EWH: INFANT APNEA MONITOR

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Abstract

Our client, Engineering World Health (EWH) is a non-profit, non-governmental organization that operates in developed and developing countries all over the world. Of particular concern to EWH is the alarming prevalence of infant mortality in the developing world (Krouse et al, 2004). Moreover, the risk of an infant dying from asphyxiation in these countries is eight times higher than in developed countries (Krouse et al, 2004). In some cases, an otherwise healthy baby dies from indeterminate causes, even after an autopsy has been performed. In this case, the blanket diagnosis of sudden infant death syndrome (SIDS) is used. EWH's ultimate goal is to reduce the number of SIDS diagnoses in these countries. Without information like what causes SIDS or what biological systems are affected, not much can be done to treat prophylactically for SIDS, but the mortality rates can be lowered with improved infantile monitoring. Our project is predicated on the fact that most life-threatening episodes will be preceded by the cessation of breathing in the infant. By monitoring the rhythmic breathing pattern of an infant, and triggering an audiovisual alarm in the event of cessation, caregivers will be altered to the presence of a possible SIDS episode and can take preventative measures, as they deem necessary. We have explored several methods of monitoring infant respiration used in the United States in hospitals as well as homes. Based on the research conducted our prototype incorporates a mechanism for measuring tidal volume feeds that data into an apnea detection algorithm.

Background & Current Methods

SIDS has been defined as "the sudden death of an infant under one year of age which remains unexplained after thorough case investigation, including performance of a complete autopsy, examination of the death scene, and review of the clinical history" (Krouse et. al 2004). While research is currently ongoing to determine the cause of SIDS, current hypotheses to explain the condition including an increased number of apneic events (defined as the cessation of breathing for greater than 20 seconds), respiratory obstruction, and critical diaphragm failure have all been suggested as potential causes of SIDS (Goldwater 2011). Because all of these hypotheses center on the failure of the respiratory system as the main cause of death, it is perceivable that the incidence of SIDS could be greatly reduced by monitoring respiration.

Being able to monitor, identify, and avoid potential cases of SIDS is of particular interest as it is currently the leading cause of death in post neonatal infants and has been the leading cause of death since the 1980s (Mitchell 2009). In recent decades however, the rate of SIDS in developed countries has been dramatically reduced through campaigns such as the American "Back to Sleep Campaign" (Mitchell 2009). Since the beginning of the campaign in 1994, the overall SIDS rates in the United States have reduced by more than 50% (NIH 2011). Unfortunately, similar successes have not been seen in developing countries. Studies looking at the relationship between high rates of neonatal mortality rates in the developing world found that in countries where the rate of neonatal mortalities are the highest that lack of oxygen supply to the body (asphyxia) was eight times more likely than countries with lower neonatal mortality rates (Lawn et. al 2005)(Figure 1). The reason for such staggering differences between asphyxia related deaths in

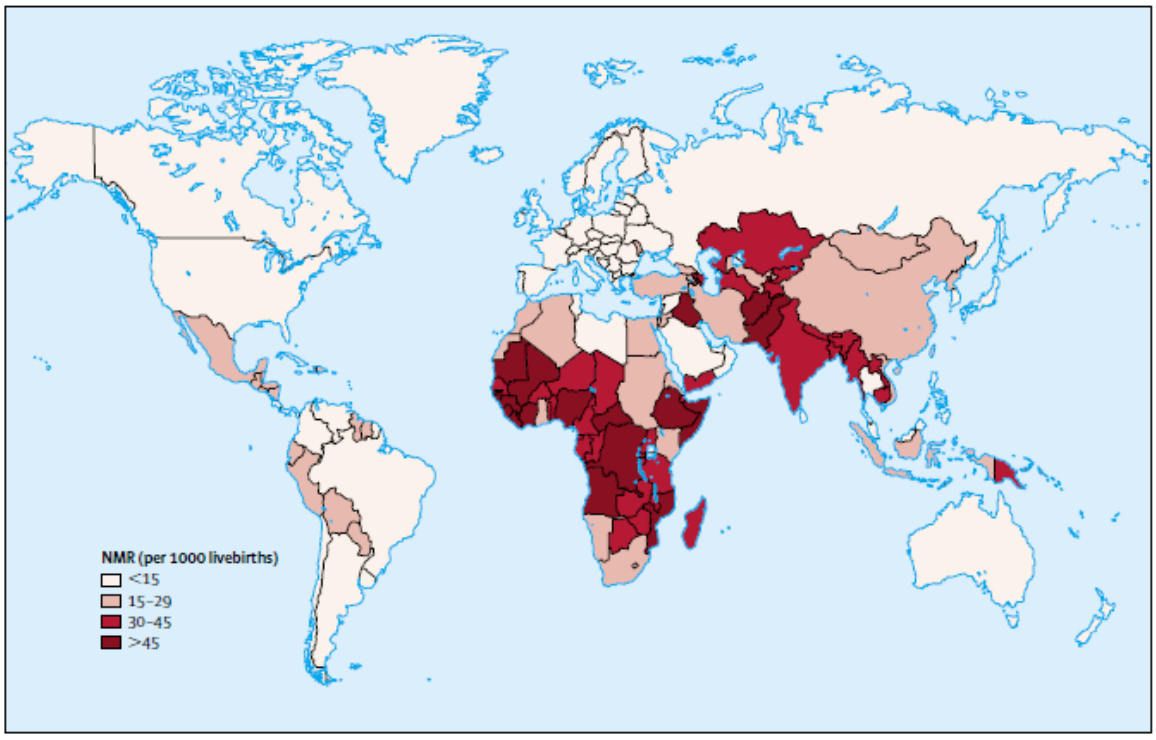

Figure 1: Map showing areas of the world with the greatest neonatal mortality rates. Increased neonatal mortality rates correlate to eight times as many infant deaths by asphyxiation (Lawn et al 2005).

developing countries and developed countries is often attributed to the inverse care and information law which states that, “the communities with the most neonatal deaths have the least information on these deaths and the least access to cost-effective interventions to avoid them” (Lawn et. al 2005). In order to address these issues, the design of a cost-effective ($10-$20) and reliable respiratory monitor was suggested as a design project by Engineering World Health (Engineering World Health 2011) and was the design challenge selected by our design team. The successful design and implementation of such a device will greatly reduce the causative factors of the care and information law by providing the necessary care interventions and providing the proper knowledge to avoid the situation.

Problem Statement

The goal of this project is to produce a prototype that will detect and alert a caregiver after an infant between 0 and 8 months has stopped breathing for more than 15 seconds. The device's intended environment will be in disaster stricken or developing regions of the world. Thus, the unit must be very inexpensive and its ease-of-use is of the utmost importance. However the device must still maintain high levels of durability, reliability, and safety.

Client Requirements & Design Constraints

Since the apnea monitor is being sent into developing countries, there are many factors that the monitor must be able to accommodate in order for it to be successful. Devices that are sent to developing countries often become unusable for a wide range of reasons. Some causes for this come from the lack of technology, training, and infrastructure. Lack of consideration for these variables will result in serious shortcomings for the monitor and so a thorough understanding of what is required by the operating environment is vital. Also, our client needs a device that is low cost yet reliable, durable, and portable.

The monitor can be a kit that can be built in country to keep costs low enough to be affordable to our client. Complete fabrication in the USA would drastically increase the price of the monitor and prevent distribution to the areas where it is needed the most. The cost of the monitor, in total, should not exceed $20 for it to be economical for our target audience. This will allow countries with limited resources to easily obtain a large enough quantity that they can be used regularly. The cost of the individual components in the design must also be low to overcome the possibility of the device being stripped for parts.

Despite the fact that the monitor must be simple and low cost, the reliability of the warning system must be high, or it will not aid in the prevention of SIDS cases. Since the monitor's only job is to alert nearby responders of a complication, there are only two errors that are possible, false positives and false negatives. While a false positive is preferred, our client needs a monitor that is always correct. All it will take is one false negative from the monitor for a life to be lost that could have been saved. This would push the detector to err on the side of being oversensitive. However, an accumulation of false positives will also reduce the credibility of the device. Constant false alarms will slow the response rate to the alarm going off, making it pointless as responders might ignore or stop using it. The speed with which the alarm is trigged must be swift also. Response time is critical in saving and infant who has stopped breathing and so the alarm must trigger as soon as possible. Since twenty seconds is the accepted time interval without breath that is accepted as apnea, the alarm must being to go off as soon as it fails to detect a normal breath in twenty seconds.

