Engineering World Health: Infant Respiratory Monitor

Final Report

Christopher Besaw (Team Leader)

Stephen Young (BWIG)

Benjamin Smith (BSAC)

Donald Weier (Communicator)

Advisor: Dr. Paul Thompson

Client: Dr. Amit Nimunkar

May 8, 2012

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Abstract

Sudden Infant Death Syndrome (SIDS) is the sudden, unexplained death of an infant under the age of one, usually while sleeping. While the national SIDS rates indicates a higher prevalence in developed countries, the lack of documentation and autopsies in third world countries has skewed this data. A more accurate portrayal of the situation worldwide is the number of neonatal deaths, or the deaths in the first four weeks of an infant's life. There are over four million neonatal deaths annually, with over 99% of these deaths occurring in low to mid income nations. Infant respiratory monitors have been shown to decrease the number of infant deaths while sleeping, but the current models on the market are much too expensive and energy dependent to be an effective means of decreasing these tragic events in resource-scarce areas. As a result, a prototype infant respiratory monitor has been developed utilizing impedance pneumography as its means of detection. The monitor has significantly reduced power consumption and initial and recurrent costs, so it can feasibly be implemented in developing countries. A PIC18F14K22 has been selected as a low power microcontroller, and two rechargeable lithium ion batteries are integrated as the power source to allow for easy recharging. Through rigorous testing, the monitor has been shown to reliably successfully set off an alarm system, audible from over 200 feet. Testing has also been conducted to determine optimal electrode placement and to demonstrate a linear relationship between changes in lung volume and the signal obtained. The total price of the unit is $30.06. The ethical considerations concerning device reliability as well as patient and user safety were integral to the development of this device. In the future, a charging circuit and an electrode belt should be designed for use with the device, and improvements to device sensitivity and general construction should be made.

Background Information

Sudden Infant Death Syndrome, or SIDS, is the sudden, unexplained death of an infant of less than one year, whose death cannot be explained by an autopsy [1]. A majority of these deaths take place when the infant is between two and four months of age [2]. While the cause of SIDS is unknown, there are some risk factors that are associated with a higher incidence of infant mortality. Stomach sleeping, cigarette smoke, soft mattresses, co-sleeping, premature births, and living in poverty conditions have all shown a positive correlation to an increased occurrence of SIDS [3]. Contrary to initial expectations, the yearly rate of SIDS is much higher in developed countries, such as the United States and Germany, than third world nations [4]. However, this has much more to do with the classification and interpretation of the autopsy findings (which are not always performed in all environments) [5]. Consequently, many SIDS deaths are incorrectly reported as being caused by infectious diseases, therefore reducing the apparent SIDS incidence rates in developing nations [6].

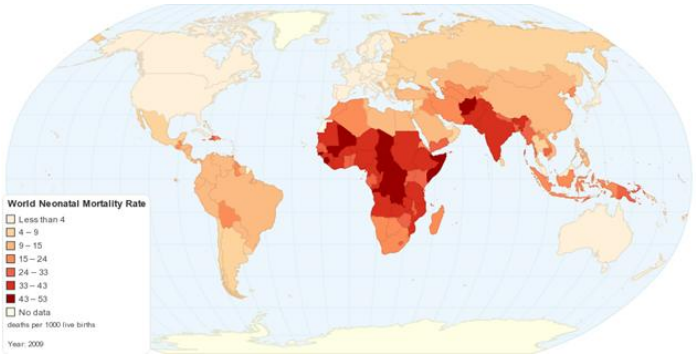

Figure 1: Neonatal deaths worldwide [5]

Over four million neonatal deaths occur every year, and over 99% of them take place in low to mid income level nations, as shown in Figure 1. This is a much more accurate portrayal of how the quality of healthcare affects infant death rates that looking at only worldwide SIDS rates. 23% of these neonatal deaths are linked to asphyxia, which can be reduced with the implementation of infant respiratory monitors – the focus of this project [6].

Engineering World Heath (EWH) focuses on developing and implementing medical technologies in resource-scarce settings. The main goal of this organization is to improve the

quality of healthcare in these areas [7]. Therefore, the final respiratory monitor design specifications should take the target implementation setting into consideration. Resources are extremely limited in these locations, so devices should be of minimal initial and recurring cost. Power sources are also very unreliable, so devices that rely on constant electric power should not be considered. Environmental conditions in these areas are typically more extreme than first world countries, as temperatures and humidity are high. Devices will often be used in mobile clinics that frequently move in an effort to reach as many people as possible. Consequently, devices should be relatively compact and moveable in nature.

