

ME450 ENGINEERING DESIGN REPORT

Low Cost Device for Detecting Respiratory Abnormalities in Low-Resource Settings

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Project 11: Team BABIES

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EXECUTIVE SUMMARY

The Mother Baby Unit (MBU) at Komfo Anokye Teaching Hospital (KATH) in Kumasi, Ghana is a unique ward dedicated to care of septic, low dependency, and high dependency newborns of approximately 30 weeks gestational age to full term. Staff members see 3-4 deaths a day on average. Many of these problems are due to respiratory distress and the underdeveloped lungs of premature infants. With treatment, continuous respiratory failure for three minutes will cause irreparable brain damage, but earlier detection will allow healthcare providers to restore proper spontaneous breathing.

In the MBU there are 70 to 100 babies in three different rooms that are visually monitored by four nurses and 1-2 doctors. These health care professionals must continuously look for a jerking or gasping for breath, a lack of chest movement, or blueness of the skin around the infant's mouth, fingernails, or skin. The MBU at KATH would benefit from a time-saving, cost-effective, easy to use device for health care providers to monitor the respiration of premature babies and alert health care providers of respiration abnormalities, allowing providers to better prioritize care.

Our multidisciplinary design team spent four weeks in August 2010 at KATH observing and interviewing the healthcare staff to co-identify problems and narrow these challenges into the final need statement. We interviewed stakeholders in the MBU, Obstetrics and Gynecology Department (where most of our observations took place), the Biomedical Engineering Department, Procurement, and the business office to determine user requirements and preliminary design specifications. Below is a summary of our top five identified user requirements and an example of an accompanying design specification.

RANK	USER REQUIREMENT	SPECIFICATION DESCRIPTION	QUANTIFICATION
1	Notifies health practitioners of problems effectively	Time taken to inform nurse (s) after occurrence of respiratory abnormality	15 seconds
2	Safe to use	Temp Range of parts touching infant (°C)	34-37
3	Low maintenance (including operational)	MTBF (months)	3 months
4	Easy to Use	Percentage of people that can successfully operate/interpret device (% total attendants)	95%
5	Easy/Fast to Attach and Initialize	Total attachment/initialization time (min)	<2 minutes

Our team generated concepts to detect a range of physical manifestations of lack of breathing including no chest movement, airflow, temperature and skin color change. Based on these requirements, we selected an alpha design that will successfully meet the majority of our specifications. This design includes a disposable bandage-like fabric slip cover that adheres to the infant's skin. It encloses a small flex sensor used to detect chest movement. This information is sent to a circuit to synthesize the output and decide whether or not to signal an abnormality. We created a prototype, and were able to validate the majority of our design specifications.

The primary goal of the design is to create a device that discovers when an infant is experiencing respiratory distress and notifies health care providers so that proper action can be taken. Such a device will save healthcare providers time and improve the care of neonatal infants in low resource settings such as KATH.

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PAPER NUMBER

LOW COST DEVICE FOR DETECTING RESPIRATORY ABNORMALITIES IN LOW-RESOURCE SETTINGS

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ABSTRACT

In the setting of a large referral hospital in a low-resource environment, large patient volume and low staff numbers contribute to insufficient or ineffective monitoring of neonatal patients. This frequently results in delayed detection of respiratory abnormalities, which can lead to brain damage or death if left untreated. Through an intensive observation and design process, our team has developed a preliminary design and prototype for a low-cost device that will detect respiratory abnormalities in infants. This device monitors infants and alerts healthcare providers of respiration problems for better prioritization of care.

1.0 INTRODUCTION

In September of 2000, the World Health Organization (WHO) created the Millennium Development Goals in an attempt to foster international development. Goals 4 and 5 on this list are to improve maternal health, and to reduce child mortality, respectively. According to the WHO, up to 360,000 women die every year in pregnancy and childbirth, and the maternal mortality rate in some developing countries is 6%. Additionally, over 4 million infants will die before they reach 4 weeks of age every year due to inadequate health care.

During the month of August 2010, a multidisciplinary design team of students from the University of Michigan performed daily observations in the OB/GYN and Pediatrics

departments of Komfo Anokye Teaching Hospital (KATH), a large referral hospital located in Kumasi, Ghana. The purpose of these observations was to identify challenges experienced by KATH healthcare workers and determine opportunities for design innovation.

Premature infants have no opportunity to develop normal respiratory reflexes when born prior to 37 weeks gestational age (GA). Therefore, it is common to see episodes of apnea of prematurity, which is the cessation of respiration. In these cases, the neonate often experiences spontaneous restoration of breathing after a few seconds, but may experience side effects due to underlying causes of the episode or its effects on other organs and systems in the body (Poets). There are two major manifestations of apnea. Obstructive apnea occurs when there is an airway blockage from a mucus plug, airway constriction, or the tongue falling backwards. Despite the lack of airflow, respiratory effort continues. Central apnea is defined as a decreased desire to breathe due to chemical imbalance or a neurogenic failure, which can lead to a decreased rate or cessation of breathing. Rates below 30 breaths per minute indicate a problem and require medical attention. Alternatively, elevated respiratory rates may indicate serious problems such as infection. Rates above 60 breaths per minute require medical attention. Therefore, neonates, especially when premature, require near continuous attention and care because problems can quickly become fatal.

Several challenges related to infant respiration were identified through observation and interviews. Though treatment is available, KATH is not equipped for timely identification of abnormalities. Current methods of automated respiratory monitoring are prohibitively expensive and impractical for purchase by the hospital. In order to detect respiratory failure, healthcare providers must visually monitor irregular movement of the infant's chest, or in some cases, discoloration of the infant's extremities or lips. The Mother Baby Unit (MBU) cares for approximately 90-100 patients at a time, sometimes with multiple babies per bed. Consequently, each of the four nurses on duty is responsible for an average of 25 patients at any given time. This nurse to patient ratio is far beyond the capacity for continuous visual monitoring.

There are numerous devices currently on the market designed to monitor infant respiration. Hospitals in the United States and other developed countries use advanced monitoring equipment, such as the Smart Monitor 2 and the GE DASH 3000 (Erlor). This equipment is designed to simultaneously measure respiration, temperature, blood pressure, heart rate, and blood oxygen levels. Though effective, these devices range in price from approximately USD4000 to USD8000. These devices are also too bulky for the crowded MBU we observed at KATH, and require continuous access to an AC power source to function, which is not always available in developing settings. Additionally, if these devices break down, the resources are not always available for repair.

Several simpler respiration monitors on the market are designed for use in the home, ranging between USD100 and USD200. The RespiSense BUZZ Infant Breathing Monitor, costing USD136, is attached to the diaper to monitor movement of the infant's abdomen to measure breathing. However, this device requires attachment to a diaper or a tightly fitting article of clothing on the infant, which, based on our observations, cannot be assumed in a developing setting. The Nanny Baby Breath Monitor is a thin mattress, with embedded force transducers to detect chest movement, placed below the existing mattress. However, this device can not differentiate signals from multiple babies when they are occupying the same bed.

Several patent-only devices were also examined. Concerns with these devices being used in a developing setting include complexity of design, safety for the infant, and the need for properly fitting clothing.

This paper describes the development of a low-cost respiration monitor designed for use on infants in a low-resource setting.

2.0 METHODS

A formal design process was used to develop the final design and prototype of the infant respiration monitor presented in this paper. This includes acquisition of end-user requirements in Ghana, creation of accompanying design specifications, and generation and selection of concepts.

2.1 USER REQUIREMENTS

After finalizing a specific need, potential stakeholders were identified, including doctors, nurses, and hospital administrators. To generate a list of user requirements, each member of the team conducted informal interviews with

stakeholders over a period of several days. Stakeholders were asked to identify necessary qualities and characteristics for a hypothetical infant monitoring device. A preliminary list of user requirements was generated based on this feedback. Relative importance of each requirement was determined using a survey with a five point Likert scale. This survey was administered to 29 staff members, and the average scores were weighted based on the respondent's expertise and position in the hospital. Using these results, a list of features to include in the design was created.

2.2 DESIGN SPECIFICATIONS

Based on feedback from surveys, interviews, as well as extensive literature review, a list of 12 user requirements was created. Design specifications were also generated to quantify each user requirement. Effective notification of abnormalities ranked as the top user requirement. Health care workers must be notified of a problem between 15 and 20 seconds after detection. Notifying too early can lead to unnecessary alerting, while notifying too late can lead to serious health concerns for the infant. It is also important that the alarm be effective from at least 15m away. Safety was ranked as the second most important user requirement. The temperature of any components in contact with the infant must be between 37 and 37 degrees Celsius, and the weight on the infant should be kept below 125g. If electrical components are required, the current must be kept below a safe value. It was also determined that the device must be easy to use, easy and fast to attach/detach, and inexpensive.

2.3 CONCEPT GENERATION

The device was separated into independent functional processes. The primary functions are to detect respiratory abnormalities and alarm in the event of a problem. Secondary functions are the attachment mechanism to the crib, the attachment mechanism to the baby, and the power source. Several ideas were developed for each functional component, and comprehensive concepts were generated by combining components. Concepts were analyzed using a Pugh chart to assess how well each idea addressed the user requirements. The final concept was selected based on variables such as accuracy, simplicity, and cost.

3.0 RESULTS

This section describes the final design, the current functional prototype, and the results of validation testing.

3.1 FINAL DESIGN DESCRIPTION

The selected design shown in Figure 1 below detects chest movement with a flex sensor, analyzes the magnitude and frequency of the signal with a microprocessor, and initiates a red light and a buzzer if the signal does not qualify as normal respiration, which is expressed by green light.

3.1.1 HARDWARE COMPONENTS

Refer to Figure 1 below for an illustration of the component being discussed.



FIGURE 1: INFANT RESPIRATION MONITOR DESIGN

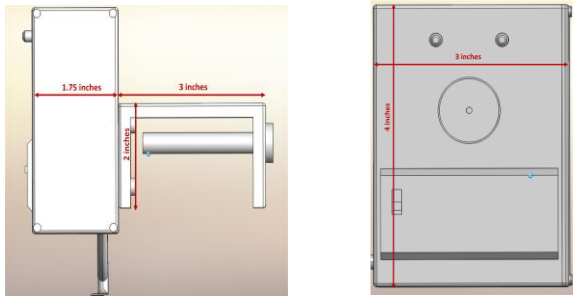


FIGURE 2: DIMENSIONED DRAWING OF FINAL DESIGN

1. Disposable Slip-Cover: The flex sensor will be encased in a thin, tight, disposable nylon/polyester polymer sheath with hypoallergenic, water-resistant adhesive on one side. Once the slipcover is adhered to the infant's chest, it should be left on for the entire duration of use, and the sensor can be easily inserted and removed as needed.
2. Battery Holder: A simple 9V battery holder is shown on the front face of the monitoring box. The case can be accessed easily from the exterior of the device in order to change the battery, and contains leads to connect the battery to the circuit.
3. Buzzer: The Pro-Signal ABT-410-RC buzzer is press fit and mounted to the front of the box. This buzzer provides a noise output of 80 dB, and can easily be soldered to the circuit.
4. Red/Green LED: The alerting mechanism includes a green LED to indicate normal respiration and a red light to indicate problematic respiration. The LEDs are press fit and glued to the front of the monitor casing.
5. Casing: The casing is rectangular because the parts adhered to the inside are rectangular. The final dimensions of the casing are 4" X 3" X 1.75" as shown in Figure 2. This accounts for wall thickness of 0.1" and a 0.05" tolerance. Analysis with CES software determined that styrene maleic anhydride is the optimal material for the walls of the monitoring box.
6. Clamp: A C-clamp on the back of the monitoring box allows it to be firmly attached to a crib of any shape. According to the CES software, the clamp should be fabricated with the same material as the casing for manufacturing purposes, and styrene maleic anhydride is the optimal material for the clamp as well. The length of the

clamp is 3.0 in, and a bolt can be tightened allowing attachment to a majority of crib sizes.

The circuit, shown in Figure 3, is contained within the box. Its components are described below.

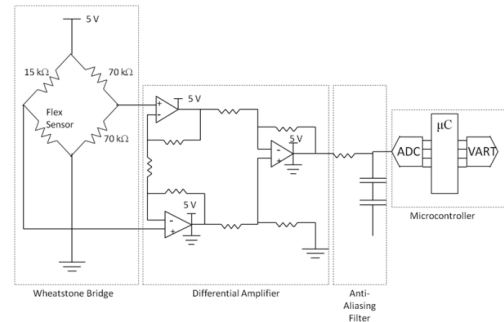


FIGURE 3: CIRCUIT SCHEMATIC

1. Flex Sensor: Chest movement is measured with a 4.5" flex sensor. The sensor, which is a variable resistor that increases in resistance as it is flexed, is attached directly to the infant's abdomen to detect movement associated with breathing.
2. Wheatstone Bridge: The flex sensor is included in the circuit as part of a Wheatstone bridge, a type of voltage divider. The Wheatstone Bridge, when used in conjunction with an amplifier, allows for greater sensitivity than a simple voltage divider. This is important because the movements associated with infant respiration are very small.
3. Resistors: The Wheatstone Bridge described in the previous section requires several resistors. The resistors must be selected so that the voltage difference between the two nodes is close to zero when the flex sensor is in its initial position. The resistances must also be selected so that the current in the circuit is kept below potentially harmful values. Although the initial degree of flexion of the resistor will vary based on the size of the infant to which it is adhered, the resistances shown in Figure 2 were determined to give sufficient sensitivity to our device, and limit current to 0.23 mA.
4. Differential Amplifier: The amplifier selected is a Maxim 4194 variable gain differential amplifier that operates on input voltages ranging from +2.7 VDC to +7.5 VDC. The device takes two voltages as inputs, measures the voltage difference between them, and amplifies the value by a specified gain of approximately 50 V/V.
5. Anti-Aliasing Filter: To improve the accuracy of the input signal, an anti-aliasing filter is included in the circuit. The cutoff frequency of the filter is set to be 5 Hz, satisfying the Nyquist-Shannon Condition.
6. Microprocessor: The microprocessor used in our final design is a PICAXE 18 Pin Power Project board. The PICAXE 18 Pin Power Project Board is a simple microprocessor board that provides up to five analog inputs and eight digital outputs rated at 800 mA. It has a maximum operating speed of 4 MHz and a 10 bit resolution. The sampling rate is digitally set to be 10 Hz which satisfies the Nyquist-Shannon condition. The board can operate on

5-20 VDC input voltage, and provide a 5 VDC output voltage.

3.1.2 ALGORITHM

An important component to this device is the algorithm used to extract necessary information from the input signal. The input data to the microprocessor during normal respiration is roughly sinusoidal, corresponding to the cyclic nature of breathing.

The algorithm uses two discrete time windows to evaluate respiratory rate and amplitude simultaneously. The length of the window to determine respiratory rate is 15 seconds, based on design specifications. Data presented by Chiarugi et al, indicates that a window of this length can provide accurate measurements of respiratory rate. (Chiarugi) When the device is initiated, a five second calibration period during regular breathing determines the approximate average value of the input signal. The average value is continually updated as respiration is measured using a floating average formula. After the calibration period, respiratory rate is determined by the number of times the signal crosses the midline during the 15 second window.

The signal amplitude is measured by a two second window. This length was selected based on the lower threshold for acceptable respiratory rate in an infant. One full cycle is guaranteed per window during normal respiration. The minimum and maximum values are determined in each two second window. If the difference between the two values is greater than a predefined threshold value, the signal is large enough to indicate breathing. If the difference is below the threshold, a timer is initiated. If the signal does not return to normal within 15 seconds, the buzzer sounds and the red LED turns on.

The threshold value was selected by determining the maximum expected noise of the signal. In order to confidently differentiate between noise and chest movement, the threshold was set 3σ above the average noise value of the circuit. After several noise trials in which the flex sensor was held stationary, the threshold was determined to be 30 units. As previously stated, the microprocessor has a 10 bit resolution. This means an input signal can be assigned a value from $0-2^{10}(1024)$. Because our input voltage is 5V, the input signal produced by the voltage divider will range between 0 and 5V. Therefore each unit increase of the input signal on the microprocessor corresponds to an increase of $5/1024$ volts. A graph with generic sinusoidal data illustrating the function of our algorithm is shown in Figure 3 below.

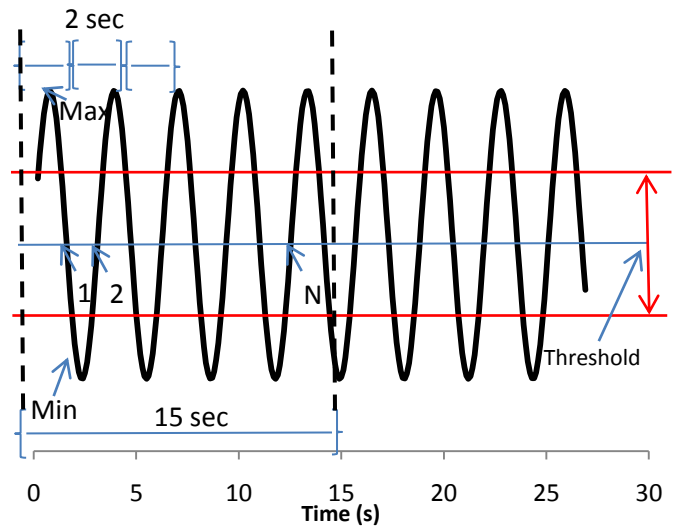


FIGURE 4: ILLUSTRATION OF ALGORITHM

FFT methods were also considered for this device. These methods were discussed in the paper “An automated algorithm for determining respiratory rate by photoplethysmogram in children” by PA Leonard et al and shown to work effectively (Leonard). However, FFT analysis is beyond the scope of low cost microprocessors considered for this device and would require additional components, increasing total cost. Windowing methods provide a necessary level of accuracy for our device as indicated by previous studies (Chiarugi, Bates).

3.2 CURRENT PROTOTYPE

The prototype used for validation in the subsequent section is functionally accurate but has several structural deviances from the final design. An Arduino microprocessor was used because it provides an easy user interface and includes a USB connection for programming purposes. This microprocessor is larger and more expensive than the microprocessor selected in our final design, but both microprocessors can perform the necessary functions this device requires. Also, the current circuit is built on a breadboard instead of a printed circuit board. Due to these dimensional differences, a larger PVC project box was purchased to temporarily enclose the circuit. It is not representative of the size of the final design.

3.3 VALIDATION

In order to simulate accurate physiological infant chest movement and breathing pattern, the Laerdal SimBaby in the Clinical Simulation Center at the University of Michigan Hospital was used. This SimBaby can simulate various respiration rates, chest movement patterns, and depths, and provides a realistic model for evaluating several measures of how accurately the monitor functions.

The accuracy of frequency measurements was tested by adhering the flex sensor to the SimBaby’s abdomen for a period of approximately 90 seconds, providing six independent measurements for each trial. Frequency readings were recorded using Arduino software on a laptop. This procedure was repeated for respiration rates 10 through 80 in

increments of 10 breaths per minute. The results are shown in Figure 4 below:

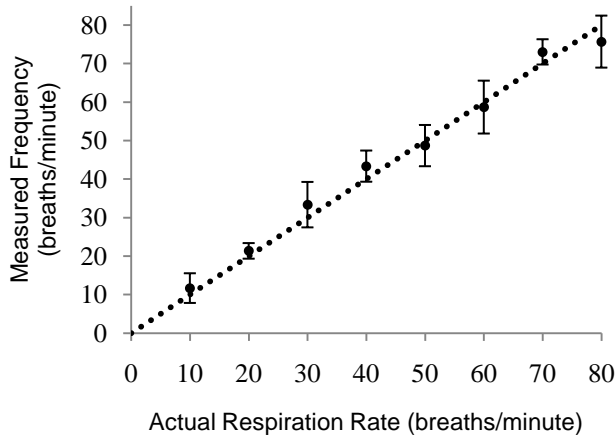


FIGURE 5: ACCURACY OF FREQUENCY MEASUREMENTS

The average measured frequency was calculated for each actual respiration rate with a range of 1.96 standard deviations, as depicted by error bars in Figure 4. Based on this analysis, the frequency values obtained at each rate are not statistically different from the target values.

The target time to alert is 15 seconds after the onset of a respiratory abnormality. Using a regular breathing pattern and normal breathing depth, several trials were combined to show averages for no breathing, three hypoventilation rates, and one hyperventilation rate.

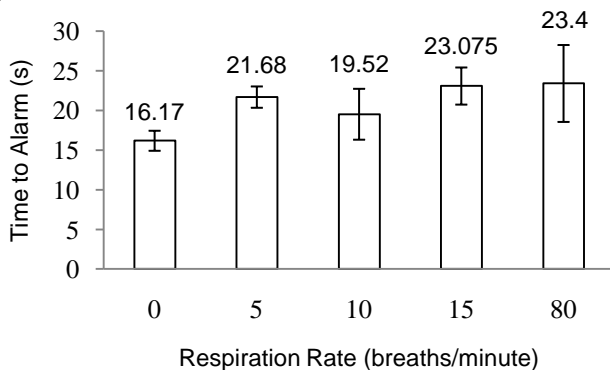


FIGURE 6: TIME TO ALARM FOR VARYING RATES

When the microprocessor did not detect any respiration, it immediately began counting because the magnitude was below the threshold. Therefore, the value for zero breaths per minute was not statistically different than 15 seconds, and gave the most accurate response time. Due to the 15-second window for measuring frequency, variability within the cycle of when abnormal respiration caused notification times greater than 15 seconds. For all respiration rates greater than zero and outside the normal range, the time to notify was approximately 20 seconds.

Figure 5 displays the results of time to alarm under different breathing conditions. The depth of breath was manipulated on the SimBaby and is shown on the x-axis. Differently shaded bars display respiration rate.

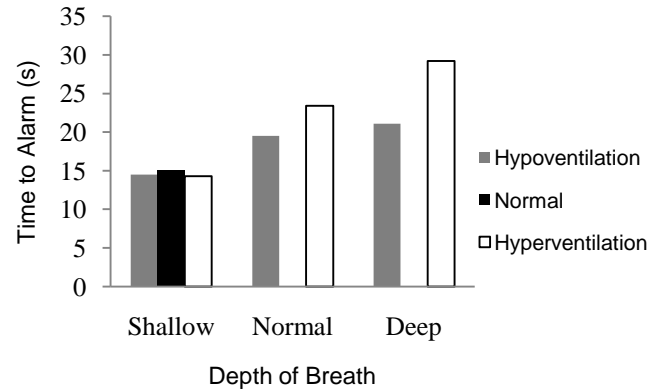


FIGURE 7: TIME TO ALARM AT VARYING BREATH AMPLITUDES

Although shallow breathing signaled within an optimal time interval for the hypo and hyperventilation states, the alarm was also initiated for normal respiration rate, which demonstrated that the device did not detect any breathing in the shallow state. Therefore, it counted to 15 seconds assuming a rate of zero and sounded the alarm at the appropriate time. It has not yet been determined whether shallow breathing is indicative of a problem and requires medical attention, regardless of the respiratory rate. If this is the case, then the device functions properly. If not, then the threshold magnitude must be adjusted so that the sensor is sensitive enough for shallow breathing.

Hyperventilation averaged a longer notification time because its more irregular pattern caused the device to give an inaccurate reading during the first window. The lack of alarm for normal rate for both normal and deep depth was expected. Similar results were found for other breathing patterns like sea saw and retraction breathing.

Human subject testing was performed to measure the average time required to initialize the device with minimal training, and how easy the alerting signals were to interpret. With a sample size of 10, 100% of subjects correctly identified the meaning of the green light, the red light with a buzzer, and no light. It took an average of 18.1 ± 4.4 s to attach the device after a 30 second training period, and 100% of subjects could hear the buzzer 15m away.

4.0 DISCUSSION

The objective of this design was to develop a low-cost, easy to use respiration monitor for low-resource settings. Moving forward, there will be several improvements to the current prototype. In order to create the final design, a casing with the correct dimensions and material will be manufactured, and the circuit will be rebuilt with a printed circuit board and a smaller microprocessor.

Several minor glitches in the code were discovered through validation testing at the Clinical Simulation Center. The time to alarm was too long for hypo and hyperventilation states, because the code evaluates the frequency over a 15 second window. The time to notify will be retested with varying window lengths to achieve a 15 second optimal delay between detection and notification.

The microprocessor was also unable to register breathing when the chest movement was too shallow or irregular. While these breathing patterns in a live infant may be indicative of a problem, the threshold amplitude should be adjusted to account for physiological differences between infant chest displacements.

Additional information will be collected from stakeholders to make the design more user-friendly and attractive. Further validation testing on user-friendliness and required training time will be performed when the final design prototype is complete.

5.0 ACKNOWLEDGEMENTS

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6.0 REFERENCES

Poets, C. F. (2010). Apnea of prematurity: What can observational studies tell us about pathophysiology? *Sleep Medicine, 11*(7), 701-707. doi:DOI: 10.1016/j.sleep.2009.11.016

A. Bates, M. J. Ling, J. Mann and D. K. Arvind. (2010). Respiratory rate and flow waveform estimation from tri-

axial accelerometer data. Paper presented at the *International Conference on Body Sensor Networks*, Scotland, UK.

Chiarugi, F., Karatzanis, I., Zacharioudakis, G., Meriggi, P., Rizzo, F., Stratakis, M., Louloudakis, S., Biniaris, C., Valentini, M., Di Rienzo, M., & Parati, G. (2008). Measurement of heart rate and respiratory rate using a textile-based wearable device in heart failure patients. *Computers in Cardiology, 2008*, 901-904.

Clifton, D., Douglas, J. G., Addison, P., & Watson, J. (2007). Measurement of respiratory rate from the photoplethysmogram in chest clinic patients. *Journal of Clinical Monitoring and Computing, 21*(1), 55-61.

Leonard, P., Clifton, D., Addison, P., Watson, J., & Beattie, T. (2006). An automated algorithm for determining respiratory rate by photoplethysmogram in children. *Acta Paediatrica, 95*(9), 1124-1128.

Thomas, Erler (2004) Monitoring of Newborns and Infants Under Ambulatory and Clinical Conditions-Indications from a Medical Perspective and Technical Requirements. *European Respiratory Disease, 4*(1)

APPENDIX A: Final Report

INTRODUCTION

As part of the world's effort to combat poverty, the World Health Organization (WHO) created the Millennium Development Goals as an overarching method to focus and consolidate aid effort. The WHO identified the reduction of infant mortality as one of these top benchmarks for improvement. Every year, over 4 million infants will die before they reach 4 weeks of age due to inadequate care and ineffective detection of preventable complications (35). A study conducted in India estimates that 948,000 of infant deaths in 2007 were neonatal, and that 81% of neonatal deaths occurred within one week of birth (34). When the rate of infant death is so high, families are more likely have increased fertility in order to anticipate these deaths. Ironically, the largest average fertility rates are seen in the most impoverished countries, which compound that family's poverty by significantly raising their costs of living. Respiratory failure, in its most general sense, is universally considered to be within the top five causes of infant death. Lahariya identified that 22% of infant deaths in India were due to respiratory infection, which makes it the second leading cause of death (34). In Uganda, the leading causes of neonatal death were identified to be sepsis or pneumonia and birth asphyxia, with the median age of death being two days (76). A study by Hibbard states that the most common cause of respiratory morbidity in neonates is respiratory distress syndrome and hyaline membrane disease (17).

Age is also a significant risk factor for respiratory distress in infants. Respiratory morbidity risk increases with decreasing gestational age, or the extent of an infant's prematurity. Even moderately preterm infants will have substantially increased risk for neonatal morbidity (5). The CDC separates infant death into neonatal death and postneonatal death. In a demographics statistics comparison, it identified birth defects, short gestation, low birth rate, and respiratory distress syndrome as the leading causes of neonatal deaths. Intrauterine hypoxia and birth asphyxia was ranked 7, and sudden infant death syndrome (SIDS) was ranked 8 (57).

The CIA World Factbook provides a comprehensive country comparison of infant mortality rates. 41 out of the top 50 countries, including Ghana, (which was the focus of our study) are located in sub-Saharan Africa. Equipped with only broad knowledge of the Millennium Development Goals #4 (reduce infant mortality) and #5 (improve maternal health) and a basic medical background, our team conducted field research to develop an unbiased opinion of a specific addressable need in low-resource hospitals.

For the month of August, 2010, our team lived in Kumasi, Ghana as adjunct observers to the medical teams at Komfo Anokye Teaching Hospital (KATH) with the hope that as less experienced outsiders, we may have a fresh take on the challenges and shortcomings of the health system in addressing problems of infant and maternal health. Each design team member was assigned to an OB/GYN medical team and participated in their daily rotations for four weeks. These rotations included elective surgery, the Outpatient Department Clinic (OPD), the Family Planning Clinic, Labor and Delivery, and rounding on the wards. In spending significant time with the doctors, nurses, midwives, and other staff of this hospital, we believe that we were able to gain a more intimate understanding of many aspects of this hospital than had we attempted problem identification from home.

Through our team's first two weeks of observation at KATH, several challenges were identified through careful analysis of hospital staff behavior, interviews, and general observation of equipment and technique. Later on, we supplemented this information with further observation and study in the Mother Baby Unit (MBU). After identifying broad infant health problems and challenges with treatment and diagnosis, we narrowed our focus within these subjects. Several of the specific problems we identified as a team resonated around the theme of infant respiration abnormalities, which, as previously described, has received global attention.

Neonates, especially when premature, require near continuous attention and care. For example, low perfusion can lead to neurological deficit in far less time than adults. Labored breathing may indicate a septic infection, which may lead to high temperature and critical condition in a matter of minutes. Though treatment is available to prevent death in these cases, KATH is not equipped for timely identification of abnormalities. Due to the almost complete absence of automated monitoring systems, current methods of respiratory failure detection involve the healthcare providers noticing blueness in the patient's extremities, a lack of chest movement, or other visible signs of failure.

According to information stated by MBU nurses, many problems are detected late or missed entirely due to an incredibly low nurse to patient ratio. As a referral hospital, the Mother Baby Unit cares for approximately 90-100 patients at one time. We saw cases of 3-4 babies in one bed because of space constraints. The nurses take shifts of 8 hours, and only 4 nurses are ever on duty at one time. Between the three rooms of the MBU (septic room, low dependency, and high dependency), two nurses are in high dependency and one nurse is in each of the other rooms. Depending on patient distribution between the rooms, that may be between 25 and 50 patients per nurse, which is far beyond the capacity for continuous visual monitoring.

Current methods of automated monitoring are prohibitively expensive for purchase by the hospital. The one monitor in the low dependency room was believed to be broken and it was never turned on while we were there. Further, only the doctors had the knowledge and training to interpret its information output.

In response to these problems, we identified an opportunity to develop a time saving, cost effective, easy to use device for health care providers to monitor the respiration of premature and neonatal babies and alert health care providers of respiration abnormalities, allowing providers to better prioritize care. While the patient population consists of mostly premature newborns and other infants showing signs of respiratory distress at birth that are being kept in the hospital for observation, the primary end users are nursing attendants, pediatricians, and mothers. Much of nurses' time is spent rounding on the infants to manually check for normal vitals. This system, paired with the mother's theoretically semi-regular feeding schedule should allow for detection of slow-developing problems. However, respiration abnormalities can occur suddenly and do not allow for lengthy time before treatment due to potential brain damage, other health problems, and possibly death. A device to automatically monitor each patient would have a dual outcome. It would increase nurses' efficiency by reducing the amount of time spent checking patients for normal breathing and would theoretically reduce the amount of time between problem manifestation and treatment.

BACKGROUND

After generating initial design specifications through surveys of KATH staff, we began to perform an in depth literature review in order to better qualify the problem we identified on a global scale and to learn about the current state of the art. We also searched clinical studies and biology textbooks in order to break down the physiological mechanism of respiration and the common causes of respiration failure in infants. This allows us to reduce our bias towards existing solutions and generate concepts based on a thorough knowledge of the problem. We started our search with online databases such as Pubmed, ISI Web of Knowledge, and Google Scholar. We also performed online patent searches and consulted science textbooks.

Mechanism of Respiration

A complex neurological, physical, and chemical feedback system regulates the rate and volume of respiration in adults. Normally, breathing is an involuntary process and responds to input from the pons and medulla in the brainstem. Unlike heart rate, however, respiratory control can be overruled by the cerebral cortex. To a certain extent, a person may voluntarily hyperventilate by breathing quickly or hypoventilate by holding his or her breath until chemoreceptors force restoration of regular respiration. Brainstem chemoreceptors detect changes in pH in the cerebrospinal fluid and peripheral chemoreceptors have similar function near the heart. A high $[CO_2]$ from hypoventilation leads to acidosis and a low pH, which increases respiration rate. A low $[CO_2]$ from hyperventilation leads to alkalosis, which decreases respiration rate to the point of unconsciousness. Other mechanoreceptors, such as stretch receptors in the lungs, provide feedback about movement in order to help regulate respiration rate.

Breathing is divided into two major phases: inspiration and expiration. Signals from the nervous system cause contraction of the diaphragm, a group of muscles located right below the ribcage. This increases thoracic volume, creating negative pressure and forcing air to flow into the trachea from the nose or mouth. In the case of labored breathing, which is frequent for newborns, the external intercostal muscles will aid in chest movement. Though expiration is usually a completely passive process, abdominal muscles and the internal intercostal muscles will work antagonistically with the diaphragm in the case of more labored respiration.

Air will then flow through the bronchi into the lungs to participate in gas exchange. In small alveolar sacs, oxygen diffuses into pulmonary arteries and binds to iron which is embedded in hemoglobin proteins in the blood. This oxygenated blood is then fed back into the heart through the pulmonary vein and distributed to the brain and the rest of the body through the aorta. Carbon dioxide from the blood simultaneously diffuses back into the alveoli and is expired as the diaphragm relaxes. The average respiration rate of a health neonate is 40-60 breaths/min (17).

Common Respiration Challenges in Newborns

Infants younger than 36 week gestation age (GA) are highly likely to have episodes of apnea of prematurity (AOP), or cessation of respiration. The neonate often experiences spontaneous restoration of breathing after a few seconds, but may experience side-effects due to underlying causes of the episode or its effects on other organs and systems in the body. There is little information available about the largely unknown mechanism and causes for AOP. Poets et. al. (51) hypothesizes that the main objective for the lungs during fetal development is muscular development and that they can afford to have apneic episodes because oxygenation comes from diffusion through the placenta. When infants are born prematurely, there is no opportunity to develop adult respiratory reflexes, and neonates usually outgrow these episodes by 36-43 weeks GA.

Most apnea is manifested in a mix of central and obstructive causes. Central apnea is defined as a decreased desire to breathe, which is often due to chemical imbalance or a neurogenic failure. Airway obstruction may occur, and the airway always begins to narrow after one second and achieves a minimum diameter due to contraction after 9 seconds. Obstructive apnea occurs when there is an airway blockage from a mucus plug, airway constriction, or the tongue falling backwards. In this case, despite the lack of airflow, respiratory effort continues. The neonate may also experience a loss of neuromuscular muscle tone and active glottic closure, which could cause the cessation of respiration (According to a lecture by Professor Lydic, lecture 10.11.10).

The real harm to the infant is the accompanying bradycardia (defined as a fall in heart rate) and oxygen saturation (SPO₂). These three physiological events, apnea, bradycardia, and decreased oxygen saturation, occur in a rapid temporal sequence. A bradycardia onset averaged 4.8 seconds after the apnea onset and 4.2 seconds after the SPO₂ fall (51).

Neonates also struggle to maintain lung volume, which contributes to the likelihood of apnea occurring. The relaxation of their lungs is as low as 10-15% of the total volume, which is very close to residual volume. In order to consistently keep lung volume higher than residual volume, neonates must breathe faster. The flexibility of their chest leads to visible chest recessions, which increases volume displacement. Prior to maturation, what should be largely pulmonary work is seen in a high amount of muscular diaphragmatic work for each breath. Also, a larger relative head size than adults creates more anatomical dead space, which increases the amount of work the infant must do to efficiently breathe. All of these factors increase caloric output and cause muscular fatigue, increasing the chance of apnea (51). An increased respiration rate can also be indicative of a serious problem, such as, an infection or fever that can cause sepsis and death within a matter of minutes.

Premature infants are particularly susceptible to injury due to oxidative stress. Fetal hemoglobin shows greater oxygen dissociation in order to compensate for constant hypoxic conditions. Theoretically, an infant begins production of adult hemoglobin immediately at birth because the environment is invariably hyperoxic. Hyperoxia, which is compounded by resuscitation or mechanical ventilation, can cause serious harm to the eyes, lungs, and brain in a neonate due to immature oxygen defenses (28).

A pediatrics clinical study emphasized the importance of sleep position on preventing respiratory failure. In particular, this study looks at learning and experience in prone sleeping as a potential major factor in development of motor skills necessary for airway protective behaviors. Therefore, it is beneficial for infants to practice prone sleep to increase ability for escape from asphyxiating sleep environments (50).

Some of these risk factors associated with sleep positioning include suffocation, choking, mucus plugs, and too much pressure on the chest.


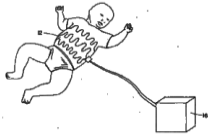


Mechanisms of Respiration Failure


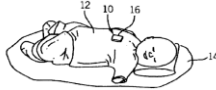
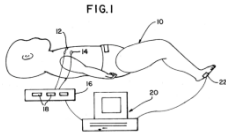
In order to assess different methods of detection, our team looked into the different physical manifestations of respiration failure. Hypoxemia is defined as decreased arterial P_{O_2} , which then leads to hypoxia, or decreased oxygen delivered to tissues. No oxygen is delivered to the brain, which can cause serious neurological deficit. In terms of motion, the chest often stops moving or slows movement. It may stop moving and have occasional jerking or gasping movements trying to compensate. There will be little or no airflow through the nose and mouth. Decreased oxygenated blood flow will decrease temperature to the extremities, which will lead to skin color change.

Technical Benchmark

Before continuing to define our own project, it was necessary to explore the current available products and concepts and assess the varying degrees of success and failure. Below is a summary of our findings that is representative of the varied approaches currently on the market. See Appendix A for a comprehensive list of available patents.

Table 1: Benchmark of related patents

Name of Device	Description	Obstacles	Price	Picture
RespiSense BUZZ Infant Breathing Monitor	Monitors movement of abdomen, attached to diaper	Exceeds target price, requires properly fitted clothing	USD\$136	
SIDS Detection Apparatus and Methods	Transilluminated optic fiber is connected to an elastic band, requires additional device to measure light intensity	Too many complex and expensive parts, may not fit all infants	Patent phase	
Nanny Baby Breathe Monitor	Pressure sensor pad to detect chest movement	Exceeds target price, assumes one infant per crib, only fits full size crib	USD\$200	
Wireless Doppler Crib Monitor	Doppler monitor attached to crib to constantly detect infant movement	Assumes one infant per crib, potential harm to infant	Prototype phase	

Smart Monitor 2 Infant Apnea Monitor	Cardio respiratory event tracking and oximeter interface	Greatly exceeds target price	USD\$4238	
Accelerometer-based infant movement monitor/alarm	Accelerometer attached to tight clothing, uses light and sound to wake infant	Requires properly fitted clothes, lacks method for tactile stimulation of infant	Patent phase	
Vibrotactile Stimulator System for Detecting and Interrupting Apnea in Infants	Contains a multi-sensing monitor and a vibrating mechanism on the extremities of infant	Too many components could lead high cost and difficulty of use, difficult to interpret signal output	Patent phase	

The major disqualifying factor in the majority of current patents and devices is cost. With such a high patient volume, it is neither practical nor cost-effective to invest in so many units if the price per unit is unreasonable. Even if the hospital were to have available funding (which KATH does), there is a tendency to prioritize bigger ticket items, such as new surgical tables. A monitoring device must be inexpensive enough that purchase of many units is not a large financial burden.

Many of the motion-sensing devices we found, such as the RespiSense BUZZ Infant Breathing monitor, have attachment mechanisms that require clothing. We cannot assume that infants in this setting will be wearing any clothing or diaper. During our observations, many neonates were loosely wrapped or covered in a blanket or sheet, completely naked, or wearing a diaper far too large. The accelerometer-based infant movement monitor/alarm is good because of its simplicity, but is also limited by its attachment mechanism. The last major movement sensing concept is the Nanny Baby Breathe monitor, which is a highly sensitive pressure pad that is placed under the infant in the crib. There are several problems with this design for a setting like KATH. First, there are often up to three babies in one crib, which would completely delegitimize this design. We also found that this specific design is so sensitive to movement that it recommends nothing within the immediate vicinity of the crib, and to limit airflow in the room, neither of which are possible at KATH.

The non motion-sensing designs include the SIDS Detection Apparatus, which is a complex fiber optic band that is constantly attached to the baby's chest. One shortcoming of this design is that it requires another device to measure light intensity, which creates too many separate components. Doppler ultrasound is another effective monitoring method, but we are concerned about the health risks of exposing a premature infant to constant radiation over a period of time because a small amount of Doppler radiation will cause a significant increase in core temperature of bone (59). It is also relatively expensive technology to be implemented for so many individual cases. Although the Smart Monitor shown above contains all desired functions, its price makes it unreasonable to implement. It was also recently recalled for a failure to detect a problem. The Vibrotactile Stimulator system is an incredibly interesting design because it includes automatic tactile stimulation to the infant to terminate an apneic

attack. Many healthcare providers at KATH and literature on infant sleep apnea discuss that tactile stimulation is enough to arouse the infant to resume normal breathing pattern. The bottom of the foot is a common location for stimulation, and length of stimulation before spontaneous breathing recommences is case-specific (42). Nurses often physically rub the entire body down at birth in order to maximize the physical stimulation of the infant’s nervous system, but a small shake or flick is often adequate as well. Automatic stimulation would further save attendants time and energy and increase efficiency in a high dependency nursery. This specific device is currently in patent stages and not on the market. It may have too much exposed circuitry and too complicated of an interface for ideal implementation.

DESIGN SPECIFICATIONS

Generating User Requirements

After finalizing a needs statement, our team identified potential stakeholders. These stakeholders include both the end users, such as, the doctors and nurses and the individuals that would be in charge of purchasing the device, such as the hospital administrators. Also, the biomedical engineers were identified as stakeholders because they would be responsible for maintaining the device. These are the people we targeted when identifying our user requirements.

Table 2: Survey Distribution Analysis

Position in Hospital	Number Surveyed
Doctors	20-30
Nurses	10-20
Midwives	8-12
Biomedical Technicians	3
Hospital Administrators	2

To generate a list of user requirements, each member of our team conducted informal interviews with all of our identified stakeholders besides mothers and neonatal infants over a period of several days. Given our position in the hospital, we did not feel it would be appropriate to conduct patient interviews with mothers. Neonatal infants were not interviewed due to lack of speech capacity. Cultural and language barriers prevented us from standardizing the interview process, but we attempted to follow a similar protocol with every stakeholder in order to minimize bias.

In the interviews, we presented a hypothetical device that would help assist with infant respiration abnormalities. We gave this device no initial shape or function. We then asked our stakeholders what qualities and characteristics such a device must have, what it should look like, and what it should do. We made every effort to not infuse our own design ideas or expectations into the interviews. From the

input, we each generated a list of user requirements based on customer demands. Our group then consolidated our individual lists to create our preliminary list of user requirements. This gave the team a large list of many different user requirements from many different individuals. This was an advantage because the team felt that the chance of missing a user requirement was low, but the list that was generated may have been too large. A list so large is difficult to accurately rank order. In addition compiling the list from each individual team members' list allowed requirements that had been possibly only mentioned by one individual to be mixed in with requirements that had been mentioned by almost every individual.

Subsequently, we determined the relative importance of each requirement based on our stakeholder's inputs. To do this, we created a survey using a 5 point Likert scale (Appendix F). The Likert scale seemed to be appropriate for our needs because we were attempting to figure out if the surveyed people agreed with the user requirements that had been obtained. Our team also wanted to figure out the extent to which they agreed that this was a necessary quality of the device. In this survey, we asked our stakeholders to rank the importance of each user requirement from 1 – 5, with 1 being least important and 5 being most important. Additionally, we left room for any additional user requirements that we had overlooked while generating our preliminary list. Finally, we included an additional section at the end of the survey in which we asked the participant to rank a list of 5 vital signs most important to monitoring or measuring respiration (Appendix F).

Approximately thirty surveys were filled out and returned to us from various stakeholders throughout the hospital. Throughout the process several changes were made to our survey as we gathered feedback. For example, the user requirement "small shape" was altered to say "portable" and the additional requirement of "durable" was added. Also, several specific user requirements such as "fast to attach/detach" and "easy to attach/detach" were consolidated into a more general user requirement of "easy to use". The revised surveys were then given out and added to our existing data.

Survey Limitations

We acknowledge that our survey has several limitations. When using a 5 point Likert scale, the mean of the responses generally tends to be shifted toward the higher end of the scale, especially when dealing with a medical device. Many health care workers will not view any potential feature as "least important" or "less important" and will rank every user requirement as a 3 or above. We tried to address this issue by giving detailed explanations of the survey to all participants about using the whole scale. However, a few of the surveys returned to us were marked all 4's or all 5's. We did not include these surveys in our data analysis. This is because responses like this indicate either a misunderstanding of the survey or a lack of critical thinking in the responses.

Additionally, our surveys were subject to interviewer bias. When passing out our surveys, we gave detailed instructions and answered questions as needed. Although we administered a uniform survey, each participant was subject to slightly different instructions that could elicit different responses. This introduces an interviewer bias to our survey.

We also believe we may have introduced other bias to our responses. We attempted to make our user requirements as clear as possible. However, requirements were not well understood and needed to be clarified for our survey participants. After hearing additional explanation for a user requirement we noticed our participants almost always gave the user requirement a ranking of 4 or 5. In these cases, the same amount of explanation was not given to every user requirement, and this introduced a bias in the responses. For example, the user requirement “locally sustainable” often required additional explanation, and this requirement was ranked surprisingly high. This is why this user requirement has been eliminated from our list of user requirements.

If given the opportunity the team would conduct another survey. This survey would have the person being surveyed rank the user requirements in order. This would make the person being surveyed choose which user requirements were absolutely necessary and would also make him or her choose which user requirements were not as important. A survey that made the individual rank the requirements would give a much larger range of scores for each requirement and make the results more conclusive. Also, the team would be more specific with who was surveyed. More people within the pediatrics department would be surveyed. Fewer students and doctors in other departments would be surveyed.

Due to these limitations and biases, we will use some engineering judgment when determining our final ranking of user requirements. To assist in this we performed error analysis on our rankings which is discussed in the following section. Although the rankings will primarily be based on feedback, we may alter some rankings as we see fit, as long as they are within a 2σ range provided by our statistical analysis.

Statistical Analysis

To generate a ranked list of user requirements based on importance, we calculated a weighted mean of the survey responses for each requirement. To do this, we assigned a weight to each person interviewed based on their position in the hospital and how relevant we thought they were to the scope of our project. The weight assignments are shown in the Table 3 below.

Table 3: Weight given to various positions of people interviewed in KATH used for calculating weighted averages

Position in KATH	Weight	Number Surveyed
MBU Doctor, Head MBU Nurse	5	5
MBU Nurse	4	1
OB/GYN Doctor, Head OB/GYN Nurse, BME Staff	3	10
Ob/GYN Nurses, Midwives	2	5
Medical/Nursing Students, Family Planning Nurses	1	6

Based on these criteria we calculated a weighted mean of our responses. With this we generated a ranked list of user requirements (see: Table 4). A graph of the weighted means for each user requirement is shown in (See Appendix B). We also calculated a standard error (σ) of the mean based on the standard deviation of the survey results. The standard deviation (STD) was calculated for each

user requirement. To calculate the standard error of the mean we used Equation (1) shown below, where N is the number of people surveyed.

$$\sigma = \frac{STD}{\sqrt{N}} \quad \text{Eq (1)}$$

We included a 2σ error range for each of our user requirements. As discussed in the “Survey Limitations” section, this error comes various biases introduced by our survey. We will use this analysis to help us refine our user requirements before starting concept generation.

Analysis of Design Specifications

Table 4: User Requirements and Engineering Specifications

RANK	USER REQUIREMENT	DESIGN SPECIFICATION DESCRIPTION	QUANTIFICATION
1	Notifies health practitioners of problems effectively	Time taken to inform nurse (s) after occurrence of respiratory abnormality	15 seconds
		Maximum distance from unit for successful notification (m)	15 meters
		Frequency of false negatives (occurrences/hour)	< Once per day
2	Safe to use	Maximum current in contact with skin	<1mA
		Pressure/force on infant (g)	<125 grams
3	Low maintenance (including operational)	MTBF (months)	3 months
4	Easy to Use	Percentage of people that can successfully operate/interpret device (% total attendants)	95%
		Training required to successfully operate device (days)	1 day
5	Easy/Fast to Attach and Initialize	Number of people required to attach (# people)	1 person
		Number of steps to attach (# steps)	<3 steps
		Total attachment/initialization time (min)	<2 minutes
6	Inexpensive	Cost per unit (USD\$)	\$40.00 -\$70.00
		Recurrent cost (USD\$/year)	\$5/year

		Number of people required to detach (# people)	1 person
7	Easy/Fast to Detach	Number of steps to detach (# steps)	<3 steps
		Total detachment time from infant (min)	<.5 minutes
		Total detachment time from crib/surroundings	<2 minutes
8	Easy to Clean	Time to clean (min)	<2 min(if not autoclave)
		Volume (m ³)	5000 cm ³
9	Compact	Surface area (m ²)	1080 cm ²
		Overall weight of device (kg)	<3 kg
		Intensity of sound disturbance (dB) *	70-80dB
10	No excessive disturbance of surroundings	Frequency of false positives (occurrences/hour)	One occurrence per 24 hours
		Overall operational time (years)	>6 years
11	Durable	Drop height (m)	>1.5 m
		Functional temperature range	60-130°F
		Functional Humidity Range	0-100%
		Range of average infant chest circumference from 28 weeks to 42 weeks gestational age	10" – 17"
		Range of average infant body length from 28 weeks to 42 weeks gestational age	17.8" – 20.2"
12	Broad Spectrum of Application	Range of average infant abdomen circumference from 28 weeks to 42 weeks gestational age	9.5" – 13.2"

Notifies health practitioners of problems effectively: It is necessary that our device function properly. It must fulfill its fundamental role to detect respiration abnormalities and alert healthcare providers. We define a “false negative” as no detected abnormality when one did actually occur. During our interviews at KATH, we asked what the maximum number of times such a device could miss a problem in a day before they threw it out. We received responses as varied as 3-4 times per day, 2 times a day in the entire room, and that it should occur as little as possible. Apnea monitors in the United States, especially home apnea monitors, require a more strict set of standards. The FDA released a warning about accuracy, warning users that missed problems do occasionally happen. On the other hand, the Respironics, Inc. SmartMonitor 2 Infant Apnea Monitor was recently forced to recall 5,000 devices due to one potentially failed alarm, though the warning light was still functioning properly (according to the FDA website). Due to the absolute importance of this specification, we will aim for <1 false negative per day, which will allow for a minimal amount of error due to improper use.