The durability of the monitor will need to be high so that it can continue to function consistently over long periods of time. Replacement parts for the wires and leads could be acquired for repairs in country, but the microcontroller that will handle the calculations necessary for the monitor to recognize apnea will not be able to be manufactured in country. Since the cost of sending in a replacement microcontroller would be practically the same as completely replacing the monitor, once the microcontroller breaks the monitor is essentially scrapped. This means the client needs the controller and any of the other internal components responsible for the alarm to last for as long as possible.

Since the device must continue to work overnight monitoring the infant, it must be able to monitor for at least eight hours straight. Client requirement dictates that the prototype be battery powered, so power management and reduction will be paramount.

Our target design for the monitor is for it to be able to be used in a mobile hospital. This means that is must be portable as well. In order to be portable, the monitor must be small, lightweight, and be able to withstand handling from moving. Besides the leads and other wiring, the components of the monitor should be able to fit into a cube 10cm x 10cm x 10cm, and it must be able to be carried with a lightweight housing. While the housing must be light, it must also be able to protect the internal components even if the monitor is occasionally dropped from shallow heights or jarred.

Last, the monitor must be safe because if it has even a remote chance of injuring the child it will not be used.

Design Options

Designing a device to monitor respiration is not a new phenomenon. There are at least six different methods currently available to monitor respiration including: measuring the difference in the conductivity of the chest cavity upon inhalation and exhalation (impedance pneumography), measuring the amount of oxygen being carried in the blood (pulse oximetry), measuring the rising and falling of the chest (force sensing resistor), measuring the temperature difference in air upon inhalation and exhalation (thermistor), and measuring the difference in the chest circumference (inductance plethysmograpy). In determining how to most effectively build an infant respiratory monitor for developing countries, we analyzed the function, advantages, and disadvantages for four of these design methods: impedance pneumography, pulse oximetry, force sensing resistor, and temperature fluctuation.

Impedance Pneumography

When air enters the lungs, the total amount of impedance between any two points through the lungs also increases. By monitoring the fluctuations in voltage of a known current through the chest during respiration, an accurate measure of tidal volume can be obtained and the signal of interest can be analyzed to determine when inhalation and exhalation occur (Figure 2).

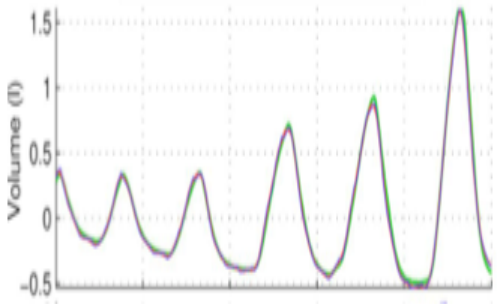

Figure 2: Tidal volume vs. time. Signal produced by monitoring impedance through chest. (AAMI, 1989)

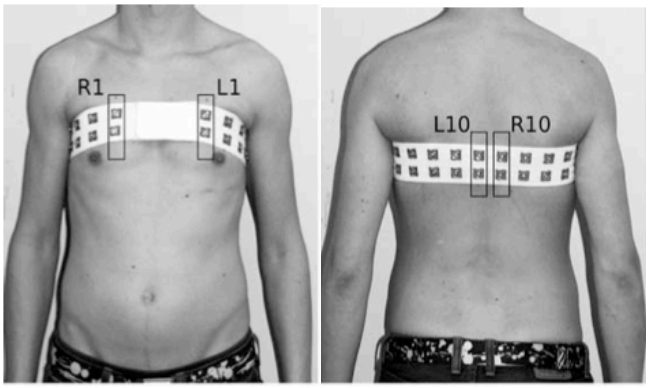

Figure 3: 4-lead placement on chest and back (AAMI, 1989)

The sample current passed through the body must be both low in amplitude and high in frequency. These constraints are put into place to avoid muscle stimulation at low frequencies, and to avoid tissue damage at larger currents. The setup of a chest impedance monitor involves the placement medical leads on the chest and back to produce a known AC current through the chest and measure voltage amplitude changes as a function of increased tidal volume. Two different systems have been used historically. One involves four leads, in which the sample current circuit is isolated from the pair of leads measuring the changes in voltage (Figure 3). The other involves two leads without bodily isolation of the source signal from the point of measurement (AAMI, 1989).

The waveform produced by impedance pneumography is a clear and direct measure of tidal volume which makes it an attractive design option. This is why it is commonly used to measure both tidal volume and cardiac output in hospitals in the United States. The sinusoidal oscillator that produces the known current and the measurement circuit can both be fabricated from several, relatively low-cost components including resistors, capacitors and operational amplifiers. Conversely, this system involves the passage of electrical current through an infant's body and has inherent safety issues in any operational capacity. In our intended implementation environment however, these safety risks would be exacerbated by the potential lack of a reliable power source. These risks can potentially be mitigated with the use of batteries

Pulse Oximetry

Pulse oximetry is a technology that allows the user to monitor oxygen saturation in the blood. This is done by measuring the change in light absorbance of hemoglobin when it is bound to oxygen. Hemoglobin, the molecule in blood responsible for the majority of oxygen transfer, is able to bond four oxygen molecules and with each additional bond, its ability to absorb red light decreases and its ability to absorb infrared light increases. The converse is also true, the lower the oxygen saturation, the more red and less infrared light is absorbed. Understanding this, the average oxygen saturation of hemoglobin in the blood can be measured by comparing the absorbance of red light to infrared light. A monitoring device can correlate the measured oxygen levels to respiration such that low oxygen levels would indicate apnea and trigger an alarm.

The materials of a pulse oximeter are relatively simple. First there is the probe itself, made up of two LEDs and a photodiode, the clip, and the processing unit. For the LEDs in the probe, one emits red light (~660nm) and the other emits infrared light (~940nm). These two LEDs are allowed to project light through a chosen test tissue. This is typically a limb, finger, or ear so that the tissue is thin enough to allow the light to pass through. The photodiode is then placed on the other side of the tissue to measure the light that is transmitted through. This is converted into electrical impulses that can be calibrated to determine oxygen saturation. Some kind of shielding around the probe should also be used to reduce background light pollution. The clip is the general means of attachment to the body. The makeup of this clip depends on where it is intended to be attached, finger or nose, or possibly a strap if a wrist or ankle is used. A finger clip seems to be the simplest to attach and is an easy area to cover for shielding of the probe. Finally the processing unit in this case will be a microcontroller.

The benefits of using pulse oximetry arise from its simplicity and its ability to measure both the blood oxygen saturation as well as the patient's pulse. Since the only contact with the infant would be a clip, it is non-invasive and possesses no real threat to the child from choking hazards. Pulse oximetry also uses very little power and is incredibly portable because of its size and simplicity, which makes it ideal for a portable monitor. Finally since it is only light that is passing through the child, it is extremely safe.

The downside to using pulse oximetry is that it isn't reliable for what we intend to use it for. Since the data collected by the oximeter needs to be averaged over anywhere from five to twenty seconds, a significant lag occurs in readings. Since the monitor must detect apnea immediately after twenty seconds have passed, a reading delay of up to twenty seconds would detect the cessation of breath too late. Also, since not a lot of light is able to pass through tissues compared to natural lighting, light pollution is a serious problem and if the probe isn't covered properly the readings will be unreliable.

Based on of these findings, pulse oximetry is typically used in conjunction with other monitors. Readings are typically used for detecting problems in breathing and not the lack of it. Using pulse oximetry as a standalone monitor is risky as an apneic event may be detected late as an entire minute after breathing has stopped.

