Fetal Heart Rate Monitor
for Resource-Limited Settings

ME 450 Fall 2012

TEAM 2
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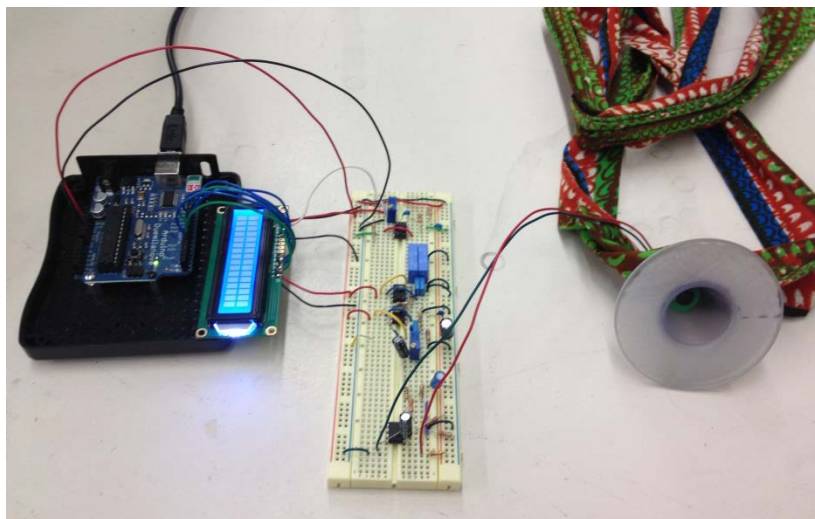University of Michigan

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Ghana Cohort 3 - From left: Elizabeth Hyde, Jenna Boeing, Tyler Gatlin, Evan Boeing

Prototype of fetal heart rate monitor at Design Expo

Close up of prototype

Executive Summary

In order to determine the challenges facing maternal health in sub-Saharan Africa, a team of four students spent the summer observing in primary and tertiary care facilities in Ghana. The resultant research led to the finding that current methods of acquiring fetal heart rate fail to yield diagnostically relevant data, primarily due to the usage of the Pinard stethoscope. A low-cost fetal heart monitor to replace the Pinard would be beneficial in aiding lesser-trained healthcare workers in determining the baseline and variability of a fetal heart rate, thereby helping to reduce the likelihood of preventable fetal and maternal casualties.

In order for the device to be effective in developing countries, it must meet several engineering specifications that are based upon the research performed while in Ghana. Three primary engineering specifications were scheduled to be met prior to the others due to an emphasis on function rather than form. It was determined that the device must be able to output the baseline fetal heart rate to within ±2 BPM, the device must be able to output the variability of the fetal heart rate to within ±2BPM, and the sound of the fetal heartbeat must be outputted at an intensity higher than 60 dB. These, along with further engineering specifications, can be found in more detail in Section 3.

These specifications were used to generate 26 possible designs to replace the Pinard. Of these, a microphone based fetal heart monitor was selected. From these concepts, an Alpha Design was planned around the microphone input mode; this design included the use of an acoustic amplifier, a condenser microphone, and a strap with which the signal acquisition device could be secured. Further analysis of the design requirements demonstrated that certain filtration techniques would be necessary in the acquisition of the fetal heart rate. This need was addressed using foam sound insulation, as well as analog filtration techniques in order to filter out frequencies above 200Hz. Parts were then selected and ordered for use in the device, and pseudocode was written as an outline of the logic necessary to process the analog input into the Arduino; this pseudocode can be found in Section 7.6.

Since Design Reviews 3 and 4, many improvements have been made upon the device, while certain aspects have been changed in order to improve upon its function. Difficulties were faced in the implementation of the analog filters that were to be used in the final design; these were removed from the device, allowing the signal to pass to the Arduino unfiltered. This led to unwanted noise in the input, but proved beneficial in the short term design, allowing the hollow cone amplifier (schematics found in Section 7.2) that was manufactured to be successful in obtaining a signal from an adult heart. Another aspect which was altered was in the processing of the analog output. Though the team had previously planned on using MATLAB to perform calculations to find the heart rate, it was found that an interface between the Arduino and MATLAB was difficult to implement. All calculations were instead coded to be performed on the Arduino and outputted to an LCD screen.

By Design Expo, the fetal heart rate monitor was able to output an adult heart rate to within 2.7 BPM when the probe was placed on the left side an adult's chest. Only a preamplifier was utilized in the analog circuit; this connected to the Arduino, which then outputted to the LCD. The LCD displayed the instantaneous heart rate, average heart rate, and a rough approximation of baseline. Validation of these results will include the use of a ballistics gelatin simulator using a recorded fetal heart beat (Section 10) until the team can acquire an IRB to begin testing upon patients. The team plans to resume work in the winter 2013 semester, hoping to successfully implement analog filtration, improve the accuracy of the diagnostic values outputted, and address need statements that could not be addressed this semester. Improvements to be addressed in the coming semester can be found in Section 11.

Contents

1 Introduction

1.1 Project Background

During the two month period between 4 May and 1 July 2012, Ghana Cohort 3, a team consisting of Jenna Boeing, Tyler Gatlin, Elizabeth Hyde, and Evan Hendler, conducted research in medical facilities in Ghana. This research was headed by Professor Kathleen Sienko, PhD, and was the third iteration of a program stemming from an agreement with several hospitals in Ghana allowing University of Michigan engineering students to perform clinical observations with the Departments of Obstetrics and Gynecology at each respective hospital. Under the guidance of Professor Sienko, the team sought to identify potential challenges in the field of maternal health specific to West Africa.

The team conducted one month of research supervised by Dr. Odoi, Head of Obstetrics and Gynecology at Komfo Anokye Teaching Hospital (KATH), a tertiary care facility centrally located in Kumasi, Ghana. This month of research served to familiarize the team with the healthcare system in Ghana as well as to allow the team to begin compiling problem statements pertaining to specific observations logged during rounds. While at KATH, the team made note of over one hundred problem statements and used these to formulate need statements, each need statement representing a potential senior design project. Following this month, permission was obtained to proceed to rural facilities in the Upper East region of Ghana for one week, allowing the team to analyze whether these need statements were applicable to Ghana as a whole, as opposed to only tertiary care facilities. The team worked in Navrongo, a small city located near the Burkina Faso border, with Dr. James Akazili. While here, the team observed and conducted interviews at War Memorial Hospital, as well as at several CHPS (Community-Based Health Planning and Services) facilities interspersed throughout the Kassena-Nankana District.

The final three weeks were spent at Korle Bu Teaching Hospital in Accra, Ghana, under the supervision of Dr. Obed, Head of Obstetrics and Gynecology. These weeks allowed the team to narrow down the need statements based upon their importance, the impact a solution would offer, and the ability of the team to address them within the scope of a senior design course. This winnowing yielded four need statements identifying needs for a device to detect cases of post-partum hemorrhage, a device to detect maternal hypertension to prevent the onset of preeclampsia, a low cost delivery bed to address shortages of bedding in hospitals, and a low-cost device to accurately determine fetal heart rate. Further research and interviews were conducted to determine specific ways in which these needs could be addressed, to determine user requirements physicians deemed important in a potential design addressing each respective need, and general information on the prevalence and importance of each need.

Upon return to the University of Michigan, Ghana Cohort 3 selected and began work on a device which could accurately determine a fetal heart rate. Professor Sienko assumed the role of sponsor for this project. The project was planned for two semesters, with the first falling under the curriculum of Mechanical Engineering 450, and the second under Engineering 455. The goals for the first semester, as set forth by Professor Sienko, focused on the function of the device, rather than form, to design a proof of concept prototype.

1.2 Problem Description

The fetal heart rate is monitored primarily using a Pinard stethoscope, commonly referred to as a fetoscope. The fetoscope is difficult to use for lesser trained healthcare workers. The fetoscope often results in an inaccurate determination of the heart rate and unnecessary referrals in cases when the heart rate cannot be heard. In fact, in 1958 Edward Hon asked 15 obstetricians to count several different rates from audiotape and found a wide divergence in counting attributed to the unreliability of human computation of the fetal heart rate. That same year Hon produced the earliest preliminary report on recording the fetal heart rate using electrocardiography via a probe on the mother's abdomen (Freeman, 2003). It is limited by its inability to record the fetal heart rate, difficulty of use when the fetal position is unclear, difficulty of use in the presence of background noise, and discomfort of use for the physician.

Developed from this understanding of the problem, there needs to be a way for lesser-trained healthcare workers to quickly determine the fetal heart rate so cardiovascular abnormalities can be reliably identified. However, little diagnostic value is placed on a fetal heart rate recorded over a short period of time due to expected variations in the fetal heart rate. Listening to the fetal heart rate in an antenatal appointment has little value more than reassurance to the mother (Steer, 1993). Normal variability reflects a well-functioning cardiac and neurological system (Freeman, 2003). Therefore, a fetal heart rate taken instantaneously without establishing a baseline and accounting for variations is clinically indeterminate. The need statement therefore has shifted to for lesser-trained healthcare workers in resource-limited settings to determine the baseline fetal heart rate and its variations so fetal distress and cardiovascular abnormalities can be quickly and reliably identified.

1.3 Potential Scope of Project

In 2004, the World Health Organization reported 133 million live births worldwide. Of these, 3.7 million died during the neonatal period, four weeks or less after birth. Another 3 million infants were stillborn. Of these 6.7 million infant deaths, ninety-eight percent occurred in the developing world (Ahman et al. 2004). Of these neonatal deaths, 99% arise in low-income and middle-income countries (Lawn, 2005). The main direct causes of neonatal deaths globally are preterm birth at 28%, severe infections at 26% and asphyxia at 23% (Lawn, 2005). The highest neonatal death rates were reported in sub-Saharan African countries, with between 40 and 46 deaths per 1000 live births. This horrifying statistic is ten times larger than the neonatal mortality rate in developed countries (four deaths per 1000 live births) (Ahman et al. 2004)

1.4 Clinical Value of Fetal Heart Rate

Fetal monitoring is a critical tool for detecting fetal distress and abnormalities so steps can be taken to manage a particular condition if necessary. The baseline fetal heart rate is the average number of beats per minute over ten minutes, rounded to the nearest increment of five beats per minute, excluding periods in which the heartbeat is more than 25 beats per minute different from the baseline. The baseline heart beat is used as a reference norm so that large deviations from the baseline can be detected and investigated. A healthy baseline fetal heart rate should be between 110 and 160 beats per minute (Nidhal, 2010).

The baseline fetal heart rate should drop gradually during gestation as the fetus' central nervous system develops. A mid-trimester fetal heart rate should be between 150 and 170 beats per minute, while a post-term fetus should be between 110 and 120 beats per minute. This drop is due to maturation of the central nervous system and increasing dominance of the parasympathetic response (Macones et al., 2008).

When the baseline fetal heart rate drops below 110 beats per minute, the fetus is bradycardic. Bradycardia can be due to hypoxemia (an oxygen deficiency in arterial blood), drugs, maternal hypotension or hypoglycemia, hypothermia, congenital heart blocks, umbilical cord compression, an amniotic fluid embolism, or can be a normal variation. Fetal tachycardia is defined as a baseline rate above 160 BPM which is indicative of fetal hypoxia, chorioamnionitis (inflammation of fetal membranes), fetal anemia, maternal hyperthyroidism, fetal sepsis, fetal cardiac tachyarrhythmia or maternal fever or drug intake (Freeman, 2003). Fetal tachycardia following a fetal heart rate deceleration is often associated with hypoxemia. Fetal bradycardia and tachycardia should be examined for variability and periodic changes.

Moderate fetal heart rate variability is the most important indicator of a healthy fetus. Variability is defined as the amplitude of peak-to-trough measurements in beats per minute. Variations of between 6 and 25 beats per minute reflects healthy fetal movement, response to stimuli such as temperature changes, loud noises, or maternal movement, sleep cycles, and influence of the developing sympathetic and parasympathetic nervous systems over the heart rate. Variations in the fetal heart rate indicate that the fetus is receiving adequate oxygen (Macones et al., 2008).

Absent or decreased variability points to inadequate oxygenation of the fetus or abnormalities of the central nervous system. If the baseline variability decreases during a period without fetal movement, the fetus could be asleep. Decreased baseline variability during a period with fetal movement can be a cause for concern, indicating hypoxemia, drugs, prematurity, arrhythmias, or fetal tachycardia (Macones et al., 2008).

Variations of greater than 25 beats per minute can be due to umbilical cord compression, which can cause hypoxia and often occurs during the second stage of labor. A fetal heart rate acceleration is quantified as an increase in the baseline peaking in less than 30 seconds. An acceleration lasting longer than ten minutes constitutes a baseline change. Accelerations can be due to a uterine contraction (periodic) or, more commonly, unassociated with a uterine contraction (episodic). Periodic accelerations can be due to fetal stimulation or compression of the umbilical vein. Episodic accelerations are generally caused by fetal movement. Variability and accelerations in the fetal heart rate can be indistinguishable and are both indicative of an oxygenated fetus. The non-stress test (NST) is an assessment of the fetus' reactivity. An NST is considered reactive when the fetal heart rate accelerates two times or more and does not decelerate during a 20 minute period (Macones et al., 2008).

Decelerations are often also associated with uterine contractions during the active stage of labor. The lowest point of the deceleration and the highest point of the contraction should occur simultaneously. Decelerations slightly before the peak of the contraction can indicate fetal head compression due to the

contraction, stimulating the vagus nerve. The heartbeat should return to normal when the compression passes. If a deceleration during a contraction occurs early in labor, it could indicate cephalopelvic disproportion; a condition that necessitates a cesarean section. Decelerations beginning after the end of a contraction can be caused by uteroplacental insufficiency. In this case, a problem exists with a uterine perfusion, uterine activity, or the placenta (Macones et al., 2008).

2 Information Sources

2.1 Ethnographic Research

A large percentage of the data used to develop user requirements and engineering specifications for this device was collected through daily interviews with doctors, nurses, midwives, and other health care workers at the observation sites in Ghana. Directly observing obstetric procedures regularly was beneficial because the team saw the current methods of monitoring fetal heart rates in action. The team regularly saw the Pinard stethoscope used and learned about its capabilities and limitations first-hand.

2.2 Benchmarking

In order to determine features to be included in the design and to justify several engineering specifications, the team looked to devices currently available to monitor fetal heart rate. Current portable devices can be divided into two main categories: acoustic and electronic, the latter of which can be further divided based upon the method by which the signal is collected for processing. The methods include passive and active signal collection, passive being collection via microphone and active being collection using Doppler ultrasound techniques. Additionally, many clinicians utilize cardiotocography (CTG) to assess the health of a fetus.

2.2.1 Pinard Stethoscope (Fetoscope)

The Pinard stethoscope (or fetoscope) is a lightweight, low-cost device invented in 1895 and is still commonly used in developing countries today. The fetoscope can be made from a multitude of different materials, including but not limited to wood, aluminum, and plastic (Medical Antiques Online, 2011). Materials used are aimed at minimizing price, with non-wholesale price generally falling between 10-30 USD. This device has a characteristic "trumpet" shape, with the wide end pressed upon the abdomen of the mother and the other end pressed to the ear of the physician. The trumpet shape amplifies the faint sound of the fetal heartbeat, allowing it to be readily heard by the physician and counted out to determine the fetal heart rate (Medical Antiques Online, 2011).

There are a multitude of issues associated with this device. The first and foremost is the training time associated with usage. From interviews with clinicians, as well as first hand observations, it was found that it takes several years of experience for clinicians to be able to reliably ascertain fetal heart rate using the fetoscope (Lawrence, 2012). The fetoscope also requires the physician to be in an awkward, uncomfortable position while he or she tries to pick out the faint fetal heartbeat over ambient noises and the maternal heartbeat. In addition to this, the device offers a very subjective read-out. According to the founder of Fetal Assessment Center in KATH, clinicians are often tempted to run a spot check using this device and report approximate rates in lieu of exact numbers (Lawrence, 2012). These

numbers also lack data regarding accelerations and decelerations of the fetal heart rate; this is particularly troublesome given that changes in the fetal heartbeat offer more insight into complications than does a baseline fetal heart rate (Anderson, 2012).

Figure 1: An aluminum Pinard Stethoscope (Rambo, 2012)

2.2.2 Doppler Fetal Monitor

The Doppler Fetal Monitor is the gold standard in non-CTG fetal heart monitoring. This device is used in the majority of developed countries. The device commonly consists of two parts – a probe, and a processing unit. Depending on the device, the probe may output numbers to the screen, a graphical representation of the rate, or simply an amplified fetal heart beat (Freeman, 2003).

This type of device is limited by its cost. The *2011 Compendium of Innovative Health Technologies for Low-Resource Settings* indicates that the most promising new device utilizing Doppler technology has a base price of $350 (WHO, 2011). This is too expensive for many hospitals in the developing world to purchase. The high cost of this device is due to its use of ultrasound technology. Like the fetoscope, however, the Doppler Fetal Monitor lacks the ability to track accelerations and decelerations in the fetal heart rate (WHO, 2011).

Figure 2: Doppler fetal heart rate monitor as described in text (WHO, 2011)

2.2.3 Microphone Fetal Monitor

A microphone fetal monitor fills the same niche as a Doppler monitor. The major difference between a microphone based monitor and a Doppler monitor lies in the method by which the signal is collected. Where a Doppler monitor actively probes for a signal using ultrasound techniques, a microphone-based monitor passively receives a signal through electro-acoustic means. This offers a major advantage in

terms of cost of manufacture – a microphone-based probe is significantly less expensive than one reliant on ultrasound.

The most relevant device of this type is the BabyBeats Fetal Monitor designed by students at Johns Hopkins. This device has all of the same features as the one highlighted in the Compendium of Innovative Health Technologies, but utilizes a microphone rather than an ultrasound probe. This significantly cuts down the price, with the designers estimating the cost at less than 10 USD (Dell, 2012). However, like the aforementioned Doppler design, this does not account for accelerations or decelerations in fetal heart rate (Dell, 2012).

Figure 3: BabyBeats prototype as of 13 June 2012. Note that there is only one numerical readout - this outputs the fetal heart rate (HopkinsEngineering, 2012)

2.2.4 Cardiotocography (CTG)

Cardiotocography (CTG) machines offer all of the features of the three aforementioned devices along with several other features clinicians find to be beneficial. The CTG machine provides a printout of data collected in graphical form. On the printout, there are two lines. The top line displays the fetal heart rate over time: the x-axis of the graph is representative of the elapsed time of the readout, while the y-axis is representative of the instantaneous fetal heart rate. The bottom line displays uterine contractions. Below is an example of a CTG graphical display.
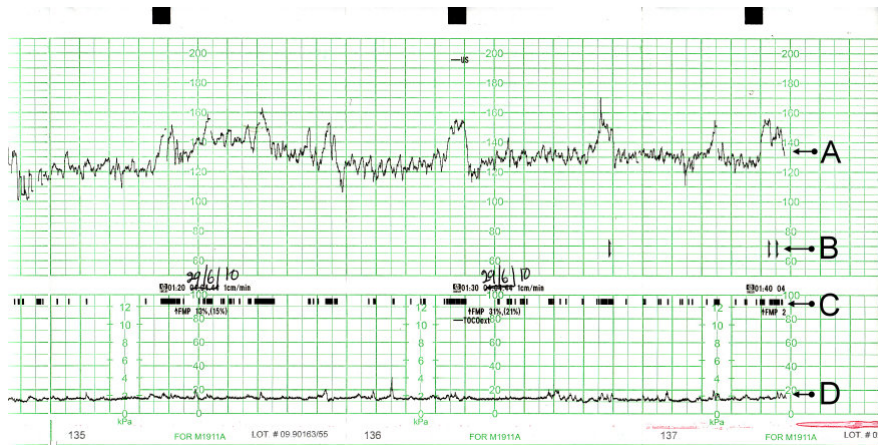
Figure 4: Example of a read out from a Cardiotocography machine. Of note are letters A and D, representing fetal heart rate and uterine contractions, respectively (Fauntleroy, 2012).

The advantage of CTG is that, unlike the other devices, accelerations and decelerations are evident in this time-dependent readout. This allows a clinician to diagnose many life-threatening conditions, including hypoxia and acidosis (Lawrence, 2012). These added features come at the expense of both affordability and portability, however. CTG machines often cost well over 500 USD, with newer models costing over 5,000 USD from wholesale medical device dealers. Most CTG machines are also too large to be transported long distances, as they are usually about the size of the tower unit on a desktop computer. This is not ideal for clinicians making house calls in developing countries. Additionally, the CTG machine must be plugged in during use; thus, it is not a viable option for clinics lacking electricity.

Figure 5: Agilent HP M1350B Viridia Series 50XM Fetal Monitor (799 USD), a comparatively low-cost CTG machine (Integris)

2.3 Mentors

Alfred Aikins, a fetal heart rate specialist, provided a thorough tour of the cardiotocography suite, or the fetal assessment center, at KBTH. Here the use of the CTG was observed and the implications of the test results were explained.

Dr. Frank Anderson is a physician specializing in obstetrics and gynecology at the University of Michigan Hospital. He holds a Masters in Public Health and is active in research and global health initiatives benefitting pregnant women worldwide. He has been indispensable in understanding the importance of fetal monitoring and the most important characteristics of a fetal heart rate monitor.

Since Cohort 3's return to the United States, contact has been maintained with several clinicians in Ghana via email, phone, and Skype. Dr. Obed, Head of Obstetrics and Gynecology at Korle Bu Teaching Hospital, and Dr. Odoi, Interim Head of Head of Obstetrics and Gynecology at Komfo Anokye Teaching Hospital, receive weekly updates by email and can be reached via the phone upon request.

3 User Requirements and Engineering Specifications

3.1 Obtaining User Requirements

The first step of user requirement identification was directly consulting health care workers in Ghana. According to the World Health Organization, keeping the final user involved during the design process is an important step to producing a successful medical device. Designs based on the designers' impressions of the users' needs are less likely to be implemented than designs created with user input (Howitt, 2012). Ghanaian health care workers were asked to identify desirable qualities for the device and to rank the user requirements based on importance.

American obstetricians were also consulted to confirm user requirements. Dr. Frank Anderson, Dr. Mike Dombrowski, and medical student Emma Lawrence from the University of Michigan Hospital helped establish the current set of user requirements. Dr. Kathleen Sienko provided guidance based on her extensive experience designing medical devices for use in developing countries.

3.2 Translating to Engineering Specifications

During interviews conducted in Ghana, healthcare workers were asked to provide numerical specifications for user requirements. Engineering specifications are supported by supplementary research. If no health care worker could confidently assign a numerical specification, numbers were found in peer-reviewed scientific literature. It is difficult to maintain contact with health care workers in Ghana, but several remote interviews have been conducted since the team's return to the United States to confirm engineering specifications.

3.3 Rank Ordering User Requirements and Engineering Specifications

User requirements were initially ranked based on interviews in Ghana and the United States. Next, user requirements were divided into "Function" and "Form" categories. Within each group, user requirements are ranked in order of importance based on interviews and supplementary research. The prioritization matrix used to rank all user requirements can be found in Appendix III. Requirements in the "Function" group are qualities needed for the device to produce diagnostically valuable information about the cardiac function of a fetus. Items in the "Form" group describe the physical characteristics and user interface of the device.

During ME 450, the team sponsor, Dr. Kathleen Sienko, advised the team to strive to meet every requirement in the "Function" category before addressing "Form" requirements due to time limitations and the complexity of the project. The objective for the first semester of design is to produce a device capable of detecting, analyzing, and outputting a fetal heart rate. Design will continue through the winter 2013 semester, during which "Form" requirements will be more closely examined. The user requirements and engineering specifications are below in Table 1.

Table 1: User Requirements and Engineering Specifications

	User Requirement	Engineering Specification
Function	Accurately determine the baseline heart rate of fetus	Outputs FHR within ± 2 BPM at a 95% confidence level ≥ 10 min monitoring time
	Accurately determines the mean variability	Outputs the mean variability within ± 2 BPM at a 95% confidence level
	Mother and user can hear the sound of fetal heart beat	Sound of heartbeat output louder than 60 dB
	Indicates whether referral is necessary	1 Indicator if the mean variability is outside the range of 5-25 BPM OR if the FHR is outside the range of 110-160 BPM
	Reliability	≥ 95% Specificity ≥ 85% Sensitivity
	Does not rely on grid electricity	Requires 0 Watts of grid electricity at time of use
	No ambiguity in performance	1 indicator for correct placement 1 indicator for low power 1 indicator for malfunction
Form	Low cost	< $40
	Reusable	0 single use parts 0 consumables needed
	Easy to use	≤ 2 steps for activation ≤ 1 hour of training 1 operator required
	Portable	Volume < 72 cubic inches (1 side ≤ 2.6 inches) Weight < 0.7 kg
	Durable	Withstand a fall from 1.6 m Lifetime > 9,125 uses
	Sterilizable	0% of 1:100 chlorine bleach applied to external surfaces of the device comes into contact with components sensitive to water damage.

3.4 Detailed Specifications

Accurately determine the baseline heart rate of fetus: The most important user requirement is that the device accurately determines the baseline fetal heart rate. ±2 BPM was chosen based off of competitive benchmarking. The SonicaidOne handheld Doppler fetal heart rate monitor is accurate within ±2 BPM. The purpose of this design is to provide a referral tool rather than a diagnostic tool, so the team adopted

the accepted research standard of a 95% confidence level. The definition of the baseline fetal heart rate is the mean FHR taken over a ten minute period excluding abnormal variations (those that exceed 25 BPM) (Macones, 2008). Thus to accurately determine the baseline, the design must monitor the heart rate and process the data for at least 10 minutes.

Accurately determines the mean variability: Normal variability reflects a well-functioning cardiac and neurological system (Freeman, 2003). Therefore, a baseline fetal heart rate without information about variability provides little diagnostic value. Though the system would ideally output a graphical representation of variations, a determination of the mean variability will provide enough information for a referral tool (Anderson, 2012). Without a benchmark to compare a mean variability output to, the accuracy of 2BPM and a confidence level of 95% were chosen in accordance with the accuracy of the baseline.

Outputs the sound of the fetal heartbeat: Listening to the fetal heart rate in an antenatal appointment has little diagnostic value other than reassurance to the mother (Steer, 1993). Outputting the sound of the heart rate can, however, provide diagnostic information about the device itself (Belt, 2012). If the device is producing the sound of the fetal heartbeat acoustically but cannot produce numerical outputs for the rate or variability, it is clear that the lack of output is due to a malfunction, not fetal distress. If the device can neither detect a fetal heartbeat nor output information about it, the womb is equally silent and there is cause for alarm. The device outputting fetal heart sounds will also help the user localize the fetal heart and will reassure the mother (Odoi, 2012). According to the Health and Safety Executive, the noise level of a conversation is 60 decibels, thus the sound output must exceed 60 decibels (HSE, 2005).

Indicates whether referral is necessary: With outputs of both baseline fetal heart rate and mean variability, the user must be able to correctly determine whether the patient should be referred to a larger hospital. To ensure the design enables users to refer patients accurately, there needs to be an indicator to refer when the mean variability falls outside the rage of 5-25 BPM or the baseline FHR falls outside the range of 110-160 BPM. These ranges are widely recognized as acceptable standards for a healthy fetus (Macones, 2008).

Reliability: This tool needs to be able to determine whether or not fetal distress is present and alert the user if the patient needs to be referred accordingly. Sensitivity is the proportion of positive test results that are true positives and specificity is the proportion of false test results that are true positives. Because this device is for referral of patients as opposed to diagnosis of patients, the sensitivity doesn't have to be very high. That is there is no harm to a patient who is referred if her baby is in fact healthy. However, there is a potential for serious harm to be done by sending a patient home who in fact needs to be referred, so the specificity of the device needs to be high. The specificity was decided to be 95% and the sensitivity was decided to be 85%. These numbers were confirmed by Dr. Anderson (Anderson, 2012).

Does not rely on grid electricity: In developing countries, the pattern of power grids and the flow of power within the grids are inconsistent. According to the World Health Organization, developing

countries have an increasing dependence on donated medical devices and in some countries up to 80% of all medical equipment is donated (WHO, Guidelines for Donations to Health Care Industry). With such devices being designed under the assumption electricity will be constantly available, sporadic blackouts have a large impact on hospitals, particularly hospitals in rural areas due to the increased frequency of such blackouts. Midwives in rural communities may have little or no access to grid electricity; thus it is important that medical devices in developing countries can be charged using solar energy, electricity from fossil fuel plants, or dams and are not dependent on reliable grid energy to function. Many developing nations have abundant natural sunlight, but harnessing it can be cripplingly expensive. Rechargeable batteries are the most cost-effective method of powering electrical devices because they are self-contained and can last for long periods of time between charges, bypassing the issue of irregular grid power (Casanova et al., 2009). Dr. Odoi indicated that the device should function for two months between charges (Odoi, 2012). As not to limit design possibilities, a specification of 0 W of grid electricity demanded at the time of use for the device to function was set.

No ambiguity in performance: This device will assess the well-being of a fetus. There should be no room for interpretation when the device outputs a result. In cases where no fetal heart rate is found, the device should indicate whether the lack of output is due to an empty battery, a malfunction in the device, or an abnormality with the fetus. The user should be able to easily verify that the device has ample charge, is working correctly, and abnormal heart beats detected are indicative of the condition of the fetus rather than of the fetal heart rate monitor. These features were suggested by Dr. Sienko (Sienko, 2012).

Low cost: The cost of medical equipment is a limiting factor for hospitals in the developing world. Robert Malkin identified the cost of equipment as the single most common barrier to implementation of health care technologies in low-resource settings (Malkin, 2007). "Low cost" is defined as costing less than $40. The price of a home fetal heart rate monitor that only outputs the sound of the fetal heart and an instantaneous heart rate in the United States varies from $10-$40. Considering the increased diagnostic value of a device capable of recording for 10 minutes or more and outputting the variability, $40 is a reasonable price limit and is still within Dr. Obed's price range.

In addition, the team observed midwives using a $90 blood pressure monitor, the Omron 7 Series, in several different rural health care centers in Ghana. If a clinic is able to purchase a $90 diagnostic device, it is reasonable to assume a $40 device is within the realm of possibility.

Reusable: The purpose of the device is to provide a low cost alternative to current devices on the market. Given that price is a major factor in whether a device gets purchased or not, particularly in resource-limited settings, it is important that single use parts are not included. Disposable parts offer a short-term price break, but based off of device usage trends in Sub-Saharan Africa, disposable parts will inevitably increase the costs of operation and maintenance of the device (Malkin, 2007). In addition, a device that requires a disposable part often ceases to be utilized upon running out of the part in question; this is due to a combination of both cost and lack of availability of the part (Malkin, 2007). Malkin also notes that the need for consumable is the third most prevalent barrier to health care

technologies in the developing world (Malkin, 2007). The design must have 0 single use parts and consumables.

Easy to Operate: This device is intended for use by midwives in rural communities that often have to travel between communities; thus they have to operate independently, forcing them to rely heavily on the degree to which a new technology is user friendly and easy to use (Beenkens et al., 2010). The American Society of Mechanical Engineering suggests that to design a device to be easy to use, you must consider the most technologically advanced innovation the end-user is used to (Thilmany, 2011). The most common fetal heart rate monitors outside the Pinard stethoscope seen in Ghana were Sonicaid Doppler monitors, which required 2 steps to begin monitoring. Thus the user must be able to activate the device in two or less steps. Dr. Obed specified that the training time be less than an hour, which was corroborated by several nurses. Dr. Jody Lori at the University of Michigan School of Nursing has worked extensively in Sub-Saharan Africa and in Ghana in particular training midwives to properly use the Pinard stethoscope. She believed that an hour to train a midwife given the nature of this device is appropriate. The device is intended for use by midwives that travel between communities often times alone. Thus it is imperative that the device is operated by only one user.

Portable: Size and weight must be taken into account when developing devices intended to be portable. Transportation in resource-limited settings can be difficult and expensive due to poor road infrastructure and challenging terrain (Gwilliam, 2008). According to the African Infrastructure Country Diagnostic, less than 40% of Africans in rural areas live within two kilometers of an all-season road (Gwilliam, 2008). Given this low percentage, accommodations must be made in order to impact the largest group possible. To maximize the ease of transporting the device, it should be small enough to be stowed in a pack or pocket, moved to a location where it is needed, and easily held in one hand by the operator for use in locations without clear and convenient work surfaces. Dr. Obed indicated that a portable fetal heart rate monitor would be approximately 3 in x 3 in x 8 in, thus the volume must be less than 72 cubic inches (Obed, 2012). According to the Association for the Advancement of Medical Instrumentation, the 2.5 percentile of men and women have a hand dorsum length of 2.8 and 2.6 inches respectfully (Jones et. al., 1988). Therefore one of the edges should not exceed 2.6 inches in order for 97.5% of women and men to be able to comfortably carry the device. Through comparative benchmarking, the weight of a hand held fetal heart rate monitor should not exceed 0.7 kg.

Durable: Anecdotal interviews with doctors at Komfo Anokye Teaching Hospital indicate that medical workers in Ghana value the medical devices they possess and treat them with care (Sutherland, 2012). The most likely cause of damage to this device is dropping, as it will be handheld. The device must be able to withstand the impact force of a fall from 1.6 meters and sustain only cosmetic damage. 1.6 meters was chosen because it is the average height of a human being in 54 low to middle income countries (Macones, et. al., 2008). Defining the durability in terms of a single fall was established by the user manual for the Philips Healthcare Avalon Fetal Monitor FM20, which defines 1 meter as the maximum height from which the device can fall onto a concrete surface and suffer only cosmetic damage (Philips Healthcare). This is the fetal monitor most commonly used at the University of Michigan Hospital Perinatal Assessment Center (Belt, 2012).

A lifetime of 5 years for a referral tool used in rural communities was suggested by Dr. Obed, although he did not provide an answer on the expected number of uses per day. Based on the interviews with midwives in rural Ghana, the device will be used approximately five times a day, resulting in 9,125 uses in a lifetime.