The standard benchmark amount of time an infant can be without oxygen before requiring resuscitation efforts is 20 seconds. The Vibrotactile Stimulator System for Detecting and Interrupting Apnea in Infants also cites 20 seconds as the lag time before alarming (42). Our mentors in Ghana decided on 15 seconds as an adequate lag time. As long as this specification is less than 20 seconds, we believe that it is more beneficial to be conservative here in order to account for longer attendant reaction time in the MBU or other crowded facilities.

The device needs to be able to effectively send an alert to a certain distance away. This could be achieved with a loud enough sound, a command center-like signal output board, or a wireless pager system. Either way, we measured minimum distance from unit for successful notification based on the dimensions of the high dependency ward in the MBU, though we realize this will only be specific to KATH. Based on these dimensions and consensus from surveys and interviews with the MBU nurses, 13 m is appropriate.

Safe to use: Multiple sources have identified 1mA as the threshold of human perception of current. In order for the device to be considered safe, the component in contact with the infant's skin must not exceed this current.

We will need to be very sensitive to the amount of physical force that is on the baby. Obviously, no testing exists to find the limits of this, but pediatricians were able to estimate that approximately 125g would be safe and not cause any negative effects to the baby or hinder breathing. This is a specification that we will need to be as conservative with as possible, and there is no lower range to what would be acceptable.

Low maintenance: All devices will inevitably require maintenance. This can range from replacing batteries or light bulbs to replacing or repairing larger components of the device. The estimated time that a device can operate before requiring maintenance is commonly expressed as the Mean Time Before Failure (MTBF). Both the RespiSense Buzz Infant Monitor and the Nanny Baby Breath Monitor advertise an average battery life of 6 months (45, 54) This is the limiting factor for the MTBF of these devices. However, these devices are designed to be used in the home and would only operate when the infant is sleeping, which is generally about half of the day. Our device will likely be designed for nearly use continuous use in a hospital setting. Because the device will be in operation twice as much, its expected battery life can reasonably be expected to be half, which is approximately three months.

Easy to use: Due to the high volume of infants, the pervasive lack of time, and the various medical backgrounds of the MBU personnel, it is necessary to have a device that is easy to operate and interpret. Ease of use implies transparency in the device's functionality and an intuitive user interface, and limited training required to operate the device. Throughout KATH we observed very expensive and complex monitoring equipment that had been donated to the hospital. Some health care workers avoided using some of this equipment because the information it displayed was difficult to interpret. No matter how accurate a monitoring device is, it is essentially useless if it can't be operated by the hospital staff and we aim to avoid this problem. Ideally, 100% of health care workers should be able to operate a device if it is being used in a hospital setting after they are trained. However, for the purposes of our design specifications, we would consider a value of 95% and above successful. We can test this by performing

subject testing with the device and determining the percentage of health care workers that can successfully operate and interpret the device.

Additionally, we must consider the training time required to successfully operate the device. While in KATH, we had the opportunity to observe the introduction of a new laparoscopic surgical device to the hospital. This device was donated by a hospital in the US and designed to assist doctors with invasive surgery. There was a two day intensive training course to teach the surgeons in KATH how to operate this device. We project that our device will be much simpler and less invasive than a surgical device and should therefore require less training. The health care workers we surveyed almost unanimously indicated that a standard training time for a device intended to be used by all the health care workers is 1 day. This would include instruction, demonstration, and supervised practice on how to use the device. Therefore our goal for training time required to successfully operate the device is one day.

Easy and fast to attach/initialize: The MBU at KATH had a high volume of patients, with new infants arriving and departing every day. If the health care workers can attach the device without additional assistance and in a short amount of time, they can have more time to attend to other patients. Due to the high patient volume and limited amount of staff we observed at KATH, it is clear that this device should not require more than one person to attach and initialize. We are aiming to better prioritize the health care workers time with this device and it is unreasonable for more than one person to be required for attachment.

The feedback from our surveys indicated that time taken for attachment should not exceed 4.5 minutes. Due to the time constraints we witnessed at KATH we believe this number is unreasonably high. We are attempting to refine this number by pursuing additional feedback from our stakeholders in Ghana and are currently awaiting results. The RespiSense Buzz Monitor takes less than 30 seconds to attach to the infant (54). The Nanny Baby Breath Monitor initially can take up to 5 minutes to initialize, because the device needs to be placed properly under the infant mattress and attached to crib (45). However, once the device is set up, the baby simply needs to be placed in the crib in order for the device to function.

The number of steps required to attach this device is also important, because many steps can make the process more complex. However, their team found little to no information explicitly describing the amount of steps that is desirable for attachment of a device. Several devices for developing settings were explained by Mainsaw and these devices all required around 3 steps for full attachment and installation (39). We believe 3 steps is a reasonable target value for steps required to attach.

Inexpensive: While cost is usually an important driver for any device design, it becomes even more important when designing for a low-resource setting. We aim to create a device that is as low-cost as possible. However, we still need to set a reasonable target for the maximum cost of this device. While in KATH, we observed that funding for medical devices, though quite inconsistent and sometimes limited, does exist. After meeting with the business manager of OB/GYN and procurement of KATH we discovered there is a contingency fund that can afford emergencies of up to USD\$5,000 or USD\$6,000. Greater amounts of money can be available to purchase a device from the yearly budget if there is significant advance notice and pressure from the clinicians. Other stakeholders in the hospital estimated an affordable cost to be around USD\$70 per device. Our team assumes KATH to be representative of many major referral hospitals in a developing country.

Literature review revealed a wide range of costs for medical devices. The least expensive benchmark we found was the Buzz Infant respiratory monitor, which can be sold for as low as USD\$135. We need to design a device that is less expensive than this. J. Wyatt (2008) showed that perinatal devices costing around USD\$30 and below showed the most successful implementation in developing settings (79). Other studies showed examples of devices costing between USD\$100-USD\$200 as being effective (39). From market research and benchmarking, we found that similar medical devices being used in developed settings can cost anywhere between USD\$130 and USD\$4250. A device for a developing setting should be cheaper than this. Taking all of this information into consideration, we have developed a maximum cost target between USD\$40 – USD\$70 for our device.

We must also consider the recurring costs when discussing the cost of this device. Our stakeholders at KATH could provide us with limited information regarding maintenance costs. They indicated that there is little to no budget allotment dedicated to yearly device maintenance. In his research regarding the cost of medical devices, J. Wyatt also discovered that if the yearly maintenance of a device exceeded USD\$5 (approximately the cost of replacing a few light bulbs), this device was very unlikely to have continued use. Therefore we will target no more than USD\$5 for yearly predictable maintenance cost for our device.

Easy and fast to detach: As previously discussed, the MBU at KATH has a high daily patient flow rate. Our respiratory monitoring device may need to be attached or removed from the infant. Additionally, mothers of the premature infants nurse every one to three hours depending on the health of baby. The infants need to be removed to allow for breastfeeding. If the infant is attached to a monitoring device, it should be easy and quick to detach to save time for the health care workers and allow mothers, who are bound to have little or no experience with medical devices, to detach the device in order to comfortably nurse. Ease and speed of detachment is also important in situations where the infant needs critical medical attention. Just as with the attachment of this device, it is clear that only one person should be required to detach or remove this device. We are aiming to better prioritize the health care workers time with this device and it is unreasonable for more than one person to be required for detachment.

Our stakeholders' feedback indicated device should not take more than 2 minutes to detach. However, we recognize 2 minutes may not be acceptable in an emergency situation if the device needs to be removed from an infant in order to provide medical attention. From our benchmarking we found that existing devices take no more than 30 seconds to fully remove from the infant, and we believe our target value should be no greater than this (45,54)

We considered the desirable amount of steps required to remove this device in very similar fashion to the number of steps needed to attach the device. Based on the same considerations, we believe 3 steps is a reasonable target value for steps required to detach (39).

Easy to clean: Although this requirement was not a part of our first round of surveys, we found that almost all the health practitioners in the MBU wanted a device that would easy to clean due to the time constraints they faced every day. Devices in KATH can be cleaned in different ways. Some devices are cleaned directly by health care workers after use, while others are sent to the autoclave for full sterilization after each use. If our device is made to be sterilized in an autoclave, the time to clean

depends heavily upon the autoclaving procedures and availability at each specific hospital, and is not in our control. However, many stakeholders at KATH indicated they would prefer a device that they could clean without sending it to the autoclave. When we surveyed our stakeholders specifying that the device would not be able to be sterilized with the autoclave, they indicated that the device should take no more than 1 minute to manually clean. Our benchmarking showed that a non invasive device if cleaned with bleach could be cleaned in sixty seconds (58). We believe 1 minute of cleaning time is a reasonable target, provided that our device will not be sterilized in the autoclave.

Compact: Due to the limited amount of space we observed in the MBU, this device needs to be compact. The dimensions of the cribs used in KATH were approximately 70 X 40 X 20 cm. As previously mentioned, there were at times up to three infants occupying one crib. The device must be designed with these spatial constraints in mind as multiple infants within the same crib may require monitoring. Our users at KATH indicated the device should be in total no larger than 5000 cm³. This number was determined by allowing users to identify other devices in the room as a basis for comparison. Additionally, health care workers or mothers may be required to frequently move the device the device from infant to infant several times a day, so the device needs to be light. Feedback from our users in KATH indicated the device should be less 3 kg. The mass of any component directly touching the infant must be less as a safety precaution and is discussed with the design specifications regarding safety. The weights of some existing bedside monitoring devices, such as the Phillips SureSigns VM1 Portable monitor, are less than 2 kg. We believe 3kg is a very conservative design specification, and this number will serve as an absolute maximum value for device mass.

No excessive disturbance of surroundings: The alerting system included on this monitoring device must be substantial enough to get the attention of the healthcare workers, while also limiting the disturbance to the other infants and health care workers in the MBU. Our users at KATH indicated that if our alarm has an auditory component, the volume should be approximately that of a cell phone ringer or a loud baby's cry. The specific cell phone model our users referred to was a Samsung E1410, which has a maximum ringtone volume of approximately 82 dB according to the manufacturer's specifications .

Research has shown the ambient noise of a typical neonatal intensive care unit in the US has been found to range from 56-72 dB (64), It has also been determined that sounds of volume greater than 90dB can be harmful to an infant (64). Additionally, extended exposure to sound pressure levels higher than 80 dB can be potentially harmful or psychologically disturbing to a developing infant (11). The sound of the alarm should be at or above the ambient room noise in order to be heard, but quiet enough so that it creates limited disturbance or harm to the infants. Because of this, we believe the volume of the alerting system should be around 80dB.

Additionally, the device should produce a limited number of false alarms. False alarms can create unnecessary work and disturbance for health care workers. Our users in the MBU at KATH suggested that if any one device produced more than one false alarm per day, they may become frustrated and cease use. Current respiration devices on the market claim to have a very low occurrence of false alarms but do not specify a frequency at which they may occur. To satisfy our users, the device should produce a false alarm no more than once per day.

Durable: In general, devices that have a long operational life are preferred, and from our observations we identified that this is important to the users at KATH. To achieve this, a device must be soundly manufactured and also tough enough to endure daily wear and tear. Many users at KATH informed us that due to the chaotic nature of a hospital, it is important that a device can withstand the impact of being dropped on a tiled floor. Because this device is likely to be used in and around cribs, it must be able to withstand being dropped from the crib height. The drop height specified by our users was 5 ft, or about 1.5 meters. The cribs in the MBU were measured at a height of less than 4ft, and a product search revealed no crib with a maximum height greater than 4.5ft, therefore we believe our device should be robust enough to withstand the impact of a 5ft drop on a hard surface.

Additionally, the device must remain functional in all climate extremes. Studies have shown that the ideal temperature for a NICU is between 72 and 78 degrees Fahrenheit (78). However, according to the National Climactic data center and the Weather Almanac, temperatures of over 120 degrees Fahrenheit, though rare, have been observed on every continent. In the settings we observed in Ghana air conditioning was not present; therefore, the device needs to be able to operate in the entire range of temperatures that the region experiences. Temperatures below 60 degrees Fahrenheit become very dangerous for the infant and this environment will not be maintained in the MBU (77). This device should remain operational over the range of 60-120 degrees Fahrenheit.

Most respiratory devices commonly used in developed countries have a two year warranty (45, 54). However, these devices are designed for home use and in many cases are no longer used after the baby is over 2 years old. We believe because our device is designed for use in a hospital, and also a low resource setting, it should have a significantly greater operational life. From our user feedback in KATH, we determined a device should have a six year minimum lifetime.

Broad spectrum of application: For the monitor to have widespread usefulness, it should be applicable to infants of most sizes. Premature infants can vary in weight and size depending on their gestational age. This device should be applicable to a wide size range of babies of varying gestational ages. It has been shown that a fetus can become viable at as little as 28 weeks gestational age (8). Therefore our device should be applicable to infants from this time until 3-4 weeks after birth, which is the age at which an infant is no longer considered “newborn”. Based on infant growth studies, both in utero and post-partum done by the American Family Physician organization (AFP) as well as the Center for Disease Control (CDC), we have developed relevant ranges for a number of key size characteristics of infants including head size, chest size, length, and weight, and lung maturity from 28 – 44 weeks gestational age. Depending on the exact form of our device, it will be required to meet any number of these ranges.

The chest average chest circumference for infants from 28-44 weeks gestational age ranges between 10” – 17”. The infant body length ranges from 17.8” – 20.2”, and the abdomen circumference ranges from 9.5” – 13.5”. Our device must be made size adjustable to fit all of these ranges.

CONCEPT GENERATION

Brainstorming Methodology

Rather than attempting to begin brainstorming full concepts, we first broke our device down into functional, independent component processes. We believed that they should be considered separately in order to objectively evaluate different ideas. Eventually, each separate component would be combined to create a full device.

We created a list of potential functions our device may have, and divided these into primary and secondary functions. The primary functions are the most basic functions absolutely necessary for the device to perform its required function. The secondary functions, while still important, are functions needed to help the device perform its primary functions. Once we had established this list, we brainstormed ways of approaching each individual function.

We began brainstorming using our basic understanding of respiration, our existing knowledge of monitoring, literature review, and benchmarking. The purpose of this brainstorming session was to generate a list of general strategies and methods to address each component of the device. All ideas were considered at this point and we did not narrow our list based on our concepts of feasibility. As our team proposed ideas, they were recorded on a chalkboard for future discussion. A record of these lists can be seen in Appendix G.

From our peer feedback and our own discussion we highlighted ideas from our first brainstorming session that we believed were the most effective and feasible. We also incorporated new ideas given to us from peer feedback. Moving forward with our brainstorming, we again focused on the primary functions of the device rather than the secondary functions and considered each function independently. During this brainstorming session, we attempted to move from general methods of approaching each component to rudimentary concept designs. Each member of our team individually created multiple comprehensive concepts using ideas from our first brainstorm and presented them to the team.

Functional Decomposition

Based on the components of our theoretical device, we created a process flow diagram in order to better understand the exact mechanism of what we were going to design. A complete function decomposition diagram can be seen in Appendix G.

Primary Functions

Detection: The first primary function of our device is detection. In order to monitor any respiratory abnormality, our device must be able to detect it. To begin brainstorming, we considered all physical outputs created or affected by respiration. We developed a basic understanding of the physiological mechanism of respiration from the Costanzo Physiology textbook (17) to assist in our brainstorming. Additionally, we began by considering the five basic human senses and tried to incorporate ways each of these senses could be used for detection. We generated a list of possible approaches to detect infant respiratory abnormalities using these strategies. Our initial list is located in Appendix G.

Alarming: The second primary function we identified was to alarm health care workers after an abnormality is detected. This is obviously of vital importance to the function of any monitoring device. We began this brainstorming session similarly to how we brainstormed for detection. All five senses were considered for possible ways to capture the attention of a health care worker in the event of a problem. We generated ideas using audio, visual, and tactile feedback to alert the health care providers.

The processing component used to convert feedback from the detection component of our device into a usable signal to initiate an alarming device had not been discussed at this point in our project. Specific processor selection is discussed in the electrical components analysis.

Secondary Functions

Attachment to crib/baby: Regardless of how we approach this problem, the device will need to be attached to the crib, infant, or MBU in some way. We brainstormed for all possible situations. We recognize that this component of our device may be dependent on how we choose to address the detection or alarming component. However, we still wished to evaluate each method independently so we could take this information into account when developing a full device.

Physical stimulation: Much of our research indicates that in the case of respiratory failure, specifically sleep apnea, tactile stimulation can be an effective means of restoring breathing in an infant. Depending on the form of our device, we believe it is possible that it could automatically perform this function. In the MBU at KATH, we observed doctors stimulating infants by flicking the sensitive bottoms of their feet. The Vibrotactile Stimulator System for Detecting and Interrupting Apnea in Infants included in our benchmarking uses physical stimulation as a primary means of addressing sleep apnea (12). At this point in our design we are still deciding if it is feasible to include a mechanism like this in our device. It was necessary that we brainstorm and evaluate all possible methods of doing this to consider how we could incorporate this into our device.

Power Sources: In order to perform its primary functions, our device will need some source of energy. Given that this design is for the developing world, it is not certain whether an electrical connection or use of batteries will be our best option to address this. We generated a list of potential ways to supply our device with power. Again, the type of power which the device requires is very dependent on how it functions, but we felt it was important to consider power sources independently.

We presented our ideas from brainstorming to our peers in ME 450 on September 28, 2010. To better illustrate some of our ideas, we created some rudimentary concepts to include in our presentation. We gathered and recorded feedback from the class and incorporated this into our next brainstorming session.

Categories for Detection

Eighteen complete concepts were created for detection using many of our initial strategies developed from brainstorming session one. We combined, modified, and discarded many of these initial designs to narrow our concepts into a more focused list. In this portion of the text, we will only include the concepts that were considered in the next step in our narrowing process, which was a Pugh chart. Each device is organized by the strategy for detection it encompasses. However, all designs are included in Appendix G.

Chest Movement:

Design 1: Accelerometer/Strain Gauge on Chest: The first design consists of an accelerometer or strain gauge that is applied directly to the infant's chest to detect the expansion and contraction associated

with breathing. It would operate similarly to the RespiSense Buzz Infant Monitor (54). However, it would be directly attached to the infant's body rather than to a diaper or article of clothing. In our initial concept generation, both an accelerometer and a strain gauge were able to do this, and at this point we view these components as interchangeable based on function. The component applied directly to the chest or abdomen would be able to detect movement. The component would be wired to an alerting device attached to the side of the crib. The signal created by the accelerometer/strain gauge would be amplified and used to initiate the alerting system when cessation of breathing is detected for a set period of time. This device could potentially detect respiration rate as well. This device would likely be simpler and less expensive than the BUZZ monitor. However, our team would need to consider a safe and reliable way to attach a component directly to the infant. Brainstorming of attachment mechanisms can be seen in Appendix G.

Design 2: Pressure Sensor Pouch: This design was inspired by the Embrace Infant Warmer, a successful infant incubating device designed for the developing world (16). The infant would be placed in a pouch made of soft material with force transducers embedded into it. Breathing would be detected by the change in force exerted in the pouch underneath the infant, similar to the Nanny Baby Breath Monitor (45). However this device would not be placed under that mattress and would be able to detect the respiration of one infant even if there are several infants occupying the same crib, provided the force transducers could be designed with the right sensitivity. This device could potentially measure both the cessation of breathing as well as respiration rate.

Design 3: Strain Gauge Belt: The strain gauge belt concept would include a size adjustable belt made of an elastic material. The belt would be fitted securely around the infant's chest or abdomen and would stretch with the expansion and contraction of the lungs. A strain gauge would be attached to the elastic belt and detect this expansion, and send a signal to the alerting component of the device attached to the crib. This device could potentially measure both the cessation of breathing as well as respiration rate. During the initial concept generation, the elastic belt concept came up several times, and different approaches of detecting the expansion and contraction were proposed, but we believed a strain gauge was the most feasible. Force transducers would run into problems with sensitivity; sensitive enough to detect movement and it is likely to pick up noise from surroundings. The accelerometer is similar in application and function to the strain gauge, but is generally more expensive. This belt is similar to design one, but circumvents the need for attaching the device directly to the infant.

Design 4: Sonar Motion Sensing This design involves using sonar to detect chest displacement. One component would be placed on the infant's back or beneath the mattress, while another would be placed on the infant's chest. The components would communicate with each other using sonar, and the distance between the two components could be continually measured. When the distance between the devices remains constant for a pre-determined period of time, the alerting system would be initiated. This device could potentially measure both the cessation of breathing as well as respiration rate. However, it would very important that different devices would not communicate with each other if used in close proximity.

Airflow through nose and mouth:

Design 5: Nostril Airflow Meter: Several concepts were generated intending to measure in some way the airflow from the nose or mouth created by breathing. Measuring pressure, flow rate, and temperature were considered. This design consists of a flow meter being placed in or around the infant's nose or mouth. When the infant is breathing, an airflow, or change in airflow could be detected. When the airflow is no longer detected, the alerting system would be initiated. For this device to work, a method of attachment would need to be used that did not in any way inhibit the infant's breathing. Also, some infants may breathe through the nose while others may use their mouths. Finally, a device attached around the mouth or nose could interfere with oxygen therapy or resuscitation. These are all challenges that will need to be considered with this design.

Design 6: Glass Condensation Beam: The glass condensation beam device takes advantage of the saturated water vapor present exhaled breath, which is referred to exhaled breath condensate (EBC). This method is used a noninvasive way to investigate the lungs and involves the cooling of exhaled breath (20). This device consists of a glass tube with a funnel to direct exhaled air into the tube. A beam of light is passed through the glass tube into a light receptor on the other side, similar to the mechanism used in many garage doors. When exhaled breath is funneled into the glass tube, water vapor will condense on the glass walls and interfere with the beam of light. When the beam of light is no longer being interfered with, this will indicate lack of exhaled breath, and the alerting system will be initiated. This device would be used to measure presence or lack of breathing.

Discoloration of Body:

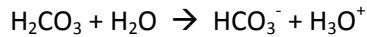
Design 7: Lip Color Gauge: This device would monitor the skin discoloration in certain areas of an infant's body in order to identify respiratory abnormalities. As previously mentioned, in KATH we observed that when an infant stopped breathing, its lips and palms would change color due to lack of oxygen. This would happen very quickly after the onset of respiratory failure. This, in fact, was one of the common ways health care workers in KATH would identify respiratory abnormalities. This device would have a component that emits and absorbs light that would be placed on the infant's lip, palm, or other region that rapidly changes color in the event of respiratory failure. It would reflect light off the skin and absorb it, to determine the color content. The device would be attached and "nulled" to provide the baseline for healthy skin color, because not all infants will have the same skin color during normal respiration. Once the detected color content varies from the baseline, the alerting system would be initiated. Since this device could potentially be attached around the mouth, it is important that it does not inhibit respiration in any way, similar to design 5.

Chemical Changes:

Design 8: CO₂ Output Monitor: This design also monitors respiration by measuring exhaled breath. Since carbon dioxide (CO₂) is a component of exhaled breath, its chemical properties can be used to identify the presence of exhaled breath, specifically, its behavior when exposed to water (H₂O). Loerting outlines the reaction of CO₂ with water in his paper "Aqueous Carbonic Acid (38). CO₂ reacts with water to produce carbonic acid (H₂CO₃) in the following reaction:



In excess of water, carbonic acid will then react with water to create bicarbonate (HCO_3^-) and hydronium (H_3O^+) ions in the following reaction.



The presence of H_3O^+ acidifies the water which can be detected by pH indicators. In this design, exhaled breath will be funneled and captured and allowed to react with water. In the presence of breathing, the water will be made acidic by the aforementioned chemical reaction. When respiration stops, the water will become less acidic. The pH of the water will be monitored by a universal indicator that changes color based on pH level which can be observed by the health care workers.

Change in Body Temperature:

Design 9: Thermocouple: This design makes use of a thermocouple to detect a difference in temperature on a baby's body. When there is a temperature drop in the extremities, for example, the difference creates a voltage, which can then be read by a microprocessor. This design requires us to look at a baby's skin sensitivity to ambient temperature in the room.

IV.6 Categories for Alerting Our team generated 6 concepts for the alerting component of our device. This is the component that would be used to notify the health care workers of a respiratory abnormality once signaled by the detection component of our device. The concepts use a mix of audio, visual, and tactile stimulation used to capture the health care workers' attention. We also considered both wired and wireless methods of notification. All concepts are listed in the following section. The final design will likely contain a combination of multiple alerting mechanisms.

Visual:

Our team explored several visual options when generating concepts for alarm systems. Visual feedback is effective because it is generally easy to interpret and does not contribute to noise pollution of the environment. However, for these concepts to be effective, the health care workers must be in the room and looking at the device in order to be notified. Notifications may go unnoticed if the health care worker is outside the room or not alert.

Design 1: Blinking Light on Crib: This concept would consist of a simple light bulb attached to the crib. In the case of a respiratory abnormality, the light will be activated and visible to the health care workers present in the room. The light would remain off during normal respiration.

In addition to the general pros and cons of visual feedback, this concept has another drawback. If the bulb is burnt out, or the device is not functioning correctly, this would be confused with normal respiration. The health care workers using this device would have no way of detecting a maintenance issue and this may contribute to false negatives.

Design 2: Red light/Green light on Crib: The red light/green light concept is similar to the blinking light on the crib, but has several important differences. The device would consist of a red and a green light attached to the crib. In the case of a respiratory abnormality, the red light would be activated. During normal respiration, the green light would be activated. If the device is off or not functioning properly, neither of the lights will be activated.

With this device, health care workers will be made aware to any maintenance issue when neither the red light nor green lights are activated. This would help prevent false negatives and call attention to a malfunctioning device as quickly as possible.

Design 3: Color Changing Material: The concept of a color changing material can be applied in several of our detection concepts. There are materials that change color at different temperatures (thermochromic), as well as materials that change color due to a chemical change such as pH level. Thermochromic materials are commonly used for commercial and industrial temperature indication. Many of these materials start at a base color and become colorless once a certain temperature threshold is reached (60). Based on respiratory feedback, the material will change color so the health care workers can be made aware of a respiratory abnormality.

This concept would likely not require electricity. This could be a major pro in many resource limited settings where the electricity supply is not reliable. However, this concept may not be as easy to interpret as the other visual concepts. Health care workers will need to know which color of the material is associated with normal respiration, and which color is associated with a respiratory abnormality. Additionally, adequate lighting must be present in order to see the material.

Audio:

We also considered several concepts that use audio stimulation. Audio stimulation is effective because it can catch the attention of a health care worker even if they are out of the room or cannot physically see the device. However, in a crowded room with several devices, it may be difficult to determine the exact source of the sound. Additionally, audio notification can contribute to noise pollution of the environment which can be harmful to infants and disturbing to health care workers.

Design 4: Bell: A bell is a simple, largely mechanical way to create an auditory alarm. A small motor can be activated and used to stimulate percussion within the bell.

The only electrical component of this concept would be the electric motor, and it would be a device that is easy to maintain and repair. However, this concept would not have an adjustable volume setting and it may be difficult to identify one volume that is suitable for all hospital settings.

Design 5: Speaker/Beeping mechanism: This device uses speakers to generate an alert sound to notify health care workers of a respiratory abnormality, similar to an alarm clock. This is the method used in most medical monitoring devices with an auditory alarm system. Both the RespiSense Buzz Infant Monitor and the Nanny Baby Breath Monitor use this method (45, 54). The noise created could be continuous or intermittent based on our design.

When using speakers, it is very easy to include adjustable volume control, which could be advantageous. This concept would have this added benefit.

Categories for Tactile Stimulation

We also explored the use of tactile stimulation as a method of alerting health care workers. The nurses would carry a small device with them that is similar to a pager that communicates remotely with the

detection device. In the case of a respiratory problem, the pager would be notified, and vibrate similar to the vibrate function of a cell phone.

This device would allow health care workers to be notified of problems even when they are not in range to detect any audio or visual feedback. However, in addition to just vibrating, the pager would need to direct the health care worker to the specific infant experiencing the problem, which may require another method of feedback in addition to the vibrotactile stimulation. Also this device would require wireless technology which is generally more complicated and expensive.

Central Monitor v. Individual Monitor

Our team also explored the idea of having one comprehensive central monitor to consolidate and display the feedback of all the respiratory detection devices in the room. The respiratory feedback for each device, and associated location in the room, would be displayed on one monitor or console. When there is a problem, the health care worker will be directed to the correct location.

This concept allows a health care worker to monitor the respiration of all infants from one central location, which has obvious advantages. As long as one health care worker is present, all infants can be monitored at the same time. However this technology requires extensive wireless integration and would be expensive, and may be beyond the scope of an ME 450 design project. When addressing the alerting component of our device, our own discussion and the class feedback was nearly unanimous.

CONCEPT SELECTION

After the team brainstorming sessions, there were fifteen concepts for detection and seven concepts for alarming systems. The team then focused on narrowing down these concepts. We began with the detection concepts, and used a star ranking system to evaluate each concept. Each team member assigned each of the fifteen ideas one, two, or three stars. One star indicated that this concept was not feasible and should not be further pursued. Two stars indicated that this idea had some potential but also had some potential drawbacks, and may not be one of the best ideas. Three stars indicated that this was one of the best ideas that should be strongly considered for the alpha design. We discussed our rankings and assigned final star values.

Table 5: Team star ratings

Concept	Number of Stars
Accelerometer/Strain Gauge	***
Pressure Sensor Pouch	***
Strain Gauge Belt	***
Distance Measuring Sonar	***
Nostril Flow Meter	**

Light Lip Color Gauge	**
Condensation Beam	**
Thermocouple	**
CO ₂ and Color Monitor	**
Air Balloon Pressure Belt	*
Pressure Sensor Belt	*
Nostril Windmill Sensor	*
Electric Field Inductor	*
Chest Sound Monitor	*
Whistle Sound Monitor	*

The ideas receiving only one star were removed from further consideration. The remaining 9 devices were discussed in the previous section. A Pugh chart was created for the 9 ideas receiving two or three stars. This was a method to evaluate how well each design addressed each of our user requirements. For each concept we assigned a +, -, or 0 for each user requirement, depending on how well we thought the concept met the requirement. We also weighted each user requirement with either a 2 or a 1, based on which requirements we considered “necessary features”, and which requirements we considered “luxury” features. A numerical analysis of the Pugh Chart data can be seen in Appendix H.

Table 6: Pugh Chart of Concepts

Design Criteria	Weight	Accelerometer/Strain gauge	Pressure Sensor Pouch	Strain Gauge Belt	Suction Electrode Displacement Monitor	Nostril Airflow Meter	Light Lip Color Gauge	Glass Condensation Beam	Thermocouple	CO ₂ Output Monitor
Number of stars		3	3	3	3	2	2	2	2	2
Notifies health care workers effectively	2	+	+	+	0	-	0	0	-	0
Safe to use	2	-	+	0	-	0	+	-	+	+
Locally sustainable	2	0	0	+	-	0	-	0	+	-
Low Maintenance	2	0	-	-	-	-	0	0	+	+
Easy to Use	2	+	+	-	+	+	+	+	0	+
Easy/Fast to Attach	2	+	+	-	-	-	-	0	-	0
Easy/Fast to Detach	2	+	+	+	+	+	+	+	+	+
Inexpensive	2	+	+	+	0	+	-	-	+	0
Easy to Clean	1	0	-	-	+	-	-	+	-	-
Compact	1	+	+	+	+	+	+	+	+	+
No excessive disturbance of surroundings	1	+	+	+	-	0	-	-	-	0
Durable	1	+	-	-	0	-	-	-	0	-
Broad spectrum of application	1	+	+	+	+	+	+	+	+	+

Eliminated designs (scoring 1 star)

- Air pressure balloon belt
- Pressure sensor belt
- Nostril windmill sensor
- Suction electrode displacement monitor
- Electric field inductor to measure chest displacement
- Chest acoustics monitor
- Whistle sound monitor

The top five designs suggested from the Pugh chart scores were the accelerometer/strain gauge, the pressure sensor pouch, the strain gauge belt, the thermocouple, and the CO₂ output monitor. The Pugh chart method was helpful in forcing us to relate our concepts back to our user requirements, but was limited in that it was a complex analysis of somewhat subjective opinions, which in the end did not account for all variables. We eliminated the thermocouple after further research which showed that in order to measure body temperature with a thermocouple the only way to get accurate measurements is by measuring the body temperature in the mouth and/or rectally (74). We also felt that the accelerometer/strain gauge, though yielding a high score, was incorporated into other designs. Therefore, our top 5 designs are shown below:

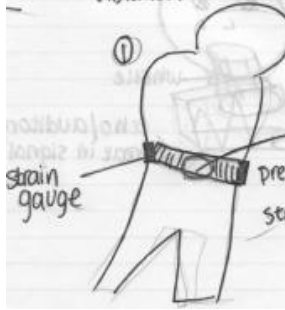


Figure 1: Strain Gauge Belt



Figure 3: Suction Electrode Displacement

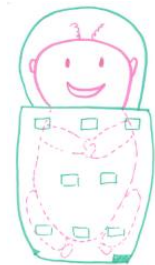


Figure 4: Pressure Sensor Pouch



Figure 2: Nostril Airflow Meter



Figure 5: CO₂ Output Monitor

The team then presented these ideas to the class to discuss feasibility and possible improvements of the ideas. The class was split up into five groups to discuss the five different designs and asked to write out their suggestions and criticisms on large sheets of paper that were placed on the wall. We then met to discuss each of the remaining concepts using the classes input and do an in-depth pros and cons analysis of our top 5 concepts.

The strain gauge belt has the benefit of sensitivity and accuracy in general. This will allow it to be very effective in detecting change in volume and frequency of chest movements. Chest movement is also a more direct form of measuring respiration and does not depend on a complex physiological process before a physical change is seen. Strain gauges are easy to acquire in country, which we know because we saw them, and the materials are very inexpensive. On the other hand, the properties of such a belt could change with fluctuating temperature and prolonged use. It also may be difficult to attach because

it would require locating the optimal attachment point where there is maximum chest movement. The high amount of motion in the MBU could also easily dislodge the belt.

We originally liked the idea of the suction electrode displacement monitor because its attachment mechanism is simple and familiar to hospital workers in almost all settings. Suction electrodes are widely used and easy to attach correctly. This device would be small, not require any cleaning if the electrodes were made to be disposable, and there would be no concern over fitting the baby. However, our greatest concern was that we could not agree on the best way to measure displacement. We considered sonar, which is expensive, but could not find information on how effective this would be or how safe it would be to constantly send a signal through the body. In a crowded space, like the MBU, there is also the possibility that these sensors might interact with each other, rendering them ineffective.

The CO₂ output monitor was one of the more creative ideas. A major bonus is that it may not require electricity because of its chemical detection properties, making the device low maintenance. It could also be easy to use if there is a good indicator that provides drastic color change (alternatively, a color gradient like a universal indicator would make it incredibly difficult to interpret), and safe because it is just a color monitor. This device may be difficult to effectively capture breath well, and difficult to clean due to the liquid and chemicals.

Measuring airflow through the nostrils was an intriguing concept because it would catch the broadest range of respiration failure, including obstructive apnea, which motion sensors might miss. However, we were concerned with the effectiveness in case the baby started breathing out of its mouth. The device would be easy to use because once it has been attached it requires no attention, there are not that many fixed parts so removal of the device would be quick and simple. Motion sensors are also inexpensive. Our concerns were that it may be difficult to attach because the sensor must be secure in the nose and it would have to be adhered to the face so that it does not slip off. Also, the life of the device and how often it needs maintenance is a negative because circuitry will be constantly in a moist environment and in contact with bodily fluids. Most importantly, a sensitive sensor may detect airflow from the room, which would render it completely ineffective.

The team thought that the last two ideas could be merged into one idea involving the positive aspects of both. The strain gauge belt and the pressure sensor pouch could be used in conjunction with one another to create one device. One of the concerns of the strain gauge was that it would be too easy for it to slip on or off of the baby. If it was connected to a pouch then it would be more likely to remain in place. The pressure sensor pouch may be too sensitive to surrounding stimulation, such as other babies in the crib, or other movement nearby. If the strain gauge was used in the pouch instead, then these sensitivity issues may be resolved because it is enclosed on the infant. This concept may still be difficult to clean because it has a larger surface area that is in contact with the infant's skin, so material selection would be critical. We would also have to consider the amount of pressure that the strain gauge would need to apply to the baby's chest in order to work. The strain gauge could also have the ability to monitor respiration rate and tidal volume instead of simply detecting the absence of breathing.

In order to determine which alarm system should be used to alert the health care staff the team created a pros and cons list for each of the nine design ideas that were brought up. This pros and cons list can

be seen in Appendix D. From this pros and cons list it was decided that an auditory alarm should be used with a light system in order to notify health workers. The auditory alarm may wake up other infants but it will be more time effective in notifying health care workers. The light system will help the health care workers quickly figure out which infant is having the problem.

CONCEPT DESCRIPTIONS

Alpha Design

Alpha Design Description: The alpha design we selected is a combination of the pressure pouch concept and the strain gauge belt concept. The strain gauge belt is integrated within the pouch to provide an additional method of monitoring the chest movement of the infant along with the method described for the pouch. The pressure pouch concept was originally designed to detect respiration using force transducers beneath the infant to detect chest movement. This is a very similar concept used by the Nanny Baby Breath Infant Monitor (45). However, extremely sensitive force transducers are required for this monitor, which may not be applicable to an environment in which multiple infants can occupy the same crib. At this point, we were unsure if we would be able to find force transducers of the right sensitivity to be effective or if we will be able to dampen outside vibrations to ensure the accuracy of the transducers. Therefore, we have also included the possibility of an elastic strain gauge belt if the force transducers are inadequate. One possibility for successful integration of the force transducers would be to insert a foam pad into the back of the pouch in order to dampen surrounding noise and increase accuracy of the sensors that would also be placed on the back of the pouch. The complete CAD model of the unfolded device is shown in Figure 1 below.

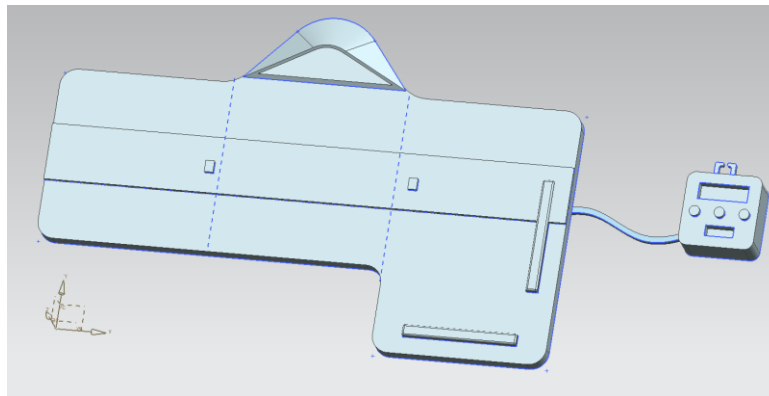


Figure 6: Preliminary CAD drawing of Alpha Design

The belt is attached to the interior of the pouch and tightened around the infant with the pouch as shown in the figure. It is also vertically adjustable in order to be in contact with the optimal location on different sized infants. We saw several advantages to including the belt within the pouch rather than by itself as described in the initial concept generation. First of all, the pouch will prevent the belt from twisting or repositioning on the infant's body and displacing the strain gauges. Additionally, we will not have to worry about the belt being placed over clothing, which could decrease the accuracy of the

device. We believe the strain gauge belt can be a very effective way to detect chest movements within the pouch.

The design can be broken up into the components seen in Figure 7 and Figure 8.

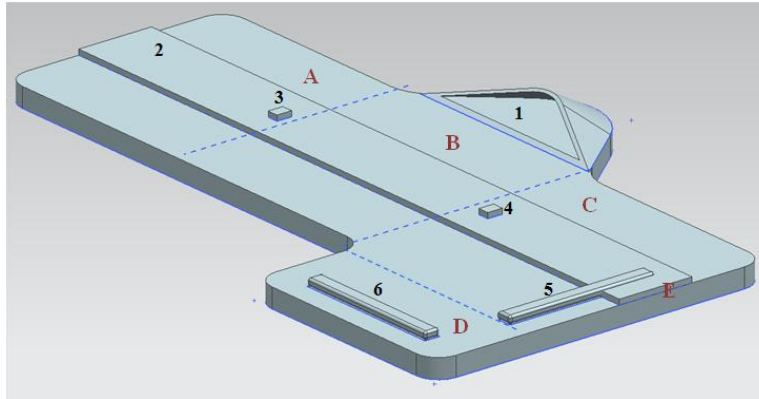


Figure 7: Unfolded View of Alpha Design with labeled Components

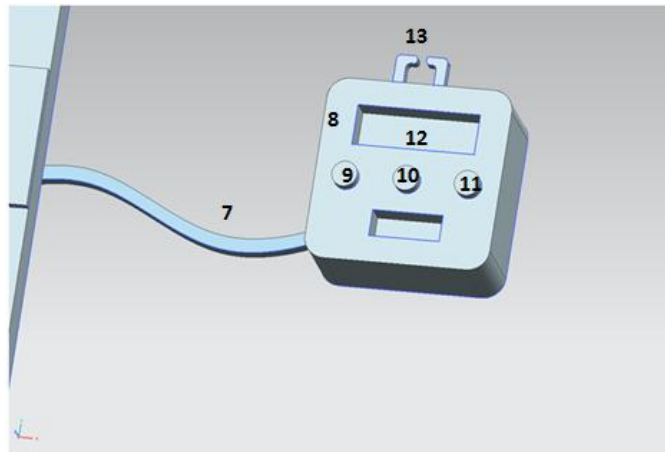


Figure 8: Wire and Monitoring Device with labeled Components

The parts listed are: 1 hood and head rest, 2 elastic belt, 3 and 4 strain gauges, 5 Velcro strip for size, 6 Velcro strip to close bottom, 7 connecting wires, 8 alarming system, 9 green light, 10 on off button, 11 red light, 12 respiration rate display, and 13 crib clamp.

Limitations of Alpha Design: After review of our alpha design mock-up and Design Review Two analysis, we acknowledged several major limitations of our alpha design. First and foremost, there is no support for the pouch component in our user requirements. What we originally viewed as a bonus of the design—that it may keep the infant warm—was not requested by our stakeholders, and so we had no background research on potential design specifications. It was unknown if this pouch is desired, would be used, or if it is culturally acceptable to limit the baby’s movement.

Additionally, it actually detracted from the accurate functioning of the monitoring system. When wrapping the infant doll in the pouch, we found it difficult to position the strain gauge belt precisely

around the infant's chest with its arms in the way. Our alpha design allowed for vertical adjustment of the belt on the pouch, which is time consuming and tedious thereby increasing attachment and detachment time. Further, the strain gauges were positioned on either side of the infant's chest, which would again be in the way of the arms.

Attaching the strain gauge to the pouch makes it more difficult to obtain an accurate reading because the belt would necessarily not be fastened as closely to the infant's chest as it would be without the pouch. If the belt were more detached from the pouch so that it could be tightened around the chest independently from tightening the pouch, as we considered for redesign, the pouch would be rendered completely useless. Moving forward, we redesigned the detection component to completely exclude the pouch. We decided that it added too much extra work to the fabrication and design process while detracting from the final product.

Beta (Final) Design

This section features the concept selected for our final design. This includes a high level description of for each functional subsystem, and how they interact. We identified concepts to address each of the primary and secondary functions identified in the concept generation phase. Also, an additional secondary function is required for this concept that was not previously identified. The device must also include a casing in order to enclose the device, protect the electrical components, provide an interface for the user, and maximize the safety of operation. This will be included as a secondary function below.

Primary Functions:

Detection: This concept uses a flexible sensor or strain gauge to detect respiratory abnormalities. The sensor is adhered to the infant's abdomen or chest in order to measure the movements associated with respiration. The movement of the sensor will correspond to the infant's breathing. A wire will connect the sensor to a voltage divider, in order to produce an analog signal that can provide necessary information about the breathing pattern to be analyzed by a microprocessing unit. The sensor attached to the infant's chest is shown in Figure 9 below.

Alarming: In the case of normal respiration, this concept activates a green light which remains on until an abnormality is detected or the device is turned off. If a respiratory abnormality is detected, the device alerts users of the problem by activating a red light and buzzer. This provides both a visual and audio means of alarming. If neither the red nor green lights are activated, this will indicate that the device is off or not functioning properly. The lights and buzzers will be attached directly to the microprocessing unit that is evaluating the respiration. The basic alerting mechanism is shown in Figure 10 below.



Figure 9: Flex sensor attached to baby

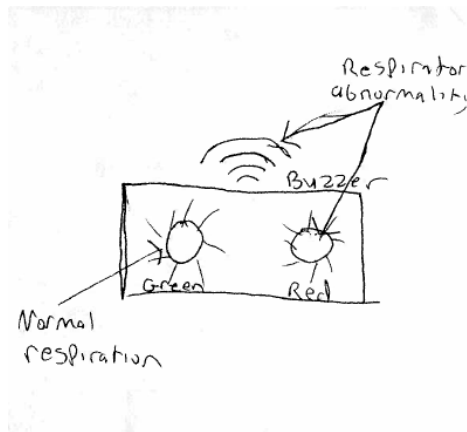


Figure 10: Preliminary sketch of monitor

Secondary Functions:

Attachment to Infant: To attach the flexible sensor or strain gauge to the infant, it will be encased in an elastic, water resistant slip-cover that has the same dimensions as the sensor. The slip cover has an adhesive portion on the bottom, similar to a Band-Aid, which can be safely and securely applied to the infant's chest or abdomen. The slip cover can remain attached to the infant while the sensor is removed from in if they must be temporarily detached from the device. The adhesive will be selected so that it will not harm the infant. This slip cover will also provide some protection to the sensor, and prevent direct contact of electrical components and the infant.

Casing: It has been indicated that this device will require several electrical components, including a microprocessor, red and green lights, and a buzzer. All of these parts are enclosed in a rectangular casing. The lights and buzzer are mounted in the surface of the casing to provide an interface to the user. There is also an on/off switch to activate the device. The casing provides protection to the components, provides a simple interface to the user, and limits the exposure of electrical components to the surroundings. It also allows the device to be easily transported. The casing is shown in Figure 11 below.

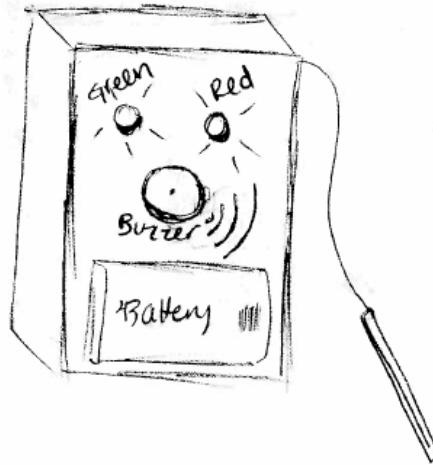


Figure 11: Preliminary Casing Sketch

Attachment to Crib: The casing can be attached to a crib by a clamping mechanism. The clamping mechanism is attached to the back of the casing, and can be tightened onto cribs of various sizes. The attachment of the clamp to the casing and to a crib is shown in Figure 12 and Figure 13 below.

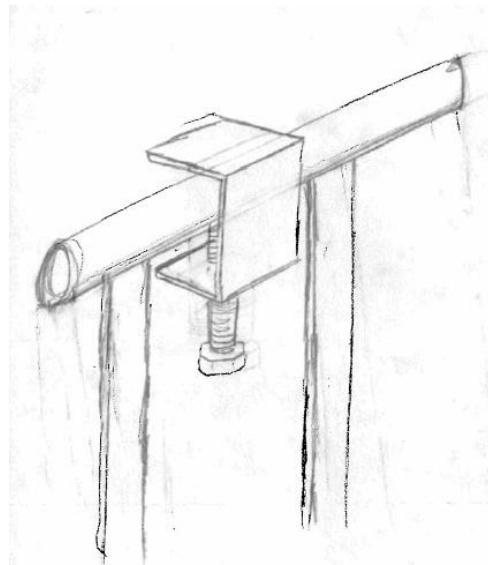


Figure 12: Clamp Attachment to Crib

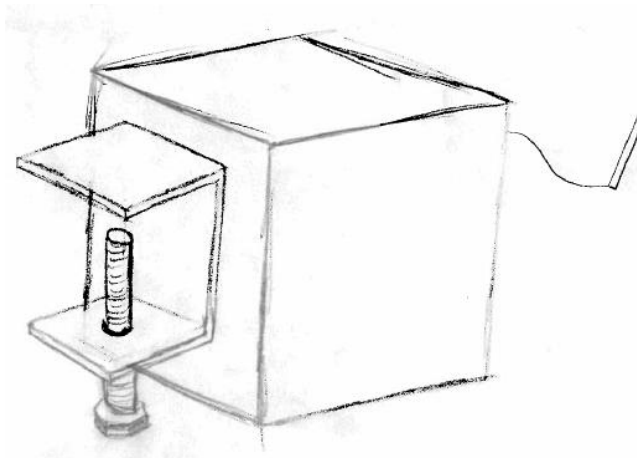


Figure 13: Clamp Attachment to Device

Power Sources: This concept contains multiple electrical components which will require a source of voltage in order to function. Power will be provided to the device by a rechargeable battery which is also enclosed in the casing. Constant connection to an AC power source is not feasible for this device. Each infant will require their own monitor, and each monitor will require power, and based on the high patient volume we observed in KATH there may be an inadequate supply of outlets. Therefore each device will be powered by a rechargeable battery, which will be included with the circuit inside the casing.