Force/Motion Detection

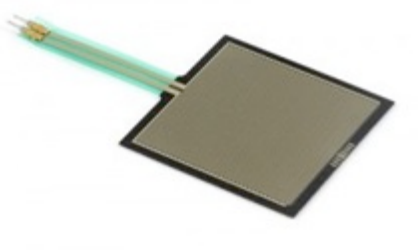

Figure 4: Example picture of a square force-sensing resistor (Mastershop 2011).

A force sensing resistor (FSR) is made of a proprietary polymer thick film ink, typically screen printed on Mylar (PET) film (Figure 4). As force is applied to the device, electrical resistance decreases. The change in resistance is converted into a change in voltage, which can be analyzed using pattern recognition with a microcontroller. One way we could use this system is with the FSR in direct contact with the infant's chest, such that the force of the chest movement during exhalation gives the signal. This would involve a belt around the chest to keep the position of the FSR fixed. Another application would be to position the FSR in a device underneath the mattress of the crib. In terms of safety, this is a clear advantage as it is the least invasive of all our options. Such a system would require the FSR to be extremely sensitive to the small changes in force caused by respiratory movement. Major possible problems with the use of FSRs are the accuracy and reliability of the signal. FSRs currently available are known to range in accuracy from ± 5% to ± 25% (Interlink, 2011). FSR response is very sensitive to the distribution of the force applied. Application of force on a curved surface may cause pre-loading due to bending tension, which would reduce the dynamic range of the sensor. This would especially problematic if the FSR was to directly contact the curved chest surface. To reduce this error and increase safety, we could use a thin elastomer between the chest and FSR. With a below-mattress FSR device, we would have to address concerns that positioning, mattress material, weight, etc., may interfere with proper functioning of the FSR. These sensors are best used in the 0-1 kg range. We envision

a device with multiple FSRs being more effective, but in this case the limitations would be cost. FSRs cost $5- 6 each which is most of our budget. If the FSR component were to fail, the device would be difficult to repair and essentially become useless.

Temperature Fluctuation

The method of measuring breathing via temperature fluctuations operates using a thermistor. A thermistor is a specific type of resistor that operates on varying resistance with varying temperature (Mastascisa, 2011). All resistors vary in their resistance due to temperature change; however, due to the semi conductive materials that thermistors are made of, they vary a great deal more than average resistors (Mastascisa, 2011). Additionally, the resistance in a thermistor can either decrease or increase as temperature goes up. The most common thermistors are negative temperature coefficient (NTC) thermistors meaning that their resistance goes down as temperature goes up. The change in the resistance in a normal circuit can then be measured by noting the change in voltage according to Ohm's law.

Figure 5: Artist's rendition of an infant nasal cannula (Thermisense 2011).

In practice, the thermistor method of measuring respiration operates using a nasal cannula, a device that sits between the bottom of the nose and the upper lip. The cannula has three different prongs, each with a thermistor attached to it. Two prongs go into the nose and the third prong faces downward over the mouth (Figure 5).

Preliminary testing of the thermistor method using the BioPac TSD202A system which consisted of just a single thermistor showed a fluctuation of approximately 1.5°C between inhalation and exhalation. The system also showed a remarkable consistency in measurements during normal respiration patterns (Figure 6). However, when respiration patterns were changed, recalibration was needed to take into account new peak and trough temperatures.

In terms of overall effectiveness in measuring respiration, measuring temperature fluctuation as the air is expired and inspired shows promise in that thermistors are an inexpensive circuit component which can be purchased for about

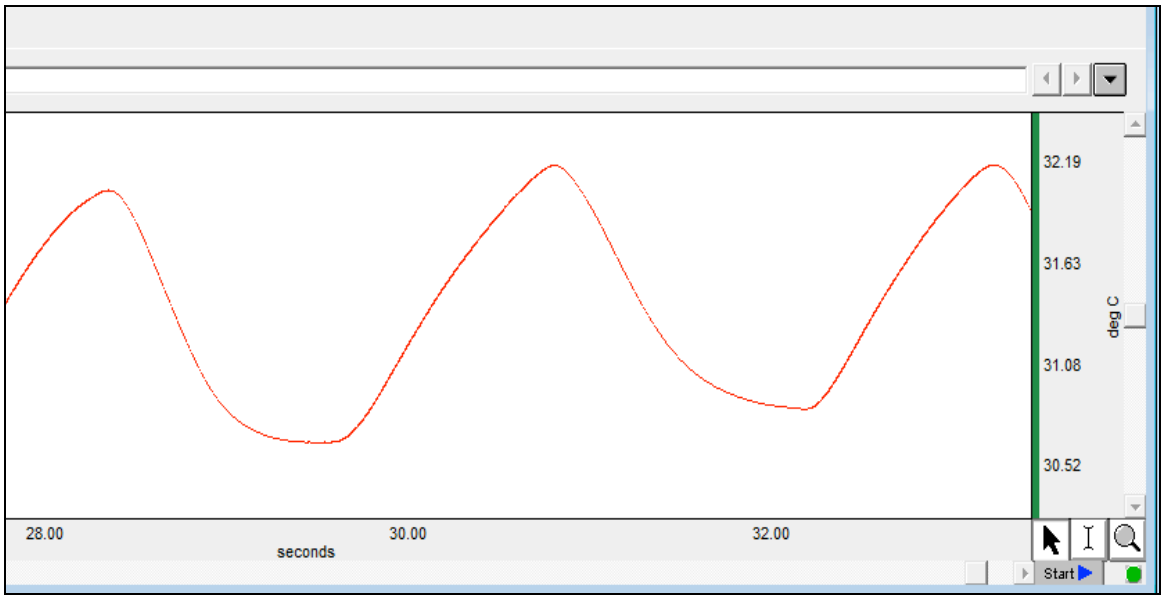

Figure 6: Data obtained from BioPac TSD202A Thermistor Temperature Control System.

$0.60 a piece (digikey.com). In addition to the cost effectiveness, this method is simple to use as it only requires the proper placement of the nasal cannula and it measures a fairly reliable temperature difference between inhalation and exhalation, despite the fact that the base values can fluctuate.

However, this method does have a few limitations in that it is not well suited to measure the quantity of exhalation and if the user is struggling to breath, the device may not be able to decipher the difference between that and normal respiration. Additionally, because the device is close to two cavities opening into the body, its ability to pick up and transfer diseases from one patient to another is high if not properly cleaned after each use. Finally, the device requires a number of wires be placed in close proximity with the face and head in order to work. If those wires are not arranged properly, the device poses a potential health risk.

Design Matrix

Design Factor	Weight	Impedance Pneumography	Pulse Oximetry	Force/Motion Sensing	Breath Temperature Sensing
Cost	.25	8	3	6	8
Safety	.30	4	6	8	5
Durability/Lifespan	.15	6	7	5	7
Ease of assembly/use/repair	.05	5	6	7	7
Signal reliability	.25	8	4	3	5
Total	**1**	**6.3**	**4.9**	**5.8**	**6.2**

Figure 7: Design factors were weighted on their importance to client, compliance with restraints, and feasibility. The four methods researched by the team are compared here. Impedance pneumography and breath temperature detection scored highest and were selected for implementation in prototype.

We researched many options for apnea sensing, but created a matrix for the top four methods that we considered viable for our project. On the matrix, we gave safety the highest weighting, as our device will be used on very young infants who are largely unattended while the device is in operation. Infants that are likely to be on the device are likely to have a pre-existing medical condition. The environment in which the device is used may be variable, as will be the people operating the device. In rural and/or impoverished hospital conditions, the device may be used with a variable power source or operated by hospital staff with very limited training. Given these conditions, it is essential that our device does not introduce additional risk of harm to an infant with already compromised health. Our least invasive devices were rated the highest in terms of safety. The FSR method was rated highest because we would have used it such that it had no direct contact with the infant. The other three methods were fairly comparable, because they each introduced some physical risk to the infant, whether it was through infection (thermistor), external physical pinching (oximeter) or electric shock (impedance pnuemography)

Our next factors in terms of priority were close behind safety, and these were cost and signal reliability. Cost is a heavy constraint mainly because our problem statement requires that we construct a design that is far cheaper than the majority of devices in use that perform the same function. Most apnea monitors in wide use cost hundreds of dollars, at least a tenfold increase on our budget. Given this constraint, it is imperative that we consider cost in every aspect of the design. The sensors we considered varied widely in costs, with force sensory resistors, a newer technology, performing the most poorly, followed by the pulse oximetry sensor, which contains expensive LED components. Impedance pnuemography performed the best in terms of cost, which gave it an advantage for the final result.