Client Description

Dr. Amit Nimunkar is an Associate Faculty Associate at the University of Wisconsin-Madison with a PhD in Biomedical Engineering. He is associated with Engineering World Health and has proposed this project in association with Dr. Laura Houser, an Assistant Professor in the Department of Pediatrics at the UW School of Medicine and Public Health, who has personal ties to improving medical technologies in Haiti.

Current Devices

There are many devices that are currently on the market that provide monitoring systems for infants while they sleep in the in-home setting. Typically, these monitors ensure that infant respiration rates maintain steady levels on a per minute basis, and that cessation of breathing does not occur. There are many ways to monitor respiration including impedance pneumography, which measures changes in chest cavity resistance during breathing [8]. Pulse oximetry can also be used to monitor respiration rates by measuring oxygen levels in the bloodstream; force plates are another form of respiration monitoring, and they monitor infant motion artifacts and sound an alarm in motion absence of more than twenty seconds [9]. A fourth way of monitoring infant respiration is using temperature sensitive thermistors to measure temperature fluctuations consistent with inhalation and exhalation and the heat content of the surrounding air [10].

The first competitive respiratory monitor currently on the market is the Babysense II, which utilizes two large force pads placed under the crib mattress to sense if the infant is

breathing properly. The Babysense depicts a green, ‘all-clear’, light when the infant is breathing normally, but emits an audible alarm if the infant’s respiration rate decreases to less than ten breaths per minute or breathing ceases for more than twenty seconds. The monitor is powered by regular AA batteries and costs $279.00 per unit [11].

Figure 3: The Babysense II monitor. [11]

Another respiratory monitor available for home use is the Angelcare 201 model. This monitor also uses a force mat that is placed under the crib mattress to monitor the infant during the night. The Anglecare model sounds an alarm when the infant stops breathing for more than twenty seconds. The power source for this monitor is an AC adaptor as well as a battery backup for use in the case of a power outage that requires eight AA batteries. The cost of the unit is $129.99 [12].

Figure 4: The Angel care Respiratory Monitor. [12]

The Respisense baby monitor differs from the previous two monitors mentioned in that it uses a motion detection method of monitoring respiration rates. The device clips onto the infant’s diaper, which allows for supervision away from the crib, which a permanent force mat does not allow. After twenty seconds of inactivity, the sensor alerts the caregivers with a built-in alarm system. The system also tickles the infant’s stomach if movement ceases for fifteen seconds. The price for the Respisense monitor is $100 [13].

Figure 5: The Respisense Monitor. [13]

While these systems are compatible for use in developed countries, all three models are incompatible with a mobile clinic setting, where resources are scarce and a consistent source of batteries is limited. The recurrent cost of replacing batteries in the Babysense and Respisense monitors is much too high, and the lack of consistent electric power and the target of mobile clinic use eliminates the Angelcare (AC adapter) from consideration [13]. In addition, they are all too expensive for widespread use in third world countries.

Design Requirements

The primary function of the device must be to effectively alert nearby caretakers in the event that the infant ceases breathing for more than 20 seconds. Therefore, the device must be capable of monitoring an infant's breathing pattern and alert nearby caretakers via audio and/or visual alarm if breathing is not detected for 20 seconds. The device must be highly reliable and consistent, since a failure of the device could result in the death of an infant. Because a failure to detect breathing cessation could have fatal consequences, the device should be designed to tend to be more oversensitive than under sensitive, as false negatives pose a greater threat than false positives. However, if the signal sounds too many false alarms, caretakers may begin to dismiss it, therefore device accuracy is important. The device must be safe to use both for the infant and operators. It cannot interfere with healthy electrical signals in the infant, nor pose the risk of shock to the infant or caretakers. Any external wiring used must not present a risk of strangulation or entanglement to the infant, and there should be no small, easily breakable parts that could present a choking hazard. The device should allow for comfortable, normal sleep for the infant. Any device components that come in contact with the infant must receive sterilization

between uses. In designing the device with the operator in mind, it must be simple to use and easy to operate with minimal training. As a medical device, the device must meet all regulatory demands outlined by the government and other agencies. Therefore, it must comply with HIPPA and patient disclosure standards, as well as receive FDA approval.

A portable device must be small with a maximum size of 10 cm x 10 cm x 10 cm and a maximum weight of 3.0 kg. The device must be robust and able to withstand reasonable wear due to use. Since acquiring replacement devices or pieces and performing repairs on the device may not be an option for organizations using the device in the field, the risk of broken parts must be minimized. The device should have a long shelf life, with the only regular maintenance needed being replenishing the power supply from time to time. This power will be provided by a battery, since power grids in many of the intended environments of operation are often either unreliable or non-existent. Ideally the power source will require minimal replacement and/or recharging, and so in addition to having a long lasting reliable power source implemented into the device, the device itself must be as power efficient as possible. Therefore, the device should operate on 40 mA or less.