Sterilizable: Although Dr. Obed indicated that cleaning a medical device used externally would not be necessary, the FDA requires that any device that cannot safely be sterilized or has impaired functionality as a result of sterilization be labeled as single use (GAO, 2008). Thus, it is essential that the interface between the sensor and the mother must be easily sterilizable to conform to FDA standards without having to designate parts of the device as single use. According to Centers for Disease Control and Prevention, a noncritical medical device is one that comes into contact with intact skin, but not mucus membranes (Rutala et al., 2008). Though there is almost no risk of transmitting infectious agents to patients directly from a non-critical device, there are risks of secondary transmission by contaminating the hands of healthcare workers or other surfaces in the hospital that may come in contact with patients (Rutala et al., 2004). Thus noncritical medical surfaces should be disinfected with an EPA-registered low or intermediate- level disinfectant (Rutala et al., 2008) Commonly used in the hospitals of Ghana are chlorine bleach solutions. A 1:100 dilution of household bleach and water should be used for surface disinfection, and must be applied for at least 60 seconds (Rutala et. al, 2008). Therefore, to use a low-level disinfectant the electrical components of the device must be sealed to the elements. There should be no effect of wiping the device with disinfectant for 60 seconds and so 0% liquid should make contact with sensitive electrical components.

4 Concept Generation and Selection

4.1 Methods

Concept generation began with a breakdown of the function of the device shown in Figure 6. Then concepts were generated for each subsection seen in Figure 6.
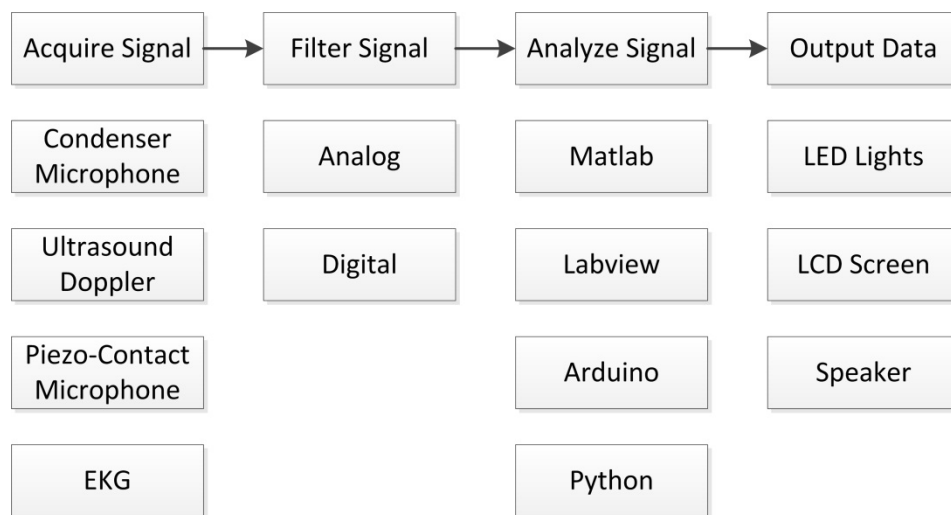

Figure 6: Concept generation for the breakdown of processes of the device.

The expectation of the device is solely function, so the user interface of the output is not a primary concern (ideally all three outputs will be utilized). Filtering the sounds will need to be done both analogously and digitally. Analyzing the sounds will most easily be done on a computer, with a software package that the team is comfortable using. In the future the computational component of the design may change to a more inclusive, efficient component, but for now a computer makes the most sense for designing the function of the device. Filtering and analyzing the data is largely dependent on the signal acquisition method, so concept generation was primarily done on the signal acquisition via independent brainstorming, collaborative brainstorming, and functional decomposition. Independent brainstorming was done in ten-minute intervals on the selected component. Every concept was sketched on a whiteboard and labeled with a number. After all concepts were up, each team member presented his or her concepts. No comments were allowed until every concept had been presented. Concepts were also generated through collaboration. Each teammate drew a design idea on a piece of paper. Papers were passed to the right. Team members examined the design passed to them and added modifications and suggestions. After a design had been seen by everyone, it was discussed among the group members. Sketches of all concepts generated can be found in Appendix I.

First, brainstorming sessions were held for the method of signal detection and a main concept was decided on. Next, brainstorming sessions were held on external noise reduction, attachment to the maternal abdomen, and acoustic amplification.

4.2 Heartbeat Signal Detection

Detecting electrical fetal cardiac activity using an electrocardiogram: An electrocardiogram (ECG) detects the electrical potential generated by cardiac muscle contractions. Electrical pulses are conducted from the sinoatrial node of the heart to the atrioventricular node and the Purkinje fibers, which contract to force blood through the heart. The signal can be collected using electrodes and analyzed to measure the heart rate and detect heart damage. During ECGs performed on adults, the electrodes are placed on the skin above the heart. ECGs have been successfully used to measure the fetal heart rate using an invasive electrode passed through the cervix to the fetus' scalp. A study conducted by Cochrane et al. showed that patients monitored with both an invasive electrode ECG and a CTG during labor required fewer surgical interventions than patients monitored with only a CTG (Cochrane, 2012). Detecting a fetal heart rate using noninvasive electrodes is significantly more difficult because the signal to noise ratio of the fetal ECG is much lower than the ratio for the maternal ECG. Noise in the fetal heart signal is due to tissue between the fetal heart and the electrode on the surface of the abdomen, the small size of the fetal heart, and contamination with electrical fetal brain activity and maternal muscle contractions. The fetal heart signal cannot be easily isolated from other biosignals based on time, space, frequency, or amplitude (Sameni and Clifford, 2012).

A noninvasive electrocardiogram setup requires between four and twelve electrodes. Two or three electrodes are placed on the mother's extremities, far away from the fetus, and function as reference electrodes. During adult ECG monitoring, reference electrodes are placed on the patient's wrists and ankles. The remaining electrodes are placed as close to the fetal heart as possible. Ready-made ECG electrodes in the United States cost between $3 and $100. Extremely inexpensive, functional ECG electrodes can, however, be assembled using bottle caps and sewing snaps using a method developed

by Engineering for Change (Engineering for Change, 2012). Conductive gel must also be spread on the patient's skin underneath the electrode so the electrical signal can pass through the insulating layer of air between the patient and the electrode. Electrically conductive gel can be mixed from flour, water, salt, and bleach (Engineering for Change, 2012).

Detecting the motion of the fetal heart using ultrasound technology: Ultrasound technology uses high-frequency sound waves to image internal body structures. A probe transducer is placed on the maternal abdomen. Ultrasound gel must be spread on the abdomen to conduct the sound waves from the probe to the patient's body.

A Doppler fetal monitor is a hand-held ultrasound transducer that uses the Doppler shift principle to create an audible recreation of the fetal heartbeat. The Doppler effect is the phenomenon of a sound wave coming from a moving source appearing compressed or expanded and the frequency of the wave changing when measured from a still reference point. The Doppler fetal monitor emits high frequency sound waves created by microscopic vibrations in piezoelectric crystals in the probe. The sound waves are reflected back to the probe. When the sound waves meet a moving object, such as the fetal heart, they bounce back to the probe at a slightly different frequency. The Doppler monitor converts the frequency change into an audible fetal heart beat (Meditech Group, 2012).

If ultrasound technology was selected for the fetal heart rate monitor device, the setup would include several pre-made components. Ultrasound machines and hand-held Doppler monitors contain extremely specialized pieces and complicated circuitry. It is likely that designing one from scratch is overly ambitious, given the time restrictions on this project, so a device based on ultrasound technology would use a pre-fabricated probe containing piezoelectric crystals.

Detecting acoustic emissions from the fetal heart using a piezoelectric film contact microphone: Piezoelectricity, also known as "pressure electricity," is a property of certain crystals. When pressure is applied to the crystals, electricity is generated (Ballou et al., 2008). The vibrations at the interface at which the crystal meets the solid compress the crystal, which then transmits the energy from the compression to produce potential. This potential is then sent through the wire as an input for signal processing. High piezoelectric response is available in ferroelectric films, which are apt for high sensitivity sensors (Maralt et al., 2009). In 1969, large piezoelectricity was discovered in elongated and poled films of polvinylidene fluoride (PVDF) (Fukada, 2000). The sensitivity of the PVDF enables its use in electronic stethoscopes, where the vibrations in the skin are picked up and transformed to electrical current using the piezoelectric properties of the film (Patent 0157888).

Measurement Specialties developed a contact microphone (CM-01) ideal for detecting body sounds. The design utilizes the sensitive PVDF film and combined with a low noise electronic pre-amplifier offering extremely high sensitivity to the vibrations (CM-10 Data Sheet). A single microphone costs $31.93, but the price decreases to $12.48 when purchased in quantities of 10,000 or more microphones (Private Quote).

Detecting acoustic emissions from the fetal heart using a condenser microphone: Microphones convert acoustic energy into electrical energy by using a diaphragm or moving surface that reacts to a sound

wave (Ballou et al., 2008). Specific sound intake requires detailed selection of the microphone used. A microphone can have an omnidirectional, bidirectional or unidirectional pickup pattern. Omnidirectional picks up sounds in all directions (corresponding to a spherical pick up pattern), a bidirectional picks up sound waves in the front and in the back equally well with no pickup from the sides and a unidirectional has a greater sensitivity to sound waves approaching from the front than any other direction. The benefits of a unidirectional microphone are less background noise, more gain before feedback and it is easier to discriminate between sound sources (Ballou et al., 2008). To reduce external noise and isolate the fetal heart rate as much as possible, a unidirectional microphone will be used in this application.

Condenser or capacitor microphones have two plates at a fixed distance apart with a fixed voltage across them. Usually one plate is a diaphragm and the other is a heavy back plate. The sound pressure waves vary the capacitance by deflecting a plate of the capacitor causing an electrical signal that varies with the sound signal (Ballou et al., 2008). A capacitor microphone requires less power and has a faster response time than a dynamic microphone because the mass of the moving part is less (Ballou et al., 2008). A condenser microphone is priced at about $2-$3 depending on the frequency range, impedance and sensitivity.

Signal Detection Selection: To help determine the most appropriate signal acquisition method for application, a Pugh chart found in Table 2 was employed, and the condenser microphone was selected.

Table 2: Signal Detection Pugh Chart

	Doppler (baseline)	Condenser Microphone	Electrocardiogram (EKG)	Piezo Contact Microphone
Power Draw (30)	0	+1	+1	+2
Cost (20)	0	+2	+1	0
Signal Quality (35)	0	-1	-2	-1
Reusable (15)	0	+1	-1	+1
Total (100)	**0**	**+50**	**-35**	**+40**

The rating was based on a five point scale, where 0 represented that the method was comparable to the baseline method, a positive number corresponds to the method being more effective than the baseline and a negative number means the method is less effective. The Doppler was marked as the baseline for this application due to the prominent use of Doppler technology as the Gold Standard in developed countries and the rare appearance of Sonicaid Doppler fetal monitors in rural Ghana. The higher the total, the better the method is for this application. The condenser microphone was chosen based on the results of the Pugh chart. The condenser microphone is the best detection method for the fetal heart rate based primarily on the low cost of the device, but also on the signal quality, low power draw, and the reusable nature of the component.

4.3 Attachment to the Maternal Abdomen

The fetal heart must be monitored for ten minutes to acquire a baseline heart rate and several minutes longer to detect variations. The device should have a mechanism to secure the detection probe to the maternal abdomen so that a healthcare worker does not have to manually hold the probe in place. Including an attachment mechanism would allow the healthcare worker to perform other tasks while the device is monitoring one fetal heart rate. It would also reduce noise interference caused by slight positional changes of the probe when the healthcare worker shifts his or her weight or adjusts the probe.

The images depicting each attachment concepts below are shown on a cone-shaped probe for simplicity and consistency. All of these concepts could be applied to any probe shape.

Velcro strap: A hole slightly larger in diameter than the detection end of the probe is cut in a Velcro strap several inches wide. The probe is assumed to be slightly wider or have a lip on the detection end so it does not escape from the Velcro strap. The probe is placed through the Velcro strap. The strap is wrapped around the maternal abdomen and secured underneath. An advantage of this design is the wide availability and low cost of Velcro in Ghana, so the strap could be replaced easily. The strap is easily adjustable to accommodate patients of all sizes.
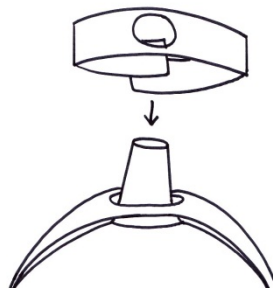
One-way air valve for suction: The rim on the detection end of the probe is made of a pliable material to closely fit the contours of the abdomen. It contains a one-way air valve. The air valve can be used to remove air from the cavity between the probe and the abdomen, creating suction. This device is not affected by the size of the patient. An advantage of this design is that it does not require any additional parts for attachment because the air valve is part of the probe.
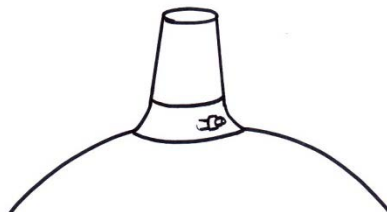
Negative pressure chamber for suction: The rim on the detection end of the probe is made of a pliable material to closely fit the contours of the abdomen. A tube connects the cavity between the probe and the abdomen, which is assumed to be airtight, to a negative pressure chamber. The chamber functions

like a large syringe; pulling the plunger from the compact position to the expanded position creates negative pressure in the chamber and forces air out of the cavity between the probe and the abdomen. This design is complicated by removal of the negative pressure chamber without releasing the vacuum. Another disadvantage is the additional price of the negative pressure chamber, which could potentially add several dollars to the total price. The chamber would also be difficult to replace and would not function if the airtight connection between the plunger and chamber was damaged.
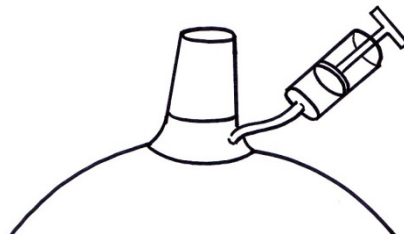
Circular weight: A sac containing a dense material (such as sand) encircles the detection end of the sound probe. The weight increases the normal force of the probe on the maternal abdomen, directly increasing the friction force and keeping the probe in place. This concept would work optimally when the probe is placed vertically on top of the abdomen, but may not be effective when the probe is placed on more inclined areas of the abdomen.
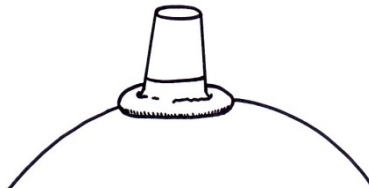
Abdomen Attachment Selection: The Pugh chart found in Table 3 was used to select the Velcro method.

Table 3: Abdominal Attachment Pugh Chart

	Velcro (baseline)	One-Way Valve	Negative Pressure Chamber	Circular Weight
Accommodates all sizes (15)	0	+2	+2	+1
Stability (40)	0	-1	-1	-2
Ease of attachment (25)	0	-1	-2	+2
Cost (20)	0	-1	-2	0
Total (100)	**0**	**-55**	**-100**	**-15**

4.4 Acoustic Amplification

With a variety of sounds capable of being picked up with a condenser microphone such as sounds of digestion and maternal pulse, hearing a low energy fetal heart rate will be a challenge. In order to help identify and isolate the faint sounding heartbeat, acoustic amplification will be necessary.

Hollow cone amplifier: This design mimics the cone shape of the Pinard stethoscope to amplify sound from the fetal heart. It is likely that Ghanaian health care workers would quickly understand and be comfortable using a device with this design because they are familiar with the shape. Sound waves are moving regions of high-pressure disturbances in the medium. When sound enters the wide end of a cone and moves toward the narrow end, the pressure disturbances are confined to smaller and smaller areas, increasing the pressure further. When the sound reaches the end of the cone, it has been amplified.

Fluid-filled sac amplifier: A sound wave travels through a medium as a pressure disturbance. Collisions between energetic molecules and molecules at rest propagate the energy wave. The speed of the wave increases with the density of particles in the medium. Liquids are denser than air, so sound moves through a liquid more quickly than through air (Thomas, 2012). Sealed, fluid-filled sacs are common and inexpensive in Ghana because they are a major source of drinking water. Sachets full of purified water are widely available, cost $0.10 or less, and are a manageable size. A balloon or condom filled with water and sealed could also be used. In this design, the fluid sac is placed on the maternal abdomen and the sound detector is placed on top of it. The fluid amplifies and transmits the sound of the fetal heartbeat to the sound detector, where it is collected for analysis. Introducing a liquid component into the design presents the risk that the sac could burst and damage the electronics of the rest of the device. In addition, a fluid sac could be difficult to secure to the maternal abdomen for an extended period of time. The sound would move even faster if the sachet was warm or hot because thermal energy increases the number of molecular collisions, increasing the propagation speed of the wave.

Vibration-sensitive diaphragm: A shallow cone is sealed by a thin membrane on the wide end and connected to a tube on the narrow end. The membrane end of the cone is placed on the surface of the maternal abdomen above the fetal heart. Vibrations caused by movement of the fetal heart propagate through the abdominal tissue and reach the membrane. The membrane moves in response to the vibrations, creating larger pressure waves inside the device. The intensified pressure waves are funneled into the tube, where they will encounter a transducer and be converted into electrical pulses.

Solid metal: The propagation speed of sound waves through a material depends on the properties of the medium. Sound travels fastest through dense metals because the energy of the sound wave is transmitted by intermolecular collisions. In a material as dense as metal, collisions happen very quickly. A solid metal piece placed directly on the maternal abdomen would transmit sound extremely quickly to the transducer. A tapered shape would focus the sound waves so they are amplified when they reach the transducer.

Acoustic Amplification Selection: The Pugh chart found in Table 4 was used to select the cone method.

Table 4: Acoustic Amplification Pugh Chart

	Cone (baseline)	Fluid-Filled Sac	Vibration-Sensitive Diaphragm	Solid Metal
Degree of amplification (35)	0	-1	+1	0
Ease of sterilization (15)	0	0	-1	+1
Durability (15)	0	-2	-2	+2
Cost (35)	0	-1	-2	-2
Total (100)	**0**	**-100**	**-80**	**-25**

4.3 External Noise Reduction

For a condenser microphone to be capable of picking up a fetal heart rate, the microphone must be very sensitive. With this increased sensitivity, the microphone is vulnerable to picking up an excessive amount of external noises, especially considering the large amount of ambient noise present in some Ghanaian health care facilities. Thus methods of reducing unrelated external noise are necessary in the design of the device.

The images depicting each noise reduction concepts below are shown on a cone-shaped probe for simplicity and consistency. All of these concepts could be applied to probe of any shape.

Insulating the probe with a plastic shell and sound-insulating foam: A hemispherical plastic shell surrounds the probe. The space between the shell and the probe is filled with noise-dampening foam. The foam layer will insulate the probe from sounds originating outside of the mother's body.

Encasing the probe in a vacuum: Sound waves only propagate in a medium. There is no sound transmission in a vacuum (Rudnick). In this design, the probe is covered by a hemisphere. The rim of the hemisphere is lined with pliable plastic so it fits the abdomen and creates an airtight seal. The junction between the plastic and hemisphere is sealed with acoustic sealant. The device is placed on the abdomen with the face of the hemisphere against the skin. The air is removed from the space inside the hemisphere using a one-way valve or a negative pressure chamber. Because there is no sound transmission in a vacuum, this design prevents noise from external sources from affecting the signal before it reaches the transducer or directly after. This design adds complexity to the fetal monitoring procedure because creating the vacuum is an additional step.
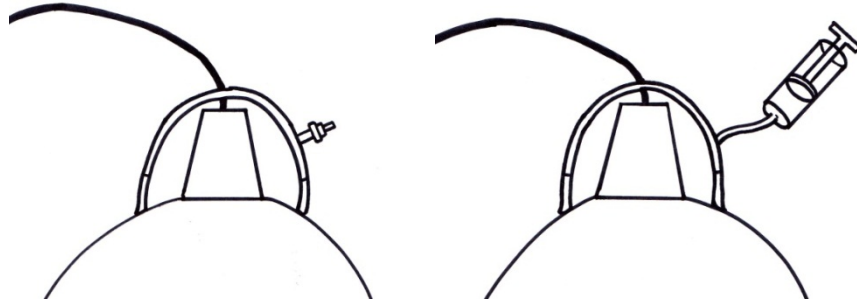
Insulation with a vacuum tube: Plastic catheter tubes are widely available in Ghana because of their many uses. In this design, a vacuum is created inside of a long catheter tube. The ends of the tube are sealed by melting. Several points in the middle of the tube are also sealed by melting so that damage to one section will not compromise the vacuum of the entire tube. The tube is wrapped around the outside surface of the sound detection probe and secured, covering the entire external surface. The tube also completes one circle below the rim of the wide end of the probe. The sturdy, cylindrical plastic structure of the tube prevents it from caving in due to the lack of internal pressure. The tube can be secured to the probe by application of heat or through mechanical means. The vacuum inside the tube prevents external sound from being transmitted from external sources to the probe because sound cannot propagate without a medium. This design is easy to clean using diluted bleach solution and would not require that the user perform any additional steps to attach the device to the abdomen before it can be used to monitor a fetal heart.
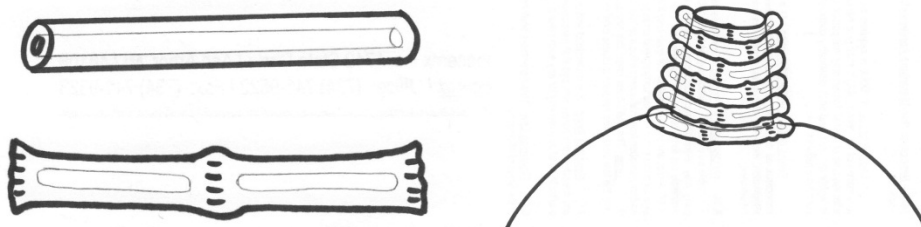
Figure 7: A catheter tube (top left) can have a vacuum created inside with the ends sealed (bottom left) and then the vacuum-interior catheter can be wrapped around a probe (right)

Active sound cancellation: Acoustic isolation by materials with sound-insulating properties is known as "passive" sound insulation. "Active" sound insulation is more complex. Devices that actively reduce external sound contain a microphone, circuitry, a speaker, and power source. The microphone detects the external sound. The circuitry receives information about the sound from the microphone and generates a new sound wave that is 180 degrees out of phase with the waves of the external noise. This out-of-phase noise is emitted from the speaker. The external sound is cancelled by destructive interference. Active sound cancellation can be extremely effective, but there are disadvantages if it was applied to a fetal heart rate monitor for developing countries. The electrical components would increase the cost and decrease the durability and ease of repair of the device. The device would require more power to support the electrical components necessary for active sound cancellation (Benoit et al). The

microphone and speaker in this design must be open to the external air, making this design difficult to clean using a dilute bleach solution.

Noise Reduction Selection: The Pugh chart found in Table 5 was used to select the shell and foam method.

Table 5: Noise Reduction Pugh Chart

	Vacuum Catheter (baseline)	Shell and foam	Vacuum Probe Encasement	Active Cancellation
Degree of isolation (35)	0	+1	+1	+2
Durability (25)	0	-1	-2	-2
Ease of sterilization (10)	0	-2	-1	-2
Cost (30)	0	+2	-1	-2
Total (100)	**0**	**+40**	**-55**	**-60**

4.4 Circuitry

Team 2 contains biomedical and mechanical engineering students who, at the beginning of this semester, had studied only basic circuits. The fetal heart monitor project was chosen partially because it presented an opportunity for the team to learn more about circuits and software. Due to the initial lack of electrical engineering background on the team, it was not possible for circuit design concepts to be generated using the process described above for other functions of the device. Rather than generating multiple concepts individually and discussing them, circuit concepts were selected as research about analog signal amplification and filtration progressed and the team consulted experts about the best way to design the circuit.

The concept of using a Sallen-Key filter to isolate the target frequencies was suggested by Jeremy Nash, who has extensive experience with designing and building circuits. Research into sound filtration resulted in the decision to use two Sallen-Key filters in series (a Butterworth filter) to sharpen the amplitude attenuation after the corner frequency. The preamplifier circuit was found online and selected because it was designed to be used with a condenser microphone like the one selected for the fetal heart monitor.

4.5 Functional Decomposition

A functional decomposition was used in the concept generation process to simplify steps that needed to be done in order to make a successful design and to make sure the generated concepts would satisfy the open ended solution. Figure 8 displays the functional decomposition.
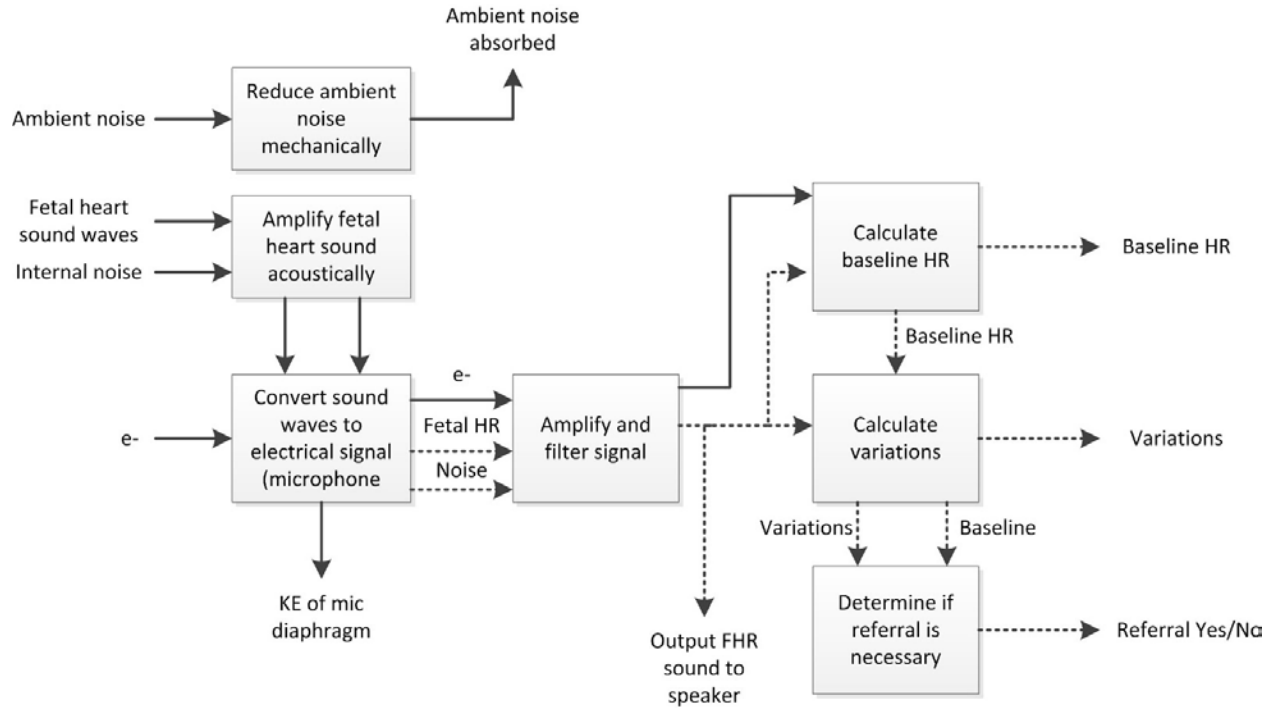
Figure 8: Functional decomposition of the device showing the flow of energy, materials and user inputs.

5 Concept Description

The final concept consists of the acoustic amplification housing for the microphone, attached to the maternal abdomen via a cloth strap with Velcro securement. Figure 9 below represents the final design. In use, the device will be strapped around the maternal abdomen (illustrated in Figure 10 below), with the acoustic cone as close to the fetal heart as possible. Healthcare workers have a good sense of this location already, one technique being to locate the fetal back through palpation. The device will stay on the mother for a minimum of 10 minutes in order to accurately determine the baseline fetal heart rate. After 10 minutes has elapsed, the variations from the baseline, as well as the actual baseline, will be displayed and can be monitored by a healthcare worker. The sound of the fetal heart rate will be output through a speaker.
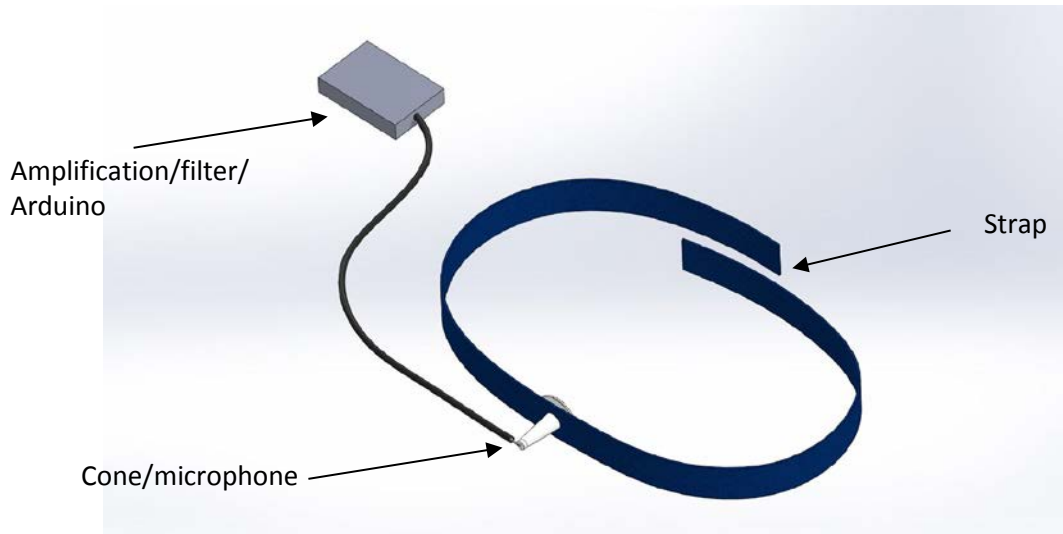
Figure 9: Representative model of the final concept. All important parts labeled.
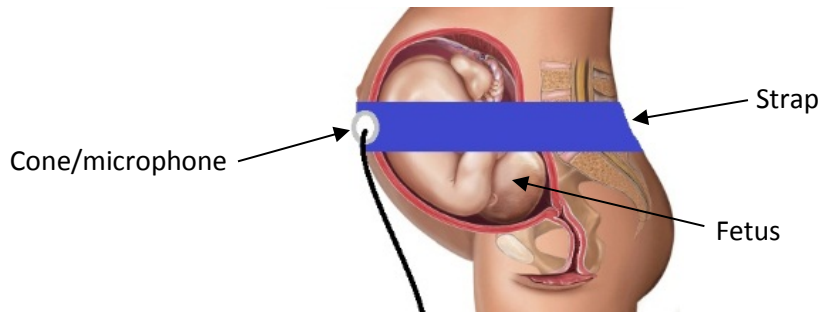
Figure 10: Prototype as it would be set up on maternal abdomen

The signal from the condenser microphone is sent through a pre-amplifier, a low pass Butterworth filter and then sent to the Arduino for digital analysis. The entire circuit will be powered from the Arduino's 5V DC power supply. The circuit will be constructed on a breadboard. Figure 11 below describes the overview of the circuitry.
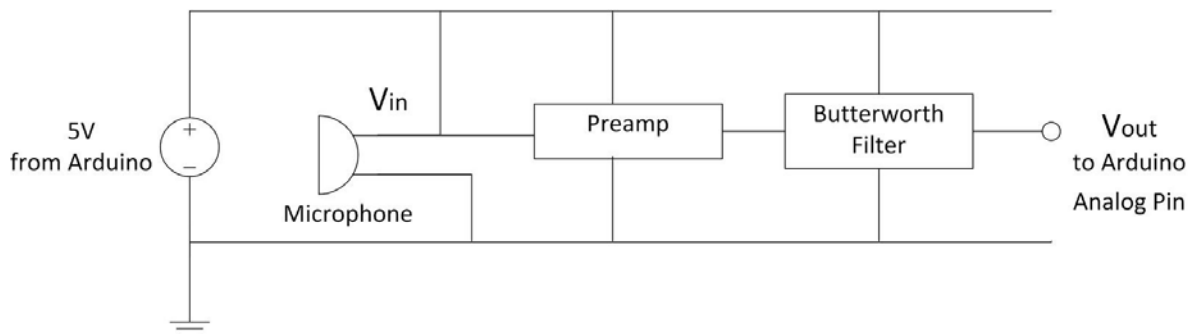
Figure 11: Overview circuit of amplification and filtering

6 Parameter Analysis

6.1 Abdominal Attachment System

6.1.1 Shape/Dimensions
The device will be secured to the maternal abdomen using a Velcro strap. The Velcro strap will be 2 inches wide and adjustable between 29 to 59 inches long. The approximate shear force it can withstand will be between 40 to 60 N as the overlap varies from 20 to 72 mm (Bader et al., 1982). A hole slightly larger in diameter than the detection end of the probe is cut in a Velcro strap several inches wide. The probe is wider on the detection end so it cannot escape from the strap and will be held in place by two snaps to make assembling the strap on a patient easier. The probe is placed through the strap which is then wrapped around the maternal abdomen and secured with Velcro strips.

A study in 2006 determined that the average abdominal circumference of 500 women in India at 38-40 weeks pregnant is 105.1 +/- 6.6 cm (Shobeiri et al., 2006). The average body mass index (BMI) of women in India is 21.3, compared to 24.3 for Ghanaian women (Chartsbin, 2011). A proportion was set up to relate the ratio of average BMI to the upper limit of average abdominal circumference at the end of the third trimester for Indian and Ghanaian women. The average abdominal circumference of Ghanaian women between 38 and 40 weeks pregnant was calculated to be 127.6 cm (about 50 inches). Based off several women's clothing size charts, a small waist size was found to be about 30 inches which was then set as the lower limit of the range for the strap. Therefore, a strap longer with an adjustability range of 29-59 inches should accommodate all the pregnant women in Ghana.

Concerns were raised about the maximum pressure that a fetus can withstand in utero without sustaining damage in regards to the abdominal attachment system. Therefore, the team benchmarked the belts maximum tension off of compression leggings, a type of clothing typically worn by pregnant women. This type of garment subjects the thighs and abdomen to compressive pressures up to 15-30 mmHg, depending on the type of leggings worn. The Absolute Support Model A718, for example, offers pressures of 20-30 mmHg when correctly sized to the woman. For this reason, we have determined that the maximum pressure our belt should subject the patient to should be below 30 mmHg (Discount Surgical Stockings).