Signal reliability was weighted similar to cost. This factor basically encompasses how well the device functions. Our aim is to design a device that

functions with the same accuracy and reliability in detecting apneic events as machines used in hospitals in the United States. In considering the "signal reliability" factor, we took into account the actual reliability of the signal, e.g. the voltage pattern, produced by the sensor, the accuracy in analysis of this data in determining the variable of interest, which is the duration of apnea, and the probability of getting an accurate and reliable signal based on the proper use of the sensor by the end user. To illustrate: consider the force sensing method. According to our research, it is fairly easy to convert the wave form of voltage change caused due to force to determine inhalation and exhalation. However, if force sensing resistors were used under mattress, it is fairly probable that the user may place them wrong, creating an unreliable signal. They are also oversensitive under certain conditions, which would lead to bad input and therefore interpretation.

Applying the same criteria to all our options, we found that impedance pnuemography by far outweighed the others in terms of signal reliability. The thermistor method was second highest in this area. In signal reliability, we also considered probability of false positives and false negatives. In our design, having a lower false negative rate (the device does not indicate a true apnea) is more important than a low false positive rate (the device gives an alarm even though a true apneic event has not occurred.) Our next factors on the matrix were at much lower weights. We designated importance to durability and lifespan, as the device will be used in sub-prime conditions as compared to hospitals in the developed world. Our device will have "one-time" shipping to the target location, and once assembled there, will not be easily fixed due to the shortage of components and technical skill in the field. Given this, we want to make our device last effectively for an extended period of time before they are disposed of. Finally, we considered ease of assembly, use, and repair as a separate category. This include considerations such as the fact that placement and rewiring of electrodes is relatively hard as compared to that of a nasal thermistor. All the devices did not show much variation in rating in these last two variables.

The devices that performed the best on the matrix overall were those that were rated the highest in reliability and cost, though not necessarily in safety. In essence, we will be using the systems that we can make in our budget that function the best. This implies that we will need to incorporate safety devices in the design to fix any shortcomings of our two highest overall options.

Final Design

Based on the tabulation of our design matrices, our current design implements the impedance pneumography method for monitoring respiration. Following the model set forth by other consumer devices, we had initially planned on implementing both temperature and impedance measurement in our prototype. This course of action was abandoned when it was determined that our use of impedance measurement alone could reliably signal of an apneic event (see Testing pg. 19). In addition, this deviation from the current model allows for our prototype to be easier to assemble and use, and cost significantly less than a prototype that has multiple layers of measurement.

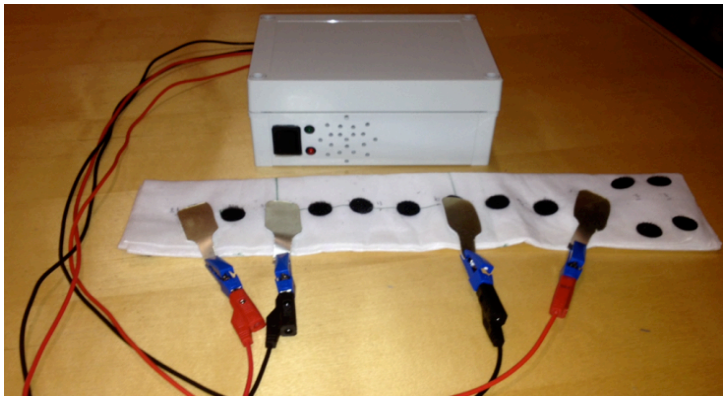

Figure 8: Current prototype including elastic band, tin leads, and junction box that houses the prototype circuitry.

The current prototype shown in figure 8 has four tin leads that are placed on Velcro pads on an elastic band. The Velcro pads, in conjunction with the elasticity of the band to which they are attached, allow for the prototype to be adapted to varying infant body sizes. The band also minimizes the need for attachment by adhesives or medical tape, which can be a skin irritant. We have marked the four optimal positions of electrodes on the band for the average infant, and recommend that these should not be changed unless necessary as per the size of the infant. To create a more conductive connection with the body, water-based lotion will be applied to the leads each time the strap is put onto a patient. Once the monitoring

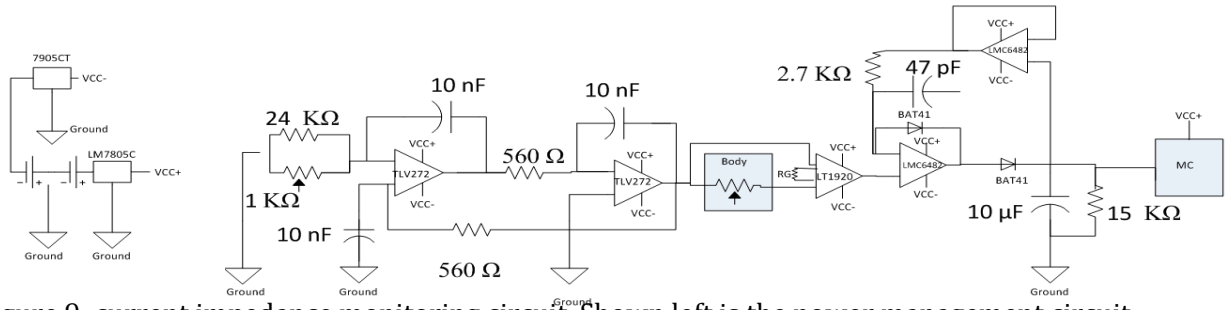

Figure 9: current impedance monitoring circuit. Shown left is the power management circuit involving the creation of +/- 5V from two 9V batteries. Shown right are the sinusoidal oscillator, body impedance model, instrumentation amplifier, and full-wave envelope rectifier followed by the ADC on the mbed microcontroller.

period is over, the leads can be cleaned, disinfected, and used again. One pair of leads provides a closed loop for passing the high-frequency carrier signal through the body and the other pair of leads provides voltage measurement points that will be differentially amplified against the given carrier wave.

The sinusoidal oscillator shown in figure 9 produces a 30 KHz wave at 3mA in accordance with medical device restrictions set forth by ANSI/AAMI (Santis 2011). As the infant inhales, the impedance of the pathway between the two electrodes rises and the voltage rises proportionately according to Ohm's law. After being amplitude modulated by the body, the signal is compared back to its original form. The LT1920 instrumentation amplifier takes the difference between the two signals and amplifies it to a magnitude that gives a larger amount of resolution between each breath taken by the infant, and the difference is at a maximum when the lungs are at maximum inhalation. The instrumentation amplifier is followed by a full wave rectification circuit that produces a waveform showing only the envelope of the waveform produced by the instrumentation amplifier.

The current design circuit is susceptible to high frequency noise as well as cardiogenic artifacts caused by the rhythmic depolarization and repolarization in the chambers of the heart. The cardiogenic artifact closely resembles the QRS complex of an EKG waveform (Figure 12). To account for these sources of noise, the mbed microcontroller was programmed to ignore abrupt changes in voltage and logically consider only on the slow, rhythmic rise and fall of the signal associated with respiration as described in figure 10 (for complete code see Appendix B).