The aim of this project is to produce one functional prototype unit. The cost of the device must be kept low, due to the nature of the project. Therefore, the target cost per unit is a maximum of $40-50 per unit. Device components will include basic circuitry such as resistors, capacitors, and amplifiers, wiring, microprocessors, batteries, a speaker, electrodes, and housing.

Current Prototype

With the design requirements in mind, a team from a previous semester fabricated a prototype device capable of monitoring respiration via impedance pneumography. The prototype utilizes a total of four leads, two of which pass the high-frequency carrier signal through the body, while the others measure voltage changes due to respiration. The carrier signal is a sinusoidal 30 KHz wave at 3 mA, in order to comply with ANSI/AAMI medical device restrictions. Body resistance rises with inspiration, and decreases during expiration, leading to measurable changes in voltage, which are picked up by the measurement electrodes. This modulated signal is compared to the original signal by an LT1920 instrumentation amplifier, which takes the difference between the signals. The signal from the LT1920 is then sent through

a full wave rectification circuit, which captures the envelope of the waveform. This is the signal that is sent to the microcontroller.

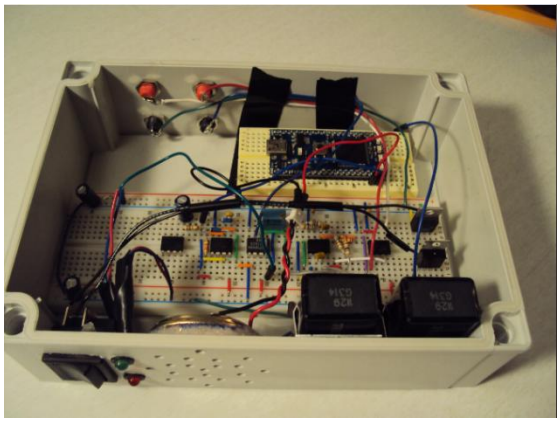

Figure 6: The current prototype with the top cover removed, exposing the circuitry. [14]

The device uses an Mbed NXP LPC 1768 microcontroller to process signals from the body and trigger the alarm when necessary. Voltage measurements read by the microcontroller are compared to a moving average in order to determine minimum and maximum values. Maximum voltages correspond to inspiration and minimum values correspond to expiration. Each time a minimum and maximum value have been determined, the difference between the two values is taken and compared to a threshold that corresponds to a full breath. If the difference is below the threshold, the timer is started. If two successful breaths have not been measured after 15 seconds, the speaker is triggered and an audible alarm sounds. The duration of 15 seconds was selected since it was between the 20 seconds requested by the client and 10 seconds, which was used in respiratory monitoring devices in hospitals that the previous team had investigated.

The circuitry that accompanies the microcontroller is built on a breadboard. The power source used is primarily two 9 V batteries, which power the breadboard circuit elements and the alarm. These batteries have a relatively short lifetime, and require frequent replacement between uses, increasing the recurring cost of the device. In addition, the microprocessor is powered separately with a computer, and so the device is not completely a stand-alone unit yet, and would require additional batteries to power the microprocessor in the absence of a computer.

Design Alternatives: Microcontrollers

The microcontroller used in this device needs to meet a checklist of requirements to perform adequately as well as minimize cost and maximize power efficiency. The device must ultimately meet the following requirements: it must include 1 analog out port, 4 analog in ports, and 2 digital out ports; it must draw a maximum of 20 mA of current; have 30 kB memory capacity; and 32 kB of RAM. In addition to these necessary features, a sleep function is largely preferred to allow the device to further minimize wasteful power consumption, and an ability to program the device in C++ would allow an easier transition from the prototype mbed controller. Finally, in order to keep the final product cost below 50 dollars, the microcontroller should cost a maximum of five dollars. Three potential microcontrollers are chosen as potential components because they meet the necessary requirements.

Cypress CY8C3244LTI – 123

The first microcontroller under consideration is manufactured by Cypress Electronics, and the pin out diagram can be seen in Figure 7. In addition to meeting the required benchmarks, the Cypress model requires only 6.6 mA to function at a frequency of 50MHz. It includes a sleep mode that allows it to draw 1 µA, and utilizes a programming and debug interface called "Programming System on Chip" or PSoC. The PSoC method allows for programming to be done in C++, and requires the use of a PSoC kit, which costs approximately 50 dollars. If ordered in bulk (greater than 100 units), the cost per unit of the controller is only 4.92 dollars. [15]