PARAMETER ANALYSIS

Heat Transfer

To determine the temperatures the many of the electrical components of this device will experience, we performed basic heat transfer analysis. This was to ensure the components would not be heated or cooled to temperatures where they are no longer functional, or could be potentially harmful to users. Heat transfer due to conduction and convection were considered using the following equations, where Q is the rate of heat transfer:

$$\text{Conduction: } Q_{\text{Conduction}} = k \times \text{Area} \times \Delta \text{Temperature} \quad \text{Eq (11)}$$

$$\text{Convection: } Q_{\text{Convection}} = h \times \text{Area} \times \Delta \text{Temperature} \quad \text{Eq (12)}$$

Appendix L has the complete calculations of the change temperature changes created by the circuit and strain gauge.

Moments

To begin with, when the monitor is clamped, it will experience a moment as shown in Figure 14 below. Figure 14 shows the dimensions of the monitor and the notions used in the equations in this section.

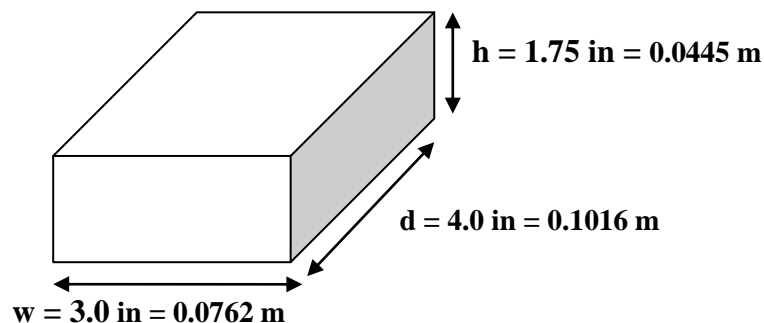


Figure 14: Dimensions of the monitoring box as used for material selection

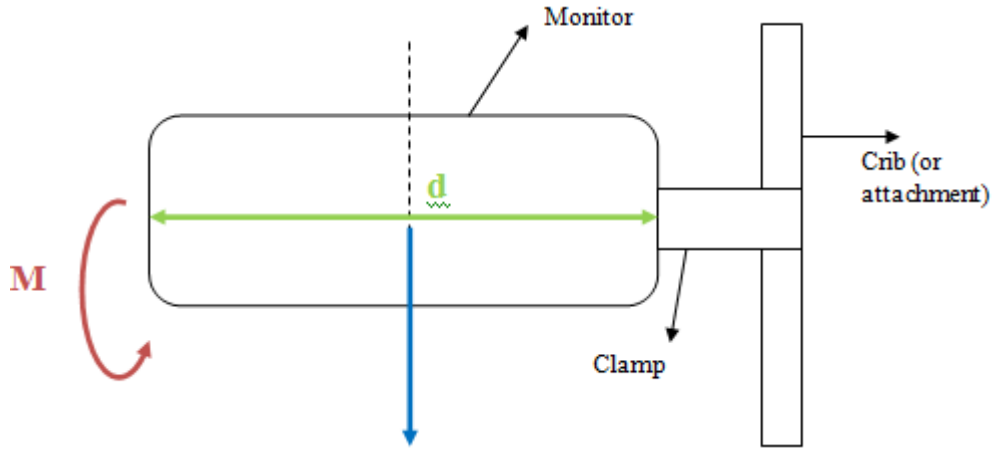


Figure 15: Moments experienced by the box

A moment is created when a force causes an object to rotate about a fixed point. The clamp fixes the body of the monitor to the crib (or any other section to the side of the infant). The weight of the monitor acting through the center of the device acts as the force, F , which would cause the rotation of the body. It acts midway through the length of the monitor giving a moment arm of $\frac{d}{2} = 2.025 \text{ in} = 0.0514 \text{ m}$. The total mass of device is given by,

$$m_{total} = (\rho_{PVC} \times V_{monitorBox}) + m_{microP} + m_{breadB} + m_{battery} + m_{clamp} + (m_{LED} + m_{buzzer} + m_{wires}) \quad \text{Eq (13)}$$

where

$$V_{monitorBox} = \text{Outer dimensions} - \text{Inner dimension} = (4.0 \times 3.0 \times 1.75) - (3.40 \times 2.40 \times 1.15) = 54.25 - 32.30 = 21.95 \text{ in}^3 = 359.65 \text{ cm}^3 \quad \text{Eq (14)}$$

$$\therefore m_{total} = \left(1.3 \frac{g}{\text{cm}^3} \times 359.65 \text{ cm}^3\right) + 31 \text{ g} + 300 \text{ g} + 45 \text{ g} + 500 \text{ g} + 60 \text{ g} = 1403 \text{ g} = 1.4 \text{ kg}$$

Thus the total force acting on the monitor is

$$F = m_{total} \times a = 1.4 \text{ kg} \times 9.81 \frac{\text{m}}{\text{s}^2} = 13.8 \text{ N} \quad \text{Eq (15)}$$

From this we get,

$$M = F \times \frac{d}{2} = 13.8 \text{ N} \times 0.0514 \text{ m} = 0.71 \text{ Nm} \quad \text{Eq (16)}$$

The moment produced on the monitor is very small. Additionally the moment of inertia I can be calculated by

$$I = \frac{1}{12} \times m_{total} \times (h^2 \times w^2) \quad \text{Eq (17)}$$

$$I = \frac{1}{12} \times 1.4 \text{ kg} \times (0.092^2 \text{ m}^2 \times 0.093^2 \text{ m}^2) = 8.54 \times 10^{-6} \text{ kg} \cdot \text{m}^2 \quad \text{Eq (18)}$$

Impact Force

Further, we have a requirement that the monitor should be able to withstand drops from about 1.5 m. Using energy equations we get

$$v^2 = v_0^2 + 2a(x - x_0) \quad \text{Eq (20)}$$

$$v^2 = 0 + 2 \cdot \left[-9.81 \left(\frac{\text{m}}{\text{s}^2} \right) \right] [0 - 1.5\text{m}] \quad \text{Eq (21)}$$

$$v^2 = 29.43 \frac{\text{m}^2}{\text{s}^2} \quad \text{Eq (22)}$$

where v is the final velocity. The time can be found using the following equations.

$$x - x_0 = v_0 t + \frac{1}{2} a t^2 \quad \text{Eq (23)}$$

$$-1.5 = 0 + \frac{1}{2} \cdot \left[-9.81 \left(\frac{\text{m}}{\text{s}^2} \right) \right] \cdot t^2 \quad \text{Eq (24)}$$

$$t = 0.31 \text{ s} \quad \text{Eq (25)}$$

With these values we can find the average force the monitor experiences when it hits the ground. The can be found using the formula for impulse, J , which is an instantaneous change in momentum, p .

$$-J = p_f - p_i = mv_f - mv_i = m\Delta v \text{ and } J = F_{avg} \Delta t \quad \text{Eq (26)}$$

In these equations, Δv is the instantaneous change in velocity when the monitor hit the ground and Δt is the time the monitor is in contact with the ground. Since we did not have the means to calculate Δt experimentally, we referred to the paper by Pouyet (53) to find an approximation of Δt for devices similar to the size of the monitor at about 28°C. We found Δt to be 0.000183 s. Therefore,

$$F_{avg} = \frac{\Delta m}{\Delta t} \Delta v \quad \text{Eq (27)}$$

$$F_{avg} = \frac{1.4 \times 5.42}{0.000183} = 41,464 \text{ N} \quad \text{Eq (28)}$$

Tensile Strength

The minimum ultimate tensile strength required of the material can be determined by calculating the maximum tensile stress and bending stress the material will experience. The maximum stresses will

occur in the clamp. The dimensions of the cross section of the clamp are 2.0 X 0.25", resulting in an area of 0.5 in². The tensile stress can be calculated using Equation (29), where σ is the stress, F is the force, and A is the area of the cross section.

$$\sigma = \frac{F}{A} \quad \text{Eq (29)}$$

The maximum force the device will experience is from the maximum allowable weight of the device, which is 3 kg, and a standard button pushing force, which is 2 KgF according to push buttons available on the market. Using these values, with a safety factor of 2, the maximum force is estimated to be 96 N. Using equation 29, the tensile stress is calculated to be .310 KPa.

The bending stress can be calculated using Equation (30) below, where M is the moment, I is the moment of inertia of the cross sectional area, and y is the distance from the horizontal axis .

$$\sigma = \frac{MI}{Y} \quad \text{Eq (30)}$$

The maximum moment has been calculated in previous sections and the moment of inertia has been calculated in previous sections. We also need to calculate the moment of inertia of a cross section of the clamp. This is done by Equation (31).

$$I = \frac{\text{Base*Height}^3}{3} \quad \text{Eq (31)}$$

Using Equations (30) and (31), the maximum bending stress was calculated to be 32.02 KPa. This is the maximum stress the clamp will experience.

Current

This device also has an electrical component that requires analysis. Voltages, currents, and power dissipations must be determined to ensure this device is safe and will not overheat. The basic methods of combining resistances were used to calculate the equivalent resistance of our circuit. These equations are shown below, where R represents resistance:

$$\text{Series: } R_{eq} = R_1 + R_2 + \dots R_n \quad \text{Eq (7)}$$

$$\text{Parallel: } 1/R_{eq} = 1/R_1 + 1/R_2 + \dots 1/R_n \quad \text{Eq (8)}$$

We also used the following equations to analyze our circuit:

$$\text{Voltage} = \text{Current} \times \text{Resistance} \quad \text{Eq (9)}$$

$$\text{Power} = \text{Current} \times \text{Voltage} \quad \text{Eq (10)}$$

Sampling

The microprocessor will convert a continuous analog signal into a discrete numeric sequence by sampling the data. If the microprocessor has a resolution of N bits, an input signal can be assigned a value from 0- 2^N.

The maximum expected frequencies expected are 100 breaths per minute, or 1.67 Hz (Poets). According to the Nyquist-Shannon Condition, the minimum rate at which this data must be sampled is two times this value, or 3.33 Hz. The sampling rate of our microprocessor is digitally set to be 10 Hz, which satisfies the Nyquist-Shannon condition.

The Nyquist-Shannon condition also specifies the use a cutoff frequency that is $\frac{1}{2}$ of the sampling rate to prevent aliasing of the signal. Aliasing occurs when different frequency signals become indistinguishable when sampled. With our sampling rate of 10 Hz, the Nyquist-Shannon condition specifies that we set our cutoff frequency at 5 Hz.

Materials Selection

Electrical Component Casing: Based on the values determined from the above analysis, we used CES software to determine the ideal material for the casing of the circuitry. Therefore, we will use Styrene Maleic Anhydride (SMA), a low cost plastic polymer that is the correct density and strength to support the weight of the internal components.

Flex Sensor Casing: Below are the top five requirements that our team identified as important for material selection.

1. **Flexible:** The device works because the flex sensor is bending as the chest moves. It is important to choose a material that is flexible in order to not interfere with the detection method of the sensor. A flexible material could encase the flex sensor without affecting the accuracy of the flex sensor.
2. **Inexpensive:** This material will be the disposable part of the device. If the device is designed for a low-resource, setting it is important that this part is inexpensive to allow for mass purchase.
3. **Breathable:** The material is surrounding the flex sensor, which is an electrical component that has current running through it. Though the flex sensor produces negligible heat, too much insulation could potentially create enough heat to interfere with the function of the flex sensor.
4. **Water resistant:** There is a high likelihood of contact with various fluids so it would be beneficial for the material to be water resistant in order to protect the sensor.

There is no comprehensive database for fabrics relating to engineering, so a general internet search was performed using the qualities described above. Searching flexible and breathable gave results including many sport fabrics. By adding in the water resistant quality a large list of rowing and biking fabrics appeared. The three fabrics listed below were the best three fabrics discovered in the search.

1. **Sport Nylon:** This is a slightly water resistant material that is very flexible and durable. It is often used for jackets, back packs or wind socks. This material is slightly breathable, but not as breathable as we would hope. This fabric can be purchased from most retail fabric stores for six dollars per yard (29).
2. **RESPIRA®:** This fabric is highly breathable as it is designed for rowing wear. It is extremely flexible because it is designed to move with the body with no extra effort. This is also water proof (18). The fabric is not inexpensive; it costs 25 dollars a yard (9).
3. **Supplex®:** This material is highly breathable. It was designed for athletic purposes so that the body has the ability to release heat. This also means that the material is flexible (18). This material is

fairly inexpensive and can be purchased from wholesale retailers for six dollars a yard (56). This fabric is also water resistant.

4. Nylon/Polyester Polyester: This material is thin, flexible, and elastic. It is also cheap, only costing about six dollars a yard. The material is breathable.

We decided that the Nylon/Polyester Polymer would be the best suited material for our purpose. It can be purchased at a reasonable price: only six dollars a yard. This material is thin making it breathable and allowing any heat from the electrical component to escape. It is also flexible and elastic, making it a good cover for a component that must easily feel the small movements of the infant.

Adhesive: Adhesive will be necessary to attach the disposable flex sensor slip cover to the infant's chest. We determined, with input from our interviews in Ghana, that the most important qualities of this adhesive material include being hypoallergenic and water resistant. An adhesive that can cause an allergic reaction is not safe for the infant, and healthcare providers in Ghana identified allergic reaction as the only adverse reaction they see to adhesives. In the humid environment the infant will sweat and the device needs to remain in place in order to accurately monitor respiration. Though we do not expect the slip cover to remain in place when completely submerged in water, like when the infant is bathed, it should be basically resistant to contact with some fluid. The team began with an overall search of medical adhesives. When manufactured theoretically in a plant, the adhesive will be continuous with the fabric, and likely painted on. However, for the purpose of this analysis, double sided tapes were most similar to our final design.

There are a wide variety of double-sided tapes made for use on the skin. 3M makes a large range of double sided tapes for medical purposes. The chart of these tapes and their properties can be seen in Appendix K. It was important for the tape to be both hypoallergenic and waterproof. This would allow it to remain in contact with the infant's skin for a prolonged period of time, and ensure that it would continue to hold the flex sensor in place even if the infant perspires or spits up. Another consideration is the infants comfort. The tape that is placed on the infant should be at least moderately comfortable.

The length wise tensile strength of the tape is about 4.5 oz/inch, which is about 803 grams/centimeter. Therefore, the tape will not rip if pulled on laterally. The typical adhesion of the tape is 25 oz/inch, or 1800 grams per centimeter. This is a large force required to break the adhesive qualities of the tape so the weight of the flex sensor will not cause the tape to fall off of the infant. It is manufactured by 3M and is called 1522 double-sided medical grade adhesive.

Summary of CES, SimaPro, and DesignSafe Results

First the team decided that the clamp and the box should be one large piece made out of the same material. Our material needed to be an insulator because it is used to enclose electrical components. It also needed to be resistant to weak alkali solutions because it will be washed with bleach. In addition to these qualitative traits, the density needed to be less than 0.8 in order to fit our design specifications and the tensile strength needed to be larger than 4.6 ksi in order to not break while in use. All of these traits combined, while continuing to maintain a low cost, lead us to determine that either polylactic acid, styrene maleic anhydride, and acrylonitrile butadiene styrene/poly vinyl chloride would be the best

material to construct the box and clamp. The full analysis of the material selection can be seen in appendix D.

We also used the SimaPro software to analyze the environmental impact of our top materials. polylactic acid, styrene maleic anhydride, and acrylonitrile butadiene styrene/poly vinyl chloride were all compared using the EI99 evaluation package included in the SimaPro software. The environmental impact of each material was calculated in three major categories, human health, ecosystem quality, and resources. The SimaPro software assigned each category a relative weight and provided a single score comparison. The results indicated that styrene maleic anhydride has the lowest negative environmental impact of our top three choices. This material was also compared against the fourth and fifth options suggested by the CES software and was determined to be more environmentally friendly than each of these as well. This analysis would support our selection of styrene maleic anhydride as our material for manufacturing the casing of the monitor. The full analysis by SimaPro can be seen in Appendix D.

Using DesignSafe, we were able to identify the key areas or 'hazard category' where there could be safety concerns with our device. These included aspects of the design related to mechanical and electrical components and also any additional aspects such as heat transfer, noise, and vibrations. Specific hazards were identified under each category applicable to the use of the device. The methods through which these hazards could potentially cause problems were described to gain a better understanding of how and when a problem could occur. Along with this, the severity and the probability of such a problem occurring were also evaluated. This gave a risk level for each problem. We then had to consider changes to the design that could be made to reduce these failures/problems from occurring and then evaluating if that would reduce the risk levels. Table D1 (in appendix D) shows that most design changes we considered and incorporated in our device reduced the risk level for each hazard to either low or negligible. The only area of 'medium' concern is the exposed strain gauge which could be problematic if the device is on and water is spilt on it. However, we did not consider any redesigns because the current flowing through the strain gauge is 0.23mA which is well below the skin's threshold to sense. In the off chance that someone holding the device was shocked, they would not feel any surge of current. Further, the device has a very distinct on off button and the green light indicating that the device is on should prevent the device from being left on unknowingly thereby saving such an accident.

DESIGN DESCRIPTION

The following section gives a detailed description of the final design for the infant monitoring system. It will be broken into the hardware and software, or programming, components of the device. It will then describe the differences between this design and the current prototype that we presented at Design Expo, and explain why these differences exist.

Hardware Components

Figure 16 below shows a labeled three dimensional drawing and an exploded view of our final design. Descriptions of each component will correspond to the number on this figure.

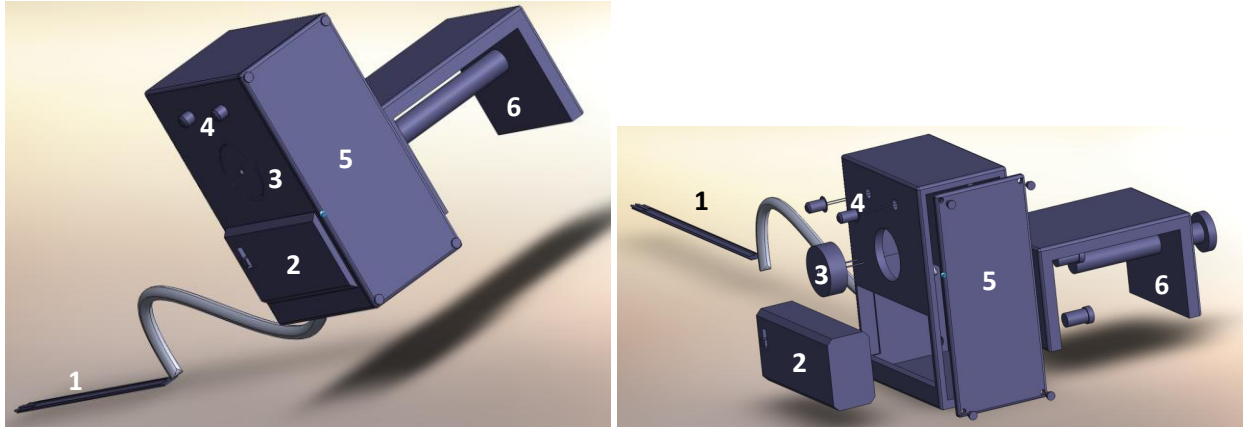


Figure 16: Image of the External Hardware Components of the Final Design

The images below are dimensioned drawings of the final design.

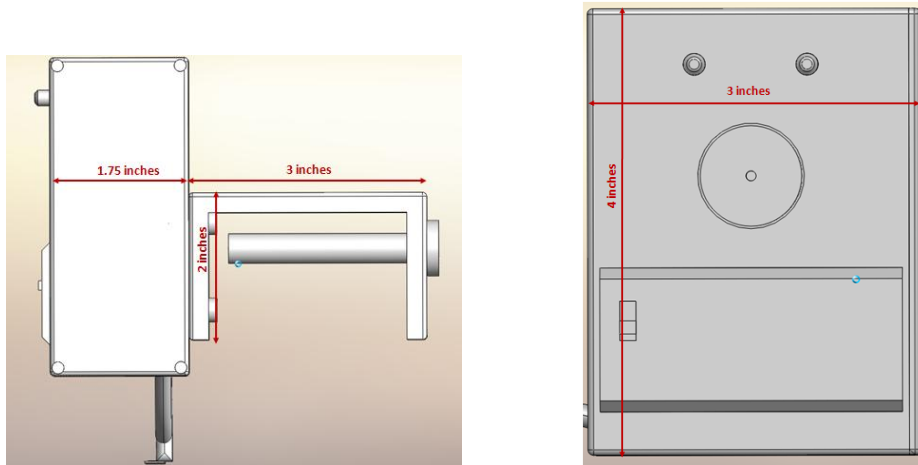


Figure 17: Dimensioned Drawings of External Hardware Components of the Final Design

1. **Disposable Slip-Cover:** The flex sensor will be encased in a thin, tight, disposable nylon/polyester polymer sheath. The slip cover is 5 inches by 0.5 inches in size, just large enough to cover the flex sensor and provide enough room to slip the flex sensor into it with ease. It has a slit on one side and an adhesive layer on the other so that it can be stuck to the infant's body, and left on for the entire duration of use. The adhesive is hypoallergenic and water resistant so that it does not harm the infant's skin and will not slip off its body. The material is sufficiently breathable to enclose the circuitry based on our calculations that the heat produced by the flex sensor is negligible.
2. **Battery Holder:** A simple 9V battery case is shown on the front face of the monitoring box. The case can be accessed from the exterior of the device in order to change the battery.
3. **Buzzer:** The Pro-Signal ABT-410-RC buzzer is press fit to the front of the box. This buzzer can provide an output of 80 dB, and can easily be soldered to the circuit.
4. **Red/Green LED:** The alerting mechanism includes a green LED to indicate normal respiration and a red light to indicate problematic respiration. The LEDs are press fit to the front of the monitor casing. The green light indicates proper functioning of the device; that is, it will indicate that the

device is in the process of monitoring the infant's respiration. The red light indicates that a respiration problem has been detected and it works in conjunction with the sound alarm.

5. **Casing:** The box is rectangular because the parts inside that are adhered to the sides of the casing are rectangular. The final dimensions of the casing are 3" width, 4" length, and 1.75" depth. This accounts for wall thickness of 0.1" and 0.25" tolerance. CES analysis determined that styrene maleic anhydride is the optimal material for the walls of the monitoring box.
6. **Clamp:** A styrene maleic anhydride C-clamp on the back of the monitoring box allows it to be firmly attached to a crib of any shape. The total length of the clamp is 3.0 in, allowing attachment to a majority of crib sizes.

The electrical circuit is a critical part of our design. A full schematic representation of the circuit is shown below, followed by detailed description of its components. The circuit will be constructed on a printed circuit board (PCB). The microprocessor will work in conjunction PCB. Including our circuit components on the PCB, the dimensions of creating such a circuit were estimated using the PCB123 software. Using preloaded components, the circuit was estimated to occupy a 1.5" by 1" area.

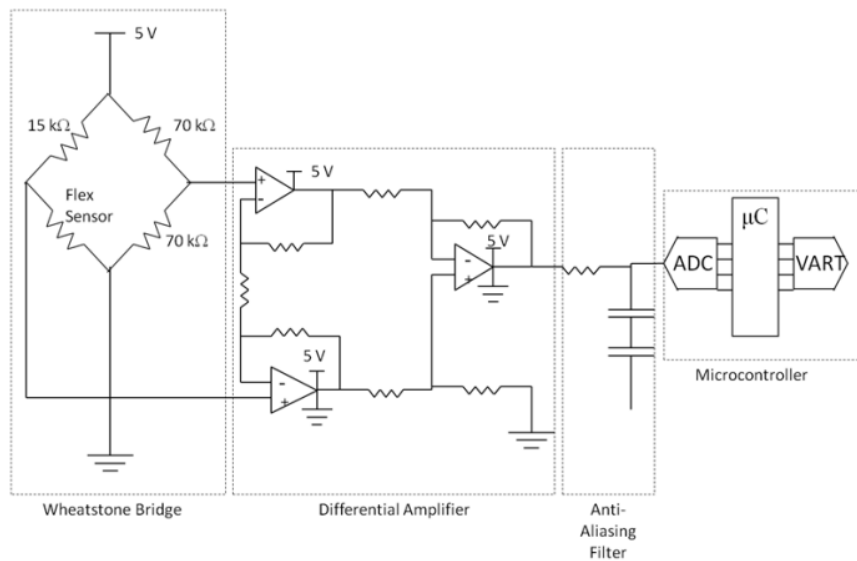


Figure 18: Complete Circuit Schematic

Analog Sensor: We selected the SEN-08606 Flex Sensor 4.5" as our analog sensor to detect infant respiration. This is a simple variable resistor that changes resistance as it is flexed. The sensor is designed to bend and flex physically with motion. The sensor is 4.5" in length. When the sensor is flat, the resistance is 10K ohms. When the sensor is flexed, the resistance can increase up to 110K ohms. It has a life cycle greater than 1 million and a functional temperature range from -35 C to 80 C.

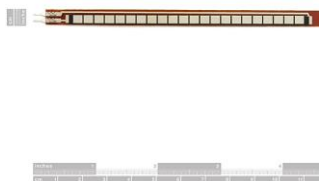


Figure 19: SEN-08606 Flex Sensor

This sensor has a very high range of resistance, which will create a larger change in resistance per degree the sensor is flexed and result in a larger output signal. This will make our output more sensitive. We also selected this sensor due to its 4.5" length. It will span across the entire infant chest and be more likely to always be in contact with a part of the chest that is moving. The length will also make contribute to the sensitivity of the device, making it better suited than other sensors to detect the small movements of the infant chest. This sensor is also functional well within in our desired temperature range, has a negligible signal to noise ratio, and can be used effectively in conjunction with the microprocessing board according to the manufacturer specifications. The full technical data sheet for the SEN-08606 can be found in Appendix K.

Wheatstone Bridge: We will make use our analog sensor by including it in a voltage divider to provide meaningful output. A basic voltage divider is made by arranging two resistors and measuring the voltage between them. This is shown in Figure 20 below, where R_1 and R_2 are resistors, V_{in} is the input voltage, and V_{out} is the voltage measurement between the resistors.

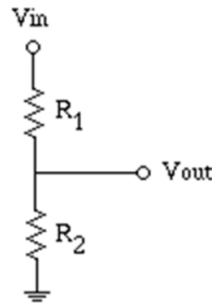


Figure 20: Simple Voltage Divider

The value of V_{out} is given by Equation 29.

$$V_{out} = \frac{R_2}{R_1 + R_2} V_{in} \quad \text{Eq (29)}$$

The analog sensor is used as one of the resistors in the voltage divider. If the value of V_{in} is known, and one of the resistors is also known and constant, then the value of V_{out} will change as the resistance of the analog sensor changes. R_1 will be replaced with Flex sensor ranging in resistance from 10 K Ω to 110 K Ω as it is flexed from 0 – 90 degrees. If R_2 is arbitrarily set to be 70 K Ω , and V_{in} is 5V, then the magnitude of V_{out} will range from 2V – 4.375V based on the degree of flex.

However, the movements we are measuring associated with infant respiration are very small. To estimate how much the flex sensor will actually bend when it is attached to an infant, we created a rough model of infant respiration. We used average data of chest circumference and expansion of the lungs for infants at 37 weeks gestational age (GA). We modeled the chest as an expanding circle. The average chest circumference for a 37 week GA infant is 15", the average lung volume is approximately 100ml, and the average tidal volume is approximately 15ml (2). As the lungs expand, the chest expands as well and the chest circumference increases. The flex sensor is attached directly to the chest and remains at a fixed length of 4.5", causing the angle at which it is flexed to change as the circumference, C , changes. The flex angle, θ , can be calculated with the following equation:

$$\theta = \frac{4.5}{C} \times 360^\circ \quad \text{Eq (30)}$$

This model is shown in Figure 21 below:

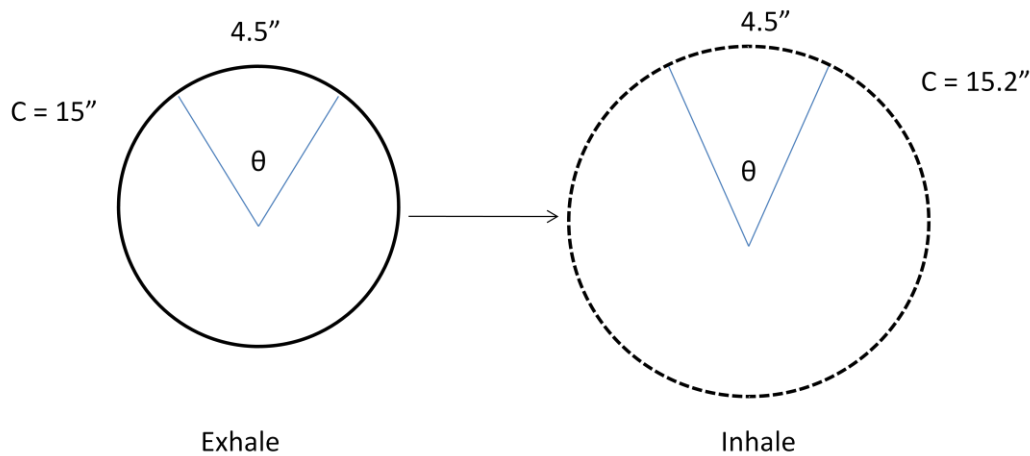


Figure 21: Model of infant chest expansion during normal respiration.

Using this model, we approximate that the change in the flex angle will be approximately 1.5° , which would result in a voltage change of .025V in our simple voltage divider model.

We acknowledge that this respiration model is a rough approximation. The true shape of an infant chest is not a perfect circle and is actually more of an ellipse. This would result in an even smaller change in flex angle of the sensor. This model also assumes a 1:1 correlation between lung expansion and chest expansion, which is not the case. Finally, this model uses data from infants at 37 weeks GA. This device will likely be used on infants at earlier gestational ages, which will have smaller tidal volumes and chest circumferences, resulting in a smaller flex angle. The true change in the flex angle will likely be even smaller than the value we approximated with this model.

However, this model was meant to be a rough estimation to determine if a simple voltage divider would be accurate enough to use in our circuit. From this model we determined that the output signal from these small movements will be hard to monitor, and the signal to the microprocessor is likely to appear as one constant value. A simple voltage divider is not ideal for our device.

A slightly more complex voltage divider is called a Wheatstone Bridge. This model consists of two simple voltage dividers wired in parallel. Voltages from each divider are then measured and compared. A basic schematic of a Wheatstone Bridge is shown in Figure 22 below:

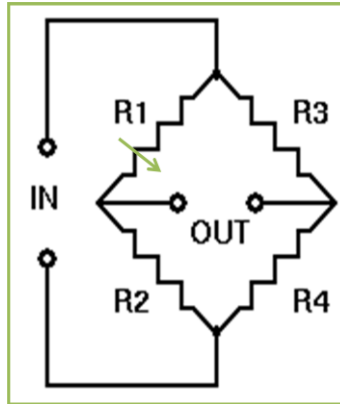
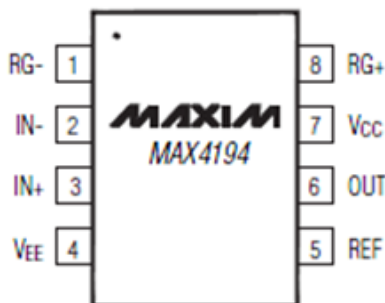


Figure 22: Wheatstone Bridge

R_3 and R_4 are fixed resistances, R_1 is a variable resistor, and R_2 is the flex sensor. The value of R_2 can be changed so that the difference in voltage of the point between R_1 and R_2 and the point between R_3 and R_4 is very close to zero for the initial position of the flex sensor. As the value of R_2 changes, a small voltage difference will be created between the two points. The small voltage difference can then be measured and amplified by a differential amplifier and input into the microprocessor. Therefore the estimated change of 0.025V could be amplified to 2.5V, and smaller outputs could be amplified to a greater degree. This would provide a more robust input signal for the microprocessor. Our final design will use a Wheatstone Bridge to measure the chest movement.

Resistors: Wheatstone Bridge described in the previous section requires several resistors. The resistors must be selected so that the voltage difference between the two nodes is close to zero when the flex sensor is in its initial position. The resistances must also be selected so that the current in the circuit is kept below potentially harmful values. Although the initial degree of flexion of the resistor will vary based on the size of the infant to which it is adhered, the resistances shown in Figure 2 were determined to give sufficient sensitivity to our device, and limit current to 0.23 mA.

Differential Amplifier: The Maxim 4194 variable gain is a differential amplifier that operates on input voltages ranging from +2.7 VDC – +7.5 VDC. The device takes two voltages as inputs and measures the difference voltage difference between them. The voltage difference is then amplified and is the output from the device. This amplifier will be connected to the Wheatstone bridge, with V_A and V_B as the input voltages (Figure 20). A schematic diagram of the Maxim 4194 is shown below along with a description of each terminal.



Pin	Name	Function
1,8	RG+/-	Connection for Gain-Setting Resistor
5	REF	Reference Voltage
2	IN-	Inverting Input
3	IN+	Noninverting Input
4	VEE	Negative Supply Voltage
6	OUT	Amplifier Output
7	VCC	Positive Supply Voltage

Figure 23: Schematic Diagram of Maxim 4194 Differential Amplifier with Pin Description

The output voltage and the gain of the device are given by the following equations:

$$V_{OUT} = (V_{IN+} - V_{IN-}) \cdot [(2 \cdot R_1) / R_G] + 1 \tag{Eq (31)}$$

$$\text{Gain} = 1 + 50k\Omega / R_G \tag{Eq (32)}$$

R_G is the value of a resistor placed between R_{G-} and R_{G+} . The gain can be manipulated by varying R_G to affect the magnitude of V_{OUT} . The output voltage needs to remain between 0V - 5V in order to be interpreted by our microprocessor. The exact value required for our gain will be determined as the prototype is built and analyzed.

We chose the Maxim 4194 for our device because it can operate with a 5VDC input, which is the voltage provided by our microprocessor. Additionally, the variable gain will allow us to have greater control of the magnitude of our output voltage. The full technical datasheet for the Maxim 4194 can be found in Appendix G.

Microprocessor:

The PICAXE 18 Pin Power Project Board is a very simple microprocessor board that can provide up to 5 analog inputs and up to 8 digital outputs rated at 800mA. The outputs can be easily wired to control motors or digital switches. The board requires a 3-5VDC power supply to operate, we we will power it with a 9V rechargeable battery. Connectors are not included in the board and must be soldered as needed. The dimensions of this board are 5.59 cm by 3.81 cm. An image and schematic of the PICAXE 18 Pin Project Board is shown in Figure 24 below.

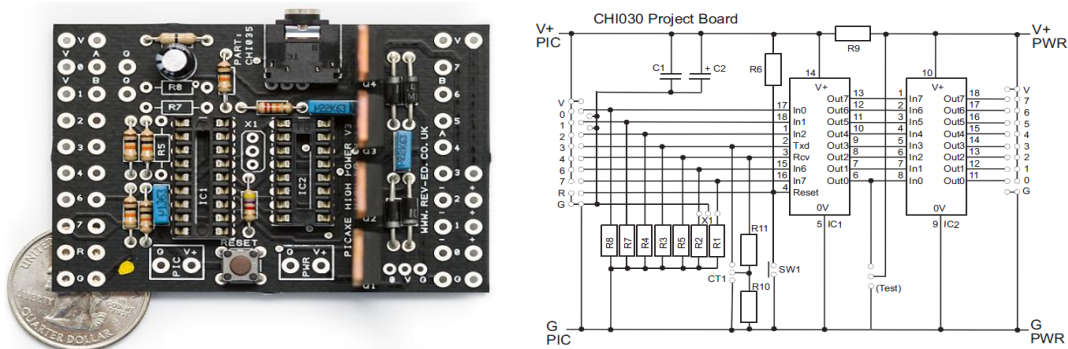


Figure 24: Image and schematic of PICAXE 18 Pin Project Board

Algorithm

The input data to the microprocessor during normal respiration is roughly sinusoidal, corresponding to the cyclic nature of breathing. The sampling frequency was digitally set at 10 Hz by the microprocessor. The cutoff frequency of the anti-aliasing filter was then selected to be 5 Hz based on the Nyquist-Shannon theorem. This was done in order to filter out potential error in the input signal due to high frequency noise.

A sample input signal of breathing at 40 breaths per minute attained from validation testing is shown in Figure 25 below. As previously stated, the microprocessor has a 10 bit resolution, meaning there are 2^{10} (1024) different values it can assign to an input signal. Because our input voltage is 5V, the input signal produced by the voltage divider will range between 0-5V. Therefore each unit increase of the input signal on the microprocessor corresponds to an increase of 5/1024 volts, and this is the value on the Y axis.

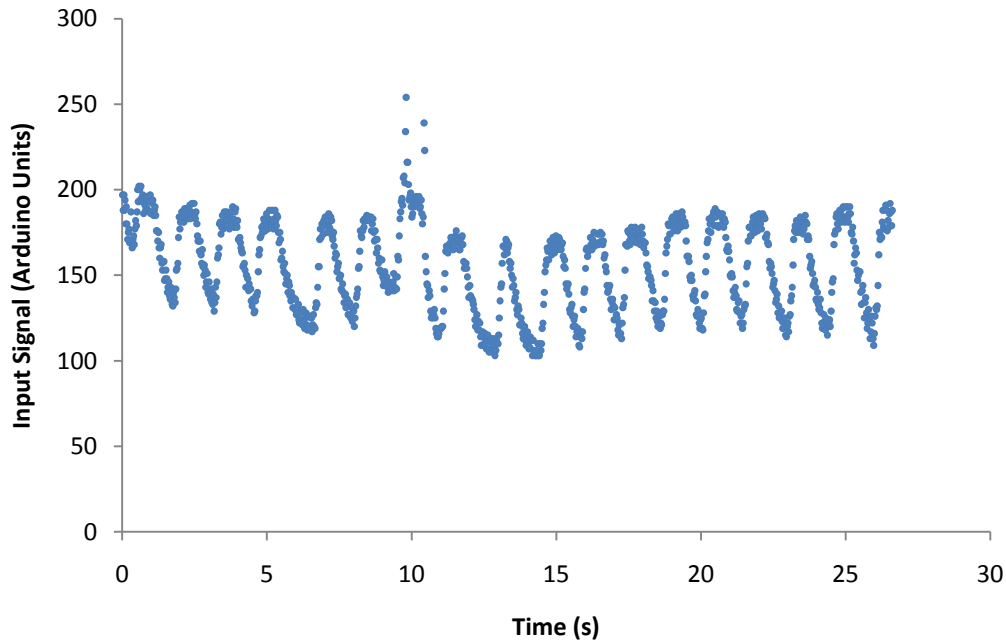


Figure 25: 30 second sample input signal to Arduino Microprocessor

After receiving the signal, the microprocessor must determine the amplitude and frequency in order to evaluate respiration. To do this, we developed an algorithm to extract all necessary information from the breathing signal.

Before creating our algorithm, we explored previous algorithms developed for similar applications. In 2009 A. Bates et al developed a device designed to continuously measure respiratory rate in adults using an accelerometer (4). In the algorithm, respiration was analyzed over discrete time windows, and the respiration rate was calculated by determining the number of qualifying breaths in the window and dividing by the window size. The window size used in this paper was 30 seconds. While developing a similar device to measure heart rate and respiratory rate, Chiarugi et al experimented with several different window sizes and determined their accuracy. Various window sizes from 20 – 80 seconds were tested, and all were shown to have less than a 1.6% error in measured respiratory rate (14). Additionally, they did not discover a strong correlation between window size and accuracy of the measured signal.

Our algorithm also uses discrete windows of time to evaluate respiratory rate. There are two simultaneous windows being evaluated in this algorithm. The first of these is a 15 second window used to determine the respiratory rate. Based on the data presented by Chiarugi et al, we believe a 15

second window can consistently provide accurate measurements of respiration. We selected a smaller window size than those evaluated in their paper because we intend for our device to notify of a respiratory abnormality within approximately 15 seconds, and therefore respiration must be evaluated at most every 15 seconds. Before respiratory rate is evaluated, there is a 5 second calibration period to determine the approximate midline of the input signal. It is important that this calibration period is performed over a period of regular breathing. The midline is continually updated as respiration is measured using a floating average. After the calibration period, breathing rate, in breaths per minute, is determined by the number of times the signal crosses the midline (N) over the 15 second window, as shown in equation 33 below:

$$Breathing\ Rate = \frac{N}{2} * 60 \frac{Seconds}{Minute} * \frac{1}{15\ Seconds} \quad Eq\ (33)$$

If the frequency is outside the range of 30-60 BPM, this indicates a respiratory abnormality.

The second window being evaluated is a 2 second window to measure the amplitude of the signal. The two second window was selected based on the lower threshold for acceptable breathing in an infant, which is 30 BPM. Therefore the smallest window in which a full breath can expect to be seen in the case of normal breathing is two seconds. In each two second window the minimum and the maximum values are determined. If the difference between the minimum and the maximum are above a predefined threshold value, it is determined that the magnitude of the signal is large enough to indicate breathing. If the difference is below the threshold, a counter is started. If the counter reaches approximately 15 seconds, this indicates a respiratory abnormality and the alarm is initialized. The threshold value will be selected by determining the expected noise of the signal. The measured signal must be far enough (3σ) above the average value noise value to be considered breathing. This allows us to maximize the sensitivity of the device, while still maintaining over 99.9% confidence that a signal with sufficient magnitude for breathing was not caused by noise. The determination of the threshold value is discussed in the validation section. A graph with generic sinusoidal data illustrating the basic function of our algorithm is shown in Figure 26 below.

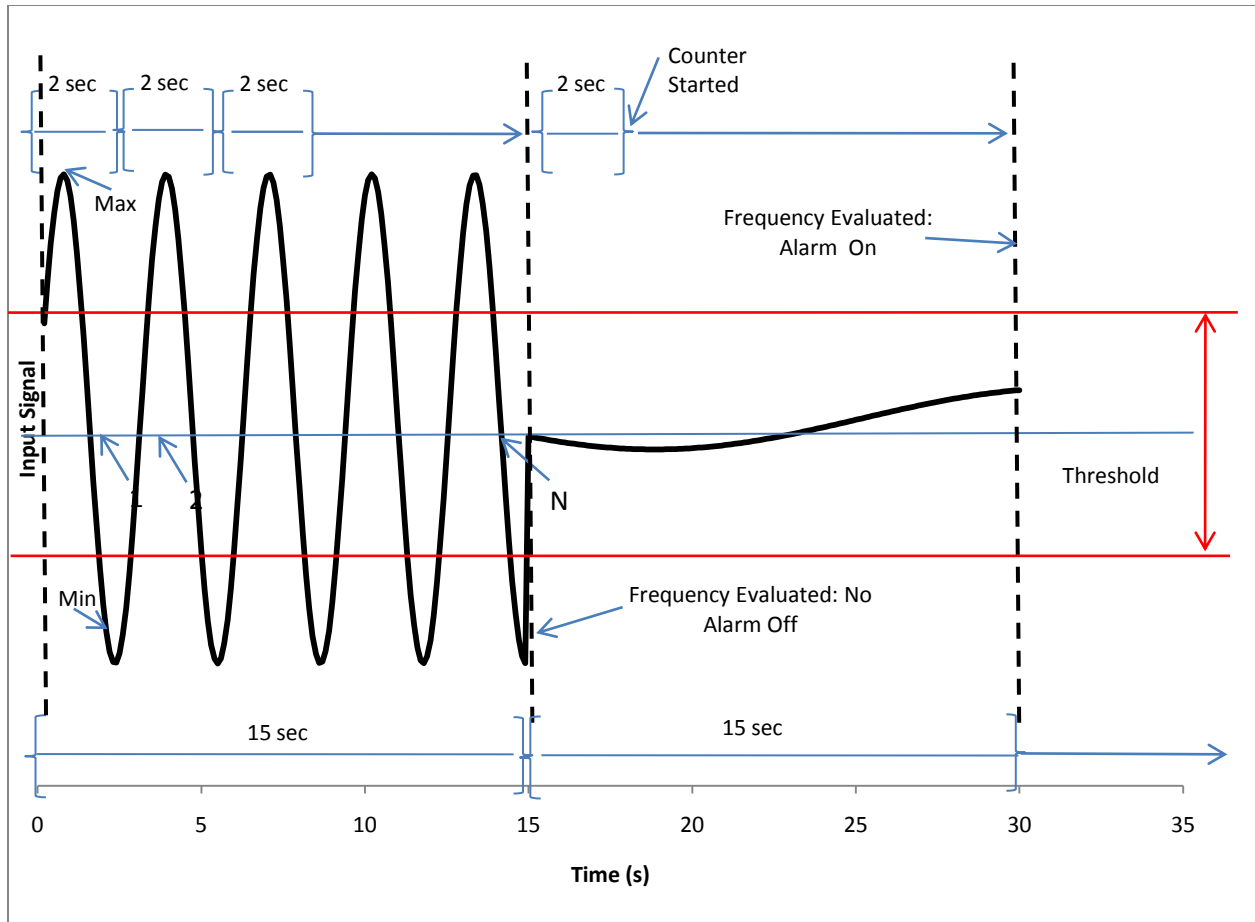


Figure 26: Theoretical data to illustrate algorithm function

The first 15 second window in Figure 26 demonstrates normal respiration. The difference between the minimum and maximum values in the 2 second windows exceeds the threshold value and, the frequency returned at the end of the 15 second window would be within the range of 30-60 BPM. The next 15 second window illustrates respiratory distress. The counter is initiated after the first two second window because the difference does not exceed the threshold, and the frequency returned at the end of the 15 second window would not be within the range of 30-60 BPM. Therefore the alarm would be turned on at the end of this window.

FFT methods were also considered for this device. These methods were discussed in the paper “An automated algorithm for determining respiratory rate by photoplethysmogram in children” by PA Leonard et al and shown to work effectively (37). However, FFT analysis is beyond the scope of low cost microprocessors considered for this device and would require additional components. We believe windowing methods provide a necessary level of accuracy for our device as indicated by previous studies (4, 14) and in the interest of creating a low-cost device, additional components to perform FFT analysis are not necessary.

Current Prototype

The prototype used for validation in the subsequent section is functionally accurate but has several structural deviances from the final design. An Arduino microprocessor was used because it provides an easy user interface and includes a USB connection for programming purposes. This microprocessor is larger and more expensive than the microprocessor selected in our final design, but both microprocessors can perform the necessary functions this device requires. Also, the current circuit is built on a breadboard instead of a printed circuit board. Due to these dimensional differences, a larger PVC project box was purchased to temporarily enclose the circuit. These components are described below.

Arduino Duemilanove: For our Microprocessor, we chose the Arduino Duemilanove. This is a 2.7" X 2.1" microprocessor board which features the ATmega168 microprocessor. It also contains everything needed to support the microcontroller including an AC/DC power connection and a USB connection. The Duemilanove has 6 analog inputs, each of which provides 10 bits of resolution (i.e. $2^{10} = 1024$ different values). It also contains 14 digital inputs/output pins, as well as several voltage outputs. The digital input/output pins can easily activate an LCD screen, a LED light, or a buzzer. The board is programmed using Arduino software. The accepted input voltage ranges between 6VDC and 20VDC of direct current, which can easily be provided with a battery in our device. It can also operate with a USB connection as a source of power. The operating voltage of this device is 5VDC, which means that the board can provide a voltage of 5V for our circuit connected to the board, as well as devices such as LEDs or buzzers. The clock speed of this device is 16MHz. Many of our selections for other components have been made so they can work in conjunction with the Arduino Demilanove.

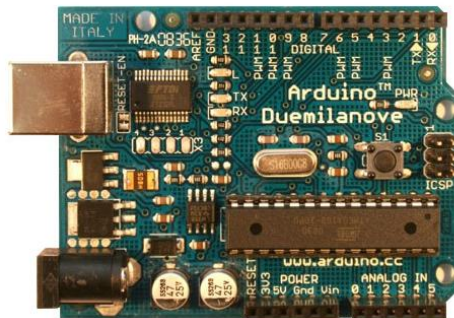


Figure 27: Arduino Deumilanove

We believe this board contains all necessary features for our device to function properly. It will work well with analog signals created by our flex sensor. The software provided by Arduino is simple and requires little direct computer programming, which could be a potential difficulty for our team given our specific engineering backgrounds. Finally, the Arduino Duemilanove is a processing board that the advisors to ME 450 are very familiar with, so any assistance our team needed when using this board can be easily provided. The full technical datasheet for the Arduino Dumilanove can be found in Appendix K.

Breadboard: The bread board is the main forum for all the circuitry to be assembled. The bread board is 8.26 cm by 4.45 cm in size making it large enough to contain all of our system's required wiring. The bread board is placed on the bottom inside the monitor's body in order to provide enough rooms for all the wires on it. The bread board has an adhesive on its bottom with which it can be stuck inside the case. The Wheatstone Bridge, differential amplifier, anti-aliasing filter, and resistors for the LED and

buzzer components of this device will all be assembled on the breadboard. This will allow us to easily wire all our circuit components together in order for them to function properly.

Although our components will be soldered to the breadboard, using a breadboard will result in exposed components, and less secure connections on our circuit. While the breadboard will still be enclosed in the PVC monitor casing, the circuit will have no further protection. This type of setup can be susceptible to disconnections, crossed wires, and increased contact between the user and the circuit.

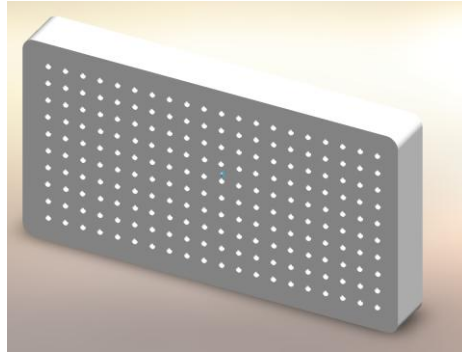


Figure 28: Breadboard

Our final design will include the use of a printed circuit board. This is a miniaturized electronic circuit manufactured on a semiconductor material using transistors. Rather than having many possible uses such as a breadboard, integrated circuits are manufactured to one specific function. They are much smaller, cheaper, and more accurate than building a circuit on a breadboard. This type of circuit is also easier to manufacture through the use of photolithography. An integrated circuit would be used in conjunction with our microprocessor in our final design.