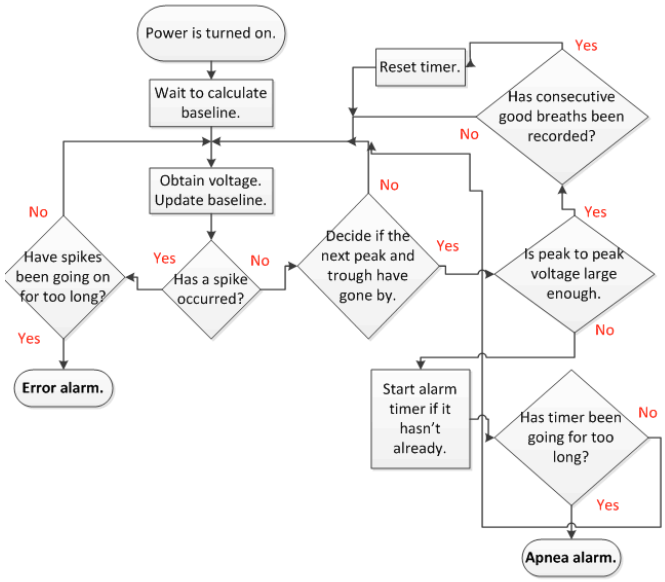

Figure 10: Diagram showing flow of logic to apnea alarm when respiration stops.

The microcontroller takes seven seconds to initialize after being powered on, and after these seven seconds, a moving voltage average is established. As the microcontroller reads in voltages, it compares them against the moving average to determine whether the upcoming values will produce a minimum or a maximum. To

reiterate, the maximum voltages correspond to moments of inspiration and minimum values correspond to moments of exhalation. Once the microcontroller has obtained both a minimum and a maximum, a difference is taken. If this difference is below a threshold corresponding to a full breath, a timer begins to measure the length of time that has passed since the last successful breath. If the timer reaches 15 seconds without reading in at least two full breaths, the apnea alarm is triggered. The prototype has been initially programmed to wait for 15 seconds of respiratory cessation before sounding an alarm and this is the value at which testing was conducted. This value was chosen because it is between the 20 second definition of an apneic event and the 10 second threshold that is the standard for devices we investigated in the NICU at Meriter hospital. When the alarm is triggered, a speaker mounted in the front of the junction box emits a high-pitched ringing sound until the device is switched off.

Testing

Lead Placement

After completing construction of the final design circuit (Figure 9), human testing on an adult male test subject was conducted to determine proper lead placement to achieve the greatest peak to peak voltage change upon inhalation. Initial lead placement was based on the design of Gupta (2011) with two leads on both halves of the ventral side of the chest (Figure 11). With this lead configuration the carrier signal is transmitted between the lateral pair of leads and the modulated wave is detected on the medial pair of leads (Figure 11). Results from this lead configuration returned a large voltage spike approximately once every second, indicating a cardiogenic artifact that was greater than the peak to peak due to respiration (Figure 12).

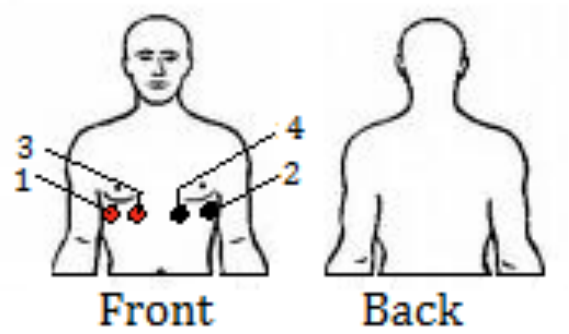

Figure 11: Diagram of lead placement on ventral side of chest cavity as proposed by Gupta (2011). Leads 1 and 2 pass carrier wave through body, leads 3 and 4 pick-up wave after it has been modulated by chest cavity.

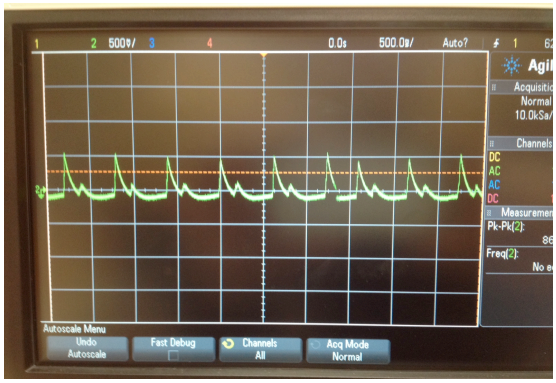

Figure 12: Picture of modulated wave from lead placement described by Gupta (2011). Lead placement shows large voltage spikes approximately once every second indicative of a cardiogenic artifact in the signal.

In order to reduce the cardiac artifact and amplify the voltage change due to respiration, two additional lead placements were tried. One lead placement was identical to the initial lead placement except that the leads were moved above the nipple line in an attempt to reduce the effect of the heart's electric signal (Figure 13). This lead configuration led to a decreased heart artifact but was subject to the electrical signal created by the pectoral muscles upon flexing and relaxing. The third lead placement incorporated leads below the nipple line on the right ventral and dorsal sides of the chest cavity with one carrier lead and one lead reading the modulated wave on both sides (Figure 14). The lateral leads were for the carrier wave and the medial leads were for detecting the modulated wave (Figure 15). This lead placement produced a peak to peak voltage of 250 mV during tidal breathing, the greatest peak to peak voltage change of the three lead placements, and also had the smallest cardiogenic artifact (Figure 15).

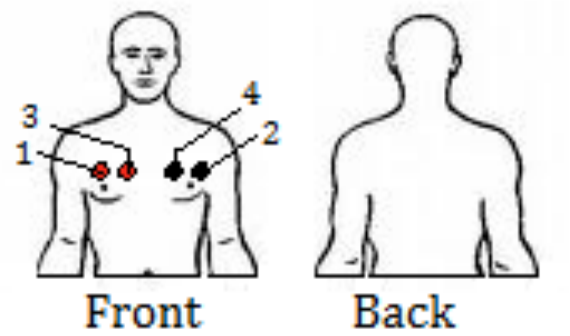

Figure 13: Diagram of lead placement above the nipple line on the pectoral muscles. Leads 1 and 2 pass carrier wave through body, leads 3 and 4 pick-up wave after it has been modulated by chest cavity.

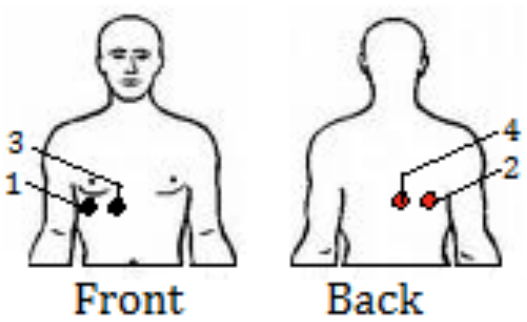

Figure 14: Diagram of lead placement on the right ventral and dorsal sides of the body. Leads 1 and 2 pass carrier wave through body, leads 3 and 4 pick-up wave after it has been modulated by chest cavity.

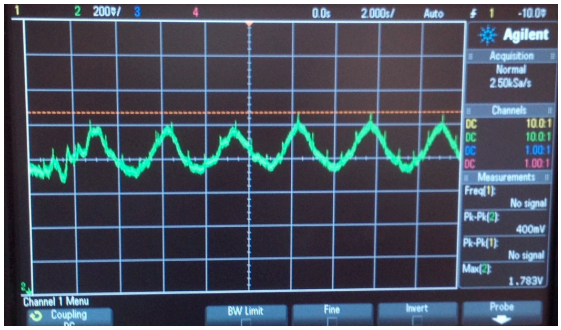

Figure 15: Picture of modulated wave from third lead placement option. Lead placement shows rhythmic voltage change on respiration. Small spikes in voltage can be seen on waveform indicating remnants of cardiogenic artifact.

Correlation of Respiration Waveform to Lung Volume

After determining the proper lead placement, testing was conducted to determine the correlation between the change in voltage caused by respiration and the volume of air in the lungs in the same male test subject used to determine lead placement. This testing was conducted using a voltmeter to monitor the output voltage of the demodulated and amplified respiratory waveform and a spirometer to measure air volume in the lungs.

All tests were started by having the test subject force exhale to the lung's residual capacity of 0.15L (Sherwood *et al.* 2005). The voltage reading at residual capacity was 1.43 V. After exhaling to residual capacity the test subject inhaled from the spirometer to various levels imitating deep, shallow, and moderate breaths. The volume of air inhaled and the voltage readout were recorded at each level. The results of voltage (V) vs. volume (L) were graphed. The results yielded a linear equation with an R^2 value of 0.987 indicating a good linear fit (Figure 16).