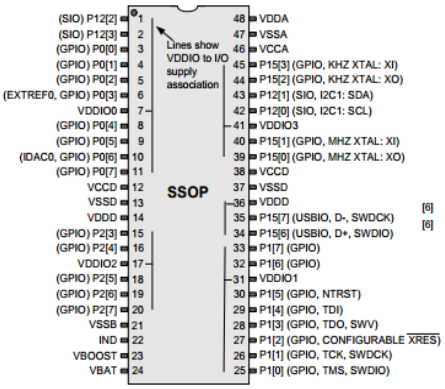

Figure 7: The Cypress microcontroller pinout diagram. [15]

Microchip PIC18F14K22-I/P

The second microcontroller considered is a product of Microchip Technology, which can be seen in Figure 8. This microcontroller again meets the minimum requirements laid out, and requires 6.55 mA when operated at 50 MHz. It includes a sleep mode that requires only 34 nA to be maintained, and uses a debug interface called "In Circuit Serial Programming" or ICSP. This interface, like PSoC, allows the device to be programmed in C++.

The ICSP starter kit costs approximately 60 dollars, but the University is already in possession of a compatible debugger that is available for use. Ordered in bulk, the PIC18 would cost approximately 1.50 dollars per unit. [16]

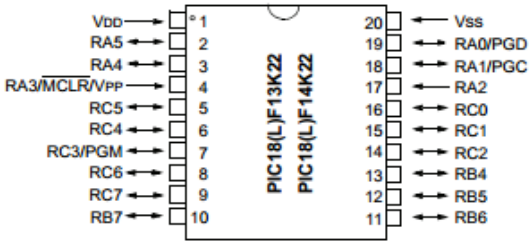

Figure 8: The pin out diagram of the microchip product. [16]

Atmel ATxmega32A4U

The third and final microcontroller considered is available for purchase from Atmel Corpoation. Like the other considerations, this microcontroller at least meets the specifications necessary for the device to function. In addition, the Atmel microcontroller requires, at its maximum running capacity of 32 MHz and 3 V_{pp}, a 9.8 mA current. The device has an idling function that allows it to draw 3.8 mA current when it is not in use. The Atmel controller is debugged in a "Program and Debug Interface" (PDI). The starter kit (STK600) sold by Atmel costs approximately 200 dollars. The PDI system does not support C++, and instead utilizes a language unique to PDI enabled microcontrollers. [17]

Design Matrix: Microcontrollers

A design matrix determining which of the three microcontrollers will be used in the device can be seen in Figure 3. Four categories are weighted based on their importance, and each

microcontroller recieves a score out of five in each category, the resulting total is normalized by five to give a percent total in the final catgory.

Table 1: The Design Matrix used to determine which of the three microcontrollers best meet the requirements set by the design team.

Category	Weight	CY8C3244LTI-123	PIC18F14K22-I/P	ATxmega32A4U
Cost	0.3	1	4	2
Programmability	0.3	4	5	5
Current Requirement	0.25	4	4	2
Required Peripherals	0.15	2	5	3
Total	1.0	0.56	**0.89**	0.61

Of the three microcontrollers, the PIC18 model scores significantly better than the alternatives with a composite score 0.28 higher than the second choice. The cost category rated the controllers on their bulk cost, and is weighted highest because of the cost goal of the overall device. The programmability category references the ability of the team to program the respective device. The Atmel model is the only device that is incompatible with C++, and therefore netted a lower score. The third category, current requirement, is also weighted highly because of its impact on the power efficiency of the final product. The Atmel scored low because it requires significantly more current than the other controllers, and due to its lack of a low power sleep mode. The final category, required peripherals, describes the cost of the necessary equipment to program each respective microcontroller. It has little to no impact on the effectiveness on the final device, and is therefore weighted lower than the other categories. Its inclusion is strictly budgetary. The PIC18 scored a five because the necessary hardware is already at the university, while the Atmel scored a one because the STK600 kit costs nearly 200 dollars. With these considerations, the team is moving forward with the PIC18F14K22-I/P.

Power Source: Battery Design Alternatives

Due to the product design specifications, the power source considered for this infant respiratory monitor is confined to batteries. This is an easy design consideration because the current device uses 9V batteries to power the monitor (apart from the MBed microprocessor) and the monitor will be used in a third world country setting without a constant power source, eliminating the option for using an outlet or reliable DC power source.

9V Batteries

The first design alternative considered to power the infant respiratory monitor is 9 V Energizer Batteries. The current device uses +/- 9V to power the operational and instrumentation amplifiers within the circuit, as well as the alarm system. The current prototype requires two 9V batteries to operate that must be replaced after approximately 8 hours of use. The 9V Energizer batteries that are proposed carry a 625 mAH capacity and have a unit cost of $1.42 [18].

