A 1.0" thick, 0.125" diameter rod stock will be attached to a 0.125" thick, 0.375" diameter rod stock using super glue. The spring will be purchased from Century Spring Corporation and measures 0.97' long, 0.01" wide, with an outside diameter of 0.203".

Sound Device
The auditory alert mechanism will be derived through empirical testing of various off the shelf devices. The team will purchase various types of whistles, kazoos, recorders, and other wind based acoustical devices. Empirical testing will be used to select the best mechanism (the sound which produces the loudest noise) and the team will then proceed with designing a similar mechanism that can be built into the pressure relief valve. No such detailed manufacturing plan exist for this procedure at the current stage.

Prototype Assembly
Assembly of the prototype is relatively simple. The spring is placed around the piston shaft, and super glue is used to attach the base of the spring to the back of the piston head. The piston assembly is placed inside the acrylic valve body, with the piston head centered above the inlet hole. The needed shim for adjusting the spring force is added to the top of the spring, the top halve of the valve body is placed over the end of the piston shaft, and the screws and wing nuts are used to connect the halves. The 1/16" inlet tube adapter is inserted in the base of the pressure relief valve. The free end of the tube from the blood pressure cuff is placed on the inlet adapter and is secured by frictional means. The seamstress stitches the cuff to the specifications provided in the CAD drawings. A hole is cut into the CVS cuff bladder and the plastic stopper is inserted and hot glued into place. The bladder is then placed inside the fabricated cuff. This completes assembly of the initial prototype. The prototype assembly process is also shown in Table 5 below.

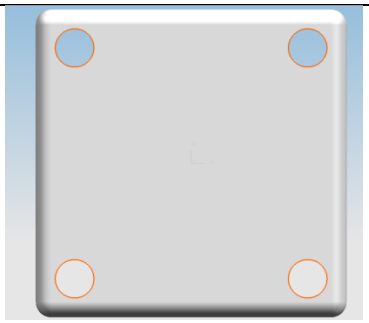
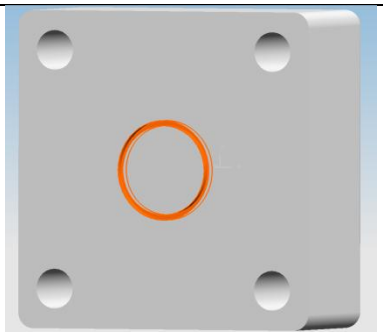
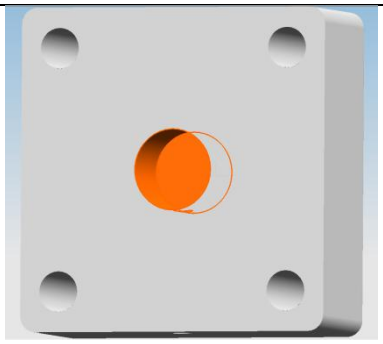
Table 5: Prototype Assembly Plan

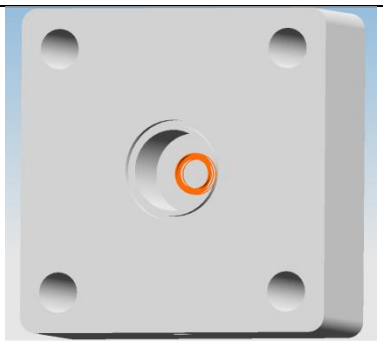
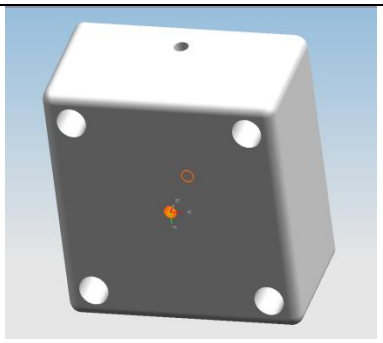
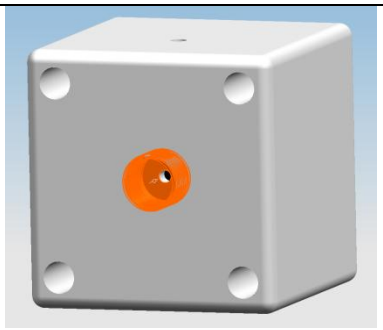
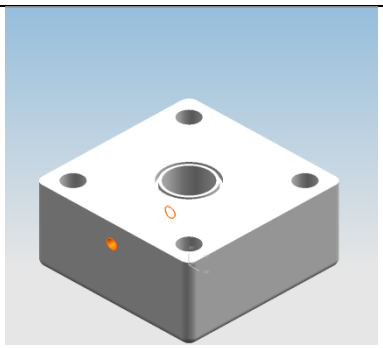
	Parts	Instruction
	Bottom half of acrylic, 1/8" o-ring, 1/16' o-ring	Press o-rings in o-ring grooves using no adhesives
	1" long 1/8" acetal copolymer shaft, 3/8" acetal copolymer head, rubber gasket material, super glue	Use super glue to combine the piston head, piston shaft, and rubber gasket material in the manner shown

	Bottom half of acrylic, assembled piston	Place piston assembly in bottom half of chamber over inlet hole
	Bottom half of acrylic, assembled piston, A-14 compression spring	Place A-14 spring around piston shaft
	Top and bottom half of acrylic, assembled piston, A-14 compression spring, ¼-20 bolts and nuts	Fasten top half of pressure valve to the bottom half using 1/4-20 bolts and nuts
	Cuff prepared by seamstress, instruction label	Iron instruction label on cuff
	Bladder from CVS cuff, hot glue, duct tape	Hot glue rubber stopper onto the bladder and with duct tape

	Cuff prepared by seamstress, bladder from CVS cuff	Insert bladder into cuff in proper orientation so that hoses come out of the insert hole and plastic stopper comes through hole in the cuff
	Assembled pressure relief valve, 1/16” NPT tubing connector, Teflon tape	Wrap 1/16” NPT tubing connect threads with Teflon tape and insert connector into pressure valve
	Hand bulb from CVS cuff, hand saw, electrical tape	Use a handsaw to cut knob off of hand bulb and wrap with electrical tape. Attach the hand bulb to the hose coming from the cuff
	Fabricated cuff, fully assembled pressure relief valve, fetoscope	The completed prototype should resemble the picture shown

Table 6: Pressure Relief Valve Fabrication Plan

Step	Machine	Tools	Procedure
	Drill Press Speed: 540 RPM	¼” Drill bit ¼” Ream Bench Vise	Drill 4 holes through acrylic cube in the indicated location
	Band saw for wood and plastic	Scribe Ruler	Cut acrylic into 2 cubes of height 1”
	CNC 3-Axis Mill Speed: 1200 RPM	1/8” End Mill Vise	Cut 1/8” wide o-ring groove to a depth of 1/8”
	Mill Speed: 1200 RPM	½” End Mill Vise	Mill ½” diameter hole a depth of ½”

	CNC 3-Axis mill Speed: 1200 RPM	1/16” End mill Vise	Cut 1/16” wide o-ring rove to a depth of 1/16”
	Drill press Speed: 540 RPM	1/8” Drill bit 1/8” Ream Bench Vise	Drill 1/8” diameter hole in indicated location to a depth of ½” Use 1/8” ream to smooth inner wall surface
	Drill press Speed: 540 RPM	0.242” Drill bit 1/16” Tap, NPT Bench Vise	Drill 0.242” diameter hole to a depth of 3/8” Tap hole using 1/16” NPT tap
	Drill press Speed: 540 RPM	1/8” Drill bit 1/8” Ream Bench Vise	Drill 1/8” diameter hole on side of bottom half in the location indicated on the drawing Use 1/8” ream to smooth inner wall surface

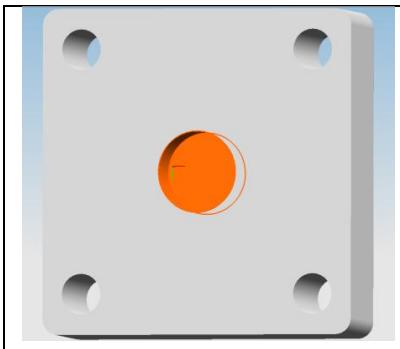
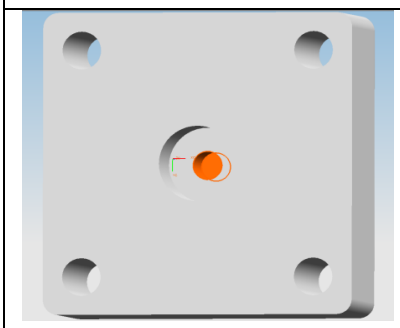
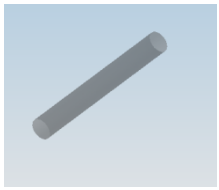
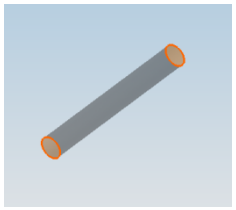
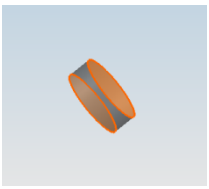
	Mill Speed: 1200 RPM	½” End mill Vise	Mill ½” diameter hole to a depth of 13/32”
	Mill Speed: 1200 RPM	3/16” End Mill Vise	Mill 3/16” diameter hole to a depth of 11/32”

Table 7: Piston Fabrication Plan

	Band saw for wood and plastic	Calipers	Measure 1/8” diameter acetal copolymer shaft to 1.0” and cut with a band saw
	Lathe Speed: 650 RPM	Tool post Turning tool 1/8” collet	Turn 1.0” long shaft on lathe and face both ends to a smooth surface
	Band saw for wood and plastic	Calipers	Measure 3/8” diameter acetal copolymer shaft to 1/8” and cut with a band saw

	Lathe Speed: 650 RPM	Tool post Turning tool 3/8” collet	Turn 1/8” long shaft on lathe and face both ends to a smooth surface

VALIDATION RESULTS

Subsequent to prototype fabrication, validation testing was conducted to prove that the device functionality and verify that it meets the engineering specifications. However all engineering specifications may not be validated through testing or experimenting. Some engineering specifications will be validated from engineering analysis.

Measures 140 mmHg, -0 mmHg, +10mmHg: A pressure relief valve is used in the blood pressure measurement device to allow only a systolic blood pressure of 140 mmHg of pressure to be applied, which is the determined danger threshold. The lower and upper bounds of error are -0 mmHg and +10 mmHg. These values were translated from customer requirements. Once 140 mmHg is applied the pressure relief valve will release any air to remain at a constant pressure of 140 mmHg. The lower bounds of the error is set at -0 mmHg because 140 is the definite cutoff for sending patients to the hospital. Even if the patient’s blood pressure measured 135 mmHg, the healthcare worker would not find necessary to recommend pregnant women to travel great distances if they do not have hypertension. The upper bound of the error is defined to be +10 mmHg, since pressures above 140 are within the hypertensive region. To ensure that the pressure relief valve is working properly, a mercury manometer will be attached in parallel and multiple tests at different orientations will be performed to guarantee that 140 mmHg pressure is being applied and releasing the excessive air pressure above 140 mmHg. A reasonable sample size for valve accuracy testing is 730, the same number for calibration testing since the device will not be in use once the device is functional. The reasons are described more in detail in the Calibrate <1 time per year section.

There may be a small percentage of patients who may develop white coat hypertension, which is a syndrome which patients experience higher blood pressure during blood pressure measurements and may be attributed to anxiety. There is a chance that this may occur, but once the pregnant woman’s blood pressure elevates, it will not drop and will then be diagnosed with preeclampsia.

1% False Alarms: A false alarm is defined as when the blood pressure device is working properly at 140 mmHg and the Korotkoff sounds can be heard, the pregnant woman will be diagnosed in the rural clinic as having high blood pressure and possibly preeclampsia. However, after traveling to the hospital to confirm the diagnosis, it is revealed that the blood pressure is below 140mmHg. Thus a false alarm has occurred. False alarms must be as low as l% because it is already inconvenient for pregnant woman to travel to the hospital and too many false alarms can discourage women from traveling to the hospital when it is necessary.

False alarms can be caused from the healthcare worker mistakenly hearing the Korotkoff sounds or the pressure valve is operating at a pressure less than 140 mmHg, which will be validated in a validation test in order to ensure that it will not. To ensure that only 1% of false alarms occur, a mercury manometer will be attached to the device and a stethoscope as well as the fetoscope will be used to hear the Korotkoff sounds. If the Korotkoff sounds are heard in the stethoscope and not in the fetoscope, this is considered as a false alarm. If the Korotkoff sounds cannot be heard in the stethoscope but heard in the fetoscope, this can also be considered as a false alarm in the validation testing. However if the Korotkoff sounds cannot be heard or can be heard in both the stethoscope and the fetoscope this is not a false alarm.

Results from testing of 25 subjects will be included to validate <1% false alarms. Since it is not feasible to test 100 subjects, given a limiting testing pool, a quarter of 100 will be tested and the information can be extrapolated. Since a 25 people of 100 are tested, then there cannot be any false alarms. Tests will be conducted on subjects after approval has been received from IRB. In addition, the device will be tested numerous times on voluntarily hypertension patients in the Women's Hospital with no official data. Because these patients have hypertension, their blood pressure is greater than 140 mmHg. Their blood pressure will be measured once the pressure relief valve is functional, using the prototype and if the Korotkoff sounds can be heard it validates that the blood pressure measurement device is working properly. However if we cannot hear the Korotkoff sounds then this is may be considered as a false alarm.

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(1) Place cuff around arm and adjust to fit
(2) Squeeze bulb until a noise caused by the pressure relief valve is heard at 140 mm Hg
(3) Place fetoscope over brachial artery where arm bends and listen for sound
(4) If no sounds are heard, the patient is not hypertensive. If Korotkoff sounds are heard send patient to hospital
(5) Deflate cuff by unplugging stopper in cuff
(6) Remove cuff.

The aneroid technique with the sphygmomanometer and stethoscope require several more steps, such as the listening of Korotkoff sounds in addition to reading the gauge while releasing pressure in the cuff through a thumb valve. The goal of the threshold-based device fulfills the simplicity requirement since it requires a fewer number steps for operation.

4.5 Avg from Likert Scale for Easy to Read Measurements: A Likert scale was utilized to verify the measurements are easy to comprehend, with an average of 4.5 of easiness. Test subjects will be presented with the threshold-based device, including the fetoscope, and the device procedure was carried through the steps 1 through 3 (mentioned in Simple procedure), and the user will try to listen through the fetoscope for Korotkoff sounds as a notification of whether hypertension is present. The test subjects will then rank the clarity on a scale from 1 to 5, with 1 being very difficult to hear Korotkoff sounds and 5 being Korotkoff sounds were clearly audible through the fetoscope. After the experiment is conducted the averaged results will

determine if the engineering specification of easy to read measurements has been satisfied. If the average is above 4.5, the customer requirement has been fulfilled and measurements are easy to understand.

Cuff Circumference Range of 9in-14in: The cuff must be versatile so that all it fits and is able to operate on all pregnant women. The engineering specification, which correlates to adjustability, is a circumference range of 9-14 inches. Research was conducted on the demographics of Nigerian women, who are similar to the women of Ghana. The range of arm sizes measures 9 to 14 inches. A cuff from the threshold-based device was obtained and strapped around cylinders of different circumferences, including one of 9 inches and 14 inches, by adjusting the Velcro and the cuff was inflated to a pressure of 300 mmHg. For all instances, the Velcro remained secure around the cylinder. The cuff was concluded to be adjustable and operational at different sizes.

Put On and Off with Two Hands in 20 seconds: To validate the ease of handling the cuff, an engineering specification was implemented with the requirement that the user puts on and takes off the cuff from the patient's arm with 2 hands in 20 seconds. This number came from experiments. To validate the ease of the requirement, seven test subjects were given an arm cuff with Velcro fastenings. The test subject was then asked to put the cuff on to another person’s arm and secure the cuff so it fit snugly around the arm while the test conductor recorded the time on a stopwatch. The timer was then stopped and restarted when the test subject began to take the cuff off from the patient’s arm and unplugged the already deflated cuff, until the cuff was completely removed.

No Electrical Power Required: The engineering specification of no electricity required for function was straightforward and easy to validate. The device is composed of all mechanical components which do not need electrical power for operation. The main component of the device is the pressure relief valve that ensures the right amount of pressure is being applied. The pressure relief valve is mechanically powered and the other components are manually operated, therefore no electricity is required to operate the blood pressure measurement device.

No Sharp Edges, No Hazardous Materials: The safety of the product was validated by the engineering specifications of no sharp edges of the device and no hazardous materials used. The most conclusive method to validate was for a test engineer to run his or her fingers across the entire device and feel for sharp edges. The prime materials used for the device are twill for the cotton, acrylic for the body of the pressure relief valve, and a rubber hose and inflatable hand pump. There are not any dangerous gas emissions associated with these materials and are safe to make skin contact with the operator and patient.

The following section discusses plans for future validation of the device, due to the nonfunctionality of the current prototype.

Measures 140 mmHg, -0 mmHg, +10mmHg: A pressure relief valve is used in the blood pressure measurement device to allow only a systolic blood pressure of 140 mmHg of pressure to be applied, which is the determined danger threshold. The lower and upper bounds of error are -0 mmHg and +10 mmHg. These values were translated from customer requirements. Once 140 mmHg is applied the pressure relief valve will release any air to remain at a constant pressure of 140 mmHg. The lower bounds of the error is set at -0 mmHg because 140 is the definite cutoff for sending patients to the hospital. Even if the patient's blood pressure measured 135 mmHg, the healthcare worker would not find necessary to recommend pregnant women to travel great distances if they do not have hypertension. The upper bound of the error is defined to be +10 mmHg, since pressures above 140 are within the hypertensive region. To ensure that the pressure relief valve is working properly, a mercury manometer will be attached in parallel and multiple tests at different orientations will be performed to guarantee that 140 mmHg pressure is being applied and releasing the excessive air pressure above 140 mmHg. A reasonable sample size for valve accuracy testing is 730, the same number for calibration testing since the device will not be in use once the device is functional. The reasons are described more in detail in the Calibrate <1 time per year section.

There may be a small percentage of patients who may develop white coat hypertension, which is a syndrome which patients experience higher blood pressure during blood pressure measurements and may be attributed to anxiety. There is a chance that this may occur, but once the pregnant woman's blood pressure elevates, it will not drop and will then be diagnosed with preeclampsia.

Low cost: The threshold-based device must be accessible to all pregnant women via health care workers, and each health care worker visiting villages should carry one. To make this possible, the cost of materials and manufacturing must remain at a minimum. The bill of materials for the prototype is included in Appendix B and the total prototype cost is approximately $70. The target price is below $7, which is the lowest price of a aneroid sphygmomanometer and stethoscope kit on the current market. However, when mass produced, the entire threshold-based device should be approximately $6.50. Through research, the materials were found to be cost efficient for the purposes the device aims to have.

Easy to transport

The Ghanaian health care workers will be transporting the blood pressure measurement device in the basket of a motorbike and may travel to several villages everyday, therefore the device should be compact in volume and weight. The engineering specifications of easy transportation were derived from the measurements of a typical sized lunch box, with dimensions 24×21×12 cm^3. The target size of the device, for ease of transportation, is having a total volume less than 24×21×12 cm^3 (12,096 cm^3) and weighing less than 500 grams, which is the typical weight of similar blood pressure measuring devices. The current pressure relief valve of the prototype measures 4.75 x4.93x4.93 cm^3 (a total of 115.5 cm^3), the cuff measures approximately 60 cm^3 when compacted folded, and the total fetoscope volume measures approximately 352.21 cm^3. The total volumes of all components add to 527.7 cm^3. The total weight of all components is 385

grams. The volume and weight of the prototyped device meets our easy to transport requirement, but will decrease once the final pressure relief valve is embedded into the cuff.

More Than 3 Years Unit Life: To ensure that the blood pressure measurement device will have a unit life of more than three years unit life, the material life of each component will be analyzed. If all material specifications exceed three years unit life, then the engineering specification is met. A typical manufacturer's guarantee of the typical aneroid method components has a lifetime of five years.

Calibrate < 1 Year: The pressure relief valve will be tested 730 times. This operational number was estimated based on the assumption there will be not more than two pregnant women from one village at a time. Each woman will have her blood pressure measured every day for one year, resulting in 2 women/day×365 days/year = 730 tests/year. If calibration is not needed then it is assumed that calibration will occur after one year.

Clean without disassembling parts in < 1 minute: To validate if the device is easy to clean, the engineering specification requires no removable parts and a maximum of one minute to wipe the superficial surfaces with a cloth. Each team member will clean it thoroughly without disassembling and timed with a stop watch to ensure that the duration time is less than 1 minute. A problem the pressure relief valve may pose is the crevice between the two halves of the acrylic valve body. If not securely sealed or enclosed, dust or dirt may become lodged within the device. However this issue will not be addressed in final design since the valve will be stowed away in the cuff.

Operates in Temperatures ≥ 40 degrees Celsius and in Humidity of 100% RH:
Since the prototype was not available for accurate testing, there were no validation tests performed for operation in high humidity and high temperature. Ghana reaches an average high of 100%RH and 40 degrees Celsius [17], and similar conditions will not be attained in local prototype testing environment. To ensure that the blood pressure measurement device can operate in such temperatures, operating temperatures of each material will be analyzed. If all operating temperatures are equal to or greater than 40 degrees Celsius, then the engineering specification for operating temperature for the device is met. In addition, for further validation, the device will be used under 40 degrees Celsius generated by a heat lamp. The parts which may be most susceptible to climate damage

Discussion
The pressure relief valve, the main component of the device, is not working as expected. Therefore, not meeting the engineering specification set for precision and accuracy. There is a leakage from the valve causing the air pressure to decrease and not maintain the set threshold pressure. The reason for the valve working improperly is due to lack of sealing in the chamber. In addition, a different spring is needed to displace a smaller distance in order for the valve to release excess air slightly above 140 mmHg +10 mmHg and maintain at 140 mmHg until the total pressure is released through the plastic stopper.