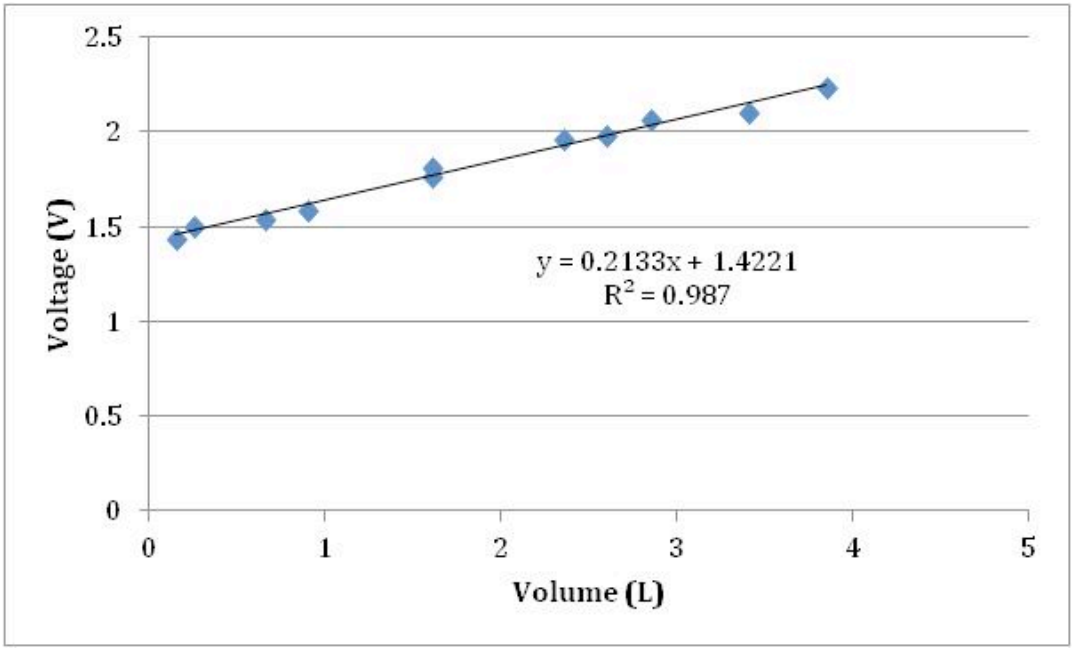

Figure 16: Graph of voltage (V) vs. volume (L) of demodulated and amplified waveform. Data represents 11 data points of varying breath sizes: deep, shallow, and moderate. Data yielded a linear relationship with a 0.987 R^2 value.

While these data were collected using only one test subject a similar linear relationship is expected for additional test subjects including infants. The specific correlation between volume and voltage, however, is expected to vary from subject to subject due to varying degrees of resistance caused by non-respiratory tissue that the signal passes through and the varying shapes and sizes of the lungs for each individual.

Respiratory Alarm Testing

The final design testing was conducted to determine the amount of time it took for the prototype to signal an alarm after the test subject stopped breathing. The test subject was the same adult male used in all previous testing. Once the prototype was turned on, the subject commenced normal breathing for seven seconds in order to allow the prototype to initialize and recognize a normal respiration wave. After seven seconds of initialization, the test subject stopped breathing and the amount of time for the prototype to set off an alarm was recorded. The expected time for the prototype to trigger an alarm is 15 seconds and the results of testing yielded an average alarm time of 15.52 seconds (Figure 17).

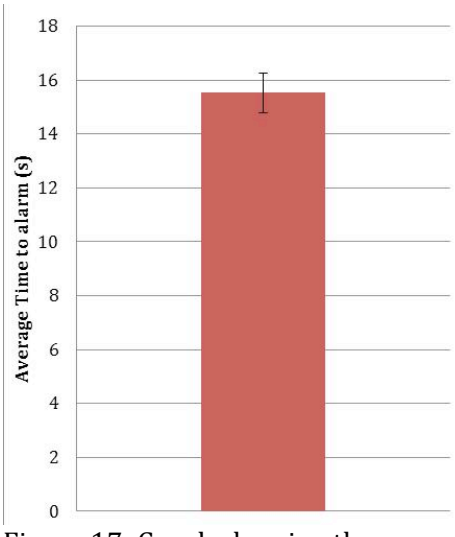

Figure 17: Graph showing the mean time the prototype took to trigger an alarm after test subject stopped breathing. Average time to trigger an alarm was 15.52 seconds (n=15). Error bars represent +/- 1 standard deviation of the mean.

Budget

An important consideration of the project was the low cost requirement. Our prototype costs greatly exceeded the target cost of $10- $20. The final cost of the prototype, including labor estimation, was $235. (Figure 18). This is expected to be much reduced past the prototyping stage. Using an mbed microcontroller prototyping kit contributed greatly to the large cost. This kit was used for easier and faster programming capability. In the final product, we aim to use an alternative microcontroller chip that would have less extraneous capabilities and cost much less, approximately $1. Another important cost reduction would be through the bulk purchase of materials. All electrical components, as well as material for the belt, were purchased in small quantities for the prototype, and are available for much lower prices when bought in bulk. Finally, we included the cost of assembly of prototype into our budget, assuming that the team members did all the work of assembly at $10/hour. The time for assembly was taken to be 10 hours based on our work; however, this included much debugging and reworking of the design, and the time for assembly is anticipated to be much less on a larger scale with trained personnel. With these reductions in cost, we expect the price to go down by at least 60%.

Another area of potential cost reduction is the cost needed to power the device. As per the prototype, where battery power is drained to run the mbed microcontroller, a 9 volt battery would power the device for approximately 9 hours, making the cost of monitoring per night around $10. The use of a simpler microcontroller chip would make power consumption much more efficient, reducing the running cost of monitoring. Removing the mbed device corresponds to a battery life of 60 hours, which reduces the cost of the device per night to $1.50.

PROTOTYPE COSTS

Item	**Price**
banana plugs	$7.00
electrode strap	$6.00
voltage regulators(2)	$5.00
operational amplifier Ics (4)	$3.00
passive components (R,C)	$7.00
mbed microcontroller	$50.00
circuitry housing	$20.00
On/Off swich	$6.00
speaker	$2.00
LEDs	$4.00
9-Volt batteries	$10.00
Breadboard	$15
Assembly (10 hours @$10/hr)	$100
TOTAL	**$235.00**

*lab parts - cost estimated

Figure 18: Budget analysis for final prototype.

Safety and Ethics

This device requires an extremely thorough consideration of safety and ethics for several distinct reasons. Firstly, ethical considerations must address the fact that this device is meant to be given to healthcare providers in impoverished areas free of cost to attend to a critical medical problem. Given this form of distribution and the user demographic, it is of utmost importance that the quality of the device must such that it could confidently used in any healthcare facility even in a developed country. The device is not meant to have all the advanced features that could come with a higher cost, but its basic function should be extremely reliable and usable as would be expected in the United States. Secondly, the apnea monitor is meant to be used on extremely young infants, which requires it to have extremely high safety standards. The device must first do no harm to the infants. It should not introduce risk of electrocution, choking, or skin irritation.

The design of our prototype addresses several safety concerns. The electrode band is washable and should be washed regularly with electrodes detached. The electrode surface can be disinfected, and should be disinfected before each use. The lead wiring is meant to be wrapped and threaded through the infant's diaper to prevent entanglement and asphyxiation. Safety considerations were also critical to determining the power supply of the device. A 9-volt battery supply was determined to be ideal because it does not pose threat of physical harm, which would be a concern if using a more powerful source such as a car battery, which was a strong contender at the brainstorming stage.

Some safety concerns in this final prototype remain to be addressed in future work. The leads of the device are not fully insulated in their connection to the electrodes, so they pose a potential safety hazard for electrocution. The Velcro attachment of leads could be improved upon such that it does not irritate the skin. The voltage and resistive values are currently set to be compatible for initial testing on adults, but will be adjusted such that they better correspond to infant body sizes.