Rechargeable 9V Batteries

The second design alternative considered for this design project are 9V rechargeable batteries from T-energy. Similarly, this alternative offers the ease of implementation into the current prototype, but has a smaller capacity than the regular 9V Energizer batteries. The capacity for the rechargeable batteries presented is 250 mAh and they have a unit cost of $4.34 [19]. Although these batteries have a higher unit cost when compared to regular 9V Energizer batteries, they can be recharged instead of needing to be completely replaced.

Figure 9: A rechargeable 9V battery pack [19].

The final design alternative considered to power the infant apnea monitor are cell phone batteries; specifically, a 3.7V Kyocera cell phone battery. The cell phone battery is substantially different from the first two alternatives and outputs 47% of the voltage as the 9V alternatives. Interestingly, the cell phone battery carries the largest capacity of the three alternatives with 1000 mAh and has a unit cost of $5.99 [20]. In addition to being able to purchase cell phone batteries at fairly low cost, there are also various organizations that collect old cell phone batteries for reuse and recycling. Such donations of cell phone batteries could aid in reducing costs of the overall device. This battery would require remodeling the circuit to be outfitted with a different physical battery source, but would offer the advantages of lasting longer and allow the device to be charged.

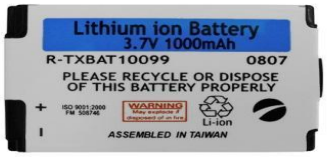

Figure 10: A 3.7 V Kyocera Phone battery [20].

Design Matrix: Batteries

To critically evaluate our design alternatives for batteries, a design matrix was created with five different categories: initial cost, recurrent cost, voltage, capacitance, and availability. The categories are objectively weighted by the team and assigned values based on their determined importance. Initial cost is defined as the upfront cost to purchase an individual battery and was given a weight of 0.1. Recurrent cost is defined as the cost to continually operate the device, based on an 8-hour nightly use for the monitor. The recurrent cost is given a weight of 0.35. The next category is the output voltage of the battery and is given a weight of 0.1. Capacity, the amount of milliamp-hours held within the battery, is given a weight of 0.2. Finally, the last category for the design matrix is battery availability, specifically in a third-world country setting, and is weighted at 0.25.

Table 2: The Design Matrix used to determine which of the three batteries best meet the requirements set by the design team

Category	Weight	9V Regular	9 V Rechargeable	Cell Phone
Initial Cost	0.1	5	3	3
Recurrent Cost	0.35	1	5	5
Voltage	0.1	4	4	2
Capacity	0.2	2	2	4
Availability	0.25	5	2	4
Total	1	0.58	0.67	**0.81**

Recurrent cost receives the largest weight allocation because EWH requires minimal operational costs in order for this device to be viable. Additionally, capacity of the battery is allocated a fairly high weight because it is vital that the device functions throughout the night. Finally, availability was given the second-highest weight because there needs to be batteries available for replacement and implementation for the device to maintain its utility.

Final Power Design

Compiling the results from the design matrix in Table 2, cell phone batteries were chosen as the power source for this design. Most importantly, the cell phone battery drastically reduces the recurrent cost of the current prototype and offers the largest capacity when compared to the other alternatives. This will be accomplished by the addition of a battery charging circuit and will be able to be charged after nightly use. However, implementation of the battery will require rearranging the current circuit to run off of 3.7V and ground, instead of the current +/-9V setup. The cell phone battery also ranked highly in availability since cell phones, and therefore cell phone batteries, are widely used even in third world countries.

Final Design

The final design applies the concept of impedance pneumography to monitor the respiration of the subject. A carrier wave is generated by a quadrature oscillator and is a sine wave oscillating at 30 kHz at 3 mA, in accordance with ANSI/AAMI medical device restrictions. The sine wave is sent through a buffer and is then delivered to the body via the carrier wave electrodes, which are placed on both sides of the subject's chest just below the nipple line. A set of sensing electrodes, positioned just below the carrier electrodes, relay the signal after it has passed through the body through another buffer to an LT1920 instrumentation amplifier for signal processing. This instrumentation amplifier compares the two signals by taking their difference and amplifies the resulting signal. The output of this amplifier is a sine wave which—in accordance with Ohm's law—increases in magnitude as the subject inhales and decreases in magnitude as the subject exhales. This change is caused by differences in resistance that occur as a result of chest cavity volume variations during the breathing cycle. The signal is then sent through a full-wave envelope rectifier, which captures the envelope of the signal and sends it to the microchip for analog to digital conversion and analysis.