6.1.2 Material Selection
Cloth is readily available all over Ghana and can be purchased at very low prices across the country. The lowest price given to the team in Ghana was 10 Cedi ($5.33 USD) for 6 yards of cloth, but the lowest price available is hard to quantify because one bargains for cost. Velcro is widely available and inexpensive in Ghanaian markets. With a strap being made from African prints and secured with Velcro at a low cost, with variable lengths if need be, and will be easily replaced. The Velcro attached to the cloth is long enough to accommodate patients with full-term pregnancies within a large BMI range.

Velcro is extremely easy to use, requiring only that the user wrap the strap around the mother's abdomen and press the ends of the strap together to secure it. The overlap region of the ends of a

standard Velcro strap must be pressed together with 8.3 kPa to achieve the maximum strength of attachment. Any force greater than 8.3 kPa yields the same degree of attachment (Bader et al., 1982).

Velcro is currently widely used in medical applications, such as attachment of orthotic devices like splints. Standard Velcro is composed of 55% polyurethane and 45% nylon (Bader et al., 1982). The hook-and-loop attachments in the region where the ends overlap must be able to withstand the sheer force exerted on them when the strap is tightened. Velcro has excellent wear properties and can handle many cycles of peeling the ends apart (Bader et al., 1982).

6.2 Acoustic Amplification System

The heartbeat will be collected and amplified acoustically by a horn before reaching the microphone. Horns do not amplify sound waves. Instead, they passively collect sound waves and funnel them from the widest end, the mouth, to the narrow end. Sound waves are focused as the horn narrows, increasing the sound energy impact at the end of the horn (Hendrix). The effectiveness of horns in collecting and concentration sound can be seen in the human ear, which uses a conical cartilage structure called the pinna to collect sound waves and direct them into the auditory canal (Hendrix).

6.2.1 Linear Horn

Several horn designs are currently used to collect and emit sounds. The internal geometry of the horn determines the sounds it conducts best. The linear conical horn is the oldest and simplest design. The linear horn, also known as the straight-sided horn, is a cone-shaped shell with no curvature. The pressure change through the horn is linear as a sound wave moves through it, so there is no distortion of the sound (Acoustic Horn Company). The gradual change in the cross-sectional area of the horn decreases distortion and provides a good phase response due to compressed air in the throat. Devices intended to reproduce human voices, such as the megaphone, are usually conical because the shape reduces the production of harmonics and presents the most accurate reproduction of the original sound (Acoustic Horn Company).

6.2.2 Tractrix Horn

The curve formula for a tractrix horn is derived by assuming that a tangent line to any point on the inner curve of the horn will arrive at the center axis of the horn with a line segment of a certain length. At the mouth of the horn, the tangent line is oriented perpendicular to the axis and decides the radius of the mouth (Patent GB278098). Tractrix horns excel for mid-range frequencies, but are not optimal for low frequency sounds. Why? The dimensions of a tractrix horn depend on the lowest and highest frequencies it is used with.

6.2.3 Exponential Horn

Exponential horns are defined as horns for which the axial length is exponentially related to the area of the horn (Murray). Exponential horns do not perform well with high-frequency sounds due to the rapidly decreasing internal diameter. This causes the radiation pattern of the sound waves to narrows as the frequency climbs, leading to a phenomenon referred to as "beaming" and a loss of information at high frequencies. What is beaming? The throat diameter depends on the frequencies that will be transmitted

through the horn. Large throats are optimal for low frequencies and narrow throats are best for high frequencies (Murray).

6.2.4 Shape Selection
Acoustic amplification in this fetal heart monitor will be accomplished by a linear horn. The linear horn produces the least distortion and the best phase response due to its gradually changing cross-sectional area (Acoustic Horn Company). Horns with more significant curvatures, such as the exponential and tractrix horns, create more sound distortion (Murray). A linear horn will also be the least expensive to manufacture.

6.2.5 Dimensions
Horns can be designed to optimize sound quality and minimize the portion of a sound wave that is reflected within a certain frequency range. The frequency range for the fetal heartbeat is 35-200 Hz (Mitra, 2004). The target frequency is the middle of this frequency range, 117.5 Hz.

The optimum length for a horn used to emit sound waves is one wavelength of the target frequency (Leonard Audio Institute). This rule guides the design of horns intended to conduct sounds out of the mouth of the cone with high directionality. To accommodate low-frequency sounds, horns can be even fractional reductions such as ½ or ¼ of the target wavelength without losing any efficiency. At lengths less than ¼ of the target wavelength, sound directionality begins to be lost.

The conical amplifier in the fetal heart monitor is receiving sound from the mouth rather than emitting it. In addition, the cone is conducting sound waves to an omnidirectional microphone at the throat. The pickup pattern of an omnidirectional microphone is spherical, so a directionalized input is not necessary. Also, the diameter of the throat of the cone is only slightly larger than the diameter of the microphone. Sound waves that reach the end of the cone will be focused due to the size restrictions near the end of the cone.

Due to the throat size and omnidirectional nature of the microphone, the length of the cone is not critical to the quality or directionality of sound reaching the microphone. It is more important that the cone is small enough to be transported, stored, and held easily in one hand. Also, the microphone at the throat of the cone should be as close to the abdomen as possible to detect the sound clearly. The wavelength of the target frequency is 2.919 m. This is not a realistic dimension for this device. Fractional reductions beyond ½ and ¼ of the target wavelength were evaluated based on the convenience of size for the user. The chamber for acoustic conduction in the cone will be 45.6 mm in length, 1/64 of its maximum length. See Appendix IV for calculations.

The microphone will be placed at the end of the throat of the horn. The microphone is shaped like a disc 6 mm in diameter and 3.4 mm thick. In order to accommodate a 57.14 mm sound path and a 3.4 mm thick microphone, the total length of the cone will be 49.0 mm.

The throat must be large enough to accommodate the microphone. To allow room for manipulation, the throat of the cone will be 8 mm in diameter. This will leave 1 mm between the edges of the microphone and the cone wall for flexibility in fastening.

The optimum mouth circumference of a sound-emitting horn is also the target wavelength (Leonard Audio Institute). Due to size restrictions and other aspects of the design which account for sound directionality, the circumference of the cone will be 1/32 of its maximum. This dimension is a larger fraction of the maximum wavelength than the length of the cone because the area of the mouth affects the amount of sound entering the cone. The diameter of the mouth will be 29.03 mm. See Appendix IV for calculations.

The linear cone between the abdomen and the microphone will not amplify the sound of the fetal heartbeat. Instead, it will collect sound waves emanating from the fetal heart that otherwise would have been dispersed and focuses them as they travel through the cone. An ear horn can increase the intensity of a sound by 15-20 decibels (Bennion, 1994). Considering the similarities between an ear horn and the cone on this device, it is reasonable to expect a similar increase in sound intensity when the cone is included in the design. Placing the mouth of the cone directly on the maternal abdomen will decrease ambient noise by directionalizing the input to the horn.

6.3 Mechanical Noise Reduction System

After analyzing the mechanical noise reduction system, it became clear that its disadvantages would outweigh the advantages. A table of three materials considered for dampening the ambient noise can be found below in Table 6. This table shows that as the frequency is increased the material can absorb more of the sound. The inverse is also true, as the frequency is decreased, very little sound is absorbed. This is a common problem in the realm of soundproofing. Higher frequency sounds move atoms back and forth faster and lose more energy to friction and attenuate quicker than do low frequency sounds. Also, if low frequency sounds have a longer wavelength than the thickness of the material through which it is passing, then they can travel right through the material. If high frequency sounds have wavelengths shorter than the material's thickness, then they will be reflected off or absorbed by the material (Exploratorium Museum, 2004).

In order to satisfy our user requirement of portability, the device has to have one side be less than 2.6 inches. If we were to have one of the materials listed in Table 6, they would have to be relatively thin in order to be wrapped around the acoustic amplification cone and still satisfy the engineering specification of one side less than 2.6 inches. And for these materials to absorb frequencies 125 Hz and higher at better than 10% of the sound, then they would have to be thicker than 1 inch, which would be too bulky for the device.

The analog Butterworth filter in our design is already getting rid of high frequency noises above 200 Hz. Adding any of the foams in Table 6 would only get rid of approximately the same noises as the analog filter is already filtering. Adding a noise reduction material would not benefit the device by blocking out more ambient noises than the analog filter is already doing.

Deciding not to use a noise reduction material in the device has several other benefits. There will be no added cost to adding another material. The device will be easier to keep clean as there will be no porous material to collect bacteria and viruses. Finally, there will not be the added worry of a porous material degrading over the lifetime of the device.

Table 6: Sound absorption coefficients of common acoustic materials (source)

Materials*	Frequency (Hz)					
	125	250	500	1000	2000	4000
Fibrous glass						
(typically 4 lb/cu ft) hard backing						
1 inch thick	0.07	0.23	0.48	0.83	0.88	0.80
2 inches	0.20	0.55	0.89	0.97	0.83	0.79
4 inches thick	0.39	0.91	0.99	0.97	0.94	0.89
Polyurethane foam (open cell)						
1/4-inch thick	0.05	0.07	0.10	0.20	0.45	0.81
1/2-inch thick	0.05	0.12	0.25	0.57	0.89	0.98
1 inch thick	0.14	0.30	0.63	0.91	0.98	0.91
2 inches thick	0.35	0.51	0.82	0.98	0.97	0.95
Hairfelt						
1/2-inch thick	0.05	0.07	0.29	0.63	0.83	0.87
1 inch thick	0.06	0.31	0.80	0.88	0.87	0.87

6.4 Microphone

Upon further research, an omnidirectional microphone will be best for this application given the smoothness of the response over a wide frequency range (no clipping or distortion will occur at low frequencies) and also because there is very little proximity effect (Ballou) which results in distortion of the signal. With the frequency range of the fetal heart rate being 35-200 Hz (Mittra, 2004), an omnidirectional microphone is better than an unidirectional microphone given the superior ability to detect low frequencies.

The frequency range, signal to noise ratio, voltage range, sensitivity, diameter and cost were the parameters considered in microphone selection. The frequency range had to include the range of the fetal heart rate (35-200Hz). Condenser microphones are particularly sensitive to noise in the signal because they require immediate preamplification of large magnitudes, thus amplifying even the slightest magnitude of noise (Owsinski, 2005). The signal to noise ratio needed to be as high as possible to reduce the amount of noise in the circuit. After researching a wide range of omnidirectional microphones a quality signal to noise ratio was found to be 60dB.To ensure the microphone element could be powered off the same supply voltage output by the Arduino, the range of the operating voltage had to include 2-5V. As the diameter of the microphone reaches the wavelength of the sound waves, the microphone will become increasingly directional; the response begins to diverge as the diameter is one tenth of the smallest wavelength (Ballou et al., 2008). Thus the diameter had to be smaller than 17.5mm (See Appendix IV). The lowest cost microphone element filling these parameters was chosen for application in this low cost design.

6.5 Analog Preamplification

A preamplifier is used to prepare the signal from the microphone to be further amplified, filtered, and processed. To determine the preamplifier, first a low noise audio operational amplifier (op-amp) was chosen. The following op-amps were considered for their high quality characteristics and their

reputation for use in audio applications, as well as holding low-to-medium price points to keep the device low cost: LM833, NE5532, OP27, and the OP37. Both the OP27 and OP37 require a supply voltage that is too high (+/- 15 V) for the microphone and for the potential low-resource environment power source that will be designed in the future. The LM833 and NE5532 require an adequate supply voltage that can be powered by a 9V battery or by the 5V from the Arduino.

The NE5532 op-amp has a superior open loop gain (about 60+ dB) than the LM833 (about 55 dB) at the end of the microphone's frequency range, 20 kHz. This fact makes the NE5532 the ideal op-amp for the preamplifier circuit found in Figure 18. This circuit has a closed loop gain of 23 dB. The higher the open loop gain is, then the more linear the amplifier is and the more proportional the output voltage will be with the input voltage. This preamplifier was selected because it worked with the NE5532, the WM-61A microphone, and the power supply that will be used.
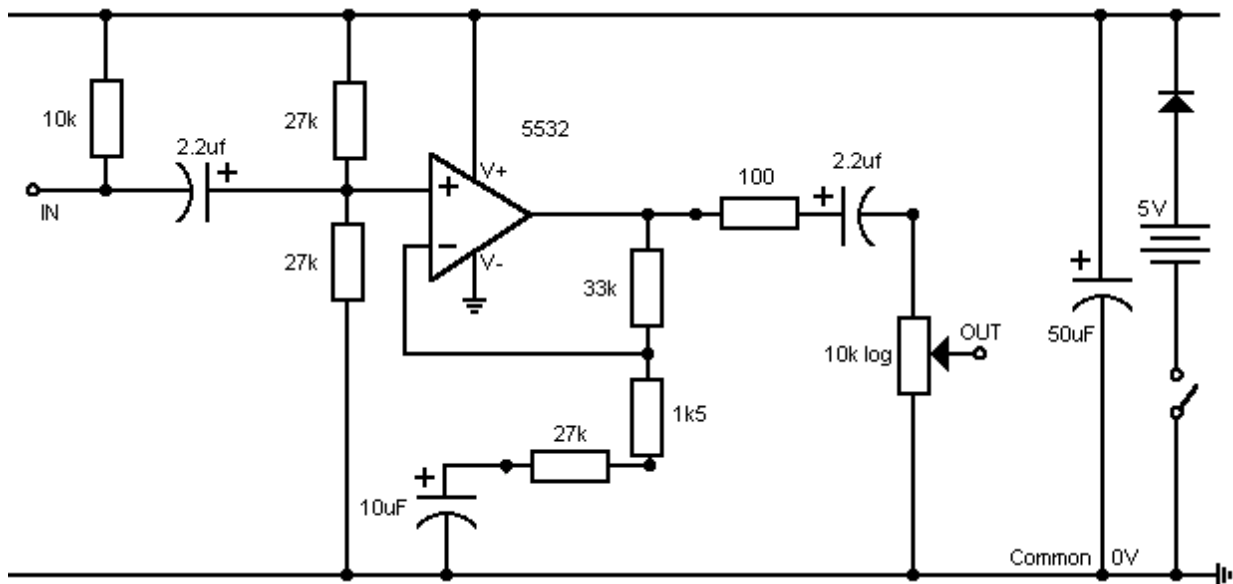
**Figure 12: Preamplifier (acquired from
http://www.minidisc.org/mic_preamp/Simple%20Stereo%20Electret%20Mic%20Preamp.htm and
modified)**

6.6 Analog Signal Filtration

Sampling is the process of turning an analog continuous-time signal into a discrete numerical sequence capable of being digitally processed. In order for the signal to be perfectly reconstructed, the frequency of the sampling rate must be at least double the highest frequency of the upper-limit of the band-limited signal (Dinez et al., 2002). This minimum sampling frequency for the sampling rate is known as the Nyquist frequency of a continuous-time signal. In order for the processing power required to be reasonable, the signal must be filtered so that the highest input frequency is not unpredictably large. If the sampling rate is not at least twice the size of the highest frequency, the signal is in danger of becoming distorted when the higher frequency input takes an alias at a lower frequency which is indistinguishable from the real lower frequency inputs. The repetitions of the spectrum interfere with

one-another and the signal cannot be perfectly reconstructed (Dinez et al., 2002). The filter will also help reduce the amount of ambient noise being introduced to the system. By attenuating high frequencies, the signal of the heartbeat is being increased relative to the noise.

To minimize the highest frequency sampled by the Arduino, a low pass filter needs to be used. Ideally, the cut-off frequency (f_c) is the frequency above which the filter will completely attenuate the signal. The theoretical response of a Low-Pass filter is given below in Figure 13.
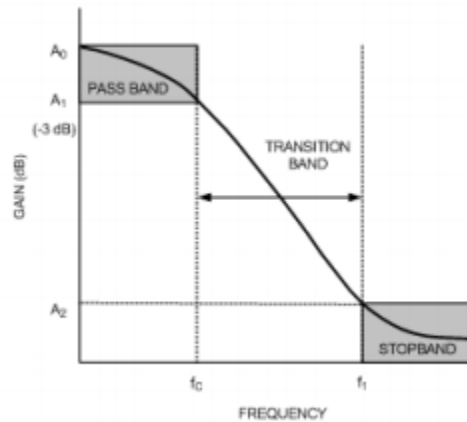
Figure 13: Response of a Low-Pass Filter (National Semiconductors, 2010).

Ideally, a low-pass filter would respond immediately such that the cut-off frequency (f_c) is equal to the highest frequency that was stopped (f_1). However in reality, there is always a transition band of frequencies that pass. A Sallen-Key filter was initially chosen over a traditional RC first order low-pass filter because it has a smaller range of transition, assuming the components are chosen appropriately. A more reliable Nyquist frequency can be determined when the transition band range is minimized. This will not only help prevent aliasing, but it will also help eliminate high frequency noise from the signal.

The most common anti-aliasing filter used in audio applications where specific signal response is required across the bandwidth of the circuit is the Butterworth filter (National Instruments, 2010). This is largely on account of the fact that the Butterworth filter has the least amount of attenuation over the pass region of the filter, resulting in the least distortion of the signals that are passed. The Butterworth filter is a higher order filter consisting of cascading first or second order filters in series. The use of the Sallen-Key filter was verified by Professor Hall. He suggested that several Sallen-Key filters would improve the gain roll-off of the response. A higher gain roll-off means that signals above the cut-off frequency will be reduced at a larger magnitude. Professor Alexander Ganago of the Electrical Engineering and Computer Science department also corroborated the use of two Sallen Key filters in series. Thus a 4th order Butterworth filter consisting of two Sallen-Key Filters would be the best for this application.
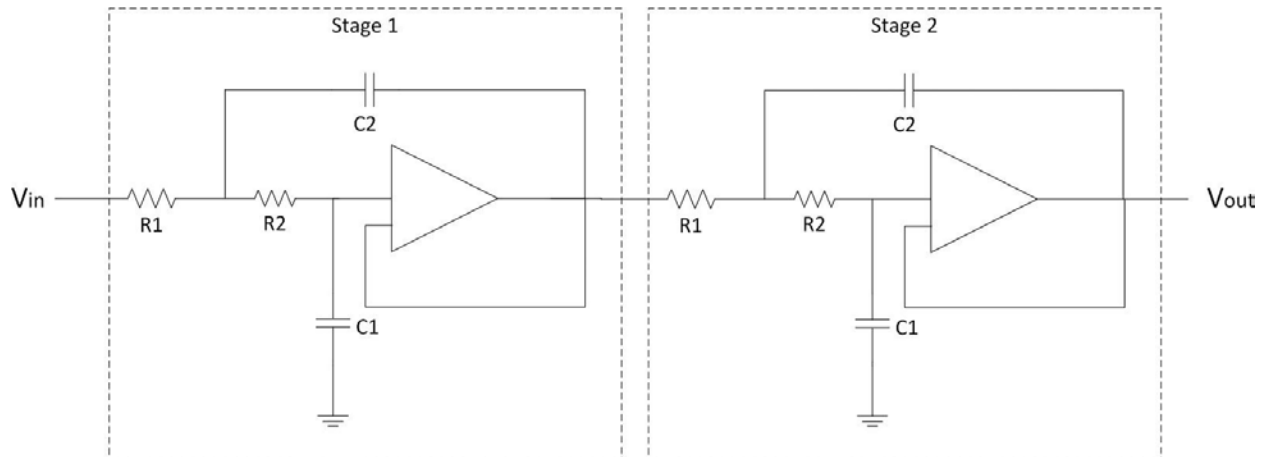
Figure 14: Butterworth filter

The values of the resistors and capacitors used in each stage of the filter were chosen using the methods described in Appendix IV. The can be found in Table 8 in the Final Design Description section.

The most precise capacitors are the COG-type ceramic available in the range of 0.5 pF to 47 nF with their tolerances ranging from ± 0.25 pF and ± 1% for higher values (Kugelstadt, 2012). X7R-type ceramic capacitors range from 100pF to 2.2 µF with a tolerance of +1%. For values higher than 2.2 µF tantalum electrolytic capacitors have the lowest tolerance. National Semiconductor suggests resistor values selected should fall within the range of 1 kΩ to 100 kΩ and capacitor values should fall within 1nF to several µF.

To select the appropriate operational amplifier used in the filter, the unity gain bandwidth was the most important characteristic. For a maximum gain error of 1% the open loop gain of the op amp should be 100 times above the peak gain of the filter. As shown in Appendix IV the maximum bandwidth needed is 24 kHz. The slew rate is another important parameter to consider and the chosen op amp must have a slew rate higher than 3.14 V/ms. The LM741 op-amp fits the given parameters and is readily available, and was thus chosen as the op-amp for both Sallen-Key filters.

6.7 Pseudocode

This section describes the pseudo-code implemented prior to the development of the C++ code. This code was developed in order to understand the scope of the programming aspect of the project by modeling the logic to be used in the final design. In drafting the pseudocode, the team went through several phases of design. The team first identified the ultimate goals of the code: to output baseline and variance, as well as an indicator that can flashes in the cases where referral is deemed necessary. With these identified the team then looked into the intermediate goals necessary to accomplish this end result. It was found that the signal must first be converted into form that could be mathematically analyzed; this signal must then be analyzed in order to convert it into a collection of instantaneous heart rates over a given time. From here, these instantaneous beats can be extrapolated over a longer period of time, which can then be analyzed for trends to yield the data that is ultimately desired. More information on each stage is presented in the following subsections.

As of this report, the pseudocode has been replaced with employable C++ code in the final design. However, this section has been intentionally left in the report to demonstrate the development of the final code, as well as to provide a clearer understanding of the logic being implemented in the final design. The currently used code, in its most recent revision, can be found in Section 7.6.

6.7.1 Signal Translation

Following conversion by the Analog-Digital Converter, the signal enters the Arduino as a time-dependent voltage. Without proper logic, this voltage provides little diagnostic information. Prior to the beginning of signal translation, the program must check the system time. This provides a zero-time as a reference to all further calculations. Following the recording of the start time into two variables, a 'while' loop is initiated; this loop will remain in use throughout both the signal translation and analysis processes for the entirety of the usage time of the device. Thus, the while loop has a run condition that the current time minus the start time must be less than ten minutes, or 600 seconds. This process is shown below in Figure 15.
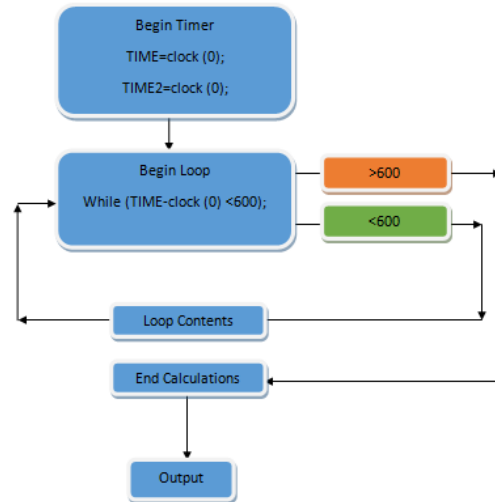
Figure 15: Flowchart of the loop containing the signal analysis code

6.7.1.1 Conversion to Unsigned Signal

As mentioned in Section 6.4, a condenser microphone works by allowing a capacitor to change in voltage as the distance between plates fluctuates. The amount the capacitors fluctuate from their initial positions is caused by the intensity of the sound wave experienced and also corresponds to the fluctuations in voltage experienced over the condenser microphone. These fluctuations in voltage therefore correspond to the heart rate in another domain.

Due to the nature of the vibrations, the capacitor plates oscillate to and from positions equidistant from the zero-axis on either side of the axis. Thus, the voltages corresponding to the sound wave vary from a negative voltage to a positive voltage of equal magnitude. This signal is a signed signal, and must be converted to an unsigned signal to be readily analyzed. In order to do so, within the loop is a section of code that checks to see whether an inputted signal is positive or negative. If negative, the signal is

multiplied by a negative one; if positive, no change is made. This effectively takes the absolute value of the signal. Visualization is offered in Figure 16.
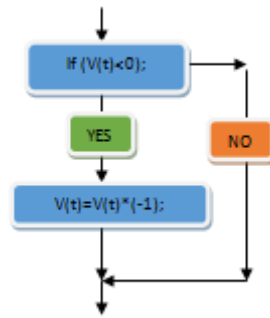
Figure 16: Conversion to Unsigned Signal

6.7.1.2 Conversion to Envelope Signal

Once the signal is converted into an unsigned signal, the signal can be converted into an envelope signal. The raw unsigned signal cannot be interpreted by code without this conversion. Each sound wave is still represented as a collection of fluctuating voltages which correspond with the vibratory nature of the wave. These collections of peaks must be represented as one rise in voltage; therefore, it is logical to represent them using a trend line tracing the peak voltage of each individual fluctuation. Should they not be represented as such, later analysis of the sound wave could result in the fetal heart rate being multiplied by a factor corresponding to the frequency of the wave.

The signal is converted by comparing voltage values at given times against those prior to them. Should the magnitude of the voltage at a given time be found to be larger than that which was passed through the code prior to it within the while loop, it is allowed to pass unchanged. However, if the magnitude of the voltage is found to be smaller than that which was passed prior, this value is instead replaced with the prior value minus a decay constant. This constant will be determined through mathematical analysis of the properties of the sound wave. In utilizing this method, sharp drops (as often seen in the representation of vibrations in voltage) are smoothed out, as a drop more rapid than that of the decay constant is not permitted.

When the peak voltages begin to decline over this time, the envelope signal will take on a linear conformation. This is due to every signal being lower to the signal prior to it. Thus, the voltage can be represented in this portion of the signal as:

$$V(t) = V(t-1)-\alpha;$$

Where α is the decay constant, and V is the voltage dependent on time (t). This relationship is used in the condition in which it is found that the voltage is beginning to drop rapidly, and will be contained within an if-loop. The conditions of this loop are such that if V(t) is less than V(t-1), the inputted V(t) will be replaced with V(t-1)-α. In order to allow for slight decreases in voltage without a linear decrease, the tolerances of the 'if' function can be altered to allow voltages to within several millivolts. However,

considering that the ultimate goal of this conversion is to simply remove dips below a certain threshold, this is not absolutely necessary.
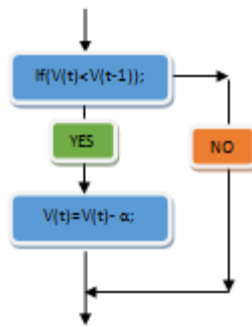
Figure 17: Conversion to Envelope Signal

6.7.1.3 Conversion to Truth Value

The next procedure in the conversion of the code is to convert it into a truth value. This logic checks to determine whether the voltage at any given time exceeds a certain threshold. This threshold will be determined based upon testing of our prototype against a representative simulator, and adjusted according to further testing. This threshold will be the conditions of another 'if' function - this function checks to see if the voltage exceeds the threshold. If it is determined that it does, it is marked that a beat occurred there (ie. one is added to a counter). This counter is unaltered if the voltage does not exceed the threshold at this time.

Due to the nature of the sound wave, the voltage will exceed the threshold for several seconds. Due to this, code must take into account whether the conditions have changed since the last beat was recorded. For example, if it was found that the voltage exceeds the threshold, yet this had already been accounted for in a prior iteration of the while loop, another counter is not added to the beats. This prevents each beat from being counted as multiple. This logic can be accomplished by utilizing a variable that is set to one upon encountering a voltage exceeding the threshold, and set to zero upon encountering a variable lower than the threshold. Thus, a counter can only be added to the beat counter should both the value exceed the threshold and the variable is set to zero. Otherwise, the code will discount the following heightened voltage as being residue from the already counted beat.

It is due to this logic that the envelope processing is absolutely imperative. Any dips that could reset this conditional variable must be eliminated in order to prevent the code from counting false beats. This is also why strict tolerances will be used in envelope processing, as described in Section 6.7.1.2. The logic associated with the beat counting process is shown below in Figure 18.
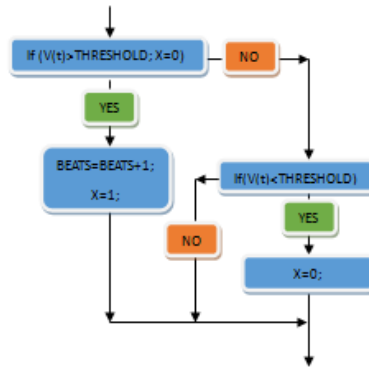
Figure 18: Logic behind the beat counter. Two 'if' loops are used - the first checks for the first increase above the threshold, the second checking for dips below the threshold to reset the sensitivity to signals above the threshold.

6.7.2 Signal Analysis

Following the conversions highlighted in Section 6.7.1, the code is left with a counter of beats. The following logic pertaining to signal analysis is still contained within the same 'while' loop that was used for the signal translation. In addition, the time called in the beginning of the code is utilized in order to determine the instantaneous heart rate (see Section 6.7.1).

6.7.2.1 Determination of Instantaneous Beat

Following the determination as to whether a beat has occurred within the time-period being analyzed, a check is ran to determine if five seconds have elapsed. This is done by using an 'if' loop with the condition that it is only run if the current time minus the time recorded before the loop is greater than 5 seconds. If so, the beat counter is multiplied by twelve (in order to convert Beats/(5s) to BPM) and is then reset. The variables that was set to system time prior to the loop and was checked as a condition of the 'if' loop is set to the current time. This ensures that the 'if' loop will be true every 5 seconds.

These instantaneous beats are then each added to an array with respect to time (t). Thus, every five values in the array will be a new value, with five repeats of each instantaneous heart rate in BPM.
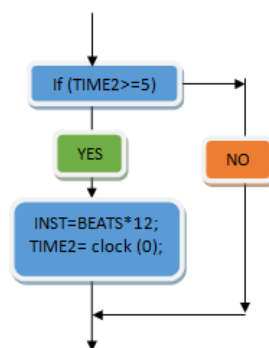
Figure 19: Diagram illustrating the determination of the heart rate in BPM

6.7.2.2 Elimination of Insignificant Values

The development of pseudocode to determine baseline is still in progress as of Design Review 3. However, the team has reached a general consensus on the basic logic that could be employed in order to determine this value. The first step necessary in making a determination of the baseline would be to eliminate values considered insignificant to the determination of the baseline. These are periods of marked increase or decrease in heart rate that last under 15 seconds (National Standards 2008). This elimination can be accomplished by comparing trends in instantaneous rates. Given that each instantaneous rate is recorded every five seconds, trends must be analyzed over three of these instantaneous values in sequence; this corresponds to 15 seconds of time.

Should it be found that all three of these instantaneous values demonstrate a net increase or decrease in heart rate, they are then considered significant and will contribute to the determination of baseline. In the opposite condition, such that there is no net increase or decrease in heart rate, the values are considered insignificant in contribution to the baseline fetal heart rate. The outliers are then altered to conform to the baseline.

Following this, all values, altered or unaltered, are added to a new 'Baseline' array.

6.7.2.3 Determination of High and Low Rates

Directly following the creation of the array containing the values significant to the baseline, the code will run a brief check of the current instantaneous value. This value will be checked with two different 'if' loops: one checking for the highest rate, the other checking for the lowest. Should the current instantaneous rate be found to be higher than the previous high rate, or lower than the previous low, the variable respective to either extreme is set equal to whichever condition is fulfilled. For example, if the previous 'HIGH' value was found to be 178 BPM, and the current value is 181 BPM, the 'HIGH' value would then be set equal to 181 BPM - the highest heart rate found thus far.

Figure 20: Finding the Highest and Lowest rates using two 'if' loops.

6.7.3 Cessation of While Loop

At this point in the code, all of the necessary input data has been collected. As shown in Figure 15, the 'while' loop has reached its end condition - the time elapsed between the start time and the current time has been found to exceed 600 seconds, and the loop is therefore terminated. From this point, a few basic calculations must be run before the data is outputted.

6.7.3.1 Baseline and Variability Determination

The baseline can now be determined from the values added to the 'Baseline' array during the while loop, assuming that the prior logic is correct. This part of the code is reliant on a 'for' loop. This loop runs iterations for the number of values contained within the 'Baseline' array. During each iteration, the code adds all of the values contained within the array to a total. Once all of the values have been added to the total, the conditions of the 'for' loop will be simultaneously be satisfied. The 'for' loop is terminated, and the total is then divided by the number of iterations of the 'for' loop. This will provide the average of the 'Baseline' array; this is the Baseline value.

To determine the variability, the 'HIGH' and 'LOW' values from the 'while' loop are called upon. The 'LOW' value is subtracted from the 'HIGH' value, giving the final result. As detailed in Section 6.7.2.3, these values were determined from the values deemed significant to the calculation of baseline - thus, short increases in heart rate are not factored into this calculation.

6.7.4 Output

Following the determination of baseline and variability, these values must be outputted to a screen. In addition to this, a referral indicator must flash if either of these values are found to be outside of acceptable ranges. This can be accomplished using two relatively simple 'if' loops. The condition of these loops will be whether either value falls outside of acceptable ranges set forth by the Journal of Obstetrics, Gynecology, and Neonatal Nursing. For baseline, the 'if' loop will check if the baseline found falls above 160 BPM or below 110 BPM. For the variability, another loop will check to see if the variability is above 25 BPM or below 6 BPM. If either condition is fulfilled, it will trigger the illumination of the referral indicator.

6.8 Summary of Material Selection

The materials of two components of the design, the acoustic amplifier cone and the abdominal attachment strap, were analyzed in the report using CES software.

The cone isolates the sound of the fetal heartbeat, protects the microphone, and reduces interference from other noises. The objectives during materials analysis were to minimize the weight in order to increase portability and maximize the stiffness in order to decrease the amount of sound absorbed by the cone.

The cone material selection was constrained by the pre-determined dimensions, material cost, electrical resistivity, resistance to damage by UV light and salt water, and resistance to damage from weak alkalis.

Materials meeting the criteria above were sorted by price. The five least expensive materials to meet the criteria for the cone were unfilled polylactic acid (PLA), Alkyd molding compound (mineral filled),

polyester BMC (7-10% glass fiber), Alkyd molding compound (glass fiber reinforced), and polyester BMC (10-20% glass fiber).

