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 will incorporate a mechanism for measuring tidal volume as well as a mechanism for sensing changes in breath temperature during exhalation. Moving forward with these methods, we have plans to design circuits, program an apnea detection algorithm, and begin testing the prototype on adult and infant subjects.

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 hypothesis to explain the condition include 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 could 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 of a device that will detect and alert of an apneic event based on a predetermined duration of respiratory arrest or apnea be used on infants under 1 year of age. The device shall function to. The device's intended environment will be in disaster stricken or under developed regions of the world. Thus, the unit cost 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 devastated or impoverished countries there are many factors that the monitor must be able to deal with in order for it to be successful. Devices that are sent to the third world are often made useless by a wide range of reasons. The cause for this comes from the lack of technology, training, and infrastructure in third world countries that is often taken for granted here. A failure to account for these variables will result in fatal shortcomings for the monitor and so a thorough understanding of what is required by the client is vital. Our client needs a device that is low cost, yet reliable, durable, and portable.

The monitor must 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. In total, the cost of the monitor must not exceed $20 as stated by our client for it to be effective. This will allow countries with limited resources to easily obtain a large enough quantity that they can be used regularly. The cost of the raw materials in the components must also be low for theft concerns as well. Devastated or impoverished countries will contain citizenry that would strip the monitor of valuable materials, rendering it useless. By only using materials that have no individual worth, the theft issue can be handled, allowing for the functionality of the monitor not to become quickly removed as soon as it arrives in country.

Despite the fact that the monitor must be simple and low cost, the reliability of the warning system must be high, otherwise 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 monitor needs to consistently function correctly in order to be used. This means that the durability of the monitor will need to be high so that it can continue to function. 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 controller would be practically the same as completely replacing the monitor, once the controller breaks the monitor is essentially scrapped. This means the client needs the controller and any

of the other internal components responsible for the alarm must be able to last for as long as possible.

Since the monitor must continue to work overnight monitoring the infant, it must be able to last for twelve hours straight. This means that if a battery is used to power the monitor is must be able to draw a great deal of operational time from it and be able to warn the user when there isn't enough charge left to last an entire night. To keep the power consumed down, the device should be able to run off of a twelve volt source and only draw one hundred milliamps of current when operational. The device could also be powered from the grid, however, since power isn't necessarily consistent, the monitor must be able to hold a charge that could last through inconstant power supply and be able to warn users when it is going to run out.

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. By being portable, the device can be moved to where it is needed, allowing for greater use. In order to be portable, the monitor must be small, lightweight, and be able to withstand handling from moving. This means the, besides the leads and other wiring, the components of the monitor be able to fit into a cube 10cm x 10cm x 10cm. 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 occasional dropped from shallow heights or jerked as those components cannot be replaced if they fail.

Last, the monitor must be safe. Since the monitor is being used to alert for complications that might never happen, if it has even a remote chance of injuring the child it will not be used. Both of our methods for monitoring the breathing of the infant involve wires. These could become possible choking hazards and so a way to prevent this from occurring is essential. Another component of safety that must be observed comes from the impedance monitoring. Since a current is being passed through the child, it could become fatal if the current frequency ever changed as this could induce muscle spasms and even cardiac arrest. Since the power supplies being used, an inconsistent grid, or batteries, the monitor must be able to maintain the same signal even when the power is out or if a power surge occurs.

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).

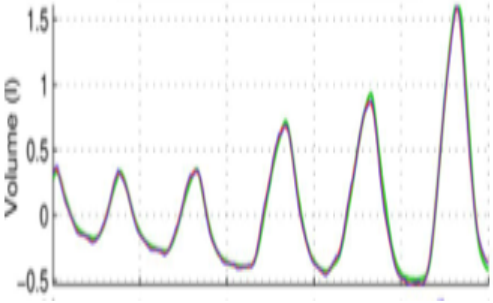

Figure 2: Tidal volume vs. time. Signal produced by monitoring impedance through chest. (AAMI, 1989)