The fetoscope was taken into consideration because it is a medical instrument that is more accessible than a stethoscope in these rural areas, as well as, less expensive. Testing determined that the fetoscope could be used to listen to Korotkoff sounds in place of the stethoscope.

The procedure for using the device was validated to be easy to use. The procedure steps of the threshold based device are less than that of the standard, non electrical way of measuring blood pressure with a sphygmomanometer. The new threshold device procedure eliminates slowly opening the relief valve located on the inflating bulb, observing the sphygmomanometer for the measurements of blood pressure, and listening to the Korotkoff sounds with the stethoscope, all at the same time. In addition, the device eliminates the confusion of the relief valve on the inflating bulb being opened or closed. The new procedure is overall easier to follow and implement and meets our engineering specification of having equal or less than seven procedural steps.

The mass manufacturing cost of the final design of the blood pressure device does not meet the required engineering specification. However, the manufacturing cost is still lower than the lowest cost of blood pressure measuring devices found on the current market.

Design Critique: One of the top customer requirements for the device is requiring no electricity. There was a lot of time spent on trying to determine an electrical concept which could have been eliminated to focus on concepts that were not electrical. In addition, parameter analysis was critical and should have utilized resources given in order to confirm analysis. Specifically, the engineering analysis may benefit from further review by statics and dynamics professors. Thereby, eliminating any design errors due to calculations i.e. spring constants and chamber size that the team may have missed..

The design of the pressure relief valve can be improved to work properly with the correct pressure being applied and no leakage. A redesign of the actual valve and chamber size should increase to machine the prototype more efficiently. A scaled up version of the prototype may also help to ease the validation process. In addition, more calculations are needed to ensure the correct spring is being used to correlate with the modified size.

Furthermore, the pressure relief valve may also benefit from being made of a different material. For example, machining the valve body from a hard rubber material will most likely provide better sealing and leakage protection. The adjustable valve is the correct direction to follow. This valve greatly reduces assembly and disassembly time so that more time can be spent on testing and validation.

Recall that under the engineering specifications the team assumed a piston of negligible weight in order to minimize the piston's affect on the spring. Perhaps a heavier (denser) piston may solve the sealing issue. A combinatory effect of the piston weight force and the spring force may prove to be more effective. The team did not have time to address this concern.

RECOMMENDATIONS

It is recommended that if the device is used in the rural areas of Ghana or anywhere in desert vicinity, to take in consideration that excessive sand can affect the functionality of the pressure relief valve. Therefore, care should be taken care in the final sealing material of the valve. The cuff should not be affected by the sand.

A redundancy plan is also recommended to ensure that the device is working properly. One might drop it and not know if the device was damaged and working improperly. If a redundancy plan is implemented it will lessen the probability of the valve not working properly. Specifically, the team has discussed placing an additional pressure valve in parallel to the first to minimize the chance that the device is working improperly. More concepts should be brainstormed before instituting a final redundancy plan.

To validate that the device is working properly, it is recommended that the pressure relief valve be tested with a constant pressure source instead of the cuff and a sphygmomanometer. This will guarantee if the spring is operating at the correct pressure, as well as, if there are any leakages. The valve should be fabricated with a mechanism for adjusting the spring force. This will help to reduce time spent fine tuning the valve operation by eliminating many assembly and disassembly cycles.

CONCLUSIONS

The low-cost easy to use threshold based blood pressure measurement device has been designed to detect preeclampsia early in pregnant women. The design makes it easier to use and more cost efficient than the current blood pressure measurement devices and procedures, to benefit rural area settings. However, further design modifications are needed in order for the pressure relief valve to work properly. Once the leakage and accuracy issues have been solved the device will be ready for further validation testing. The results of the validation testing will give a better idea as to whether or not the device meets the customer requirements and engineering specifications.

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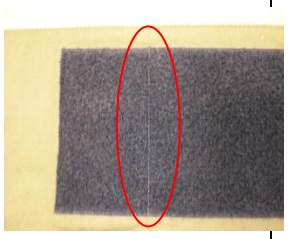
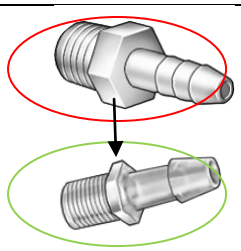
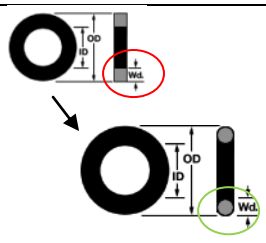
Appendix B: Bill of Materials

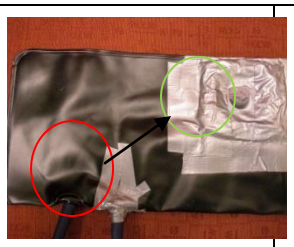
DESCRIPTION	QTY.	SOURCE	CATALOG NO.	UNIT	UNIT PRICE	TOTAL
CLEAR CAST ACRYLIC CUBE, 2" SQUARE	3	MCMASTER	8680K28	EA	8.66	25.98
18-8 SS PRECISION SHAFT SPACING SHIM, .010" THICK, .125" ID, .187" OD	1	MCMASTER	99040A310	PK	7.81	7.81
DURABLE NYLON MULTI-BARBED TUBE FITTING, ADAPTER FOR 3/16" TUBE ID X 1/4" NPT MALE PIPE	1	MCMASTER	5372K121	PK	5.28	5.28
SQUARE BUNA-N O-RING, AS568A DASH NUMBER 209	1	MCMASTER	4061T231	PK	13.82	13.82
SQUARE BUNA-N O-RING, AS568A DASH NUMBER 009	1	MCMASTER	4061T114	PK	10.48	10.48
ACETAL COPOLYMER ROD, 3/8" DIAMETER, WHITE	4	MCMASTER	8497K171	FT	0.82	3.28
ACETAL COPOLYMER ROD, 1/8" DIAMETER, WHITE	4	MCMASTER	8497K11	FT	0.41	1.64
CLEAR POLYCARBONATE SNGL-BARBED TUBE FITTING, ADAPTER FOR 3/16" TUBE ID X 1/16" NPT MALE PIPE	1	MCMASTER	5117K89	PK	7.00	7.00
18-8 SS PRECISION BEARING SPACING SHIM, .020" THICK, .167" ID, .248" OD	1	MCMASTER	93574A213	PK	7.81	7.81
HAND-OPERATED MINIATURE AIR CONTROL VALVE, SPRING RETURN,3-WAY,1/8"NPT MALE INLET,PUSH BUTTON	1	MCMASTER	62475K11	EA	9.79	9.79
ACETAL COPOLYMER ROD, 1/2" DIAMETER, WHITE	4	MCMASTER	8497K211	FT	1.35	5.40
FDA VITON(R) FLUOROELASTOMER O-RING, AS568A DASH NUMBER 010	1	MCMASTER	5577K31	PK	10.30	10.30
SOFT BUNA-N O-RING, AS568A DASH NUMBER 009	1	MCMASTER	2418T115	PK	9.40	9.40
CVS BLOOD PRESSURE MEASUREMENT CUFF	2	CVS	SKU #156062	EA	16.99	33.98
INFLATABLE SOCCER BALL	1	PARTY CITY	Item #179226	EA	1.99	1.99
FETOSCOPE	2	EBAY	N/A	EA	2.99	5.98
SEAMSTRESS LABOR TO FABRICATE BP CUFF	2	QUALITY ALTERATIONS	N/A	EA	30.00	60.00
BALLOONS	1	TARGET	N/A	PK	2.00	2.00
WHISTLES (DOLLAR TREE)	1	DOLLAR TREE	N/A	PK	1.05	1.05

ASSORTED SPRINGS FROM CARPENTER BROS.	10	CARPENTER BROS.	N/A	EA	0.69	6.90
1/4" BARBED TEE CONNECTOR FROM ACE HARDWARE	1	ACE HARDWARE	48800	EA	1.99	1.99
1/4" BARBED TEE CONNECTOR FROM CARPENTER BROS.	1	CARPENTER BROS.	N/A	EA	1.19	1.19
1/4" STEEL HEX BOLTS, 2 1/2" LONG	4	CARPENTER BROS.	N/A	EA	0.23	0.92
1/4" WING NUT	4	CARPENTER BROS.	N/A	EA	0.23	0.92
03434 SEALER, SWITCH PLATE	1	CARPENTER BROS.	264903	PK	3.79	3.79
78113 BUMPER CLEAR 1/2"	1	CARPENTER BROS.	229776	EA	2.99	2.99
CERTAIN SEAL GASKET	1	CARPENTER BROS.	DANCO88247	EA	1.99	1.99
78115 BUMPERS CLR 3/8"	1	CARPENTER BROS.	229773	EA	2.99	2.99
STRETCHABLE FABRIC TRANSFERS	1	OFFICEMAX	72782033026	PK	10.59	10.59
PRINTABLE FABRIC SHEETS (5 PK)	1	OFFICEMAX	72782033842	PK	15.15	15.15
ARMY GREEN CLASSIC TWILL COTTON FABRIC	0.375	JOANN FABRIC	400085727784	YD	7.99	3.00
WEATHERSTRIPPING	1	THE HOME DEPOT	43374025767	PK	6.14	6.14
COMPRESSION SPRING, A-14 (FREE SAMPLES)	1	CENTURY SPRING	A-14	EA	0.00	0.00
COMPRESSION SPRING, KK-50 (FREE SAMPLES)	1	CENTURY SPRING	KK-50	EA	0.00	0.00
COMPRESSION SPRING, B8-12 (FREE SAMPLES)	1	CENTURY SPRING	B8-12	EA	0.00	0.00
COMPRESSION SPRING, PP-26 (FREE SAMPLES)	1	CENTURY SPRING	PP-26	EA	0.00	0.00
COMPRESSION SPRING, 11163 (FREE SAMPLES)	1	CENTURY SPRING	11163	EA	0.00	0.00
SHIPPING	N/A	MCMASTER	N/A	N/A	N/A	12.75
SHIPPING	N/A	MCMASTER	N/A	N/A	N/A	4.25
SHIPPING	N/A	MCMASTER	N/A	N/A	N/A	8.75
SHIPPING	N/A	MCMASTER	N/A	N/A	N/A	10.50
TOTAL						**317.80**

Appendix C: Engineering Changes

The following table is a documentation of the engineering changes that were made to the prototype from DR#3 up until the end of the semester. Most of the changes were related to fabricating the prototype pressure relief valve and the blood pressure cuff. The main driver for changes to the pressure relief valve was air sealing issues.

DESCRIPTION			
WAS	**IS**	**DETAILS**	**CHANGED BY**
16” Long Blood Pressure Cuff	17” Long Blood Pressure Cuff **Why:** Provides a more secure fit		Team BP
Seamless cuff with no stitch across the width	Cuff with stitch across width in location shown **Why:** Keeps bladder from “bubbling” during inflation by dispersing the air evenly		Team BP
3/16" Tube ID X 1/4" NPT Male Pipe Connector	3/16" Tube ID X 1/16" NPT Male Pipe Connector **Why:** Tools were not available to machine the original hole		Team BP
1/16” wide o-ring with square cross section	1/16” wide o-ring with circular cross section **Why:** Research indicated that o-rings with circular cross sections performed better in dynamic applications, such as valves		Team BP
3/8” diameter acetal copolymer piston head with no gasket material	3/8” diameter PVC piston head with gasket material **Why:** Troubleshooting to resolve air leakage issues at piston and inlet hole interface		Team BP

Plastic stopper placed near hoses of bladder	Plastic stopper relocated to corner of bladder **Why:** This region of the bladder undergoes smaller strain than the previos area. Better for sealing		Team BP

Appendix D: Design Analysis Assignment

A- Material Selection Assignment

Part 1: Piston shaft

Function: Guide the spring; prevent piston head from compressing the spring beyond the elastic region.

Constraints:

Cross section diameter must be smaller than the inner diameter of the spring: $2r < 0.187$ inches

Material must resist impact when valve pops open: Ductile

Material must be easily attached to the piston head: Plastics

Objective: Minimize weight, minimize cost

Material Index:

$$m = \frac{\sigma_f}{\rho}$$

CES Selection:

Limit: Plastics

Figure 1 relates fracture toughness to density and shows the guide line with a slope of 1. 5 top materials that have the highest material index are:

-Polypropylene (PP)

-Polyamides (Nylons, PA)

-Polycarbonate (PC)

-Polyurethane (tpPUR)

-Polyethylene terephthalate (PET)

Figure 2 relates fracture toughness to cost per unit mass and shows the guide line with a slope of 1. It is seen from Figure 2 that polypropylene(PP) is the best performing material which is also at the top of the materials obtained from Figure 1.

Figure 1: Fracture toughness vs. Density

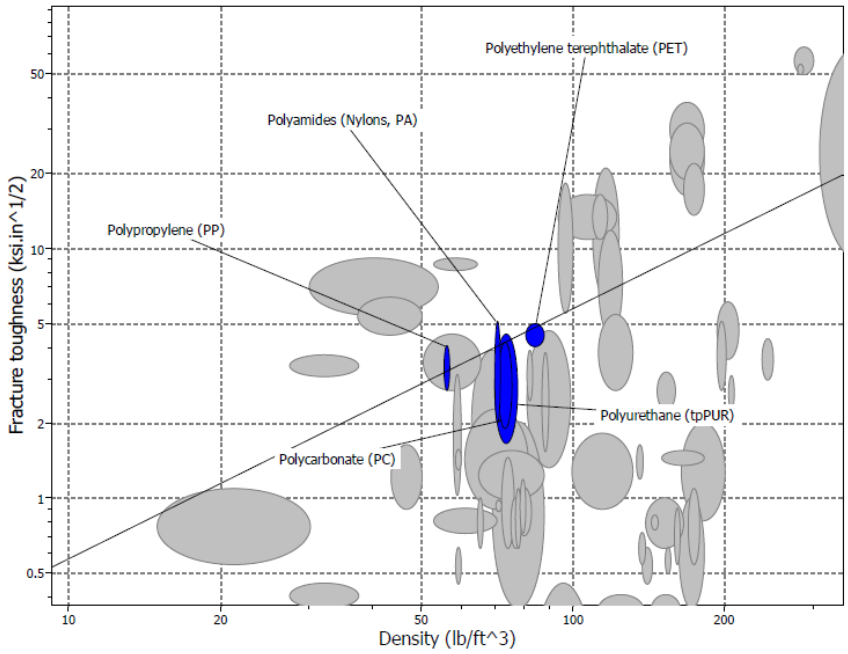
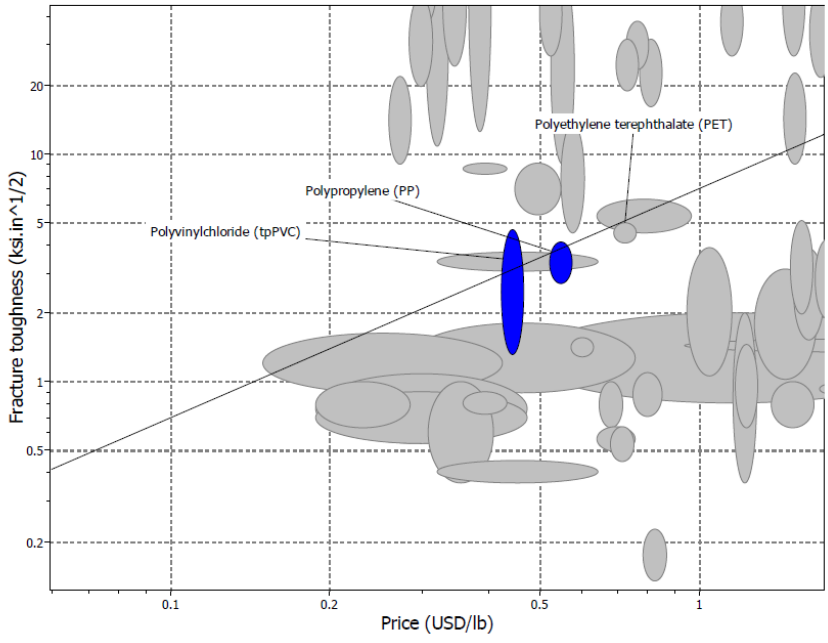


Figure 2: Fracture toughness vs. cost per unit mass



Part 2: Spring

Function: Provide force on the piston to seal the inlet hole.

Constraints:

Corrosion resistant

Flexible: High fracture toughness

Objective: maximize stored elastic energy per unit mass, minimize cost

Material Index:

$$m = \frac{\sigma_f^2}{E\rho}$$

CES Selection:

Figure 3 relates fracture toughness^2 to elastic modulus*density and shows the guide line with a slope of 0.5. 5 top materials that have the highest material index are:

-Low alloy steel

-Stainless steel

-Nickel based superalloys

-Nickel

-Nickel-chromium alloys

Figure 4 relates fracture toughness^2 to cost per unit mass*elastic modulus and shows the guide line with a slope of 0.5. It is seen from Figure 4 that low alloy steel is the best performing material, which is also at the top of the materials obtained from Figure 3.

Figure 3:

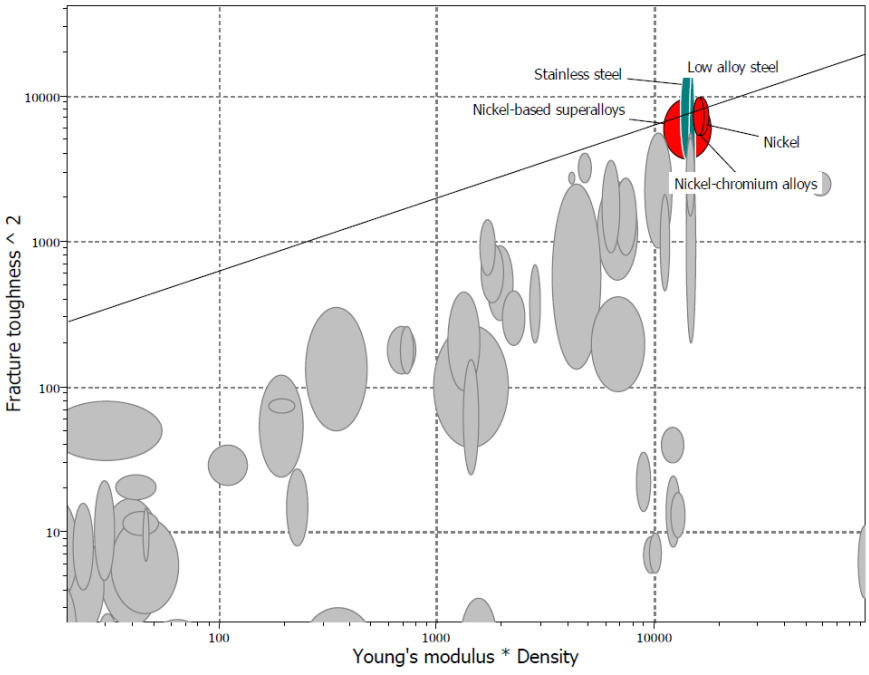
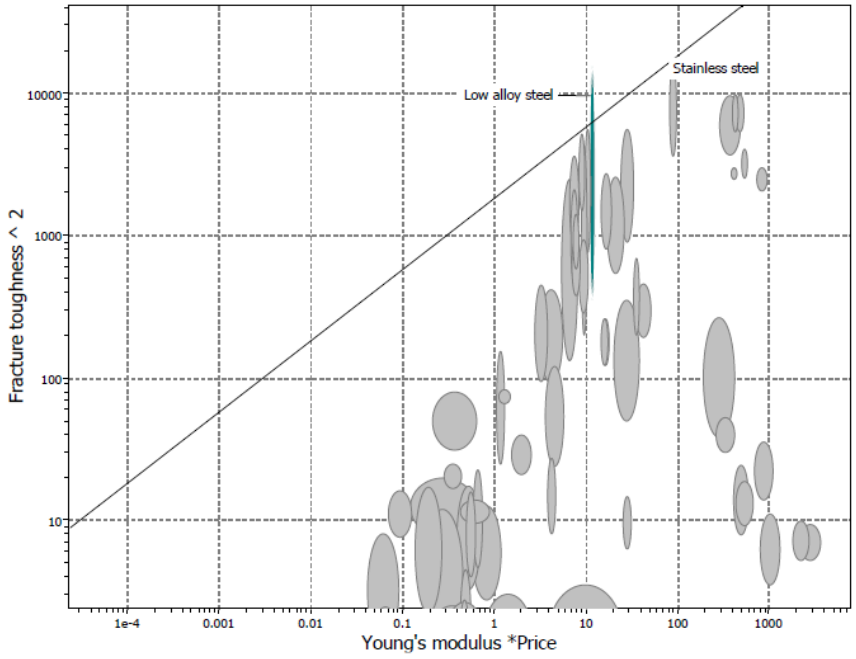


Figure 4:



B. Material Selection Assignment

Part 1: Piston Shaft, Polypropylene, Volume: $0.25 \times \pi \left(\frac{0.125}{2}\right)^2 inches^3 = 0.00307 inches^3$,

Mass: 1 x 10^{-6} pounds.