The cone in the prototype is made out of Accura 60 resin because the Viper si2 3D printer at the Medical Innovation Center uses this material only. Accura 60 resin meets all of the constraints for cone material except the price. The high price of Accura 60 is largely due to the intricate 3D printing process. If the device was manufactured on a larger scale, cones would not need to be 3D printed and could be injection-molded out of a different material. The optimal material for mass manufacturing would be unfilled PLA because of its low cost, high stiffness, low conductivity, and low density.

The material for the abdominal attachment strap was also optimized. The strap holds the cone to the abdomen to free the healthcare worker's hands and reduce noise caused by the cone moving on the abdomen. The objectives of the materials analysis were to maximize the tensile strength of the cone and minimize the cost.

The material selection of the strap was constrained by the pre-determined dimensions of the strap, the flexural modulus to allow the strap to conform comfortably to the patient's body, electrical resistivity, resistance to weak alkalis, resistance to damage from salt water and UV light,

Materials meeting the criteria above were sorted by cost. The five least expensive materials to fit the criteria for the strap were polysulphide rubber, perfluoro elastomer, polyetherimide foam, zirconia mullite alumina foam, and aluminum-SiC foam.

The strap in the prototype is made out of cotton. The strap is likely to be the first element of the fetal heart monitor in need of replacement because of the tension and torsion on it during every use. Cotton was chosen based on its high availability in Ghana, low cost, and flexibility. The materials that met the constraint during the CES analysis are not widely available and do not have any characteristics significantly superior to cotton. Further research into the top five material choices will be done during the second semester of design on this project.

The Materials Selection Report is located in Appendix VII.

6.9 Summary of Manufacturing Report

The first round of production would yield 10 cones. This is the number that is going to be used for the rest of this assignment. Also, the form may change between the 10 to try out different sizes and shapes. However, if the device testing was final and done, the volume would be more like a 1000 to distribute to all the health care facilities in Ghana. The best manufacturing process for the cone will be 3D printing for the first round of production where medical testing and approving will be done. Although it is expensive and the roughness is not ideal for sound propagation it is satisfactory for a first round of manufacturing, and our material Accura 60 can be used in a 3D printer. The best manufacturing process for the strap was hard to determine using CES Process Selector. When trying to select a process for manipulating fabric (cotton), CES was not very helpful. However, if cutting speed was maximized it would reduce labor costs. CES recommended water jet as the best method, but intuitively this would be unnecessary, as scissors work perfectly fine when cutting fabric at small production volumes.

The Manufacturing Report is located in Appendix VII.

6.10 Summary of Environmental Sustainability

The environmental impacts of two potential materials for the cone were evaluated using SimaPro software. The materials were unfilled polylactic acid (PLA) and polyester BMC (7-10% glass fiber). The most similar materials found in SimaPro were polylactide granulate and glass fiber-reinforced polyester resin, respectively.

Polylactide showed more liquid waste but significantly less air and raw waste output than the glass fiber reinforced polyester resin. Both materials created negligible soil waste.

Polylactide and polyester resin were also evaluated for damage to ten categories of the environment. Polylactide had less of a negative impact on the environment than polyester resin in all of the categories except land use. It is important to note that, of the nine categories in which PLA outshined polyester resin in environmental friendliness, both materials produced extremely small (perhaps negligible) amounts of damage in four categories. Therefore, PLA is only significantly less environmentally damaging than polyester resin in four categories: carcinogens, respiratory inorganics, climate change, and minerals.

The ten categories can be grouped into three groups: human health, ecotoxicity, and resources. The natural resources group had the largest damages to the environment by the two materials being tested.

The two abdominal attachment strap material candidates selected to evaluate in terms of environmental impact were polysulphide rubber and zirconia mullite alumina foam. The most similar materials found for each in SimaPro were synthetic rubber and alumina, respectively. Of the three large groups (human health, ecotoxicity, and resources) that the ten categories can be divided into, resources proved to be the most important, as shown in Fig. 11.

The Environmental Sustainability Report is located in Appendix VII.

6.11 Summary of Safety

Safety issues of each element of the final design and the testing process were analyzed separately in the safety report. A Designsafe Analysis risk assessment and an FMEA analysis were performed to identify the safety hazards involved with each component of the device and the final assembly. The engineers designing and building the component, the user of the component, and the patient the component is being used on were considered in each analysis. Both analyses concluded that the device is extremely safe.

The device does not present significant dangers in terms of mechanical impacts or causing lacerations because there are no moving parts or sharp edges. As with any device involving electricity, there is a risk of electric shock for the people in contact with the device. In this case, two people will be involved when the device is used: the user and the patient. Electrocution, death due to electric shock, occurs when a shock carrying enough current to stop the heart passes through the body. Five mA is the maximum amount of the current that can enter the body without causing respiratory arrest and possibly death

(Safety Management). The dangers of exposure to electricity are addressed in this design in several ways. The greatest voltage drop in the circuitry is five volts at the power source. The approximate resistance inside the human body is 400 Ohms (Safety Management). This means that the greatest current that could be induced in the body due to contact with a five-volt difference is 12.5 mA. This amount of current will cause a shock, but is not likely to produce permanent damage (Safety Management).

The only components of the device that interface with the patient are the conical acoustic amplifier and the abdominal attachment strap. These parts are made of plastic and cotton, respectively; two highly insulating materials. The wire connecting the microphone inside the acoustic amplifier with the box containing the circuitry is insulated with plastic. The patient or user should never be in contact with the energized circuit when the device is in use. The wire presents a minimal risk because it could induce a 12.5 mA current in a person if the insulation is removed and the person touches the another exposed electrical location to close the circuit.

DesignSafe analysis yielded a total of 60 risks associated with all parts of the device and the assembly as a whole. All risks were deemed negligible or low upon first assessment. After including risk reduction strategies, all risks were classified as negligible. From these results, we can conclude that the fetal heart monitor and its components will not be dangerous to build or use. All assembly of the device occurred in the Mechatronics Lab in the G. G. Brown Building.

7 Final Design

7.1 Attachment to the Maternal Abdomen
The attachment system can be seen in Fig. 21. Shape/Dimensions of the abdominal attachment system and are found below in Figure 22. The strap can accommodate circumferences between 29 and 59 inches. This range should be sufficient for women in any stage of pregnancy. The strap will be made from cotton fabric and the ends will be secured with Velcro.

Figure 21: Close-up of attachment strap. The hole in the middle is for the acoustic cone.
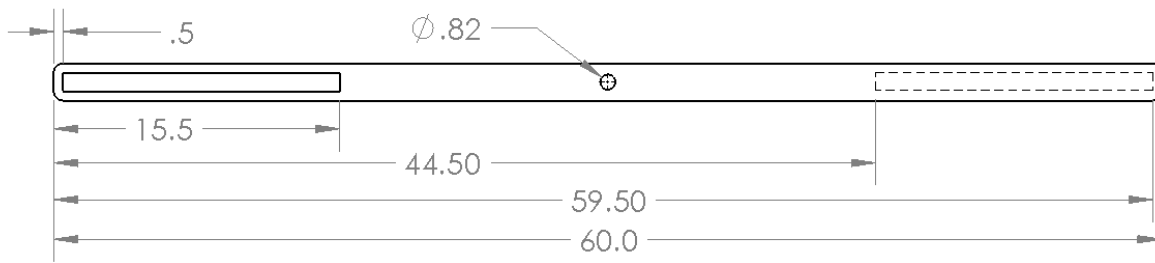
Figure 22: Detailed dimensions of attachment straps. The rectangles on either side of the strap are Velcro strips (inches).

7.2 Acoustic Amplifier

The acoustic amplifier interfaces with the patient. The hollow cone is placed on the maternal abdomen, where it collects and focuses sound waves toward the condenser microphone at the throat. The correct placement of the cone on the abdomen should be determined by palpating the maternal abdomen and looking for the fetal back. The cone should be placed as close to the fetal back as possible to detect a clear heartbeat. The lip around the edge of the cone is used for attachment to the abdomen.
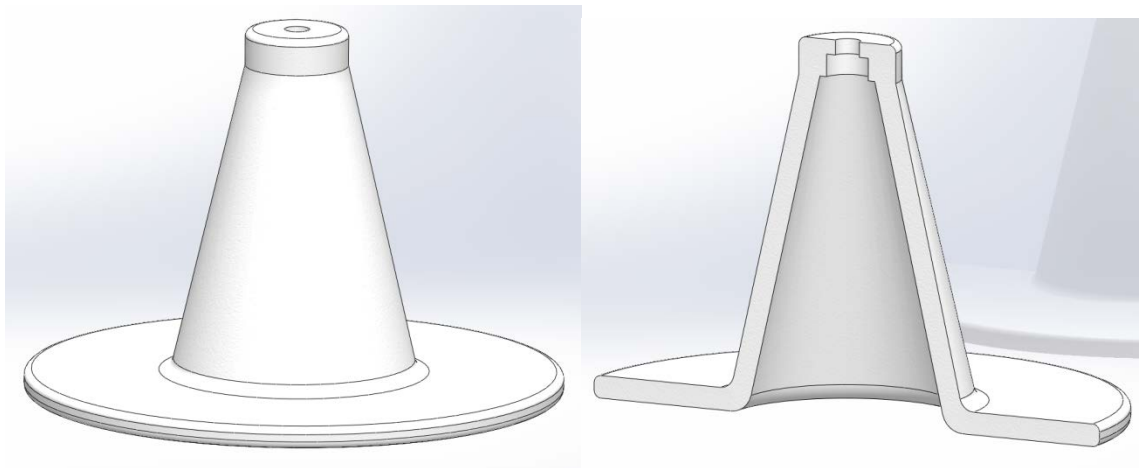
Figure 23: Representative model of the acoustic cone (left) and cross-sectional view (right).
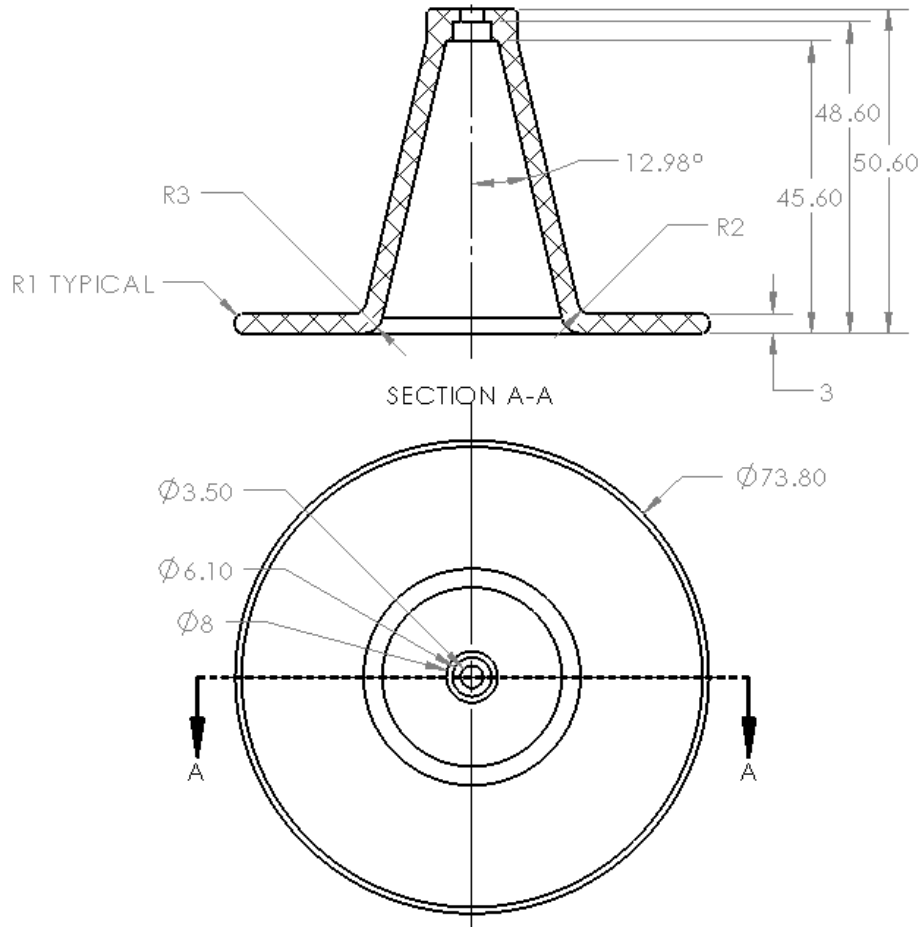
Figure 24: Dimensioned drawing of the acoustic cone (millimeters).

7.3 Microphone

In Design Review 3, the omnidirectional Panasonic WM-61A condenser microphone was chosen for the final design. Its frequency range is 20 Hz to 20 kHz, its signal-to-noise ratio is greater than 62 dB, its sensitivity is -35 ± 3 dB, its impedance is 2.2 kΩ, its voltage supply range is 2-10 V, its diameter is 6 mm, and it costs $1.92. The diameter is 6 mm.

In the past few weeks, the device was tested with a different microphone, the CUI, Inc. CMA-4544PF-W electret condenser microphone. Like the previous microphone, it is omnidirectional and has the same frequency range and impedance. The diameter is 9.7 mm. The signal-to-noise ratio is slightly lower, 60 dB. The sensitivity is also lower, -44 ± 2 dB. In testing, this microphone was the only one capable of detecting the heart rate. This could be due to the decreased sensitivity. Initially, the lower sensitivity was expected to decrease the effectiveness of the microphone. It is possible, however, that the decreased sensitivity improves the performance of the microphone because it decreases the amount of high-frequency ambient noise that the microphone detects. The wider diameter may also contribute to

the satisfactory performance of the microphone because wider diameters improve detection of low-frequency sounds.

Further testing must be done to determine which of the two microphones would be most effective.

7.4 Noise and Vibration Reduction

In Design Review 3, the final design did not include an ambient noise reduction system. However, when the prototype was tested without any kind of noise reduction system, external noise was a significant problem. In the final design presented in Design Review 3, the microphone was press-fit into the cone. During testing, sound vibrations from the surroundings were conducted through the plastic of the cone to the microphone, causing high interference.

The final design presented in this report includes a different noise and vibration reduction system. Instead of placing a layer of foam on the outside of the cone, there is a layer of foam around the microphone in the throat of the cone. See Fig. 25 for a depiction of this design. The insulating foam used is Model Magic molding foam purchased from Meijer. The foam reduces the mechanical vibrations in the plastic cone from movements and shocks from reaching the microphone and causing interference, however it has little effect on blocking out ambient noise. The sound from the fetal heartbeat will travel as a pressure wave through the air in the center of the cone, so adding insulating foam between the microphone and cone will not affect how the microphone detects fetal heart tones. The foam moves the microphone placement to be 33 mm from the wide side of the cone.

Insulating foam

33 mm
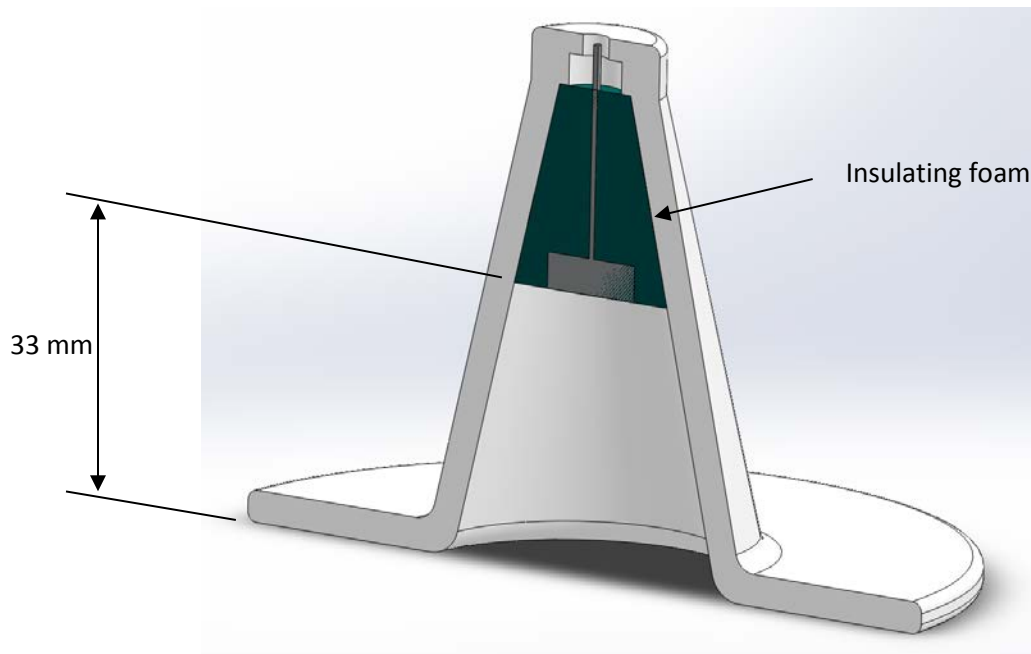
Figure 25: CAD of foam and microphone inside the cone

7.5 Circuitry

The final design circuit consists of a preamplifier and a Butterworth filter. It is powered with 5V from the Arduino's power supply. The circuit diagram can be seen Fig. 26 below.
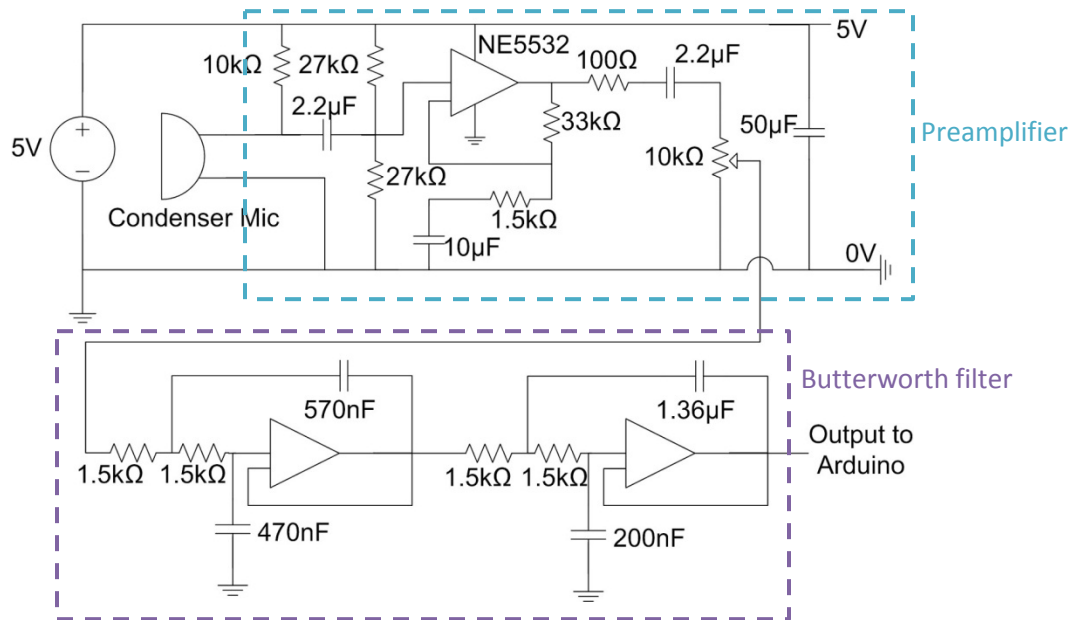
Figure 26: total circuit diagram

7.5.1 Analog Pre-Amplification

A preamplifier is used to prepare the signal from the microphone to be further amplified, filtered, and processed. To determine the preamplifier, first a low noise audio operational amplifier (op-amp) was chosen. The following op-amps were considered for their high quality characteristics and their reputations for use in audio applications, as well as holding low-to-medium price points to keep the device low cost: LM833, NE5532, OP27, and the OP37. Both the OP27 and OP37 require a supply voltage that is too high (± 15 V) for the microphone and for the potential low-resource environment power source that will be designed in the future. The LM833 and NE5532 require an adequate supply voltage that can be powered by a 9V battery or by the 5V from the Arduino.

The NE5532 op-amp has a superior open loop gain (about 60+ dB) than the LM833 (about 55 dB) at the end of the microphone's frequency range, 20 kHz. This fact makes the NE5532 the ideal op-amp for the preamplifier circuit found in Figure 12. This circuit has a closed loop gain just under 2. The higher the open loop gain is, then the more linear the amplifier is and the more proportional the output voltage will be with the input voltage. To increase the gain of the preamplifier, the 27 kΩ resistor in the lower middle portion of the schematic was removed. The gain of the amplifier after this resistor is removed is 23 db. This preamplifier was selected because it worked with the NE5532, the WM-61A microphone, and the power supply that will be used.

7.5.2 Analog Low-Pass Signal Filtration

The final design utilizes a Butterworth 4th order filter. Initially a filter was designed according to Appendix IV, however the filter wasn't responding as we expected. Rather than abruptly attenuating

frequencies above the corner frequency, 200 Hz, and fully passing frequencies lower than 200 Hz, the filter was significantly attenuating frequencies as low as 100 Hz. There was no significant increase in attenuation above the corner frequency. The maximum attenuation of high frequency signals was approximately 85% of the original amplitude. The components used from the independent calculations are given in Table A1 in Appendix IV.

A second fourth-order Butterworth filter was built with different resistance and capacitance values in an attempt to achieve greater and more rapid attenuation. This filter was designed using the online Butterworth calculator (Daycounter, 2004) for a cutoff frequency of 200 Hz. The insufficient sound intensity reduction percentages of the first filter were seen again in the second filter. The second filter, however, attenuated the signal less at all frequencies. For this reason, the second filter was used in the final prototype. The performances of both filters can be seen in Figure 27.

It must be noted, that the testing of these two filters was not properly done with a signal generator. Rather a frequency tone generator iPhone application was played through Bose headphones into the acoustic amplification cone and at the same volume and the amplitude of the output voltage as measured on the oscilloscope was recorded at various. The original filter was disassembled before a proper Bode diagram was made. The tone generator on an iPhone is not only likely to produce a slightly incorrect frequency, but also may not be capable of producing the lower frequency sound waves with the same intensity of the higher frequency sound waves. Also the condenser microphone in general collects lower frequencies with less intensity that high frequencies, so signal output is a very poor representation of the filter performance.
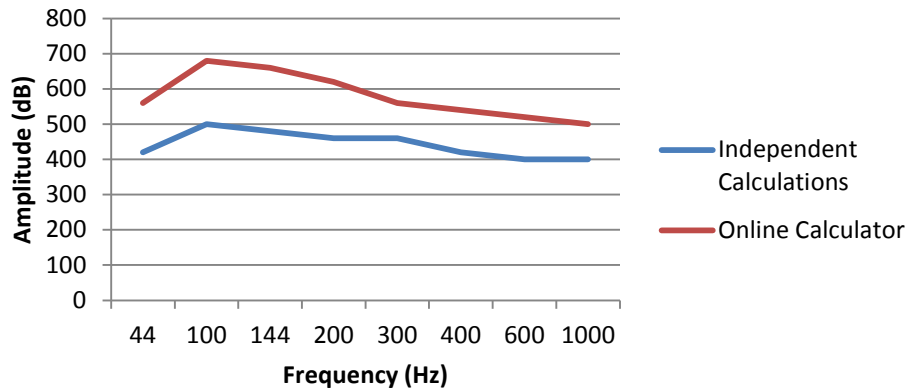
Figure 27: Filter performance

The components used in the final design of the 4th order Butterworth filter are summarized in the Table below.

Table 8: Percent difference between the values output by the calculator and the values implemented in the final design

Stage	Capacitor	Values given by Calculator (F)	Implemented Capacitance (nF)	Percent Difference
1	C1	5.7449091980174E-7	570	0.83
1	C2	4.9038039936758E-7	470	4.26
2	C1	1.3869144520638E-6	1380	0.07
2	C2	2.0312650594001E-7	200	1.54

7.6 Digital Calculations

Upon leaving the analog circuit, the filtered signal is fed into the "0" port of an Arduino Deumilanove device. This device then performs all of the digital calculations necessary to output diagnostically relevant information pertaining to the instantaneous and baseline heart rates, as well as the variability of this data. The code is comprised of two functions, the setup function and the loop function. They are called as *void setup()* and *void loop()*, respectively.

As the code is initialized, it sets up the LCD screen for use. The first line of the code calls for the inclusion of the Liquid Crystal library. Line 3 then specifies the digital output ports that will be used to supply information to the screen.

```
#include <LiquidCrystal.h>

LiquidCrystal lcd(11, NULL, 12, 7, 8, 9, 10);
```

Following this, the variables that will be used are called (lines 4-9). These are all called as integers. They are as follows: *a*, *b*, *c*, *d*, *atot*, *average*, *btot*, *baseline*, *high*, *low*, *variability*, *accel*, *decal*, *time*, *time0*, *pretime*, *pretime0*, and a thirty component array *inst[x]*.

```
LiquidCrystal lcd(11, NULL, 12, 7, 8, 9, 10);
int a=0,b=0,c=0,d=0;
int atot=0, average=0, btot=0, baseline=0, high=0, low=0, variability=0;
int accel=0,decel=0;
int time=0, time0=0;
int pretime=0, pretime0=0;
int inst[30];
```

After these are called, the code begins the setup loop.

7.6.1 Setup

The setup function serves to prime the LCD screen to receive output data as well as to provide an initial value for the instantaneous heartbeat array.

The setup first works by clearing the screen, and then initializes the LCD screen, declaring the size of the screen as 16 characters by 2. The device then outputs a simple message to notify the user that it has been powered on and will be ready to receive input soon. This message is generated by using a *for* loop over nine iterations, causing the words "Akwaaba!" and "Welcome!" to scroll in opposite directions across the screen. Following this, the device delays for 1000 milliseconds, and then clears the screen. Another *for* loop is then implemented, which runs for thirty iterations. This loop sets all of the values in

the instantaneous array equal to 120 BPM, providing a reference by which the baseline can be calculated.

```
void setup() {
  lcd.clear();
  lcd.begin(16,2);

  for (int n=0;n<9;n++){
    lcd.clear();
    lcd.setCursor(0+n,0);
    lcd.print("Akwaaba!");
    lcd.setCursor(8-n,1);
    lcd.print("Welcome!");
    delay(200);
  }
  delay(1000);
  lcd.clear();
  for (int n=0;n<30;n++){
    inst[n]=120;
  }
}
```

Once the setup has completed this, the device is ready to begin acquiring and analyzing signals using the loop function of the code.

7.6.2 Loop

As the name implies, this part of the code runs continuously as long as the device is running, repeating as often as the processing power of the Arduino will allow. There are several components to this code, as there are several parts to the logic that is necessary to provide an output to the Arduino screen. The first part of this code involves the acquisition and counting of the raw signals being outputted from the onboard A/D converter. Following this, a check is made to see whether the device run time has exceeded 5000 milliseconds. If it has, the code begins instantaneous calculations, filters the array of instantaneous values to remove values insignificant to baseline calculations, and then calculates the baseline heart rate as well as the variability using this filtered array. The final part two parts of the code involve outputting whether the current baseline and variability are out of acceptable bounds, as well as the output of the diagnostically relevant values calculated.

7.6.2.1 Counting Beats

As mentioned the subsection prior, the loop function of the code runs on as continuous loop. The calling of the function was included in the code below in order to demonstrate this. Within this function, an *input* variable is called and then set equal to the output of *analogRead(0)*. The analogRead function receives an input of 0 in this case, instructing it to read the voltage at pin 0. Thus, during each of the iterations of the loop, the voltage at pin 0 is checked and set equal to input. From here, the code checks this input against two thresholds as shown below.

```
void loop() {
  int input = analogRead(0);
  if (input<0) input=-1*input;
  if (input>45) a=a+1;
  if (input>45) delay(300);
```

The first of these thresholds acts as a function by which the absolute value of the incoming voltages can be acquired. This is necessary to allow any negative voltage spikes caused by heart beats to be applied

to the same threshold as those that are positive. This accomplished by checking to see if the incoming signal is below zero, and if so, multiplying it by a negative 1 to change its sign. The second threshold is the voltage above which the device will register the incoming sound as a beat. This value can be altered based upon the intensity of the sound being fed into the input. For the purposes of this report, it is set to 45 mV, the intensity necessary to discern between a quiet room and an adult heartbeat. Unless significant mechanical sound amplification is attained, it is likely that this threshold will need to be lower when applied to a fetal heart beat.

Should the threshold be exceeded, the code then adds one to a counter, *a*. This counter is a tally of all of the beats that have occurred over the past five seconds. The code then delays for 300ms, which prevents the code from continuing until 300ms has elapsed. This prevents the logging of the diastolic beat as a beat (this would double the outputted heart rate).

7.6.2.2 Instantaneous Heart Rate

After the counting of the beat (if one was counted at all), the *time* variable (previously set to 0), is now set to the device time, minus a variable *time0*. The *time0* variable is set within the subsequent *if* logic, but is currently set to 0. If the time variable is greater than or equal to 5000ms, this indicates that 5 seconds have elapsed, and the code begins the instantaneous calculations.

```
time=millis()-time0;
if (time>=5000){

    lcd.clear();
    inst[0]=a*12;
    a=c=0;
    lcd.setCursor(2,0);
    lcd.print(inst[0]);
```

Within the *if* function, the LCD screen is cleared to prevent any remnants from previous outputs from being displayed. For example, if a previous heart rate was logged as 108 BPM, and the current heart rate is 72 BPM, this would display as 728 BPM unless the LCD is cleared before the new heart beat is registered. Following this, *inst[0]*, the current instantaneous heart rate, is set equal to *a* multiplied by twelve. Next, *a* is set equal to 0, allowing the variable to be reused. The new *inst[0]* values is outputted to the LCD screen on the first row, in the second position.

7.6.2.3 Average Heart Rate

If it is found that this instantaneous value exceeds a given threshold, another part of the code is run to allow the calculation of average heart rate and the baseline to occur. The reason for this being contained within a threshold based *if* function is to prevent the inclusion of heart rates in the average and baseline that may be artificially low due to the accidental removal of the device from the mother. The threshold, set at 48 BPM for the purpose of this report, is at an appropriate level for an adult. A fetal heart beat would likely require a high threshold to be effective (around 80 BPM). This *if* logic also contains the baseline filtration, baseline calculation, and variability calculation functionality.

```
if(inst[0]>=48){
  d=d+1;
  atot=atot+inst[0];
  average=atot/d;
```

Above is the calculation of average heart rate. This is a relatively simple piece of code, utilizing a counter *d*, a counter *atot* that keeps a total of all of the instantaneous heart beats that have occurred thus far, and finally a variable *average* that is set equal to *atot* divided by *d.*

7.6.2.4 Baseline Filtration

The baseline filtration code is a bit more difficult to implement. Baseline fetal heart rate determination is often a subjective process; as mentioned prior in the report; one cardiotcography strip may have different interpretations, diagnoses, and prognoses by different doctors. Therefore, the logic in this section is subject to change as more reliable methods of baseline determination are found. The following code is contained within a *for* loop running for 25 iterations. This allows all values within the *inst[x]* array to be compared. Within this *for* loop, there are four different distinct sections. These are the acceleration determination, the deceleration determination, the acceleration spike detection, and the deceleration spike detection.

The acceleration determination compares the current instantaneous heart rate to the five prior to it. This is equivalent to 30 seconds of values, as each instantaneous value is 5 seconds apart. An *if* function determines if the current instantaneous rate is greater to the one prior to it. If so, a counter *accel* is added to. If *accel* is greater than 3, this it is considered significant enough to be logged as a potential acceleration; thus, an analogous deceleration counter is set equal to 0. If *accel* is higher than 6, all of the past five instantaneous values are set equal to the earliest value. This prevents the inclusion of accelerations, defined as any increase of fetal heart rate lasting for over 30 seconds and/or higher than 25 BPM.

```
for (int n=0;n<=25;n++){
  if (inst[n]>inst[n+1]){
    accel=accel+1;
    if (accel>=3){
      decel=0;}
    if (accel>=6){
      inst[n]=inst[n+1]=inst[n+2]=inst[n+3]=inst[n+4]=inst[n+5];
    }
  }
```

The deceleration code follows the same logic, checking for decreases rather than increases.

```
if (inst[n]<inst[n+1]){
  decel=decel+1;
  if (decel>=3){
    accel=0;}
  if (decel>=6){
    inst[n]=inst[n+1]=inst[n+2]=inst[n+3]=inst[n+4]=inst[n+5];
  }
}
```

The acceleration and deceleration spike codes check to determine whether the current instantaneous fetal heart rate is 25 BPM greater than or less than that of the previous instantaneous fetal heart rate. If so, it sets the current rate equal to the one prior to it, thereby eliminating spikes in the fetal heart rate from the calculation.

```
if (inst[n]>=inst[n+1]+25){
  inst[n]=inst[n+1];
}
if (inst[n]<=inst[n+1]-25){
```

```
            inst[n]=inst[n+1];
        }
    }
```

After these parts of the code, the instantaneous heart rate has effectively been filtered and all of the sections that would not typically be included in the determination of the baseline are removed. More will be added to this code in the future, as many improvements can be made to increase the scope of the analysis performed. With the filtration of the instantaneous array, the baseline can be determined.

7.6.2.5 Baseline Calculation

The baseline calculations work similarly to the average calculations, keeping a running total of all of the instantaneous values logged. The primary difference between the two lies in that the baseline calculation is contained within its own *for* loop. This allows for any retroactive changes made to previously included values in the instantaneous array to be logged.

```
for(int n=0;n<29;n++){
  btot=btot+inst[n];
  baseline=btot/n;
  if ((inst[n]>high)&&(inst[n]<160)) high=inst[n];
  if ((inst[n]<low)&&(inst[n]>110)) low=inst[n];
  if (low<40) low=low+100;
  inst[29-n]=inst[28-n];
  }
```

Several other calculations are included in the loop beyond the baseline calculations. The two lines of code following the baseline calculations serve to determine whether the current instantaneous value is the highest logged or the lowest logged, as long as it remains within acceptable bounds. The line of code following the comparison with the lowest value serves to push the low value within acceptable bounds if it is not already. This is necessary as the *low* variable is initially set equal to 0. Future iterations of the code will do away with this, instead setting *low* equal to 160 BPM.