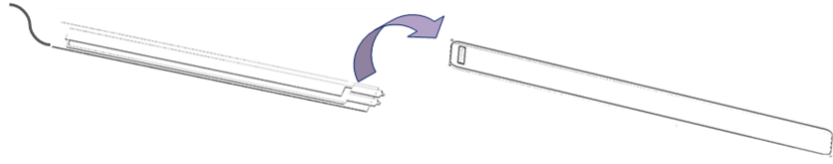
Despite the differences between our final design concept and our prototype, we believe our prototype is a valid representation of our final design. The prototype we manufacture will be able to continuously monitor infant respiration, and provide an alert if the respiration rate becomes abnormal or ceases altogether. The same microprocessor programming and logic will be used, and circuit design in the prototype will be identical to that in the final design. Our prototype will be able to prove the most important elements of our design through testing on an accurate infant respiration model. The success of this prototype will validate the success of our final design.

Process for Using the Device

The complete design is easy to operate. The steps to attach and set up the device are as follows.

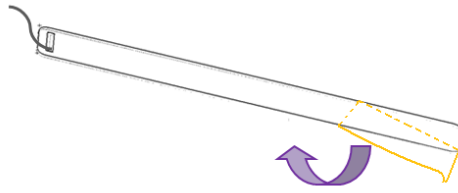
Step 1

The flex sensor is inserted into the slip cover through the slit. Although the delicate parts of the flex sensor are protected with a plastic covering, it has to be made sure that it is not pushed into the slip cover too hard. The nylon material is flexible but it has been dimensioned such that it closely fits the flex sensor.



Step 2

Once the flex sensor has been inserted into the slipcover, the adhesive on the other side of the cover is peeled off. This step is similar to taking off the adhesive covers on a band-aid before sticking it onto the designated area.



Step 3

The slipcover with the flex sensor is then attached horizontally to the infant's torso where it will experience maximum displacement from the greatest chest movement. This step is important in order for the flex sensor to take the most accurate readings.

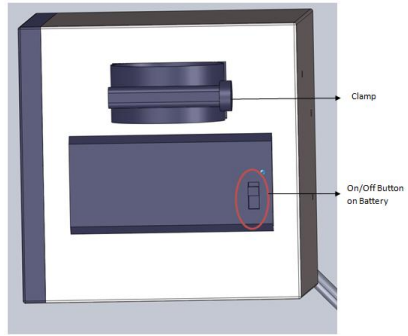


Step 4

The device is then either clamped onto a bar of the crib the infant is in or placed by its side. The monitor does not have any sharp edges making it safe to be placed near the infant. Precaution should be taken to not place the monitor too close to the infant's face. This should prevent any possible ear problems due to the loudness of the alarm or any discomfort caused in case the body of the monitor were to heat up.

Step 5

The monitor is then switched on from the back. This should actuate the microprocessor which starts the operation of the flex sensor.



FABRICATION PLAN

This section contains a detailed manufacturing and assembly plan for our prototype.

Slip Cover

Fabric will be cut into 24.13 cm by 1.9 cm rectangle. The ends that are 2.54 cm long will be folded in 1.9 cm. A straight seam will be placed 0.3175 of a cm below the seam making this fold permanent. This will make the length of the fabric 22.86 inches. The fabric needs to be placed with the seams down. This length would be folded two more times. One fold would be 1.9 cm from the end. The second fold would be 13.33 cm from the end. This would leave a total length of the device of 11.43 cm. Two seams would then be placed .32 cm from the edge of the fabric along both 11.43 cm lengths. The slip cover then needs to be turned inside out so that the seams are now on the inside of the cover. An 11.43 cm long piece of the double sided tape is then cut. The sticky side of the tape is then placed along the length of the fabric. This leaves the paper covered part of the tape covered to be removed when placed on the infant.

Electrical Circuit

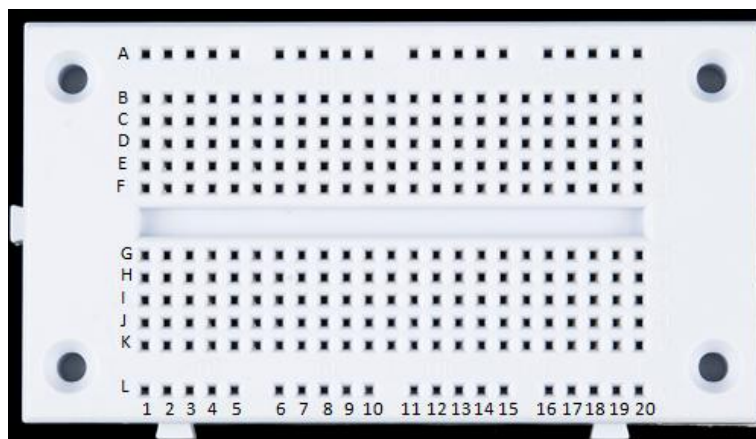


Figure 29: Labeled Breadboard

Powering the Breadboard: To provide a voltage to the breadboard, a wire was connected from the “5V” pin of the Arduino Duemilanove to port A1 on the breadboard. This provided 5 volts to row A. To provide a ground on the breadboard, a wire was connected from the “Gnd” pin on the Arduino Duemilanove to port L1 on the breadboard. This provided a ground connection to all of row L.

Constructing the Wheatstone bridge: To construct the Wheatstone bridge on the breadboard, a wire will be connected from port A2 to port B1. This provides 5 volts to ports B1 – F1. 70KΩ resistors will then be connected from port C1 to port C3 and from port D3 to port D5. A 20KΩ potentiometer will be connected from port D1 to port D2.

To connect the flex sensor to the Wheatstone bridge, a 2ft wire will be connected from port E2. The other end of this wire will be soldered to one terminal of the 4.5” flex sensor. The solder and exposed wire will be covered by heat shrinking. Another 2ft wire will then be connected to port F5. The other end of this wire will be soldered to the other terminal of the flex sensor. This solder will be covered by heat shrinking.

A wire will then be connected from port D5 to port L5. This will provide a ground connection to ports B5-F5. This will complete the assembly of the Wheatstone Bridge. One output signal of the Bridge will come from ports B3-F3 and the other will come from ports B2-F2.

Assembling the Differential Amplifier to the Circuit: To wire the differential amplifier, wires will be soldered to all connection ports of the Maxim 4194. The wire connected to the “IN-” port will be connected to port E5. The wire connected to the “IN+” port will be connected to port F2. The wire connected to the “VEE” pin will be connected to A3, and the wire connected to pin “VCC” will be connected to port L2. This will provide a 5V power input for the differential amplifier. The wire connected to the “OUT” pin will be connected to port B11. The wire connected to the “REF” pin will be connected to port L10. The wire connecting to “RG+” will connect to port G9, and the wire connecting to “RG-” will connect to port G7. A 20KΩ potentiometer will be connected from port I7 to I9. This will allow for adjustment of the amplifier gain with the potentiometer.

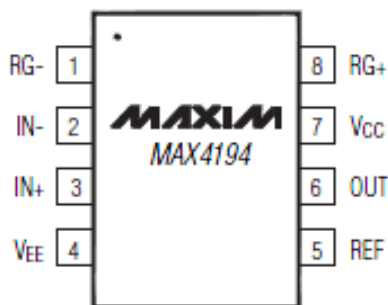


Figure 30: Labeled Differential Amplifier

Attaching LEDs to the Circuit: A red and green LED light will be selected. For both LEDs, wires will be soldered to each of the terminals. One wire from the red and green LEDs will be connected to the “Digital 9” and “Digital 8” pins on the Arduino, respectively. The other wire from the red LED will be

connected to port G16. The other wire from the green LED will be connected to port I17. 10KΩ resistors will be placed from ports H16 to H18 and from ports J17 to J19. A wire will connect from port K18 to port L18. Another wire will connect from port K19 to L19.

Attaching the Buzzer to the Circuit: The ABT-410-RC buzzer will have two pins. Wires will be soldered to each of the pins. The other end of the wire connected to positive port buzzer will be connected to the “Digital 6” pin on the Arduino. The other end of the wire connected to the negative port of the buzzer will be connected to port L20. No resistor is required for the buzzer.

Manufacturing Plan of Prototype

Since we are using an appropriately sized project box for casing the electronics, we are only fabricating the aluminum clamp from scratch. We are using a 7” x 5” x 3” project box made of PVC with 0.1” wall thickness which we purchased from RadioShack. We created engineering part drawings for all the holes and cuts that needed to be made on it so as to have precise dimensions and not make mistakes during manufacturing. The same applies to clamp. The engineering part drawings found in Appendix J have detailed dimensions for all the parts (including ones we bought) so that there is a clear understanding of how the parts interact with each other.

The manufacturing plan section (Appendix N) has been developed in order to serve as a reminder of all the important machining details such as tolerances and tools, the order in which the machining processes should take place and speeds and feed rates where applicable for all parts. Having such a plan ready will make the manufacturing process more energy and time efficient and will also allow for greater accuracy in manufacturing. This is necessary since we have limited machines in the machine shop and the amount of time we can use them.

Along with parameter details it is also necessary to consider certain machining details. For the PVC casing, the feed rates need to be medium or high so that the plastic does not develop cracks, show poor finish and lose the accuracy in dimensions. When drilling holes the area should be well lubricated to avoid the same results. Further, since the parts can't be press fit into PVC, the cuts and holes should be dimensioned slightly smaller than their actual size so that all the parts can be fit/glued in tightly into the casing. Since the casing is only 0.1” thick, it is likely to bend during machining so it should be supported well from the inside and held securely in the mill. The cutting speeds and tool sizes determined in the table below have been obtained from the Machinery's Handbook . The book has a section dedicated to plastics such as PVC. The cutting speeds (CS) provided are in feet per minute can be converted to rotations per minute (RPM) using the following formula

$$RPM = \frac{3.82 \times CS}{D}$$

where D is the diameter of the tool being used.

All the threads are tapped into the holes manually with an appropriately sized tap.

Design for assembly is the process of designing the product to improve the efficiency of assembly. Assembly includes four main operations amongst others – grasp, move, orient, insert. The objective of DFA is to make each operation easier or to eliminate it. This full analysis can be found in Appendix O.

VALIDATION

Once we began to model and prototype our design, it was important to develop methods to test all possible design specifications. This will ensure that our device meets our user requirements and allow us to measure the success of our design. This section will describe the various methods used to perform validation testing, the results obtained, and the justification for specifications that were not validated.

Methods

A summary of validation methods used is shown in Table 7 below.

Clinical Simulation: The Laerdal SimBaby in the Clinical Simulation Center at the University of Michigan Hospital was used to simulate accurate physiological infant chest movement and breathing pattern in a young infant. This simulator can vary respiration rate, chest movement pattern, and chest movement depth, and it provides a realistic model for evaluating several measures of how accurately the monitor functions.

Though this was not a specific engineering specification, we tested the accuracy of the frequency measurements in order to ensure that the code works. This was tested by taping the flex sensor firmly to the SimBaby's abdomen for a period of approximately 90 seconds, which yielded six readings, and recording the frequencies using Arduino software on a laptop. This procedure was repeated for respiration rates 10 through 80 in increments of 10 breaths per minute.

In order to examine the time interval between detection and notification, the flex sensor was similarly attached to the SimBaby's abdomen. First, we calibrated the device for five seconds at 45 breaths/min and then set the rate to the desired value. Using a stopwatch, we recorded the time between when the rate was set to the desired value and when the alarm was sounded. This procedure was repeated for five to eight trials in a no respiration condition, three hypoventilation conditions (5, 10, and 15 breaths/min), and one hyperventilation condition (80 breaths/min). We also performed this test for varying chest movement depths for hypoventilation, normal breathing, and hyperventilation. Finally, the previous chest depth test was repeated with sea saw breathing pattern and retraction breathing pattern.

Human Subject Testing: We developed a standardized protocol and script for our human subject testing to reduce bias between trials. First, the subject was given a two sentence description of the purpose of the device and shown our current prototype. Next, the subject was asked how he or she would interpret the three possible signals the device may have: a red light and a buzzer, a green light with no buzzer, and both lights off with no buzzer. The verbal responses were recorded.

The subject was then presented with a detached flex sensor by itself, a to-scale picture of a baby, the manufactured aluminum clamp, and a PVC block mock-up of our final design. Training time was

recorded with a stopwatch while the subject was told to attach the clamp to the table, place the sensor on the accurate location on the picture of the baby, and to “turn on” the device by pressing the power button on the mock-up, and then was allowed to ask questions. Time to attach was then recorded using a stopwatch while the subject completed the described task.

Finally, a group of eight subjects was told to stand 15 meters away from the prototype and asked to close their eyes in a mildly noisy classroom. When they heard the buzzer go off, they were asked to raise their hand. The number of subjects that could hear the buzzer 15 meters away was recorded.

Table 7: Summary of Validation Methods

Engineering Specifications	Test Method
Time to Alarm	Measure using a stopwatch on Laerdal SimBaby over several conditions, 5-8 trials each and take average
Minimum Distance Alarm is Heard	Turn buzzer on and survey subjects whether or not it is audible 15m away
Current of Component in Contact with Skin	Measure with a multimeter
Pressure/Force on Infant	Weigh the flex sensor on a scale
% of People that Can Successfully Interpret Device	Survey 10 people how they would interpret 3 different signals from device
Training Required to Successfully Operate Device	Measure with stopwatch the length of explanation time before subject is comfortable attaching and initializing
Total Attachment/Initialization and Detachment Time	Measure using a stopwatch after subject has received training
Cost per Unit	Calculate final cost of device when mass manufactured based on website prices of purchased components, material costs, and manufacturing costs from CES
Size/Weight	Measure based on dimensions and estimates of the weight of the final components and materials

Results

The average measured frequency was calculated for each actual respiration rate with a range of 1.96 standard deviations, as depicted by error bars in Figure 31. Based on this analysis, the frequency values obtained at each rate are not statistically different from the target values. The results are shown in Figure 31 below.

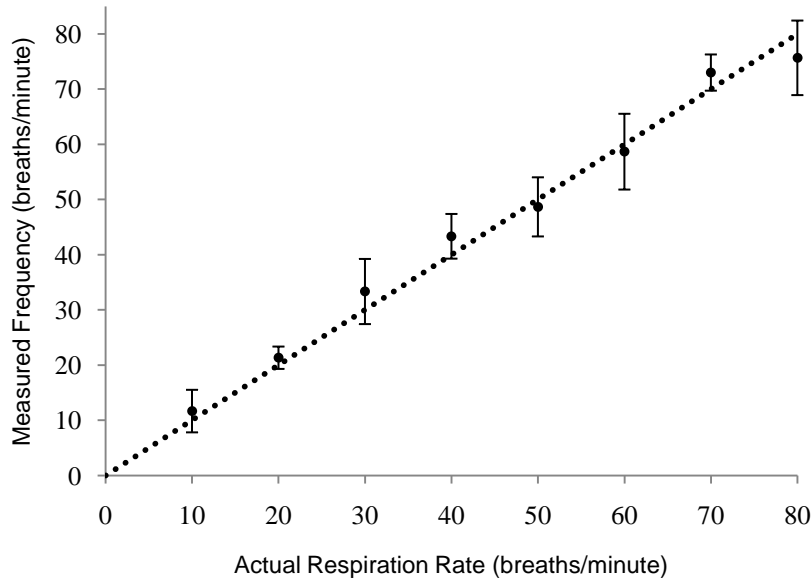


Figure 31: Accuracy of Frequency Measurements

The target time to alarm is 15 seconds after the onset of a respiratory abnormality. Under normal conditions, several trials were combined to show averages for no breathing, three hypoventilation rates, and one hyperventilation rate, as seen in Figure 32.

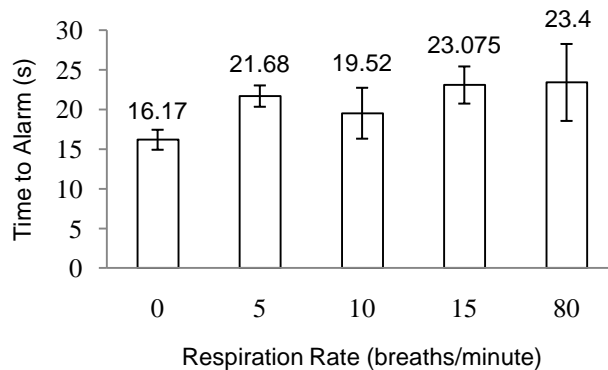


Figure 32: Time to alarm for varying rates

When the microprocessor did not detect any respiration, it immediately began counting because the magnitude was below the threshold. Therefore, the value for zero breaths per minute was not statistically different than 15 seconds, and gave the most accurate response time. Due to the 15-second window for measuring frequency, variability within the cycle of when abnormal respiration caused notification times greater than 15 seconds. For all respiration rates greater than zero and not within the normal range, the time to notify was approximately 20 seconds.

Figure 33 displays the results of time to alarm under different conditions. The depth of breath was manipulated on the SimBaby and is shown on the x-axis. Differently shaded bars display respiration rate.

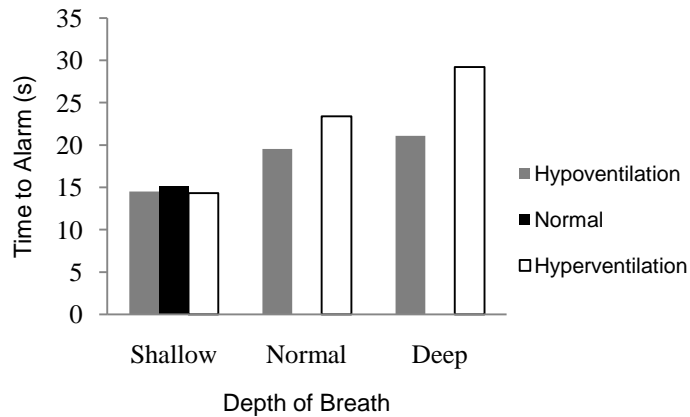


Figure 33: Time to alarm at various breathing amplitudes

Although shallow breathing signaled within an optimal time interval, the alarm was also initiated for normal respiration rate, which demonstrated that the processor did not detect any breathing. Therefore, it counted to 15 assuming a rate of zero and sounded the alarm at the appropriate time. Although this falls within our desired time interval, assuming insufficient amplitude, it has not yet been determined whether shallow breathing should be indicative of a problem enough that a nurse should be notified regardless of the rate. If this is the case, then the device functioned properly. If not, then the threshold magnitude must be adjusted so that the sensor is sensitive enough for shallow breathing.

Hyperventilation averaged a longer notification time because its more irregular pattern caused the processor to occasionally miss the first frequency reading. The lack of alarm for normal rate for both normal and deep depth was expected. Similar results were found for other breathing patterns like sea saw and retraction breathing.

100% of subjects were able to accurately interpret the meaning of the red light, the alarm, the green light, and what is happening when neither light is on without prior knowledge of the device or its function. Therefore, we can conclude that the user interface of our device is sufficiently intuitive. Further, 100% of subjects were able to hear the buzzer 15 m away. The simulated initialization and attachment of the device took subjects an average of 18.1 s with a standard deviation of 4.4 s when n=10, which is well below our target value.

Many of our specification simply required measurements or calculations. The dimensions of the final monitor casing are 3" by 4" by 1.75." This yields a volume of 21 in³ and a surface area of 48.5 in². These values are converted to centimeters in Table 8 below for direct comparison to the specifications procured in Ghana. The flex sensor was weighed and found to be ___g, which we can conclude is a safe amount of pressure to put on an infant's chest or abdomen. The weight of the final device was estimated based on selected components and material and found to be ___kg. The current through the flex sensor, which is the only component in contact with skin, was measured to be 0.23 mA, which is below the human sensory threshold of 1 mA. Based on our final operation plan of the device and by watching subjects interact with our current prototype, no more than 3 steps are required to initialize the device: the clamp is attached, the flex sensor is attached to the baby, and the device is turned on.

Finally, the estimated cost of our final design, assuming bulk purchasing, is approximately USD\$33.00. A comprehensive cost analysis of both the prototype and final design can be found in Appendix B.

A list comparing our original design specifications table to the results that we obtained from validation is displayed below. This table shows that most of the engineering specifications were achieved.

Table 8: Summary of Validation Results

User Requirement	Engineering Specification	Target Value	Measured Value	Achieved?
Notifies Effectively	Time to Alarm	15 s		
	Minimum Distance Alarm is Heard	15 meters		
Safe to Use	Current of Component in Contact with Skin	<1mA	0.23mA	Yes
	Pressure/Force on Infant	<125g		
Low Maintenance	MTBF (months)	3 Months	TBD	TBD
Easy to Use	% of People that Can Successfully Interpret Device	95%	100%	Yes
	Training Required to Successfully Operate Device	1 Day	28 s	Yes
Easy/Fast to Attach/Initialize	Number of People to Attach	1 Person	1 Person	Yes
	Number of steps to attach (# steps)	<3 Steps	3 Steps	Yes
	Total attachment/initialization time (min)	<2 min	18.1 ± 4.4 s	Yes
Inexpensive	Cost per Unit	USD\$40.00-70.00	USD\$33.64	Yes
	Recurrent Cost	USD\$5.00/year	USD\$20.00	No
Easy/Fast to Detach	Number of people required to detach (# people)	1 Person	1 Person	Yes
	Number of steps to detach (# steps)	<3 steps	3 Steps	Yes
	Total detachment time from infant (min)	<.5 min		
	Total detachment time from crib/surroundings	<2 min		
Easy to Clean	Time to clean (min)	<2 min(if not autoclave)		
Compact	Volume (m ³)	5000 cm ³	344.13 cm ³	Yes

	Surface area (m ²)	1080 cm ²	312.9 cm ²	Yes
	Overall weight of device (kg)	<3 kg		
No excessive disturbance of surroundings	Intensity of sound disturbance (dB) *	70-80dB		
	Frequency of false positives (occurrences/hour)	One occurrence per 24 hours		
Durable	Overall Operational Time	>6 years	TBD	TBD
	Drop Height	>1.5 m	TBD	TBD
	Functional temperature range	60-130°F		
	Functional Humidity Range	0-100%		
Broad Spectrum of Application	Range of average infant chest circumference from 28 weeks to 42 weeks gestational age	10" – 17"		
	Range of average infant body length from 28 weeks to 42 weeks gestational age	17.8" – 20.2"		
	Range of average infant abdomen circumference from 28 weeks to 42 weeks gestational age	9.5" – 13.2"		

Justification for Unvalidated Specifications

Though we were able to achieve the majority of our target values for engineering specifications, there were several specifications that we chose not to test. Though low maintenance was ranked highly and we do not deny its importance, we were not able to perform or accurately simulate three months of use yet. There is not enough time in the given semester to validate this over three months, and there are too many variables to create any kind of shorter experiment. For example, though the flex sensor should be capable of one million cycles according to the manufacturer, it will not be continuously used in a clinical setting. We also chose not to test durability. The first specification, an operational time of greater than six years, was not possible for the same reason as low maintenance. Drop height and functional temperature and humidity range were not worth testing because the electrical components of our final design, namely, the printed circuit board, will be significantly more durable than the breadboard that is part of our current prototype and we reserve this validation for the prototype of the final design in the future. We did not test the time to clean because cleaning methods will vary based on the material of our final design. Also, the parts of the device that make skin contact are disposable.

Finally, though we can speculate that the flex sensor will accurately measure respiration for a range of sizes due to its simplicity and its length, our only working, breathing model was the SimBaby, which is slightly larger than the average premature infant. It was not feasible to acquire equivalent models of

varying sizes to test this specification. However, our validation results showed that shallow chest movement did not yield enough flexion for the processor to register any respiration. This is a concern with varying chest sizes, and we plan to do more research regarding anthropometric data chest displacement at different ages to ensure that the threshold for the amplitude is adequate to detect respiration for the desired ages.

DISCUSSION

The prototype we built is a close functional representation of our final design. The main highlights of the device include the fact that it is light, inexpensive, has few components and meets the majority of our design specifications.

While our design was successful in meeting almost all of our user requirements and specifications, it has its short comings. Two major adjustments should be made to the code. The length of the frequency window was 15 seconds, which caused it to notify an average of 20 seconds after the onset of abnormal respiration ate. The error associated with this window size could be attenuated by testing the code with smaller window sizes for frequency readings.

We had set the threshold amplitude to be 30. However, this was not adequate to register “shallow” breathing. Lowering the threshold will greatly decrease accuracy because the noise of the flex sensor may start to register as chest movement. However, this is a major shortcoming because this “shallow” breathing on the SimBaby may be normal in an infant with a different size chest. We will need to perform much more in depth anthropometric research to determine the range of chest displacements for newborns of varying sizes, or use a more accurate flex sensor.

Since we want the device to be capable of being used in for various crib sizes and with all space constraints, we originally determined that the ideal size of the cord attaching ht flex sensor to the main casing should be 2 feet. However, the chord we used was a little less than a foot long and would be impractical to use in situations where the monitor has to be attached far away from the infant. Further, for a chord as long as 2 feet, we also need to be able to store it effectively. Currently, we do not have any feature on the casing to allow the chord to either retract into or be stored in a safe, compact manner. We could possibly include an extrusion at the back of the device with a lip to wrap the cord around since we need the feature to be simple and low cost.

The flex sensor we used did not prove to be very durable. The manufacturers estimated that the flex sensor should last more than at least one million cycles. However, after a couple of days of using the flex sensor it stopped functioning properly and did not detect lack of breathing as it should have. The positioning of the flex sensor on the infant’s torso was also somewhat of a problem. We needed to spend time finding the part of the torso on the Laerdal SimBaby (during validation) with maximum expansion and contraction in order to obtain accurate results from monitoring. This adds to the attachment time of the device. Further, the flex sensor costs \$12 which isn’t too high for the prototype, but it makes up a large portion of the cost of our final design (estimated cost ~ \$33). We are looking into more types of flex sensors which are more robust and cost effective.

CONCLUSION

Our design team spent four weeks during the month of August performing clinical observations in Komfo Anoyke Teaching Hospital (KATH) located in Kumasi, Ghana. The purpose of these observations was to identify first-hand the challenges faced in the hospital, and to work with the staff at KATH to collaboratively identify areas of need. After generating over 100 problem statements based on our observations, we created needs statements based on these problem statements. With the help of the KATH staff, and considering factors such as impact, scope of ME 450, and feasibility, we decided on one needs statement to address with our project. The needs statement on which our project is based reads as follows:

There is an opportunity to develop a time saving, cost effective, easy to use device for health care providers to monitor the respiration of premature babies and alert health care providers of respiration abnormalities, allowing providers to better prioritize care.

After developing a needs statement, we continued our observations and conducted numerous surveys and interviews to generate a ranked list of user requirements. This list underwent several iterations based on continuous feedback from our peers and KATH staff members. After establishing our user requirements, we used the same process to generate engineering specifications for each user requirement. We also developed target values for each design specification. After returning from Ghana, we met with local sponsors and mentors that have experience working in hospitals in low-resource settings. We also performed an extensive literature search to validate our customer requirements and design specifications.

Using these user requirements, we conducted two brainstorming sessions that were used to generate as many concepts as possible that could be used to monitor infant respiration and notify health care workers. Ideas were generated by component. These components included detection, notification, attachment to crib and infant, power sources, and possible tactile stimulation. Then, these ideas were formed into eighteen complete concepts which were narrowed down with input from a Pugh chart analysis and further research.

The design that was chosen includes a disposable slip cover that is tightly adhered to the infant's torso. A flex sensor that is attached to the circuit and therefore reusable will be inserted and held within this slip cover during use. The flex sensor will record minute changes in voltage during normal chest movement and output a signal to an amplifier. The amplifier will then amplify the signal to the microcontroller. If the respiration rate encoded by the microprocessor is outside normal range, the alarm will be sounded.

We created a prototype of this design in order to understand if the prescribed circuit design and chosen components would work as desired. To validate our prototype, we conducted preliminary tests on a Laerdal SimBaby in the Clinical Simulation Center at University of Michigan hospital which simulated accurate physiological chest movement and breathing patterns of infants. We tested the accuracy of the frequency measurements to check if the code works and we also examined the time interval between detection and notification. We also carried out human subject testing where we asked the subjects to identify if they understand what the green and red lights indicate, how well they could attach the flex

sensor on a to-scale picture of an infant and how long it took them to attach the clamp. All of these results were recorded and used to make further improvements to the design.

Through the validation of the prototype we found that we could make changes to the algorithm and certain aspects of the hardware for further work. We also carried out a material and process selection analysis on CES, a design for assembly analysis, a design for environmental sustainability on SimaPro and an analysis on how safe the device is on DesignSafe. All of these together gave us several ideas on how we can produce a better design in the future.

REFERENCES

1. Retrieved 11/2, 2010, from <http://www.professionalplastics.com/PLEXIGLASS-ACRYLIC SHEET-EXTRUDED>
2. (1998). Retrieved 10/10, 2010, from <http://www.aafp.org/afp/980501ap/trachten.html>
3. (2008). Retrieved 10/11, 2010, from www.ssddrives.com/usa/doc/HA351948.pdf
4. Bates, M. J. Ling, J. Mann and D. K. Arvind. (2010). Respiratory rate and flow waveform estimation from tri-axial accelerometer data. Paper presented at the *International Conference on Body Sensor Networks*, Scotland, UK.
5. Altman, M., Vanpée, M., Cnattingius, S., & Norman, M. Neonatal morbidity in moderately preterm infants: A Swedish national population-based study. *The Journal of Pediatrics*, *In Press*, *Corrected Proof* doi:DOI: 10.1016/j.jpeds.2010.07.047
6. *Angelcare baby movement and sound monitor deluxe plus*. Retrieved 09/22, 2010, from http://www.amazon.com/Angelcare-Movement-Sound-Monitor-Deluxe/dp/B002ZB82CU/ref=pd_sbs_hpc_7

7. Antloga, K., Meszaros, J., Malchesky, P. S., & McDonnell, G. E. (2000). Prion disease and medical devices.[miscellaneous article]. *ASAIO Journal*, 46(6), 69--72.
8. Araujo, D., Sampaio, P. C., Damiao, R., Dantas, P., & Fonseca, E. B. (2010). In Puertas A., Montoya F., Romero J., Hurtado J. and Manzanares S. (Eds.), *Outcomes of early preterm birth and late-preterm infants admitted in the neonatal intensive care unit: A retrospective, single-center study*. BOLOGNA; VIA ROBERTO LONGHI, 14/A, BOLOGNA, 40128, ITALY: MONDUZZI EDITORE S P A.
9. Bailey, R. W. (1996). *Human performance engineering: Designing high quality professional user interfaces for computer products, applications and systems* (3rd ed.). New Jersey: Prentice Hall PTR.
10. *Biemme sport*. (2009). Retrieved 11/02, 2010, from <http://www.biemmesport.com>
11. Blennow, G. (1974). Noise levels in infant incubators (adverse effects?). *Pediatrics*, 53(1), 29-32.
12. Branson, K. L. *Infant respiratory monitor* Retrieved from <http://www.google.com/patents?id=nb8WAAAAEBAJ&zoom=4&pg=PA1#v=onepage&q&f=false>
13. Buschmann, J. *SIDS detection apparatus and methods* Retrieved from <http://www.google.com/patents?id=xJMaaaaEBAJ&zoom=4&pg=PA1#v=onepage&q&f=false>
14. Chiarugi, F., Karatzanis, I., Zacharioudakis, G., Meriggi, P., Rizzo, F., Stratakis, M., Louloudakis, S., Biniaris, C., Valentini, M., Di Rienzo, M., & Parati, G. (2008). Measurement of heart rate and respiratory rate using a textile-based wearable device in heart failure patients. *Computers in Cardiology*, 2008, 901-904.
15. Clifton, D., Douglas, J. G., Addison, P., & Watson, J. (2007). Measurement of respiratory rate from the photoplethysmogram in chest clinic patients. *Journal of Clinical Monitoring and Computing*, 21(1), 55-61.
16. Committee on Fetus and Newborn,. (2003). Apnea, sudden infant death syndrome, and home monitoring. *Pediatrics*, 111(4), 914-917. doi:10.1542/peds.111.4.914
17. Costanzo, L. (2006). *Physiology* (3rd ed.). Philadelphia, PA: Saunders Elsevier.

18. *DiBi performance fashion*. (2007). Retrieved 11/02, 2010, from http://www.dibisport.co.uk/performance_fabrics.php
19. Erik Oberg, Franklin D. Jones, Holbrook L. Horton and Henry H. Ryffel. (2004). In Christopher J McCauley, Riccardo M. Heald, Muhammed Iqbal Hussain (Ed.), *Machinery's handbook* (27th ed.). New York: Industrial Press.
20. Eunice Mueni, Newton Opiyo, and Mike English. (2009). Caffeine for the management of apnea in preterm infants. *United Kingdom Pub Med Central Author Manuscripts*, 1(2), 190--195.
21. Gelfer, M., & Mikos, V. (2005). The relative contributions of speaking fundamental frequency and formant frequencies to gender identification based on isolated vowels. *Journal of Voice*, 19(4), 544-554.
22. Genzel-Boroviczény, O., Hempelman, J., Zoppelli, L., & Martinez, A. (2010). Predictive value of the 1-min apgar score for survival at 23-26 weeks gestational age. *Acta Pædiatrica*, , no-no. doi:10.1111/j.1651-2227.2010.01937.x
23. Halleck, M. E., & James, D. N. In I Am Fine I. (Ed.), *Respiration monitor with simplified breath detector*
24. Higgins, J., Everbach, E. C., & Parker, K. J. *Infant health monitoring system* Retrieved from <http://www.google.com/patents?id=-BUjAAAAEBAJ&zoom=4&pg=PA1#v=onepage&q&f=false>
25. *HiSense BabySense V baby safe infant movement monitor*. Retrieved 9/22, 2010, from http://www.amazon.com/HiSense-BabySense-Baby-Safe-Movement/dp/B000LVEYG4/ref=pd_bxgy_ba_img_b
26. Horvath, I. (2005). Exhaled breath condensate: Methodological recommendations and unresolved questions. *The European Respiratory Journal*, 26(3), 523-548.
27. How Products Are Made (Volume 3). (2010). *How a disposable diaper is made*. Retrieved October, 14th, 2010, from <http://www.madehow.com/Volume-3/Disposable-Diaper.html>

28. Ikonomidou, C., & Kaindl, A. (2010). Neuronal death and oxidative stress in the developing brain. *Antioxidants Redox Signalling*,
29. Joann fabrics. (2010). Retrieved 11/02, 2010, from <http://joann.com>
30. Kayrouz, I., Das, B., Gowans, G., & Johnsrude, C. (2010). A two-month-old infant with respiratory distress and left ventricular hypertrophy. *The Journal of Pediatrics*,
31. Ketelhohn, C. H. In Milwaukee Electronics Corporation (Ed.), *Accelerometer-based infant movement monitoring and alarm device* Retrieved from <http://www.google.com/patents?id=0fQRAAAAEBAJ&zoom=4&pg=PA1#v=onepage&q&f=false>
32. Kim, B. H. (1996). *Sudden infant death syndrome monitor*
33. Knobel, R., Holditch-Davis, D., & Schwartz, T. (2010). Optimal body temperature in transitional extremely low birth weight infants using heart rate and temperature as indicators. *Journal of Obstetric, Gynecologic, and Neonatal Nursing*, 39(1), 3-14.
34. Lahariya, C., & Paul, V. K. (2010). Burden, differentials, and causes of child deaths in india. *Smposium on Child Survival-III*, doi:10.1007/s12098-010-0185-z
35. Lawn, J., Cousens, S., & Zupan, J. (2005). 4 million neonatal deaths: When? where? why? *Lancet*, 365(9462), 891-900.
36. *LEDs super bright*. (2010). Retrieved 11/03, 2010, from <http://www.ledssuperbright.com/3mm-led-c-7>
37. Leonard, P., Clifton, D., Addison, P., Watson, J., & Beattie, T. (2006). An automated algorithm for determining respiratory rate by photoplethysmogram in children. *Acta Pædiatrica*, 95(9), 1124-1128.
38. Loerting, T., & Bernard, J. (2010). Aqueous carbonic acid (H₂CO₃). *ChemPhysChem*, 11(11), 2305-2309.

39. Mainsaw, B. (2008). *Important factors for the design of medical devices for developing countries*. (Unpublished Bachelors of Science). Worcester Polytechnic Institute,
40. Malkin, R. A. (2007). Design of health care technologies for the developing world. *Annual Review of Biomedical Engineering*, 9, 567-587. doi:10.1146/annurev.bioeng.9.060906.151913
41. Mann, K. *Infant monitoring system* Retrieved from <http://www.google.com/patents?id=HnunAAAAEBAJ&zoom=4&pg=PA1#v=onepage&q&f=false>
42. Marayong, P., & Mostoufi, M. (2009). Foot vibrotactile device for central apnea interruption in premature infants. *Studies in Health Technology and Informatics*, 142, 180-182.
43. MatWeb. (2010). *Material properties of PVC - high impact*. Retrieved October, 14th, 2010, from <http://www.matweb.com/search/DataSheet.aspx?MatGUID=61176b35d92c4a5e9834c7a97a989fc3&ckck=1>
44. Mauricio Ochoa, J., Osorio, J. S., Torres, R., & McLeod, C. N. (2009). Development of an apnea detector for neonates using diaphragmatic surface electromyography. *Engineering in Medicine and Biology Society, 2009. EMBC 2009. Annual International Conference of the IEEE*, 7095-7098.
45. *Nanny baby-breath monitor*. Retrieved 09/22, 2010, from <http://dsguide.stores.yahoo.net/nanny-baby-breath-monitor.html>
46. NASA Innovative Partnerships Program. (March 25, 2010). ***Reflecting on space benefits: A shining example***. Retrieved October, 14th, 2010, from http://www.sti.nasa.gov/tto/Spinoff2006/ch_9.html
47. Newborns in Need. *Premie size chart*. Retrieved October 10th, 2010, from http://www.newbornsinneed.org/html/size_chart.html
48. Orlando, C. *Heart and breathing alarm monitor* Retrieved from <http://www.google.com/patents?id=evQqAAAAEBAJ&zoom=4&pg=PA1#v=onepage&q&f=false>

49. OSHA. (2008). Retrieved 11/6, 2010, from http://www.osha.gov/SLTC/etools/construction/electrical_incidents/eleccurrent.html#wet_conditions
50. Paluszynska, D. A., Harris, K. A., & Thach, B. T. (2004). Influence of sleep position experience on ability of prone-sleeping infants to escape from asphyxiating microenvironments by changing head position. *Pediatrics*, *114*(6), 1634--1639.
51. Poets, C. F. (2010). Apnea of prematurity: What can observational studies tell us about pathophysiology? *Sleep Medicine*, *11*(7), 701-707. doi:DOI: 10.1016/j.sleep.2009.11.016
52. POUYET, J., & LATAILLADE, J. (1975). DYNAMIC INVESTIGATION OF HARD VISCOELASTIC MATERIALS BY BALL BOUNCING EXPERIMENTS. *Journal of Materials Science*, *10*(12), 2112-2116.
53. POUYET, J., & LATAILLADE, J. (1975). DYNAMIC INVESTIGATION OF HARD VISCOELASTIC MATERIALS BY BALL BOUNCING EXPERIMENTS. *Journal of Materials Science*, *10*(12), 2112-2116.
54. *RespiSense BUZZ infant breathing movement baby monitor*. Retrieved 09/22, 2010, from http://www.amazon.com/RespiSense-Infant-Breathing-Movement-Monitor/dp/B001JJOE76/ref=pd_sbs_hpc_1
55. Richmond, K. H., Konkle, D. F., & Potsic, W. P. (1986). ABR screening of high-risk infants: Effects of ambient noise in the neonatal nursery. *Otolaryngology and Head and Neck Surgery*, *94*(5), 552-560.
56. *Rocky woods outdoor fabrics*. (2010). Retrieved 11/02, 2010, from <http://www.rockywoods.com/Fabrics-Kits/Supplex-Nylon-Fabric/Supplex-Nylon-Fabrics>
57. Rowley, D., Iyasu, S., MacDorman, M., & Atrash, H. (1993). Neonatal and postneonatal mortality. *Data to Action: CDC's Public Health Surveillance for Women, Infants, and Children*, , 251--262.
58. Rutula, W., & Weber, D. (2004).
Disinfection and sterilization in health care facilities:
what clinicians need to know. *Healthcare Epidemiology*, *39*, 701--709.

59. Sahlstrand-Johnson, P., Jansson, P., Persson, H., Holmer, N., Jannert, M., & Jansson, T. (2010). In vitro studies and safety assessment of doppler ultrasound as a diagnostic tool in rhinosinusitis. *Ultrasound in Medicine Biology*,
60. Scanlon, M. In The United States of America as represented by the Secretary of the Army (Ed.), *Sudden infant death syndrome (SIDS) monitor and stimulator*
61. Schmölzer, G., Morley, C., & Davis, P. (2010). Respiratory function monitoring to reduce mortality and morbidity in newborn infants receiving resuscitation. *Cochrane Database of Systematic Reviews*, (9) doi:10.1002/14651858
62. Shankaran, S., & Laptook, A. R. (2007). Hypothermia as a treatment for birth asphyxia. *Clinical Obstetrics and Gynecology*, 50(3), 624--635.
63. Sharpe, S. M., Seals, J., MacDonald, A. H., & Crowgey, S. R. In Georgia Tech Research Corporation (Ed.), *Non-contact vital signs monitor* Retrieved from <http://www.google.com/patents?id=TFMhAAAAEBAJ&zoom=4&pg=PA1#v=onepage&q&f=false>
64. Shenai, J., & SHENAI. (1977). Sound levels for neonates in transit. *The Journal of Pediatrics*, 90(5), 811-812.
65. Silva, C. D. In Silva C. D. (Ed.), *Device for monitoring respiratory movement* Retrieved from <http://www.google.com/patents?id=T2-nAAAAEBAJ&zoom=4&pg=PA13#v=onepage&q&f=false>
66. Silvestri, J. M. (2009). Indications for home apnea monitoring (or not). *Clinics in Perinatology*, 36(1), 87-99. doi:DOI: 10.1016/j.clp.2008.09.012
67. Silvia, C. D. In Silva C. D. (Ed.), *Monitoring respiratory movements device*
68. Silvia, C. D. (2005). In Silvia C. D. (Ed.), *Monitoring respiratory movements device* (660th ed.) A61B.
69. Silvia, C. D. (2008). In Silvia C. D. (Ed.), *Device for monitoring respiratory movements* (600th ed.) A61B.

70. *Smart monitor 2 infant apnea monitor W/modem*. Retrieved 09/22, 2010, from <http://www.greatmedicalsupplies.com/supply~apnea-monitors~smart-monitor-2-infant-apnea-monitor-wmodem-4003.htm>
71. Telatar, B., Comert, S., Vitrinel, A., & Erginz, E. (2009). Anthropometric measurements of term neonates from a state hospital in turkey. *Eastern Mediterranean Health Journal*, 15(6), 1412-1419.
72. Teodorescu, H., & Mlynek, D. J. In Sensitive Technologies L. (Ed.), *Respiration and movement monitoring system* Retrieved from <http://www.google.com/patents?id=WvUAAAAAEBAJ&zoom=4&pg=PA1#v=onepage&q&f=false>
73. The Consortium on Safe Labor,. (2010). Respiratory morbidity in late preterm births. *JAMA: The Journal of the American Medical Association*, 304(4), 419-425. doi:10.1001/jama.2010.1015
74. Togawa, T. (1985). Body temperature measurement [Abstract]. *Clinical Physics and Physiological Measurement*, 6(2) 83.
- This article reviews present techniques of body temperature measurement. The extent to which currently available thermometers satisfy the various requirements of medical thermometry are discussed.
75. University of Florida. (2008). Wireless crib monitor keeps tabs on baby's breathing. *ScienceDaily*,
76. Waiswa, P., Kallander, K., Peterson, S., Tomson, G., & Pariyo, G. W. (2010). Using the three delays model to understand why newborn babies die in eastern uganda. *Tropical Medicine & International Health*, 15(8), 964-972. doi:10.1111/j.1365-3156.2010.02557.x
77. Watkinson, M., & WATKINSON. (2006). Temperature control of premature infants in the delivery room. *Clinics in Perinatology*, 33(1), 43-53.
78. White, M. A., & LeBlanc, M. (1999). Thermochromism in commercial products. *Journal of Chemical Education*, 76(9), 1201.

79. Wyatt, J. (2008). Appropriate medical technology for perinatal care in low-resource countries.
Annals of Tropical Paediatrics: International Child Health, 28(4), 243--251.

APPENDIX B: Bill of Materials

Table B1: Bill of Materials in the Prototype

Item	Quantity	Source	Catalog Number	Cost	Contact	Dimensions
Arudino Duemilnove Microprocessor	1	Arduino Duemilnove	DEV-00666	25.00 USD	Sparkfun.com	2.1x.1x2.6 inches
4.5" Flex Sensor	2	Spectra Symbol	SEN-08606	12.95 USD	Sparkfun.com	4.5 inches
70 KOhm Resistor	2	UMich Mechatronics Lab	N/A	N/A	Toby Danajkowski (tdona@umich.edu)	
10K Resistor	2	UMich Mechatronics Lab	N/A	N/A	Toby Danajkowski (tdona@umich.edu)	
20KOhm Potentiometer	1	UMich Mechatronics Lab	N/A	N/A	Toby Danajkowski (tdona@umich.edu)	
Maxim 4194 Differential Amplifier	1	Maxim	41.94	4.00 USD	Maxim-ic.com	0.15x0.22x0.34 inches
Green LED	1	RadioShack	276-022	1.69USD	Radioshack.com	0.118 inches
Red LED	1	RadioShack	276-026	1.69USD	Radioshack.com	0.118 inches
Piezo Buzzer	1	Pro-Signal	ABT-410-RC	1.95USD	Sparkfun.com	0.472 inches
Small Self Adhesive Breadboard	1	SEN	PRT-00137	5.95USD	Sparkfun.com	3.2x.4x1.8 inches
PVC box	1	RadioShack	270-1807	5.99USD	Radioshack.com	7x5x3 inches
9V batter	1	Energizer	L522	5.99USD	Batteryspace.com	1.2x.8x2.7 inches
9V battery holder	1	Powerizer	SBH-9VAS	1.69USD	Batteryspace.com	2.7x1.3x.8 inches
Aluminum Clamp	1	UMich Machine Shop	N/A	N/A	Machine Shop	2.5x2x2 inches

Medical Grade Adhesive	5 inches	3M	1522	0.06 USD	3m.com	5 inches
Fabric	10 inches ²	JoAnn Fabric	N/A	0.04 USD	Joann.com	1x5 inches

Table B2: Bill of Materials in the Final Design

Item	Dimensions	Quantity	Catalog #	Manufacturer	Contact	Cost (USD)
PICAXE 18 Pin Project Board Microprocessor	2.1"X1.8"	1	DEV-08316	PICAXE	Sparkfun.com	7.96
Flex Sensor	4.5"	1	SEN-08606	Spectra Symbol	Sparkfun.com	10.36
Printed Circuit Board	1" X 1.5"	1	N/A	PCB123 (Sunstone)	sunstone.com	3.77
Casing	4"X 3"X 1.75"	1				0.35
Maxim 4194 Differential Amplifier		1	Maxim 4194	Maxim	Maxim-ic.com	1.75
LED Lights	5 mm	2	COM-00529/ COM-08285	SUN LED TECHNOLOGY CO., LTD.	Sparkfun.com	0.45
Buzzer	0.472"	1	ABT-410-RC	CUI Inc.	Sparkfun.com	1.61
On/Off Switch	6 mm	1	COM-00097	Sparkfun	Sparkfun.com	0.28
Battery	48 mm x 25 mm x 15 mm	1	ID # 27	Adafruit Ind.	Adafruit.com	3.96
Battery Holder	2.68 "x 1.29 "x 0.81"	1	SBH-9VAS	PowerRizer	Batteryspace.com	1.35

APPENDIX C: Engineering Changes since Design Review #3

WAS: An Algorithm that only allowed for the device to determine the presence of respiration was originally used.

Need image

IS: An algorithm that can detect the magnitude and frequency of respiration is now used.

Need image

This was done in order to increase the usefulness of the device. The device instead of only alerting when respiratory failure occurred will now alert when respiration is outside of the normal range. This will help the healthcare practitioners identify problems earlier.

University of Michigan, Ann Arbor

Team 11: Team Babies

Reference Image: Algorithm Image

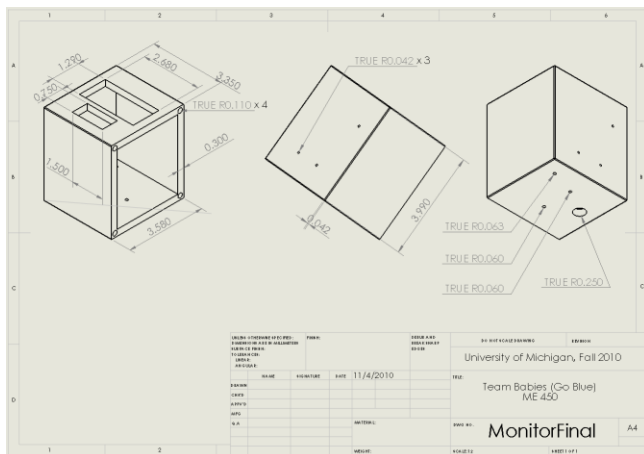
Engineer: Christopher Maue

December 1, 2010

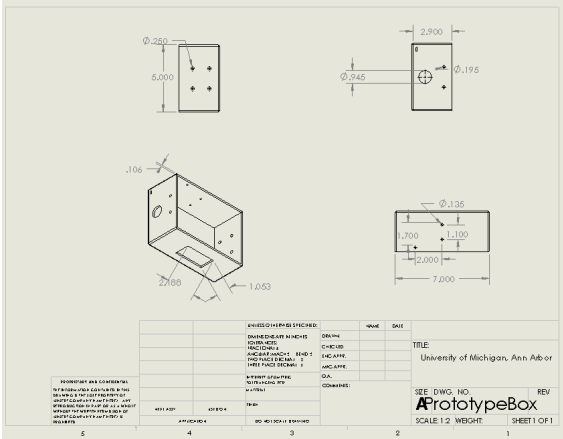
Sponser: Kathleen Sienko

December 1, 2010

2. Electrical Components Casing



Was:



Is:

This change was made in order to better fit the electrical components into a box, while using a box that was prefabricated. This reduced the time that the team needed to spend in the machine shop and increased the time that the team could spend on validation and machining a clamp. This also decreased the cost of the prototype.