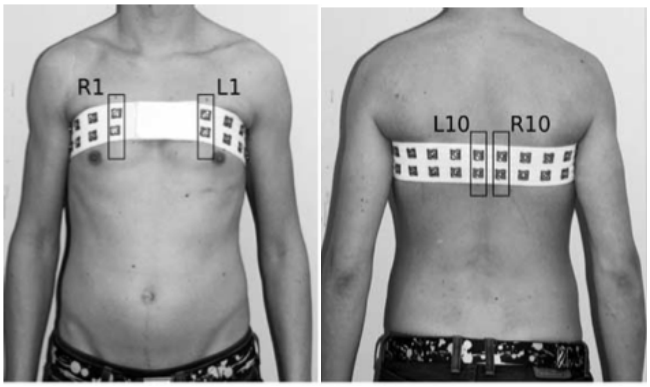

Figure 3: 4-lead placement on chest and back (AAMI, 1989)

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 as well transduce voltage 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 will be producing 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 indented implementation environment however, these safety risks are 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 light is absorbed and the less infrared light is. Understanding this, the average oxygen saturation of hemoglobin in the blood can be measured by comparing the absorbance of red light to infrared light. This technology is planned to be adapted to an infant monitor to detect the lack of breadth in an infant and set off 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 patients 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 downsides 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 off of these findings, pulse oximetry is typically used as a monitor for patients that are being watched or 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 alarm may sound as late as an entire minute after breathing has stopped.

Force/Motion Detection

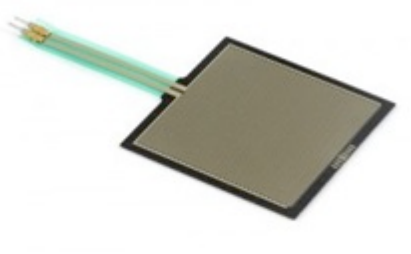

Figure 4: Example picture of a square force sensing resistor.

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 where the FSR is in direct contact with the infant's chest, and 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. An FSR costs $5- 6, which is most of our budget. This also impedes using the FSR in conjunction with another sensor, an option we had considered. Finally, 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.

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^{o}C between inhalation and exhalation. The system also showed a remarkable consistence 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 an 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 apiece (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 weightage, 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 possibly 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 actually 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 devices 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 this field. Given this, we want to make our devices last effectively for an extended period of time before it has to be disposed. 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.

Preliminary Design

Based on the results from the design matrix, the two highest scoring methods were impedance pneumography and the thermistor method of measuring temperature fluctuation. Following the model set forth by caretakers and monitor manufacturers in the United States, we have decided to use both of these methods in tandem in our final design. We chose to use two methods in our final design in order to increase device reliability. We believe that this two method system will decrease our number of false positives without increasing the rate of false negatives. Owing to the cost effectiveness of both of these designs, we believe that the added safety measures will out-weigh the added costs while still keeping the device within our $10-$20 budget range.