Part 2: Spring, Low alloy steel, Volume: 1.94x10^{-4} inches^3, Mass: 5.5 x 10^{-5} pounds

Figure 5: Total Masses of Emissions Generated
(units in mg)

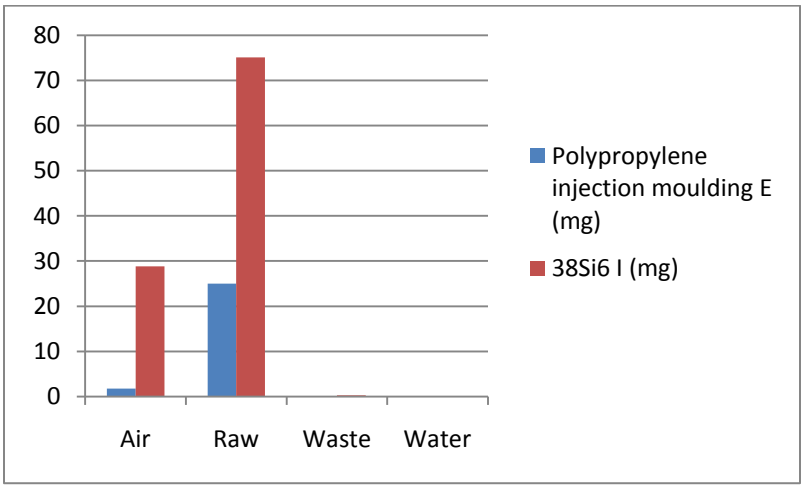


Figure 6: Relative Impacts in Disaggregated Damage Categories

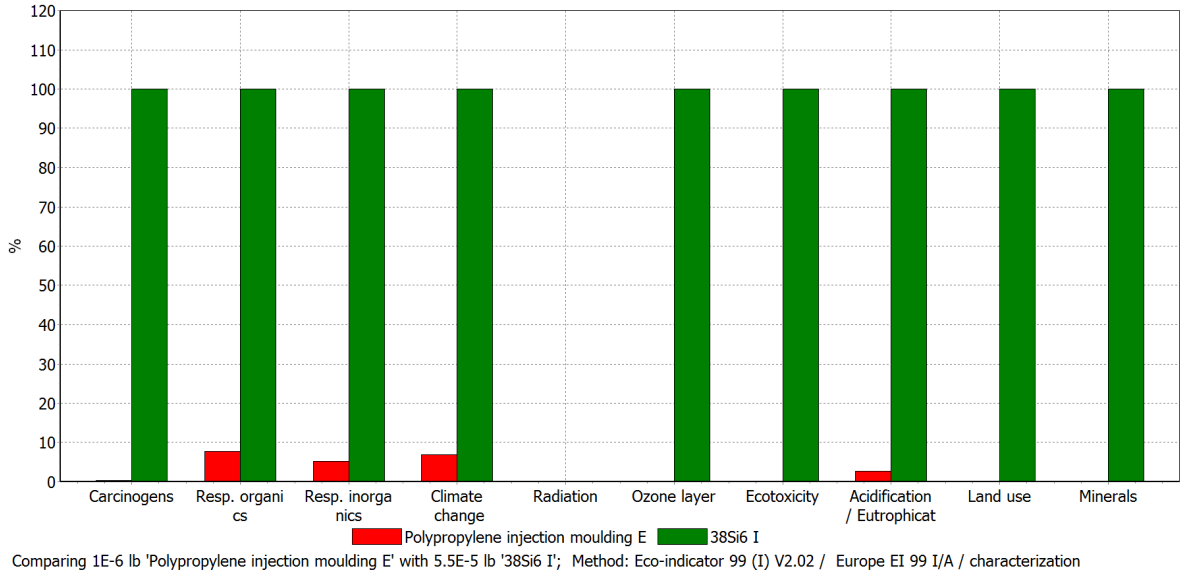


Figure 7: Normalized Scores in Human Health, Eco-Toxicity, and Resources

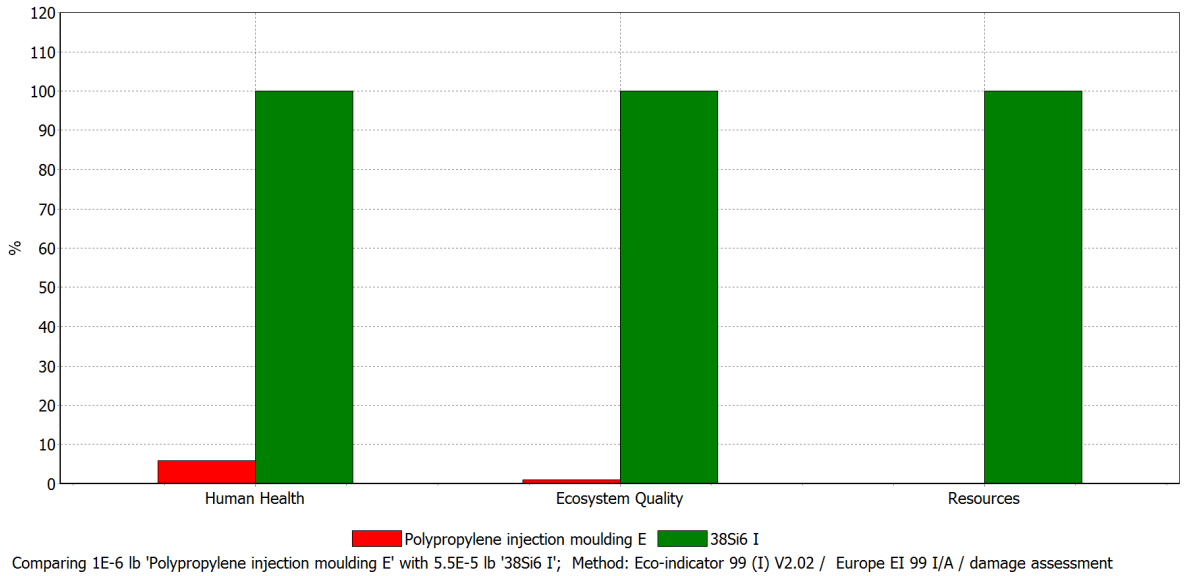
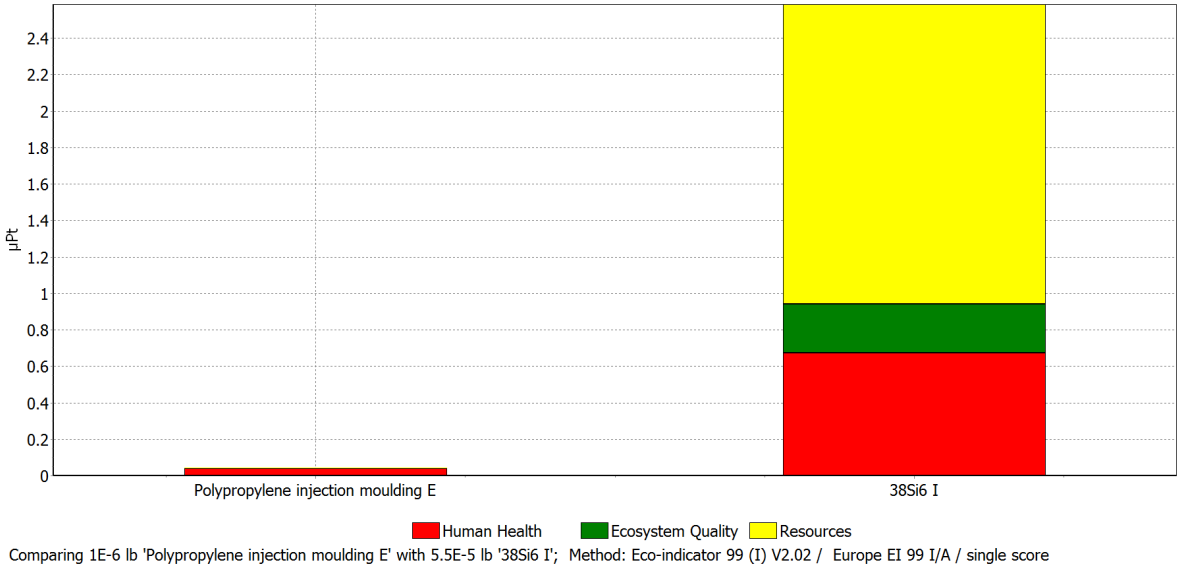


Figure 8: Single Score Comparison in Points



Simapro analysis using Eco Indicator 99 Method shows that the spring material (low alloy steel) has a much larger impact on human health, the ecosystem and natural resources than the comparably sized piston material (PP).

Although consideration of full life cycle increases the importance of the shaft material (PP), the impact low alloy steel is orders of magnitude larger than polypropylene and thus should not change the ranking compared to each other.

The most important impact of low alloy steel is resource consumption. A way to make the product more resource friendly is to redesign the product to omit the use of springs. This change would allow a drastic drop in EI99 ratings.

C. Manufacturing Process Selection Assignment

1. Potential production volume

There are 2.3 healthcare workers per 1000 people in Africa [1]. Africa has a population of 1,001,320,281 people [2]. As mentioned in the report, since the majority of preeclampsia related deaths occur in Africa, these numbers are enough to give us a potential user number of 2,303,036. An initial market penetration goal of 10% gives us 230,303 users. This translates to 230,303 units.

2.Production Methods

For part 1, the shaft:

<u>Using CES Selector with the following selection steps:</u>

-Tree: Polymers and Elastomers (as previously selected in part 1)

-Limit:

- Shape: Circular prismatic

-Surface roughness: Smooth and Very Smooth (minimize friction with the spring and chamber walls)

-Labor intensity: Low and Medium (high volume production, labor is a major cost driver)

Following methods were selected:

3-D Printing, Injection molding, polymer extrusion, resin casting

Looking at their economical batch sizes and eliminating low batch size processes gives us:

Injection molding and Polymer Extrusion

Considering that the shaft and the piston head can be made up of a single piece with injection molding, injection molding is the chosen process for this part.

For part 2, the spring:

Using CES Selector with the following selection steps:

-Tree: Metals and Alloys \ Ferrous \ Low alloy steel

-Limit:

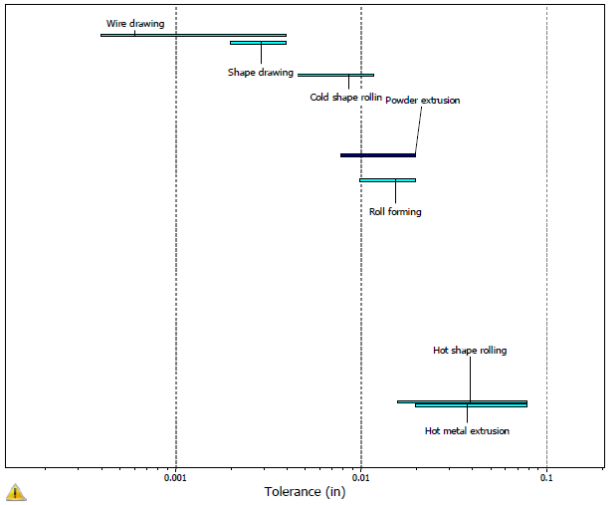
- Shape: Circular prismatic

-Range of Section Thickness: Minimum: 0.0001

-Process Characteristics: Continuous (considering high volume wire shape), primary shaping processes

-Graph: Find the best tolerance value by Graphing tolerance capabilities of selected processes.

Figure 9: Tolerance range of different processes



This analysis gives us the wire drawing as the best process to use for this operation.

References:

[1] Naicker, . "Shortage of Healthcare Workers in Developing Countries-Africa." *Ethnicity disease* 19.1 (2009): 60. Print.

[2] "Africa."Web. <http://en.wikipedia.org/wiki/Africa#Territories_and_regions>.

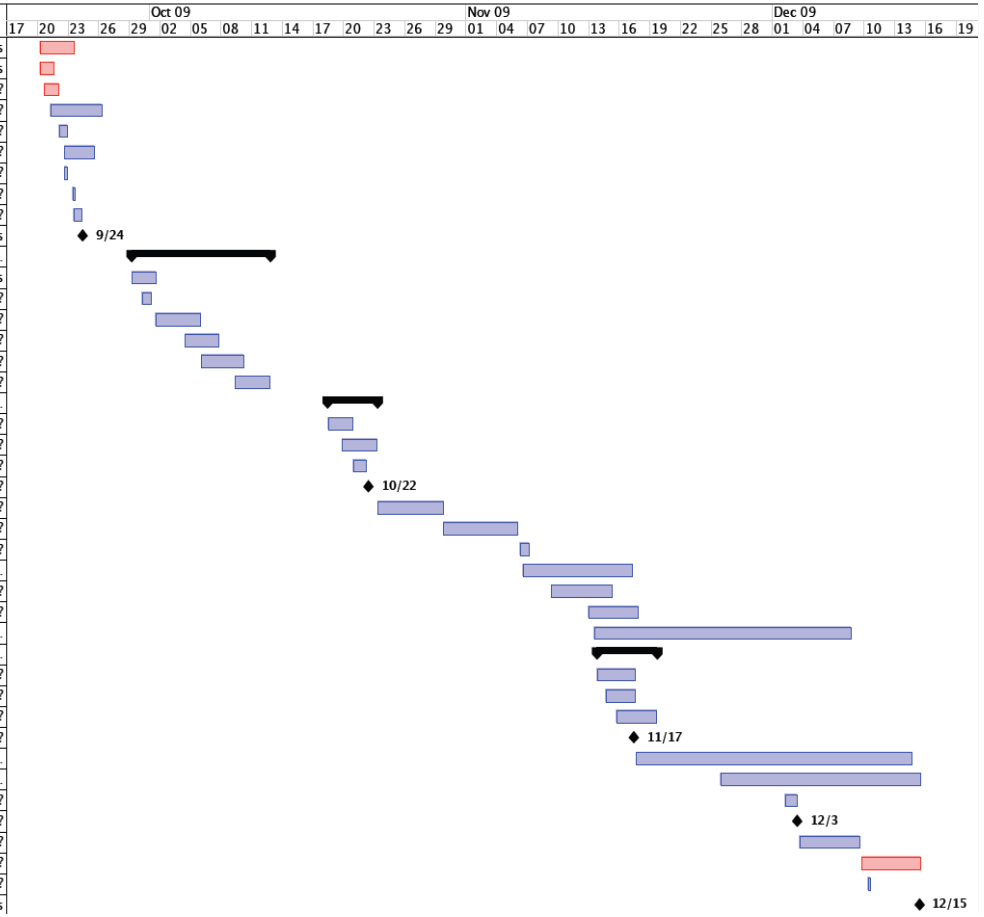
Appendix E: Blood Pressure Measurements Techniques

Method Name	Procedure	Technical Requirements	Accuracy	Reliability	Limitations	Advantages	Cost
Auscultatory	-Characterized by the use of mercury, aneroid, or hybrid sphygmomanometers -The brachial artery blocked by inflating cuff at upper arm. As the pressure is released a person listens to Korotkoff sounds with a stethoscope/microphone to determine blood pressure.	-Operator trained in the positioning of cuff and tested for auditory acuity	- Current acknowledgement that it is inaccurate due to observer bias and improper methodology (aside Hg) - Dr. Van de Ven regards method as accurate - Tends to underestimate systolic pressure and over estimate diastolic pressure	-High reliability is achieved if proper method followed with a good stethoscope -Depends on calibration	-auditory acuity -need for adequate training in proper procedure -terminal digit preferences	-high accuracy if Hg is used -wide availability	$7-$100
Oscillometric	-Characterized by the measurement of variations in pressure oscillations due to arterial wall movement under an occluding cuff -Oscillations in pressure under a sphygmomanometer cuff are measured during gradual deflation. Highest frequency recorded is MAP	-patient should remain still and resist low frequency vibrations	- Results depend heavily on manufacturer specifications, which can cause inaccurate BP measurements - Tests have shown considerable error in low side systolic measurements - Dr. Van de Ven has stated he "prefers" MAP measurement (*Need threshold)	-Excellent	-Systolic and diastolic pressure must be estimated using algorithms -algorithms vary depend on manufacturer specs -stiffness of arteries may interfere with test results	-Placement of cuff is not critical - ease of use for day to day life -minimal technical training required -less acceptable to external noise	$20-$2500
Palpatory	-a finger is used to detect a pulse at the wrist while pressure is released from a cuff placed around the upper arm -same as auscultatory only pulse is searched for instead of Korotkoff sounds	-finger placement over the artery is crucial to obtaining accurate BP -a method MUST be developed that is easy to use, accurate, and reliable	-low accuracy due to estimation of pressure from pulse rather than sound - typically you can hear the flow of blood before you can feel a pulse	-low (estimation)	-Diastolic pressure cannot be obtained by this method	-helps avoid overestimation of systolic pressure -more comfortable cuff pressure than other cuff methods -can detect auscultatory gap -no stethoscope required	$7-$100
Tonometry	-an array of transducers is placed across the artery (usually at the wrist) to measure pulsations and convert this information into pressure measurements	-clinician/patient must be trained in the positioning of the transducer because the technique is highly position sensitive	-inaccurate results may be obtained from improper placement of the device over the radial artery	-low reliability due to the fact that one must calibrate for each individual and place the device directly over the center of the artery	-not suitable for clinical use because each transducer array must be calibrated for each individual patient	-lightweight -measurements can be taken at the finger tip	$50-$300
Ultrasound	-an ultrasound transmitter and receiver is placed inside a cuff over the brachial artery - as the cuff deflates movement of the arterial wall at systolic pressure causes a Doppler phase shift and the diminishing of the movement of the walls represents the diastolic pressure	-knowledge of ultrasounds and wave phenomena -reliable ultrasound transmitter and receiver -method for analyzing received signals	-high accuracy as one can 'see' the blood as it begins to flow through the artery (systolic pressure)	-moderately high	-elasticity of the arterial walls -price increases with portability of ultrasound equipment	-useful in measuring blood pressure in patients with very faint Korotkoff sounds (muscular atrophy)	$400-???

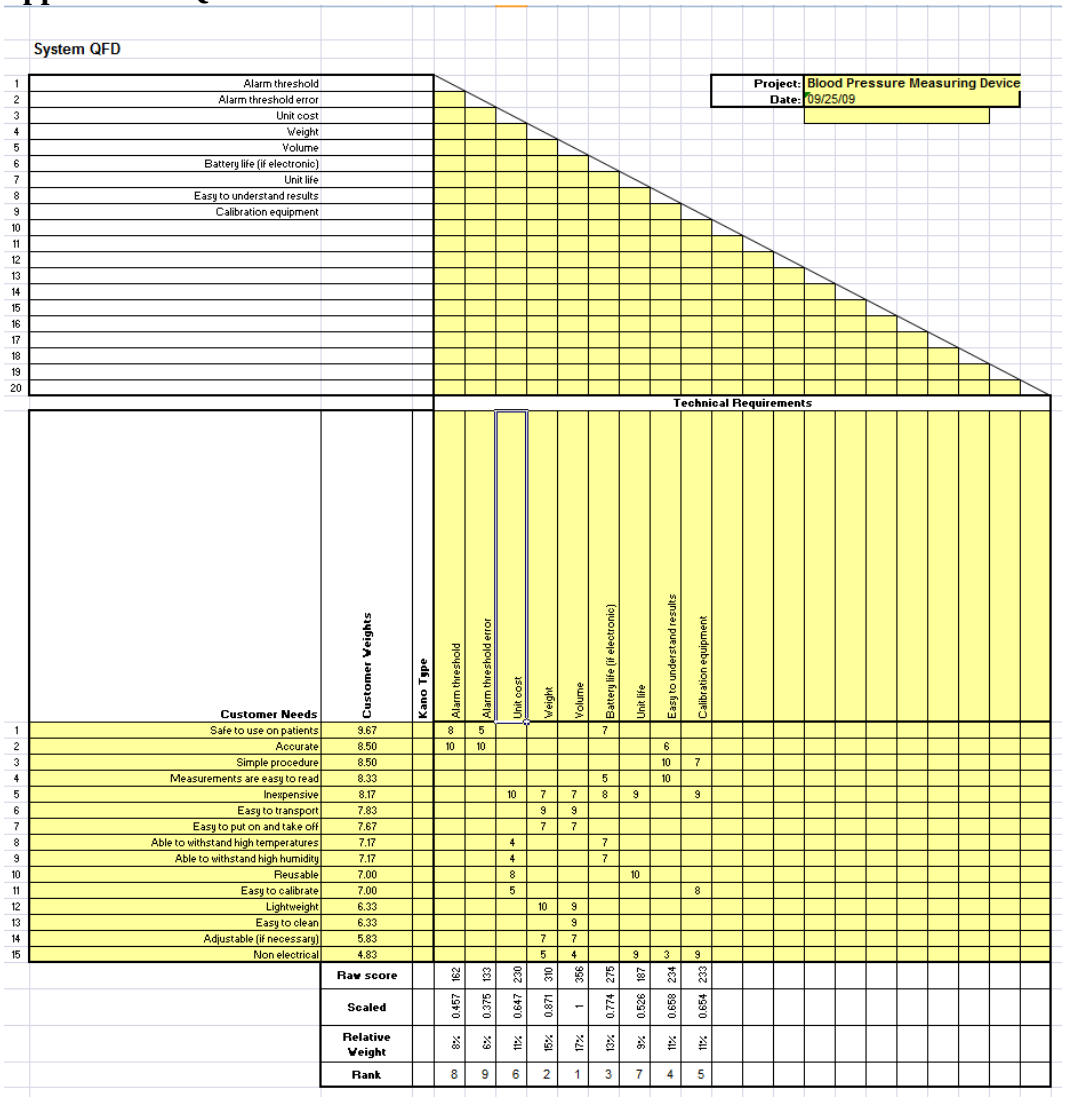
"Recommendations for Blood Pressure Measurement in Humans and Experimental Animals." American Heart Association, 2009. <http://hyper.ahajournals.org/cgi/content/full/45/1/142> 20 Dec 2004.