University of Michigan, Ann Arbor

Team 11: Team Babies

Reference Image: Part Drawing of Monitor Box

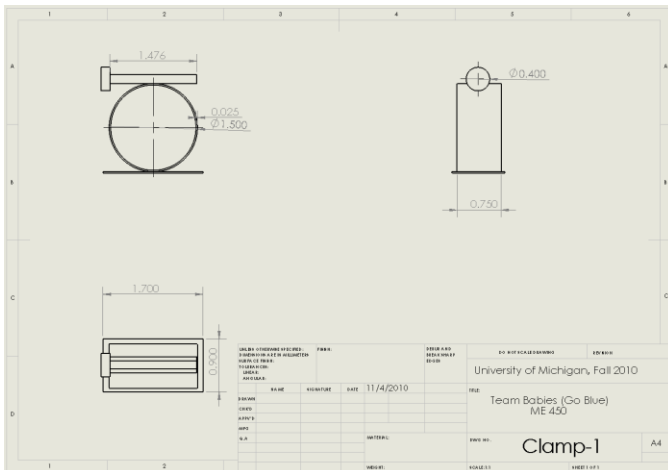
Engineer: Malvika Bhatia

November 30, 2010

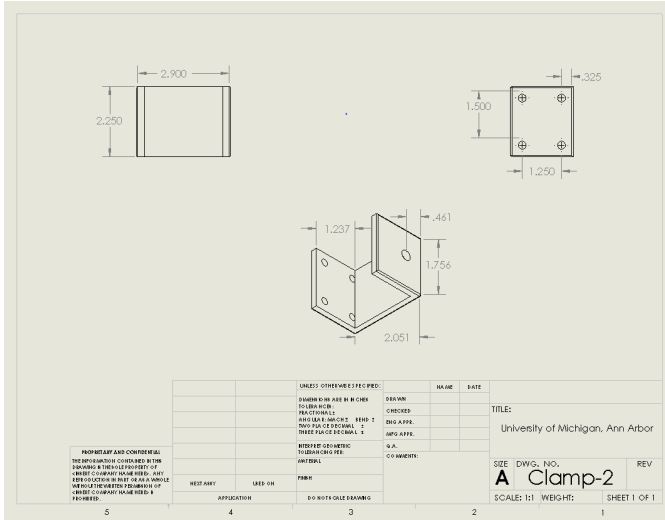
Sponser: Kathleen Sienko

November 30, 2010

3. Clamp



Was:



Is:

It was decided that a clamp manufactured specifically for our purposes would much better address the problem. A c-clamp is much easier able to attach to a crib.

University of Michigan, Ann Arbor

Team 11: Team Babies

Reference Image: Part Drawing of the Clamp

Engineer: Malvika Bhatia

November 30, 2010

Sponser: Kathleen Sienko

November 30, 2010

APPENDIX D: Design Analysis

Appendix D1: Material Selection Assignment (functional)

Function

The material will be used for a clamp and a box. We are hoping to make this one large piece. The box is used to house the electrical components including a printed circuit board, battery, and microprocessor. The clamp will attach the box to the side of a crib.

Necessary Properties

It is necessary that it be water resistant because the hospital is a moist environment because of liquids like breast milk and spit up. It is necessary that the density be less than $.8 \text{ lb/in}^3$ in order to keep the weight less than the 3kg that is part of our design specifications. In order for the clamp to not fail it is necessary for the tensile strength to be large than 4.6 ksi. Also because it is house electrical components it is necessary that the material be an insulator not a conductor. In order to be sure that the material was an insulator we decided that the electrical resistivity must be larger than $10^8 \Omega\text{-cm}$. All

medical equipment is cleaned with a bleach solution. This means that the material should be able to withstand constant contact with a weak base. Because we are designing for low resource setting it is necessary to keep the cost as low as possible.

Figure D1 shows a graph of all of the possible materials. The materials that are highlighted fit all of the above criteria. These materials were then sorted through to obtain our top five material list, which is shown below.

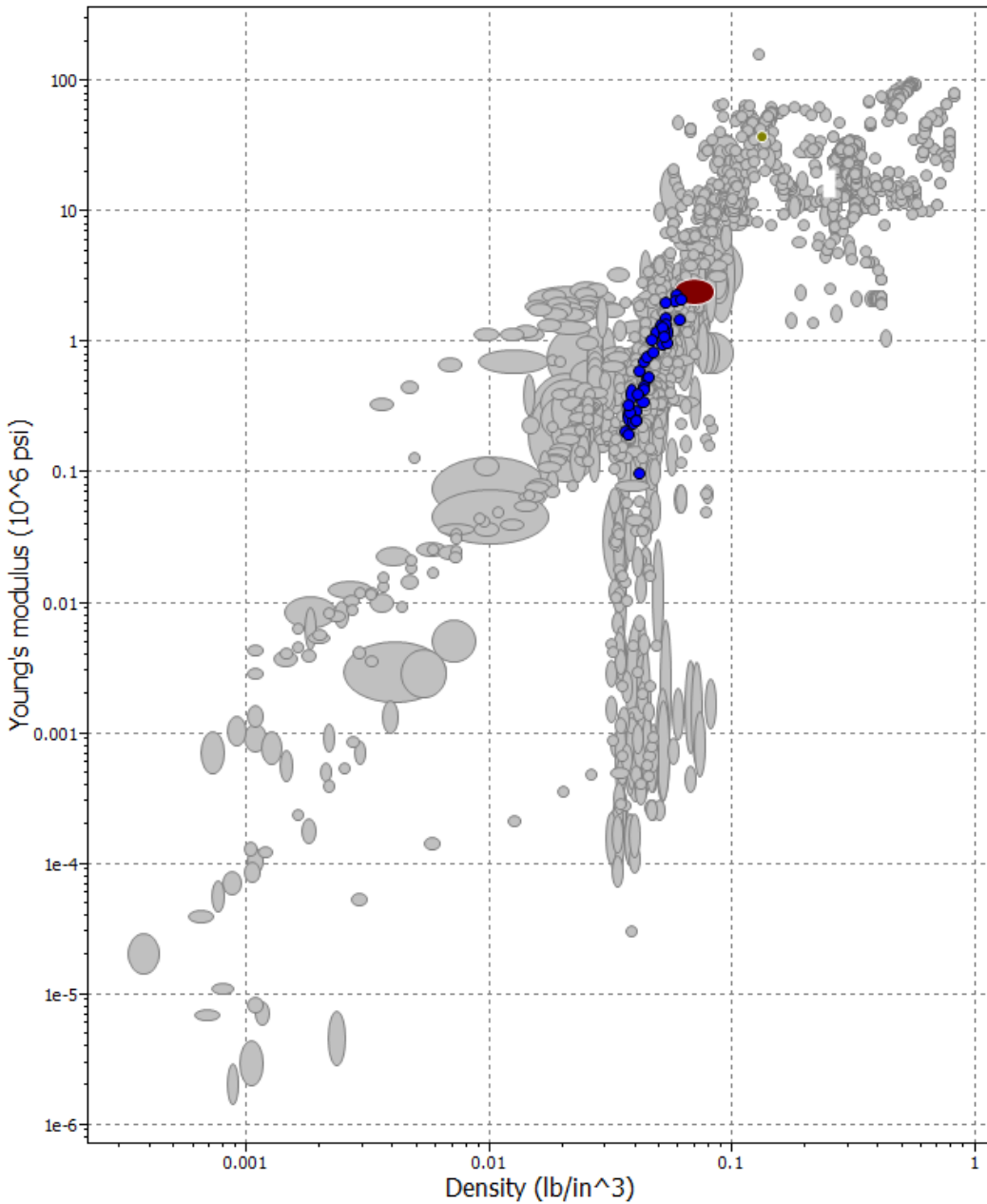


Figure D1: Possible materials to be used organized by density and Young's modulus

Top Possible Options

1. PLA (polylactic acid)- This material is a thermoplastic. Its density is approximately .044 lb/in³. The minimum tensile strength is 6.96 ksi. Its electrical resistivity is 10¹⁷. It is acceptably resistant to fresh water, salt water, and weak alkalis.
2. SMA (styrene maleic anhydride)- This material is a thermoplastic. Its density is approximately .038 lb/in³. The minimum tensile strength is 7.72 ksi. Its electrical resistivity is 1.8 x 10²¹ Ω-cm. It is acceptably resistant to fresh water, salt water and weak alkalis.
3. ABS/PVC (acrylonitrile butadiene styrene/poly vinyl chloride)- This material is a thermoplastic. Its density is approximately .04 lb/in³. The minimum tensile strength is 5.8 ksi. Its electrical resistivity is 1 x 10²⁰ Ω-cm. It is acceptably resistant to fresh water, salt water and weak alkalis.
4. PA (polyamide type 46)- This material is a thermoplastic. Its density is approximately .04 lb/in³. The minimum tensile strength is 8.09 ksi. Its electrical resistivity is 1 x 10¹⁹ Ω-cm. It is acceptably resistant to fresh water, salt water and weak alkalis.
5. PEI/PCE (Polyetherimide +polycarbonate ester alloy 30% glass fiber, impact grade)- This material is a thermoplastic. Its density is approximately .05 lb/in³. The minimum tensile strength is 19.3 ksi. Its electrical resistivity is 1.06 x 10²² Ω-cm. It is acceptably resistant to fresh water, salt water and weak alkalis.

Final Choice

SMA (styrene maleic anhydride) is our choice for the material to be used for our box and clamp. This material seems like the best choice because it has one of the lowest costs according to CES, and compared to the other thermoplastics in its price range (PLA and ABS/PVC) it is the most easily processed using molding and extrusion. It also has the highest tensile strength and the largest electrical resistivity.

Appendix D2: SimaPro

SimaPro-PVC vs. Polyactic Acid

Environmental impact is also an important factor to consider during the material selection process. The top three materials suggested by the CES software were polylactic acid, styrene maleic anhydride, and acrylonitrile butadiene styrene/poly vinyl chloride. While these materials may most adequately meet our design specifications, they may have a large negative impact on the environment.

The environmental impact of the top three materials were compared the using SimaPro software. The mass required for each material was determined using a total volume of 7.985 in³ for our device and the material densities. Using the "E199" evaluation method, the SimaPro software allowed us to compare the overall amount of emissions for two materials. First, we compared PVC and Polyactic acid, which

were materials 1 and 3 suggested by the CES software. The total mass comparison of the two materials is shown in Figure D2 below.

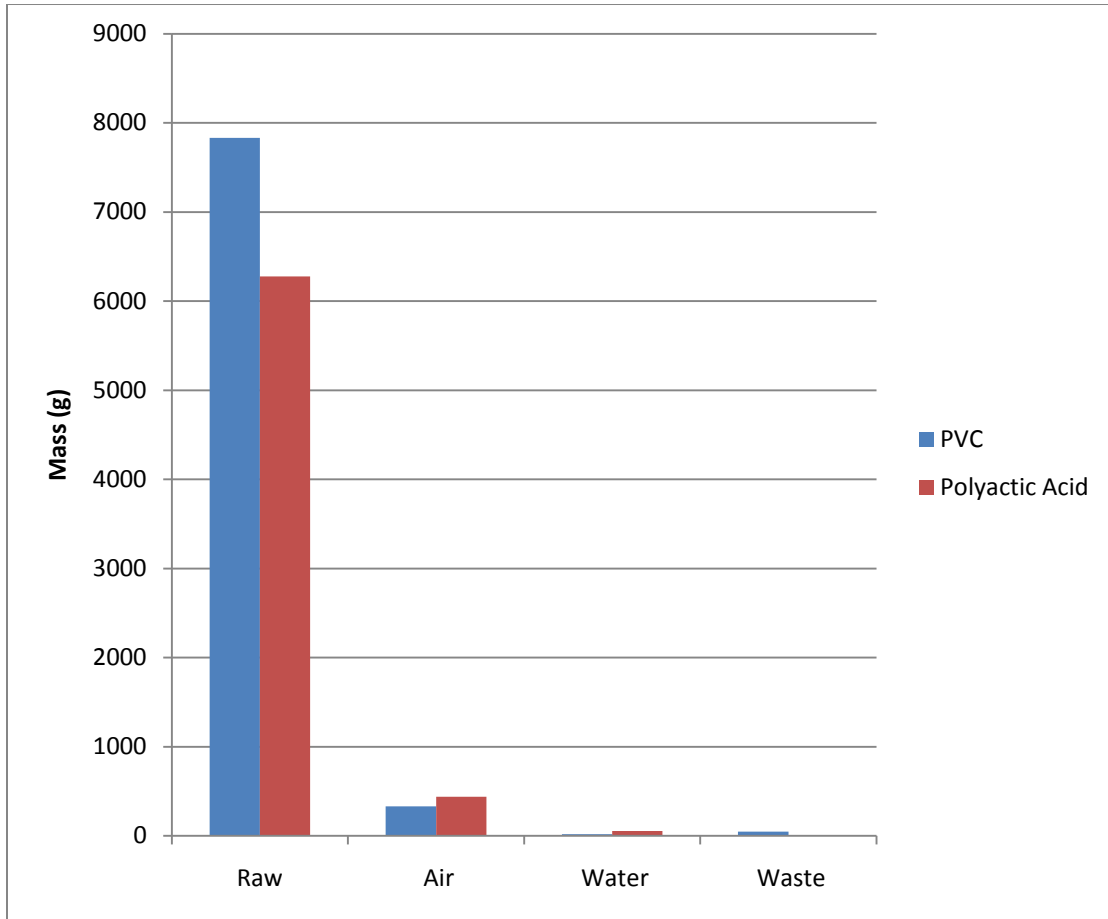


Figure D2: Mass of pollutants from production

The emissions were also expressed in terms of human health, eco-toxicity, and resource usage. 100% is standardized as the maximum emission and the other results are compared to it. The results comparing PVC and Polyactic acid are shown below.

Impact assessment | Inventory | Process contribution | Setup | Checks (568)

Characterisation | Damage Assessment | Normalisation | Weighting | Single score

Skip categories: Never

Exclude long-term
 Per impact category

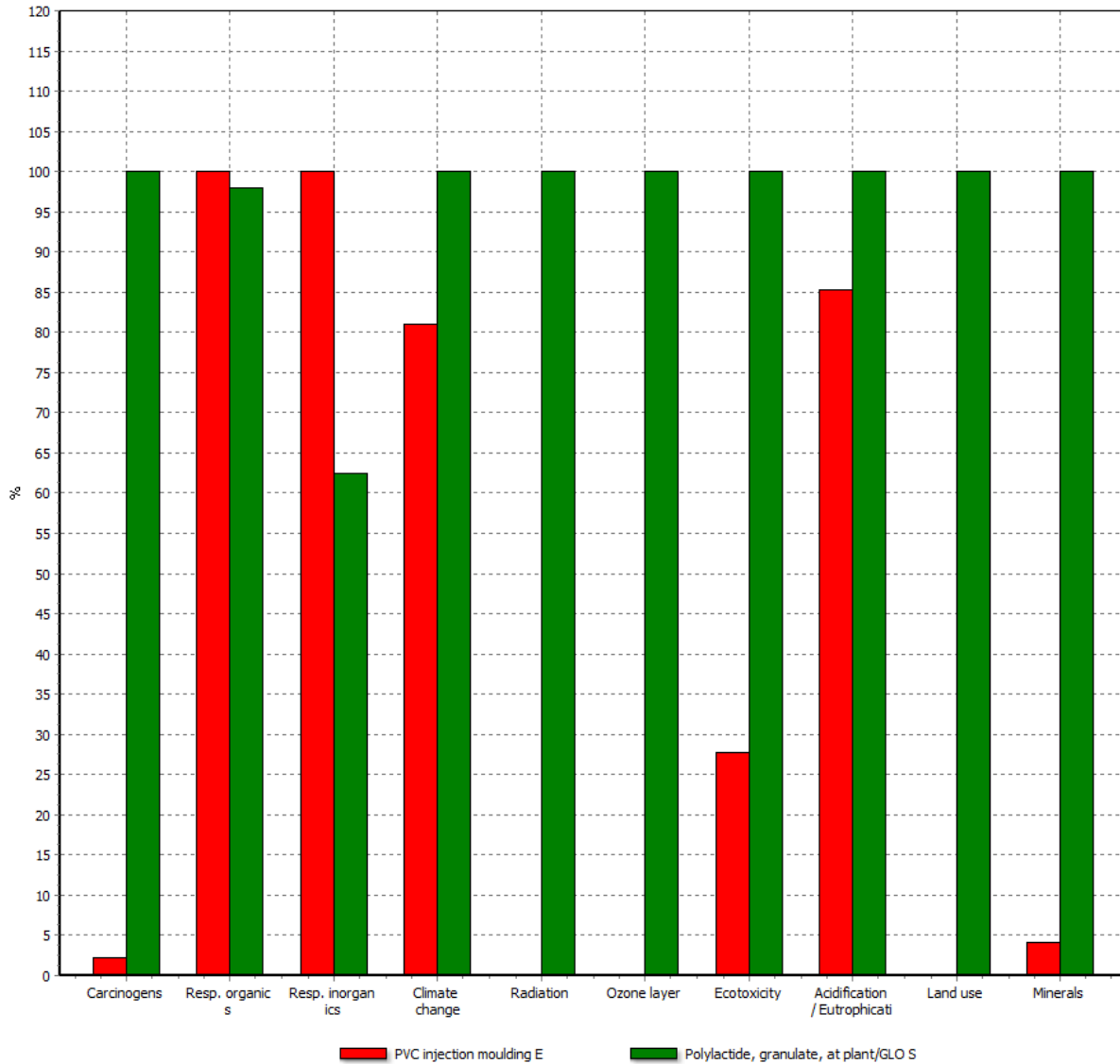


Figure D3: Characterization Indicator

The software allowed us to collapse the environmental impact into 3 categories and normalize them with average damage caused by an “average European person” over 1 year. PVC outperformed Polyactide in two of the three categories. The results are shown below.

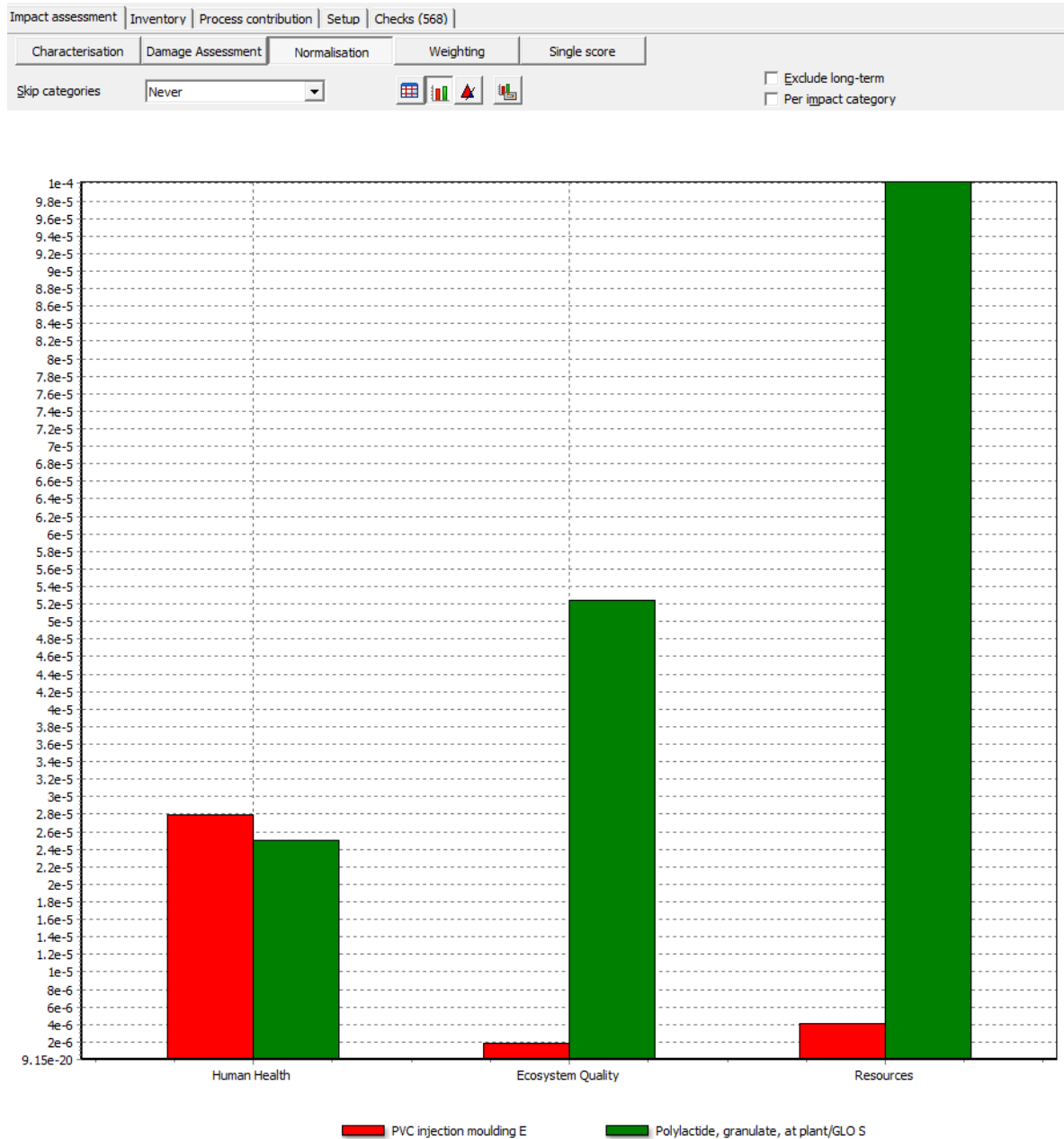


Figure D4: Normalized Indicator

Finally, the software converted the results to a “point” system, in which the scores were weighted according to the EI99 method, expressing the relative importance of human health, eco-toxicity, and resource consumption. The material with less “points” is considered to have less of a negative environmental impact, according to the EI99 evaluation method in the SimaPro software. According to our results, PVC is more environmentally friendly than the Polyactide.

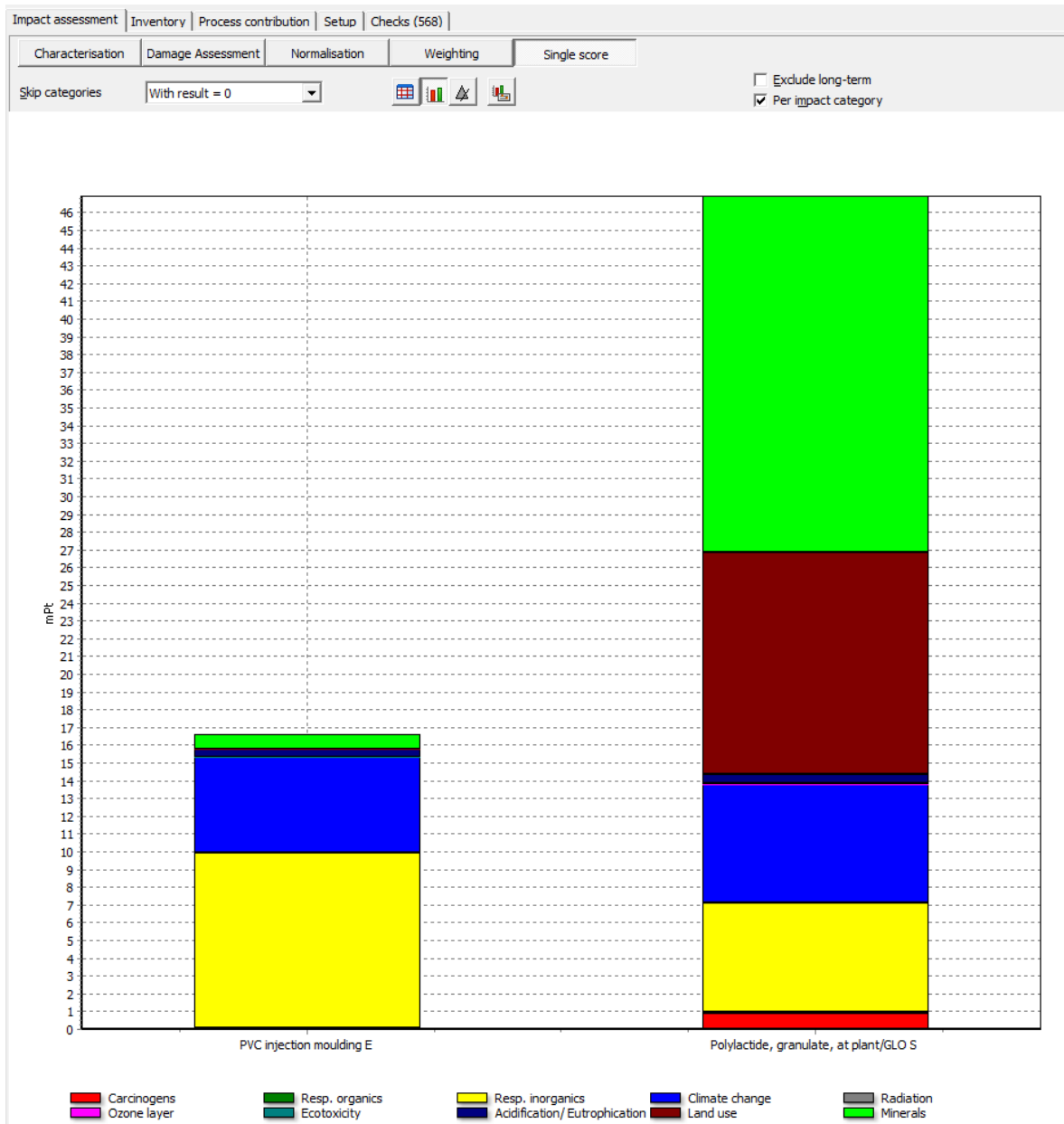
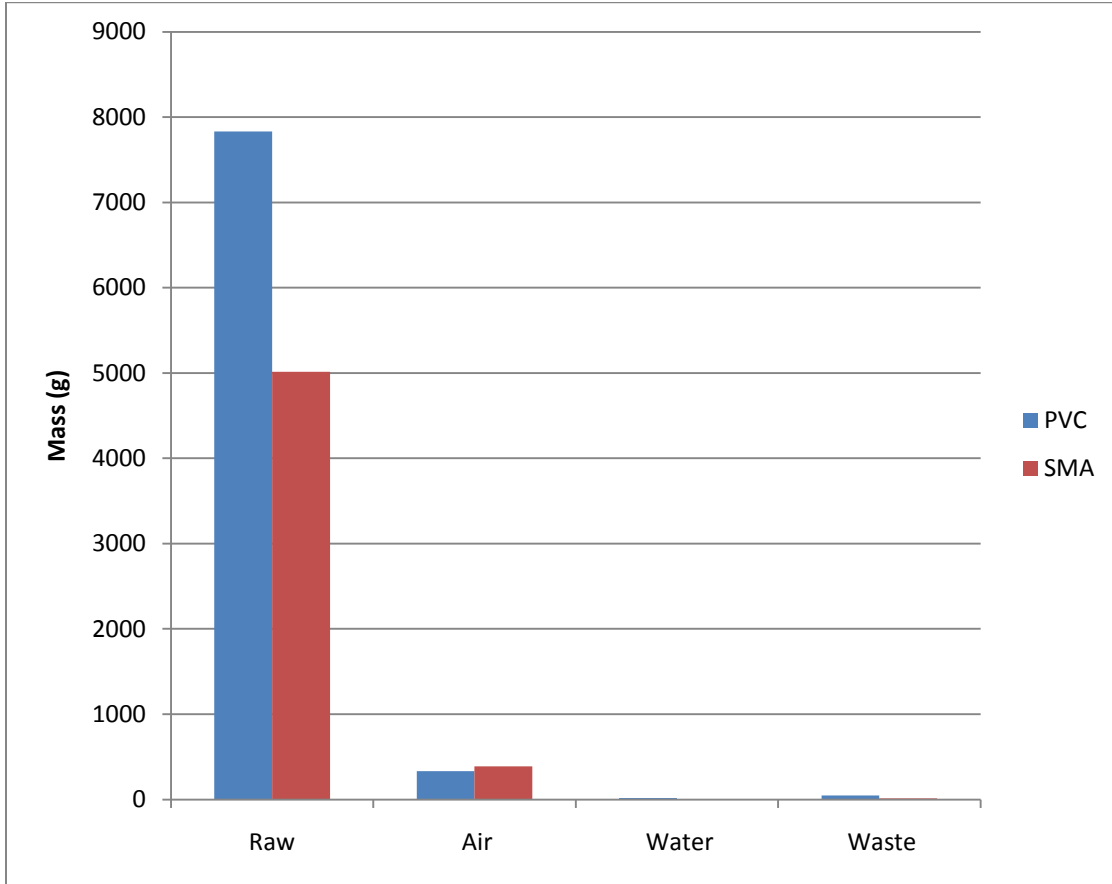


Figure D5: Single Score Indicator

PVC vs. Styrene Maleic Anhydride

The environmental impact of PVC was also compared to styrene maleic anhydride, which is a type of high impact polystyrene which was ranked highly according to the CES software. The identical analysis that was used to compare PVC and Polyamide was used to compare PVC and Styrene Maleic Anhydride. The results are shown in the figures below.



Impact assessment | Inventory | Process contribution | Setup | Checks (133)

Characterisation | **Damage Assessment** | Normalisation | Weighting | Single score

Skip categories: Never

Exclude long-term
 Per impact category

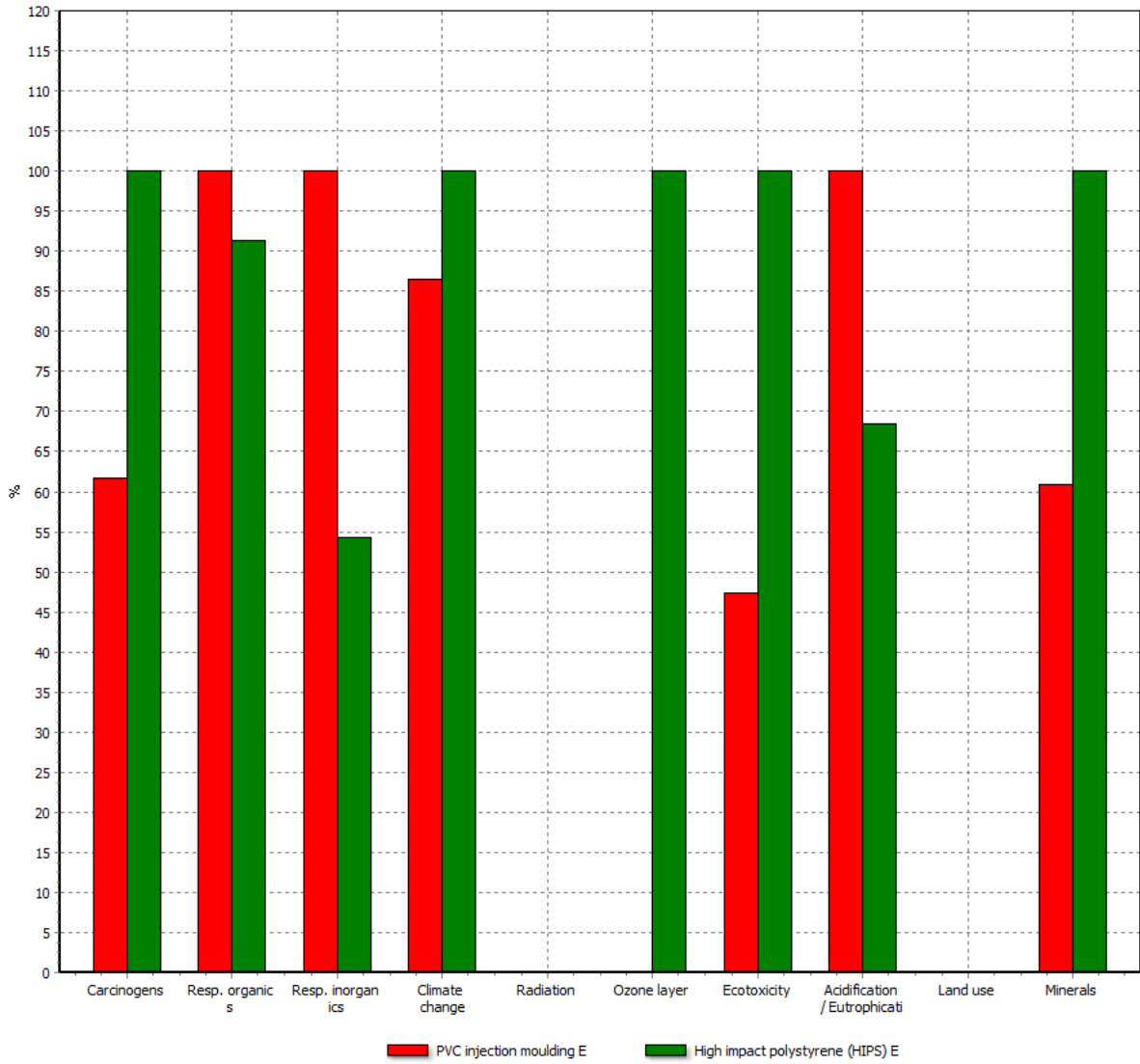


Figure D6: Characterization Indicator

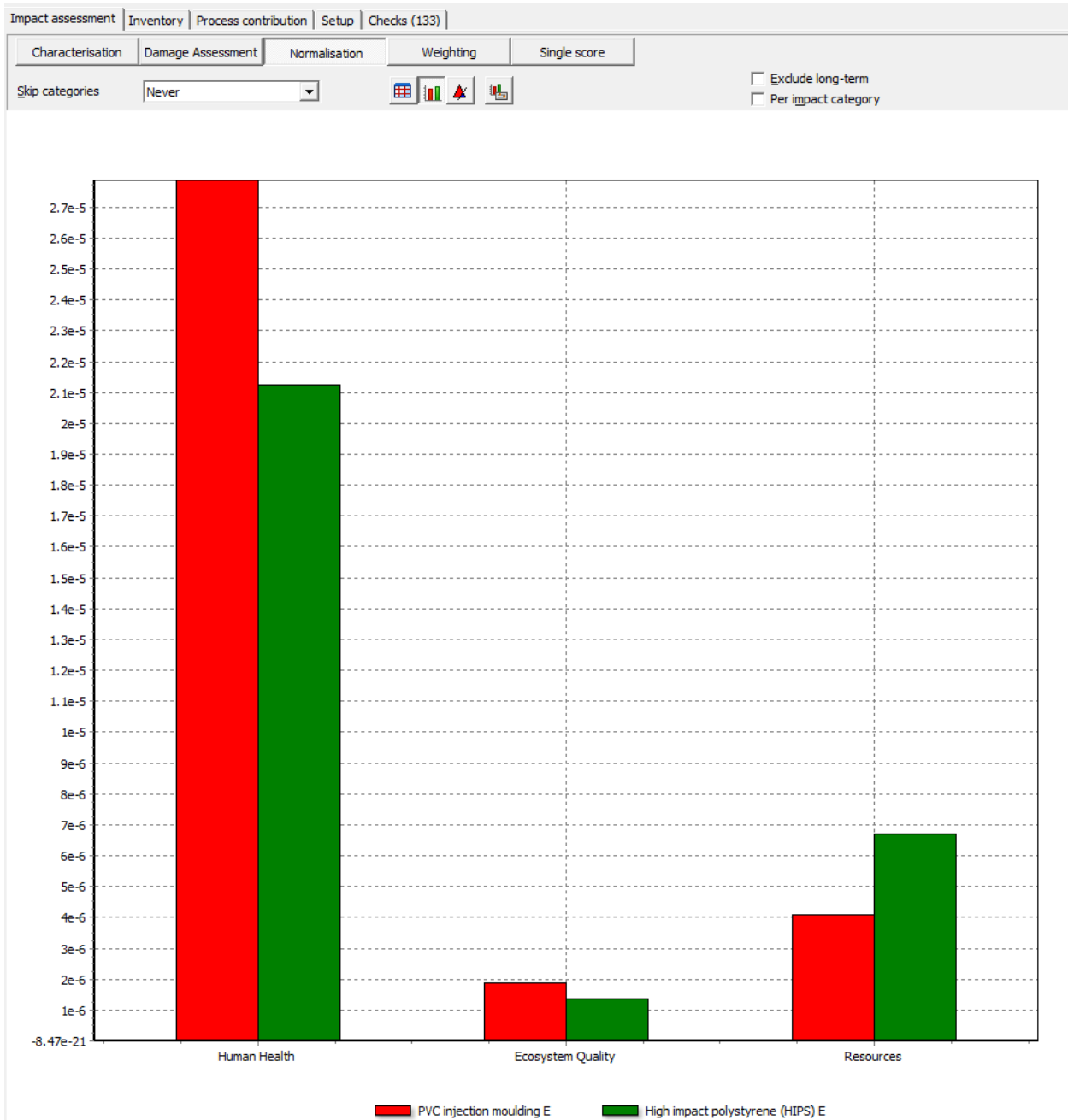


Figure D7: Normalized Indicator

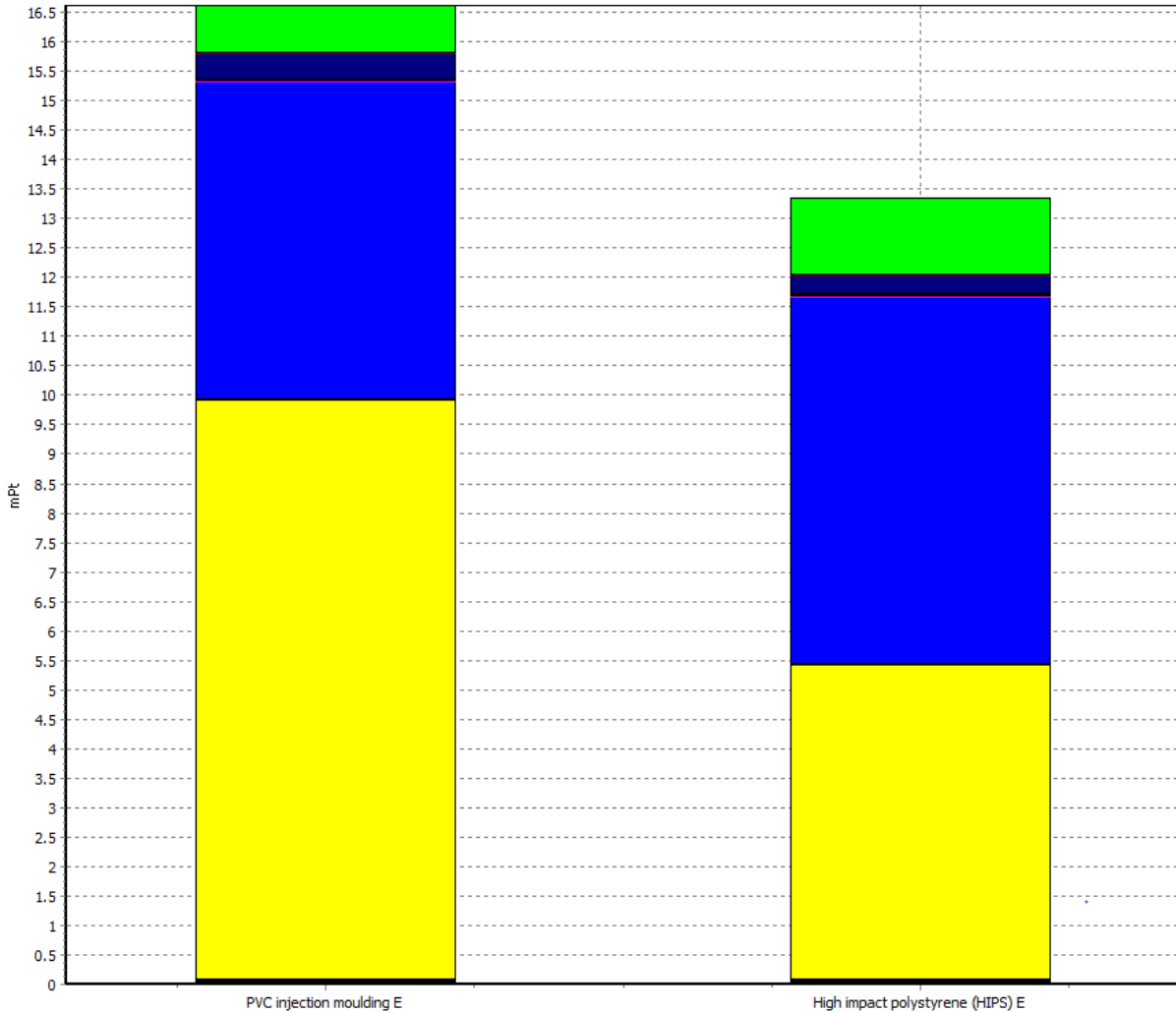
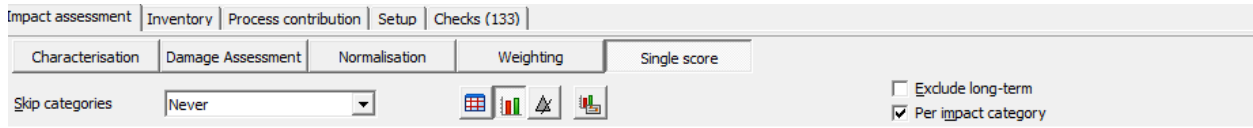


Figure D8: Single Score Indicator

Polystyrene outperformed PVC according to the weighted points system provided by the SimaPro software. Of the top three materials suggested by the CES software, Polystyrene has the lowest negative environmental impact. However, this does not necessarily indicate that it either material is good. Styrene Maleic Anhydride was therefore compared against the other top materials suggested by the CES software and shown to have less of an environmental impact. Therefore it appears that this

material is the most environmentally friendly. This confirms our selection of Styrene Maleic Anhydride as the primary material in our monitor.

Appendix D3: Manufacturing Process Selection

Manufacturing Process Selection Assignment

Real World Volume Estimation

In order to estimate the number of units to be created we started with what we knew about Ghana. The population of Ghana is about 25 million and the population of sub Saharan Africa is about 800 million. We also know that there are 3 tertiary care hospitals in Ghana that would potentially use the device. In each of these tertiary care hospitals there would be about 75 units. Using the population to tertiary care hospital ratio in Ghana we determined that there are about 96 tertiary care hospitals in sub Saharan Africa. This means that there would be about 7200 devices that would need to be manufactured. We used a range of 7000 to 7500 devices as the input to CES.

Other CES Inputs

First the shape of the box and clamp combination is both a hollow 3-D shape and a solid 3-D shape. The mass of our item will be between .5 and 6 lbs. This was found by using the volume and the material density (for the minimum) and by using the maximum weight given by our specifications. This process will be used to shape the box and the clamp, therefore it is a primary shaping process. Making the maximum relative cost index per unit 20, it reduced the number of processes to five.

Best Manufacturing Process

Injection molding (thermoplastics) seems to be the best option. This process can be used for both solid 3-D and hollow 3-D shapes. It can be used from .022 – 55.1 lbs. It is made to be used on thermoplastics, which is what our selected material is. It is used for primary shaping processes. It has a low labor intensity. The relative cost index can be as low as 18.2.

Appendix D4: Design Safe Analysis

Table D1: Output table from Design Safe

Item Id	User	Task	Hazard Category	Hazard	Cause/Failure Mode	Severity	Probability	Risk Level	Reduce Risk	Severity	Probability	Risk Level
1-1-1	All Users	Common Tasks	mechanical	drawing-in / trapping / entanglement	This refers more to the clamp. It is possible that other wires (for example) could get caught in the clamp screw and cause entanglement.	Moderate	Likely	Medium	Make sure bolt is completely inserted into the clamp when not in use so that there is no portion of the bolt sticking out. File the edges of the clamp such that there are no sharp ends for wires to get caught on.	Moderate	Unlikely	Low
1-1-2	All Users	Common Tasks	mechanical	pinch point	A pinch point in the device could be between the bolt of the clamp and the surface the clamp is being attached to. It is possible that one slips their finger in the area thereby experiencing a pinch.	Moderate	Unlikely	Low	The end of the bolt is covered with a rubber cap in order to minimize the effects of pinching.	Minor	Unlikely	Negligible
1-1-3	All Users	Common Tasks	mechanical	fatigue	It is possible that the plastic material for the monitor casing could go through fatigue failure if heavy loads are put on it from any direction. The clamp will experience fatigue failure because it will be clamped and unclamped several times.	Minor	Likely	Low	A small circular rubber attachment can be made to the surface of the bolt hole so that the edges do not form cracks due to repeated use. The thickness and material of the casing is selected such that it can tolerate large loads w/o excessive bending.	Minor	Unlikely	Negligible
1-1-4	All Users	Common Tasks	electrical / electronic	energized equipment / live parts	The strain gauge used will be exposed when the device is not attached to an infant but the device will be turned off during that time (not harmful). If the device is turned on and there is a fluid spill on it, it could potentially cause a shock.	Moderate	Likely	Medium	There is no specific design change to the device to be made except maybe adding an extra cover for the strain gauge during storage and making sure that the on/off button only works when certain forces are put on it.	Moderate	Likely	Medium
1-1-5	All Users	Common Tasks	electrical / electronic	insulation failure	The insulation failure will occur if and when the insulation on the wire attaching the strain gauge to the electronics in the casing tears or breaks at some point.	Moderate	Likely	Medium	The insulation material for the wire will be a polyethylene which is a good electrical insulator and strong enough to withstand forces from relatively sharp objects.	Moderate	Unlikely	Low
1-1-6	All Users	Common Tasks	electrical / electronic	contaminants	Contaminants could enter the casing through any small gaps. These could cause the electronics within the casing to malfunction.	Moderate	Likely	Medium	The casing will be created so that parts fit as tightly as possible with very low tolerances. This should reduce any gaps for contaminants to enter the device.	Minor	Unlikely	Negligible
1-1-7	All Users	Common Tasks	electrical / electronic	water / wet locations	When the device is being cleaned, water could enter the casing through small gaps. These could cause the electronics within the casing to malfunction.	Moderate	Likely	Medium	In addition to manufacturing the casing with low tolerances, the electronics within the casing will be coated in silicone conformable water-proof spray to prevent any water damage to the internal parts.	Minor	Unlikely	Negligible
1-1-8	All Users	Common Tasks	electrical / electronic	power supply interruption	If the battery which powers the device becomes weaker, there will be an interruption in the power supply to the device.	Minor	Likely	Low	The microprocessor used in the device operates on voltages between 3V to 20V. If the 9V battery used gets weaker, the device will still run until it is supplying a third of its power.	Moderate	Unlikely	Low
1-1-9	All Users	Common Tasks	heat / temperature	radiant heat	Since there are a couple of electronic components operating within the casing for long periods of time, there is likely to be some heat that is radiated.	Minor	Likely	Low	The casing is made out of a plastic polymer so that it does not become hot. Since the electronic components being used are not very large too much heat should not be dissipated from them. Any small gaps in device eg press fit LEDs should dissipate heat	Minor	Unlikely	Negligible
1-1-10	All Users	Common Tasks	noise / vibration	noise / sound levels > 80 dBA	The buzzer sounds an alarm at 80 db which is just a little lower than the harmful threshold for adults. However, this loudness could be harmful for infants around.	Moderate	Likely	Medium	The buzzer used sounds the alarm at 80 db or less. The buzzer goes off only until the device is switched off so the exposure to the sound isn't very great.	Moderate	Unlikely	Low
1-1-11	All Users	Common Tasks	noise / vibration	fatigue / material strength	Due to continuous use and possible knocking around, the casing and the clamp could experience fatigue failure.	Minor	Likely	Low	The size of the device is 4"x3"x1.75" small enough so that it doesn't get in the way reducing its likelihood of being knocked about. The clamp is sturdy enough to withstand strong forces so that the connection of the clamp to the casing is not damaged	Minor	Remote	Negligible

APPENDIX E: Background

Table E1: Other Patents Relevant to Monitoring Infant Respiration

Patent Name	US Patent Number	Description of Technology
Sudden Infant Death Syndrome Monitor	5,505,199	This monitor has both a blood oxygen saturation detector and a motion detector. Alarm only sounds if there is a lack of motion and blood oxygen saturation outside of the normal range (13)
Sudden Infant Death Syndrome (SIDS) monitor and stimulator	5,515,865	This monitor has both a motion detector in a fluid filled mattress and a transducer to detect the noises of breathing. If both motion and breathing are absent then the caregivers in another room are notified with both an audible sound and visual indication (23)
Monitoring Respiratory Movements Device	Application 2005/0277842	This is a monitor that uses nanotechnology for a silica chip to create an accelerometer that can sense the slight movements of the baby's chest when it is breathing. This accelerometer is connected to a micro controller that interprets the signals from the accelerometer and emits and signal to sound an alarm. This device is also intended to be used on animals for veterinary purposes (28)
Device for Monitoring Respiratory Movements	Application 2008/0015457	This is a continuation of the previous patent application. The essential idea is the same but now the microcontroller does not emit the signal to sound the alarm, but instead continuously inhibits the alarm unless the infant or animal stops breathing (29)
Infant Monitoring System	Application 2008/0024311	This monitor is a blanket that monitors pressure differences. This blanket then wirelessly transmits signals to a data processing module that is separate from the crib in which the infant is sleeping. This then signals an audible alarm system (15)
Heart and Breathing Alarm Monitor	4,738,264	A single transducer is used to detect both the heart rate and breathing rate. The circuit detects the integrated energy of the two signals from and a deviation for the standard energy range causes an audible signal for the caretaker (18)

Respiration and Movement Monitoring System	6,011,477	This monitoring system first consists of a monitor that monitors the infant's respiration. Also, it includes an optional sensor for sensing the infants overall movements. In addition it includes an optional accelerometer to sensor the movement of the platform supporting the infant. Finally it includes an optional audio sensor to detect noises of the infant. A single controller interprets all of these sensors and sounds an alarm if any of them are not within normal range (31)
Accelerometer- based Infant Movement Monitoring and Alarm Device	6,765,489	An accelerometer is attached to the baby in order to detect movement of the baby. When no movement is detected the device produces light and sound to hopefully encourage movement from the infant. The device also will alert the infant's caregivers if there is no longer infant movement (11)
Non- Contact Vital Signs Monitor	4,958,638	There is a beam of frequency similar to that of a radio wave that is continuously emitted in the direction of the body. The movement of the body that occurs when the body is breathing will create a variance in the frequency of the wave as it returns to the receiver. If the beam that returns has a constant frequency then it is known that the infant is longer breathing and the caretaker is notified (26)
SIDS Detection Apparatus and Methods	5,241,300	A transilluminated optical fiber is connected to an elastic band that is put around the infant's body. As the infant inhales and exhales the intensity of the light emitted from the optical fiber changes. This intensity is then recorded as the infants breathing pattern. If the intensity becomes constant it is known that the infant is no longer breathing (4)
Infant Health Monitoring System	5,479,932	This monitoring system has a pad that is placed under the baby. This pad monitors the baby's breathing, heart rate, and other movements. When all three of these items are lacking, then the monitoring system sounds an alarm. Monitoring all three of these things allows for a decreased number of false alarms (9)
Respiration Monitor with Simplified Breath Detector	5,611,349	This monitor has a breath detector that is attached around the torso of the infant. This monitors the movement of the infant and allows for the monitoring of breathing. In order to filter out movement that is not breathing the signal is filtered by a program that only records the movements that

would be indicative of breathing (8)

Infant Respiratory
Monitor

5,993,397

A motion sensor is clipped to a baby's clothing in the stomach area. Also in the housing that holds the motion sensor is a circuit that contains a processor and a means for audio output. The audio output signals caretakers when the movement of the infant shows respiratory distress. (3)

APPENDIX F: Design Requirements and Engineering Specifications

DESIGN SURVEY FOR INFANT RESPIRATION MONITOR

Name: _____ Email: _____
 Phone Number: _____ Position in hospital: _____

We are conducting a survey to develop a design for an **infant respiration monitor**. The table below lists all the criteria we think would be important to consider for the design.