The final line of code pushes each value in the instantaneous array back, with *inst[29-n]* equaling *inst[28-n]* for values *n=0-28*. This is in preparation for the addition of the next instantaneous value, which will be stored as *inst[0]*.

7.6.2.6 Variability Calculation

The variability calculation utilizes the *high* and *low* values that were logged within the baseline calculation. *Variability* is set equal to *high-low,* the peak to peak difference in the instantaneous heart rates considered relevant to the baseline. As a precaution, a line of code was added that prevented a negative variability from being outputted; this will be removed next semester, as it is used to prevent volatility in the values assigned to the instantaneous array (this issue is detailed in Section 11.3.3).

```
    variability=high-low;
    if (variability<0) variability=variability*-1;
    inst[0]=0;
    btot=0;
  }
 }
```

Inst[0] and *btot* are set equal to 0, to help prevent this same volatility from occurring in other calculations.

7.6.2.7 Bounds Check

The next part of code contains three parts: a baseline bounds check, a variability bounds check, and a baseline and variability bounds check.

```
if (((baseline>160)||(baseline<110))&&(baseline>0)){
  lcd.clear();
  lcd.setCursor(0,0);
  lcd.print("  Baseline Out  ");
  lcd.print("    of Bounds    ");
}
if (((variability>25)||(variability<6))&&(variability>0)){
  lcd.clear();
  lcd.setCursor(0,0);
  lcd.print("Variability Out ");
  lcd.print("   of Bounds    ");
}
if ((((baseline>160)||baseline<110)&&((variability>25)||variability<6))&&(baseline>0)){
  lcd.clear();
  lcd.setCursor(0,0);
  lcd.print("Baseline and Var");
  lcd.print(" Out of Bounds  ");
}
```

The baseline bounds check and variability bounds check work by checking the value in question against the appropriate bounds. For baseline, the values should fall within 110 to 160 BPM; variability should have values falling within 6 to 25 BPM. The final bounds check runs both determinations simultaneously, only being true if the baseline and variability are both out of bounds. Should any of the three *if* loops have their conditions fulfilled, a message pertaining to which bounds were violated is outputted to the screen. This serves to fulfill the engineering specification calling for a referral indicator in cases of abnormal fetal heart rate patterns.

7.6.2.8 Output

The output section of the code is the final part of the code contained within the loop function. It contains 14 lines of code, alternating between the positioning of the cursor, printing of the label, positioning of the cursor, and then printing of the value corresponding to the label (in that order). The only value not printed at this stage is the instantaneous heart rate (as it was printed earlier in the code.

```
lcd.setCursor(0,0);
lcd.print("I:");
lcd.setCursor(6,0);
lcd.print("A:");
lcd.setCursor(8,0);
lcd.print(average);
lcd.setCursor(0,1);
lcd.print("B:");
lcd.setCursor(2,1);
lcd.print(baseline);
lcd.setCursor(6,1);
lcd.print("V:");
lcd.setCursor(8,1);
lcd.print(variability);
}
```

The labels printed are *I, A, B,* and *V*, with semicolons printed after each. These correspond to instantaneous heart rate, average heart rate, baseline heart rate, and variability, respectively. Printed after the semicolons of each label is each respective value. The current configuration of the design can be seen below in Figure 27.
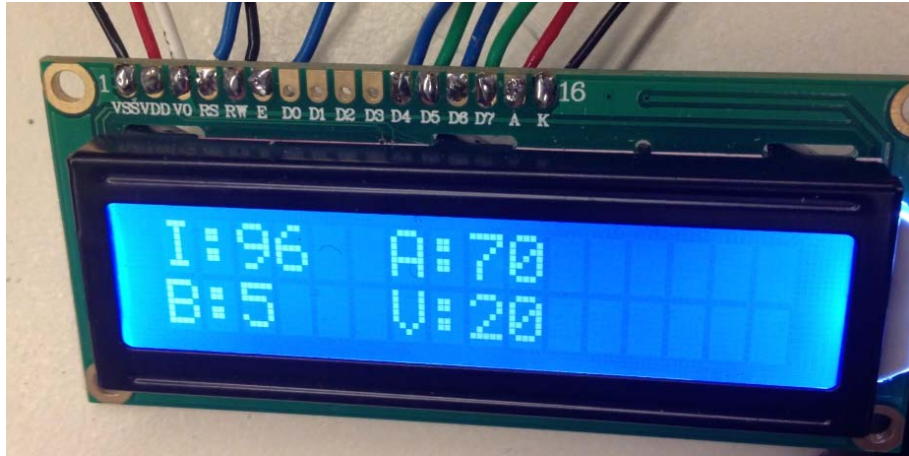
Figure 27: Example Output of LCD Screen

In future iterations of the design, this display will only show the instantaneous heart rate, baseline heart rate, and variability of the heart rate, as average heart rate does not offer any diagnostically relevant data. Improvements will also be made to make this display more aesthetically pleasing. More information out this can be found in Section 11.3.

7.7 Sound Output

Ideally, the device should output the sound of the heartbeat as it is detected. This function is not working yet. When hooked up to the circuit, too much noise is produced from the speaker to identify a heartbeat. It is likely that this is due to the performance of the filter. When the filter is able to isolate the target frequencies more effectively, the speaker will emit only those frequencies without interference from high-frequency noise.

Also, the speaker produces high-intensity, high-frequency sounds when placed too close to the microphone due to interference. A larger degree of separation between these two elements is required to reduce the interference from the microphone.

7.8 Powering Device

The prototype is powered using the 5 volt power supply from the Arduino. The Arduino has two pins associated with power: one pin to supply 5 volts and the other to ground the circuit. The 5V pin is connected to the positive bus line of the breadboard and the GND pin is connected to the negative bus line.

7.9 Prototype

As mentioned previously, the housing and user interface for the device are not included in the final design because they will be addressed when the development of this device continues during the winter 2013 semester. The sections below describe the individual components of the design. A bill of materials can be found in Appendix V.
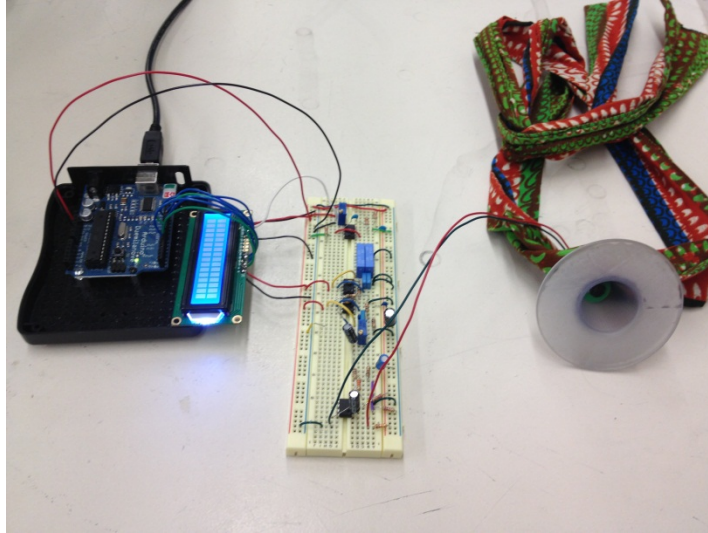
Figure 28: Picture of prototype

8 Fabrication Plan

8.1 Manufactured Parts

The cone and the strap are the only parts that required manufacturing. The acoustic amplifier cone was printed using stereolithography (SLA) 3D printing, specifically the Viper si2 SLA system. The surface finish is superior while the cost of materials is less expensive than other options. Accura 60 plastic was used so the piece is durable and the surface is smooth as not to distort the sound waves.

The strap was built using a sewing machine. Two pieces of fabric were cut according to the dimensions and sewn together according to Figure 28. The Velcro was also sewn in place accordingly. A circular hole was cut in the strap to accommodate the mouth of the cone. Finally two X shaped incisions were made for the female side of the snaps to be attached to the strap, and the male side of the snaps was placed on the cone with double sided adhesive tape.

8.2 Purchased Parts

All resistors and capacitors not available through the Mechatronics lab, the Industrial Operations Engineering Lab, or the Embedded Systems Hub were bought through DigiKey.com. The snaps and Velcro were purchased at Meijer. The op-amps have been purchased through DigiKey. The Ghanaian fabric was purchased at the Kumasi market in Ghana. The breadboard, Arduino, 22 gauge copper wires and solder are from the University of Michigan Mechatronics Lab.

A full list of the materials and parts can be found in the Bill of Materials in Appendix V.

8.3 Assembly

The female half-snaps were sewn to the fabric and secured according to Figure 33. The male snap was attached to the acoustic cone by double sided adhesive tape, according to Figure 34. The center of the snaps will be 2.1 inches apart.

Two 22-gauge copper wires were soldered to the microphone element according to its data sheet, one wire associated with ground and the other with signal and power. The microphone was encased in dampening foam, Model Magic, as seen in Figure 25 above, and then the microphone and foam was pressed into the top of the cone after feeding the wires through the throat hole of the cone. The microphone cannot be permanently fixed to the cone because as the circuit is being further developed and tested, there is a chance that the microphone element could be blown or damaged, so it needs to be easily ready to be changed out. Once the function of this device is final, the form of the secure attachment of the microphone to the cone can be developed. However, the microphone and dampening foam can be temporarily secured in the top of the cone by shrink wrapping the microphone wires together after they have been passed through the throat hole of the cone. The shrink wrap holds the microphone in place as it cannot fit through the throat hole of the cone.
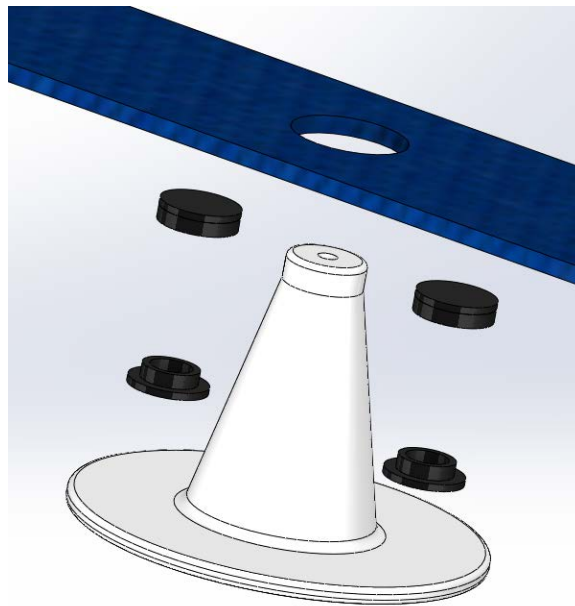
Figure 29: Exploded view of method of attaching the cone to the strap.

Assembling the circuit requires the circuit diagram found in Figure 26 and a breadboard. The microphone wires plug into the breadboard at the input of the preamp and to the ground of the circuit. The preamplifier was assembled on the breadboard according to the pre-amplification circuit in Figure 26 above using the resistors, capacitors, operational amplifier and potentiometer denoted Pre-Amp in the function category of the Bill Materials located in Appendix V. The preamplifier sends the signal into the Butterworth low-pass filter also assembled on the breadboard according to the circuit diagram in Figure 26 with the resistors, capacitors and operational amplifiers denoted Filter in the function category of the Bill of Materials. The filtered signal is then passed to a computer through the Arduino

Duemilanove from the output of the filter with copper wires to the analog pins on the Arduino. The Arduino is then connected to a computer with a USB cord. Power was connected to the circuit with two copper wires, one going from the 5V pin on the Arduino to the positive bus line on the breadboard and the other going from the GND pin to the negative bus line.

9 Preliminary Validation

Due to the nature of this design project, the top two user requirements for function can be divided up into sub requirements that must be met before the top requirements can be satisfied. In order to obtain a baseline fetal heart rate and variations from the baseline within ± 2 BPM at a 95% confidence level, the device first needed to be able to isolate a heartbeat, filter out unwanted frequency ranges and have an accurate analysis of the acquired signal in the Arduino code.

9.1 Heartbeat Isolation

An adult heart was used to test the signal acquisition and isolation design, as it is safe and accessible. Testing on a maternal abdomen and listening for an actual fetal heart rate requires an IRB approval and is not nearly as accessible. Listening for an adult heart with the device proves that condenser microphone technology can indeed pick up heartbeat sounds. The device can be modified further to acquire fetal heartbeats once adult heartbeats are successfully obtained. An adult heartbeat also allows the team to test the digital analysis in the Arduino code, before testing on fetal heartbeats.

The device's probe, or acoustic amplifier with the microphone, was strapped to an adult chest with only one layer of shirting between the acoustic amplifier and the skin of the subject (Figure 30). The acoustic amplifier was placed approximately over the heart of the subject, just as a healthcare worker would search for the approximate location of the fetal heart before attaching the device.
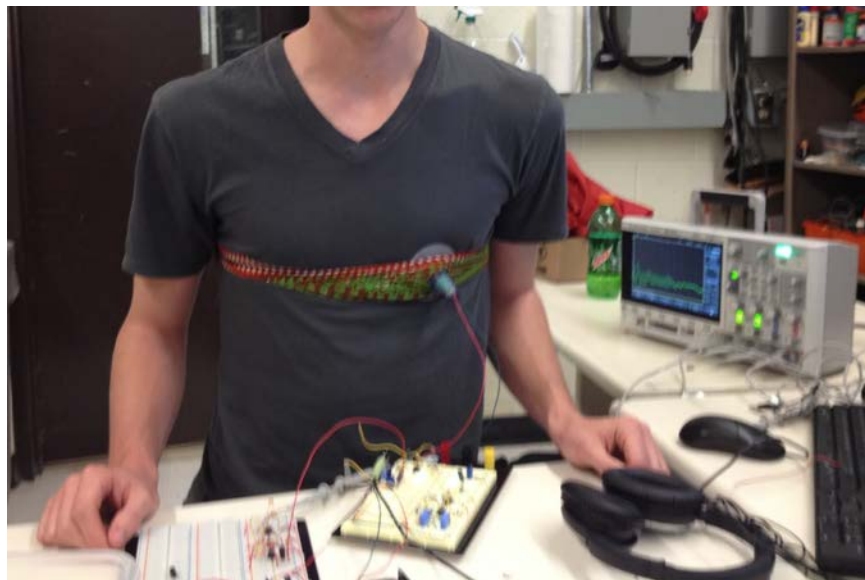
Figure 30: The fetal heart rate monitor prototype strapped on adult subject

After the probe was attached, the output of the preamplifier of the device was measured on an oscilloscope (Figure 31). The device displayed great clarity in the adult heart rate signal when the subject was in a quiet room, sitting still, and not talking. As you can see in Figure 31 below, the heartbeat signal is clearly distinguishable. Even both the systolic and diastolic pulses of the heart can be seen.
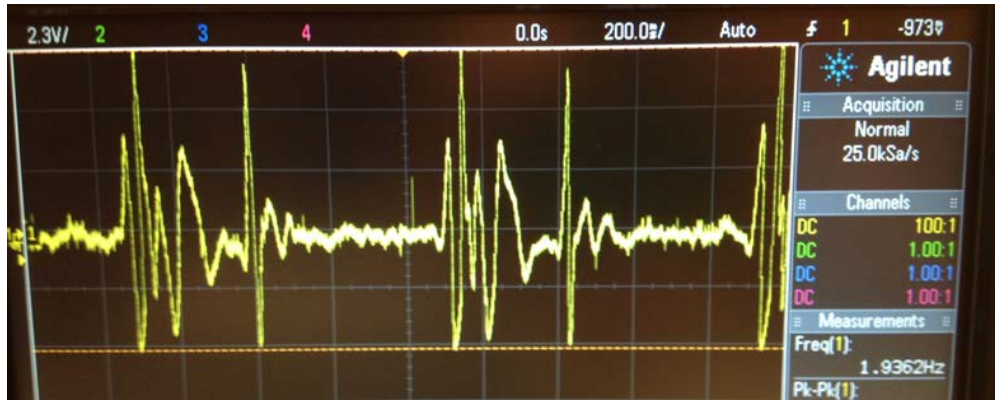
Figure 31: The heartbeat of adult subject displayed on oscilloscope as a voltage output of the prototype

9.2 Accuracy of Arduino Code Analysis

The Arduino code was tested for accurate calculation of the adult heart rate. The heart rates of the four team members were measured using the prototype and a standard medical stethoscope. A stethoscope is an accepted way to measure heart rates and was used to compare the prototype to a standard. In order to limit human error in counting the beats with the stethoscope, only one team member did the stethoscope measurements. A picture of the setup can be found below in Figure 32.
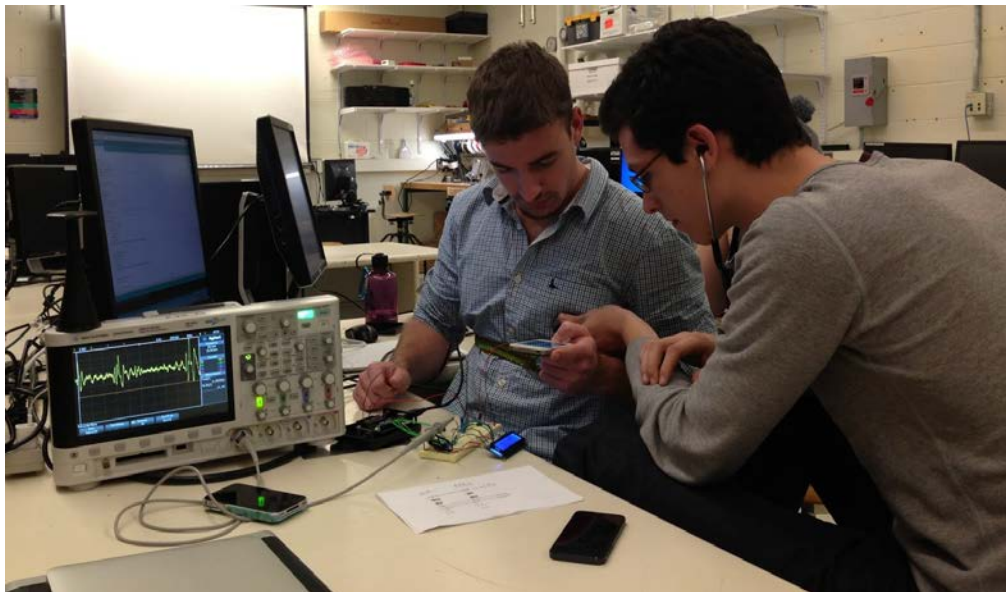
Figure 32: Preliminary testing with stethoscope

The heart rates of all four team members were monitored for 1 minute to determine the beats per minute with both the prototype and the stethoscope. Twenty-two trials were recorded and the average difference between the two devices was 2.7 BPM. At this stage in the design of the fetal heart rate monitor, this result is encouraging.
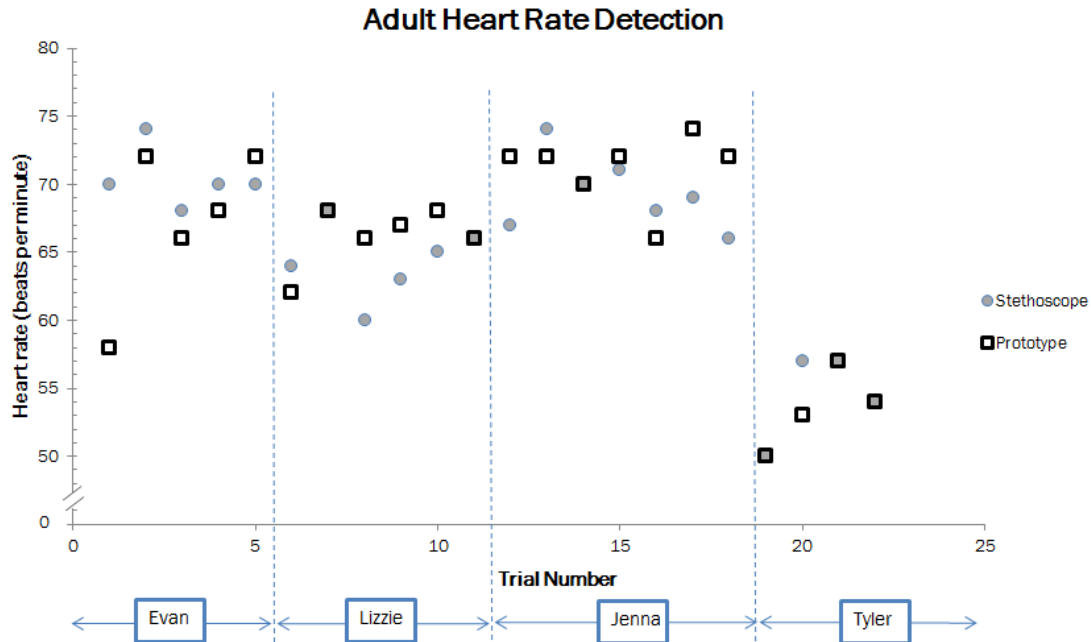
Figure 33: The preliminary testing of heart rate detection showed an average difference of 2.7 BPM between the prototype and a stethoscope

9.3 Filter Performance

The performance of the filter was determined by recording the output of the filter on an oscilloscope as the frequency of an input sine wave created by a signal generator was changed from 20Hz to 2000Hz. The filter was tested separately from the microphone and preamplifier because the microphone does not produce sound waves of different frequencies with the same intensity. Figure 33 below shows the Bode plot for both a second order Sallen-Key filter and the fourth order Butterworth filter described in Section 7.

Frequency Response of Filters
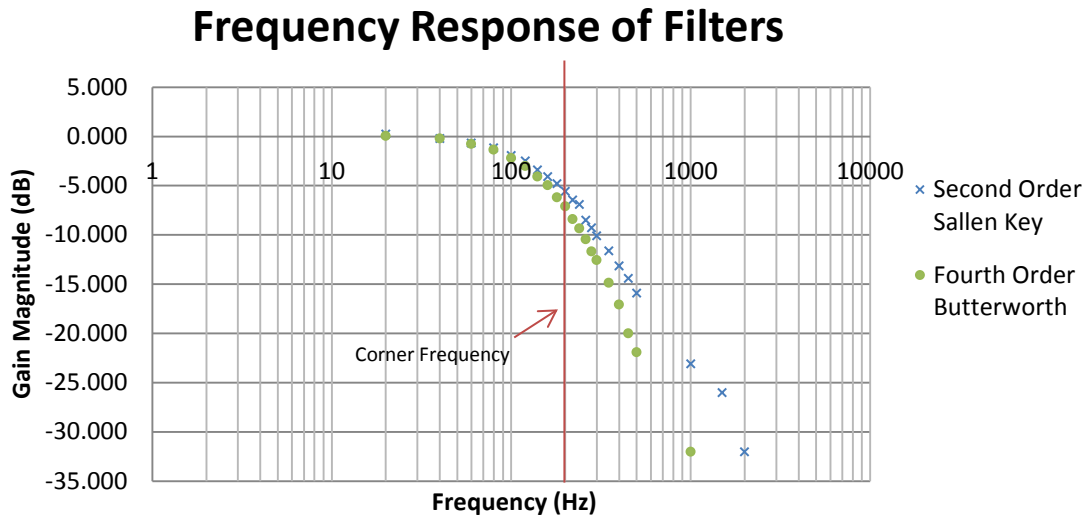
Figure 33: Frequency response of filters

The second order filter responds slightly better than expected with a frequency roll off of -25 dB per decade and the fourth order filter has a frequency roll off of about -38 dB per decade as expected. The Butterworth filter is clearly performing better than the Sallen-Key filter as expected for the frequency roll off.

At the corner frequency the magnitude of the gain should be -3 dB, but the gain is -5.6 dB to -7.19 dB for the Sallen-Key and Butterworth filters respectfully. This performance characteristic is not ideal and means that the filter is attenuation the signal much before the cut off frequency.

10 Validation Plan

The fetal heart monitor prototype cannot be tested on women until it has been approved by the Institutional Review Board (IRB). The application process for approval is underway so the prototype can hopefully be tested in the next few months. During the application process for IRB approval, the prototype will be tested using a simulator.

10.1 Simulator

The simulator will consist of a speaker and a hemisphere of ballistics gelatin with dimensions approximately equal to the average maternal abdomen at full term. In previous Design Review Reports, the simulator was described as containing a cavity approximately the size and shape of the speaker so the speaker could be placed underneath the simulator. A simulator built according to this design, shown in Figure 34, was found to have lower performance than expected. It is likely that the cushion of air between the speaker and the bulk of the ballistics gel caused increased sound dampening as sound pressure waves were forced to move between materials. In addition, sound moves most efficiently through materials in which molecules are densely packed and elastically colliding with each other often.

Therefore, sound propagation through the air cushion is much less efficient than propagation through the ballistics gel.

Fig. 34: Ballistics gel simulator approximating the size and shape of a maternal abdomen at full term.

The simulator design has been revised to remove the air gap between the speaker and ballistics gel. Instead of placing the speaker in a cavity in the gel, the speaker will be placed into the ballistics gel while it is setting. Care will be taken to prevent the speaker from sinking deeper than directly below the flat surface on the back of the hemisphere of gel. The speaker will be encased in the gel when the simulator has finished setting.

10.1.1 Speaker Selection

Speakers consist of three essential parts: a box, a crossover network and at least one driver. The driver is responsible for turning electric signals into sound waves, if multiple drivers are necessary the crossover network decides how the signal is divided between them, and the box houses both the drivers and the crossover network. To create low frequencies, a driver must have a fairly large diaphragm consisting of enough mass to resonate at low frequencies. To produce high frequencies, the diaphragm must have a small diameter and a relatively low mass, enabling the driver to resonate at high frequencies. Thus, having a single driver capable of producing sound waves over the entire frequency range of human hearing, 20 Hz-20 kHz, is seemingly impossible to develop (Harrison Technologies, 2011). High fidelity speakers usually use a variety of different size drivers with a complex crossover network to help solve this problem, but high fidelity speakers are costly. In order to recreate the sound of the fetal heart rate as accurately as possible, a driver designed to transmit low frequencies, commonly known as a woofer was chosen.

A waterproof Pyle (Model PLMR60W) was chosen with a frequency range of 45 Hz to 16 kHz, because it was the lowest frequency speaker available at a reasonable price and size. Though some sounds of the

fetal heart rate lie within the 35-45Hz range, a speaker capable of producing such sounds needs a subwoofer driver, which is not feasible in this application. The frequency response range of a speaker means that the sound waves across that range will be reproduced with the same sound intensity. Thus the speaker chosen may be able to create those low frequency sounds at a lower intensity relative to some higher frequency sounds that lie within the response range of the speaker. Though the sound quality may not be perfect, the speaker should have an adequate frequency response to be used in the simulator.

10.1.2 Material Selection
The maternal abdominal tissue between the fetus and the surface of the mother's abdomen was approximated as a material with constant density. Ballistics gel was selected to represent the maternal abdominal tissue because it is widely used in research and testing capacities to represent human flesh. In this case, it recreates the sound-dampening effects of the maternal abdominal tissue above the fetus. Ballistics gel was mixed using Knox Original Unflavored Gelatin, Pam non-stick cooking spray, plastic wrap, and water (Custom Cartridge, 2002). Cartridge, Inc., an ammunition company that uses ballistics gel to test the penetration of bullets into biological tissue, endorses this recipe for ballistics gel.

10.1.3 Dimensions and Molding
Ballistics gel was poured into a mold to force it to take the shape of the maternal abdomen. Fundal height was the key size characteristic of a pregnant woman's abdomen used to define the dimensions of the mold. The fundal height is the distance from the top of the uterus to the pubic bone (Harms, 2012). Although abdominal size is commonly used to estimate gestational age, it is not always an accurate indicator of the size of a fetus because some of the uterus lies below the pubic bone in the pelvis (Fundal Height Measurement, 2007). However, the fetus grows in the section of the uterus above the pubic bone. Therefore, the fundal height is a legitimate method of gauging gestation age, despite its exclusion of the cervix (Fundal Height Measurement, 2007). To provide a space for microphone placement, the team floated a bowl within the liquid gelatin. When the gelatin solidified, this served to provide a socket in which the speaker could be placed.

The fundal height used to define the dimensions of the simulator represents the abdomen of a woman pregnant with a full-term fetus. A study published by Challis et al. in 2002 reported that the average distance between the pubic symphysis and fundus for 817 Mozambican women who were 38-41 weeks pregnant is 38 cm (Challis, 2002). It is likely that this average fundal height calculation can be applied to a device engineered for women in Ghana without excessive error due to the geographical proximity.

If the maternal abdomen is approximated to a hemisphere, then the fundal height, 38 cm, is half of the circumference. Using the equation for arc length, s:

$$S = r * theta \qquad 38 \text{ cm} = r * pi \text{ radians} \qquad r = 12.09 \text{ cm}$$

The radius of the hemisphere of ballistics gel should be 12.09 cm to represent the size and shape of a maternal abdomen when the fetus is full-term or post-term. A ballistics gel hemisphere larger than this would decrease the sound propagation, making it more difficult to detect a fetal heart rate. The dimensions of the simulator are slightly larger than the acceptable radius defined above to ensure that

the fetal heart monitor is sensitive enough to be used with mothers with higher body-mass indices or for cases in which the uterus is enlarged, such as polyhydramnios.

10.2 Recordings and Analysis

The baseline of a fetal heart rate is found by approximating the mean heart rate rounded to the nearest increment of five beats per minute over ten minutes. Periods of accelerations, decelerations, and marked variability are excluded. Marked variability implies an amplitude range greater than 25 beats per minute (Tomich, 2011).

The variability of the fetal heart rate is an indication of the status of the fetal central nervous system. As the sympathetic branch of the autonomous nervous system develops, it will periodically increase the heart rate. Accelerations will be countered by the parasympathetic nervous system, which stabilizes the heart rate (Woods, 2006). Irregular fluctuations in the baseline fetal heart rate over ten minutes define the variability. Minimal variability contains fluctuations of up to 5 beats per minute. Moderate variability falls between 6 and 25 beats per minute. Marked variability is greater than 25 beats per minute [1].

An acceleration lasting ten minutes or longer redefines the baseline. The formula to define the baseline fetal heart rate is somewhat rigid. Variability, however, relies more on the judgment of the physician. In a 2005 study, medical residents and experienced physicians were asked to assess variability from electrocardiogram recordings. Both groups calculated the variability with approximately 80% accuracy when compared to a computer analysis (Tongson, 2005). Due to the considerable differences between physicians' interpretations of variability, the validation plan for the prototype includes input from several physicians.

An unfiltered sound recording of a fetal heartbeat will be obtained using an electronic stethoscope with the assistance of an obstetrician. The recording will be played from the speaker embedded in the ballistics gel simulator. The appropriate volume will be found by matching the volume at which the sound was detected by the electronic stethoscope and the volume at which the sound reaches the outside of the simulator. The sound intensity will be measured using the Omega HHSL1 Sound Level Meter.

The recording will be imported into MATLAB and formatted to match the scale of a cardiotocography (CTG) tracing. The tracing will be given to five obstetricians at the University of Michigan Hospital for each to calculate baseline and variability independently. The baseline and variability calculations of all doctors will be averaged. The average baseline and variability numbers will then be compared to the result of testing the prototype with the recording on the simulator.

The engineering specifications for baseline and variability state that the prototype must be accurate within two beats per minute at 95% confidence. In order to determine whether the device is meeting the confidence interval, the procedure above will need to be repeated 20 times.

It is likely that performing this procedure 20 times would take much longer than the four months of the winter 2013 semester. Only one obstetrician at the University of Michigan Hospital is confident in his ability to consistently locate a fetal heartbeat using a stethoscope. Aligning his valuable time with the

appointment of a consenting patient in the Perinatal Intensive Care Unit is difficult. In addition, requesting that busy physicians take time to analyze twenty fetal heart rates irrelevant to their present patients will necessitate patience.

10.3 IRB Approval Process

The University of Michigan has a program called the Human Research Protection Plan through the Office of the Vice President for Research that helps students and faculty on campus go through the IRB approval process. The university has nine registered IRBs under the Federal wide Assurance of Protection for Human Subjects with the U.S. Department of Health and Human Services. The IRBMED application is suitable for the testing of this prototype because the research involves using patients and facilities in the University of Michigan Health Services. The initial application will be submitted in January 2012.

A pivotal consideration of the IRB process, is whether the device qualifies as a significant risk (SR) device study or a non-significant risk (NSR) device study. According to guidelines set by the FDA, a significant risk device study is one that is intended as an implant and presents serious potential risk, represented to be for use supporting or sustaining human life, for use of substantial importance in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to the health, safety or welfare of a subject. Seeing as the prototype is used as a referral tool, which loosely fits the description of a diagnostic device, the testing may qualify as SR device testing.

However, under IDE regulations of 21 CF 812, it clearly states that a diagnostic device is exempt if the testing is noninvasive, does not require an invasive sampling procedure that presents significant risk, does not by design or intention introduce energy into a subject, and is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic procedure. Seeing as even in the field, this device is not intended as a sole diagnostic tool for fetal distress, the device presented in this paper should qualify as a non-significant device test.

As long as the review board agrees that the research is a NSD study, the IRB will act as a surrogate for the FDA during the process of the study and the FDA does not need to be made aware of the study. NSR device studies do not need IDE (Investigational Device Exemption) application approval from the FDA and also follow an abbreviated set of requirements as given by 21 CFR 812.2(b).

Therefore, as long as the IRB declares the testing of the prototype as a NSR device study, the device should be approved for testing by late February. This will enable the testing of the device on 20 different women with ease. If the device is considered a SR device, then the timeline for approval will not enable the testing to be done prior to the conclusion of next semester. If such is the case, then recordings from 20 different women will attempt to be collected assuming an obstetrician is willing to dedicate the time necessary to acquire the recordings.

11 Design Critique and Recommendations

Over the course of the semester, the team faced many deadlines that required immediate solutions to challenges that were faced in the design. There were several instances in which this caused the team to decide upon certain design features that must be revisited in coming semesters. The team has noted that improvements can be made in four general categories, with specific recommendations as to how these improvements can be implemented included in each respective section. The first section of Design Critique seeks to look into problems faced by the current method of signal acquisition. Following this, issues in sound filtration and processing will be addressed in the second and third sections, respectively. The final section seeks to point out shortcomings in the logic used in the instantaneous, baseline, and variability calculations.