Appendix F: Gnatt Chart

		Name	Start	Finish	Duration
7		Research on Preeclampsia	9/20/09 8:00 AM	9/23/09 5:00 PM	3.375 days
8		Market Research on Existing BP Devices	9/20/09 8:00 AM	9/21/09 5:00 PM	1.375 days
9		Gather information on Potential User Profiles	9/20/09 5:00 PM	9/22/09 5:00 AM	1.5 days?
23		Get Feedback for Top Concepts	9/21/09 8:00 AM	9/26/09 10:00 AM	5.083 days?
10		Determine Initial Customer Requirements and Eng...	9/22/09 4:00 AM	9/23/09 12:00 AM	0.833 days?
12		Write DR 1 Report	9/22/09 5:00 PM	9/25/09 5:00 PM	3 days?
13		Prepare Powerpoint Presentation for DR 1	9/22/09 5:00 PM	9/23/09 12:00 AM	0.292 days?
11		Prepare the Initial QFD	9/23/09 1:00 PM	9/23/09 6:00 PM	0.208 days?
14		Practice DR 1 Presentation	9/23/09 3:00 PM	9/24/09 1:00 PM	0.917 days?
1		Design Review 1	9/24/09 1:00 PM	9/24/09 1:00 PM	0 days
15		**Initial Design Process**	**9/29/09 6:00 AM**	**10/12/09 10:00 PM**	**13.667 d...**
16		Team Brainstorming for Alpha Design	9/29/09 6:00 AM	10/1/09 5:00 PM	2.458 days
21		Engineering Analysis of the Alpha Design	9/30/09 8:00 AM	10/1/09 8:00 AM	1 day?
17		Individual Brainstorming for Alpha Design	10/1/09 2:00 PM	10/6/09 3:00 AM	4.542 days?
18		Team Meetings and Individual Concept Feedback	10/4/09 11:00 AM	10/7/09 9:00 PM	3.417 days?
19		Refine Concepts	10/6/09 3:00 AM	10/10/09 7:00 AM	4.167 days?
20		Pugh Chart and Go-No Go Analysis of Top 3 Co...	10/9/09 10:00 AM	10/12/09 10:00 PM	3.5 days?
24		**Prepare Design Review 2 Deliverables**	**10/18/09 11:00 AM**	**10/23/09 9:00 AM**	**4.917 day...**
26		Prepare Powerpoint Presentation for DR 2	10/18/09 11:00 AM	10/20/09 11:00 PM	2.5 days?
25		Write DR 2 Report	10/19/09 10:00 PM	10/23/09 9:00 AM	3.458 days?
27		Practice DR 2 Presentation	10/21/09 1:00 AM	10/22/09 6:00 AM	1.208 days?
2		Design Review 2	10/22/09 1:00 PM	10/22/09 1:00 PM	0 days?
28		Engineering Analysis of the Alpha Design	10/23/09 10:00 AM	10/29/09 10:00 PM	6.5 days?
30		Patent Research and Brainstorming for Beta Design	10/29/09 7:00 PM	11/6/09 4:00 AM	7.375 days?
22		Go – No Go Analysis on Beta Design Alternatives	11/6/09 7:00 AM	11/7/09 7:00 AM	1 day?
32		Parameter Analysis of the Beta (Prototype) Design	11/6/09 2:00 PM	11/17/09 9:00 AM	10.792 d...
29		Manufacturing Plan Preparation	11/9/09 10:00 AM	11/15/09 10:00 AM	6 days?
31		Safety Plan Preparation	11/13/09 1:00 AM	11/18/09 12:00 AM	4.958 days?
39		Order Parts	11/13/09 2:00 PM	12/8/09 6:00 PM	25.167 d...
33		**Prepare Design Review 3 Deliverables**	**11/13/09 9:00 PM**	**11/19/09 7:00 PM**	**5.917 day...**
34		Practice DR 3 Presentation	11/13/09 9:00 PM	11/17/09 5:00 PM	3.833 days?
35		Prepare Powerpoint Presentation for DR 3	11/14/09 5:00 PM	11/17/09 5:00 PM	3 days?
36		Write DR 3 Report	11/15/09 7:00 PM	11/19/09 7:00 PM	4 days?
3		Design Review 3	11/17/09 1:00 PM	11/17/09 1:00 PM	0 days?
37		Manufacturing	11/17/09 5:00 PM	12/14/09 7:00 PM	27.083 d...
38		Testing	11/25/09 11:00 PM	12/15/09 2:00 PM	19.625 d...
40		Practice DR 4 Presentation	12/2/09 8:00 AM	12/3/09 1:00 PM	1.208 days?
4		Design Review 4	12/3/09 1:00 PM	12/3/09 1:00 PM	0 days?
41		Design Expo Preparation	12/3/09 5:00 PM	12/9/09 5:00 PM	6 days?
42		Write Final Report	12/9/09 7:00 PM	12/15/09 3:00 PM	5.833 days?
5		Design Expo	12/10/09 10:00 AM	12/10/09 5:00 PM	0.292 days?
6		Final Report	12/15/09 12:00 PM	12/15/09 12:00 PM	0 days



Appendix G: QFD



System QFD

Project:	Blood Pressure Measuring Device	
Date:	09/25/09	

Technical Requirements

	Customer Needs	Customer Weights	Kano Type	Alarm threshold	Alarm threshold error	Unit cost	Weight	Volume	Battery life (if electronic)	Unit life	Easy to understand results	Calibration equipment
1	Safe to use on patients	9.67		8	5				7			
2	Accurate	8.50		10	10						6	
3	Simple procedure	8.50									10	7
4	Measurements are easy to read	8.33							5		10	
5	Inexpensive	8.17				10	7	7	8	9		9
6	Easy to transport	7.83					9	9				
7	Easy to put on and take off	7.67					7	7				
8	Able to withstand high temperatures	7.17				4			7			
9	Able to withstand high humidity	7.17				4			7			
10	Reusable	7.00				8				10		
11	Easy to calibrate	7.00				5						8
12	Lightweight	6.33					10	9				
13	Easy to clean	6.33						9				
14	Adjustable (if necessary)	5.83					7	7				
15	Non electrical	4.83					5	4		9	3	9
	Raw score			162	133	230	310	396	275	187	234	233
	Scaled			0.457	0.375	0.647	0.871	1	0.774	0.526	0.658	0.654
	Relative Weight			8%	6%	11%	15%	17%	13%	9%	11%	11%
	Rank			8	9	6	2	1	3	7	4	5

Appendix H: Customer Survey

User Requirements		**Importance (1-10 Scale) (1=Less Important, 10=Very Important)**
Accurate		
Reliable		
Inexpensive		
Has storage capabilities		
Reusable		
Requires no electricity		
Safe to use on patients		
Easy to use	Simple procedure	
	Measurements are easy to read	
	Easy to put on and off	
	Adjustable (if necessary)	
Easy to Transport	Lightweight	
	Low volume	
Easy to maintain	Easy to clean	
	Easy to transport	
	Easy to calibrate or requires no calibration	
Durable	Can withstand high temperatures	
	Can withstand high humidity	
Other		
Please add any other elements you think is necessary for this product		

Appendix I: Generated Concepts

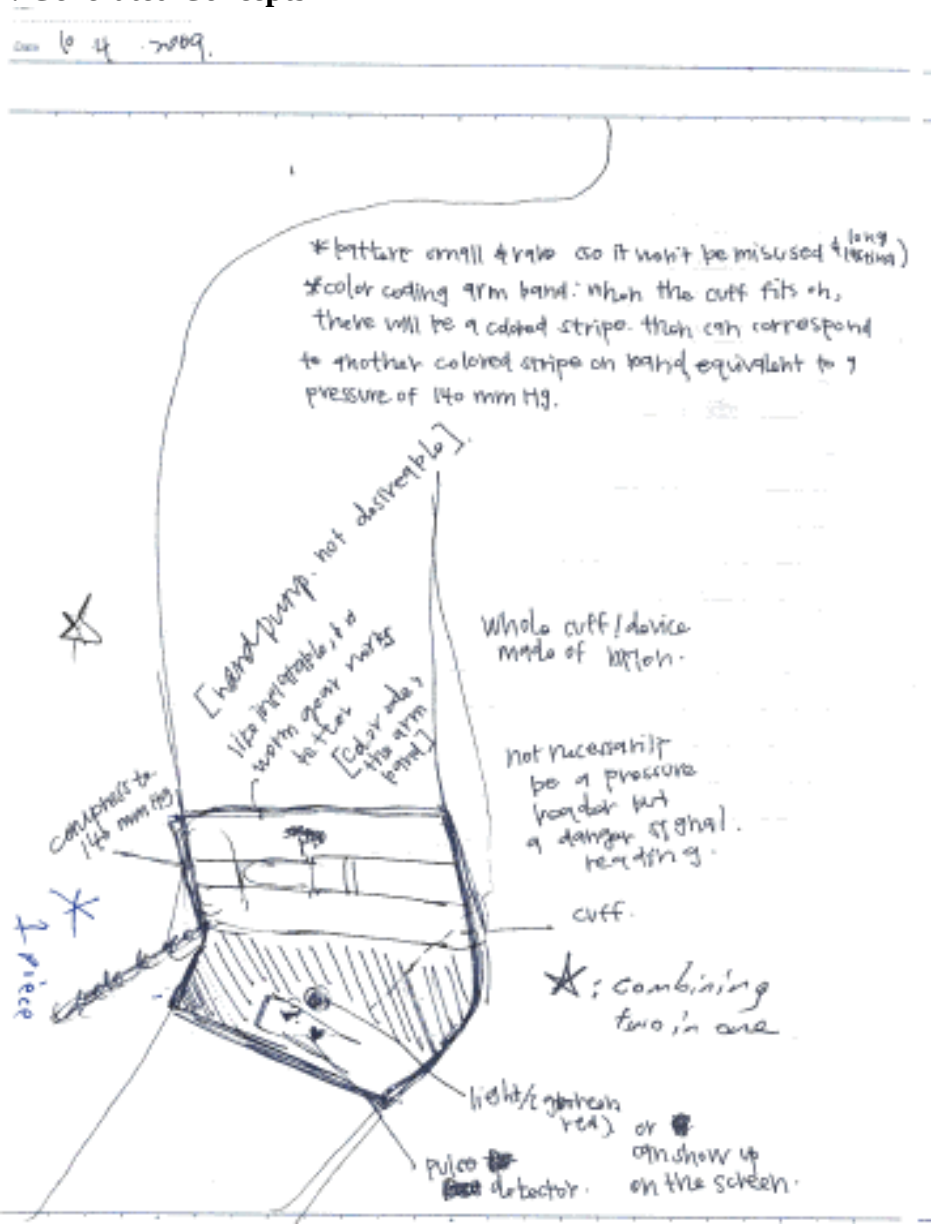


Figure 1: This concept is a one piece device which has a tightening mechanism above the elbow and a pulse sensor below the elbow, all connected by a piece of nylon or other elastic material. The top part could have a worm gear concept or adjustable elastic band, which can be tightened to a force equivalent to 140 mm Hg. The lower part would be battery operated and when the pressure is applied, the pulse detector can indicate if there is blood flow through the forearm. If there is a pulse detected, then it is a "red light" meaning that the blood pressure has reached the danger threshold.

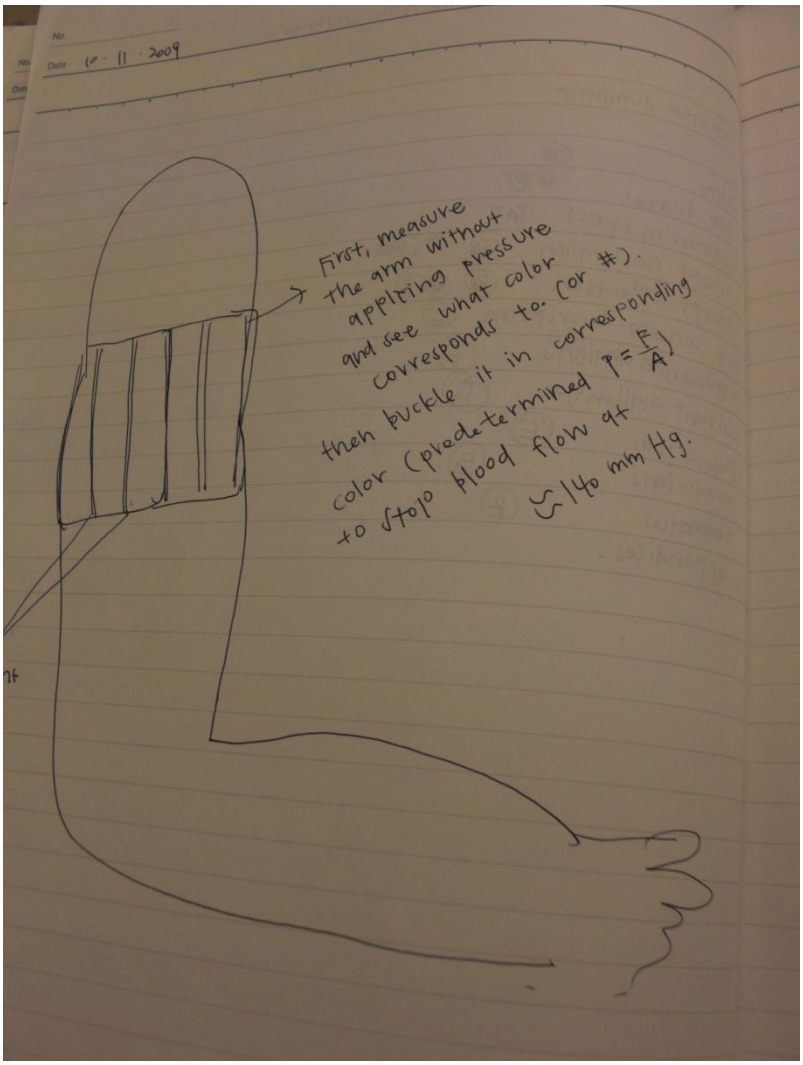


Figure 2: A pressure concept: This device, made from a strong yet elastic material, is applied to the upper arm. First, use the cuff to wrap loosely around the patient's arm, for the purpose of measuring the arm width, and note which color (or other indicator) the end of the cuff lies on when wrapped around. Then, buckle or tighten the band to the corresponding color (or indicator) on the band. The location is predetermined on the arm band by the equation: Force=(Pressure/Area), and we know the desired pressure (140 mm Hg), and to determine the corresponding location, area (radius of the arm) should be measured first. This cuff will be manually adjusted to a force equivalent to a pressure of 140 mm Hg.

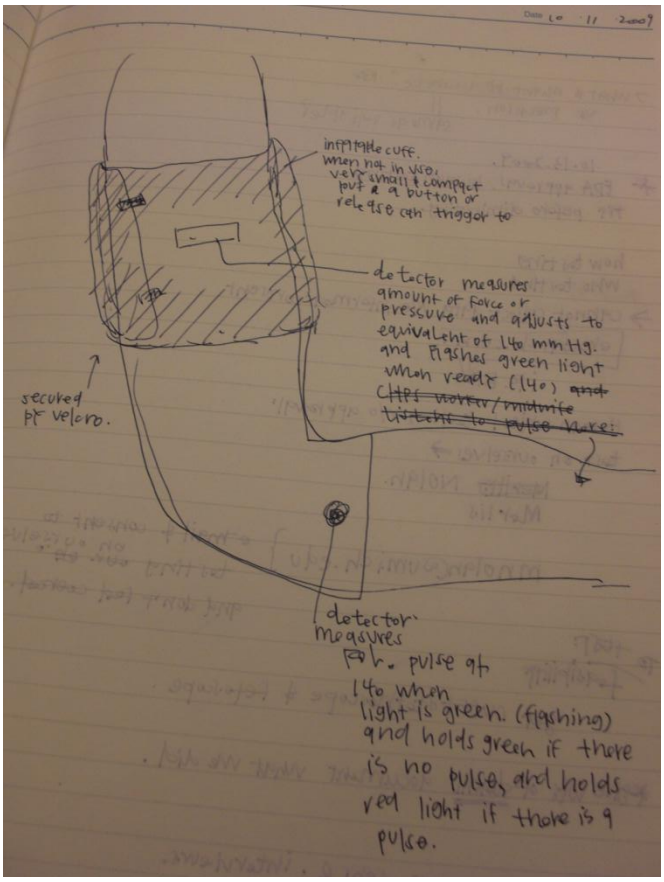


Figure 3: This design shows concepts for both arm compression and blood flow measurement. When not in use, the self inflatable cuff is very small and compact. Since this device is battery operated, a button or switch on the cuff will trigger the cuff to inflate automatically to a pressure of 140 mm Hg. On the arm cuff there is a detector which measures the amount of force/pressure and when 140 mm Hg has been reached, a blinking light will indicate that the pulse will be measured. At this time, if there is a pulse detected, the flashing light will become a continuous red light, and if there is no detectable pulse, then the light will be held at a constant green light.

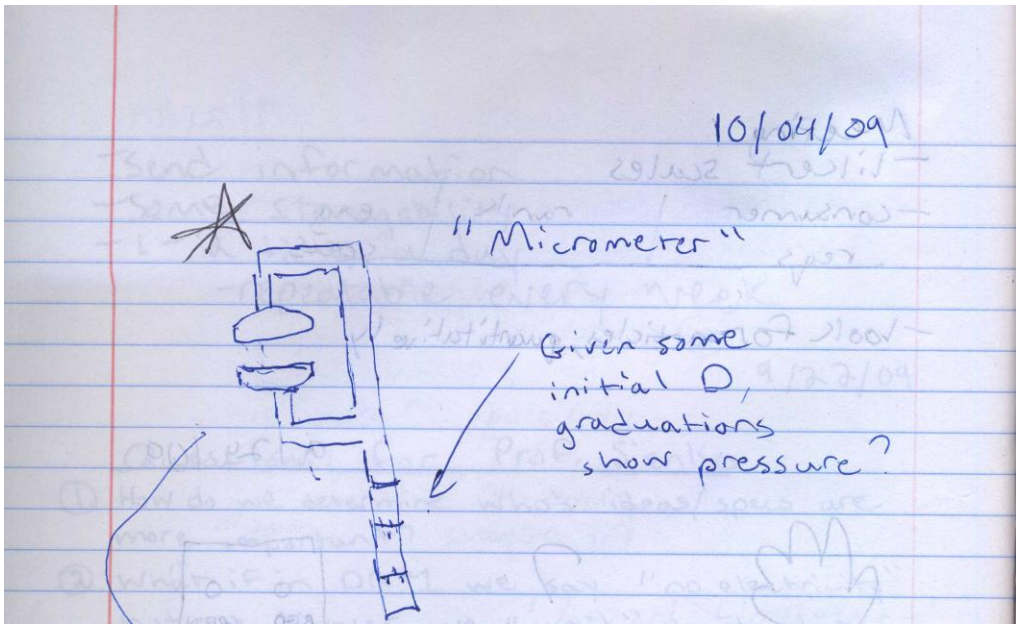


Figure 4: Micrometer-This device used to apply pressure is based on the design of a micrometer. The handle would be turned and the jaws would close around the arm or wrist to apply pressure. Based on an initial diameter the handle would already be calibrated to let the user know the pressure applied.

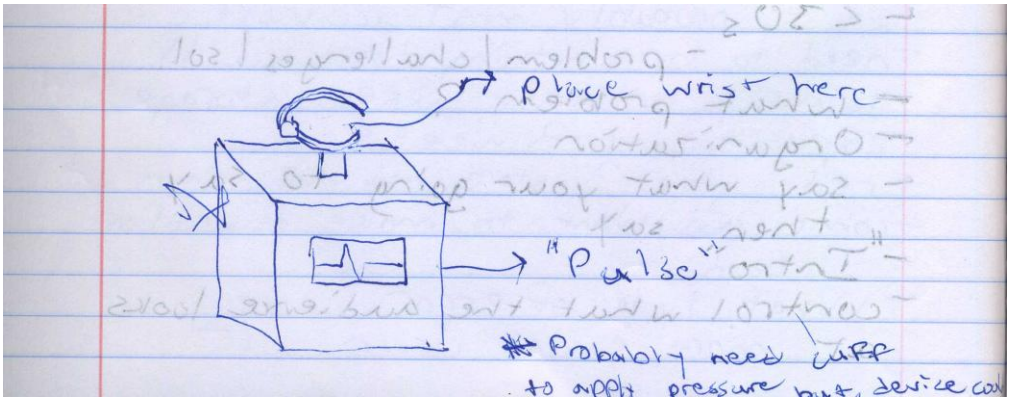


Figure 5: All in one box- The box would have a mechanism to apply pressure and would use the oscillometric technique to determine blood pressure. It is an electric device.