Please rank the criteria from 1 – 5:

- 1 **Least important**
- 2 **Somewhat important**
- 3 **Important**
- 4 **Very important**
- 5 **Most important**

Each number can be applied to as many criteria as necessary.

Criteria	Importance – Rank from 1-5				
Monitors respiratory abnormalities	1	2	3	4	5
Notifies nurses of problem quickly	1	2	3	4	5
Small Shape	1	2	3	4	5
Easy to attach	1	2	3	4	5
Easy to detach	1	2	3	4	5
Fast to attach	1	2	3	4	5
Fast to detach	1	2	3	4	5
Low cost	1	2	3	4	5
Can be repaired with local materials	1	2	3	4	5
Low maintenance	1	2	3	4	5
Low negative impact on baby's health	1	2	3	4	5
Comfortable for baby	1	2	3	4	5
No excessive disturbance of surrounding people/babies	1	2	3	4	5
Low occurrence of false positives (false alarms)	1	2	3	4	5
Low occurrence of false negatives (misses problem)	1	2	3	4	5
Adjustable to any baby size	1	2	3	4	5
Low impact on baby's mobility	1	2	3	4	5
Other _____	1	2	3	4	5

Please *number* the following from 1 - 5 (5 - most important, 1 - least important) in the order of importance for monitoring an infant:

- Oxygen Saturation Respiration Rate
 Heart Rate Presence of Respiration
 Blood Pressure

Do you have any additional comments or criteria that could help us develop a better design for an infant respiration monitor?

Figure F1: User Requirement Survey Used in Ghana to Rank User Requirements

User Requirement Rankings

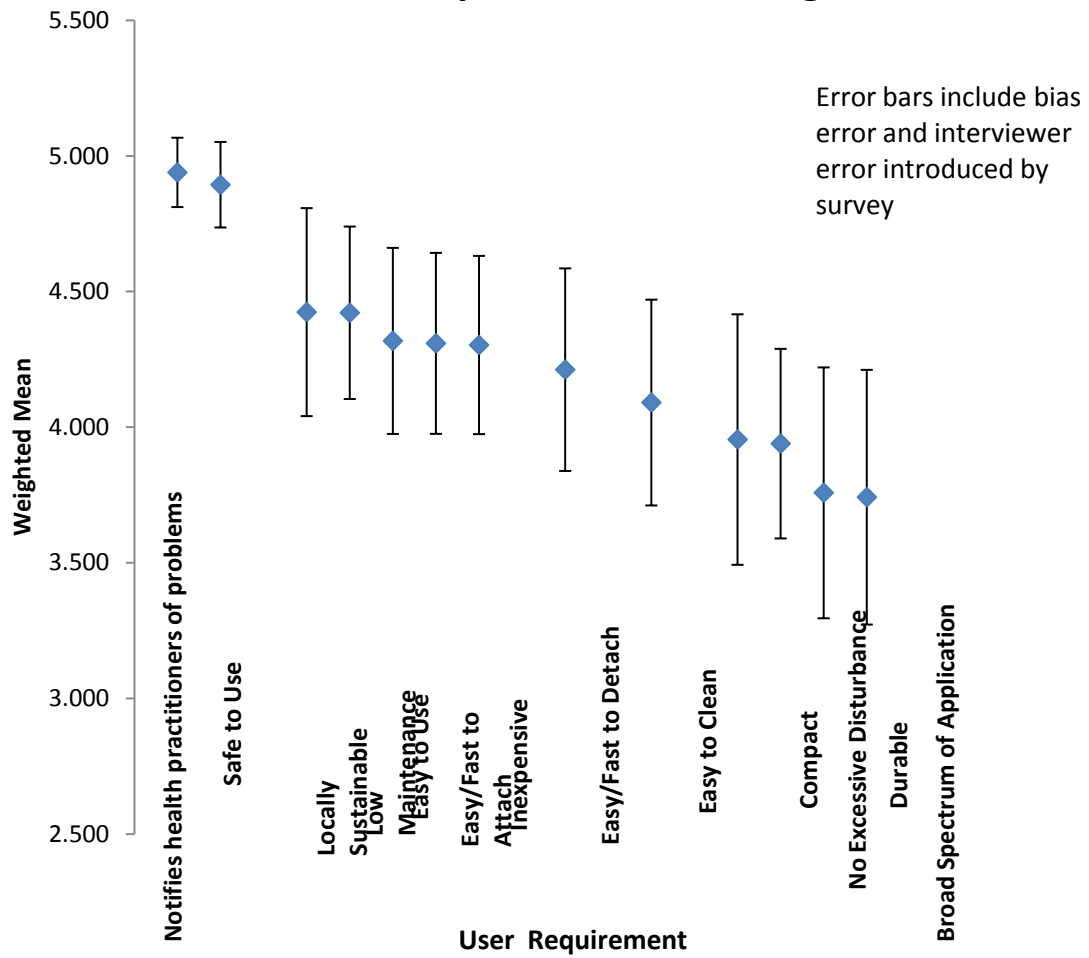


Figure F2: Statistical Analysis of User Requirement Rankings

Engineering specifications	Ped Nurse1	Ped Nurse 2	BME 1	BME2	FamPlan Nurse 1	FamPlan Nurse 2	OB/GYN Resident	Nurses	OB/GYN doctors	OB/GYN Nurse	OB/GYN Doctor	Weighted Averages	Std. Dev.
WEIGHT	5	5	3	3	1	1	30.40	3	4	2	3	#VALUE!	#DIV/0!
Acceptable range of respiratory rate (breaths/min)	12.5	10					40-60	15.00	12.30	20	20	14.342	4.472136
time taken to inform nurse (s)	30			100								87.500	14.14214
percentage of times nurse is successfully notified (% of total alarms)	20	5					13.72	15	12	10		12.825	5.032932
maximum distance from unit for successful notification (m)	0.0021	0.001769603	0.00083		0.001048772	0.0096	0.03	0.0005	0.00216	0.00216	9.29091468 × 10 ⁴	0.005	0.010094
volume (m ³)												0.108	0.067896
surface area (m ²)	2	2						0.1272	0.1272	0.1272		3.105	0.643168
overall weight of device (kg)	1							1	1	1	1	1.000	0
number of people to attach (# people)	2			2		2		3	3	3	3	2.526	0.534522
number of steps to attach (# steps)								100	100	100	100	100.000	0
percentage of people who can successfully attach device (% total attendants)								1	1	1	1	50.000	#DIV/0!
force required to set up device (N)								3	3	3	3	3.000	0
number of people to detach (# people)								1	1	1	1	1.000	0
number of steps to detach (# steps)								1	1	1	1	3.000	0
total attachment time (min)	5				1	2		2	2	10	5	4.316	3.132016
total detachment time (min)					5	2		1	2	5	2	2.643	1.722401
cost per unit (USD)	70	70										70.000	0
cost of maintenance (USD/year)				35								21.000	19.79699
percentage of locally available material (% of components)									100	80		90.769	14.14214
MTBF (months)	3	6		3		3				6	3	4.143	1.549193
MTTF (days)												0.000	#DIV/0!
number of parts (#)	fewer accessories	teach easily	circul vs small parts									#VALUE!	#DIV/0!
time taken to clean (min)	5			10 - 15		30						#VALUE!	10
time to detect maintenance issue (hrs)				1	1.5					5	10	1.000	0.408248
overall operational time (years)				4	10					0.5	1	6.333	3.21455
percentage of babies that experience negative health effects (% of total users)	0	0								0	0	0.167	0.447214
soft material (roughness factor)	metal with plastic covering	cotton/foam	tissue/cotton like	foam					soft as cotton fabric, smooth	Clothing or Blanket		#VALUE!	#DIV/0!
pressure/force on infant (g)	350			10					19	62.5	50	125.853	142.4888
max temp of parts touching baby (degrees C)	34								38.5	40	37	37.000	2.561738
min temp of parts touching baby (degrees C)	30								36.5	36.5	37	34.250	3.341656
intensity of disturbance sound (dB)	80	85				80		80	80	85		84.400	7.582875
duration of notification (s)		10		60		30		5	3.5	indefinite*	10	17.065	21.854603
Time between notifications after detection(s)									45			45.000	#DIV/0!
frequency of false positives (occurrences/hour)			0.0694 - 0.138				0.07 - 133	0.83 - 168	0.5 - 10			0.048 - 0.11	#DIV/0!
frequency of false negatives (occurrences/hour)			0.0694 - 0.138						3	0		0.0414	1.732051
percentage of babies & fits (percentile range)										95	95	93.889	0.888751
time to clean (s)	300								10	30	300	220.588	241.5988
cost to clean (USD)	0											0.000	#DIV/0!
percentage of disposable parts (% of total components)	0							5	3	0	3	2.647	2.738613
frequency of checking proper functioning of device (checks/hour)	0							0.25	0.00595		0.0417	0.122	0.1318
time taken to fix operational maintenance issue (min)				60						60	1440	465.000	796.7434
total time for full installation (min)									60	120	60	75.000	30
training required to successfully operate device (days)									7	2	1	3.803	3.201562

notes

monitor doesn't need to be on while baby is with mother, babies can be born at 700 g

flat apnea monitor to go underneath the baby?

some small devices like resistors can be found locally, IC's difficult.

should be able to be dropped from 5 feet, dust resistant for dry season, temp range of kumasi is hot, electrical components should work in hot climate (up to 40 C)

Figure F3: Weighted Mean of User Requirements Based on Responses from Likert Scale

Engineering specifications	Weighted Averages
Acceptable range of respiratory rate (breaths/min)	#VALUE!
time taken to inform nurse (s)	14.342
percentage of times nurse is successfully notified (% of total alarms)	87.500
maximum distance from unit for successful notification (m)	12.825
volume (m ³)	0.005
surface area (m ²)	0.108
overall weight of device (kg)	3.105
number of people to attach (# people)	1.000
number of steps to attach (# steps)	2.526
percentage of people who can successfully attach device (% total attendants)	100.000
force required to set up device (N)	50.000
number of people to detach (# people)	1.000
number of steps to detach (# steps)	3.000
total attachment time (min)	4.316
total detachment time (min)	2.643
cost per unit (USD)	70.000
cost of maintenance (USD/year)	21.000
percentage of locally available material (% of components)	90.769
MTBF (months)	4.143
MTTF (days)	0.000
number of parts (#)	#VALUE!
time taken to clean (min)	#VALUE!
time to detect maintenance issue (hrs)	1.000
overall operational time (years)	6.333
percentage of babies that experience negative health effects (% of total users)	0.167
soft material (roughness factor)	#VALUE!

pressure/force on infant (g)	125.853
max temp of parts touching baby (degrees C)	37.000
min temp of parts touching baby (degrees C)	34.250
intensity of disturbance sound (dB)	84.400
duration of notification (s)	17.095
Time between notifications after detection(s)	45.000
frequency of false positives (occurrences/hour)	0.048 - 0.11
frequency of false negatives (occurrences/hour)	0-.0414
percentage of babies it fits (percentile range)	93.889
time to clean (s)	220.588
cost to clean (USD)	0.000
percentage of disposable parts (% of total components)	2.647
frequency of checking proper functioning of device (checks/hour)	0.122
time taken to fix operational maintenance issue (min)	405.000
total time for full installation (min)	75.000
training required to successfully operate device (days)	3.833

Figure F4: Summary of Results from F3

APPENDIX G: Concept Generation

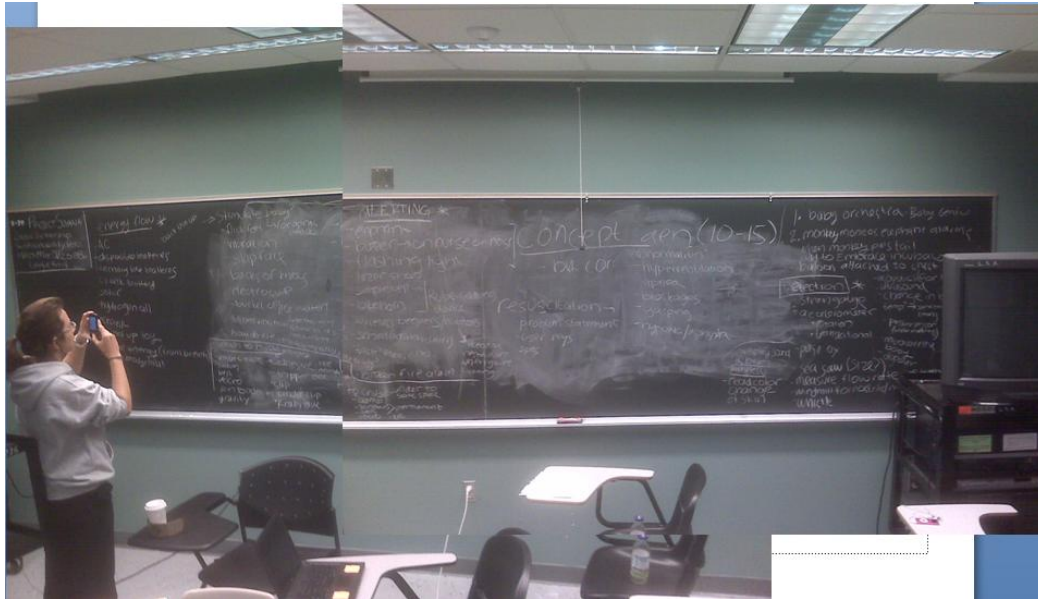


Figure G1: Brainstorming Session 1

Table G1: Comprehensive List of Ideas by Component from Brainstorming Session 1

“Great” (initial) ideas:

- Baby orchestra
- Monkey monitor—elephant alarms
- when monkey pulls its tail

- Add to the Embrace incubator
- Balloon attached to the chest

Detection:

- Strain Gauge
- Accelerometer
 - Rotational
 - Translational
- Pulse Oximeter
- Sea saw (size change) from chest to stomach
- Measure flow rate of air out of mouth or nose
- Windmill for nostrils or mouth
- Whistle
- Acoustics (for heart rate or listening to breath sounds)
- Ultrasound
- Change in body temp (sensitivity, timing)
- Pressure sensor (under mattress)
- Microwave the baby
- Doppler
- Sonar
- Amplify sound

- Electromagnetic induction
- IR beam
- Read color change of skin

Alerting

- Elephant
- Buzzer → on nurse or noise
- Flashing light
- Simple bell
- Bike horn → Rube-Goldberg device
- Wireless beepers/vibrators
- Smell—scratch and sniff
- Taste—please no.
- Broken fire alarm

Energy Flow

- AC
- Disposable batteries
- Rechargeable batteries
- Crank battery
- Solar
- Hydrogen cell battery
- Crank
- Wind up toy
- Wind energy (from breath)

- From body heat

Stimulate baby?

- Flick feet
- Vibration
- Slap face
- Backs of knees
- Electrocute
- Bucket of ice water → Not feasible in Ghana b/c ice is not available
- Full bed vibration

Attachment

- Athletic tape
- Suction
- Belt
- Velcro
- Pin to clothes
- Gravity
- Adhesive (like electrodes)
- Stripper bra
- Clip
- Binder clip
- Crazy glue
- To crib?
 - Clamp
 - Screws
 - Nails
 - Velcro
 - Tie
 - Under bed

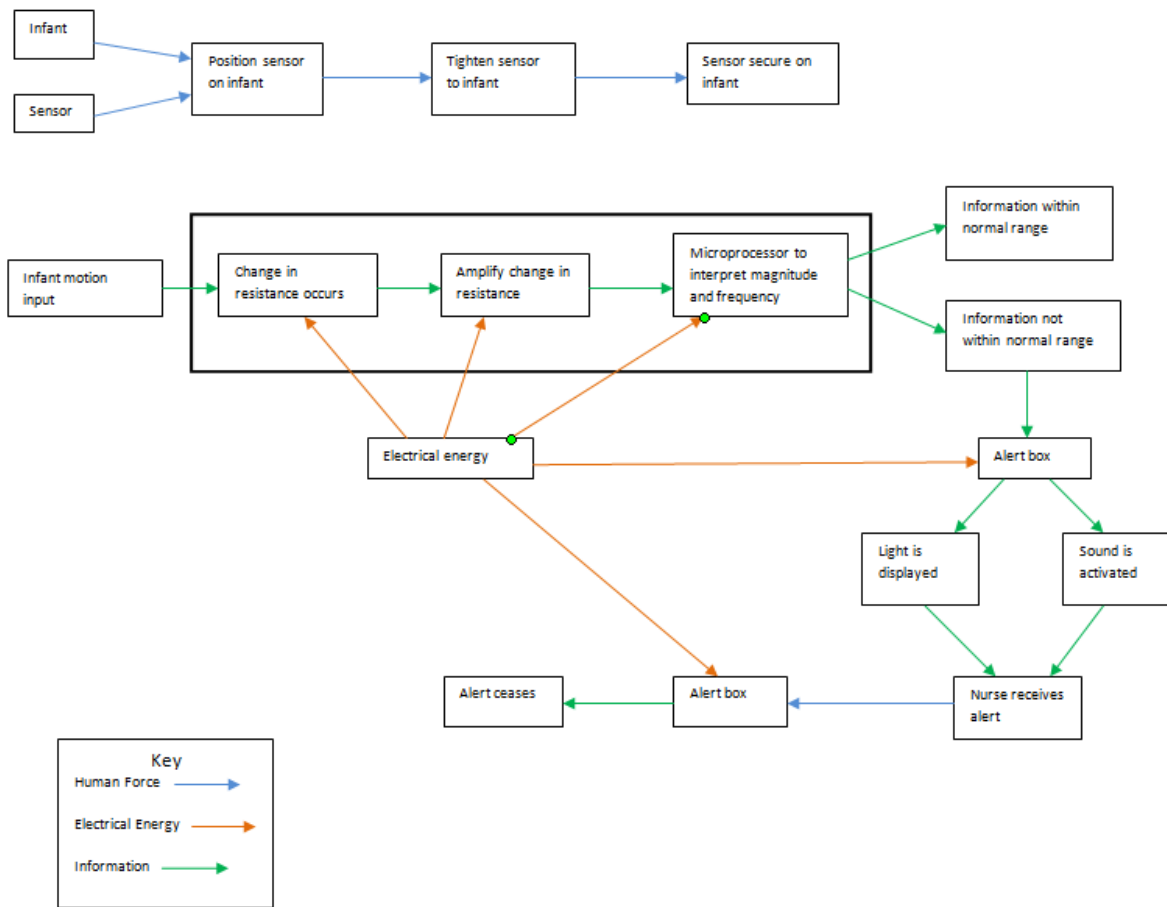
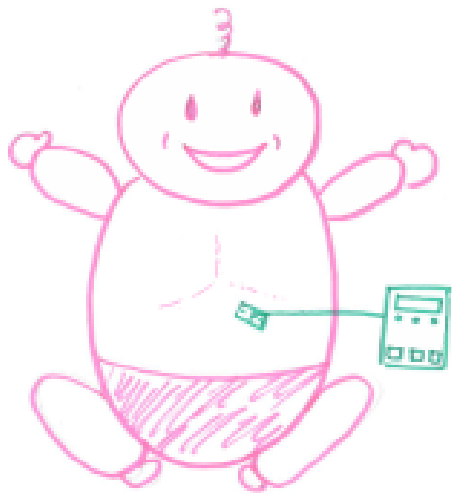
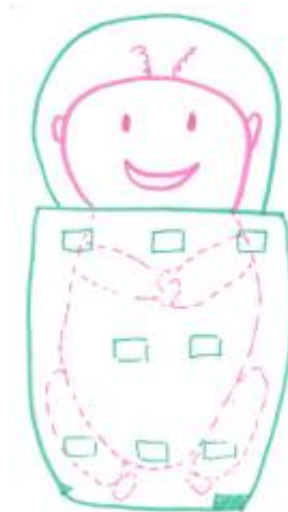


Figure G2: Functional Decomposition Diagram

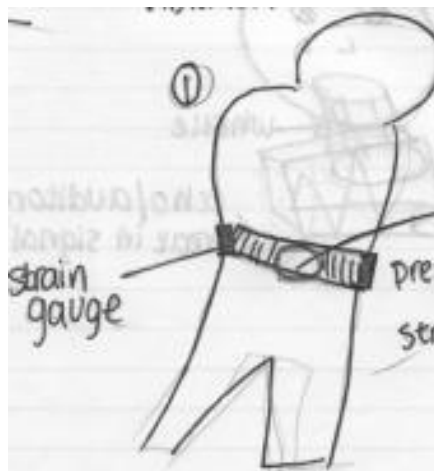
Accelerometer/Strain Gauge



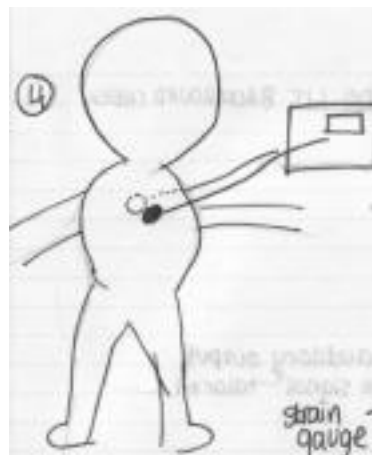
Pressure Sensor Pouch



Strain Gauge Belt



Suction Electrode Displacement Monitor



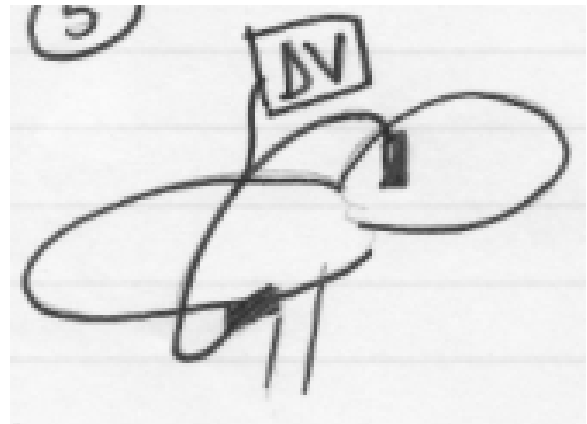
Nostril Airflow Meter



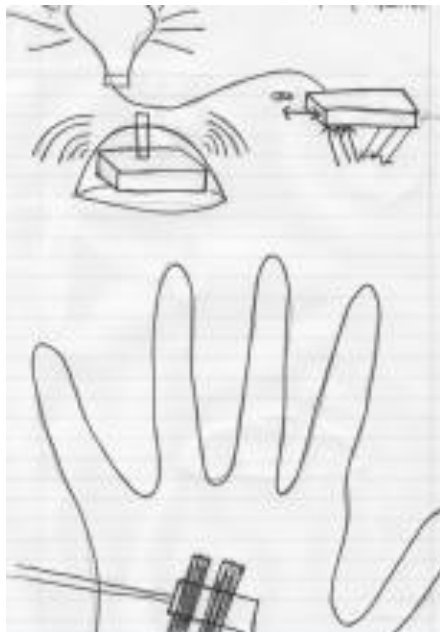
Glass Condensation Beam



Thermocouple



Light Lip Color Gauge



CO₂ Output Monitor

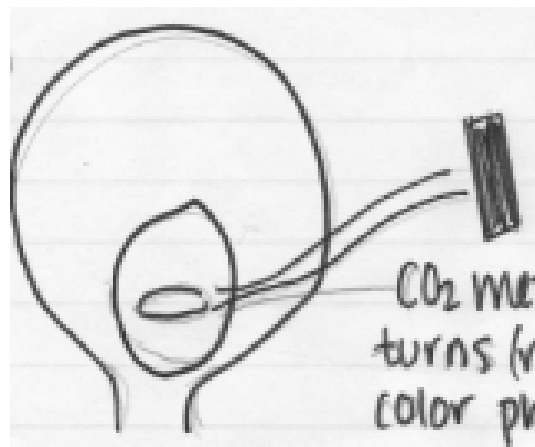


Figure G3: Top Nine Concept Drawings

Description of Eliminated Designs

Sound Amplifier- A microphone would be placed near the infant's mouth and nose. This microphone would pick up the sound of the air moving into and out of the infant. This sound could then be amplified and read in order to get a respiration rate. This idea was discarded because in the Mother Baby Unit (MBU) there is a lot of ambient noise. This ambient noise would also be picked up in the microphone and would make it difficult to get a respiration rate purely from sound.

Under Infant Pressure Sensor- A pressure sensor pad that would be small enough to be placed directly under the infant. The pad would have force transducers that would monitor the movement of the infant. This idea is unrealistic because the force transducers would have to be sensitive enough to monitor minor movements, but would have to be able to not read the movement of the other infants in the crib. Because there are multiple infants on one mattress this idea is not feasible.

See Saw Rotational Accelerometer- A bar with an implanted accelerometer would be placed longitudinally across the torso of the infant. As the infant inhaled and exhaled there would be a motion of both the chest and stomach moving the bar and accelerometer would move and monitor the respiration of the infant. The major problem with this concept was that all infants do not have rotating movement between the stomach and the chest. This means that the device would not interpret the breathing of this infant and would be useless.

Air Balloon Pressure Belt- This device consists of a belt that would be placed around the infant's chest with an air filled pouch between the infant and the chest. The air pressure inside of the air pouch would change as the infant inhaled and exhaled. This change in air pressure could be measured and would give the respiration rate of the infant. This idea was eliminated because it was similar to the strain gauge belt, and the team felt that the strain gauge belt was a better fit for our project.

Pressure Sensor Belt- This is another belt idea similar to both the strain gauge belt and the air balloon pressure belt. This belt, like the others, would be wrapped around the infant's chest. In between the belt and the chest there would be pressure sensors. The pressure on these sensors would increase when the infant's chest expanded as it inhaled, and it would decrease when the infant's chest contracted as the infant exhaled. This was eliminated because it was very similar to the strain gauge belt, which the team liked better.

Nostril Windmill Sensor- A very small windmill would be placed at the exit of the infants nostril in order to monitor air flow through the nostril. As the infant inhaled the windmill would rotate one way creating a current. As the infant exhaled the windmill would rotate the opposite way also creating a current. These currents could be interpreted in order to obtain a respiration rate. The major problem is that not all infants breathe through their noses. Also many infants are hooked up to oxygen in the nostril area. This means that this device would not work on these infants, which are the infants that have the greatest need to be monitored.

Electric Field Inductor- A piece of metal would be placed on the infant's chest. There would be an electric field surrounding the infant. As the infant breathed the piece of metal would move creating a

current. This current would move into a fire alarm like device. When there was no longer a current the alarm would sound. This idea was removed because a room full of electric fields did not seem very safe for the infants. Also the electric fields and currents of the different babies have the potential to interact with each other because the infants are in such close proximity. This would increase the chance of the device missing a problem.

Chest Sound Monitor- When the infant inhales and exhales there is sound that is created by air movement in the chest. This sound could be monitored by a microphone placed directly onto the chest. The microphone would need to be surrounded by a noise canceling device so that the ambient noise in the room would not affect the reading. This device is not feasible because it would also pick up the heart rate of the infant. It would be very difficult to separate the noise produced by the heart from the noise produced by the lungs because they are so close to each other.

Whistle Sound Monitor- A small whistle would be placed at the side of the infant's mouth or nose. This whistle would amplify the sound of the infant's breathing pattern. The sound would then be contained within a sound proof cavity that contained a microphone. This microphone would internalize the noise that would then be interpreted to the infant's respiration pattern. This problem with this device is capturing the infant's air flow. Infants vary whether they breathe through their mouth or nose which would make it difficult to continuously monitor the breath.

Pros and Cons of Eliminated Designs

The glass condensation beam idea was a design that had a glass shape in front of the infant's mouth and nose that would collect condensation when the infant was breathing. There would then be a light beam that would shine through the glass into a receptor on the other side. If the baby stopped breathing, then there would no longer be condensation on the glass and the receptor would see the full strength of the light beam and alert health care workers. This would be a good idea because all babies would create condensation when breathing, and light waves will not be as strong when passing through condensation instead of clear glass. This idea would require that the glass be kept clean. This could be difficult and could create many false alarms. Also, if a glass device was dropped it would shatter. This means that it would not be very safe for the surrounding babies that could be hit with glass shards and that the device would not be very durable because a major part would have to be replaced every time the device was dropped.

The light color gauge device was a design that had a light that would shine at either the hand or the bottom of the foot of the infant. There would then be a light receptor that would read the color composition of the light. If the hand or foot of the infant changed color then the alarm would sound notifying health care workers of the problem. This incorporated the way that the health care workers at KATH already detect respiratory problems, which is by visually looking at the color of the infant. The team was concerned with the rate at which an infant changes color after respiratory failure, the other problems that could create a color change, and the difficulty of having infants with many different skin colors. Another idea that was looked at was using LCD technology in order to amplify the temperature change of the infant's skin. This was ruled out because of the cost of LCD technology.

APPENDIX H: Concept Selection

Design Criteria	Weight	Accelerometer/Strain Gauge	Nostril Airflow Meter	Light Lip Color Gauge	Pressure Sensor Pouch	Strain Gauge Belt	Condensation Beam	Thermocouple	CO2 Output	Sonar Blanket	air balloon pressure belt	Pressure sensor belt	Nostril windmill sensor	Suction electrode distance monitor	Electric Field Inductor	Chest Sound Monitor	whistle sound monitor	
Number of stars!		3	2	2	3	3	2	2	2	3	1	1	1		1	1	1	1
Notifies health care workers effectively	2	2	-2	0	2	2	0	-2	0	0								
Safe to use	2	-2	0	2	2	0	-2	2	2	2								
Locally sustainable	2	0	0	-2	0	2	0	2	-2	-2								
Low Maintenance	2	0	-2	0	-2	-2	0	2	2	-2								
Easy to Use	2	2	2	2	2	-2	2	0	2	2								
Easy/Fast to Attach	2	2	-2	-2	2	-2	0	-2	0	-2								
Easy/Fast to Detach	2	2	2	2	2	2	2	2	2	2								
Inexpensive	2	2	2	-2	2	2	-2	2	0	0								
Easy to Clean	1	0	-1	-1	-1	-1	1	-1	-1	1								
Compact	1	1	1	1	1	1	1	1	1	1								
No excessive disturbance of surroundings	1	1	0	-1	1	1	-1	-1	0	-2								
Durable	1	1	1	-1	-1	-1	-1	0	-1	0								
Broad spectrum of application	1	1	1	1	1	1	1	1	1	1								
Counts	-	-1	-4	-6	-3	-5	-4	-4	-3	-4								
	0	3	3	2	1	1	4	2	4	3								
	+	9	6	5	9	7	5	7	6	6								
	w/weight	12	2	-1	11	3	1	6	6	1								
	w/o weight	8	2	-1	6	2	1	3	3	2								

Figure D1: Numerical Pugh Chart Analysis

Pugh Chart Justifications

1. Airflow/nose

- Effective: the baby may start breathing out of its mouth
- Safe: Could cause blockages for noise
- Durable: circuitry constantly in a moist environment around nose may cause it to wear out
- Local: sensor may or may not be there
- Applicable: different nose sizes, some babies may breath out of their mouths due to sinus trouble
- Maintenance: fluids coming out of nose may ruin sensor
- Easy to use: once its in there is nothing else to do
- Attach: must secure in nose, can slip off face, have to adhere to face
- Detach: take off easily
- Inexpensive: it just is
- Easy to clean: it's in the nose, body fluids
- Compact: probably just a small sensor
- Disturbance: a little more sketchy in its detection, looking at dealing with air flow from room

2. Lip color gauge

- Effective: meh, don't know enough yet about body temps
- Safe: no circuitry, just color detection
- Local: weird materials
- Maintenance: depends if you need to purchase a new part, don't know enough about the design (DO NOT KNOW)
- Easy to use: simple mechanism
- Attach: secure to lip??
- Detach: Same as nose sensor

- h. Inexpensive: would need very complicated technology, and you have to set a null default color, and sensitive sensors
 - i. Easy to clean: fluids from mouth, electrical to clean, needs to be constantly sanitized
 - j. Compact: One small device, all inclusive
 - k. Disturbance: Babies color changes for all different reasons, may turn red when they cry
 - l. Applicable: can set a null
 - m. Durable: dealing with fluids and possible disposable materials
3. Pressure motion pouch
- a. Effective: pressure is a basic measure that would definitely measure motion, which is reliable of breathing
 - b. Safe: pouch
 - c. Local: sensor, depends if the design is all inclusive and the pouch is attached to the sensor
look up astronaut blankets for after marathons
 - d. Maintenance:
 - e. Easy to use:
 - f. Attach:
 - g. Detach:
 - h. Inexpensive: cheap materials for pouch and sensor
 - i. Clean: lots of crevices, baby could pee in it
 - j. Compact:
 - k. Disturbance:
 - l. Durable: dealing with moisture and mess
 - m. Applicability:
4. Glass condensation gauge
- a. Effective:
 - b. Safe: made of glass
 - c. Local:
 - d. Maintenance: may have to replace the light
 - e. Easy to use:
 - f. Attach:
 - g. Detach:
 - h. Inexpensive: glass, more difficult manufacturing, laser beam
 - i. Clean: glass is super easy to clean
 - j. Compact:
 - k. Disturbance: many variable factors
 - l. Durable: material is not
 - m. Applicability:
5. Thermo-couple
- a. Effective: Temperature is an indirect method to measure respiration, and thermocouples have difficulty with measuring less than 1C
 - b. Safe:
 - c. Local:
 - d. Maintenance:
 - e. Easy to use: variables with placement
 - f. Attach: multiple components to attach
 - g. Detach:
 - h. Inexpensive: cheap metals
 - i. Clean: corrosive metal?

- j. Compact:
 - k. Disturbance:
 - l. Durable:
 - m. Applicability: looks at a temp difference, not a null value
6. CO2 sensor
- a. Effective: is there a chemical that would change color?
 - b. Safe: just a color monitor
 - c. Local: finding chemical
 - d. Maintenance:
 - e. Easy to use: very visible, look at color
 - f. Attach: needs to catch breath
 - g. Detach:
 - h. Inexpensive: depends on chemical properties
 - i. Clean: have to clean tubes, careful with chemicals
 - j. Compact: just a mask
 - k. Disturbance: no clue how effective this will be, but there will be a color change which is easy to see
 - l. Durable: housing gasses
 - m. Applicability: just CO2
7. Suction electrode
- a. Effective: measuring motion, direct measure of respiration, could different baby's electrodes communicate with each other?
 - b. Safe: electrodes are safe?
 - c. Local: kind of advanced equipment
 - d. Maintenance:
 - e. Easy to use: once it's on, and it's on correctly you don't need to do anything
 - f. Attach: needs to be lined up well
 - g. Detach:
 - h. Inexpensive: common technology
 - i. Clean: would use disposable electrodes
 - j. Compact: small
 - k. Disturbance: could be interacting with each other
 - l. Durable: maybe delicate
 - m. Applicability: all baby's chests move when they breathe
8. Pressure belt
- a. Effective:
 - b. Safe: belt could be constricting
 - c. Local: stretchiness factor could be difficult, but we can use a rubberband
 - d. Maintenance: properties could change with temperature and use
 - e. Easy to use: requires more attention than other things
 - f. Attach: needs to be in exactly the right spot
 - g. Detach:
 - h. Inexpensive: strain gauge and rubber are very easy to find and cheap!
 - i. Clean: material issues
 - j. Compact: folds up
 - k. Disturbance: sensitive
 - l. Durable: stretchy things wear out, getting wet could be a problem
 - m. Applicability: easy to adjust a belt

APPENDIX I: Alpha Design

Figures I1 to I2 show different views of the CAD drawing made for the alpha prototype. Figure I3 shows the part drawings of the device.

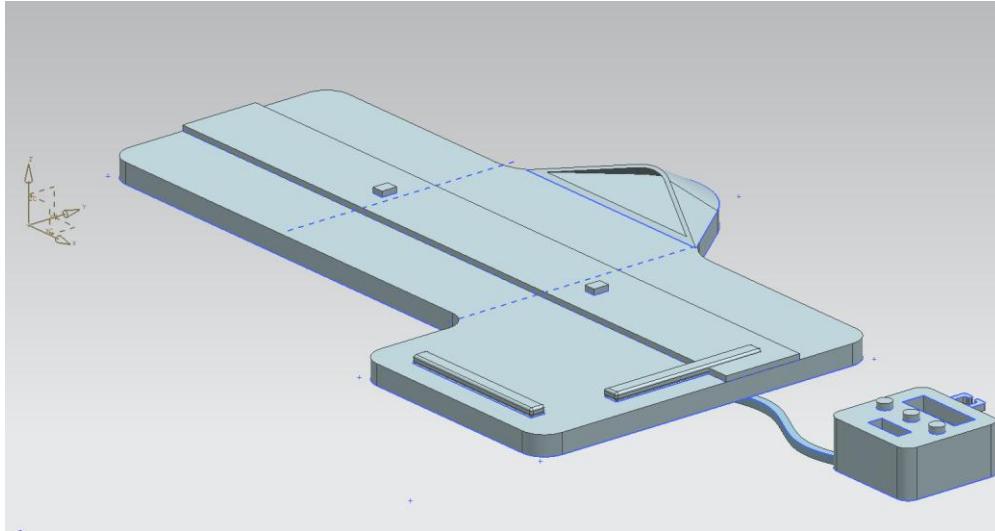


Figure I1: Isometric View of the Alpha Prototype

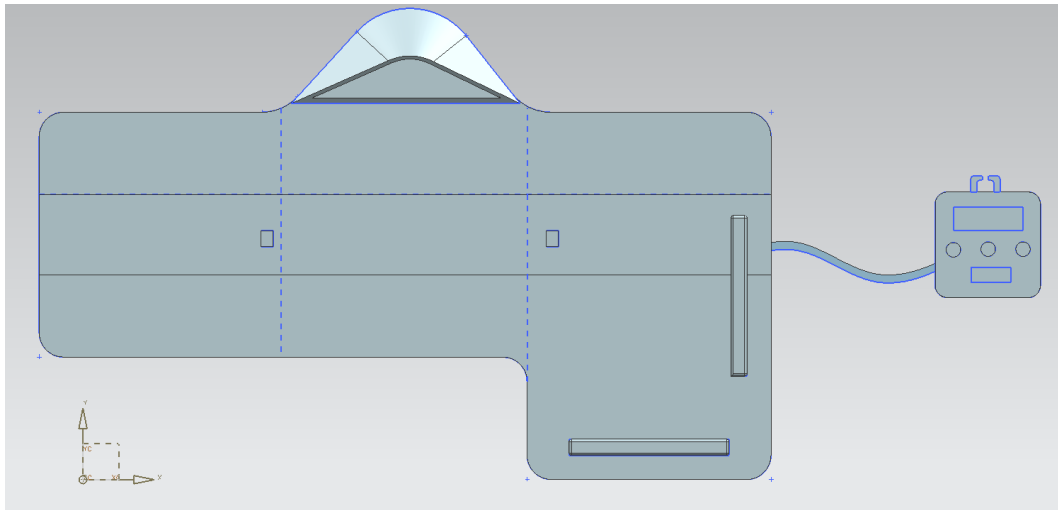


Figure I2: Top View of the Alpha Prototype

Figure I3 below shows the dimensions of the alpha design. The dimensions for the device were finalized by using anthropometric data for infants of gestational age 38 weeks. The monitor has not been drafted because its dimensions were arbitrary and are subject to extensive changes.

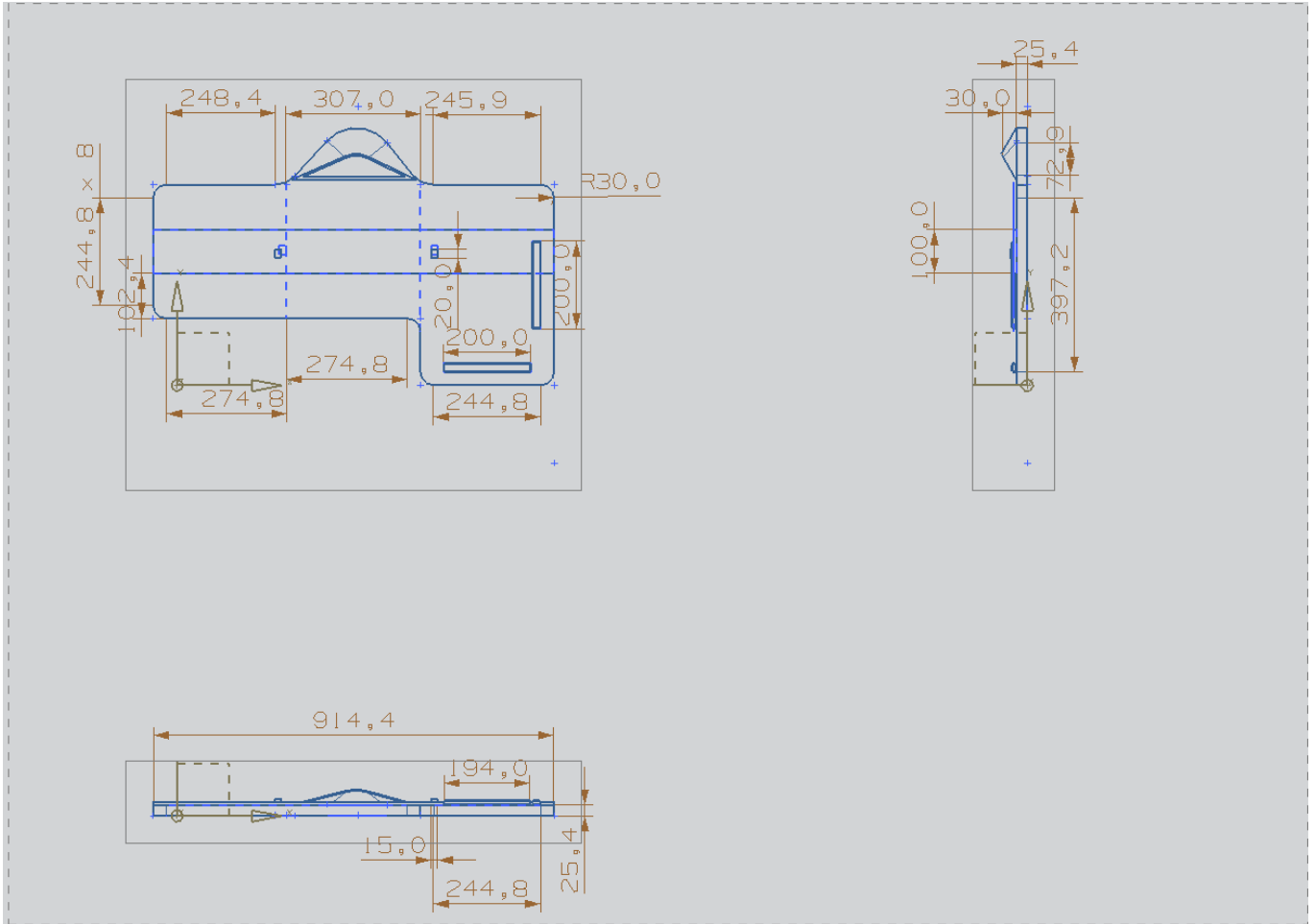


Figure I3: Part Drawings of the Alpha Prototype

APPENDIX J: Lines drawings of parts

Figure J1: Part drawing of Buzzer

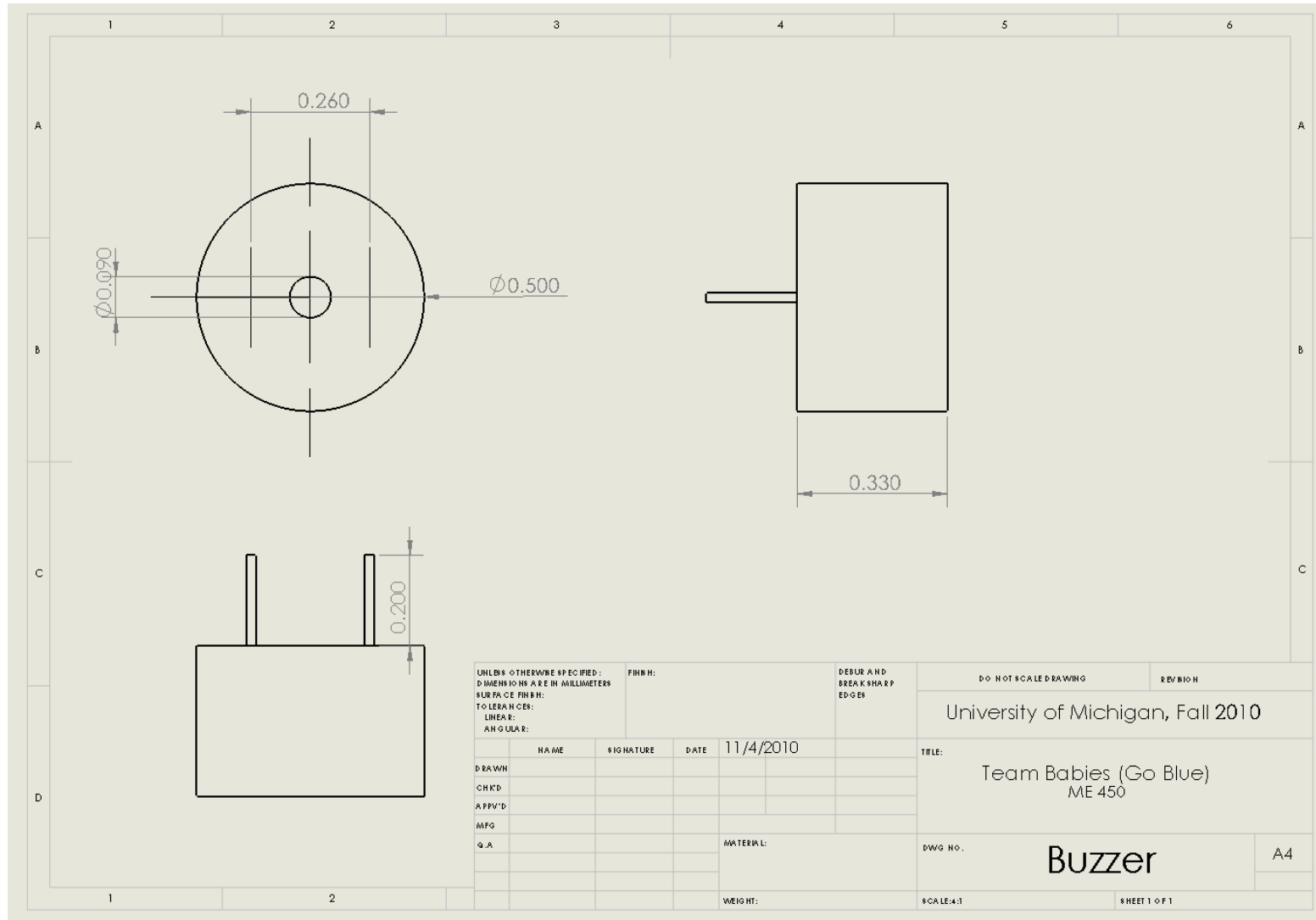


Figure J2: Part drawing of Monitor casing prototype

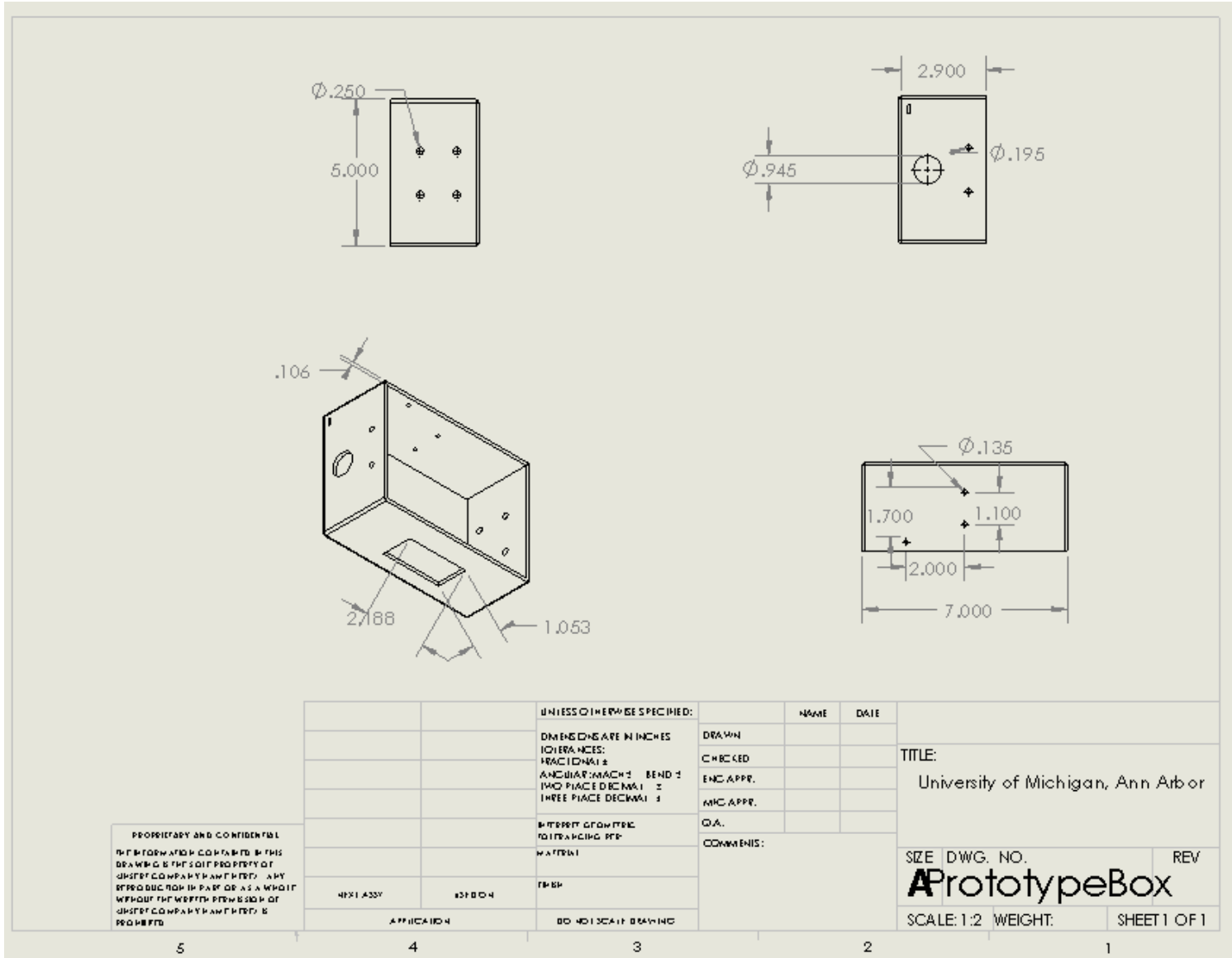
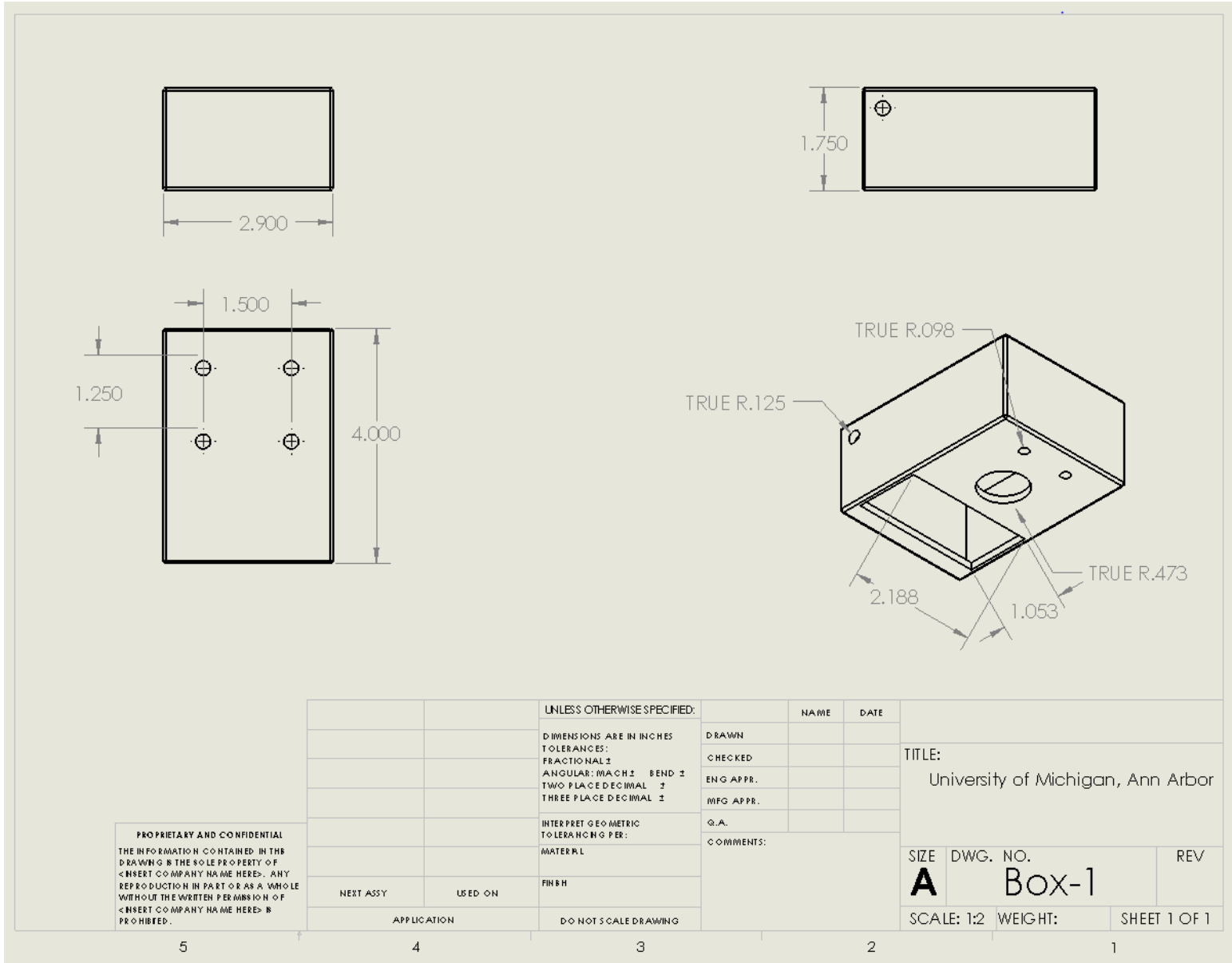