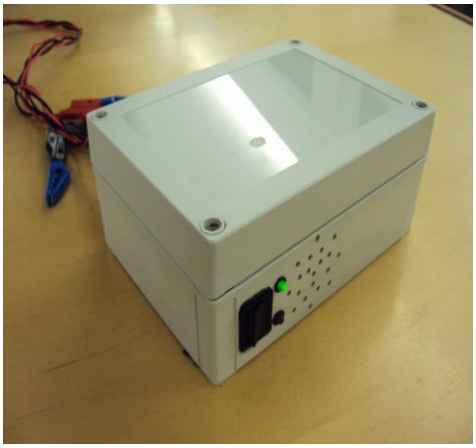

Figure 11: The completed device as it would appear during use.

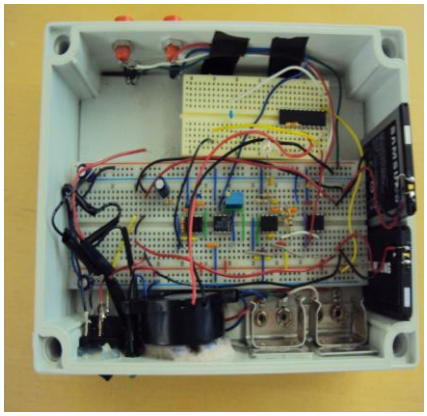

Figure 12: The internal circuitry of the device exposed without the top cover

The prototype is powered by two cell phone lithium ion batteries, which create a +/- 3.7 V power supply. The batteries have a capacitance of 960 mAh and are implemented into the circuit with soldered wires to the battery contacts. The device runs on approximately 22 mA, so the calculated battery life for the device is about 43 hours, or about 5 nights of use between charges. This is a significant improvement over the previous prototype's battery life of approximately 8 hours when powered by two 9 V batteries. The use of the cell phone battery not only eliminates the recurrent cost associated with

replacement batteries, but it also reduces the initial cost of the device when one considers that cell phone batteries can easily be obtained via donation or recycling for free. The team collected 17 lithium ion batteries for this project from students on campus and a U.S. Cellular store in Madison at no cost. Due to the widespread use of wireless communication and fast turnover of cell phones, used cell phone battery supply is immense. Customers dispose of old cell phones, and the associated batteries, long before the battery is actually unusable, so it would be easy to collect these usable cell phone batteries for use in the production of this device. Collection agencies at local cell phone stores and department stores are already in place and a similar approach could be applied to an increase in production of this device.

The PIC18F14K22 microcontroller chosen for implementation in this device is a low-cost, low-power alternative to a typical prototyping microcontroller. The code can be seen in **the *Appendix***. The logic tree that the microcontroller utilizes can be seen in Figure 13.