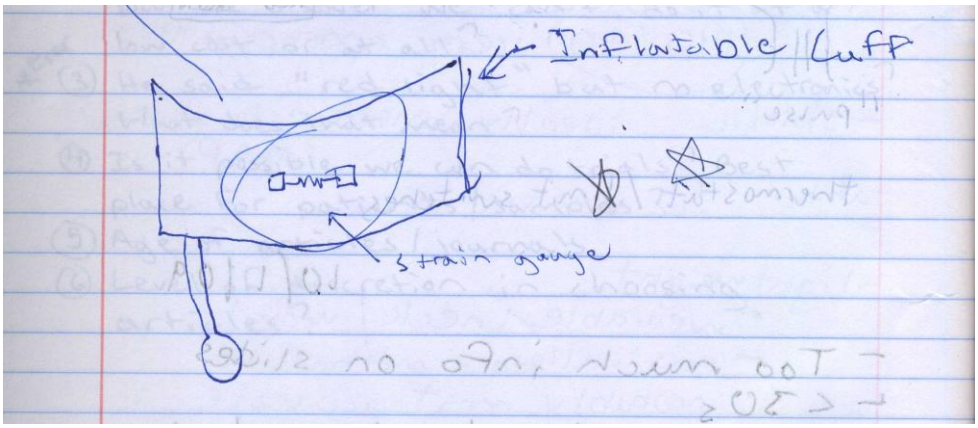


Figure 6: Inflatable cuff with a strain gauge- The cuff would be inflated using a hand pump, and a strain gauge is used to show a pressure reading on a pre-calibrated scale.

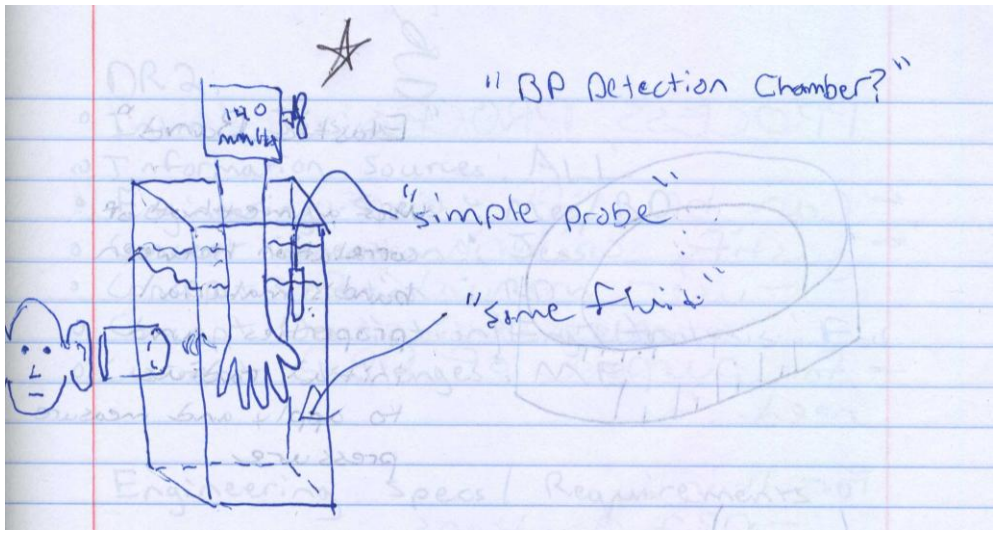


Figure 7: BP detection chamber- A standard cuff is used to apply the desired pressure to the arm. The arm is submerged in water or some other acoustic coupling fluid, which amplifies Korotkoff sounds. The clinician listens for the sounds.

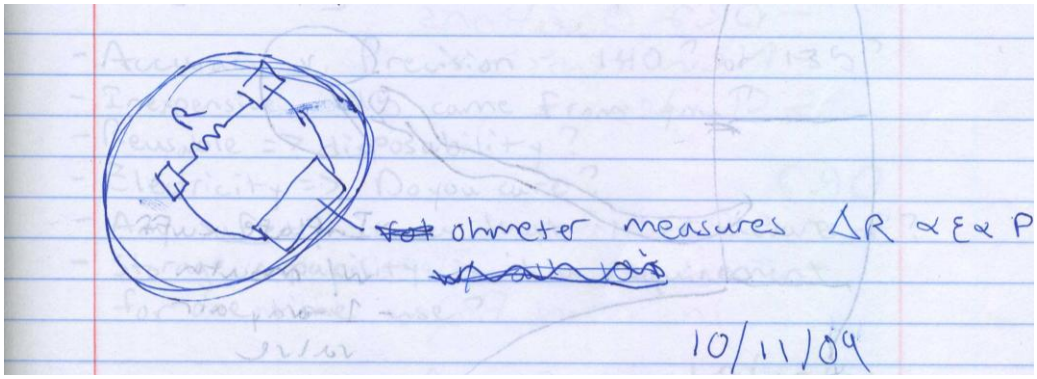


Figure 8: Strain Gauge- An ohmmeter measures changes in resistance and correlates this to changes in strain and then to pressure. This requires electricity and calibration.

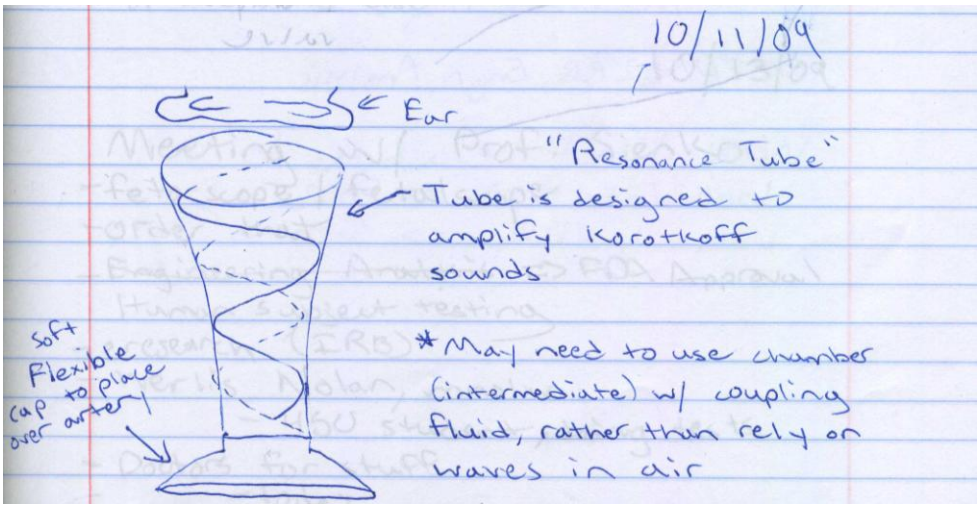


Figure 9: Resonance tube- A tube will be manufactured to amplify the Korotkoff sounds. The sounds may also be amplified by using a coupling fluid in an intermediate chamber.

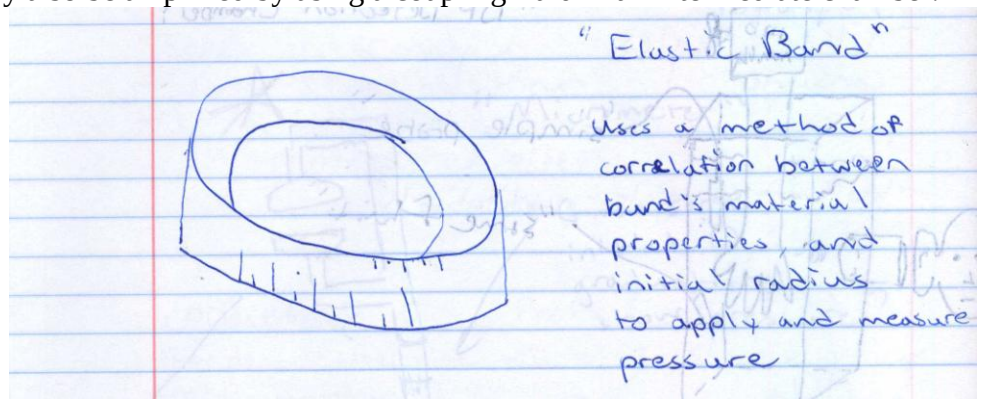


Figure 10: Simple elastic band- The material properties of an elastic band are used to determine how much pressure is applied.

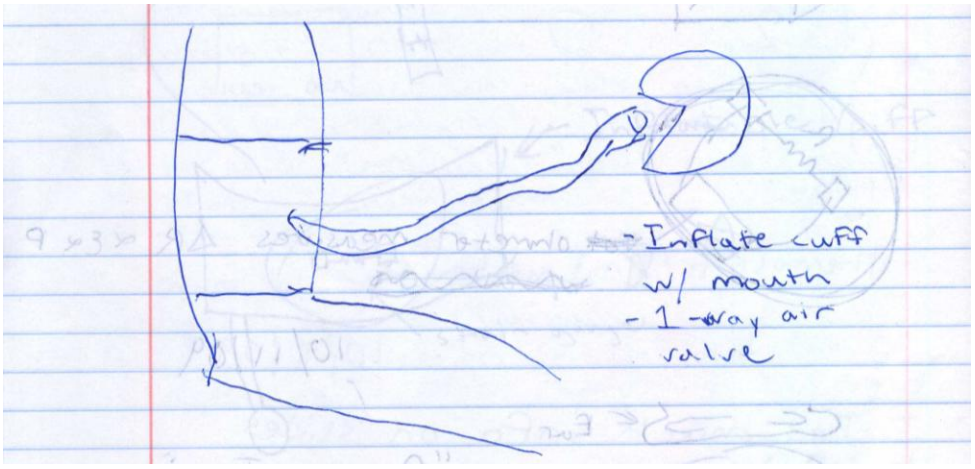


Figure 11: Breadth to inflate cuff- This is an inflatable cuff which uses a tube that the clinician can blow in to inflate the cuff and apply the needed pressure.

Appendix J: Class Discussion Concepts

Figure 1: Baloon- The intention of this idea is to use a balloon that has 140 mmHg of air initially, and is attached to the cuff. The balloon is squeezed and the cuff is inflated to 140 mmHg.

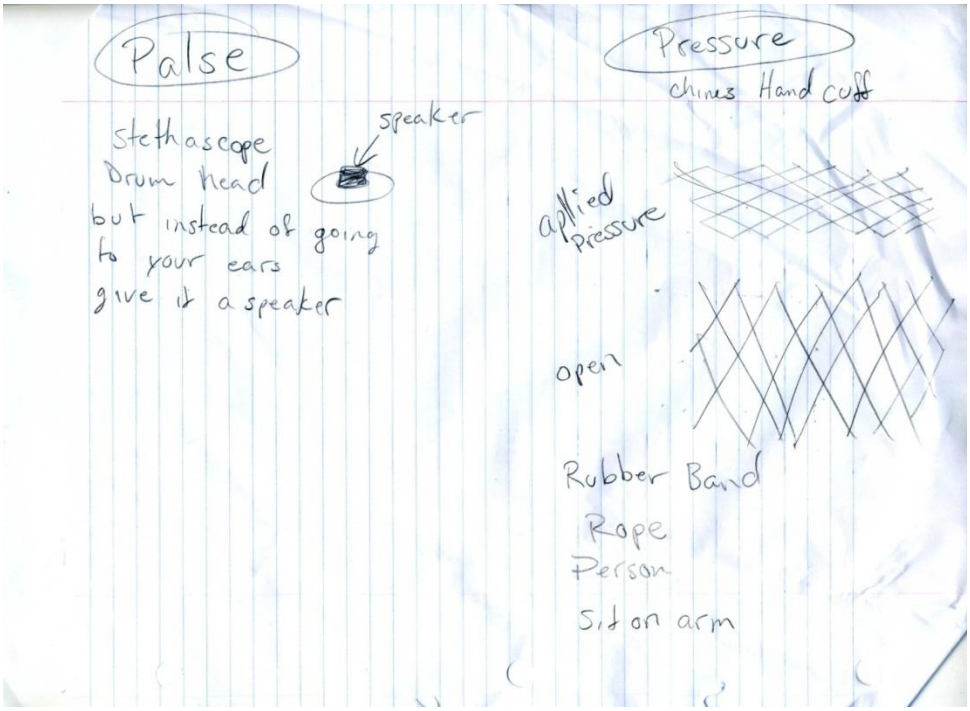


Figure 2: Stethoscope with speaker and Chinese finger cuff: This was a complete device concept which applied pressure using a Chinese finger cuff, and used a stethoscope head with a speaker on the back to detect Korotkoff sounds.

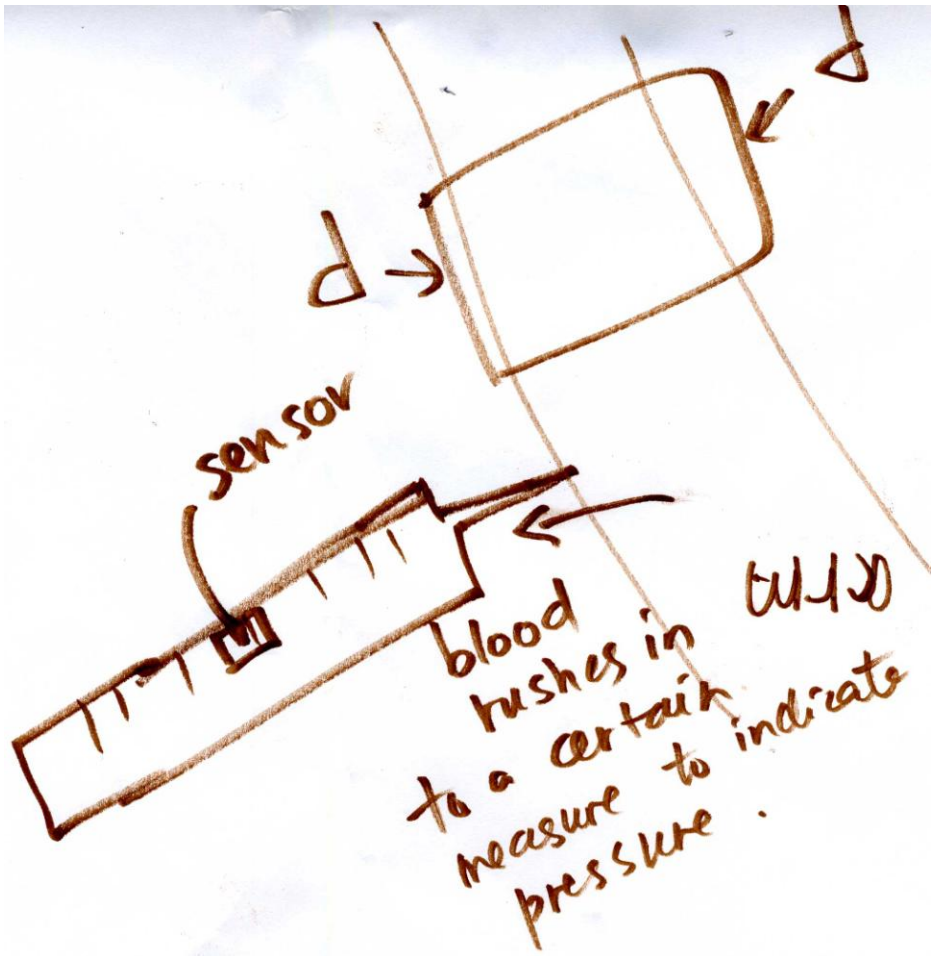


Figure 3: Invasive syringe- Pressure would be applied using some sort of cuff, and a syringe is injected in to the occluded artery. The level of the blood that rushes into the

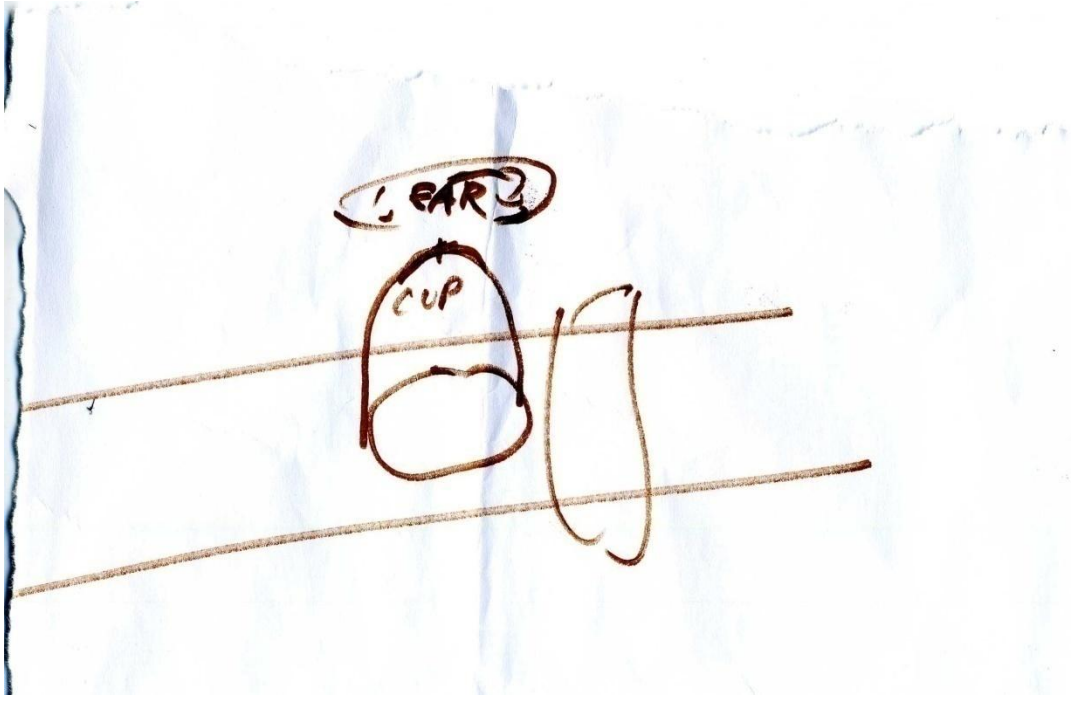


Figure 4: Cup- This is a simple procedure where a cup is place over the artery to hear the Korotkoff sounds

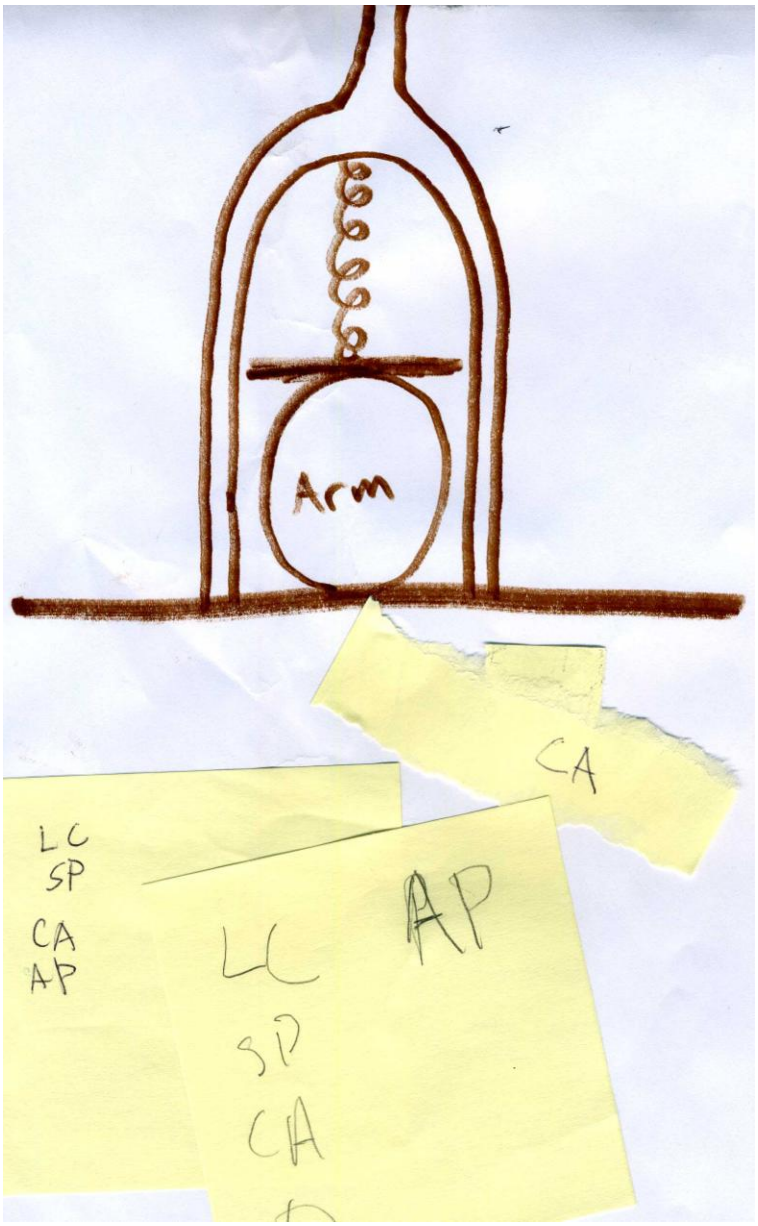


Figure 5: Bagel Cutter- The mechanism used to cut bagels is used to apply pressure by replacing the cutting blade with a flat surface. The user pushes down on the top to apply pressure. Also shown in this picture are examples of the post-it notes used by the class to vote for a particular concept.