Figure J3: Part drawing of monitor casing final design



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		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	
		DIMENSIONS ARE IN INCHES	DRAWN			TITLE: University of Michigan, Ann Arbor
		TOLERANCES:	CHECKED			
		FRACTIONAL ±	ENG APPR.			
		ANGULAR: MACH ± BEND ±	MFG APPR.			
		TWO PLACE DECIMAL ±	G.A.			
		THREE PLACE DECIMAL ±	COMMENTS:			SIZE DWG. NO. REV
		INTERPRET GEOMETRIC TOLERANCING PER:				A Box-1
		MATERIAL				SCALE: 1:2 WEIGHT: SHEET 1 OF 1
		FINISH				
	NEXT ASSY	USED ON				
	APPLICATION	DO NOT SCALE DRAWING				

5

4

3

2

1

Figure J4: Part drawing of clamp

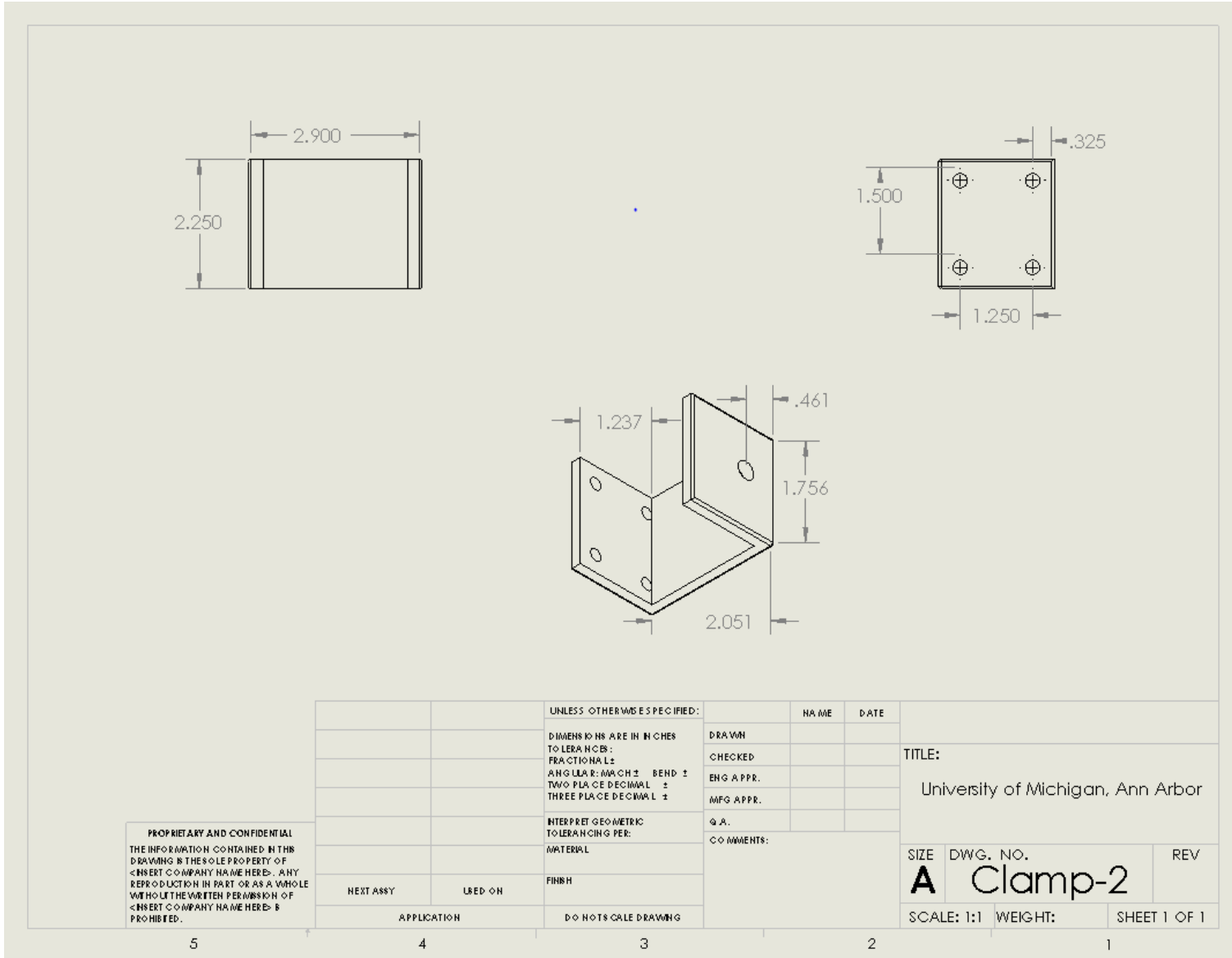


Figure J5: Part drawing of battery

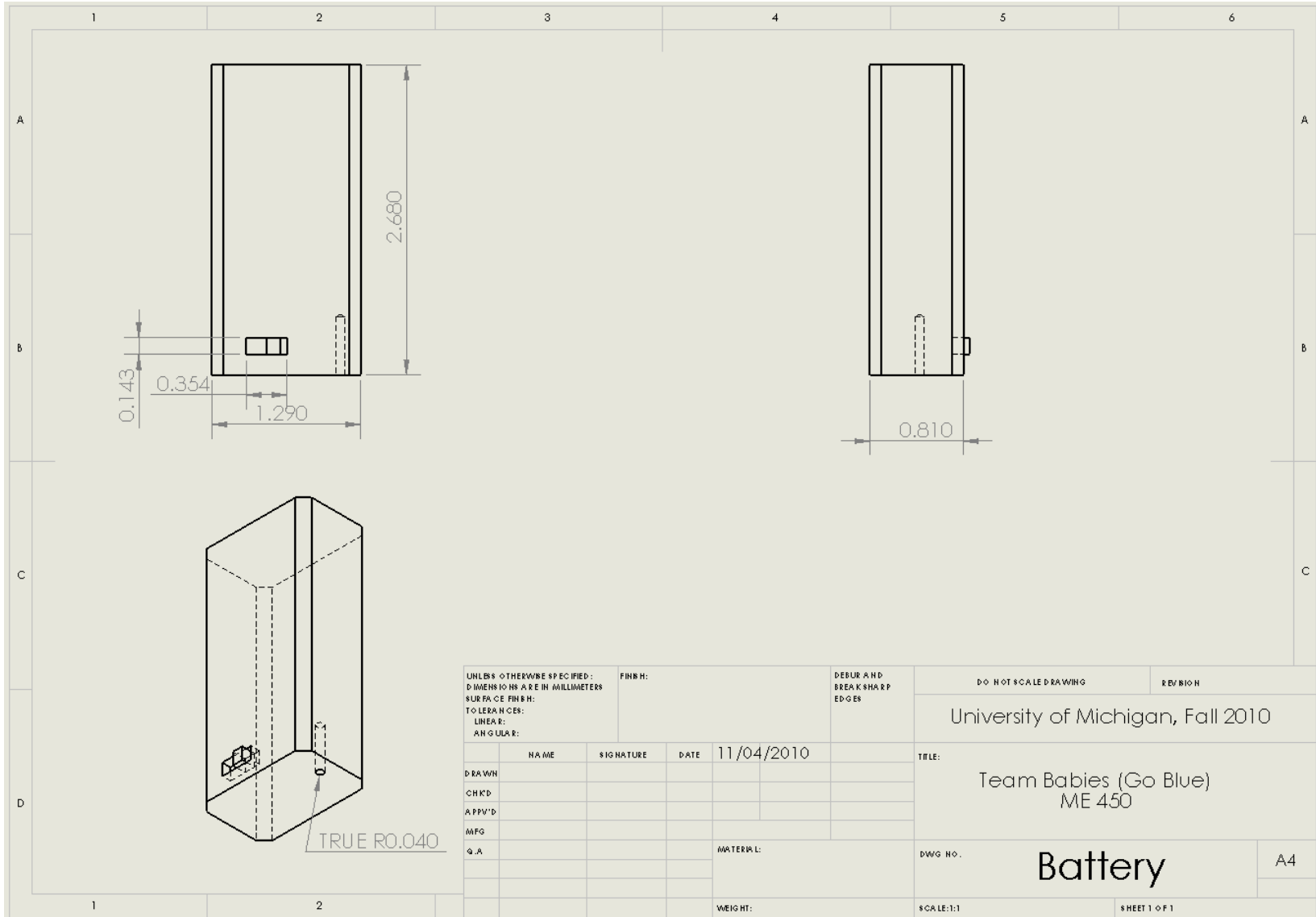


Figure J6: Part drawing of Bread-board

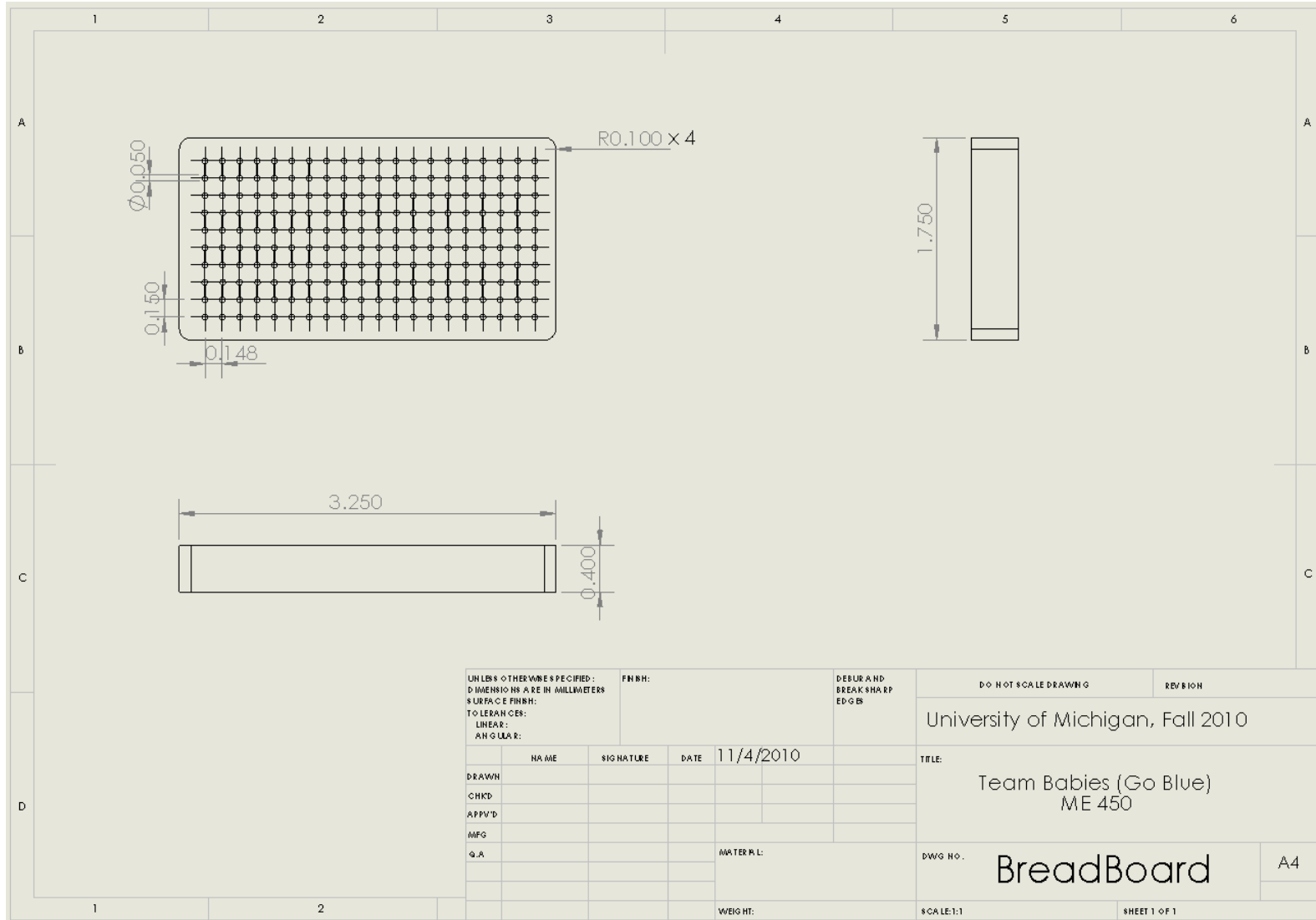


Figure J7: Part drawing of LED

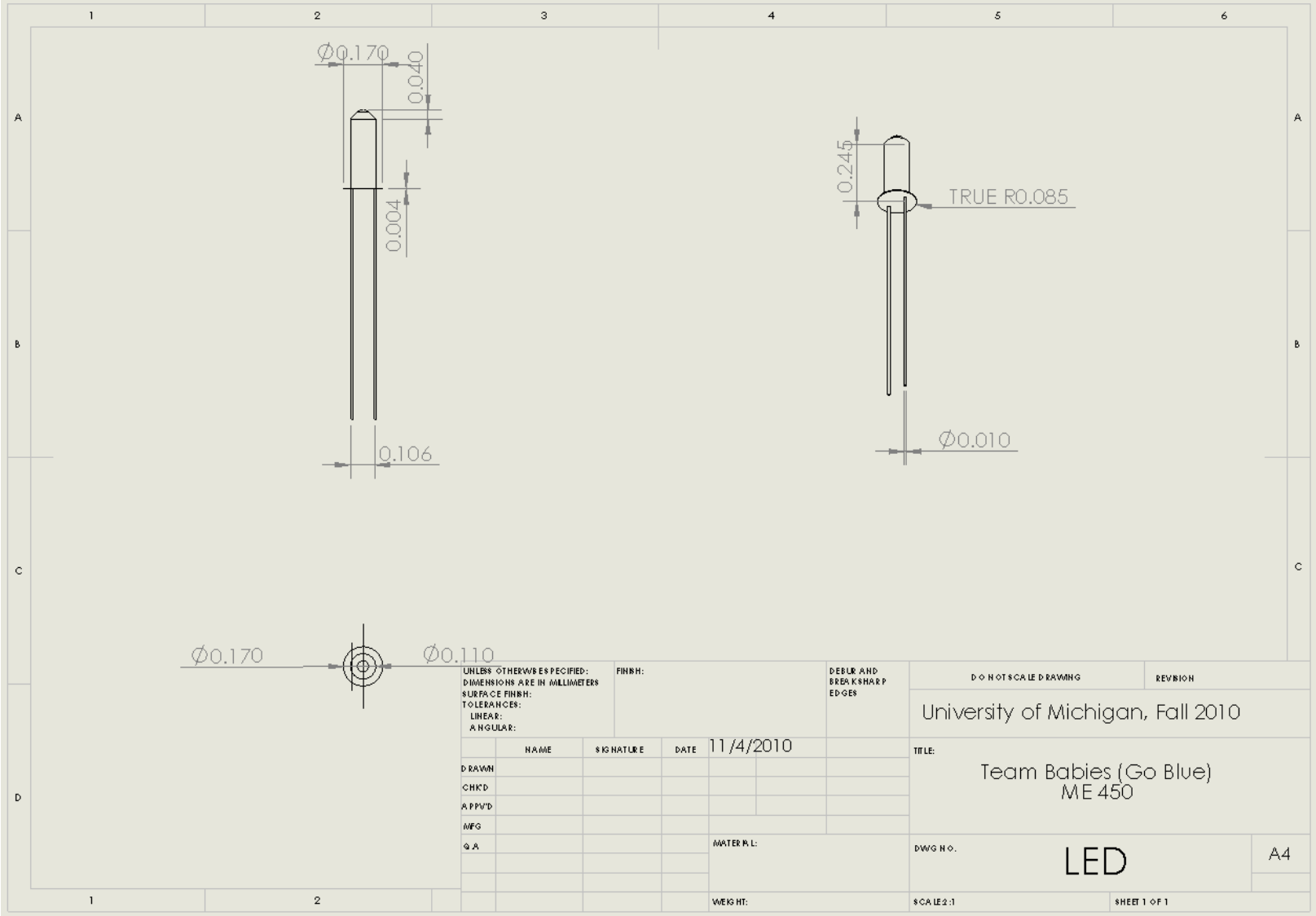


Figure J8: Part drawing of microprocessor

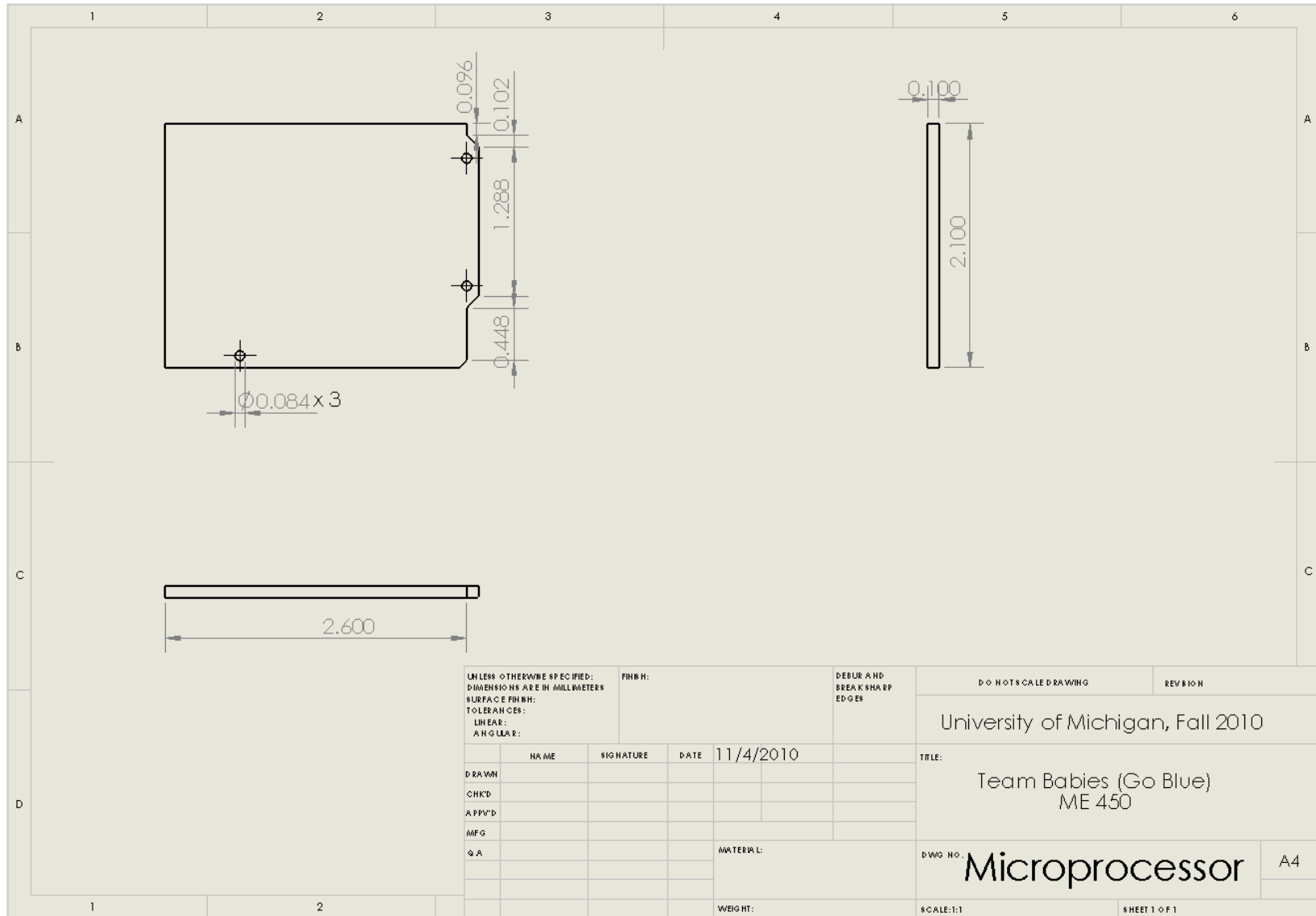


Figure J9: Part drawing of slip cover

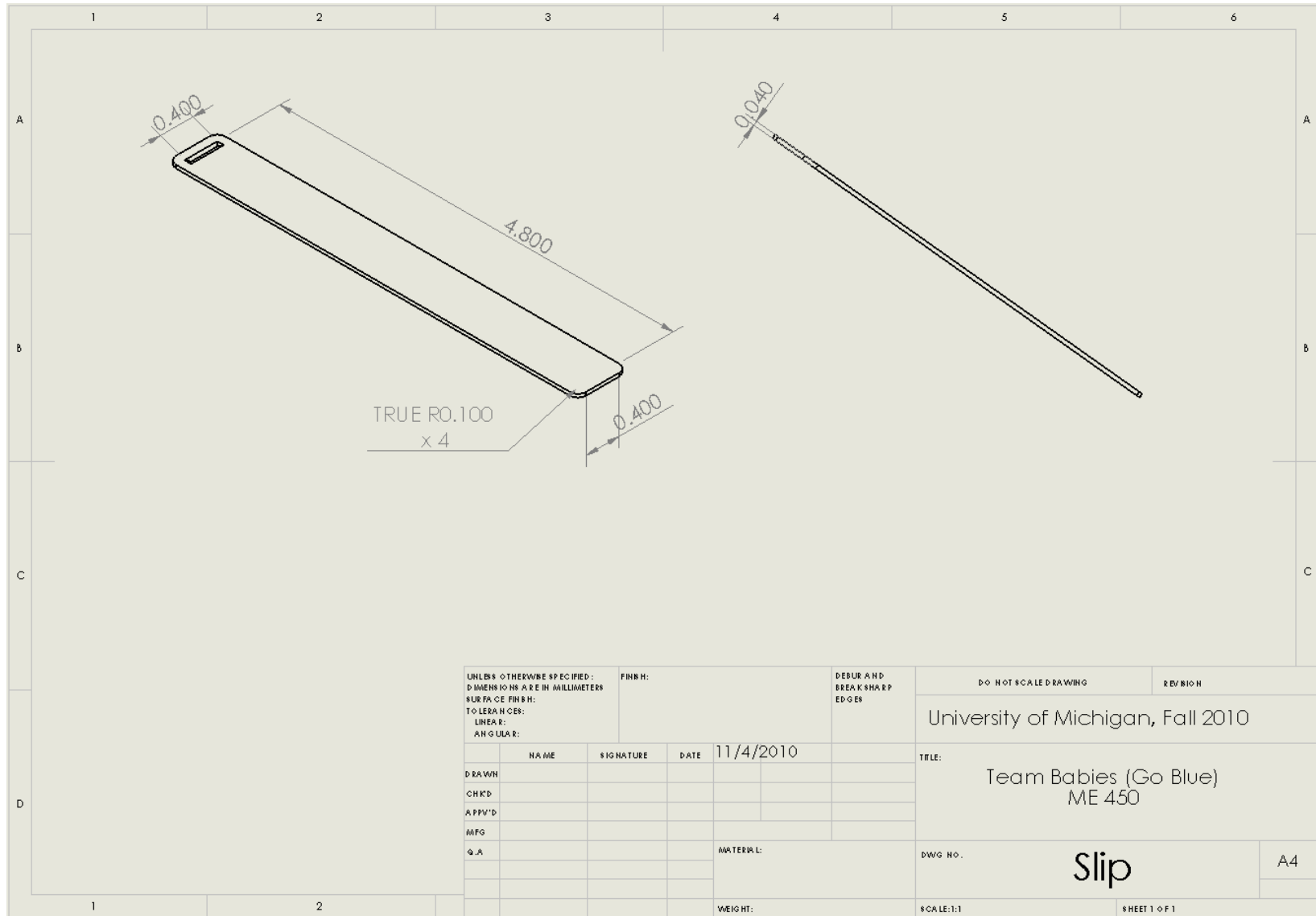
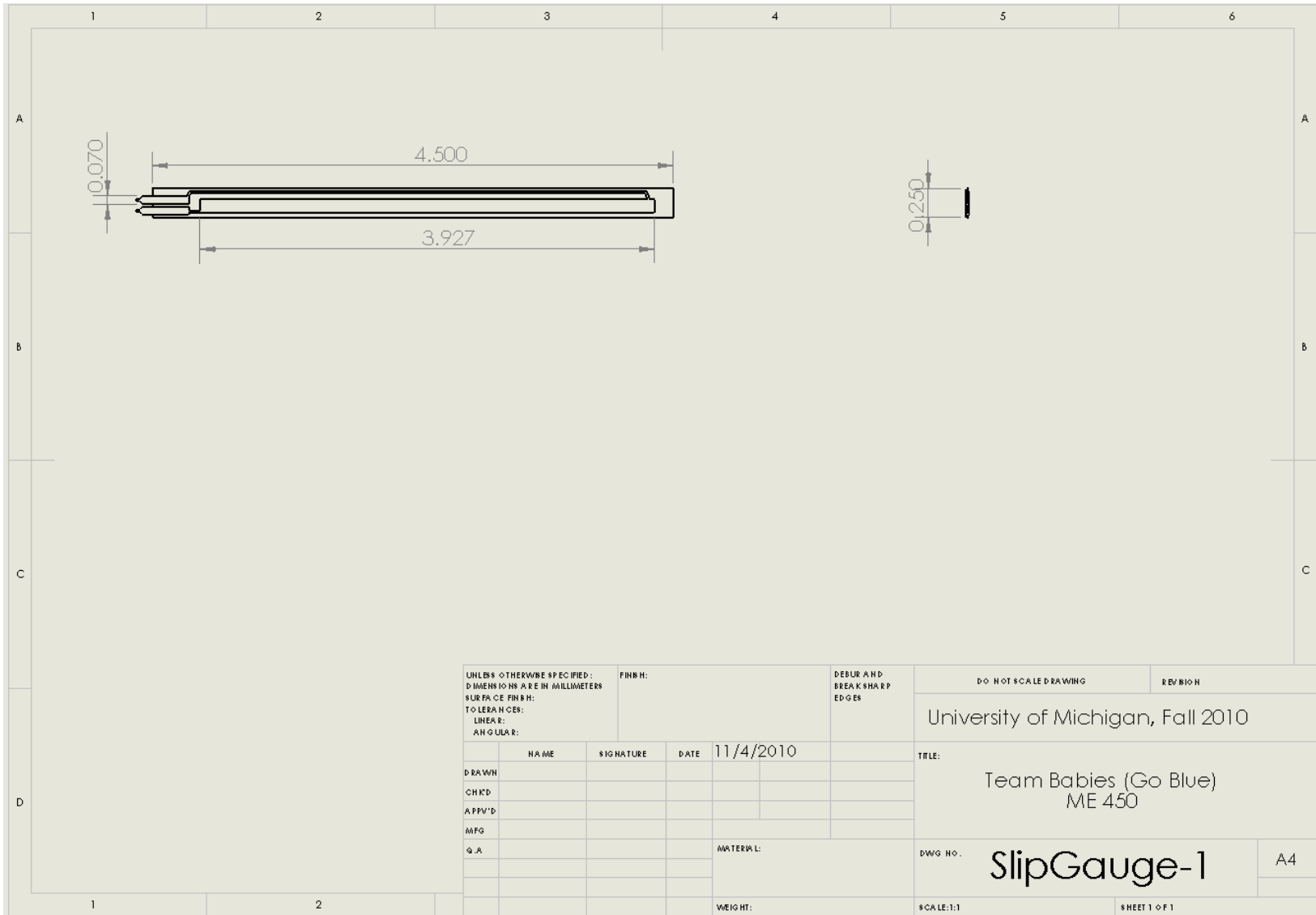


Figure J10: Part drawing of flex sensor



APPENDIX K: Component Selection and Information

Table K1: Medical Double Coated Tapes & Transfer Adhesive Selection Guide

Medical Double Coated Tapes & Transfer Adhesive Selection Guide

Properties ¹	Polyethylene Carrier						Polyester Carrier				N/W	Transfer Adhesive			
	1509	1510	1517	1522	9874	9889	1513	1567	1577	9877		9917	1504XL	1524	1524A
1. Sterilization ² (G=Gamma; E=Ethylene Oxide; S=Steam Autoclave)	G, E	G, E	G, E	G*, E	G*, E	G, E	G, E, S	G, E, S	G, E, S	G, E, S	G*, E	G*, E	G, E, S	G, E, S	
2. Hypoallergenic	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
3. Repeat Skin Contact	No	No	No	Yes	Yes	No	No	No	No	No	Yes	No	No	No	
4. Conformable (L=Low; M=Medium; H=High)	M	H	H	M	M	M	L	L	L	L	H	M	H	H	
5. Fluid Resistance	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	
6. Typical Tensile MD	lbs/inch	4.5	1.8	1.8	4.5	4.5	4.5	20	20	20	20	17	N/A	N/A	N/A
	Newtons/25mm	20	8	8	20	20	20	89	89	89	89	75	N/A	N/A	N/A
7. Elongation	percentage	200	800	800	200	200	200	135	135	135	135	30	N/A	N/A	N/A
8. Typical Adhesion/(Faceside) Stainless Steel	oz/inch	53	45 LDPE	30 LDPE	25	19	53	61	175	A/SR 48/100	120	27/23	200	40	40
	Newtons/25mm	14.7	12.5	8.3	7	5.3	14.7	17	48.6	13/29	33.4	7.5/6.4	55.6	11	11
9. Tape Caliper without Liner	mil	4.9	3.8	4.4	6.3	4.9	4.9	3.4	5	3.6	4.5	12	4.0	2.5	2.5
	millimeters	0.12	0.1	0.11	0.16	0.12	0.12	0.09	0.13	0.09	0.11	0.3	0.10	0.06	0.06
10. Adhesive Coating (each side)	mil	0.95	1.4	1.7	1.65	0.95	0.95	1.2	2	1.75	1.75	1.4	4.0	2.5	2.5
	millimeters	0.02	0.04	0.04	0.04	0.02	0.02	0.03	0.05	0.04	0.04	0.04	0.10	0.06	0.06
11. Carrier Caliper	mil	3.0	1.0	1.0	3.0	3.0	3.0	1.0	1.0	1.0	1.0	12	N/A	N/A	N/A
	millimeters	0.08	0.03	0.03	0.08	0.08	0.08	0.03	0.03	0.03	0.03	0.3	N/A	N/A	N/A
12. Liner Caliper	mil	4.5	3.2	4.4	4.5	3.6	3.5	4.5	3.5	3.6	3.6	3.5	3.5	3.0	4.5
	millimeters	0.11	0.08	0.11	0.11	0.09	0.09	0.11	0.09	0.09	0.09	0.09	0.09	0.08	0.11
13. Liner Weight	lbs/ream	80	54	58	80	60	60	80	60	60	60	62	62	54	78
14. Maximum Liner Release	gm/inch	50	40	50	30	30	50	50	50	60	60	35	35	29	—
	Newtons/25mm	0.49	0.39	0.49	0.29	0.29	0.49	0.49	0.49	0.59	0.59	0.34	0.34	0.28	—
15. Maximum Width	inches	48	27	27	48	48	48	48	48	48	48	48	6	48	48
	centimeters	122	69	69	122	122	122	122	122	122	122	122	15	122	122
16. Maximum Length	yards	600	360	360	550	700	700	700	700	700	700	400	600	400	400
	meters	548	329	329	503	640	640	640	640	640	640	366	549	366	366
17. Approx. Roll Diameter	inches	17	13.5	13.5	17	17	17	17	17	17	17	17	15	12	13
	centimeters	43	34	34	43	43	43	43	43	43	43	43	38	31	33
18. Shelf Life	years	2	2	2	3	2	2	2	TBD	2	2	2	2	2	2

¹ Properties listed are based on limited testing and for comparative purposes only. It is the customer's responsibility to determine the final suitability of our products for use in their application.

² Recommended suitability based on the processability of product through typical sterilization conditions.

*Reduced adhesion levels and increased liner release may occur after gamma irradiation.

Figure K1: 3M Double Coated Medical Tape Material Safety Data Sheet (Relevant Components)

MATERIAL SAFETY DATA SHEET 3M™ Double Coated Medical Tape 1522, 1522EL 06/08/09



Material Safety Data Sheet

Copyright, 2009, 3M Company. All rights reserved. Copying and/or downloading of this information for the purpose of properly utilizing 3M products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from 3M, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

This material safety data sheet (MSDS) is provided as a courtesy in response to a customer request. This product is not regulated under, and a MSDS is not required for this product by the OSHA Hazard Communication Standard (29 CFR 1910.1200) because, when used as recommended or under ordinary conditions, it should not present a health and safety hazard. However, use or processing of the product not in accordance with the product's recommendations or not under ordinary conditions may affect the performance of the product and may present potential health and safety hazards.

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: 3M™ Double Coated Medical Tape 1522, 1522EL
MANUFACTURER: 3M
DIVISION: Skin & Wound Care Division
ADDRESS: 3M Center
 St. Paul, MN 55144-1000

EMERGENCY PHONE: 1-800-364-3577 or (651) 737-6501 (24 hours)

Issue Date: 06/08/09
Supersedes Date: 06/01/09
Document Group: 06-5836-9

Product Use:
 Intended Use: Medical tape.

SECTION 2: INGREDIENTS

<u>Ingredient</u>	<u>C.A.S. No.</u>	<u>% by Wt</u>
Silicone Coated Paper Liner	None	40 - 55
Acrylate adhesive	Trade Secret	20 - 50
Polyethylene backing	Unknown	15 - 30

SECTION 3: HAZARDS IDENTIFICATION

3.1 EMERGENCY OVERVIEW

Specific Physical Form: Roll of Tape
Odor, Color, Grade: Tape with slight acrylic odor.
General Physical Form: Solid

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specific Physical Form:	Roll of Tape
Odor, Color, Grade:	Tape with slight acrylic odor.
General Physical Form:	Solid
Autoignition temperature	<i>No Data Available</i>
Flash Point	<i>Not Applicable</i>
Flammable Limits - LEL	<i>Not Applicable</i>
Flammable Limits - UEL	<i>Not Applicable</i>
Boiling point	<i>Not Applicable</i>
Density	<i>Not Applicable</i>
Vapor Density	<i>Not Applicable</i>
Vapor Pressure	<i>Not Applicable</i>
Specific Gravity	<i>Not Applicable</i>
pH	<i>Not Applicable</i>
Melting point	<i>No Data Available</i>
Solubility In Water	<i>No Data Available</i>
Evaporation rate	<i>Not Applicable</i>
Volatile Organic Compounds	<i>No Data Available</i>
Percent volatile	0 %
VOC Less H2O & Exempt Solvents	<i>No Data Available</i>
Viscosity	<i>Not Applicable</i>

SECTION 10: STABILITY AND REACTIVITY

Stability: Stable.

Materials and Conditions to Avoid: None known

Hazardous Polymerization: Hazardous polymerization will not occur.

Hazardous Decomposition or By-Products

<u>Substance</u>	<u>Condition</u>
None known.	Not Specified

SECTION 11: TOXICOLOGICAL INFORMATION

Please contact the address listed on the first page of the MSDS for Toxicological Information on this material and/or its components.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION

Figure K2: Datasheet for buzzer

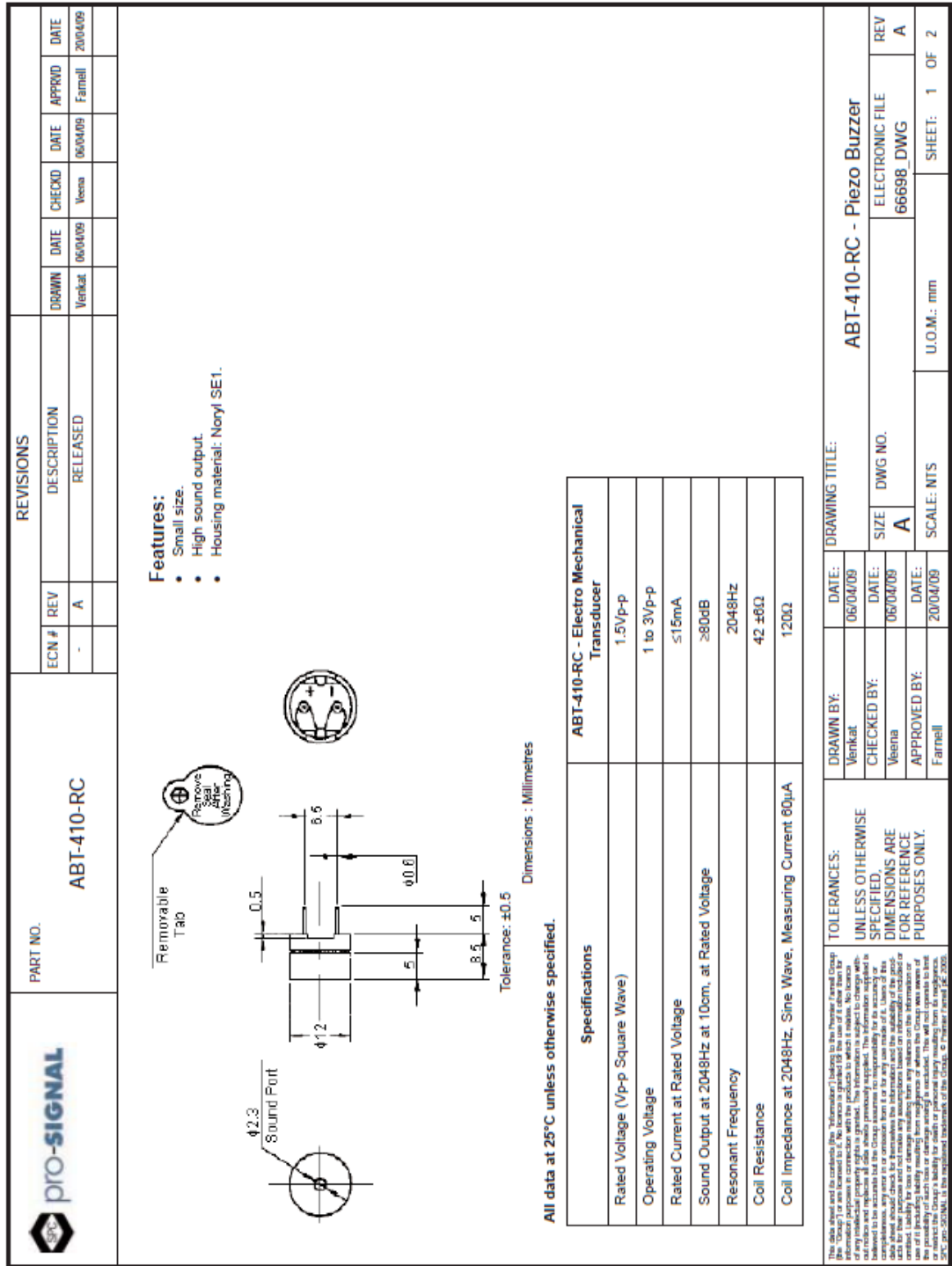


Figure K3: Datasheet for Red/Green LED (Continued over next page)



深圳市昱申科技有限公司
CHINA YOUNG SUN LED TECHNOLOGY CO., LTD.

TEL: (86) 755-28079401 28079402 28079403 28079404 28079405
FAX: (86) 755-28079407 E-mail: info@100LED.com Web: www.100LED.com

Model No.: YSL-R341K3D-D2

Applications:

- Decorations
- Bill Inspector
- Inceticidal Lights
- Medical Appliance

Absolute Maximum Ratings: (Ta=25 °C) .

ITEMS	Symbol	Absolute Maximum Rating	Unit
Forward Current	I _F	20	mA
Peak Forward Current	I _{FP}	30	mA
Suggestion Using Current	I _{SU}	16-18	mA
Reverse Current (V _R =5V)	I _R	10	uA
Power Dissipation	P _D	65	mW
Operation Temperature	T _{OPR}	-40 ~ 85	°C
Storage Temperature	T _{STG}	-40 ~ 100	°C
Lead Soldering Temperature	T _{SOL}	Max. 260°C for 3 Sec. Max. (3mm from the base of the epoxy bulb)	

Absolute Maximum Ratings: (Ta=25 °C)

ITEMS	Symbol	Test condition	Min.	Typ.	Max.	Unit
Forward Voltage	V _F	I _F =20mA	2.0	----	2.4	V
Wavelength (nm) or TC(k)	Δλ	I _F =20mA	590	----	595	nm
*Luminous intensity	I _V	I _F =20mA	40	----	100	mcd
50% Viewing Angle	2θ 1/2	I _F =20mA	30	----	40	deg



深圳市昱申科技有限公司
CHINA YOUNG SUN LED TECHNOLOGY CO., LTD.