Our device follows the safety standards for electrical medical equipment by the International Electrotechnical Comission. For frequencies less than 2.5 kHz, IEC states a threshold current value limit of 0.5 mA for the general public, but allows for larger currents at correspondingly higher frequencies. Limits for touch or *leakage* currents are also to be below 0.5 mA to prevent perception and reaction (Santis 2011).

Future Work

There are improvements that can be added to our design that will allow it to be more reliable, user friendly, and be able to function in a developing country. The core focus for the future is to reduce

Of our top concerns, the signal clarity of the monitor can be improved. As it runs right now, the voltages that are being generated from the circuit still contain heart artifacts and high frequency noise from surrounding electrical devices. The heart artifacts cause voltage spikes that make accurate data collection from the microcontroller suspect even though the code has been adapted to ignore them. Testing of the monitor has shown that if these artifacts occur consecutively at specific times during data collection, they can result in a false positive. While the chance of this occurrence for each individual breath is quite small, the probability that the monitor will last through an entire night without falsely triggering an alarm is unacceptably low. To eliminate this issue, better coding can be implemented for breath detection to distinguish between respiration and signal noise. Also, the addition of phase-sensitive demodulation to the existing circuit can eliminate heart artifacts as the heart appears as a second source to the circuit modulating the signal. By this property, the demodulator will be able to filter out the cardiac artifact. A block diagram for this phase sensitive demodulator is shown below (Figure 19). In addition, a band-pass filter can be used to eliminate much of the extraneous signal noise.

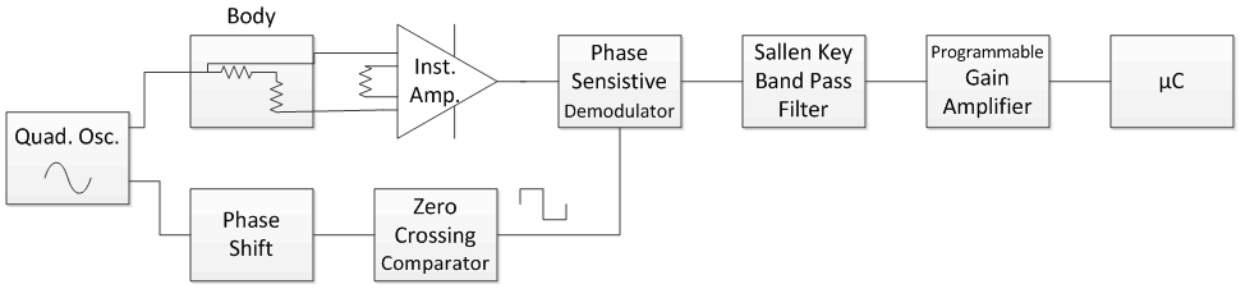

Figure 19: A block diagram of the components to be added for phase sensitive demodulation.

Another concern that must be addressed is power consumption. As directed from our client, the monitor must be able to be run off of battery power. While the monitor is currently able to be run from two 9-volt batteries, it drains them in only 8.3 hours (current draw 180mA), which is barely enough to last a night and would require battery swapping every time the monitor is used. This greatly raises the costs of running the monitor as 9-volt batteries would be expensive and hard to obtain in developing countries. The greatest source of power drain that occurs while the monitor is on comes from the mbed prototyping board that is currently being used. The board contains the microcontroller that reads in the voltage data and decides when to set off the alarm, but it also contains many other features that are built in to make prototyping easier that are not required for the finished product. These additional components all siphon power. In subsequent design iterations, the mbed should be replaced with a simpler, more cost effective, microcontroller that contains only the processor as well as an analog input for the

incoming voltages, one analog output for the audio alarm, and two digital outputs to power two LEDs (which will be added for a visual component of the alarm). This will greatly reduce the power consumed and increase the longevity of the batteries.

The monitor has so far been tested using disposable leads, on an adult test subject, in place of an infant. Moving forward, a number of changes will have to be made in order to allow usage on infants to be conducted. First, the circuit and coding will need to be readjusted for the large reduction in size from an adult to an infant. Having a smaller chest cavity, infants will have smaller voltage changes associated with their breaths. Detection and successful evaluation of these finer voltage changes will require the voltages to be amplified in the circuitry.

Improvements that must be made to the band include making in more durable, washable, and elastic. This will help keep the infants healthy, the band more reusable, and allow for greater variances in the sizes of infants being monitored. Other improvements also include better attachment and insulation of the electrodes on the band, developing a protocol to adjust for various infant sizes, and increasing the durability of the leads

Finally, instructions must be included with the kit to allow for easy use, replacement, and repair. These instructions must include information on how to use the monitor, proper maintenance, and simple troubleshooting if the monitor malfunctions. Picture-based instructions would allow them to better understand how the monitor is to be attached, ensure it is attached correctly, and fix errors as they arise. Another goal of these instructions is to allow simple diagnosis of component failures so that they can be replaced if the resources are available. This would increase the longevity of the monitor.

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Appendix A: Product Design Specifications

Function: The function of the device being designed is to supply populations in the third-world with a low-cost early warning or alarm system that will reduce the number of infant deaths that are preceded by respiratory arrest. The device shall be used as a possible preventative measure against Sudden Infant Death Syndrome (SIDS). The causes of the phenomenon are not well understood at this point in time. In most cases however, it is assumed that early warning of respiratory arrest will give caretakers enough time to resuscitate the affected infant.

Client Requirements:

1. Device must be simple enough to assemble in country
2. Device must be low cost ($10-$20)
3. Device should *consistently* warn if breathing ceases for 15 seconds
4. Implementation in the third-world is paramount

Design Requirements:

1. Physical and Operational Characteristics

a. *Performance Requirements:* Continuous monitoring both during the day and at night. Must provide continuous 8 hours of uninterrupted monitoring

b. *Safety:* The device cannot introduce any harmful electrical current or voltage to the patient or anyone operating the device. Furthermore, the device must be approved for use by the proper committees and hospital staff members.

c. *Accuracy and Reliability:* The device must *consistently* sound an alarm after 15 seconds of respiratory arrest.

d. *Life in Service:* There is no specific life in service characteristic for this device, but it likely needs to be reliably used for multiple years.

e. *Shelf Life:* The device will likely be battery powered and thus batteries will need to be replaced regularly with frequent usage

f. *Operating Environment:* Preliminary iterations will be provided to mobile hospital units in Haiti.

g. *Ergonomics:* Infants should be able to sleep comfortably while still wearing the attached components of the device

h. *Size:* The circuitry will be housed in a cube volume of no larger than 10 cm x 10 cm x 10 cm

i. *Power Source:* The device will rely on two 9V batteries as a power source with less than 200mA drain during operation

j. *Weight:* Overall weight of the system cannot exceed 3.0 kg.

k. *Materials:* Device will be made out of various active and passive circuit components. Materials cannot create electrical interference that would jeopardize patient or operator safety, or interfere with other nearby medical instruments.

k. *Aesthetics, Appearance, and Finish:* Device should not be exotically

colored and follow standard operating room style.

2. Production Characteristics:

a. *Quantity:* One
b. *Target Unit Cost:* $10-$20

3. Miscellaneous:

a. *Standard and Specification:* Built to legal standards. Must be approved by proper hospital committees and staff to comply with HIPPA and patient disclosure or release. Needs to receive FDA approval.
b. *Customer:* Engineering World Health
c. *Patient-Related Concerns:* The device will need to receive proper sterilization between uses as laid out in operating room protocol.
d. *Competition:* Multiple similar devices are on the consumer market including products by Respisense, AngelCare, and Snuza.