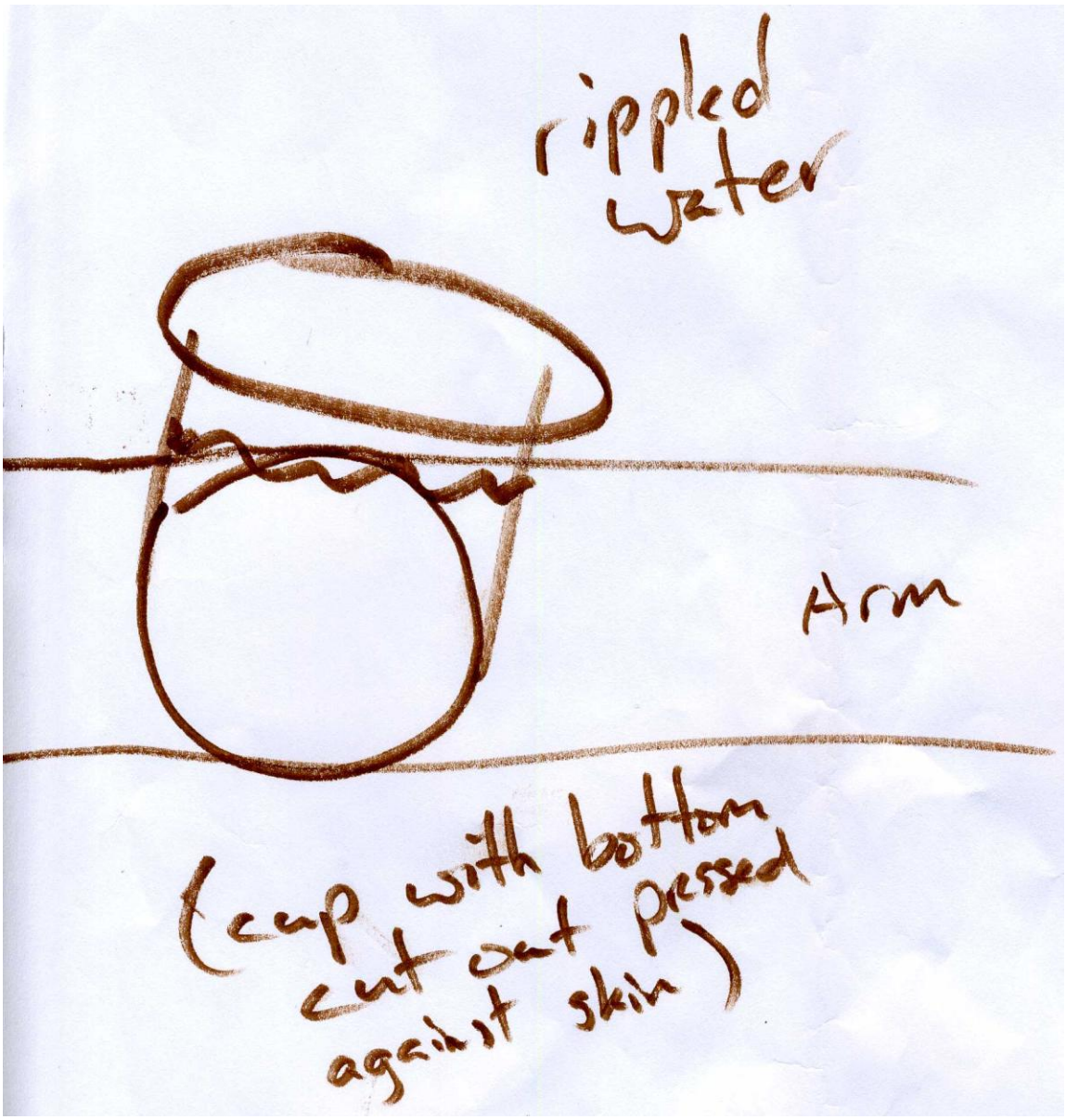


Figure 6: Cup with rippled water- This is similar to the idea that uses a cup to listen to Korotkoff sounds, however the cup is filled with water and the aim is to see ripples in the water due to pulse.

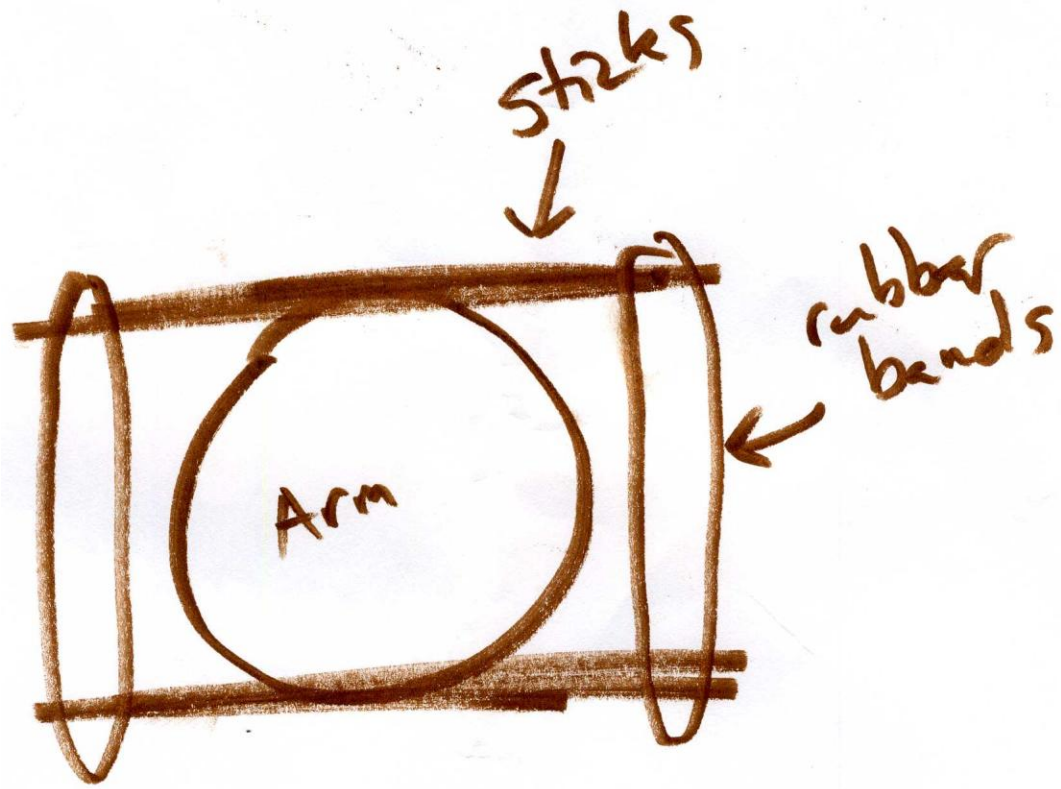


Figure 7: Sticks with rubber bands- Above is an apparatus made of sticks and rubber bands that is used to apply pressure to the arm

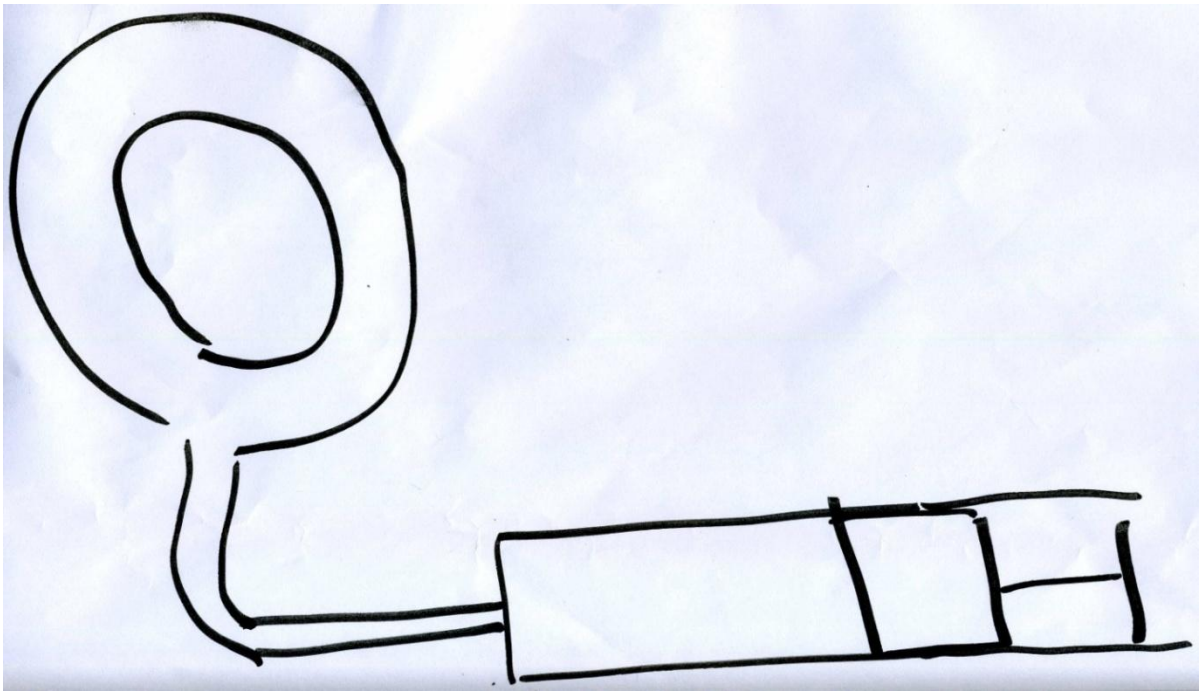


Figure 8: Cuff with graduated plunger for pressure- The cuff is inflated to the desired pressure using air pressure generated by a plunger mechanism.

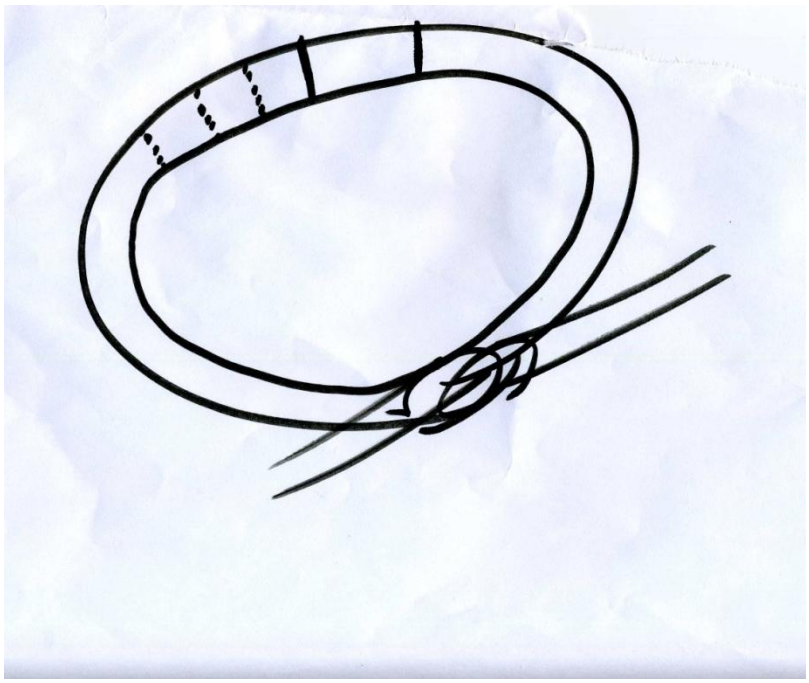
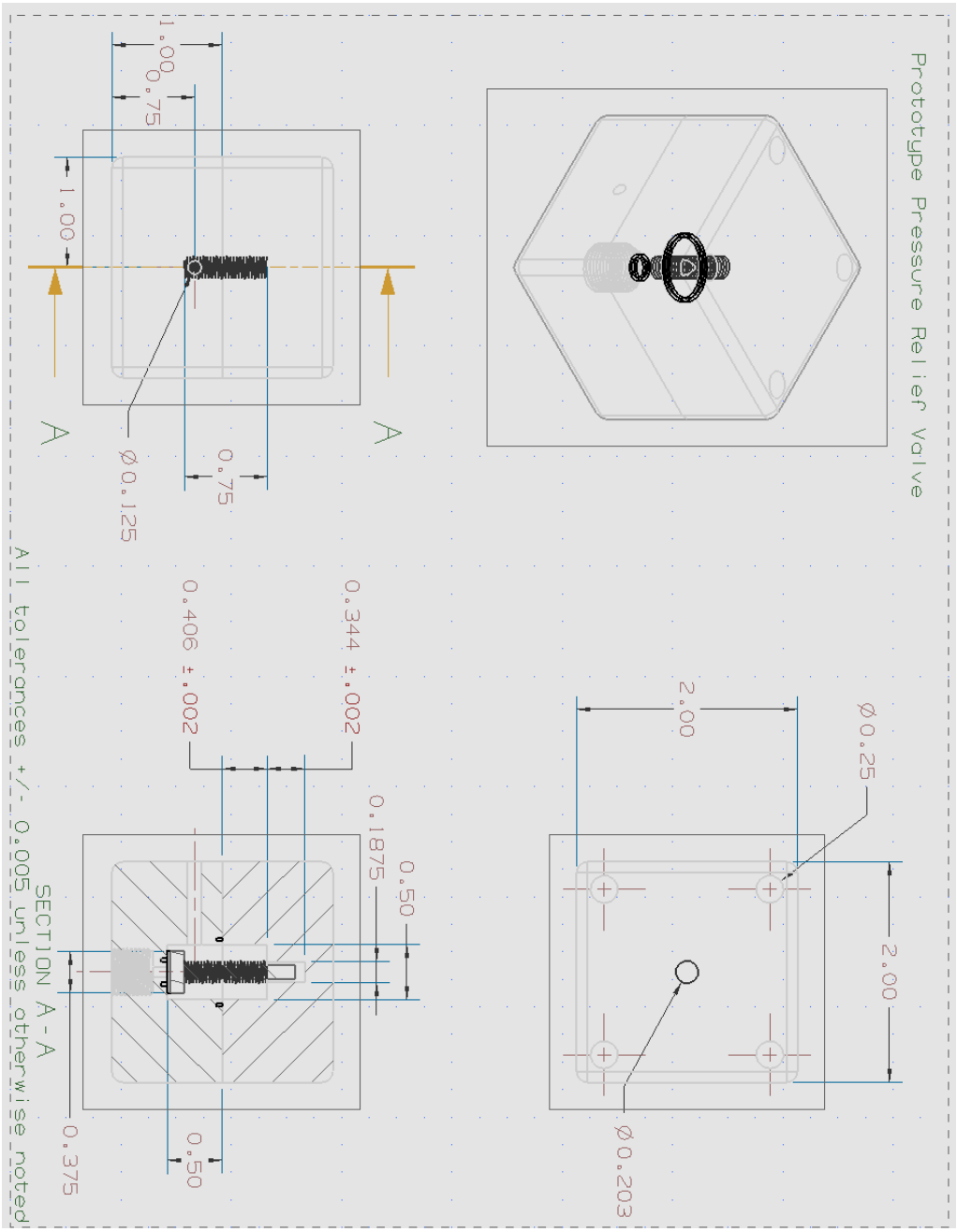
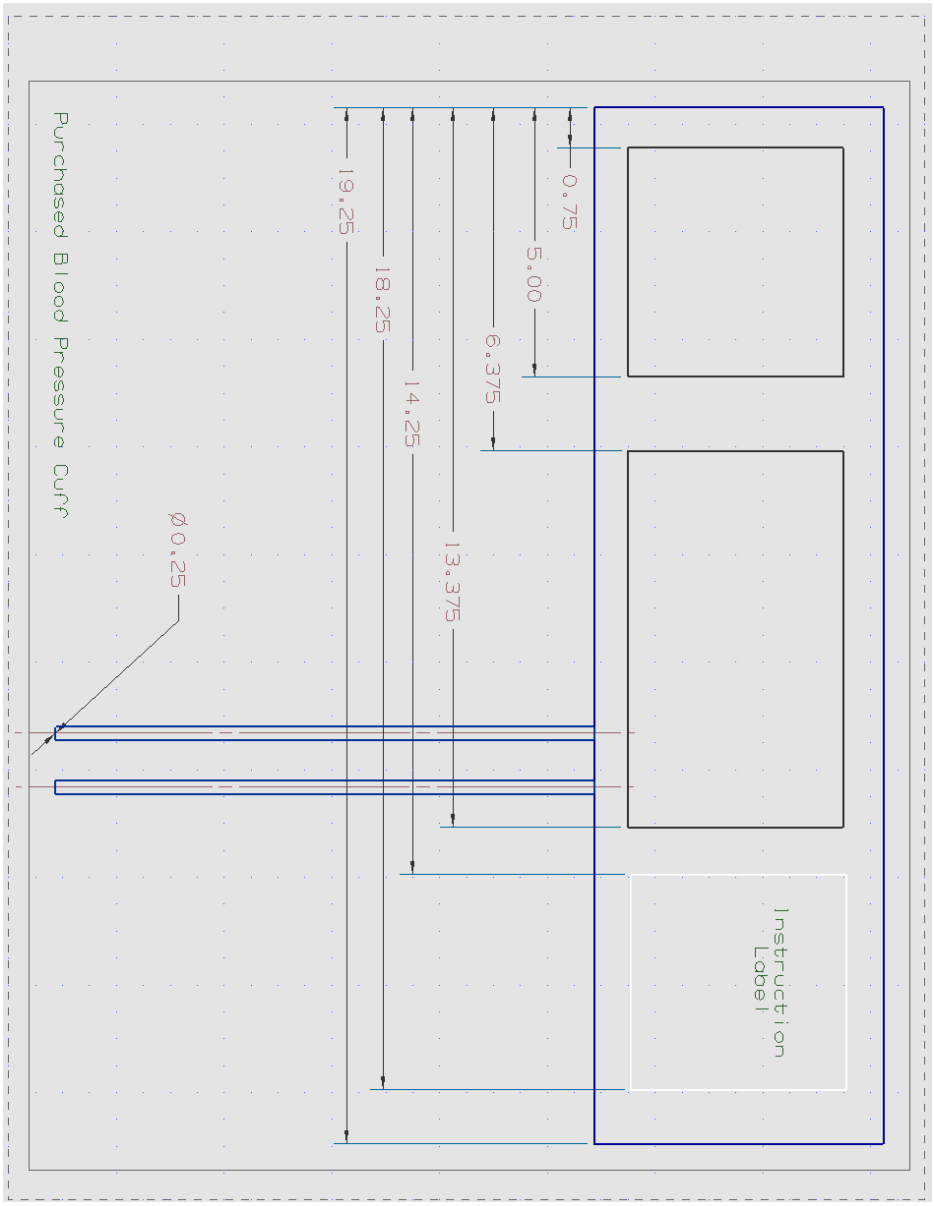
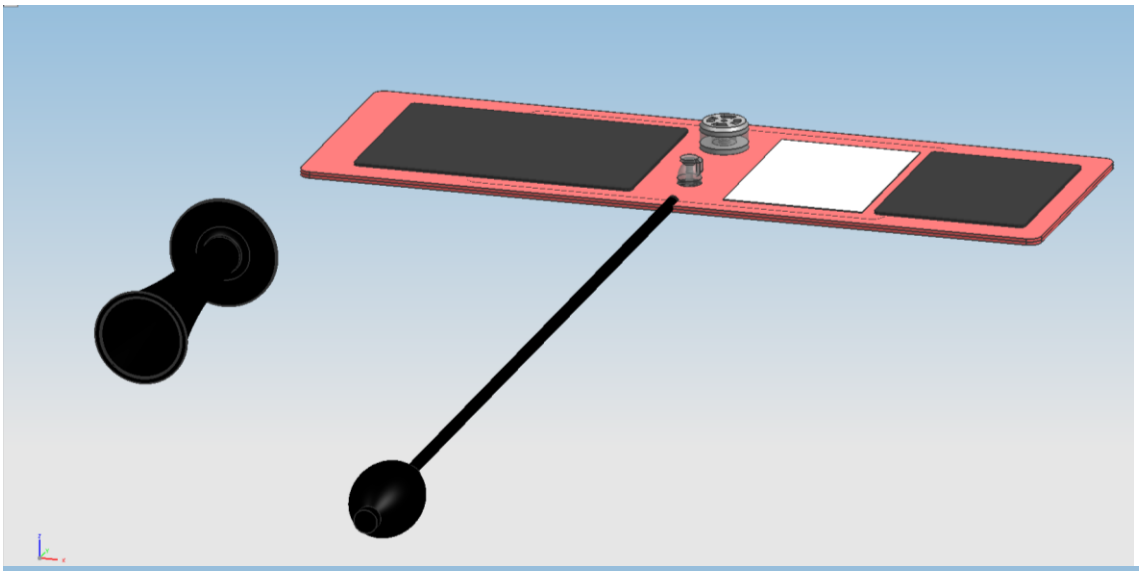


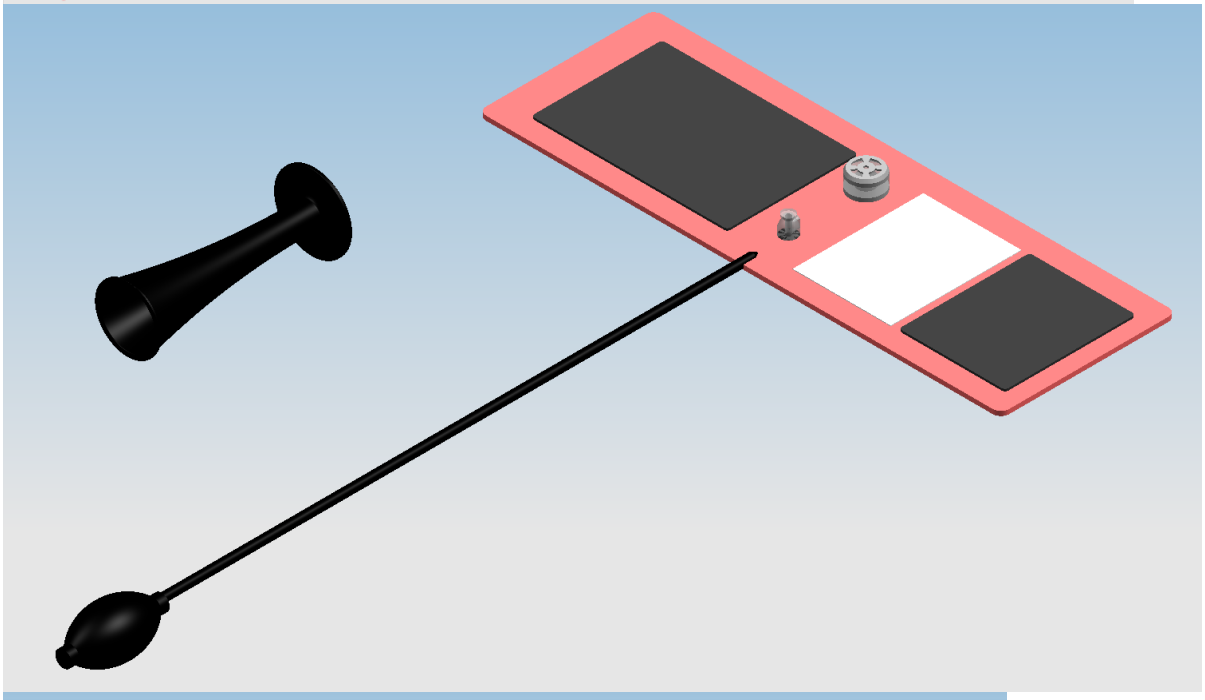
Figure 9: Calibrated rubber band: A rubberband of known material properties is tied or fastened around the arm or wrist to apply pressure.