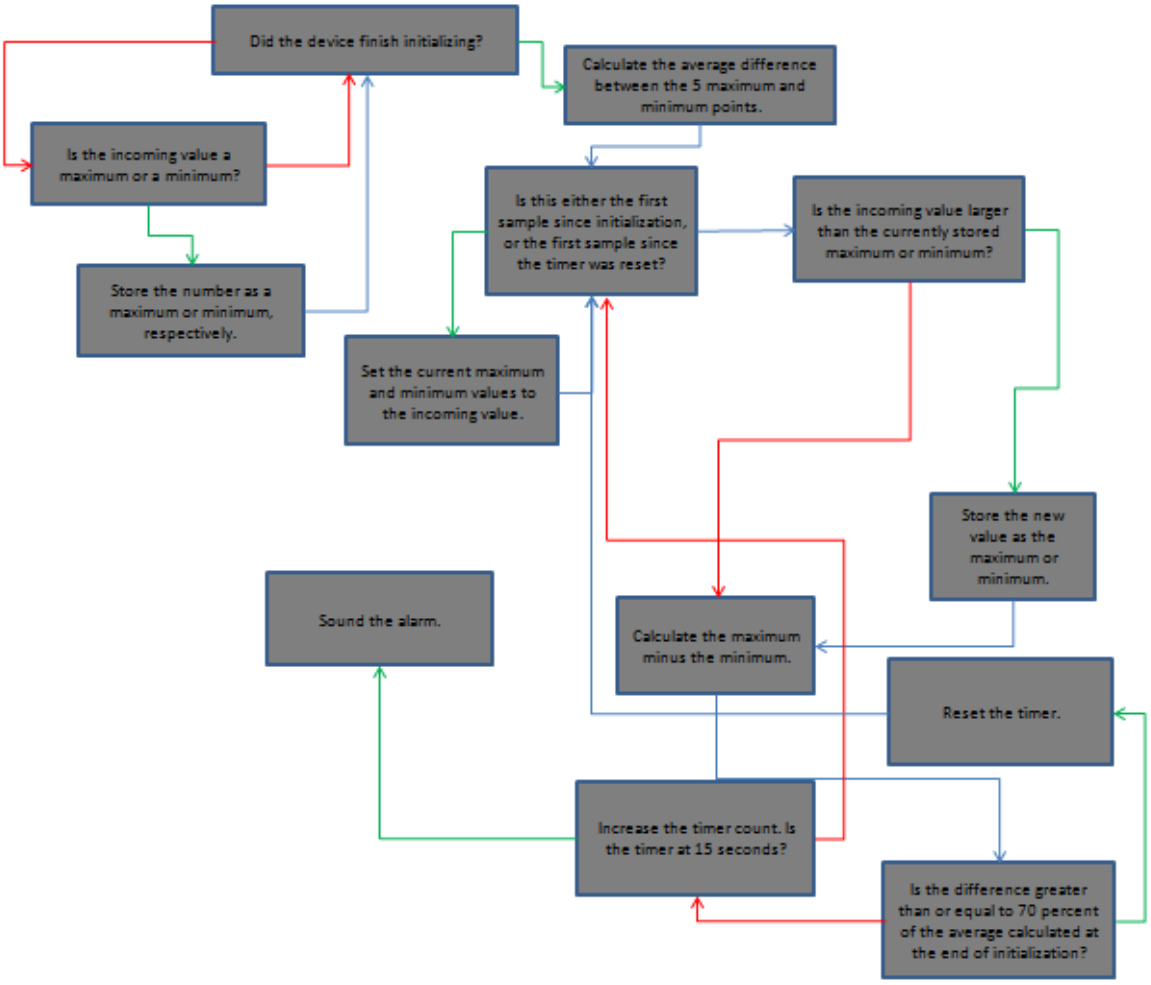

Figure 13: This is the decision tree that the PIC18F14K22 follows to determine if the alarm should be sounded.

The incoming signal from the envelope detector resembles a low frequency sine wave, with maximum voltages corresponding to the peak lung volume of the patient, while the minimum values correspond to the values at the end of exhalation. The microcontroller is programmed to recognize the incoming wave from a patient after it is turned on, and to use this initial data to operate until it is turned off.

First, the microcontroller initializes and determines the comparison value that it will use during the course of its operation. When the microcontroller is started, it undergoes a thirty second initialization that stores the five maximum points, as well as the five minimum points during these thirty seconds. At the completion of this period, an average difference is calculated between the waves. This average difference is used to establish a threshold which defines a successful breath.

Once this average difference has been stored, the program continually checks the new incoming voltages and identifies minimum and maximum voltages in the signal. Once both a minimum and maximum voltage have been identified, the microcontroller calculates the difference the two values. If this value satisfies the necessary threshold (40 percent of the initialized value in the current prototype), the timer is reset and the process is repeated. In the event that the threshold is not met for a full fifteen seconds, the alarm is sounded to alert caretakers that a satisfactory breath has not occurred for fifteen seconds.

The microchip samples at a frequency of 10Hz, and must wait in between samples. During these waiting periods, the microcontroller is not needed to function at its full capacity, an idle mode is enabled to allow it to draw less current. The 10-bit analog to digital converter that the PIC18F14K22 uses allows for a sensitivity of 3 mV when it is powered at 3.7 V. Since the envelop detector fluctuates by as much as 500 mV in the tests that have been completed thus far, this is sufficiently sensitive to set off the alarm in the case of breathing cessation.

Testing

In order to evaluate the efficacy and reliability of the prototype infant respiratory monitor, several tests were performed, including electrode placement testing, alarm audibility testing, signal-tidal volume testing, and device reliability testing. After completion of these evaluations, it was determined that the prototype performs its functions consistent and ly

Electrode Placement Testing

An optimal signal from the respiratory monitor, through the body, and then back to the device is essential in the successful detection of cessation of breathing while a subject is using

the monitor. Disposable electrodes are used to transmit the signal from the device to the body, and the specific placement of these parts plays a major role in achieving the best contact to the skin. Originally, last semester's team used the electrode placement, as shown in figure 17, with one pair of electrodes placed on the right ventral side of the body, and the other pair placed on the right dorsal side of the body, with the carrier signal passing through the outside electrode. Four other electrode positions were considered in the test, and they can be seen in figures 18 – 22. In order to evaluate which electrode position yielded the best signal, an oscilloscope was used to monitor the voltage coming from the output of the envelope detector. The subject then inhaled as much as possible, and the corresponding voltage was recorded. Then, the subject exhaled as much as possible without activating the internal intercostals muscles that aid in forced exhalations, as this causes the chest cavity to expand even though air is leaving the lungs. When all air left the lungs, the voltage was recorded again, and the difference between the two was calculated. As the difference in voltages is sent to the microcontroller to determine delta values (discussed in the final design), the largest change in voltage indicates the best electrode placement. The various placements, along with their associated voltage changes can be seen in Table 3.