TEL: (86) 755-28079401 28079402 28079403 28079404 28079405
FAX: (86) 755-28079407 E-mail: info@100LED.com Web: www.100LED.com

Light Degradation in mcd: (I_F=20mA)

Colors \ Hours	Light Degradation in mcd after Different Hours					
	216 Hrs	360 Hrs	792 Hrs	1104 Hrs	1992 Hrs	2328 Hrs
Red	1.52%	-1.22%	-3.10%	-4.68%	-5.72%	-8.27%
Yellow	-1.71%	-2.97%	-5.93%	-8.13%	-8.90%	-11.10%
Blue	3.13%	-0.33%	-3.84%	-8.23%	-21.32%	-24.92%
Green	-8.02%	-9.78%	-14.25%	-17.37%	-20.79%	-22.30%
Hours	48 Hrs	168 Hrs	336 Hrs	528 Hrs	744 Hrs	1008 Hrs
Cool White	5.28%	3.36%	-1.15%	-3.84%	-8.66%	-11.24%
Pure White	6.83%	4.11%	-0.73%	-4.25%	-9.76%	-12.63%
Warm White	1.51%	-2.19%	-7.59%	-10.53%	-13.58%	-14.98%

Mechanical Dimensions:

- ☐ All dimension are in mm, tolerance is ±0.2mm unless otherwise noted
- ☐ An epoxy meniscus may extend about 1.5mm down the leads.
- ☐ Burr around bottom of epoxy may be 0.5mm Maximum

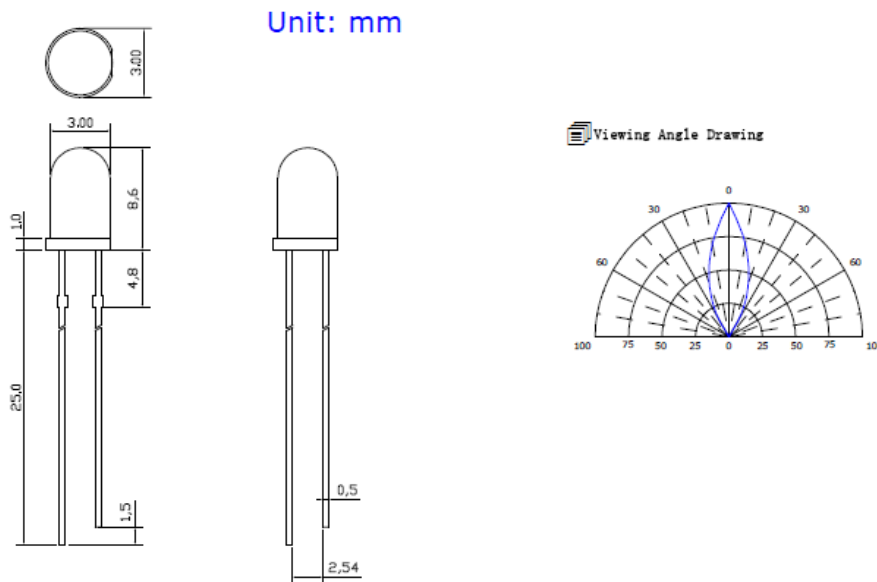
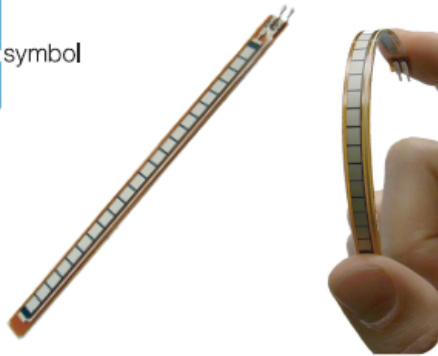


Figure K4: Datasheet for Flex Sensor (Continued over next page)



FLEX SENSOR FS

Features

- Angle Displacement Measurement
- Bends and Flexes physically with motion device
- Possible Uses
 - Robotics
 - Gaming (Virtual Motion)
 - Medical Devices
 - Computer Peripherals
 - Musical Instruments
 - Physical Therapy
- Simple Construction
- Low Profile

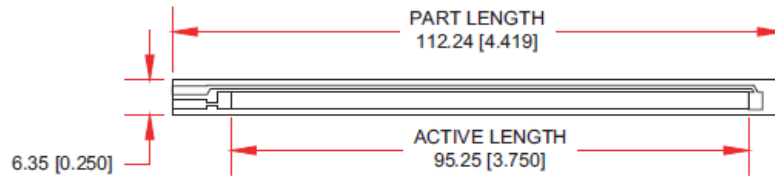
Mechanical Specifications

- Life Cycle: >1 million
- Height: $\leq 0.43\text{mm}$ (0.017")
- Temperature Range: -35°C to $+80^{\circ}\text{C}$

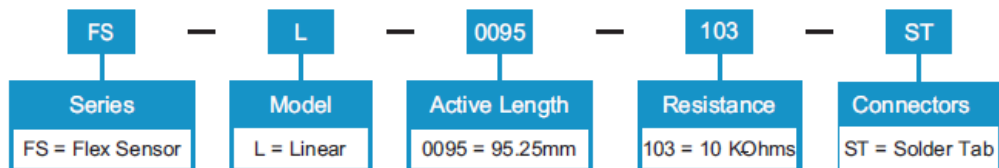
Electrical Specifications

- Flat Resistance: 10K Ohms
- Resistance Tolerance: $\pm 30\%$
- Bend Resistance Range: 60K to 110K Ohms
- Power Rating : 0.50 Watts continuous. 1 Watt Peak

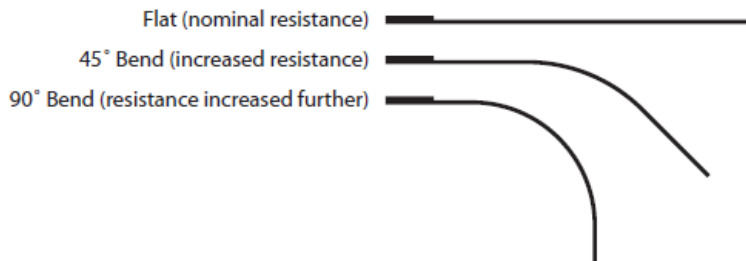
Dimensional Diagram - Stock Flex Sensor



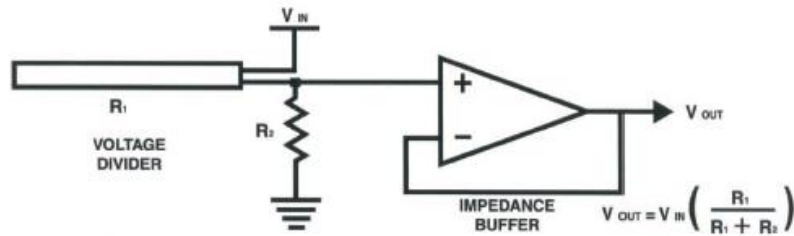
How to Order - Stock Flex Sensor



How It Works



BASIC FLEX SENSOR CIRCUIT:

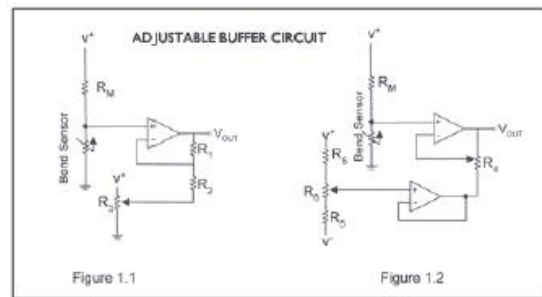


Following are notes from the ITP Flex Sensor Workshop

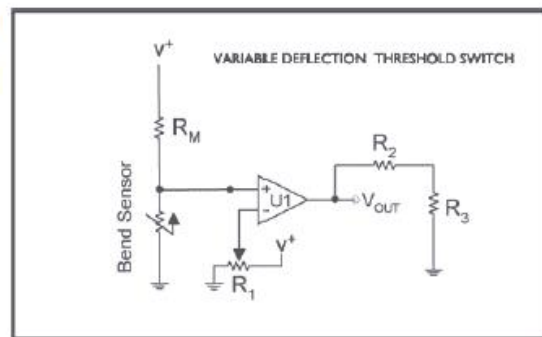
"The impedance buffer in the [Basic Flex Sensor Circuit] (above) is a single sided operational amplifier, used with these sensors because the low bias current of the op amp reduces error due to source impedance of the flex sensor as voltage divider. Suggested op amps are the LM358 or LM324."

"You can also test your flex sensor using the simplest circuit, and skip the op amp."

"Adjustable Buffer - a potentiometer can be added to the circuit to adjust the sensitivity range."



"Variable Deflection Threshold Switch - an op amp is used and outputs either high or low depending on the voltage of the inverting input. In this way you can use the flex sensor as a switch without going through a microcontroller."



"Resistance to Voltage Converter - use the sensor as the input of a resistance to voltage converter using a dual sided supply op-amp. A negative reference voltage will give a positive output. Should be used in situations when you want output at a low degree of bending."

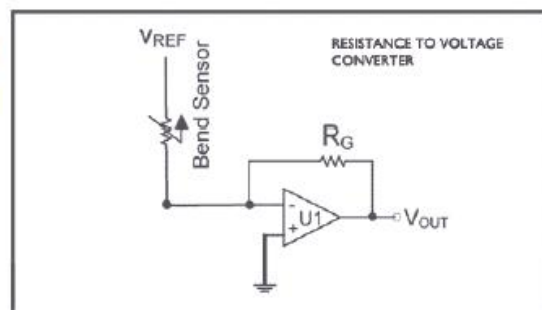
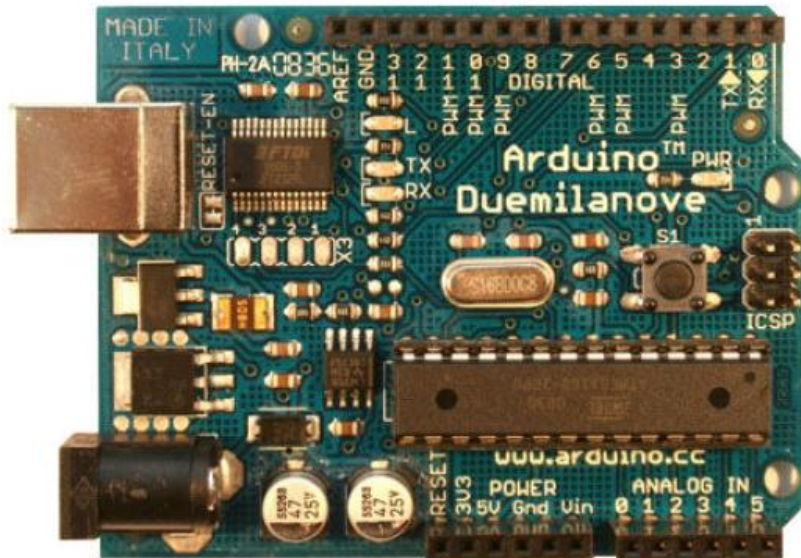


Figure K5: Arduino Duemilanove Technical Data Sheet (Continued over 3 pages)

Arduino Duemilanove



Overview

The Arduino Duemilanove ("2009") is a microcontroller board based on the ATmega168 (datasheet) or ATmega328 (datasheet). It has 14 digital input/output pins (of which 6 can be used as PWM outputs), 6 analog inputs, a 16 MHz crystal oscillator, a USB connection, a power jack, an ICSP header, and a reset button. It contains everything needed to support the microcontroller; simply connect it to a computer with a USB cable or power it with a AC-to-DC adapter or battery to get started.

"Duemilanove" means 2009 in Italian and is named after the year of its release. The Duemilanove is the latest in a series of USB Arduino boards; for a comparison with previous versions, see the [index of Arduino boards](#).

Schematic & Reference Design

EAGLE files: [arduino-duemilanove-reference-design.zip](#)

Schematic: [arduino-duemilanove-schematic.pdf](#)

Summary

Microcontroller	ATmega168
Operating Voltage	5V
Input Voltage (recommended)	7-12V
Input Voltage (limits)	6-20V
Digital I/O Pins	14 (of which 6 provide PWM output)
Analog Input Pins	6
DC Current per I/O Pin	40 mA
DC Current for 3.3V Pin	50 mA

Flash Memory	16 KB (ATmega168) or 32 KB (ATmega328) of which 2 KB used by bootloader
SRAM	1 KB (ATmega168) or 2 KB (ATmega328)
EEPROM	512 bytes (ATmega168) or 1 KB (ATmega328)
Clock Speed	16 MHz

Power

The Arduino Duemilanove can be powered via the USB connection or with an external power supply. The power source is selected automatically.

External (non-USB) power can come either from an AC-to-DC adapter (wall-wart) or battery. The adapter can be connected by plugging a 2.1mm center-positive plug into the board's power jack. Leads from a battery can be inserted in the Gnd and Vin pin headers of the POWER connector.

The board can operate on an external supply of 6 to 20 volts. If supplied with less than 7V, however, the 5V pin may supply less than five volts and the board may be unstable. If using more than 12V, the voltage regulator may overheat and damage the board. The recommended range is 7 to 12 volts.

The power pins are as follows:

- **VIN.** The input voltage to the Arduino board when it's using an external power source (as opposed to 5 volts from the USB connection or other regulated power source). You can supply voltage through this pin, or, if supplying voltage via the power jack, access it through this pin.
- **5V.** The regulated power supply used to power the microcontroller and other components on the board. This can come either from VIN via an on-board regulator, or be supplied by USB or another regulated 5V supply.
- **3V3.** A 3.3 volt supply generated by the on-board FTDI chip. Maximum current draw is 50 mA.
- **GND.** Ground pins.

Memory

The ATmega168 has 16 KB of flash memory for storing code (of which 2 KB is used for the bootloader); the ATmega328 has 32 KB, (also with 2 KB used for the bootloader). The ATmega168 has 1 KB of SRAM and 512 bytes of EEPROM (which can be read and written with the [EEPROM library](#)); the ATmega328 has 2 KB of SRAM and 1 KB of EEPROM.

Input and Output

Each of the 14 digital pins on the Duemilanove can be used as an input or output, using `pinMode()`, `digitalWrite()`, and `digitalRead()` functions. They operate at 5 volts. Each pin can provide or receive a maximum of 40 mA and has an internal pull-up resistor (disconnected by default) of 20-50 kOhms. In addition, some pins have specialized functions:

- **Serial: 0 (RX) and 1 (TX).** Used to receive (RX) and transmit (TX) TTL serial data. These pins are connected to the corresponding pins of the FTDI USB-to-TTL Serial chip.
- **External Interrupts: 2 and 3.** These pins can be configured to trigger an interrupt on a low value, a rising or falling edge, or a change in value. See the [attachInterrupt\(\)](#) function for details.
- **PWM: 3, 5, 6, 9, 10, and 11.** Provide 8-bit PWM output with the [analogWrite\(\)](#) function.
- **SPI: 10 (SS), 11 (MOSI), 12 (MISO), 13 (SCK).** These pins support SPI communication, which, although provided by the underlying hardware, is not currently included in the Arduino language.
- **LED: 13.** There is a built-in LED connected to digital pin 13. When the pin is HIGH value, the LED is on, when the pin is LOW, it's off.

The Duemilanove has 6 analog inputs, each of which provide 10 bits of resolution (i.e. 1024 different values). By default they measure from ground to 5 volts, though is it possible to change the upper end of their range using the AREF pin and the [analogReference\(\)](#) function. Additionally, some pins have specialized functionality:

- **I²C: 4 (SDA) and 5 (SCL).** Support I²C (TWI) communication using the [Wire library](#).

Figure K6: Maxim 4194 Differential Amplifier Technical Datasheet (Relevant Components) (continued over 3 pages)

19-1468; Rev 1; 6/03



Micropower, Single-Supply, Rail-to-Rail, Precision Instrumentation Amplifiers

MAX4194-MAX4197

General Description

The MAX4194 is a variable-gain precision instrumentation amplifier that combines Rail-to-Rail® single-supply operation, outstanding precision specifications, and a high gain bandwidth. This amplifier is also offered in three fixed-gain versions: the MAX4195 (G = +1V/V), the MAX4196 (G = +10V/V), and the MAX4197 (G = +100V/V). The fixed-gain instrumentation amplifiers feature a shutdown function that reduces the quiescent current to 8µA. A traditional three operational amplifier configuration is used to achieve maximum DC precision.

The MAX4194-MAX4197 have rail-to-rail outputs and inputs that can swing to 200mV below the negative rail and to within 1.1V of the positive rail. All parts draw only 93µA and operate from a single +2.7V to +7.5V supply or from dual ±1.35V to ±3.75V supplies. These amplifiers are offered in 8-pin SO packages and are specified for the extended temperature range (-40°C to +85°C).

See the MAX4198/MAX4199 data sheet for single-supply, precision differential amplifiers.

Applications

- Medical Equipment
- Thermocouple Amplifier
- 4-20mA Loop Transmitters
- Data-Acquisition Systems
- Battery-Powered/Portable Equipment
- Transducer Interface
- Bridge Amplifier

Features

- ◆ +2.7V Single-Supply Operation
- ◆ Low Power Consumption
 - 93µA Supply Current
 - 8µA Shutdown Current (MAX4195/MAX4196/MAX4197)
- ◆ High Common-Mode Rejection: 115dB (G = +10V/V)
- ◆ Input Common-Mode Range Extends 200mV Below GND
- ◆ Low 50µV Input Offset Voltage (G ≥ +100V/V)
- ◆ Low ±0.01% Gain Error (G = +1V/V)
- ◆ 250kHz -3dB Bandwidth (G = +1V/V, MAX4194)
- ◆ Rail-to-Rail Outputs

Ordering Information

PART	TEMP RANGE	PIN-PACKAGE
MAX4194ESA	-40°C to +85°C	8 SO
MAX4195ESA	-40°C to +85°C	8 SO
MAX4196ESA	-40°C to +85°C	8 SO
MAX4197ESA	-40°C to +85°C	8 SO

Selector Guide

PART	SHUTDOWN	GAIN (V/V)	CMRR (dB)
MAX4194	No	Variable	95 (G = +1V/V)
MAX4195	Yes	+1	95
MAX4196	Yes	+10	115
MAX4197	Yes	+100	115

Pin Configurations



Rail-to-Rail is a registered trademark of Nippon Motorola, Ltd.



Maxim Integrated Products 1

For pricing, delivery, and ordering information, please contact Maxim/Dallas Direct! at 1-888-629-4642, or visit Maxim's website at www.maxim-ic.com.

Micropower, Single-Supply, Rail-to-Rail, Precision Instrumentation Amplifiers

ABSOLUTE MAXIMUM RATINGS

Supply Voltage (V_{CC} to V_{EE}).....	+8V	Operating Temperature Range	-40°C to +85°C
All Other Pins	($V_{CC} + 0.3V$) to ($V_{EE} - 0.3V$)	Junction Temperature	+150°C
Current into Any Pin.....	±30mA	Storage Temperature Range	-65°C to +150°C
Output Short-Circuit Duration (to V_{CC} or V_{EE}).....	Continuous	Lead Temperature (soldering, 10s).....	+300°C
Continuous Power Dissipation ($T_A = +70^\circ\text{C}$) 8-Pin SO (derate 5.9mW/°C above +70°C).....	471mW		

Stresses beyond those listed under "Absolute Maximum Ratings" may cause permanent damage to the device. These are stress ratings only, and functional operation of the device at these or any other conditions beyond those indicated in the operational sections of the specifications is not implied. Exposure to absolute maximum rating conditions for extended periods may affect device reliability.

ELECTRICAL CHARACTERISTICS

($V_{CC} = +5V$, $V_{EE} = 0V$, $R_L = 25k\Omega$ tied to $V_{CC}/2$, $V_{REF} = V_{CC}/2$, $T_A = T_{MIN}$ to T_{MAX} , unless otherwise noted. Typical values are at $T_A = +25^\circ\text{C}$.)

PARAMETER	SYMBOL	CONDITIONS	MIN	TYP	MAX	UNITS
Supply Voltage Range	V_{CC}	Inferred by PSR test	Single supply	2.7	7.5	V
			Dual supplies	±1.35	±3.75	
Quiescent Current	I_{CC}	$V_{IN+} = V_{IN-} = V_{CC}/2$, $V_{DIFF} = 0V$		93	110	µA
Shutdown Current	I_{SHDN}	$I_{SHDN} = V_{IL}$, MAX4195/MAX4196/MAX4197 only		8	12	µA
Input Offset Voltage	V_{OS}	$G = +1V/V$, $V_{CM} = V_{CC}/2$, $T_A = +25^\circ\text{C}$		±100	±450	µV
		$G = +10V/V$, $V_{CM} = V_{CC}/2$, $T_A = +25^\circ\text{C}$		±75	±225	
		$G = +100V/V$, $V_{CM} = V_{CC}/2$, $T_A = +25^\circ\text{C}$		±50	±225	
		$G = +1000V/V$, $V_{CM} = V_{CC}/2$, $T_A = +25^\circ\text{C}$		±50		
		$G = +1V/V$, $V_{CM} = V_{CC}/2$, $T_A = T_{MIN}$ to T_{MAX}		±100	±690	
		$G = +10V/V$, $V_{CM} = V_{CC}/2$, $T_A = T_{MIN}$ to T_{MAX}		±75	±345	
		$G = +100V/V$, $V_{CM} = V_{CC}/2$, $T_A = T_{MIN}$ to T_{MAX}		±50	±345	
Input Offset Voltage Drift (Note 1)	TC_{VOS}	$G = +1V/V$		±1.0	±4.0	µV/°C
		$G \geq +10V/V$		±0.5	±2.0	
Input Resistance	R_{IN}	$V_{CM} = V_{CC}/2$	Differential	1000		MΩ
			Common mode	1000		
Input Capacitance	C_{IN}	$V_{CM} = V_{CC}/2$	Differential	1		pF
			Common mode	4		
Input Voltage Range	V_{IN}	Inferred from CMR test	$V_{EE} - 0.2$		$V_{CC} - 1.1$	V
DC Common-Mode Rejection	CMR_{DC}	$V_{CM} = V_{EE} - 0.2V$ to $V_{CC} - 1.1V$, $T_A = +25^\circ\text{C}$, $\Delta R_S = 1k\Omega$ (Note 1)	$G = +1V$	66	78	dB
			$G = +10V$	80	94	
			$G = +100V$	86	99	
		$V_{CM} = V_{EE} - 0.2V$ to $V_{CC} - 1.1V$, $T_A = T_{MIN}$ to T_{MAX} , $\Delta R_S = 1k\Omega$, (Note 1)	$G = +1V$	60	78	
			$G = +10V$	74	94	
			$G = +100V$	77	99	

Micropower, Single-Supply, Rail-to-Rail, Precision Instrumentation Amplifiers

Table 1. MAX4194 External Gain Resistor Selection

GAIN (V/V)	CLOSEST R _G (1%) (Ω)	CLOSEST R _G (5%) (Ω)
+1	∞*	∞*
+2	49.9k	51k
+5	12.4k	12k
+10	5.62k	5.6k
+20	2.61k	2.7k
+50	1.02k	1.0k
+100	511	510
+200	249	240
+500	100	100
+1,000	49.9	51
+2,000	24.9	24
+5,000	10	10
+10,000	4.99	5.1

*Leave pins 1 and 8 open for G = +1V/V.

V_{CM} vs. V_{OUT} Characterization

Figure 4 illustrates the MAX4194 typical common-mode input voltage range over output voltage swing at unity-gain (pins 1 and 8 left floating), with a single-supply voltage of V_{CC} = +5V and a bias reference voltage of V_{REF} = V_{CC}/2 = +2.5V. Points A and D show the full input voltage range of the input amplifiers (V_{EE} - 0.2V to V_{CC} - 1.1V) since, with +2.5V output, there is zero input differential swing. The other points (B, C, E, and F) are determined by the input voltage range of the input amps minus the differential input amplitude necessary to produce the associated V_{OUT}. For the higher gain configurations, the V_{CM} range will increase at the endpoints (B, C, E, and F) since a smaller differential voltage is necessary for the given output voltage.

Rail-to-Rail Output Stage

The MAX4194-MAX4197's output stage incorporates a common-source structure that maximizes the dynamic range of the instrumentation amplifier.

The output can drive up to a 25kΩ (tied to V_{CC}/2) resistive load and still typically swing within 30mV of the rails. With an output load of 5kΩ tied to V_{CC}/2, the output voltage swings within 100mV of the rails.

Shutdown Mode

The MAX4195-MAX4197 feature a low-power shutdown mode. When the shutdown pin (SHDN) is pulled low, the internal amplifiers are switched off and the supply current drops to 8μA typically (Figures 5a, 5b, and 5c).

This disables the instrumentation amplifier and puts its output in a high-impedance state. Pulling SHDN high enables the instrumentation amplifier.

Applications Information

Setting the Gain (MAX4194)

The MAX4194's gain is set by connecting a single, external gain resistor between the two R_G pins (pin 1 and pin 8), and can be described as:

$$G = 1 + 50k\Omega / R_G$$

where G is the instrumentation amplifier's gain and R_G is the gain-setting resistor.

The 50kΩ resistor of the gain equation is the sum of the two resistors internally connected to the feedback loops of the IN+ and IN- amplifiers. These embedded feedback resistors are laser trimmed, and their accuracy and temperature coefficients are included in the gain and drift specification for the MAX4194.

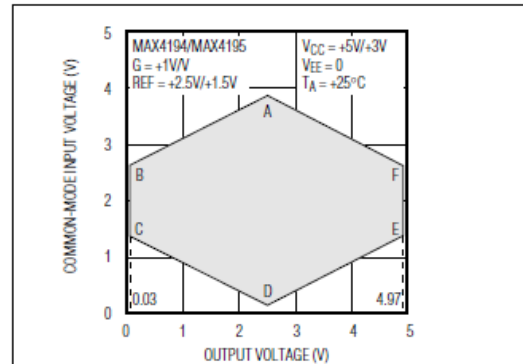


Figure 4. Common-Mode Input Voltage vs. Output Voltage

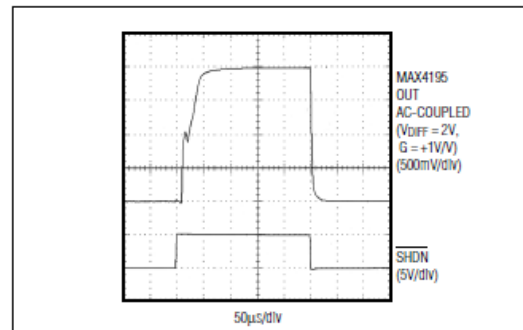


Figure 5a. MAX4195 Shutdown Mode

APPENDIX L: Additional Engineering Analysis

Heat Transfer Circuit Components

$$\text{Heat Generation} = P = I * V$$

$$\text{Power} = 0.00028 * 2.5 = 0.0007 \text{ watts, maximum power for any circuit component}$$

$$P = e * \sigma * A * (T^4 - T_c^4) \text{ Stefan Boltzmann Law}$$

$$e = 5.6703 \times 10^{-8} \text{ Stefan Boltzmann Constant}$$

$$A = 0.1143 \text{m} * 0.0127 \text{m} * 2 = .0029$$

$$T_c = 298 \text{ K upper end of room temperature}$$

$$0.0007 = 0.98 * 5.6703 \times 10^{-8} * 0.0029 * (T^4 - 298^4)$$

$$T = 298.04 \text{ K}$$

This temperature change is insignificant so heat transfer to the infant would also be insignificant.

Temperature of Strain Gauge

$$Q_{\text{Conduction}} = kA\Delta T$$

$$Q_{\text{Conduction}} = hA\Delta T$$

$$q_{\text{internal}} = P = IV$$

$$T_{\text{Body}} = 36.5^\circ \text{C}$$

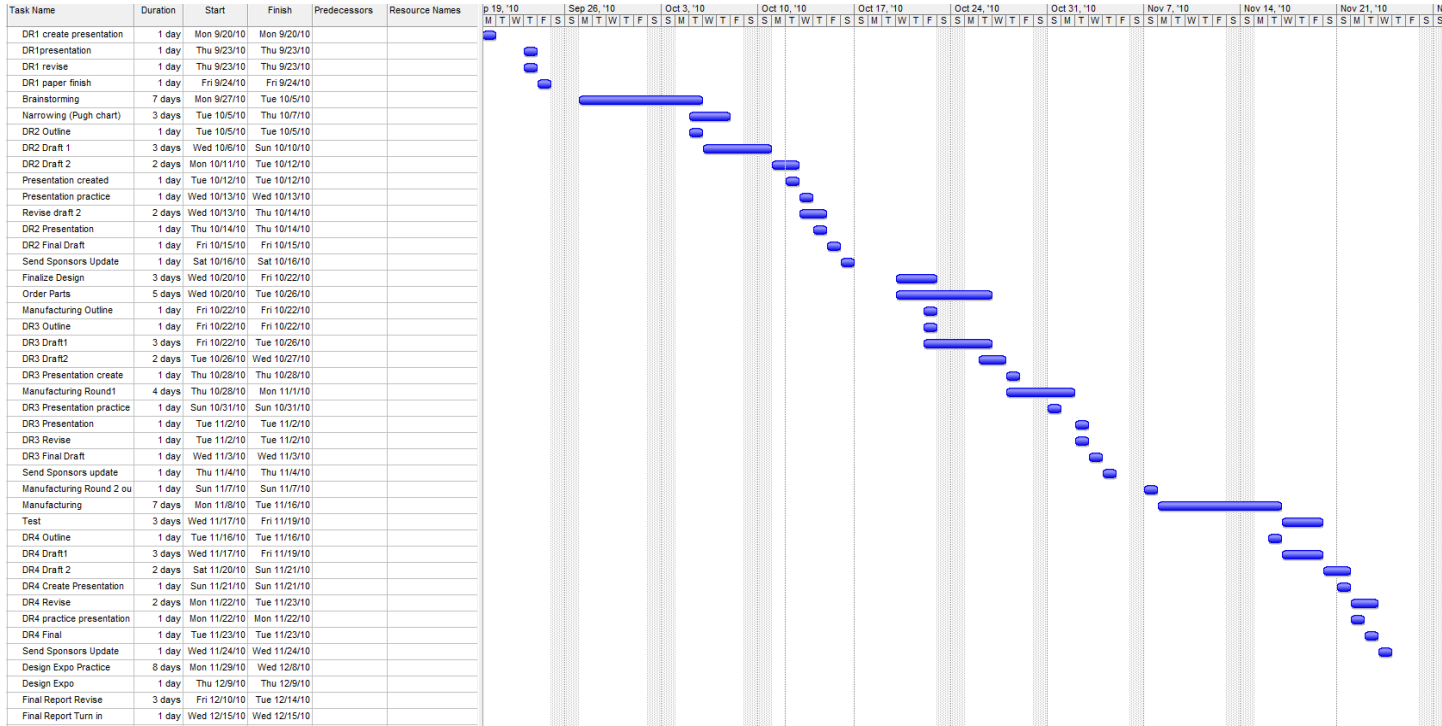
$$T_{\text{Ambient}} = 30^\circ \text{C}$$

$$\text{Thickness} \approx 0.08 \text{mm} + 0.16 \text{mm} + 10 \text{mm}$$

Lumped parameter analysis of adhesive material, flex sensor, and slip cover fabric. $T_{\text{Surface}} = 31.5^\circ$.
Surface touching infant will adhere to body temperature, treating body as heat sink.

APPENDIX M: Project Plan

Figure M1: Gantt Chart



APPENDIX N: Manufacturing and Assembly Plan

Table N1: Manufacturing plan for casing

	Machine or device	Activity or Tool	Parameters	RPM and feed	Tolerance
1	Scribe, ruler and center punch	Mark dimensions for microprocessor holes on 7" by 3" side. One hole 0.5" from the top and in the middle of the face, one hole 2" to the right and 1.7" below the first hole and one hole 1.1" above the last hole. Center punch these holes	Refer to drawing	N/A	±0.005"
2	Scribe, ruler and center punch	Mark points for LED holes on the 5" by 3" face close to the microprocessor holes. Each hole is 0.6" from the top and 0.75" on either side of the center vertical line. Center punch these holes	Refer to drawing	N/A	±0.05"
3	Scribe, ruler and center punch	Mark point for buzzer hole 2" from the top along the center vertical line. Center punch these holes	Refer to drawing	N/A	±0.05"
4	Scribe, ruler and center punch	Mark points for clamp holes. The first hole is marked 1" from the top, 1.125" on the left of the center vertical line; the second hole is marked 1.25" below it; the third hole is 1.5 inches to the right of the second hole; the last hole is 1.25" above the third hole. Center punch these holes	Refer to drawing	N/A	±0.05"
5	Drill press	Drill three through holes for the microprocessor using a #29 drill	0.135" diameter hole	RPM = 410	±0.005"

		bit		F = 0.04"/s	
6	Drill press	Drill two through holes for the LEDs using a #10 drill bit	0.195" diameter hole	RPM = 410 F = 0.04"/s	±0.05"
7	Drill press	Drill the through hole for the buzzer using a 15/16 th drill bit	0.945" diameter hole	RPM = 410 F = 0.04"/s	±0.05"
8	Drill press	Drill four through holes for the clamp attachment using 1/4 th drill bit	0.25" diameter hole	RPM = 410 F = 0.04"/s	±0.05"
9	Drill press	Drill a 0.25" hole on the front face of the casing near the bottom to fit the strain gauge wire	0.25" diameter hole	RPM = 410 F = 0.04"/s	±0.05"
10	Mill	Find edge using an edge finder from the top left corner of the other 7" by 3" face of the casing.		N/A	±0.05"
11	Mill	Move co-ordinates 3.5" to the right and 0.6" down.	3.5" right, 0.6" down		±0.05"
12	Mill	End mill 2.68" long, 1.29" wide through cut for the battery		RPM = 410 F = 0.04"/s	±0.05"

Table N2: Manufacturing plan for clamp

	Machine or device	Activity or Tool	Parameters	RPM and feed	Tolerance
1	Scribe and ruler	Mark dimensions to be cut on aluminum block	3.2" x 2.2" x 2.45"	N/A	±0.2"
2	Bandsaw	Cut out block using marked lines	3.2" x 2.2" x 2.45"		±0.2"
3	File	File off sharp edges	Rough file		
4	Mill	Face mill sides of the block till flat, 4 flute 2" face mill 0.1"	3" x 2" x 2.25"	RPM=410	±0.05"

		diameter		F = 0.04"/s	
5	Mill	Find edge using edge finder from the top left corner with the 3" side placed horizontally		N/A	
6	Mill	Move co-ordinates 0.25" to the right	0.25" side thickness		±0.05"
7	Mill	End mill 2.5" long, 2" wide and 1.75" deep slot for main area of the clamp	Refer to drawing	RPM=410 F = 0.04"/s	±0.05"
8	Mill	Find edge using the edge finder from the top left corner of the 2.25"(horizontal) x 2" face		N/A	
9	Mill	Move co-ordinates 0.375" to the right and 0.375" down	0.375" to the right 0.375" down		±0.05"
10	Mill	Position and mark center using a center drill	At co-ordinate above		±0.05"
11	Mill	Move co-ordinates 1.25" down	1.25" down		±0.05"
12	Mill	Position and mark center using a center drill	At co-ordinate above		±0.05"
13	Mill	Move co-ordinates 1.5" to the right	1.5" right	N/A	±0.05"
14	Mill	Position and mark center using a center drill	At co-ordinate above		±0.05"
15	Mill	Move co-ordinates 1.25" up	1.25" up		±0.05"
16	Mill	Position and mark center using a center drill	At co-ordinate above		±0.05"
17	Mill	Drill through hole with #7 tap drill at marked centers (0.201" diameter, 20 threads)	0.25" diameter hole	RPM = 1000 F = 0.08"/s	±0.05"

18	Mill	Find edge using the edge finder from the bottom right corner of the other 2.25"(horizontal) x 2" face (milled side facing away)		N/A	
19	Mill	Move co-ordinates 1.125" to the left and 0.6" down	1.125" left, 0.6" down		
20	Mill	Position and mark center using a center drill	At co-ordinate above		
21	Mill	Drill a through hole with a 5/16 th tap drill at marked center (0.3125", 16 threads)	0.375" diameter	RPM = 410 F = 0.04"/s	±0.05"
22	Tap	Tap the holes using a 0.25" tap for the back of the clamp and a 0.375" tap for the bolt	0.25" tap – 16 threads 0.375" tap – 20 threads	N/A	
23	File	File off sharp edges	Rough file		

Assembly plan

1. The first step will be to screw on the microprocessor (Name/part) to the side of the casing. This step has to be done first because the room inside the casing is required to position the microprocessor correctly while it is being screwed on.
2. Once the holes on the processor are aligned with the respective holes in the monitor casing, a 0.135" diameter bolt, 0.25" in length is inserted into each of the holes. The holes in the body are not tapped because nuts are added from inside to secure the bolts.
3. The bread board is then attached onto the base of the monitoring box. First, using a scribe, precise markings are made on the base of the body for where the bread board should be placed. The dimensions of the base are much larger than that of the bread board allowing for more space to be left between the walls and other internal components near it. It also important to make sure that the bread board is close to the front of the casing because where the LEDs and buzzer will be connected so that the connecting wires do not come lose. The adhesive is carefully removed from the base of the bread board and it is positioned on the points marked with the scribe. Assembly of steps 1 and 2 is shown in Figure N1 below.

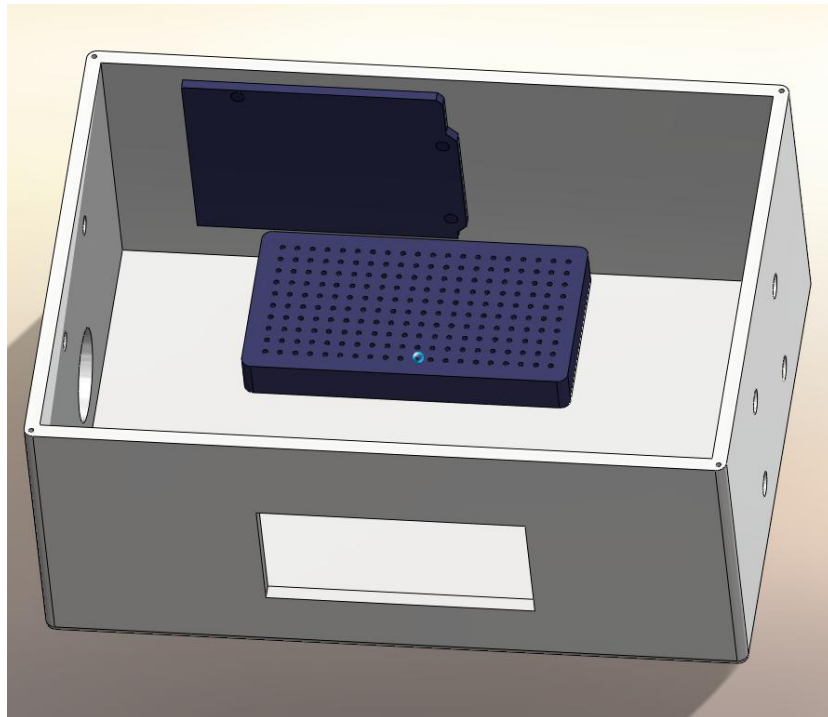


Figure N1: CAD model of the assembly steps one and two

4. The buzzer (Name/part) is then fixed into its hole using either a plastic epoxy or lock-tight. It has to be made sure that the front face of the buzzer is flushed with the wall of the monitor.
5. The LEDs (Name/part) are then fixed into their holes using a plastic epoxy or lock tight. The bulb region of the LEDs should jut out of the wall of the monitor. Assembly steps 4 and 5 are shown in Figure N2 below.

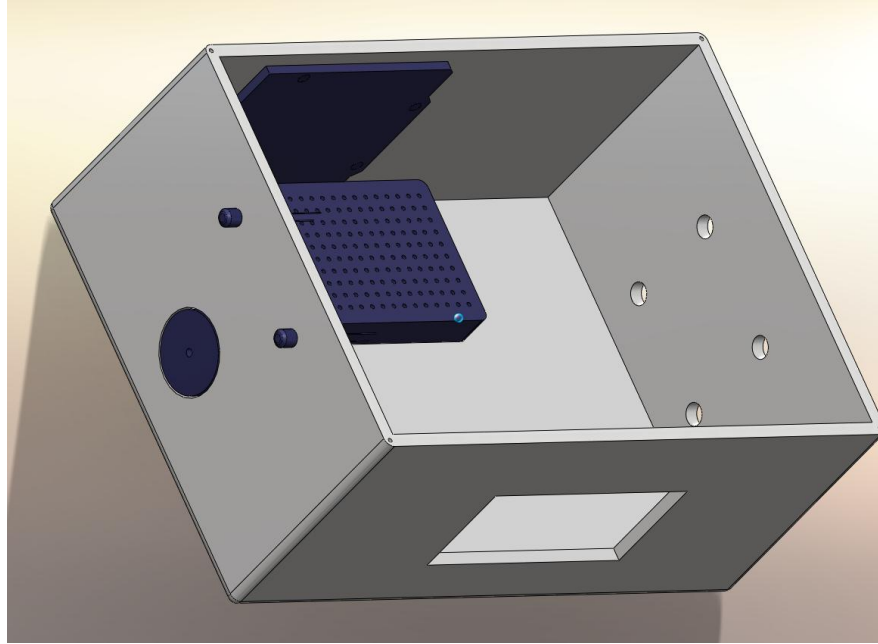


Figure N2: CAD model for assembly steps 4 and 5

6. The battery and its cover (Name/part) are then fixed into their slot using a plastic epoxy or lock tight. The battery has to be positioned such that the area with the on/off switch is on the outside and flushed with the side wall of the casing.
7. The holes on the base of the clamp are aligned with the holes at the back of the casing. Using a bolt 0.25" in diameter and 0.5" long, the clamp is screwed onto the back of the casing leaving the main clamping area unhindered.
8. The 0.375" diameter bolt is screwed into its slot in the clamp. The bolt is 2.5 inches long so its head flushes with the outer face of the clamp. Assembly steps 6 to 8 are shown in Figure N3 show below

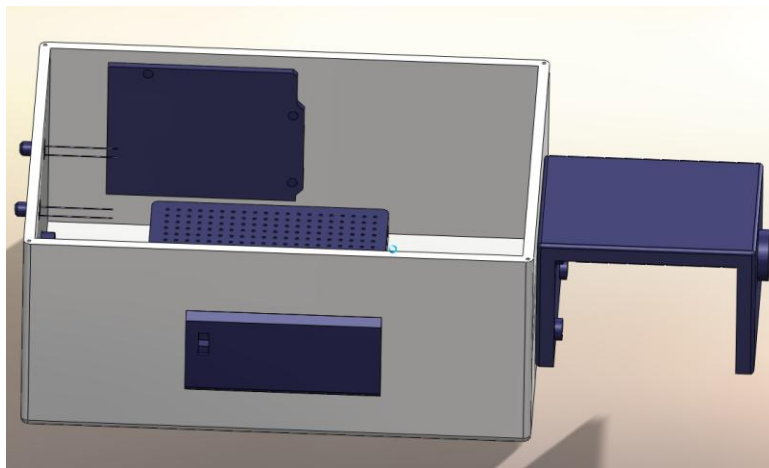


Figure N3: CAD model for assembly step 6 and 8

9. The wire soldered on the strain gauge is then attached to the bread board through the hole on the front of the monitor.

10. Once it has been determined that all the wires inside the casing are in place, the cover of the body is attached using 0.1" screws. The holes on the two sections are aligned and the screws are tightened using an appropriately sized screw driver and wrench. The final assembly of the monitoring box is shown in Figure N4 and Figure N5 below.

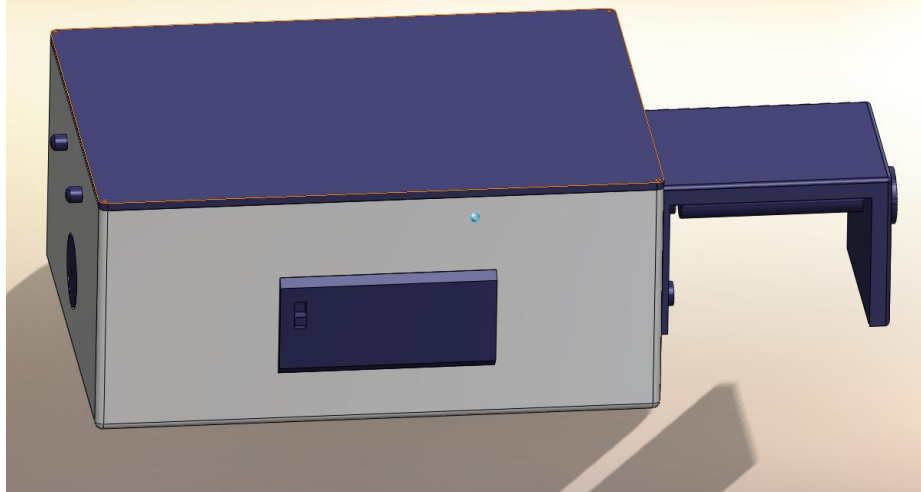


Figure N4: Final assembly of the monitoring box

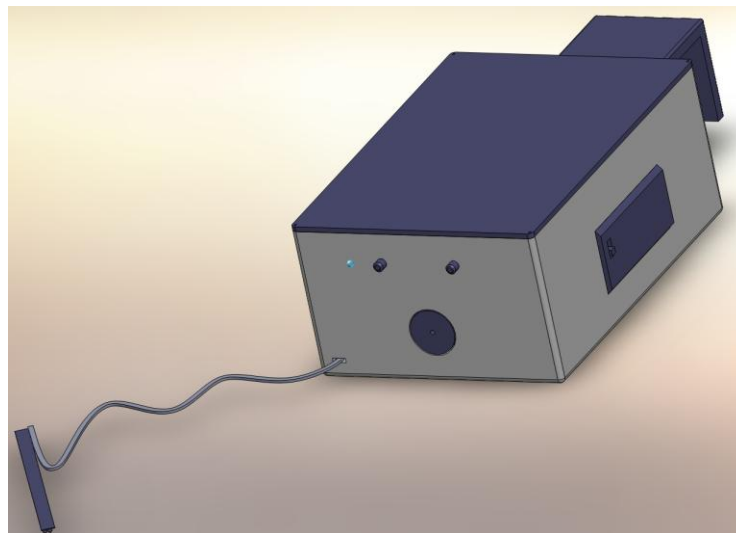


Figure N5: Final assembly of the monitoring box including flex sensor

Appendix O: Design for Assembly (DFA)

Design for assembly is the process of designing the product to make it easier to assemble and handle by making the overall design simple. Assembly includes four main operations amongst others – grasp, move, orient, insert. The objective of DFA is to make each operation easier or to eliminate it.

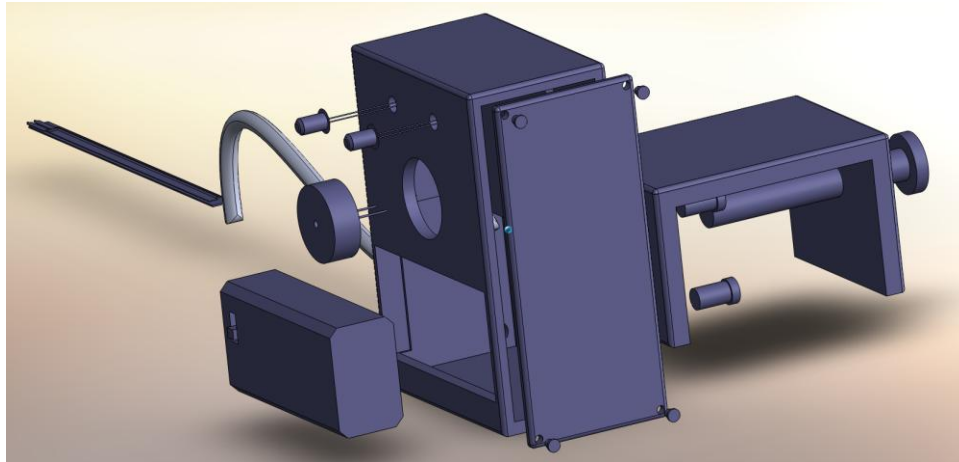


Figure O1: Exploded visual of parts for assembly

There are several guidelines for ease of assembly. These include reducing the number of parts, using modular designs, avoiding parts that may tangle or nest, eliminate fasteners and assembling in the open amongst others. Due to time constraints and the fact that our device is quite simple to manufacture we were unable to apply all of the DFA concepts but we did find some that will be relevant.

Reduce part count

We can reduce the number of parts by injection molding the PVC casing with the clamp – creating a modular design. This would reduce the number of assembly steps required to attach the clamp.

Eliminate fasteners

The bolts used to attach the cover to the casing can be eliminated by using snap fits.

Provide nesting features

In order to minimize errors with positioning, the external components such as the battery and buzzer could have some sort of nesting plane so that the parts naturally fit in place and don't need to be positioned as precisely. This saves time too.

Assemble in the open

To add the internal parts – the microprocessor and the printed circuit board – to the casing body, the design could be modified by making the front face the part to be fastened onto the main body. By doing this there will be increased visual feedback and access to the inner parts of the casing.

Applying the above methods should reduce assembly time but they will increase material cost, increase part mass and require die changes which also increases costs. Further, none of the parts move relative to one another, the materials for the parts do not need to be changed and combining parts does not affect assembly time considerably. In interest of time, cost and material considerations, the above recommended changes to assembly don't necessarily have to be applied.

Appendix P: Team Biographies



My name is Malvika Bhatia and I am from Mumbai, India. I should clarify what I mean when I say I am 'from' Mumbai – my parents currently live there and I go back to Mumbai every summer and for Christmas. However, my friends know me as being from 'the world' because I have been to nine schools, lived in twelve cities (for as little as a month to a couple of years) and I have travelled to every continent other than Australia (I have no desire to go to the poles so I'm just going to leave them out of the equation!) My almost nomadic lifestyle allowed me to see the world in many different ways, one of which was figuring out how things work and even taking them apart and putting them back together (a practice my mother never really approved of). Operations, control systems (even control systems in nature!), designs and building things has always been my passion so studying

Mechanical Engineering seemed to be the most obvious choice. And after these three years at Michigan, I can't thank my seventeen-year-old-self enough for making this choice because I absolutely love what I do.

I chose to go to Michigan initially because as everyone knows, it has one of the best programs in the country for Mechanical Engineering. But this place has offered me a lot more than I could have ever dreamed of. I got to be an instructor with the Michigan salsa group, I joined Theta Tau professional engineering fraternity and got to be the head of professional development which helped me a lot in defining my professional side, I helped fundraise several thousand dollars for underprivileged children in India through iPace, and I met some of the most incredible human beings along the way who are not only my dearest friends, but also people who have helped me become who I am today. I love my friends, I love my family and I believe in making a difference by being the change I want to see (just as Mahatma Gandhi said). I also believe that sometimes, just having faith and believing in things can make them happen but hard work and perseverance are a must. That's a brief summary of me and my life – my short biography!



My name is Bethany Schroth I grew up in Troy, a suburb of Detroit with my two loving parents, Jan and Jim, and younger sister, Diane. I went to Troy High School where I fell in love with science classes and was a very active athlete. I spent my summers living with my grandparents, parents, and sister in Traverse City, Michigan. I chose to go to the University of Michigan because of its long standing tradition excellent engineering programs, and of course because of my

strong allegiance to the Michigan football team. I am actively involved in the Pan-Hellenic sorority Alpha Delta Pi, Dance Marathon, and New Life Church. I am a senior chemical engineering student, but was looking for a way to round out my educational experience here at U of M. That is why I am pursuing a

minor in Global Health Multidisciplinary Design, which is why, as a chemical engineer, I am taking a mechanical engineering senior design course. I chose to pursue this minor because of an interest in the health field and in order to get a better perspective into some of the challenges of designing for cultures other than my own.



My name is Jilly Plonsker and I am a junior neuroscience major at the University of Michigan, and I have hopes to eventually attend medical school. I grew up in a suburb of Chicago with my parents and two siblings. In high school I was on my schools track and field and field hockey teams, and I also became a black belt in karate. At the University of Michigan I work in a cognitive neuroscience lab, am an editor on the board of University of Michigan Undergraduate Research Journal, am in the Tai Kwon Doe club, and am a member of Alpha Delta Pi. I got involved with this project because I have an interest in the medical field in low resource areas.



My name is Chris Maue and I am from Grand Rapids MI. I am the oldest of three children, and have a younger brother of age 18 and a younger sister of age 14. I am a senior Mechanical Engineering student graduating in December. After taking a course focused on global health design last winter with Professor Sienko, I have developed a strong interest in global health and design for the developing world. I plan on pursuing a Masters degree in Biomedical Engineering after graduation. Also, I have a specific interest in medicine and am considering medical school. I hope to continue working in low resource settings throughout the world. I am involved with several clubs here at the University including the Ice Carving Team, Circle K, Cycling Club, and the Center for Global Health. My hobbies include running, cycling, and any sport, especially basketball.