11.1 Microphone Critique

In the implementation of the hollow cone amplifier, the team noted that the junction between the microphone and the hollow cone amplifier caused by the press-fit configuration led to the unintended ambient noise being received by the microphone. The microphone used in the final design was also not adequately investigated, but merely chosen because it was the first microphone to acquire a heartbeat. Further investigation is needed to ensure the microphone is the highest performance option.

11.1.1 Securing the Microphone inside the Cone

Issues lie in the fastening of the microphone to the cone. When the microphone is hard pressed into the top of the acoustic amplification cone, mechanical vibrations in the cone drown out the sound of the heartbeat. Vibrations through the cone are passed to the microphone with far more intensity than that of the heartbeat. When the microphone is encased in dampening foam and then wedged into the top of the cone, the heart beat is clearly seen on the oscilloscope and the friction between the cone and the strap holding it in place interfered less with this signal.

Though the damping foam currently improves the performance of the microphone during preliminary testing, the fastening of the microphone to the acoustic amplification cone in the future does need to be made more secure. When moving the microphone and cone fixture in testing, the foam could easily slip out of the top of the cone; though it is easy to move the microphone back in place, it is an uncontrollable parameter that greatly affects the performance of the prototype.

Although omnidirectional microphones are less subject to mechanical shock as unidirectional microphones, some kind of isolation such as a microphone shock mount may be needed to prevent the back plate of the condenser microphone from experiencing too much movement (Ballou et al., 2008). The condenser microphone is also most vulnerable to movement in the z-axis considering that the face of the back plate is perpendicular to that axis (Ballou et al., 2008), thus the method used to suspend the microphone needs to be most forgiving along that axis. The shock-mount needs to be designed such that the resonant frequency is at least 2.5 times lower than the lowest frequency response of the microphone. The resonant frequency, f_n, of a mechanical system is given by the equation below:

$$f_n = \frac{1}{2\pi}\sqrt{\frac{Kg}{w}}$$
(Eq. 1)

Where *K* is the spring rate of the isolator, *g* is acceleration due to gravity and *w* is the load. Since the frequency range of the microphone in the prototype has a lower bound of 20 Hz, the resonant frequency of the system must be at least 8 Hz for the microphone to be well isolated. With the microphone weighing as little as 0.8 grams, the spring constant of the system, *k*, needs to be 2.02 N/m as given by Equation 1 above. The spring isolator is commonly tough to scale because plastics that can rigidly connect the microphone are limited by material properties and spring or elastic materials commonly get worn out causing their material properties to can change drastically (Ballou et al., 2008).

Future Design Considerations

Rycote 'lyre' web: The Rycote 'lyre' webs (shown in Figure 35 below) rely on their shape to give different performance on different axis and therefore are commonly used to hold a microphone during studio recordings (Ballou et al., 2008). They are robust and precise allowing the design to overcome the potential wear of elastic or rubber bands and exceed the limitations of the material parameters of plastics commonly used to attach the microphone (Rycote Lyre Suspension Datasheet).

Figure 35: Rycote 'lyre' web commonly used as shock mount for microphone in studio recordings.

Fastening the microphone to the inside of the cone in a similar manner may prove to be effective even though the application is quite different. Dampening foam securely fastened between the cone and the outer housing of the microphone by means of glue or tape may still provide enough insolation from vibrations.

Permanent dampening foam: Another design for future consideration is to permanently incorporate the dampening foam. In a dynamic microphone, the transducer element is mounted within an inner capsule and isolated from the outer housing by means of a shock absorber (Ballou et al., 2008). This type of design may be able to be used for the condenser microphone as well. Also, FXI is a company that designs vibration damping material, acoustical foam and vibration isolation products. Their solutions include application in healthcare electronics and should be explored in the future.

Elastic bands/springs: Though Rycote 'lyre' webs appear to be the most popular shock mounts, other shock-mount styles used in studio recordings incorporate elastic bands in order to minimize the interference of mechanical vibrations through the microphone with the sound signal. (Microphone Shock Mount System, Patent: 096073979). Though elastic bands may not seem secure enough for permanent fastening, the possibility cannot be ruled out.

11.1.2 Microphone Selection

The microphone used in the final design did not go through any rigorous testing. The CMA-4544 was used in for the final design simply because it was the first microphone that picked up the heartbeat. Due to the time constraints of the class, the other microphones were not able to be tested in the same manner. The Panasonic WM61A may have been better, but was never tested in a very quiet environment.

Future Solution

All four of the condenser microphones need to be tested to see if they can pick up a heartbeat. The CMA-4544, the CMB-6544, the Panasonic WM61A and finally the Panasonic WM64K. All microphones should be tested in a room with the same ambient sound intensity and all should be tested on the same person. There should be at least three trials of each attachment of the amplification cone because the device uses directionality in the acoustic amplification. The intensity and clarity of each trial should be noted.

11.2 Challenges in Sound Filtration

In the final design as presented at expo, the team presented an analog circuit that did not utilize the Butterworth filters designed over the course of the semester, due to difficulties in implementation. Though the lack of analog filtration had an impact on the vulnerability of the device to ambient noise, it was not the sole reason the device could only be tested in quiet environments. Even when the signal was passed through the filter, the signal was still very responsive to the sound intensity of the environment in which it's being used. Lastly, the threshold method of digital signal processing assumes that sound filtration is perfect and that the FHR is the loudest input signal of the microphone.

11.2.1 Difficulties Analog Filtering

Through interviews with electrical engineering professors on campus, it was discovered that Butterworth filters are notoriously hard to tune to the precise cut off frequency. The performance of the ideal analog filter did not line up with the performance of that filter once built on a breadboard. As is seen in PRELIMINARY TESTING OF FILTERS SECTION, the filter is attenuating the signal far before the cut off frequency. Butterworth achieves the maximally flat response at the expense of a fairly large transition from pass band to stop band (Zumbahlen, 2008). This could have contributed to the early attenuation of the signal.

Potential Future Designs

Circuit Simulators: Moving forward the team will utilize online circuit simulators in order to help tune the filter more accurately. Considering how sensitive the performance of the filter is to component selection (i.e. values of resistors and capacitors) using online filter design tools that do not compute the values as standard value components most likely hurt the filter performance. If the values of the resistors and capacitors used to design the filter are not exactly the same as the values given by the filter calculator, the filter won't work ideally. Circuit simulators will help the team explore the difference between how a filter should ideally work from how it works on the breadboard.

Operational amplifier power: During the testing of the filters, it must be noted that the input signal had to be offset in order for the signal to get passed through the filter. Because the op-amp is being powered from a single power supply and ground, a virtual ground needs to be created at the input signal. An op-amp can only output the signal if it falls within it's rails. Therefore, a signal oscillating at 0V when an op-amp runs from 0V (ground) to +5V will not be passed through. How to correctly power an op-amp with minimal distortion with a single positive voltage supply needs to be explored. Both the LM741 and the NE5532 need a dual supply to operate demanding the creation of a virtual ground. This was realized late and was accounted for by offsetting the input signal of the signal generator, but needs to be incorporated into the hardware. Properly powering an op-amp requires extra considerations that may drastically affect the filter response.

Printed Circuit Board: Once a filter on a breadboard is close to the expected performance as determined by the circuit simulator, the filter will be moved to a printed circuit board. Breadboards are notorious for creating noise, harboring internal resistance and producing an overall noisy signal. A printed circuit board may help perfect the performance of the filter by eliminating the interference produced by the infrastructure of the breadboard.

Higher Order Filter: Condenser microphones tend to have a wide range in the amplitude of the signals being passed. At low frequencies the intensity of the signal is less than that at high frequencies, thus the needed performance characteristics of the analog Butterworth filter are tough to determine. A fourth order Butterworth filter may not have a steep enough frequency roll off to eliminate as much noise as wanted. A higher order Butterworth, whether implemented via analog hardware or digital software, may be necessary to properly isolate the FHR.

11.2.2 Interference of Ambient Noise

One of the problems using an omnidirectional condenser microphone to collect a signal as faint as a heartbeat is that the noise in the room in which the device is being used is often times much larger than the signal itself. Even after acoustic amplification, the prototype was not able to be tested in loud environments on account of the fact that the intensity of the heartbeat was drowned out by the intensity of the ambient noise. The method of collecting a fetal heart beat via a passive transducer placed on the maternal abdomen is known as fetal phonography (Jimenez-Gonzalez, 2009). On account of the acoustic dampening of the maternal fluid and tissue, the acoustic energy fetal activity collected via abdominal phonography is very low and thus vulnerable to external sources from the environment (Jimenez-Gonzalez, 2009). Knowing the signal would be low, a microphone with a high sensitivity was chosen. However, the increased sensitivity also increased the response of the microphone to ambient sound sources. In order to filter out the signal of the FHR, the signal must first be present. Thus it is imperative that loud sounds in the room are not drowning out the signal of the FHR.

Potential Future Designs

Placing the microphone closer to the sound source: The housing for the microphone was designed solely to amplify the sound waves of the fetal heart rate. The distance from the microphone to the maternal abdomen as a factor in the signal intensity was not considered. Placing the microphone closer to the

sound source may provide more directivity. The sound signals will be isolated closer to the microphone in order to increase the relative intensity.

Using a second microphone: Another option to explore in order to isolate the weak signal of the FHR from the ambient noise in the room, is to use another open-air microphone to capture the ambient noise and then use adaptive filtering technology to isolate the FHR (Mittra, 2009). Using the open air microphone to remove the ambient sounds from the microphone placed over the maternal abdomen will help increase the signal to noise ratio of the FHR.

11.2.2 Difficulties of Threshold Based Coding

The current code for digital signal processing operates under the assumption that the heart rate is the strongest signal being picked up by the microphone. Unfortunately as mentioned earlier, analog filtering of higher frequencies is not as efficient as expected; oftentimes, this leads to the heart beat being drowned out by louder ambient noise. The prototype will only work well if it is being used in a quiet room with no interference from mechanical vibrations of the cone such as the friction from the chest rubbing against the bottom of the cone if someone took a deep breath.

Also, it is impossible to tell which sound source set off the threshold counter. The code is run on the Arduino and is run directly to an LCD screen, so without an oscilloscope monitoring the output, there is no way of telling whether the counter actually picked up a heartbeat. Though this won't be a problem once the prototype is complete, testing in loud environments will be inconclusive without understanding what sounds are exceeding the threshold.

Potential Future Solutions

Recreate the analog signal digitally: Being able to isolate the fetal heart beat can be more easily accomplished with advanced signal processing. Once the analog signal is moved into the digital world it is easier to define filter parameters and isolate the heartbeat more. The frequency range of the signal can be defined more exactly and sounds with intensity greater than a specific threshold (such as the large signals from mechanical vibrations of the cone) can be easily thrown out. Digitally recreating the analog signal will also provide a better visual of the signal. Whereas the threshold method allows the code to count a heartbeat, it doesn't provide a visual representation of the signal and thus it is hard to verify that the sound was in fact a heartbeat.

11.3 Heart Rate Analysis Critique

The digital aspects of the current design require much overhaul in the next iteration of the design. This subsection and the subsequent subsection on baseline calculations serve to address issues faced in the implementation of the C++ logic uploaded to the Arduino used in the final design.

11.3.1 Inaccurate Calculation of Instantaneous Heart Rate

The current code uploaded to the Arduino receives the analog input and compares this against a voltage threshold, adding to the value of a counter every time this threshold is exceeded. After five seconds elapse, this counter is multiplied by twelve and is then treated as the instantaneous heart rate. This only allows heart rates to be multiples of twelve (ie. the heart rates an adult reading may record would

include 48, 60, and 72 BPM). This does not pose an issue when applied to long periods of monitoring, as different weights associated with the occurrence of different values would serve to normalize the heart rate to the average. However, during short term monitoring, this leads to inaccuracies in the output.

Proposed Solution

The proposed solution for this problem involves making changes to the code to allow for the instantaneous heart rate to be determined every beat. This would involve recording the time at which each beat is logged, and then calculating the trend based upon the difference in time since the last beat. For example, if the time between a beat and the beat subsequent to it was recorded to be 1.45 seconds, the code would implement the following calculation:

$$\frac{1\ Beat}{1.02\ seconds} * \frac{60\ seconds}{1\ minute} = 58.82\ BPM$$

If the next beat occurred 2.25 seconds later, the instantaneous heart rate for this time period would be:

$$\frac{1\ Beat}{0.92\ seconds} * \frac{60\ seconds}{1\ minute} = 65.22\ BPM$$

In this version of code, the times between the beats would need to be stored in a separate array to effectively calculate the baseline and variability, given that the baseline calculations are heavily reliant on the exclusion of accelerations. Furthermore, the average of the two example equations is 62.02 BPM, whereas the calculation for both beats over 1.94 seconds is 61.85 BPM. This could be fixed by calculating for the entire time over which the device has been running each time a beat is logged, but this would prove difficult to incorporate into the baseline calculations. Despite its shortcomings, however, this logic provides a much more accurate analysis of heart rate than the currently implemented code.

11.3.2 Challenges in the Calculation of Baseline

The baseline is particularly difficult to calculate using algorithms due to the subjectivity of the calculations. As mentioned several times throughout the report, cardiotocography read outs are often subject to many different interpretations depending on the physician performing the analysis. This is troublesome in the determination of baseline algorithmically; though there are set rules regarding the calculation of baseline and variability, discrepancies occur. Thus, any algorithm seeking to make any type of calculation would be complex, having to account for multiple scenarios.

The currently used algorithm accounts for accelerations and decelerations that last for over 30 seconds and increases and decreases in heart rate that are over 25 BPM in magnitude. However, the code, as implemented, runs into an issue caused by a reset function in acceleration and deceleration determination. If this reset function was not implemented, the code would to determine whether an acceleration or deceleration has ended. If an acceleration is found to have been occurring for over 15 seconds, and previous deceleration logged is reset, and vice versa. This prevents a single deceleration lasting 5 seconds from resetting the entire acceleration and allowing uncontrolled acceleration. However, it also has the unintended effect of making baseline changes rare. The current constraints are extremely conservative, only allowing a change in baseline if the change would be almost negligible. In

conjunction with the baseline initializing at the beginning of the program at 120 BPM, the "baseline" as outputted has little diagnostic relevance. As time elapses during device use, the baseline recorded by the device will gradually move towards the actual baseline, but will do so increasingly slowly.

Proposed Solution

Initialization with a more accurate value would be beneficial. Instead of using a constant 120 BPM for each patient, baseline initialization dependent on preliminary calibration in the code should be utilized. An ideal implementation of this would be to run a preliminary loop that takes the average heart rate for anywhere from 30 seconds to 5 minutes. This average heart rate could be then fed into the primary loop as the reference with which the baseline is calculated. The average heart rate would be significantly closer to baseline than an arbitrary value, though the two values would still be different. The primary loop would serve to bring the average value closer to the actual value.

11.3.3 Challenges in the Calculation of Variability
Currently, the variability calculations are off due to several factors. The most pressing factor is that the lowest recorded instantaneous heart rate falls too low. This is caused by the fact that variables are called with a value of 0, meaning that the variability outputted is essentially equal to the high value. The current code has a "safety net," which in cases of the low value falling too low, a certain value is added to it to bring it back to an acceptable value. The only actual time when this is implemented is in the very beginning of the code in order to bring to low value from the declared 0 to a value higher than what would be expected. This allows subsequent low values to factor into the variability calculation.

This has the unintended side effect of bringing this value too high, however. If the high values are too low, and the low value is set above the high value, a negative variability value is outputted. The current code addresses this with an absolute value function, but this is only fixes the presentation of the problem, not the underlying issues that is causing it.

Proposed Solution

The high and low values can begin at the same value, which is the same value that will be assigned to the baseline reference. Thus, if the preliminary loop finds that the baseline will likely fall near 130 BPM, for example, the high and low as well as the current baseline are set to this value. If subsequent values are found to be 128 BPM and 131 BPM, this would alter the high and low values accordingly, providing a variability output of 3 BPM.

11.3.4 Unintuitive Display
The current display has been found to be confusing by many people outside of the team. The current labels are single letters representing their respective output. For example, the output "A:" on the device is the label for the average heart rate. This issue is particularly difficult to address due to the small size of the LCD screen. Only two rows may be outputted, with 16 characters per row. The word "Variability," for example, has 11 characters, consuming the bulk of one row. If the entire word were to be used on the display, there would only be enough room for its respective output. In this configuration, only two values could be outputted based upon the space limitations of the screen.

Proposed Solution

In the next semester, the team can print these labels onto the housing of the device. Supposing the instantaneous heart beat were outputted to the top left corner of the LCD, the label "Instantaneous Heart Beat (BPM)" could be printed, etched, or otherwise made visible on the housing. This would prove to be more useful than outputting this label directly to the LCD screen, as more information could be made available to the user due to the lack of space constraints. This could be done for every label necessary for the interpretation of the data on the device screen.

12 Conclusion

Over the course of ME450, Ghana Cohort 3 has made much progress in addressing many of the engineering specifications set forth by consumers in Ghana. The current prototype serves as a proof of concept model, allowing the team to demonstrate the functionality of the device. The hollow cone amplifier, printed using a Viper Si2 3D printer, has succeeded in acquiring an adult heart rate, though it remains to be seen whether it is sufficient in amplifying a fetal heart beat to the levels necessary for acquisition by a low-cost (Panasonic WM61-A) microphone. When routed through a preamplifier with a gain of 23, the voltage difference across the microphone caused by an adult heartbeat is significant enough to surpass thresholds within the C++ code used to determine whether a single beat has occurred. This code uploaded to the Arduino then works to convert this beat count into an instantaneous heart rate in beats per minute (BPM), and further logic allows these values to be converted into diagnostically important data.

Using the current device, the team was able to partially validate two of the three engineering specifications targeted for completion by the end of the semester. Goals were set for the device to be able to output the baseline and variability of a fetal heartbeat to within ±2 BPM by the end of the semester, and for it to be able to output the sound of the fetal heartbeat at an intensity of over 60 dB. Currently, the device is able to output the baseline of an adult heart beat to within ±2.7 BPM, has the groundwork laid for variability calculations, and is able to reproduce sound that was filtered through the analog circuit using a Pyle Home Audio PMS2R speaker.

Though the device has exceeded expectations in terms of completion this semester, there are still many challenges in fully meeting each of the engineering specifications. The largest challenge faced in meeting these lies in the signal acquisition of the design. The hollow cone amplifier should theoretically be able to optimally amplify the sound of the heartbeat, but it is possible that even this amplification is not enough to allow the microphone being used to obtain a signal. Another significant challenge lies in the implementation of sound processing techniques. Currently, analog sound processing techniques have been researched and implemented, but the team has faced difficulty in obtaining a signal after it has been filtered through a Butterworth filter. Thus, the team plans to address noise reduction digitally. However, this presents a final challenge in the programming logic necessary to convert these signals into diagnostically relevant data, as digital sound processing would either have to be written as another function or integrated into the architecture of the current software.

In the winter 2013 semester, Ghana Cohort 3 aims to address the three shortcomings mentioned prior, as well as begin addressing and validating further engineering specifications. The winter 2013 semester will likely begin to see a shift from function to form, with the functionality of the device being fine-tuned and work being done to ensure that the device is suitable for use in the environment for which it was designed. User requirements that were previously ignored due to the scope of ME450 will be revisited as well, allowing the team to ensure that the device meets all of the specifications desired by target market.

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15 Biographies

Jenna Boeing

Jenna Boeing grew up in Bedford, Massachusetts, a small town twenty minutes northwest of Boston. Upon graduating high school, Jenna took a year off before going to college during which she traveled to Nepal to work in an orphanage with a team of ten people. Leading the team were two civil engineers who completely revamped the entire structure. Watching them make a sustainable change in the quality of life for the orphans was an eye-opening experience that inspired her to pursue a career in engineering. She is now in her final year at University of Michigan pursuing a career in mechanical engineering. She plans on graduating in May of 2013 and hopes to attend the Rackham Graduate School to pursue a M.S. in mechanical engineering. Jenna has a passion for a variety of music flavors and loves to rock climb in her free time.

Tyler Gatlin

Tyler Gatlin grew up in Swartz Creek, a small town just outside of Flint, Michigan. With a natural fascination for how things work, Tyler was always looking for something new to build or something old to take apart, the latter often resulting in a scolding from his old man. He now attends the University of Michigan College of Engineering, pursuing a degree in mechanical engineering with a minor in multidisciplinary design. He decided to spend a summer abroad in Ghana to immerse himself in a new culture and further learn and experience the entire engineering design process. Tyler is developing a passion for design and has been leading a lab section of a design class for first-year engineering students at Michigan. He plans on graduating in the spring of 2013 and landing a job in the medical device design field, with hopes to someday go back to school to receive his masters. Chances are if Tyler is not outdoors right now, he would rather be. He loves to backpack and has recently started rock climbing.

Evan Hendler

Evan Hendler is from Rochester, Michigan, a small city in the suburbs of Detroit. From a young age, he knew he wanted to go into medicine, thanks to his younger sister's diagnosis with acute lymphocytic leukemia. Pursuing whatever means to achieve that goal, he enrolled at the University of Michigan and is now in his final year of Biomedical Engineering. Although becoming a doctor is his ultimate goal, Evan also has a passion for the military that led him to enroll in USMC ROTC for two years. Should the opportunity arise, he plans seeking a commission in the Marine Corps before becoming a doctor. Evan's interests include finance, business, politics and writing; in his free time, he enjoys writing essays on political matters as well as philosophical subjects. Africa has been of particular interest to him from a young age, driving him to become a part of this project. After medical school, he hopes to pursue a career in oncology, having been inspired by the doctors who saved his younger sister's life.

Elizabeth Hyde

Elizabeth is a fourth year undergraduate student attending the University of Michigan studying Biomedical Engineering. She read about the Design for Maternal Health program during her freshman

year and decided to pursue a place in the program immediately. The immersion experience in Ghana and subsequent engineering design process have been an invaluable part of her personal and professional development. Elizabeth has worked in academic medical research and in the medical device industry. She spent a semester interning at Stryker Orthopaedics in artificial hip research and development. She has worked in a hearing and cochlear implant research lab in Kresge Hearing Research Institute at the University of Michigan Hospital for three years. In addition to her summer observations in Ghana, Elizabeth studied abroad at Nanyang Technological University in Singapore during her sophomore year. She is pursuing a career in global health with an emphasis on healthcare in developing countries. Elizabeth loves traveling, reading, sketching, volunteering, and playing piano.

Appendices
Appendix I: Concepts
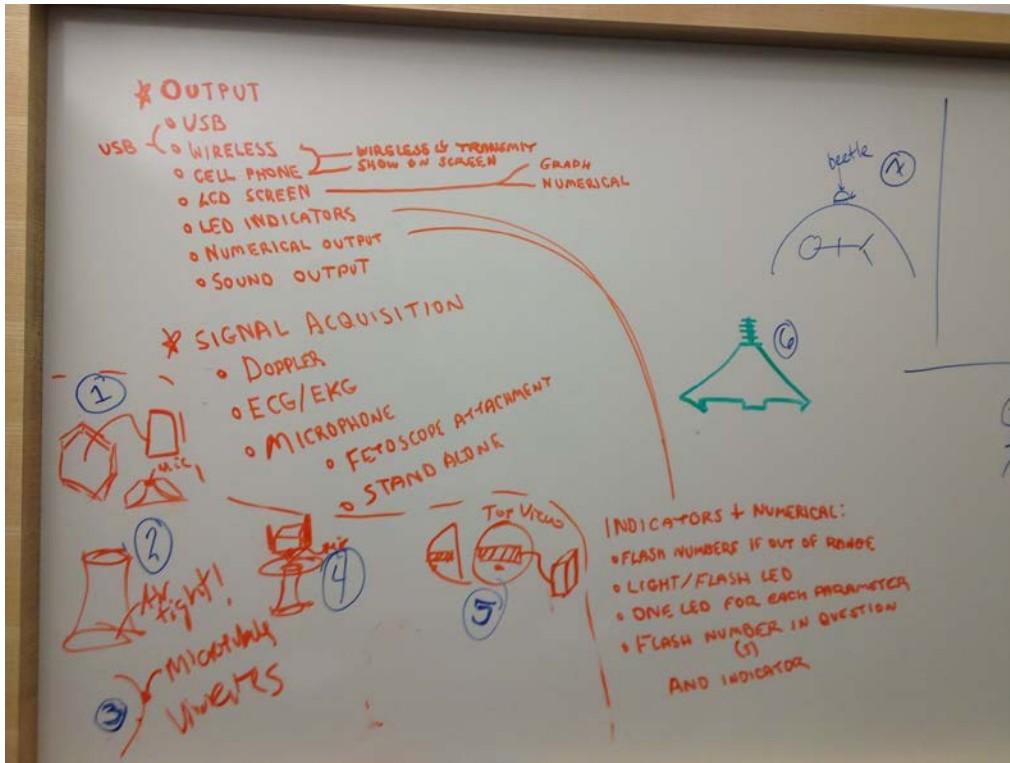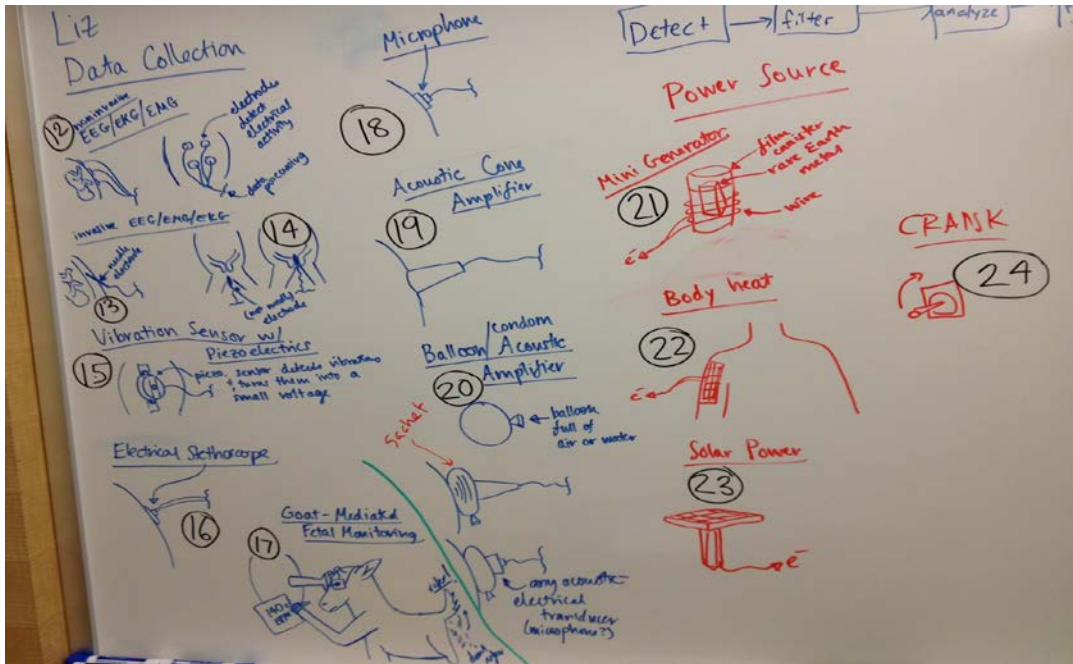
Descriptions of Concepts Generated

1. **Hexagonal Cap and Microphone:** A small microphone is placed in the inlet of a shallow, flexible, plastic hexagonal cone. The hexagonal plastic piece can be pressed into the skin of the maternal abdomen. When the pressure is removed, the hexagon acts like a suction cup, holding the microphone in place above the abdomen, where it can record sounds from the fetal heart.

2. **Airtight Cone:** A long cone, modeled after a Pinard stethoscope, collects and amplifies acoustic sounds from the fetal heart. The cone must be placed over the fetal heart on the surface of the abdomen. The cone is airtight. A slight vacuum is created inside the cone to hold the cone in place.

3. **Microtubule Vibration Sensor:** A capsule containing microtubules is placed on the maternal abdomen above the fetal heart. The microtubules vibrate when the fetal heart beats and transmit the vibrations to the rest of the device to be analyzed.

4. **Pinard Stethoscope Attachment Mechanism:** The transducer to convert an acoustic sound into an electrical signal is suspended above the earpiece of a Pinard stethoscope by a device similar to a pair of forceps. The opposite end of the forceps is placed into the canal of a Pinard stethoscope. Sounds from the fetal heart are amplified by the cone and collected by the transducer.

5. **Multi-Source Ultrasound Detector:** Three ultrasound probes are enclosed in a small pad. The pad is placed over the maternal abdomen. The three probes all emit high frequency sound waves. Feedback from the three probes allows the device to describe the fetal heartbeat in extreme detail. This design can detect a fetal heartbeat over a large percentage of the maternal abdomen, unlike more directional designs that require specific probe placement.

6. **Conical Pinard Stethoscope Attachment:** In this design, a plastic conical device has three pieces of plastic hanging over the edge. The earpiece of a Pinard stethoscope can clip into the mouth of the cone.

7. **Vibration-Sensitive Beetle:** A beetle capable of detecting and recording fetal cardiac activity is placed on the maternal abdomen. After the testing period is over, the beetle is removed and placed on a smooth, hard surface. The beetle uses its front legs to tap out the heartbeat and communicate the baseline and variations to the midwife using Morse code.

8. **Mobile Electric Probe:** An electrical probe is constructed with a sensitive microphone. The probe is able to move under its own power. The probe climbs into the vagina and settles on the cervix, where it picks up the sounds of the fetal heart. The information is wirelessly transmitted to an external processor.

9. **Cell Phone and Microphone Combination:** A microphone and cell phone are linked so that information collected by the microphone is displayed on the screen of the cell phone. The microphone is placed against the maternal abdomen, where it listens for sounds from the fetal heart.

10. **Edible Microphone:** A device approximately the size of a marble is built with a microphone inside a watertight seal. The microphone device is swallowed by the patient. When the device reaches the stomach, it records sounds from the fetal heart. It is passed normally as digestion continues.

11. **Vibration-Sensitive Mat**: A layer of piezoelectric crystals is enclosed in a mat. The patient lies down on the mat. The piezoelectric crystals detect vibrations from the fetal heart. The crystals convert the vibrations into voltages, which are sent to the computing segment of the device to be analyzed.

12. **Noninvasive EKG:** In this concept, an electrocardiogram would be used to detect the changes in electrical potential generated by fetal cardiac muscle contractions. Electrodes would be placed on the surface of the maternal abdomen, as close to directly above the fetal heart as possible.

13. **Invasive EKG:** An electrocardiogram is used to detect electrical activity from the fetal heart beating. In this design, the electrode is embedded in a needle. The needle is inserted under the skin of the maternal abdomen, directly above the fetus, but not puncturing the amniotic sac. This eliminates noise caused by the cushion of air between the patient's skin and a noninvasive electrode. Air is not conductive, so noninvasive EKG electrodes require electrically conductive gel to be spread under the electrode so the electrical pulses are transmitted to the machine for analysis.

14. **Invasive EKG:** This design also uses an electrocardiogram. The electrode to detect the signal is slightly larger, blunt, and placed in the vagina to reduce the amount of tissue between the electrode and the fetus and improve sound quality.

15. **Vibration Sensor with Piezoelectric Crystals:** A sensor containing piezoelectric crystals is placed on the maternal abdomen. Vibrations originating from fetal cardiac activity cause the crystals to vibrate and translate the vibrations into voltages.

16. **Electrical Stethoscope**: An electrical stethoscope is used to listen to the movement of blood through the fetal heart. The diaphragm of the stethoscope is placed on the maternal abdomen, approximately above the fetal heart. The electrical stethoscope contains an electromagnetic diaphragm transducer to convert acoustic sounds into electrical signals.

17. **Goat-Mediated Fetal Monitoring**: A goat is enlisted to assist health care workers in determining the fetal heart rate. Goats displaying an intense interest in maternal health care are enrolled in a

rigorous fetal monitoring training program. After graduation, the goat uses a Pinard stethoscope to calculate the fetal heart rate and uses his or her tail to indicate to the midwife whether the patient should be referred. The tail is held high when the patient is in need of referral and held down when the patient is healthy.

18. **Microphone**: In this design, a contact microphone is held directly against the maternal abdomen above the fetal heart. Ventricular contractions and blood flow in the heart creates noise, which is detected by the microphone.

19. **Acoustic Cone Amplifier**: A solid metal cone is placed on the maternal abdomen. Sound moves through dense mediums quickly. Metal is extremely dense and conducts sound very well. A transducer at the narrow end of the cone converts the acoustic signal into an electrical signal.

20. **Fluid-Filled Balloon Acoustic Amplifier**: Sounds are conducted through dense materials faster than through less dense mediums. In this design, a fluid-filled sac is placed between the maternal abdomen and a transducer to convert the acoustic sound into an electrical signal. The sac can be a balloon or condom filled with water or a water sachet.

21. **Film Canister Electrical Generator**: A Neodymium rare Earth magnet is placed inside a film canister. Copper wire is wrapped around the canister several times. When the canister is shaken, the magnet moves, moving the magnetic field around it. This incites a voltage in the copper wire, creating a current and sending electricity down the wire.

22. **Body Heat**: A mat is designed to collect heat from the human body when placed on skin. The mat is able to convert the heat into energy to power the device. This technology is not yet available.

23. **Solar Power**: Power to collect sound, convert it into electrical signals, and analyze the heartbeat is harvested from a small solar panel set in the sun.

24. **Crank**: A handheld electrical crank generator is used to power the device. A cylinder is wrapped in coils of wire. A rare Earth magnet is attached to the crank. When the crank is turned, the magnet turns, moving its magnetic field and inducing a voltage and current in the wire.