Appendix B: Programming Code

```
//This program is desinged for an apnea monitor. It will read in voltage values that
//measure tidal volume of a patients lungs and set off an alarm when the change in
//the lungs has stopped or become too small.
#include <cmath>
#include "mbed.h"
using namespace std;
AnalogIn ain(p19);
AnalogOut signal(p18);
Timer apnea;
Timer tdrift;
Timer noise;
DigitalOut led(LED1);
Serial pc(USBTX, USBRX);
//Functions
double getvolt(); //Used to obtain a voltage over one tenth of a second that is the average of 100
values.
double findmax(double volt, double premax); //Used to compare two values and return the largest.
double findmin(double volt, double premin); //Used to compare two values and return the lower.
int gethistory(double volt[]); //Used to first fill the voltage array with values before the program
beings to loop.
int next(int count); //Used to find the next spot in the array since it loops from 49 to 0.
int last(int count); //Used to find the last spot in the array since it loops from 0 to 49.
bool fchange(bool fmax, double volt, double average); //Used to determine if the voltage has changed
which side of the base line it was on.
bool compare(double max, double min); //Used to compare the peak and trough values obtained and
see if they vary enough for a healthy breath.
const double dif = 0.1; //A constant that states a change in voltage from the previous value that is too
large and probably is from baseline traveling or a heartbeat.
const double driftravel = 0.5; //A constant that states a change in voltage from the average that is too
large and probably is from the baseline traveling.
const double shallow = 0.03; //A constant that states the minimum required change in voltage
between the peak and trough in a healthy breath.

int main()
{
bool alarm = false; //Used to determine if the alarm should be triggered.
bool change = false; //Used to determine if the voltage has changed which side of the base line it was
on.
bool fmax = true; //Keeps track of what is being obtained, a max(peak) or a min(trough).
bool warning = false; //If true, then the last comparison between the max and min was too small.
bool rapoccur = false;
double sum = 0;
unsigned int count = 0;
unsigned int c = 0;
int point = 0;
int odd = 0;
int rapid = 0;
double average = 0; //The running average of the voltage array.
double volt[50]; //The voltage array.
double max = -1; //The max value that will be compared.
double min = -1; //The min value that will be compared.
double tempmax = 0; //A place holder for the max.
```

```
double tempmin = 3.3; //A place holder for the min.


pc.printf("\r\n\r\nInitializing.");
wait(2);
pc.printf("\r\nObtaining baseline.");
gethistory(volt);

//Generates the intial value of the moving average.
while (c < 50)
{
sum += volt[c];
c++;
}
average = sum / 50;

pc.printf("\r\nMonitoring...");
//This loop is the contiuous part of the program that will run until the alarm is triggered.
while (!alarm)
{
volt[count] = getvolt();

average = average + (volt[count] / 50) - (volt[next(count)] / 50); //Updating the moving average.

//This if statement decides if the new value is from a spike or not, whether from the heartbeat or a
change in baseline.
//If it finds a spike has occured it prevents the program from: using the incoming values for max and
min values, as well as stops any comparisons.
//It will also trigger an alarm timer so that if these oddities continue two long the alarm will go off.
//If it finds a spike did not happen it will run the rest of the code.
if ((abs (volt[count] - average) > driftravel) || (abs (volt[count] - volt[last(count)]) > dif))
{
pc.printf("\r\nDisregarded voltage spike.");
if (tdrift.read() == 0)
{
tdrift.start();
}
if (tdrift.read() >= 10)
{
alarm = true;
pc.printf("\r\nAlarm triggered from voltage spikes.");
}
}
else
{
//pc.printf("\r\nVolt okay");
tdrift.stop();
tdrift.reset();
if (rapoccur == true)
{
rapoccur = false;
if (volt[count] > average)
{
fmax = true;
}
```

```
else
{
fmax = false;
}
}
change = fchange(fmax, volt[count], average); //Checks if the voltage has crossed the baseline.

//If the voltage hasn't crossed the baseline the program will continue to search for the extreme it is
currently searching for.
//If the voltage does cross the base line, it take the extreme found and exports it to be compared and
switches to search for the other.
//<Need to check if rapid change will screw this up.>
if (volt[count] > average)
{
if (change)
{
fmax = true;
min = tempmin;
//pc.printf("\r\nmin = %f", min);
point++;
tempmin = 3.3;
if (noise.read() == 0)
{
noise.start();
}
}
else
{
tempmax = findmax(volt[count], tempmax);
}
}
else
{
if (change)
{
fmax = false;
max = tempmax;
//pc.printf("\r\nmax = %f", max);
point++;
tempmax = 0;
if (noise.read() == 0)
{
noise.start();
}
}
else
{
tempmin = findmin(volt[count], tempmin);
}
}

//Once a new max and min have been obtained, the are compared to see if they differ enough.
//If they don't the 20 second timer is started, otherwise the program continues.
//If compare sends back that something is wrong, the timer is started.
//Once the timer is started, it will not be deactivated until multiple comparisons have return as
```

```
normal.
if ( point == 2)
{
point = 0;
if (noise.read() <= 0.2)
{
rapid++;
pc.printf("\r\nArtifact.");
rapoccur = true;
}
else
{
rapid = 0;
warning = compare(max, min);
if (warning)
{
if(apnea.read() == 0)
{
apnea.start();
odd = 2;
}
}
else
{
if (odd > 0)
{
odd--;
}
if (odd == 0)
{
apnea.stop();
apnea.reset();
}
}
}
noise.stop();
noise.reset();
}
}
count = next(count);

if (rapid >= 3)
{
if (apnea.read() == 0)
{
apnea.start();
//pc.printf("\r\nRapid start.");
}
}

if (apnea.read() >= 10)
{
alarm = true;
pc.printf("\r\nApnea detected!.");
}
```

```
}

//Alarm code.

while (1)
{
signal = 1;
wait(0.000175);
signal = 0;
wait(0.000175);
}

/*while (1)
{
led = 1;
wait(0.5);
led = 0;
wait(0.5);
}*/
return 0;
}
////////////////////////////////////////////////////////////////////////////////////////
////////////////////////////////////////////////
//This function takes in voltage 100 values over a tenth of a second
//and returns their average.
double getvolt()
{
double avg = 0;
double sum = 0;
for (int n = 1; n <= 100; ++n)
{
sum += (ain.read() * 3.3);
//pc.printf("\r\nVolt input = %f", (ain.read() * 3.3));
wait(0.001);
}
avg = sum / 100;
//pc.printf("\r\n volt = %f", avg);
//pc.printf("\r\n getvolt()");
return avg;
}


//This fucntion is going to be used to detect the max.
double findmax(double volt, double premax)
{
double newmax;
if (volt > premax)
{
newmax = volt;
}
else
{
newmax = premax;
}
//pc.printf("\r\nfindmax()");
```

```
return newmax;
}

//This fucntion is going to be used to detect the min.
double findmin(double volt, double premin)
{
double newmin;
if (volt < premin)
{
newmin = volt;
}
else
{
newmin = premin;
}
//pc.printf("\r\nfindmin()");
return newmin;
}
//This function spends 5 seconds getting an array
//of 50 voltage readings to start the running average.
int gethistory(double volt[])
{
for (int k = 0; k < 50; ++k)
{
volt[k] = getvolt();
}
//pc.printf("\r\ngethistory()");
return 0;
}
int next(int count)
{
int counterN;
if (count == 49)
{
counterN = 0;
}
else
{
counterN = count + 1;
}
return counterN;
}
int last(int count)
{
int counterL;
if (count == 0)
{
counterL = 49;
}
else
{
counterL = count - 1;
}
return counterL;
}
```

```
bool fchange(bool fmax, double volt, double average)
{
bool change;
if (fmax)
{
if (volt > average)
{
change = false;
//pc.printf("\r\nfchange() = false");
}
else
{
change = true;
//pc.printf("\r\nfchange() = true");
}
}
else
{
if (volt < average)
{
change = false;
//pc.printf("\r\nfchange() = false");
}
else
{
change = true;
//pc.printf("\r\nfchange() = true");
}
}
return change;
}
bool compare(double max, double min)
{
bool warning;
if ((max - min) > 0)
{
pc.printf("\r\nPeak to peak voltage difference = %f", (max - min));
}
else
{
pc.printf("\r\nArtifact.");
}
if ((max - min) <= shallow)
{
warning = true;
//pc.printf("\r\n Shallow");
}
else
{
warning = false;
//pc.printf("\r\n Fine");
}
//pc.printf("\r\ncompare()");
return warning;
}
```