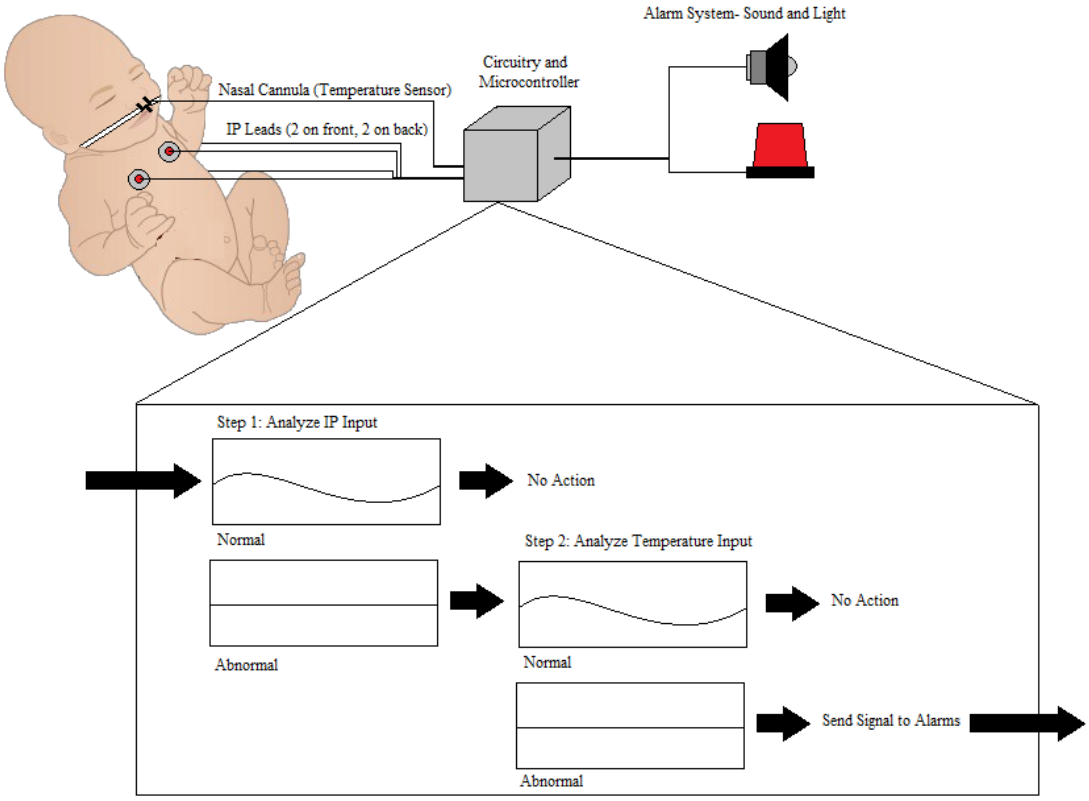

Figure 8: Design factors were weighted on their importance to client, compliance with restraints, and feasibility. The four methods researched by the team are compared here. Impedance pneumography and breath temperature detection scored highest and were selected for implementation in prototype.

Our preliminary design schematic (Figure 8) shows four impedance pneumography leads (two on the chest and two on the back) and a three-pronged nasal cannula placed between the bottom of the nose and the upper lip. Both of these inputs will feed into a central box which will be run on batteries (having the capability to run on a car battery, a common power source in the developing world). The central box will contain a microcontroller which will analyze the inputs from the impedance pneumography leads and the thermistors by measuring changes in voltage. An

algorithm for normal pattern recognition will be developed to process the inputs and trigger the alarm output. The program will employ hierarchical logic in determining when to trigger an alarm. Whenever tidal volume ceases to display and changes in voltage for a duration of 20 seconds an alarm will be triggered regardless of the feedback provided by the thermistor. This choice was made because the impedance pneumography method is more reliable over breath temperature. In the event that IP fluctuations are occurring, but are sub threshold, the program will then consider the input provided by the thermistors in the cannula. If there is a lack in temperature fluctuation from this sensor an alarm will be triggered to alert of a possible apneic event. The alarm system will consist of an audible signal as well as a visual signal that will alert the caregiver to the abnormal or arrested breathing and allow them to provide the proper care. The current goal is to have on/off functionality by adding an SPST switch as well as a method for silencing the alarm and resetting the monitor.

Future Work

Further research is needed to determine the materials best suited for our design, specifically which types of leads to be used in measuring the tidal impedance. The fabrication process will begin with the designing of the component circuits and ordering them from online distributors. Before implementing a control system, each component shall be bread boarded and tested on team members to determine its ability to produce the waveforms of interest. Once the circuits have been debugged and are able to produce signals of interest, the team will select a microcontroller to integrate the inputs and outputs of the prototype. Working from a logical flow diagram the team will produce a digital algorithm that interprets the signals from the mouth and chest and determine when cessation of breath has occurred for each.

After the microcontroller has been programmed and is detecting apneic events according to specification, the audiovisual output of a small speaker and warning light will be added to the prototype. Taking into account the current drains produced by all components in the design; the team will choose the correct type of battery power source to power the prototype.

Once a working prototype is in existence, testing will need to be conducted on infant patients. Given current regulations involving medical testing, the team will be unable to rely on UW hospital as a source for testing the prototype. Thus, we will need to rely on volunteers from the UW community.

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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 cheap early warning or alarm system that will reduce the number of infant deaths attributed to respiratory arrest. The device would 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 20 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 12 hours of uninterrupted monitoring

b. *Safety:* The device cannot introduce any harmful electrical interference 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 20 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 wall powered and the only shelf life concern is lead replacement with every new patient.

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 12V power source with less than 100mA 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 varying upon which design option is selected. Materials cannot create electrical interference that would jeopardize patient or operator safety.

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 Product 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.