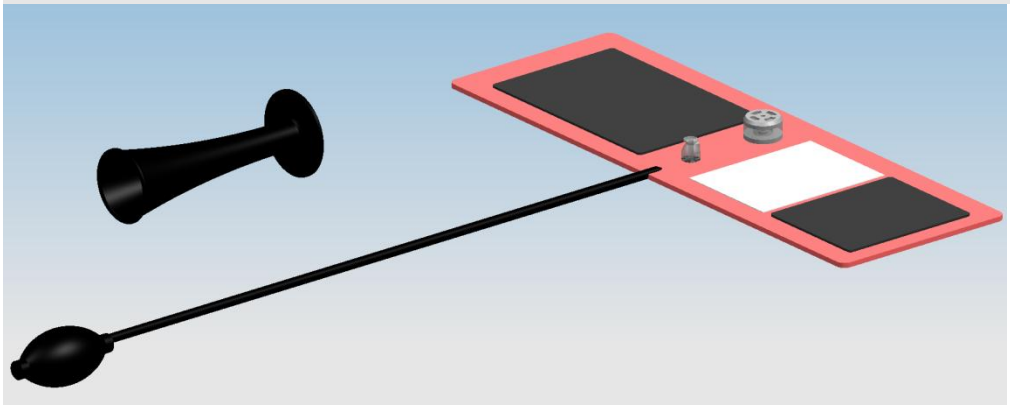
Appendix J: Final Design CAD Models with Dimensions

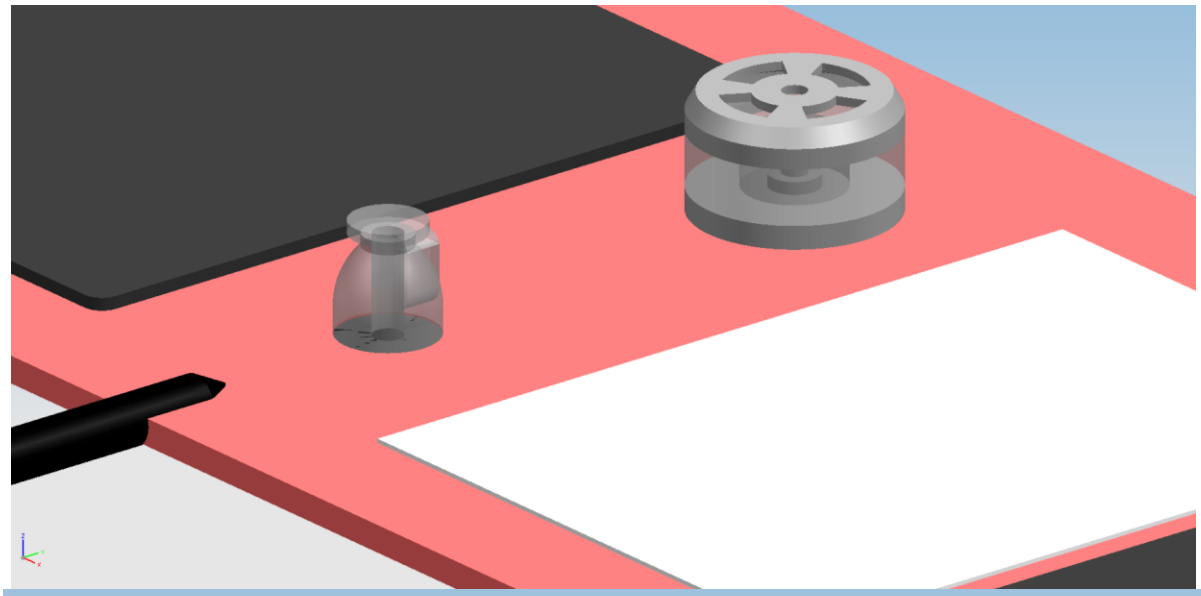


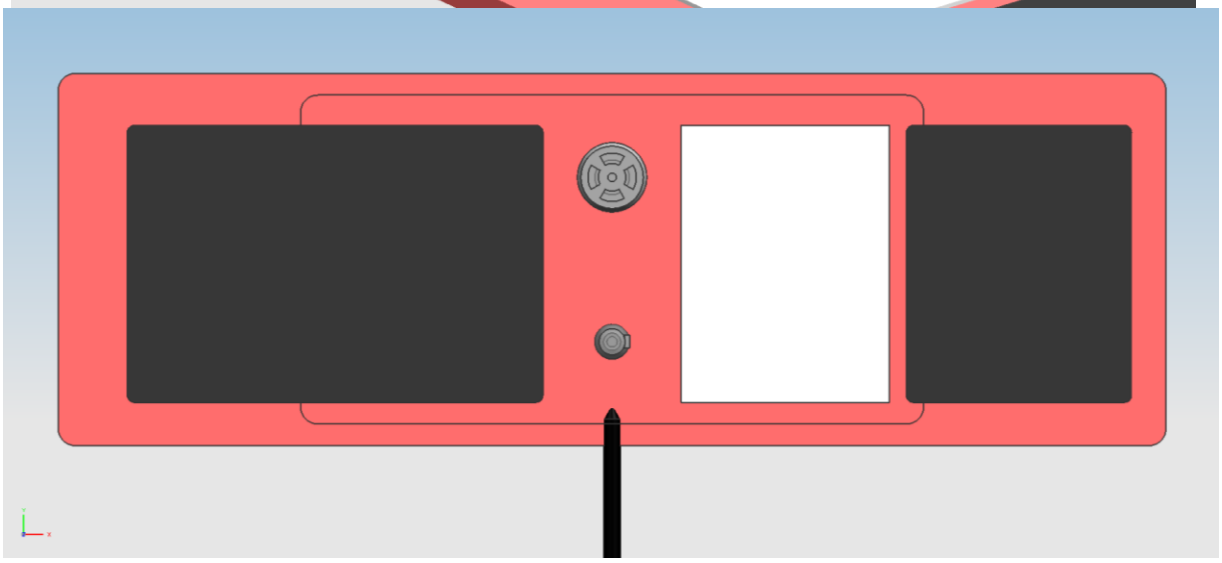

Purchased Blood Pressure Cuff
Ø0.25
19.25
18.25
14.25
13.375
6.375
5.00
0.75
Instruction Label

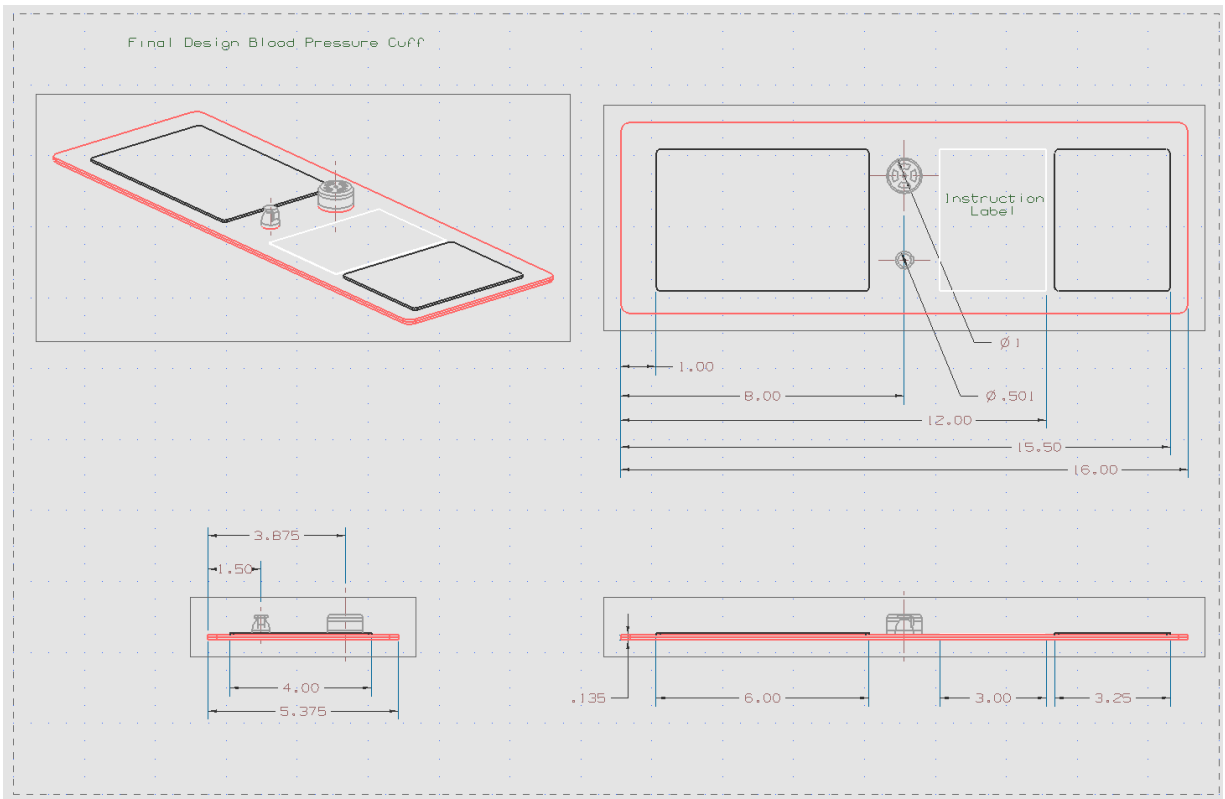


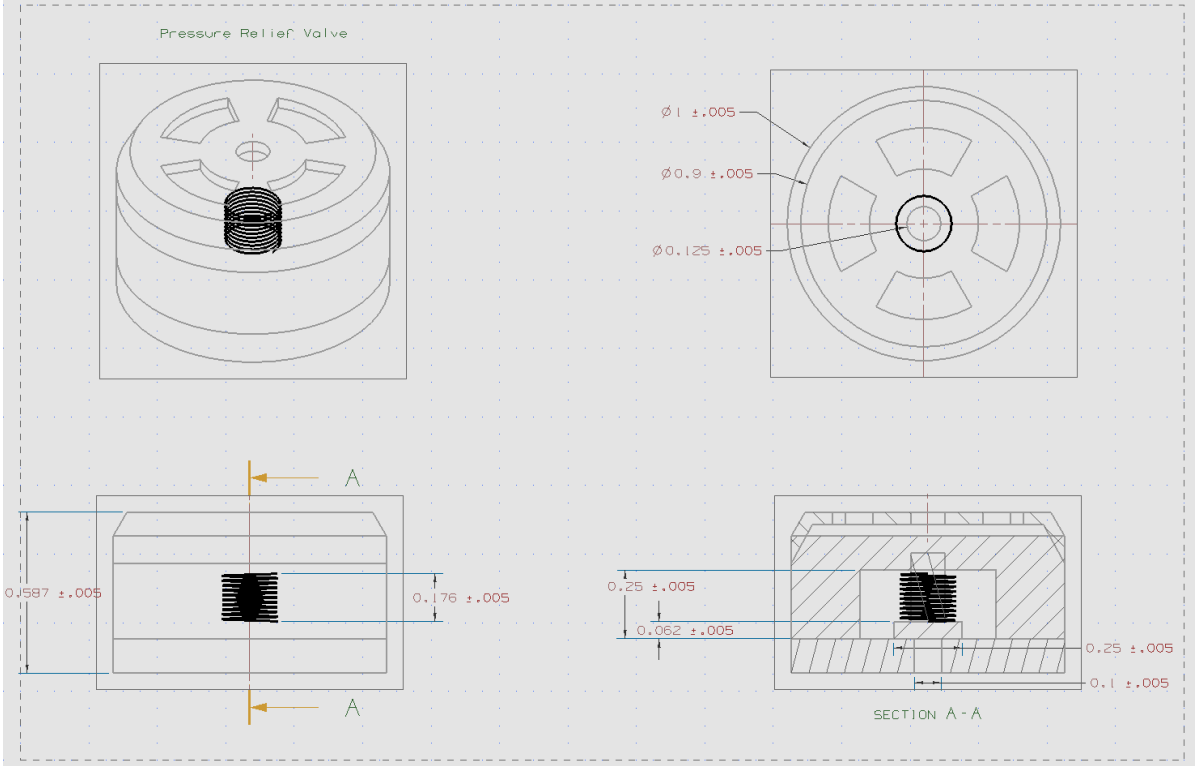


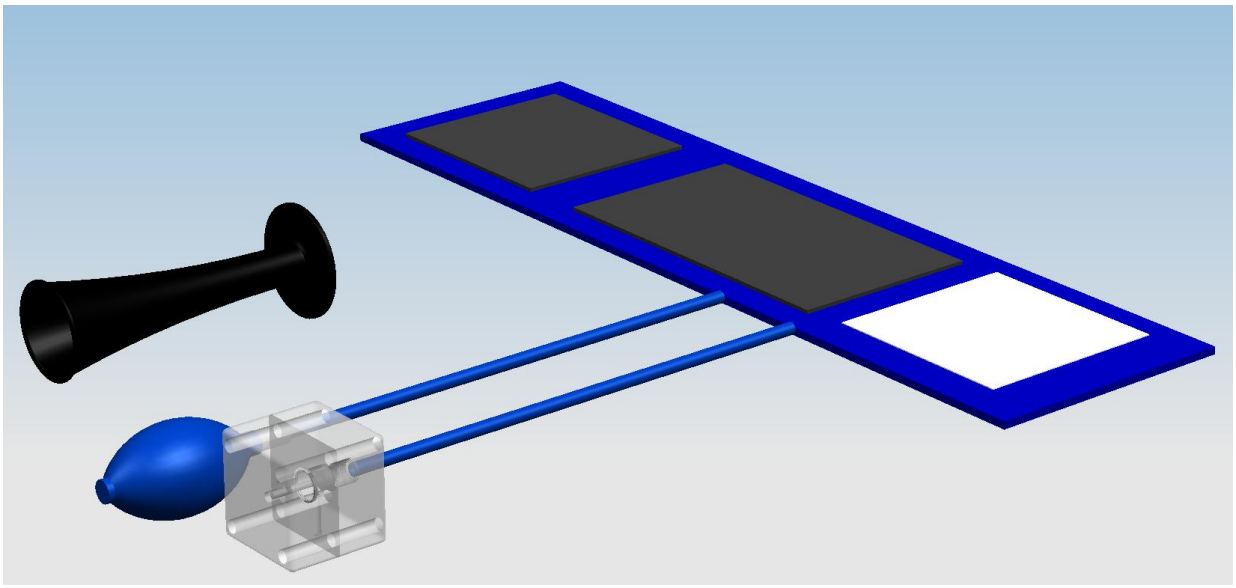







Final Design Blood Pressure Cuff
Instruction Label
Ø1
1.00
8.00
Ø.501
12.00
15.50
16.00
3.875
1.50
4.00
5.375
.135
6.00
3.00
3.25


Pressure Relief Valve
Ø1 ±.005
Ø0.9 ±.005
Ø0.125 ±.005
A
0.587 ±.005
0.176 ±.005
A
0.25 ±.005
0.062 ±.005
0.25 ±.005
0.1 ±.005
SECTION A-A



Appendix K: Safety Report.

SAFETY REPORT

A- ANALYSIS OF EXPERIMENTING

Empirical Testing

In order to determine if the main components of are beta design are working properly, empirical testing must be performed. Empirical testing will be performed on the valve, display mechanism, and pressure relief valve.

Valve: Empirical testing will be performed on the manufactured test valves to determine the best possible air flow within the valve to release the maximum outlet air pressure. The outlet air pressure will be measured using air volume flow meter. The outlet will be plugged if necessary to create other possible outlets to ensure the maximum pressure is being released. The air pressure being released will be released into a display mechanism either being auditory or visual. If the air pressure is too low then the display mechanism may not operate.

Risks involved with empirical testing of the valve are valve not opening to relive excess air pressure, machine instability from poor fabrication, airflow direction, a vacuum may develop within the valve if not sealed properly, and fatigue depending on the number of tests it requires to determine the maximum air flow.

Display Mechanism: After the empirical testing of the valve is completed with the maximum air pressure being released through the outlet, empirical testing will be done to determine if an auditory or visual display will be considered the best to utilize as a display mechanism to notify the health worker that 140mmHg pressure has been applied and to listen in the final prototype.

Auditory: The empirical testing for an auditory display will consist of different type of whistles. 140mmHg will be applied and the excess pressure will be released through the outlet of the valve. Attached to the outlet will be a type of whistle to determine if amount of air pressure is enough to output sound through the whistle. Each type of whistle will be tested and if the testing is unsuccessful, other auditory items such as a kazoo will be considered to perform more empirical testing.

Visual: The empirical testing for a visual display will consist of a pin with a 90° angle partially inserted in the outlet of the valve. 140mmHg will be applied and the excess pressure will be released through the outlet of the valve to determine if the pin will move due to the air pressure being released.

Pressure Relief Mechanism: A stopper from an inflatable beach ball will be detached and sewed onto an opening in the bladder of the cuff creating an easy way to release the pressure in the cuff. A pressure of above 140mmHg will be applied to determine if the stopper can withstand the operating pressures.

A risk that may be considered is a vacuum developing in the bladder.

Validation Testing

Experimenting and specific testing will be performed to prove that the device will actually work properly, meeting each engineering specification.

Measures 140mmHg +10mmHg: A pressure relief valve is used in the blood pressure measurement device to allow only 140mmHg of pressure to be applied. Once 140mmHg is applied the pressure relief valve will release any air to remain at a constant pressure of 140mmHg. To ensure that the pressure relief valve is working properly and only operating at 140mmHg + 10mmHg, a mercury manometer will be attached and multiple testing at different orientations will be performed to guarantee that 140mmHg pressure is being applied and releasing the air pressure above 140mmHg.

Any risks involved with validating a threshold pressure of 140mmHg will be referenced to the valve. Risks to consider for the valve are the valve not opening to relive excess air pressure, machine instability, airflow direction, and a vacuum may develop within the valve if not sealed properly.

1% False Alarms: To ensure that only 1% of false alarms occur, a mercury manometer will be attached to the device and a stethoscope as well as the fetoscope will be used to hear the Korotkoff sounds. If the Korotkoff sounds are heard in the stethoscope and not in the fetoscope, this is considered as a false alarm. If the Korotkoff sounds cannot be heard in the stethoscope but heard in the fetoscope, this can also be considered as a false alarm in the validation testing. However if the Korotkoff sounds cannot be heard or can be heard in both the stethoscope and the fetoscope this is not a false alarm. This test will be performed 42 times and if 1% false alarms occur during the test validates that the engineering specification of only having 1% of false alarms has been met.

Risks to consider can be caused from the valve, stethoscope, fetoscope, as well as from the test subject. Risks involved are machine instability, posture of the test subject to listen to the fetoscope, and repetition depending on the number of tests.

7 Step Procedure: For the device to be easy to use it must have the least amount of steps possible to operate. To ensure that the device can be used within a seven step procedure volunteers from our class will use the device to take a blood pressure measurement and the steps to operate will be recorded. The steps will include putting on the cuff up unto the cuff is taken off.

4.5 Avg from Likert Scale for Easy to Read Measurements: Blood measurements will be taken using the device in front of our class. Each classmate will fill out a 1-5 likert scale questionnaire, 1 being hardest and 5 being the easiest, based on how they thought the measurements were easy to read.

Put off and on with 2 hands in 20 seconds: It is necessary that the device can be put on the patients arm easily. To ensure that the device can be put on easily with two hands and in 20 seconds, volunteers from the class will put the cuff on and off and record the time using a stop watch to determine the time duration.

Clean without disassembling parts in < 1 minute: The device should be easy to clean if necessary in the least amount of time. Each team member will clean it thoroughly without disassembling and timed with a stop watch to ensure that the duration time is less than 1 minute.

A risk to consider is that the device may have sharp edges.