Appendix II: Gantt Chart

Task Name	September	October	November	December	J
Problem identification and need statement development in Ghana					
Gather user requirements and engineering specifications in Ghana and Ann Arbor	Team				
Conduct user and expert interviews	Team				
Find a pinard stethoscope	Tyler				
Benchmark fetal heart monitoring other solutions	Evan,Jenna				
Do literature review and research fetal heart rate monitoring and analysis for resource-limited settings	Jenna,Lizzie				
Design Review 1 - 9/20	◇ 9/20				
Refine user requirements and engineering specifications		Lizzie,Jenna			
Start thinking about testing of device		Evan			
Concept generation		Team			
Decide on best heartbeat signal acquisition technique		Team			
Perform functional decomposition		Tyler			
Build Mockup		Evan,Lizzie			
Get feedback from users in Ghana and experts in Ann Arbor		Evan			
Design Review 2 - 10/9		◇ 10/9			
Build Sallen-Key filter into design		Lizzie			
Select microphone and op-amp		Tyler			
Build FHR simulator		Evan,Jenna			
Build acoustic amplifier and noise reduction		Jenna,Lizzie			
Design Review 3 - 10/30		◇ 10/30			
Select speaker		Team			
Write program		Evan,Tyler			
Test prototype		Team			
Research if resource-limited manufacturing is possible		Lizzie			
Design Review 4 - 11/20			◇ 11/20		
Make final prototype			Team		
Thank sponsors and other help			Evan		
Design Expo - 12/6				◇ 12/6	
Final Report - 12/11				◇ 12/11	

Appendix III: User Requirement and Engineering Specifications Ranking Prioritization Matrix

	Easy to Use	Doesn't Rely on Grid Electricity	Accurately Determine the baseline heart rate of fetus	Portable	Low Cost	Reusable	Outputs Sound	Steralizable	Durable	Accurately Determines variability of heart rate	Indicates if Referral is necessary	No Ambiguity in Performance	Total Incidence
Easy to Use													5
Doesn't Rely on Grid Electricity	B												6
Accurately Determine the baseline heart rate of fetus	C	C											11
Portable	A	B	C										4
Low Cost	E	E	C	E									8
Reusable	F	F	C	F	E								7
Outputs Sound	A	B	C	D	E	F							2
Steralizable	A	B	C	D	E	F	G						0
Durable	A	B	C	D	E	F	G	I					1
Accurately Determines variability of heart rate	J	J	C	J	J	J	J	J	J				10
Indicates if Referral is necessary	K	K	C	K	K	K	K	K	K	J			9
No Ambiguity in Performance	A	B	C	D	E	F	L	L	L	J	K		3

Quality Function Deployment (QFD)

System QFD

Technical Requirements (roof / correlation matrix)

#	Technical Requirement	Correlations (reading left→right)
1	Accuracy (+)	
2	Grid Electricity (-)	
3	Training Time (-)	
4	Steps for Use (-)	9
5	Operators (-)	
6	User Identification of Referral Indicator (+)	
7	Operation Time (-)	3, 1, -1, -1
8	Volume (-)	-1
9	Weight (-)	-1, 1
10	Cost (-)	9, -3, 3, 9
11	Single Use Components (-)	-3
12	Sound Level (+)	
13	Withstands fall from Height (+)	
14	Lifetime (+)	1, -3, 3
15	Indicates Device Malfunction (+)	3, 3, 1
16	Indicates Low Power (+)	9, 3, 1, 1
17	Indicates if FHR or Variability is Abnormal (+)	3, 3, 1
18	Indicates for Correct Placement (+)	3, 3, 1
19		
20		

Relationship Matrix — Customer Needs vs Technical Requirements

#	Customer Needs	Customer Weights	Accuracy (+)	Grid Electricity (-)	Training Time (-)	Steps for Use (-)	Operators (-)	User Identification of Referral Indicator (+)	Operation Time (-)	Volume (-)	Weight (-)	Cost (-)	Single Use Components (-)	Sound Level (+)	Withstands fall from Height (+)	Lifetime (+)	Indicates Device Malfunction (+)	Indicates Low Power (+)	Indicates if FHR or Variability is Abnormal (+)	Indicates for Correct Placement (+)
1	Accurately Determine the baseline heart rate of fetus	12	9		1				9			3					3	1	3	3
2	Accurately Determines variability of heart rate	11	9		1				9			3					3	1	3	3
3	Indicates if Referral is necessary	10			1			9	1										9	
4	Reusable	9										3	9		1	1				
5	Low Cost	8		3	3				3			9	3			1				
6	Doesn't Rely on Grid Electricity	7		9					3					3				1		
7	Easy to Use	6			9	9	9	9	1					3			1	1	1	1
8	No Ambiguity in Performance	5	3														9	9	9	9
9	Portable	4								9	9				1					
10	Outputs Sound	3												9						1
11	Durable	2									1				9	9				
12	Steralizable	1												3						
13																				
14																				
15																				

	Accuracy (+)	Grid Electricity (-)	Training Time (-)	Steps for Use (-)	Operators (-)	User Identification of Referral Indicator (+)	Operation Time (-)	Volume (-)	Weight (-)	Cost (-)	Single Use Components (-)	Sound Level (+)	Withstands fall from Height (+)	Lifetime (+)	Indicates Device Malfunction (+)	Indicates Low Power (+)	Indicates if FHR or Variability is Abnormal (+)	Indicates for Correct Placement (+)
Raw score	246	87	87	54	54	144	268	36	38	168	108	66	31	35	120	81	210	123
Scaled	0.918	0.325	0.325	0.201	0.201	0.537	1	0.134	0.142	0.627	0.403	0.246	0.116	0.131	0.448	0.302	0.784	0.459
Relative Weight	13%	4%	4%	3%	3%	7%	14%	2%	2%	9%	6%	3%	2%	2%	6%	4%	11%	6%
Rank	2	9	9	13	13	5	1	16	15	4	8	12	18	17	7	11	3	6
Technical Requirement Units	BPM	W	min	#	#	%	min	cubic	kg	$	#	dB	m	uses	#	#	#	#
Technical Requirement Targets	2	0	60	2	1	100	10	72	0.7	25	0	60	1.6	9125	1	1	1	1

Appendix IV: Parameter Analysis Calculations

Cone Dimensions

Length:
Target frequency = middle frequency of the range of the fetal heart beat = (200+35)/2 = 117.5 Hz

The wavelength of a particular frequency is given by the equation below.

$$\lambda = \frac{v}{f}$$

Where λ is the wavelength in meters, v is the velocity in m/s, and f is the frequency in Hertz. The speed of a sound wave in air at ambient pressure and temperature is 343 m/s and was the velocity used in wavelength calculations.

According to Eq. 1 above, using the target frequency of 117.5 Hz, the target wavelength was found to be 2.919 m.
Target wavelength =(343 m/s)/117.5 Hz = 2.919 m

1/64 target wavelength=0.0456 m

Mouth diameter:
Target circumference= 2.919 m
1/32 target circumference= 0.0912 m
2pi*r=0.0912 m
r=0.0145 m

Microphone Diameter

The largest frequency in the range of the fetal heart beat is 200 Hz. Based on Eq. 1 above the shortest wavelength corresponds to the largest frequency. The shortest wavelength is thus 1.715 m.

Shortest wavelength = (343 m/s)/200 Hz = 1.715m.

The diameter must be less than one tenth this value, thus the diameter must be less than 0.1715 mm.

Diameter = 1.715 m/ 10 = 0.1715 m

Butterworth Component Values

For a higher order filter, the general transfer function of second order filters is given by Eq. 1 below. The Butterworth filter used in this application is given by a series of 2 cascading unity gain Sallen-Key filters.

$$A(s) = \frac{A_0}{\prod_i (1 + a_i s + b_i s^2)} \qquad \text{(Eq.1)}$$

The function can be broken down into stages such that the transfer function of each stage is given by Eq. 2 below.

$$A(s) = \frac{A_0}{1 + a_i s + b_i s^2}$$

(Eq. 2)

Table A1: The coefficients a_i and b_i for a Butterworth filter of the nth order is given by the Table below.

n	i	a_i	b_i	$k_i = f_{ci}/f_c$	Q_i
1	1	1.0000	0.0000	1.000	—
2	1	1.4142	1.0000	1.000	0.71
3	1	1.0000	0.0000	1.000	—
	2	1.0000	1.0000	1.272	1.00
4	1	1.8478	1.0000	0.719	0.54
	2	0.7654	1.0000	1.390	1.31
5	1	1.0000	0.0000	1.000	—
	2	1.6180	1.0000	0.859	0.62
	3	0.6180	1.0000	1.448	1.62
6	1	1.9319	1.0000	0.676	0.52
	2	1.4142	1.0000	1.000	0.71
	3	0.5176	1.0000	1.479	1.93
7	1	1.0000	0.0000	1.000	—
	2	1.8019	1.0000	0.745	0.55
	3	1.2470	1.0000	1.117	0.80
	4	0.4450	1.0000	1.499	2.25
8	1	1.9616	1.0000	0.661	0.51
	2	1.6629	1.0000	0.829	0.60
	3	1.1111	1.0000	1.206	0.90
	4	0.3902	1.0000	1.512	2.56
9	1	1.0000	0.0000	1.000	—
	2	1.8794	1.0000	0.703	0.53
	3	1.5321	1.0000	0.917	0.65
	4	1.0000	1.0000	1.272	1.00
	5	0.3473	1.0000	1.521	2.88
10	1	1.9754	1.0000	0.655	0.51
	2	1.7820	1.0000	0.756	0.56
	3	1.4142	1.0000	1.000	0.71
	4	0.9080	1.0000	1.322	1.10
	5	0.3129	1.0000	1.527	3.20

For a forth order Butterworth filter, two Sallen Key filters in series will be used where the parameters of each stage of the filter are given in Table 1 found above. In order to determine the components used in each stage of the filter, the transfer function of a unity gain Sallen-Key Filter was used with the parameters being governed by Table A1. The unity gain topology is given in the figure below:
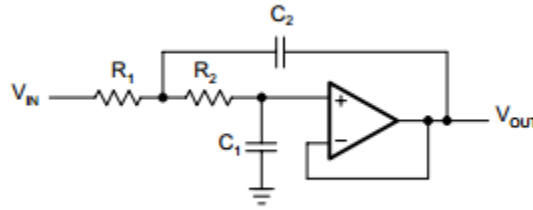
In this schematic the transfer function is given by the Equation X below.

$$A(s) = \frac{1}{1 + \omega_c C_1 (R_1 + R_2) \cdot s + \omega_c{}^2 R_1 R_2 C_1 C_2 \cdot s^2} \qquad \text{(Eq.3)}$$

Where ω_c is the cutoff frequency given in radians per second, and the components are as labeled in Figure 1 above. The coefficients a_i and b_i as they appear in Eq. 1, are therefore defined by the below equations:

$$a_i = \omega_c C_1 (R_1 + R_2)$$

$$b_i = \omega_c{}^2 R_1 R_2 C_1 C_2$$

In such a configuration, the capacitance for the first capacitor should be chosen arbitrarily. Capacitors are manufactured without as many subdivisions as resistors, so the capacitors should be chosen first. Manipulation of the equation above allows the second capacitor to be selected by:

$$C_2 \geq C_1 \cdot \frac{4 b_i}{a_i}$$

The resistors are then determined by the following Equation:

$$R_{1,2} = \frac{a_i C_2 \mp \sqrt{a_i{}^2 C_2{}^2 - 4 b_i C_1 C_2}}{4 \pi f_C C_1 C_2} \qquad \text{(Eq.3)}$$

Where a_i and b_i are given by Table A1 above. Each stage was determined using the Matlab code found below. Capacitor 1 was chosen arbitrarily, the minimum value for the second capacitor was determined by Eq. 3 above. A Capacitor with a higher value within 5% of that minimum value was then chosen.

MatLab Code:

```
a1=1.8478;
b1=1;

c1=0.047E-6;

c2b=c1*4*b1/a1^2;

disp(c2b);
c2=input('Enter actually c2 value \n');

R1=((a1*c2)-sqrt(a1^2*c2^2-4*b1*c1*c2))/(4*pi*200*c1*c2)

R2=((a1*c2)+sqrt(a1^2*c2^2-4*b1*c1*c2))/(4*pi*200*c1*c2)
```

Final Component Values Tested during Parameter Analysis:

Table A2: Values of resistors and capacitors used in Butterworth filter as given by Figure 1 below

Stage	C1 (µF)	Minimum C2 (µF)	Purchased C2 (µF)	% error between the Butterworth and Purchased Capacitors	Resistor 1 (kΩ)	Resistor 2 (kΩ)
1	0.02	0.02343	0.024	2.375%	31 (0.316%)	42.4 (0.057%)
2	0.047	0.32091	0.33	2.754%	5.4 (0.076%)	7.55 (0.066%)
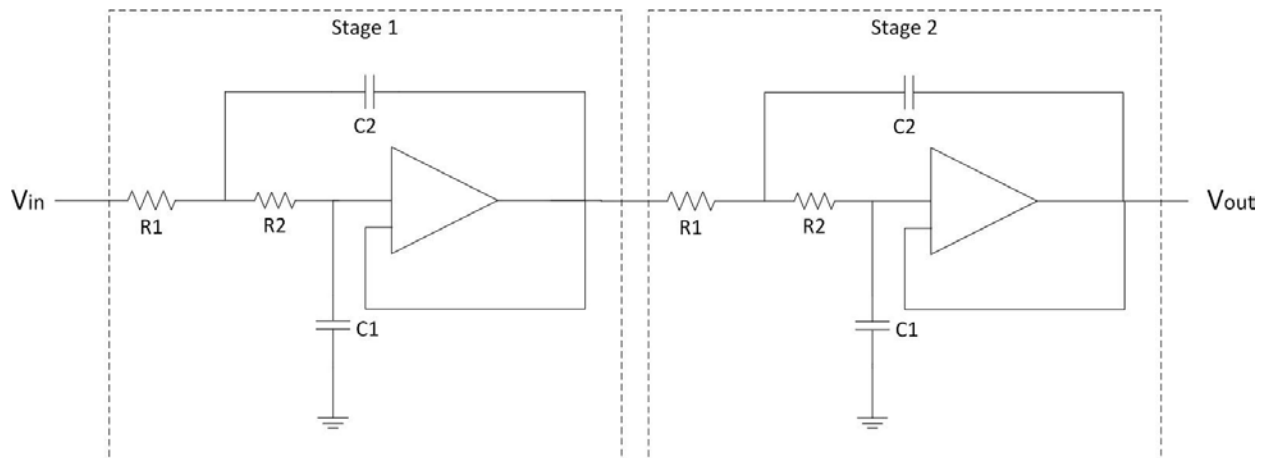
Op-Amp Selection

The most important parameter is the unity-gain bandwidth of an op-amp

$$f_t = 100 \cdot Gain \cdot \frac{f_c}{a_i} \sqrt{\frac{Q_i^2 - 0.5}{Q_i^2 - 0.25}} \text{ for Q>1}$$

$$f_t = 100 \cdot Gain \cdot f_c \cdot k_i \text{ for Q<1}$$

For the first stage Q=0.54 so Eq. X was used to find a bandwidth of 14.34 kHz and for the second stage Q=1.31 so Eq. X was used to find a bandwidth of 21.674 kHz.

Another parameter considered is the slew rate. For good full power response, the slew rate must be at least:

$$SR = \pi \cdot V_{PP} \cdot f_C$$

The slew rate should be greater than 3.14 V/ms which will not be a limiting factor in the op-amp selection seeing as the vast majority of op amps have a larger slew rate.

Appendix V: Bill of Materials

Part Number	Part Name	Qty.	Material	Manufacturing Process	Function	Price
296-1410-5-ND	Op-Amp NE5532	1	N/A	N/A	Analog Amplification	$0.60
WM-61a	Panasonic Microphone	1	N/A	N/A	Signal Acquisition	$1.92
N/A	Strap cloth	1	Cotton	Sewing	Abdominal attachment	$5.33
N/A	Acoustic Cone	1	Accura 60	SLA	Isolation	$67.00
N/A	Dampening foam	1 oz	Model Magic	N/A	Shock absorption	$0.25
9273K52	Hook and loop strip for strap (1" width)	5ft	Nylon	Sewing	Abdominal attachment	$4.46
N/A	Fabric Snaps (male and female)	2	Plastic/brass	Adhesive/press through fabric	Strap to cone attachment	$2.02
N/A	22 Gauge wire		Copper	N/A	Circuitry	$1.80
N/A	5-Core Solder		Sn63Pb37	N/A	Circuitry	$0.20
N/A	Arduino Duemilanove	1	N/A	N/A	Circuitry	$30.00
Radioshack	Breadboard		N/A	N/A	Circuitry	$16.00
LM741CNNS/NOPB-ND	Op-Amp LM741	2		N/A	Filter	$0.70
	Shrink Wrap		PVC Heat Shrinkable	N/A	Circuitry	$1.00
718-1421-1-ND	10 μF Capacitor	1	Tantalum Electrolytic	N/A	Pre-Amp	$1.34
478-6110-ND	50 μF Capacitor	1	Tantalum Electrolytic	N/A	Pre-Amp	$38.57
718-1214-ND	2.2 μF Capacitor	2	Tantalum Electrolytic	N/A	Pre-Amp	$0.81
445-8610-ND	470 nF Capacitor	1	Ceramic (X7R)	N/A	Filter	$0.34
478-4013-ND	570 nF	1	Ceramic (X7R)	N/A	Filter	$4.00
445-8611-ND	0.68 μF	2	Ceramic (X7R)	N/A	Filter	$0.68
SA305C204KAA-ND	200 nF	1	Ceramic (X7R)	N/A	Filter	$0.34
CF14JT10K0CT-ND	10 kΩ Resistor	2	Carbon Film (5%)	N/A	Pre-Amp	$0.16

S27KHCT-ND	27 kΩ Resistor	2	Carbon Film (5%)	N/A	Pre-Amp	$0.09
P33KBACT-ND	33 kΩ Resistor	1	Carbon Film (5%)	N/A	Pre-Amp	$0.09
S1.5KQCT-ND	1.5 kΩ Resistor	5	Carbon Film (5%)	N/A	Pre-Amp	$0.40
P100BATB-ND	100Ω Resistor	1	Metal Film (1%)	N/A	Filter	$0.09
3296X-103LF-ND	10 kΩ Trim Potentiometer	1		N/A	Pre-Amp	$2.56
	Total					$180.75

Appendix VI: Description of Engineering Changes since Design Review 3

Microphone: At the last second, the CMA-4544 microphone was able to clearly pick up a fetal heart rate in a quiet room. For this reason, the microphone was chosen for the final design as opposed to the Panasonic WM61A presented in DR3. The microphone is slightly less sensitive, which reduces its susceptibility to ambient noise. The diameter is larger by 3.7mm, which improves the response to low frequency sound waves. Further testing must be done to fully validate this decision.

Fastening: In DR3, the Panasonic WM61A was designed to be press fit directly into the top of the cone. Due to the intensity of the interference of the mechanical vibrations in the cone, this design was not incorporated into the final design. Instead, the CMA-4544 microphone was surrounded by dampening foam (Model Magic was used due to time constraints), and then loosely wedged into the top of the cone. This reduced the intensity of the mechanical vibrations in the cone and allowed the signal of the adult heart rate to be detected more clearly. The differences between the design for DR3 (shown on the left) and the final design (shown on the right) are presented below.
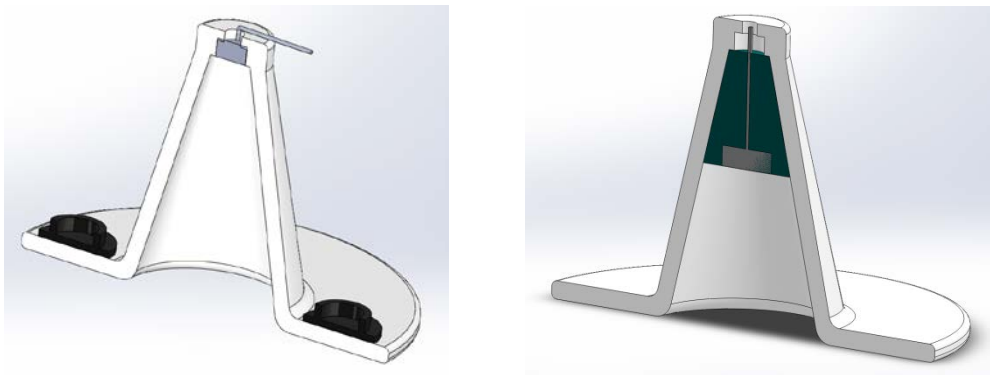
Butterworth Components: Though the layout of the Butterworth filter remained the same, the components of the filter in the final design are different than the components from DR3. For Design Review 3, the values were calculated based on Appendix IV, given in Table 1 below:

Stage	C1 (µF)	Minimum C2 (µF)	Purchased C2 (µF)	% Between Minimum and Purchased C2	Resistor 1 (kΩ)	Resistor 2 (kΩ)
1	0.02	0.02343	0.024	2.375%	31 (0.316%)	42.4 (0.057%)
2	0.047	0.32091	0.33	2.754%	5.4 (0.076%)	7.55 (0.066%)

For the final design, an online filter calculator was used (http://www.daycounter.com/Filters/Sallen-Key-LP-Calculator2.phtml) and with a corner frequency of 200 Hz and a resistor value of 1.5 kΩ, the values used in the final design are given in Table 2 below:

Stage	Capacitor	Values given by Calculator (F)	Implemented Capacitance (nF)	Percent Difference
1	C1	5.7449091980174E-7	570	0.83
	C2	4.9038039936758E-7	470	4.26
2	C1	1.3869144520638E-6	1380	0.07
	C2	2.0312650594001E-7	200	1.54

Appendix VII: Materials Selection, Environmental Sustainability Reports, Manufacturing Plan

Material Selection (Functional Performance)

ACOUSTIC AMPLIFIER CONE

Function and Objective

The function of the acoustic amplifier cone is to isolate the sound of the fetal heartbeat and reduce interference from external ambient noise. The cone also protects the microphone and increases the robustness of the device.

The primary objectives during the materials analysis were to minimize the weight and maximize stiffness of the cone. The weight of the cone must be minimized because the device must be portable. The cone must have a high Young's Modulus because sound from the fetal heartbeat will be conducted through the cone in addition to through the air inside the cone. Flexible materials absorb sound and would dampen the already faint signal from the fetal heart.

Constraints

The first constraint during the materials analysis of the cone is its dimensions. The dimensions of the cone were chosen to optimize transduction of sound through the cone and surface area over which sound is collected. The dimensions of the cone can be found in Fig. 1.
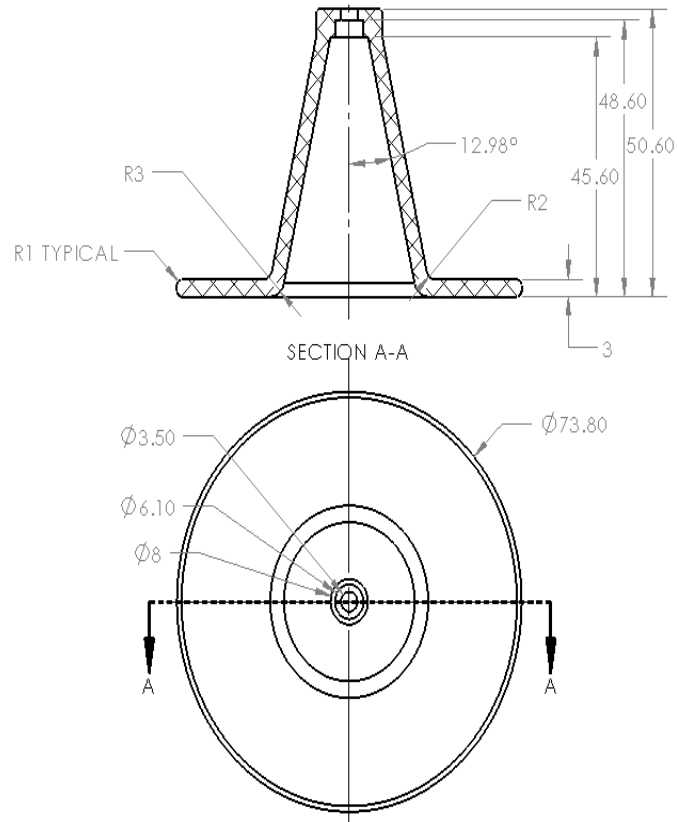
Fig. 1: Dimensions of the acoustic amplifier cone

The second constraint was the cost of the material. This device is intended to be used in low-resource settings. One of the engineering specifications requires that the complete device costs less than $40 USD. Electrical components like the microprocessor will be the most expensive parts of the device. Approximately $10 per pound is a reasonable price for the cone materials before manufacturing costs.

The third constraint, and possibly the most important, is electrical resistivity. The cone is the only component between the electrical circuit and the patient. It is critical that the cone is an effective insulator so that the patient is protected from the possibility of receiving a shock if the device malfunctioned. Materials with electrical resistivities greater than 10^{16} Ω·m are considered good insulators (Watson, 1996).

The cone must also be acceptably resistant to damage due to UV light because of the high possibility of this device being exposed to sunlight for long periods of time. The cone must also be acceptably resistant to damage from salt water because it will rest on the patient's abdomen during use, in contact with perspiration, for ten minutes or more. Because the device is intended to be highly reusable, it could potentially spent significant lengths of time resting in perspiration.

High reusability necessitates that the cone is easy to clean and does not sustain damage during cleaning. A constraint applied to reflect this is resistance to corrosion by weak alkalis. According to Centers for Disease Control and Prevention, a noncritical medical device is one that comes into contact with intact skin, but not mucus membranes (Rutala et al., 2008). Though there is almost no risk of transmitting infectious agents to patients directly from a non-critical device, there are risks of secondary transmission by contaminating the hands of healthcare workers or other surfaces in the hospital that may come in contact with patients (Rutala et al., 2004). Thus, noncritical medical surfaces should be disinfected with an EPA-registered low or intermediate- level disinfectant (Rutala et al., 2008). Ghanaian hospitals commonly use a 1:100 chlorine bleach solution to sterilize equipment. The device must not be damaged when exposed to this dilute alkali solution.

A CES analysis was performed to identify materials within the constraints above for the acoustic amplifier cone. See Fig. 2 for a graphical display of all materials meeting the criteria. After all criteria had been applied, the remaining material options were sorted based on their cost because price is an important factor for any device intended to be used in resource-limited settings.

The five least expensive materials that match the criteria most closely are unfilled polylactic acid (PLA), Alkyd molding compound (mineral filled), polyester BMC (7-10% glass fiber), Alkyd molding compound (glass fiber reinforced), and Polyester BMC (10-20% glass fiber).
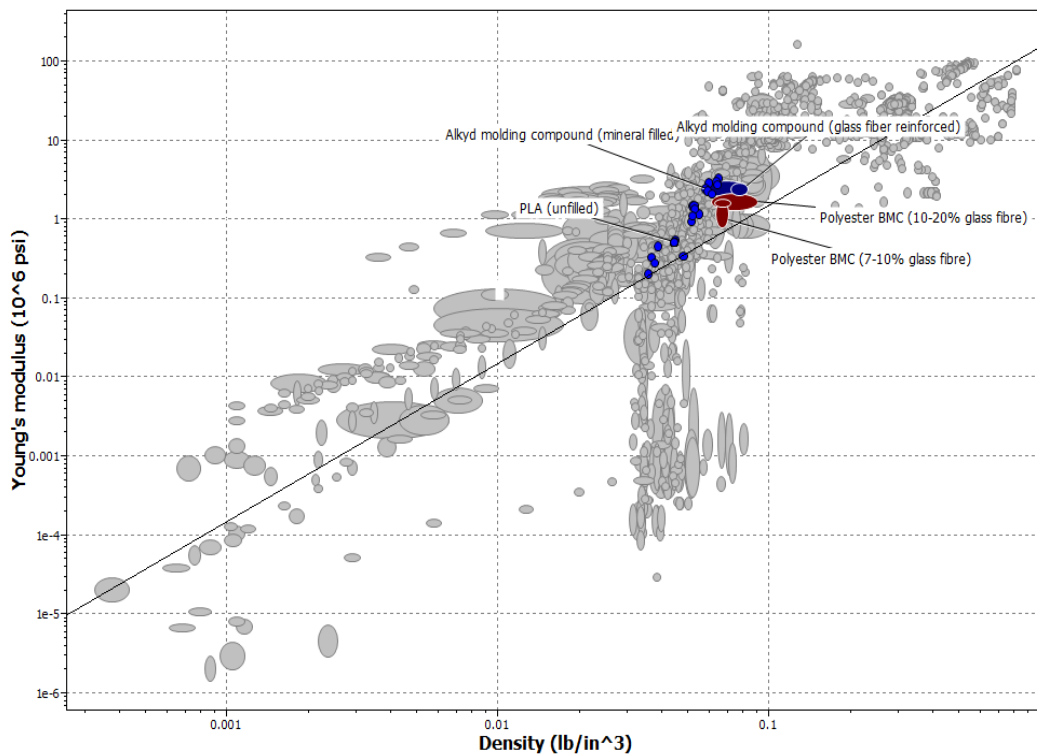

Fig. 2: CES analysis of acoustic amplifier cone material selection

Selection

The acoustic amplifier cone is made out of Accura 60 resin. This material was chosen primarily because the cone was constructed via 3D printing and Accura 60 is the only material available to use in the Viper si2 3D printer at the Medical Innovation Center. Accura 60 resin does, however, meet many of the requirements used to narrow down materials during the CES analysis. The Young's modulus of Accura 60 is 390 KSI, the density is .04 lb/in^3, and it is nonconductive because it is a plastic. Accura 60 is mostly similar to unfilled PLA. Accura 60 is expensive because of the precise 3D printing process.

As stated in the Final Report, the development of the fetal heart monitor for resource-limited settings was entirely focused on meeting engineering specifications describing the function of the device. The most important function specifications are the ability of the device to detect a heartbeat and calculate the baseline rate and variability. Printing the cone from Accura 60 resin was convenient for rapid prototyping, but would not be repeated for larger-scale manufacturing. For mass manufacturing, the optimal material for the cone would be unfilled PLA because its low cost, high stiffness, low conductivity, and low density.

ABDOMINAL ATTACHMENT STRAP

Function and Objective

The function of the strap is to secure the cone and microphone to the maternal abdomen for at least 10 minutes for monitoring of the fetal heart. The strap also allows the user to operate the device without constantly holding it in place. This reduces external noise interference caused by small movements of the cone as muscles contract repeatedly while apparently holding steady. It also allows the user, presumably a healthcare worker, to tend to other patients or tasks while the device is calculating.

The primary objectives during material selection were to maximize the tensile strength of the cone and minimize the cost. The strap must be able to withstand the tension experienced when snugly fastened to the maternal abdomen. Cost is an important consideration when designing for low-resource settings.

Constraints

The first constraint of the attachment strap is its dimensions. The dimensions are based on the average size of a maternal abdomen at full term, which the strap should be able to fasten around comfortably. See Fig. 3 for the dimensions of the strap.
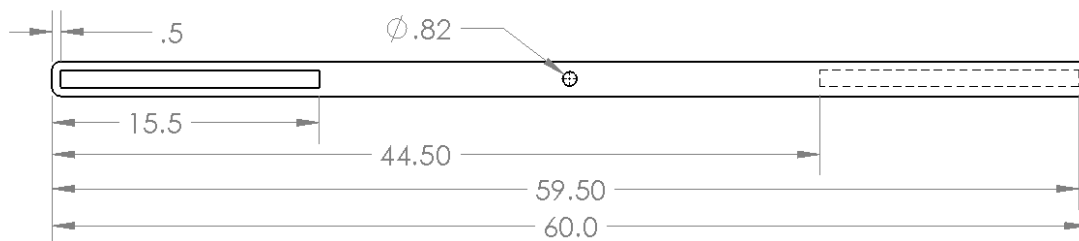
Fig. 3: Dimensions of the abdominal attachment strap.

The second constraint is the flexural modulus. The flexural modulus must be low because the strap must be flexible so that it can conform to the shape of the patient's body when it is wrapped around the abdomen. This is important for the patient's comfort and for isolating the inside of the amplifier cone, which sound pressure waves from fetal heartbeats will travel through. The threshold flexural modulus during selection of the strap material is $1.015 \cdot 10^6$ psi; the modulus of acrylonitrile butadiene styrene (ABS). This modulus was selected because ABS is a polymer slightly stiffer than the optimal strap. Therefore, materials with lower flexural moduli would be appropriately compliant to be used for the strap.

The third constraint was electrical resistivity. Like the acoustic amplifier cone, the strap must not conduct any electricity to the patient. The electrical resistivity of the strap must be $1 \cdot 10^{17}$ $\Omega \cdot m$ or more. The strap must also be resistant to damage from salt water and UV light exposure for the same reasons as the acoustic amplifier cone. The strap must also be resistant to weak alkalis because it will be cleaned with diluted soap, which is basic.

The materials meeting the constraints above were sorted by price. As mentioned previously, the cost of the total device must not exceed $40. The five least expensive materials to fit the criteria for the abdominal attachment strap were polysulphide rubber, perfluoro elastomer, polyetherimide foam, zirconia mullite alumina foam, and aluminum-SiC foam. See Fig. 4 for the graphical representation of the CES material analysis.
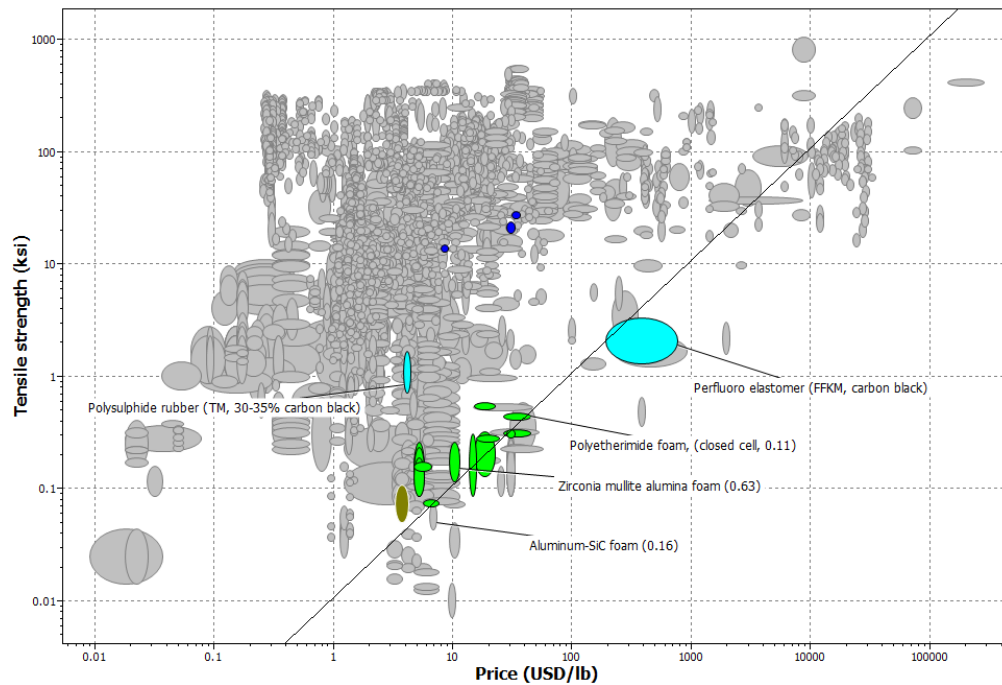

Fig. 4: CES analysis of abdominal attachment strap material selection

Selection

The material used for the abdominal attachment strap in the final prototype is cotton. It is likely that the strap will need to be replaced before any other elements of the device because it is difficult to sterilize cloth and will experience torsion and tension during every use of the device. Material availability in Ghana, cost considerations, ease of replacement, and engineering intuition were used to select this material. The material, purchased in Ghana, is very inexpensive and easily washable or replaceable. The materials meeting the constraints for the strap during the CES analysis are not widely available and do not have any characteristics significantly better than simple cotton to warrant a re-design. Further research of the top five material choices above will be done during the second semester of design during Winter 2013, but a cotton strap is used in the final prototype.