Calibrate < 1 Year: The pressure relief valve will be tested in an estimated cycle of 126 times. The number of times tested is estimated for two pregnant women having their blood pressure measured every day from the 31 week of pregnancy until labor which is about 40 weeks. Testing 126 times will allow the determination if calibration is required. If calibration is not needed then it is assumed that calibration will occur after one year.

Risks involved are machine instability, fatigue in the materials, valve not opening to relive excess air pressure, and a vacuum may develop within the valve if not sealed properly.

Operates in Temperatures >/= 40 degrees Celsius: The climate of Ghana is tropical reaching temperatures above 30 degrees Celsius. To ensure that the blood pressure measurement device can operate in such temperatures, manufacturing specifications for each material will be analyzed. If all material specifications are equal to or greater than 40 degrees Celsius, then the engineering specification for operating temperature for the device is met. In addition, for further validation, the device will be used under 40 degrees Celsius from a heating lamp.

Risk to consider are severe temperatures, valve not opening to relive excess air pressure, machine instability, airflow direction, and a vacuum may develop within the valve if not sealed properly.

B- ANALYSIS OF PURCHASED PARTS

For the fetoscope, hand pump and rubber hose, and the cuff and inflatable bladder, there are no electrical/electronic hazards nor slips/trips/falls hazards, and are not susceptible to fire and explosions, ingress/egress, material handling, confined spaces, ventilation, chemical and gases, radiation, or lasers hazards.

1) Fetoscope

It was defined in DesignSafe that an operator, the health care worker, will be using the fetoscope to listen for Korotkoff sounds. With a normal operation. In mechanical operation, it is susceptible to crushing and impact. In ergonomics the posture poses a hazard for the health care worker because he or she will have to bend down to the patient's arm to listen for Korotkoff sounds; additionally could be bending and twisting their body as well. For heat and temperature hazards, radiant heat and severe heat are problems in Ghana which could affect the fetoscope. There are no noise or vibration hazards.. For environmental hazards, the plastic material may corrode. For biological and health hazards, there may be unsanitary conditions if the health worker is using the fetoscope on multiple patients without cleaning the device, and bacteria may be an issue. There are no fluid or pressure hazards. After evaluating the severity, exposure, and probability of each hazard, it was concluded that the hazards of crushing, impact, posture,

lifting/bending/twisting, radiant heat, unsanitary conditions, and bacterial hazards have moderate risk levels. Severe heat conditions and corrosion have low risk levels.

Identify Hazards | Assess and Reduce Risk

	Item Id	User	Task	Hazard Category	Hazard
3	1-1-3	operator	normal operation	ergonomics / human	posture

	User	Task	Hazard Category	Hazard	Severity	Exposure	Probability	Risk Level
1	operator	normal operation	mechanical	crushing	Slight	Occasional	Unlikely	Moderate
2	operator	normal operation	mechanical	impact	Slight	Occasional	Unlikely	Moderate
3	operator	normal operation	ergonomics / human factors	posture	Slight	Frequent	Unlikely	Moderate
4	operator	normal operation	ergonomics / human factors	lifting / bending / twisting	Slight	Frequent	Unlikely	Moderate
5	operator	normal operation	heat / temperature	radiant heat	Minimal	Frequent	Possible	Moderate
6	operator	normal operation	heat / temperature	severe heat	Minimal	Occasional	Unlikely	Low
7	operator	normal operation	environmental / industrial hygiene	corrosion	Minimal	Remote	Unlikely	Low
8	operator	normal operation	biological / health	unsanitary conditions	Minimal	Frequent	Unlikely	Moderate
9	operator	normal operation	biological / health	bacterial	Minimal	Frequent	Unlikely	Moderate

2) Hand pump/Rubber hose

Similarly, the same operator (health care worker) will operate the rubber hand pump, connected to rubber hose which leads to the cuff. The pump and the hose will be evaluated together since both are constructed from the same material and will be exposed to the same hazards. For mechanical hazards, the pump and hose may fail due to stabbing or puncture and fatigue. There is an ergonomic hazard to the user due to repetition of pumping the bulb through the hoses. For heat and temperature hazards, radiant heat and severe heat are problems in Ghana which could affect the hand pump and hoses. There may be a noise/vibration hazard when the rubber fails due to fatigue and material strength. For environmental hazards, the rubber material may corrode over time. For biological and health hazards, there may be unsanitary conditions if the health worker is continuously using the hand pump without cleaning the device, and bacteria may be an issue. For fluids/pressure hazards, there is air traveling from the pump into the cuff which may build up high pressure. Also the connection between the pump, hose, and cuff creates a vacuum within the pump, hose, and cuff. After evaluating each hazard on severity, exposure, and probability, the risk level of stabbing/puncture, repetition, radiant heat, unsanitary conditions, and bacterial hazards all received moderate risk levels. Fatigue and material strength, severe heat, corrosion, high pressure air, and vacuum hazards received low risk levels.

Identify Hazards | Assess and Reduce Risk

	Item Id	User	Task	Hazard Category	Hazard
9	1-1-9	operator	normal operation	biological / health	bacterial

	Item Id	User	Task	Hazard Category	Hazard	Severity	Exposure	Probability	Risk Level
1	1-1-1	operator	normal operation	mechanical	stabbing / puncture	Catastrophic	Remote	Unlikely	Moderate
2	1-1-2	operator	normal operation	mechanical	fatigue	Slight	Remote	Unlikely	Low
3	1-1-3	operator	normal operation	ergonomics / human factors	repetition	Minimal	Frequent	Unlikely	Moderate
4	1-1-4	operator	normal operation	heat / temperature	radiant heat	Minimal	Frequent	Possible	Moderate
5	1-1-5	operator	normal operation	heat / temperature	severe heat	Minimal	Occasional	Unlikely	Low
6	1-1-6	operator	normal operation	noise / vibration	fatigue / material strength	Slight	Remote	Unlikely	Low
7	1-1-7	operator	normal operation	environmental / industrial hygiene	corrosion	Minimal	Remote	Unlikely	Low
8	1-1-8	operator	normal operation	biological / health	unsanitary conditions	Minimal	Frequent	Unlikely	Moderate
9	1-1-9	operator	normal operation	biological / health	bacterial	Minimal	Frequent	Unlikely	Moderate
10	1-1-10	operator	normal operation	fluid / pressure	high pressure air	Slight	Remote	Unlikely	Low
11	1-1-11	operator	normal operation	fluid / pressure	vacuum	Minimal	Frequent	Negligible	Low

3) Cuff/inflatable bladder

The operator of the cuff will be the health care worker. There are several mechanical hazards associated with the cuff and inflatable bladder. Firstly, stabbing/puncture of the cuff or bladder will prevent it from being able to inflate. Also, since the cuff is adjusted so frequently around the

arm it may be susceptible to fatigue due to wearing of material, or break up during operation due to fatigue, corrosion, aging, or rupture. There are may be ergonomic hazards resulting from interactions between the patient and health care worker. Either the patient or worker may become the process of applying the cuff or while listening for Korotkoff sounds. The cuff possesses heat/temperature hazards since it is exposed to radiant and severe heat, which is expected in Ghanaian environments. There are also concerns regarding biological and health hazards, since the cuff is applied to the arms of many expectant mothers there are unsanitary conditions and bacteria may cause danger to both the patient and the health care worker's health. For fluid/pressure hazards, there is high pressure air contained in the bladder and throughout the cuff/bladder, pump, and hose there is a vacuum. After evaluating each hazard on severity, exposure, and probability, the risk level of stabbing/puncture, break up during operation, radiant heat, severe heat, unsanitary conditions, bacterial, high pressure air, and vacuum hazards are all moderate. Fatigue, interactions between persons, and fatigue/material strength all have low risk levels.

	Item Id	User	Task	Hazard Category	Hazard
11	1-1-11	operator	normal operation	fluid / pressure	vacuum

	Item Id	User	Task	Hazard Category	Hazard	Severity	Exposure	Probability	Risk Level
1	1-1-1	operator	normal operation	mechanical	stabbing / puncture	Catastrophic	Remote	Unlikely	Moderate
2	1-1-2	operator	normal operation	mechanical	fatigue	Slight	Remote	Unlikely	Low
3	1-1-3	operator	normal operation	mechanical	break up during operation	Slight	Remote	Possible	Moderate
4	1-1-4	operator	normal operation	ergonomics / human factors	interactions between persons	Minimal	Remote	Possible	Low
5	1-1-5	operator	normal operation	heat / temperature	radiant heat	Minimal	Frequent	Possible	Moderate
6	1-1-6	operator	normal operation	heat / temperature	severe heat	Minimal	Frequent	Unlikely	Moderate
7	1-1-7	operator	normal operation	noise / vibration	fatigue / material strength	Slight	Remote	Unlikely	Low
8	1-1-8	operator	normal operation	biological / health	unsanitary conditions	Slight	Frequent	Unlikely	Moderate
9	1-1-9	operator	normal operation	biological / health	bacterial	Slight	Frequent	Unlikely	Moderate
10	1-1-10	operator	normal operation	fluid / pressure	high pressure air	Serious	Remote	Possible	Moderate
11	1-1-11	operator	normal operation	fluid / pressure	vacuum	Minimal	Frequent	Unlikely	Moderate

C- ANALYSIS OF DESIGNED PARTS

Pressure Relief and Notification Mechanism

The pressure relief mechanism will be used by operator (healthcare worker) for normal operation. It has a high risk level for failure from crushing and high pressure air. The risk from crushing is decreased to moderate by supplying a rigid carrying case with the device. It has a moderate risk level from breakup during operation, machine instability, severe heat and acids. Risks from severe heat and acids are reduced to low by writing warnings on the device. It has a low risk level from corrosion, radiant heat and vacuum.

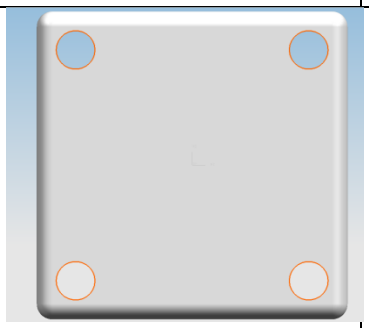
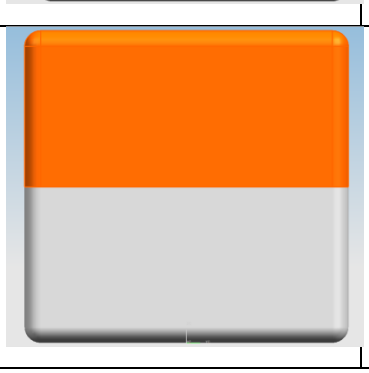
The design safe chart can be seen below.

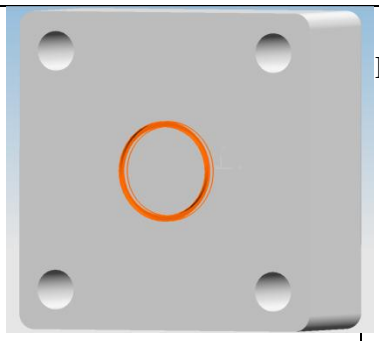
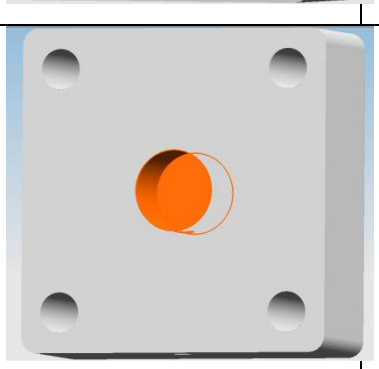
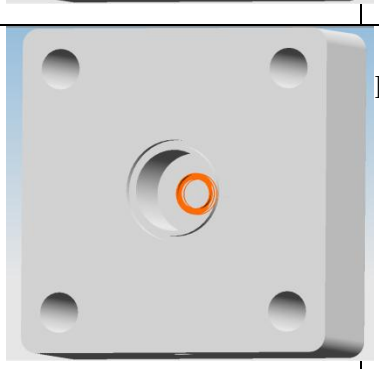
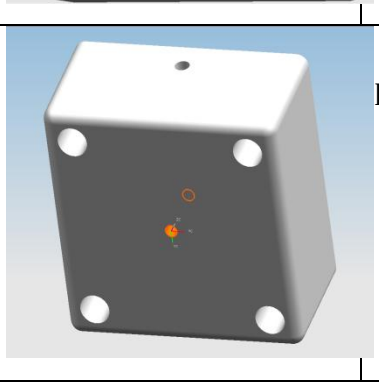
	Item Id	User	Task	Hazard Category	Hazard
8	1-1-8	operator	normal operation	fluid / pressure	high pressure air

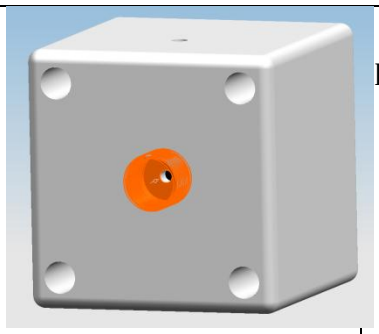
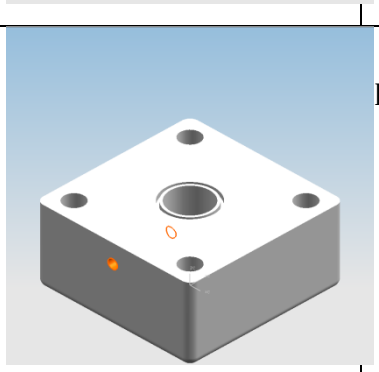
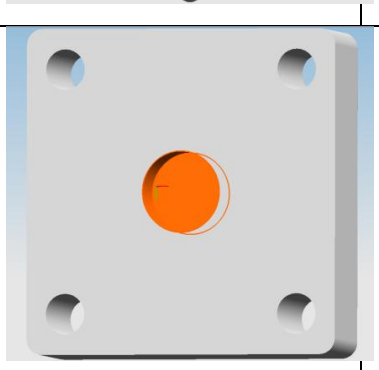
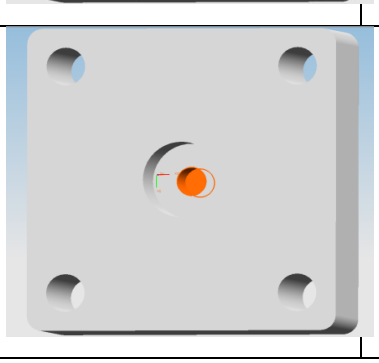
	Item Id	User	Task	Hazard Category	Hazard
1	1-1-1	operator	normal operation	mechanical	crushing
2	1-1-2	operator	normal operation	mechanical	break up during operation
3	1-1-3	operator	normal operation	mechanical	machine instability
4	1-1-4	operator	normal operation	heat / temperature	radiant heat
5	1-1-5	operator	normal operation	heat / temperature	severe heat
6	1-1-6	operator	normal operation	environmental / industrial hygiene	corrosion
7	1-1-7	operator	normal operation	chemical	acids
8	1-1-8	operator	normal operation	fluid / pressure	high pressure air
9	1-1-9	operator	normal operation	fluid / pressure	vacuum

Severity	Exposure	Probability	Risk Level	Reduce Risk	Severity	Exposure	Probability	Risk Level
Catastrophic	Occasional	Possible	High	Provide a carrying case with the device	Catastrophic	Remote	Negligible	Moderate
Catastrophic	None	Unlikely	Moderate					
Minimal	Occasional	Possible	Moderate					
Slight	Remote	Unlikely	Low					
Serious	Remote	Unlikely	Moderate	Write warnings about heat	Serious	None	Negligible	Low
Serious	Remote	Negligible	Low					
Serious	Remote	Unlikely	Moderate	Write warnings on acid use	Serious	None	Negligible	Low
Slight	Occasional	Probable	High					
Slight	Remote	Negligible	Low					

D- MANUFACTURING PLAN

Step	Machine	Tools	Procedure
	Drill Press	¼” Drill bit ¼” Ream Bench Vise	Drill 4 holes through acrylic cube in the indicated location
	Band saw	Scribe Ruler	Cut acrylic into 2 cubes of height 1”

	Center Lathe	1/8” O-ring groove cutter	Cut 1/8” wide o-ring groove to a depth of 1/8”
	Mill	½” End Mill Vise	Mill ½’ diameter hole a depth of ½’
	Center lathe	1/16” O-ring groove cutter	Cut 1/16” wide o-ring groove to a depth of 1/16”
	Drill press	1/8” Drill bit 1/8” Ream Bench Vise	Drill 1/8” diameter hole in indicated location to a depth of ½” Use 1/8” ream to smooth inner wall surface

	Drill press	3/8” Drill bit 3/8” Tap, NPT Bench Vise	Drill 3/8” diameter hole to a depth of 3/8” Tap hole using 3/8” NPT tap
	Drill press	1/8” Drill bit 1/8” Ream Bench Vise	Drill 1/8” diameter hole on side of bottom half in the location indicated on the drawing Use 1/8” ream to smooth inner wall surface
	Mill	½” End mill Vise	Mill ½” diameter hole to a depth of 13/32”
	Mill	3/16” End Mill Vise	Mill 3/16” diameter hole to a depth of 11/32”

Appendix L: Pugh Charts

Problem Area: Many Pregnant women in rural areas are dying from preeclampsia which can be diagnosed through the blood pressure measurment

		PULSE/KOROTKOFF CONCEPTS											
		Nurse listens for korotkoff sounds through stethoscope		Oscillometric Technique (pulse detector)		Stethoscope head		Beads in drum		Fetoscope		Stethoscope head with Amplfier/Speaker	
Design Criteria	Weight	Rank	Weighted Score	Rank	Weighted Score	Rank	Weighted Score	Rank	Weighted Score	Rank	Weighted Score	Rank	Weighted Score
Accurate	20	3	0.6	4	0.8	3	0.6	2	0.4	2	0.4	3	0.6
Inexpensive	15	3	0.45	2	0.3	4	0.6	4	0.6	5	0.75	2	0.3
Reusable (durable)	12.5	3	0.375	2	0.25	3	0.375	3	0.375	4	0.5	2	0.25
Requires no electricity	10	3	0.3	2	0.2	3	0.3	3	0.3	5	0.5	1	0.1
Safe to use on patients	9	3	0.27	3	0.27	3	0.27	3	0.27	3	0.27	3	0.27
Simple Procedure (to measure pulse)	8	3	0.24	4	0.32	2	0.16	2	0.16	3	0.24	2	0.16
Pulse readings easy to understand	8	3	0.24	4	0.32	3	0.24	3	0.24	2	0.16	4	0.32
Adjustable (move to get better reading)	7.5	3	0.225	3	0.225	3	0.225	3	0.225	3	0.225	3	0.225
Easy to put on and off	7.5	3	0.225	2	0.15	4	0.3	4	0.3	3	0.225	3	0.225
Easy to transport	5	3	0.15	4	0.2	4	0.2	4	0.2	4	0.2	4	0.2
Easy to clean	1	3	0.03	4	0.04	4	0.04	4	0.04	4	0.04	3	0.03
Easy to calibrate or requires no calibration	2.5	3	0.075	2	0.05	3	0.075	3	0.075	3	0.075	3	0.075
Operates in high humidity and temperatures	2.5	3	0.075	2	0.05	3	0.075	3	0.075	4	0.1	2	0.05
Total Score			3.255		3.175		3.46		3.26		3.685		2.805
Rank			4		5		2		3		1		6

Problem Area: Many Pregnant women in rural areas are dying from preeclampsia which can be diagnosed through the blood pressure measurment

		APPLYING PRESSURE CONCEPTS											
		Standard Cuff with Sphygmomanometer		Worm Gear		lf-inflatable		Elastic Band		Spring loaded		"Bagel Cutter"	
Design Criteria	Weight	Rank	Weighted Score	Rank	Weighted Score	Rank	Weighted Score	Rank	Weighted Score	Rank	Weighted Score	Rank	Weighted Score
Accurate	20	3	0.6	2	0.4	2	0.4	2	0.4	2	0.4	2	0.4
Inexpensive	15	3	0.45	3	0.45	1	0.15	4	0.6	4	0.6	3	0.45
Reusable	12.5	3	0.375	2	0.25	2	0.25	2	0.25	3	0.375	3	0.375
Requires no electricity	10	3	0.3	3	0.3	1	0.1	3	0.3	3	0.3	3	0.3
Safe to use on patients	9	3	0.27	1	0.09	2	0.18	3	0.27	2	0.18	2	0.18
Simple procedure	8	3	0.24	3	0.24	4	0.32	4	0.32	4	0.32	4	0.32
Measurements are easy to read	8	3	0.24	4	0.32	4	0.32	2	0.16		0		0
Adjustable (if necessary)	7.5	3	0.225	3	0.225	3	0.225	2	0.15	2	0.15	2	0.15
Easy to put on and off	7.5	3	0.225	2	0.15	4	0.3	3	0.225	4	0.3	3	0.225
Easy to transport	5	3	0.15	3	0.15	3	0.15	4	0.2	4	0.2	3	0.15
Easy to clean	1	3	0.03	3	0.03	3	0.03	3	0.03	4	0.04	4	0.04
Easy to calibrate or requires no calibration	2.5	3	0.075	2	0.05	2	0.05	1	0.025	2	0.05	2	0.05
Operates in high humidity and temperatures	2.5	3	0.075	3	0.075	2	0.05	2	0.05	3	0.075	3	0.075
Total Score			3.255		2.73		2.525		2.98		2.99		2.715
Rank			1		4		6		3		2		5