Material Selection (Environmental Performance)

ACOUSTIC AMPLIFIER CONE

The cone material candidates selected to evaluate in terms of environmental impact were unfilled polylactic acid (PLA) and polyester BMC (7-10% glass fiber). The most similar materials found for each in SimaPro were polylactide granulate and glass fiber-reinforced polyester resin, respectively.

Fig. 5 is a graphical comparison of the solid, liquid, and gaseous wastes produced by the masses of each material that would be required to produce the cone.
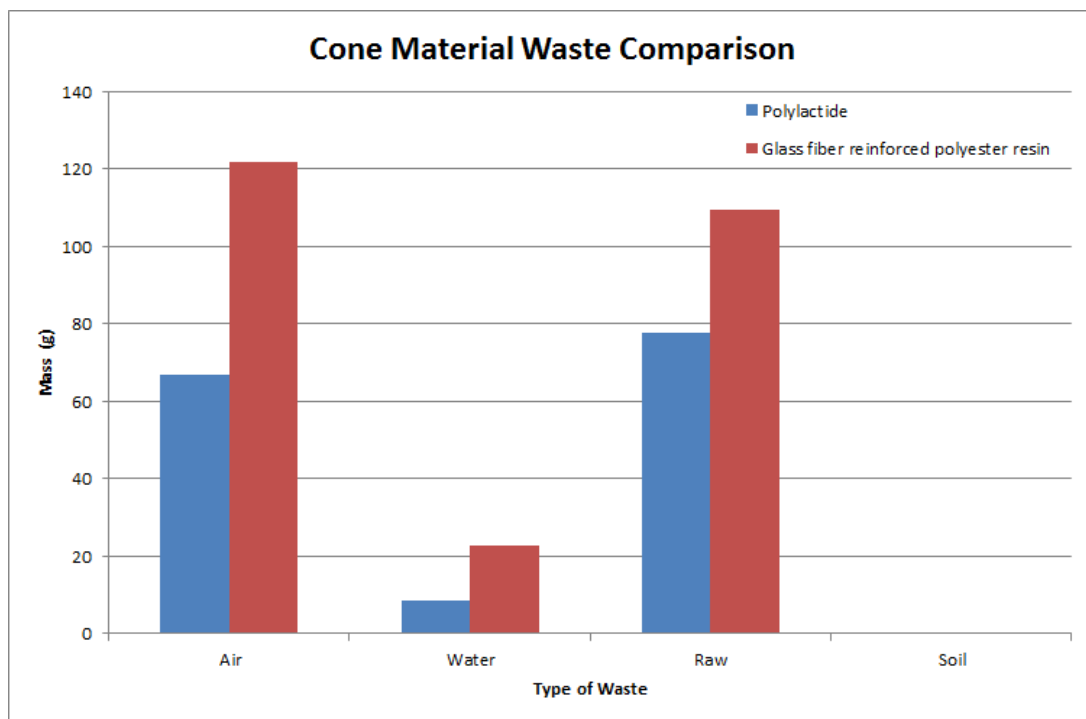

Fig. 5: Waste output of potential cone materials

The polylactide, which represents unfilled PLA, showed significantly less air and raw waste output than the glass fiber-reinforced polyester resin, which represents 7-10% glass fiber-containing polyester. PLA also, however, produced more liquid waste than the polyester resin. Both materials created negligible soil waste.

Figures 6, 7, and 8 display the environment impacts of the two materials in several ways. Figure 7 shows the relative impacts of each material in ten categories. In each category, the material with the larger impact is shown as a full 100% bar. The material with the lesser impact is shown as a proportion to the full bar.
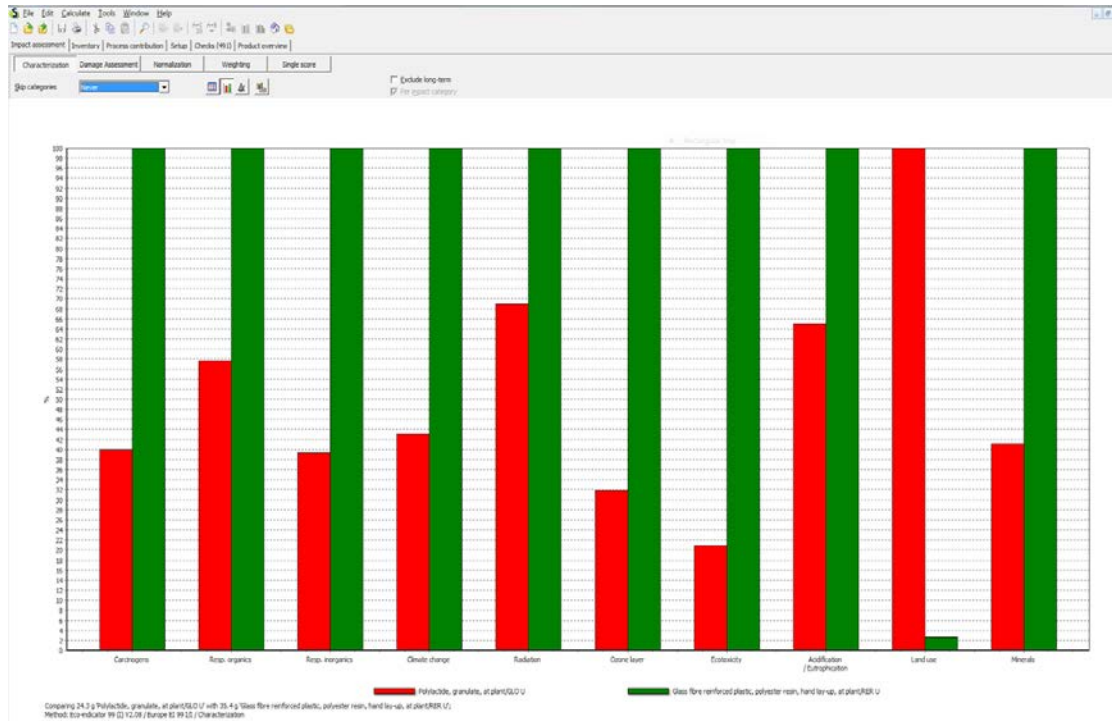
Fig. 6: Relative impacts in ten environmental damage categories

In Fig. 7 is similar to Fig. 6 because the comparison categories are the same. In Fig. 7, however, the amount of damage each material produces in a category is represented as an absolute number rather than as a relationship to the other material.
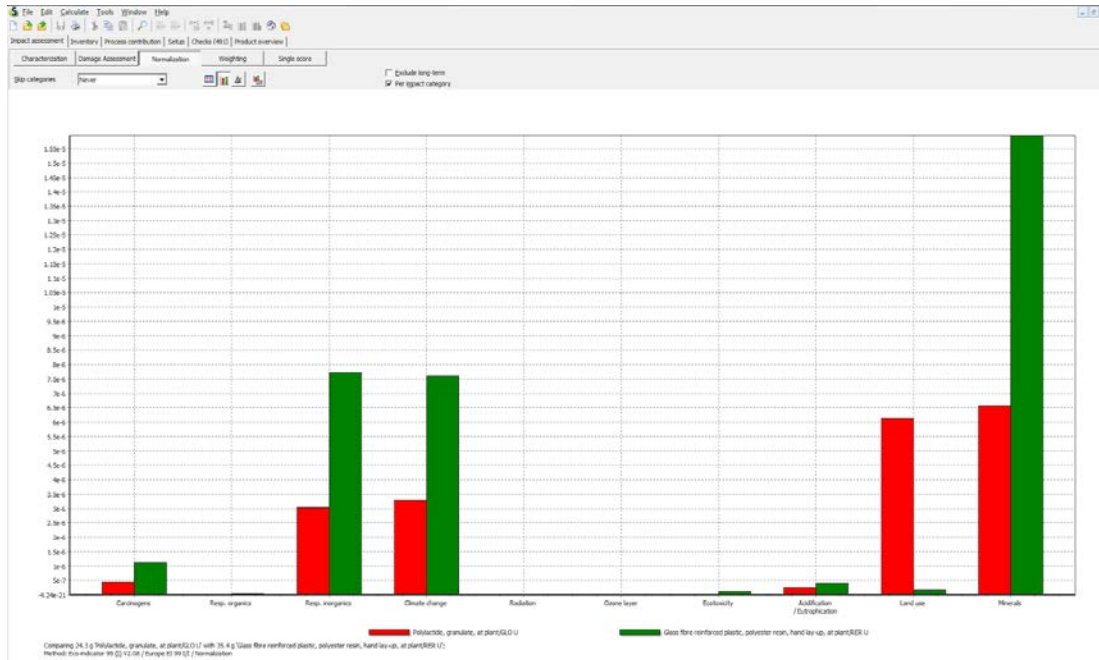
102

Fig. 7: Normalized impact assessment score in Human Health, Ecotoxicity, and Resource categories

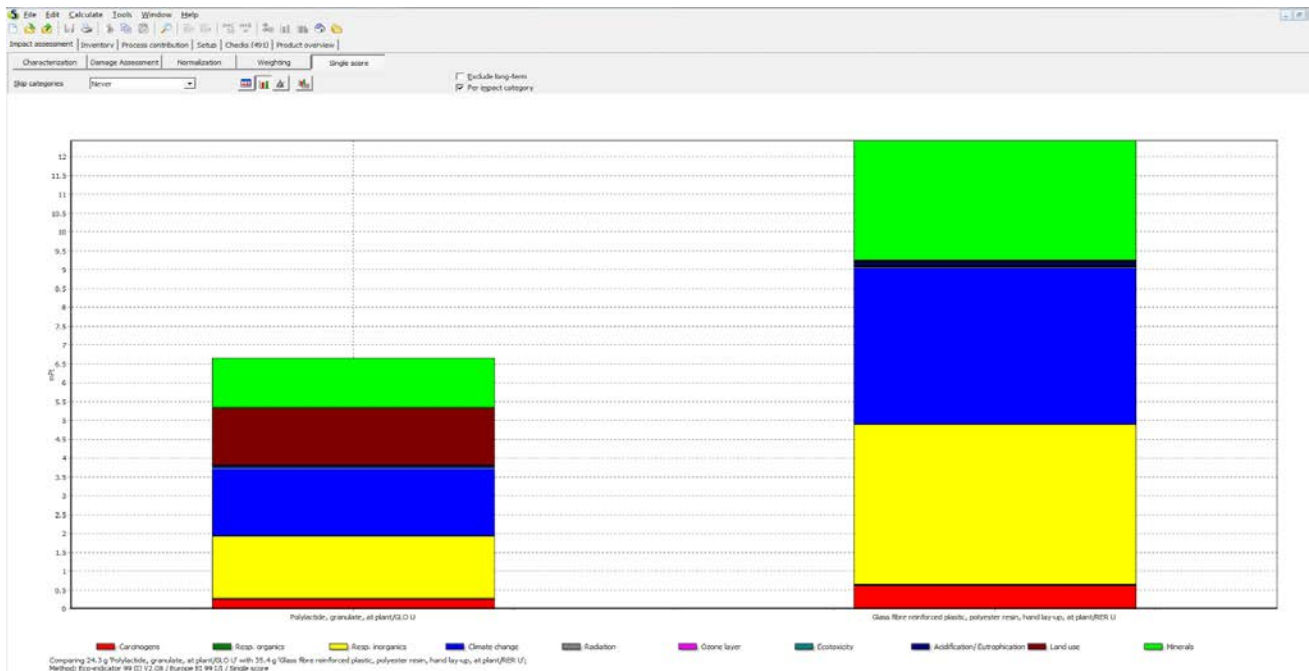In Fig. 8, the all of the damages in every category are combined to give an overall "point" score to each material.

Fig. 8: Single score impact assessment comparison in "Points"

It is apparent from Figures 6, 7, and 8 that PLA has less of a negative impact on the environment than the polyester resin. The only category in which PLA has a greater negative impact is land use. It is

important to note that, of the nine categories in which PLA outshined polyester resin in environmental friendliness, both materials produced extremely small (perhaps negligible) amounts of damage in four categories. This can be seen in Fig. 7. Therefore, PLA is only significantly less environmentally damaging than polyester resin in four categories: carcinogens, respiratory inorganics, climate change, and minerals. As shown in Fig. 8, PLA received approximately six "points" for damage, while polyester resin received thirteen.

The ten categories can be grouped into three groups: human health, ecotoxicity, and resources. As shown in Fig. 7, the overall points contributed in the health group is $1.325 \cdot 10^{-5}$. The overall points in the ecotoxicity group is $1.1 \cdot 10^{-5}$. The overall points in the resources group is $3.33 \cdot 10^{-5}$. Therefore, impact on natural resources is the largest contributor to environmental impact between these two materials.

ABDOMINAL ATTACHMENT STRAP

The abdominal attachment strap material candidates selected to evaluate in terms of environmental impact were polysulphide rubber and zirconia mullite alumina foam. The most similar materials found for each in SimaPro were synthetic rubber and alumina, respectively.

Fig. 9 is a graphical comparison of the solid, liquid, and gaseous wastes produced by the masses of each material that would be required to produce the cone.
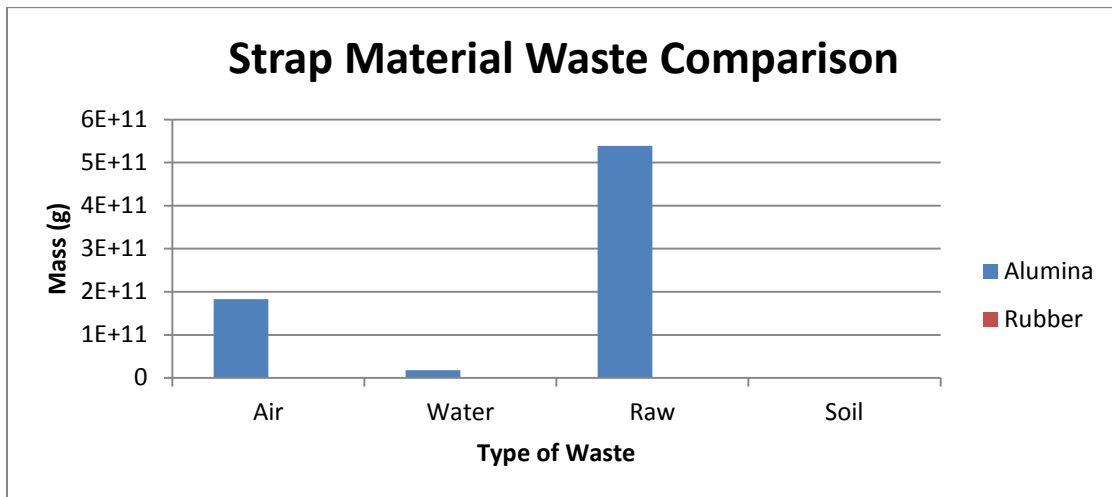

Fig. 9: Waste output of potential strap materials

As shown in Fig. 9, Alumina produces more waste in every category analyzed by SimaPro. Fig. 10 shows the relative impacts of each material in ten categories of environmental impact. In each category, the material with the larger impact is shown as a full 100% bar. The material with the lesser impact is shown as a proportion to the full bar. In every area, the environmental harm done by the synthetic rubber is negligible when compared to the harm of the alumina.

Fig. 10: Relative impacts in ten environmental damage categories
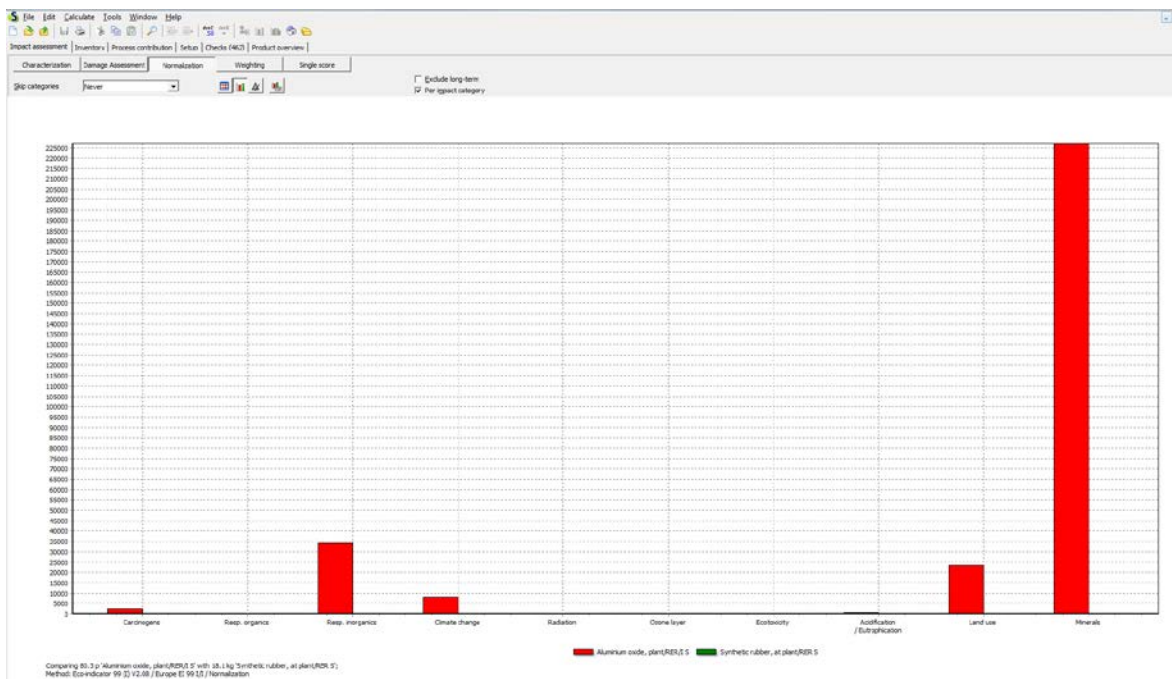

Fig. 11: Normalized impact assessment score in Human Health, Ecotoxicity, and Resource categories

As shown in Fig. 11, the three greatest areas of negative environmental impact of alumina are minerals, land use, and respiratory inorganic materials. In Fig. 8, the all of the damages in every category are combined to give an overall "point" score to each material.
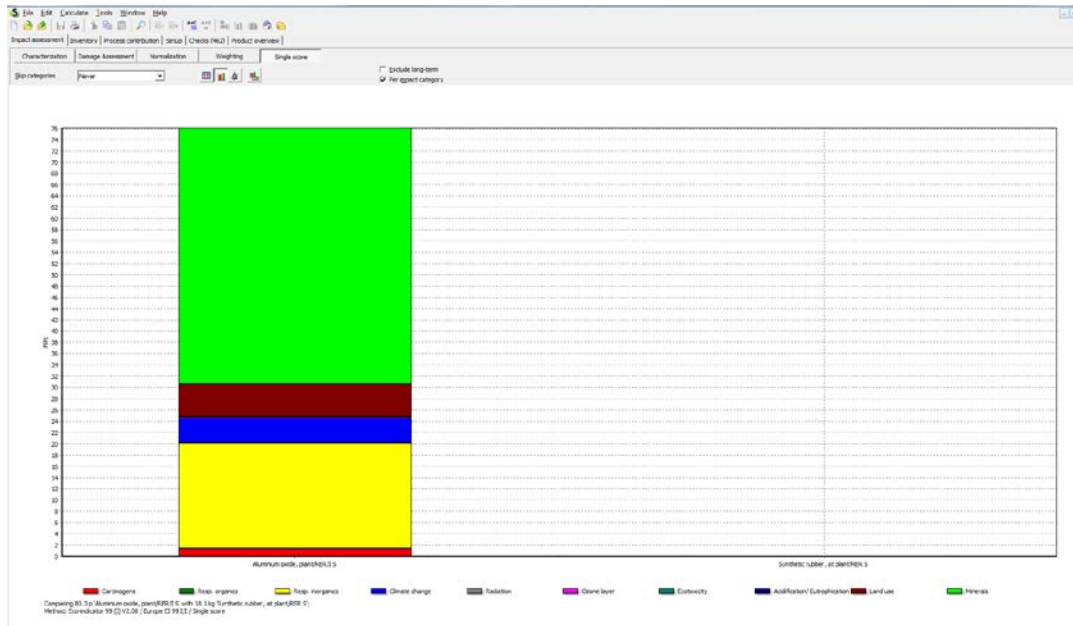
Fig. 12: Single score impact assessment comparison in "Points"

Of the three large groups (human health, ecotoxicity, and resources) that the ten categories can be divided into, resources proved to be the most important, as shown in Fig. 11.

Manufacturing Process Selection

REAL WORLD PRODUCTION VOLUME

The first round of production devices would be used for preliminary testing in real medical situations. Since this would be for testing we would need a largest enough sample to see if the device is working correctly and accurately.

The production volume would be 10 to accomplish this first round of testing. This is the number that is going to be used for the rest of this assignment. Also, the form may change between the 10 to try out different sizes and shapes. However, if the device testing was final and done, the volume would be more like a 1000 to distribute to all the health care facilities in Ghana.

BEST MANUFACTURING APPROACHES

Cone

The best manufacturing process for the cone will be 3d printing for the first round of production where medical testing and approving will be done. Although it is expensive and the roughness is not ideal for sound propagation it is satisfactory, and our material Accura 60 can be used in a 3d printer.

The limits in the CES Process Selector were economic batch size set to 10 and prototyping characteristics selected. Prototyping is important to tweak and refine the cone shape, as well as the all in one device's shape. Based on Fig. 13, if a good signal can be collected with a 3d printed device, then there would be no problem using a more ideal molded plastic and it is cheap and smoother.
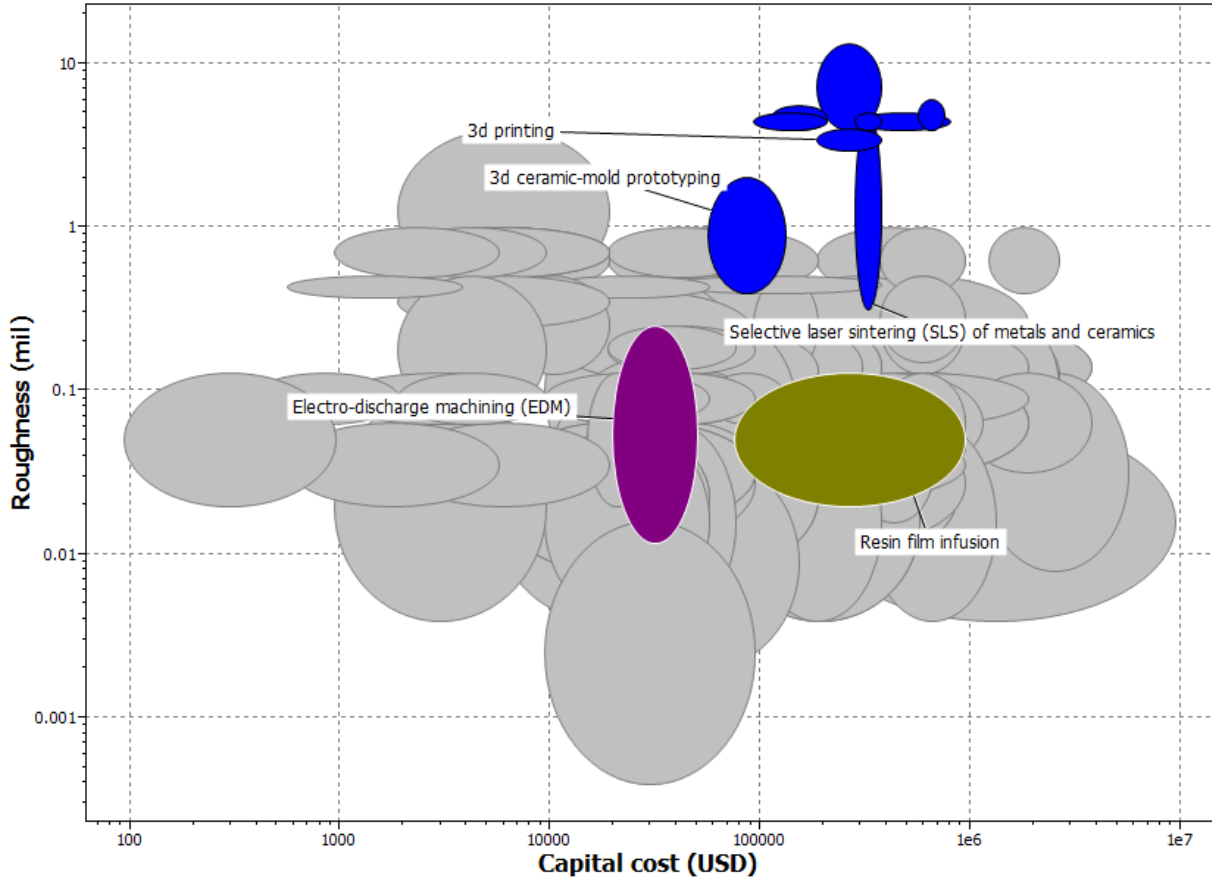

Fig. 13: Manufacturing process selector graph for acoustic cone first round production

Strap

The best manufacturing process for the strap was hard to determine using CES Process Selector. When trying to select a process for manipulating fabric (cotton), the X-axis was set to Flat Sheet and the Y-axis to cutting speed. If cutting speed was maximized it would reduce labor costs. CES recommended water jet as the best method, but intuitively this would be unnecessary, as scissors work perfectly fine when cutting fabric at small production volumes (10).
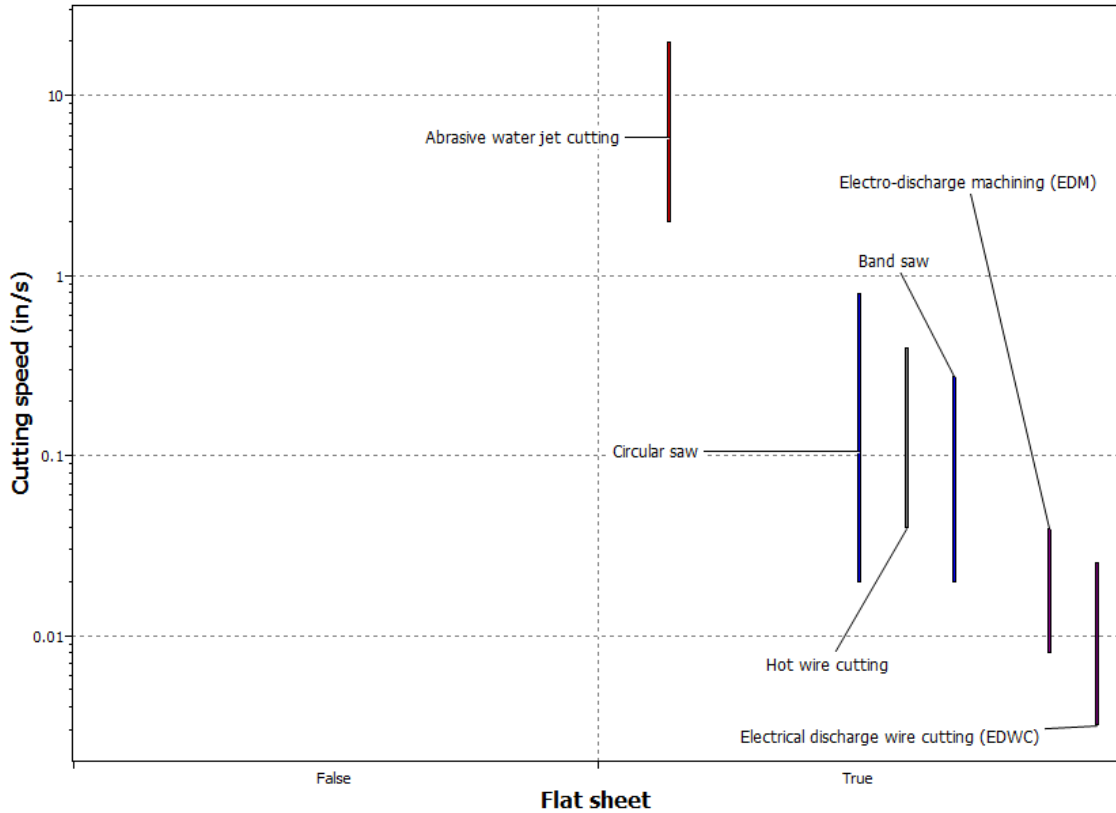
Fig. 14: Manufacturing process selector graph for attachment strap first round production

References

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clinicians need to know. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America, 39(5), 702–9.

Watson, George. "Insulators." *Insulators: Written for MacMillan Encylopedia of Physics (1996)*.

University of Delaware, 31 Oct. 1996. Web. <http://www.physics.udel.edu/~watson/scen103/insulato.html>.

Appendix VIII: Preliminary Testing Analysis

Adult Heart Rate Data:

Trial	HR by Stethoscope (BPM)	HR by Prototype (BPM)
1	70	58
2	74	72
3	68	66
4	70	68
5	70	72
6	64	62
7	68	68
8	60	66
9	63	67
10	65	68
11	66	66
12	67	72
13	74	72
14	70	70
15	71	72
16	68	66
17	69	74
18	66	72
19	50	50
20	57	53
21	57	57
22	54	54

Black: Evan Hendler
Red: Elizabeth Hyde
Orange: Jenna Boeing
Blue: Tyler Gatlin

Filter Analysis:

Raw Data:

Frequency (Hz)	2nd order Sallen Key Output (mV)	4th Order Butterworth (V)
20	410	2.01
40	390	1.95
60	370	1.83

80	350	1.71
100	320	1.55
120	300	1.41
140	270	1.25
160	250	1.13
180	230	0.98
200	210	0.88
220	190	0.76
240	180	0.68
260	150	0.60
280	137	0.52
300	125	0.47
350	105	0.36
400	88	0.28
450	76	0.20
500	64	0.16
1000	28	0.05
1500	20	0.03
2000	10	0.01

Sallen Key Test Parameters: 400mV Pk-Pk input voltage, 1.2V offset voltage

Butterworth Test Parameters: 2V Pk-Pk input voltage, 1.5 offset voltage

Bode Plot:

The magnitude of the gain in decibels, G_{dB}, is given by the equation below:

$$G_{dB} = 20 \cdot log_{10}(\frac{Vout}{Vin})$$

Where Vout is the output voltage of the signal and Vin is the input voltage of the signal. This was plotted against frequency on the logarithmic scale to get the Bode plot. The source values of the magnitude of gain in the graph found in Performance Analysis of the Filter are found below:

Gain Sallen Key Output (dB)	Gain Butterworth (dB)
0.214	0.043
-0.220	-0.220
-0.677	-0.772
-1.160	-1.361
-1.938	-2.214
-2.499	-3.036

-3.414	-4.082
-4.082	-4.959
-4.807	-6.196
-5.597	-7.131
-6.466	-8.404
-6.936	-9.370
-8.519	-10.458
-9.307	-11.701
-10.103	-12.579
-11.617	-14.895
-13.152	-17.077
-14.425	-20.000
-15.918	-21.938
-23.098	-32.041
-26.021	-36.478
-32.041	-46.021

 To find the approximate roll off rate, a line was best fit from the cut off frequency (200 Hz) to the maximum frequency tested as shown in the graph below.
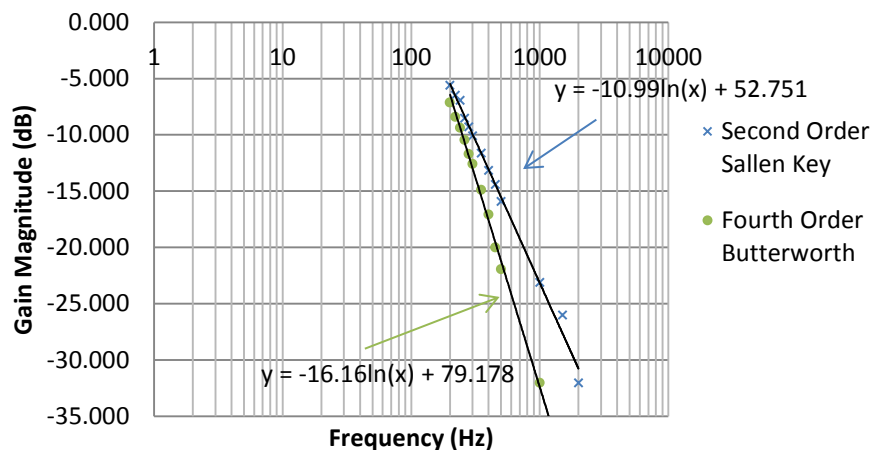
The difference between the y values when x equals 100 and when x equals 1000 give you the approximate roll off rate per decade. Which was found to be -25.3 dB/decade for the Sallen Key filter and -37.2 for the Butterworth filter.

The Sallen Key filter tested was built using an online calculator (http://sim.okawa-denshi.jp/en/OPseikiLowkeisan.htm). The corner frequency was set to 200 Hz and the damping ratio was 1. R1=R2=8.2kΩ and C1=C2=0.1μF.