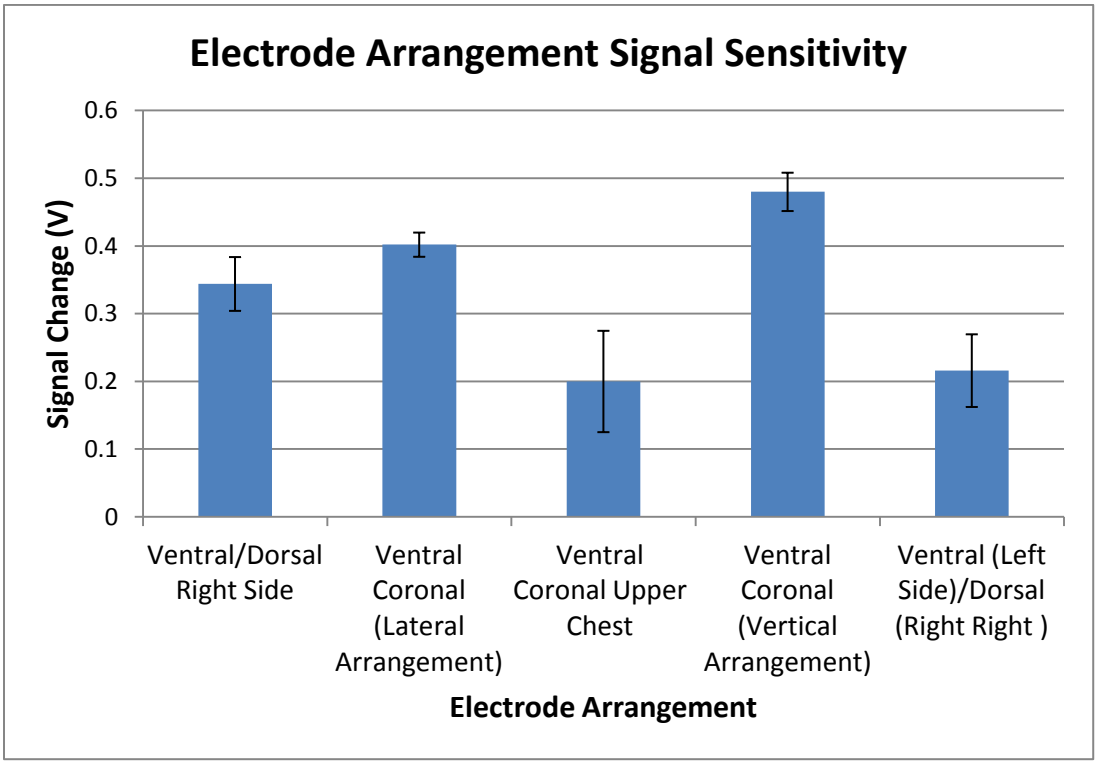

Figure 14: Electrode Placement Testing Graph

After calculating the mean voltage difference and standard deviations, it was determined that electrode placement with both pairs of electrodes on the ventral side of the body, arranged vertically with the top electrode carrying the original signal created the best signal and will be used as the optimal placement in the future.

Alarm Audibility Test

An extremely important aspect of the respiratory monitor design is its ability to alert nearby caretakers in the event of the infant ceasing to breathe. To determine if the piezo siren integrated into the device is loud enough to function in the mobile clinic setting, the device was sounded at various distances from a subject, who then indicated whether they could hear the alarm or not. As mobile clinics are relatively small in size, distances up to 200 feet were considered using increments of 50 feet. The device was clearly audible at all distances, which proves that if the alarm sounds, nearby caretakers will be able to respond.

Signal-Lung Volume Test

In order to prove the relationship between the amount of air in each respiration and the change in voltage from the output of the envelope detector is linear, a signal-lung volume test was performed. The linear relationship is very important to the successful detection of any stoppage of breathing, because it is essential for lower volumes of air to result in detectable changes in voltage going to the microcontroller. This test also confirms the application of impedance pneumography for this device. If the correlation between the two is exponential, for example, very low lung volume changes would result in even lower changes in voltage, and the piezo siren would be set off without direct cause. A spirometer was used in this test to measure the volume of a number of breaths, and the oscilloscope showed the associated changes in voltage. A wide variety of respiration volumes were used, so as to sample the entire spectrum that could be encountered during use. After performing fifteen trials at various volumes, a linear regression was created with the equation $y = 0.0897x - 0.1067$ and $R^2 = 0.9316$ indicating there is a very strong correlation between the two variables. Thus, it can be assumed that even very small lung volumes will create an equivalent change in voltage that the microcontroller can detect.

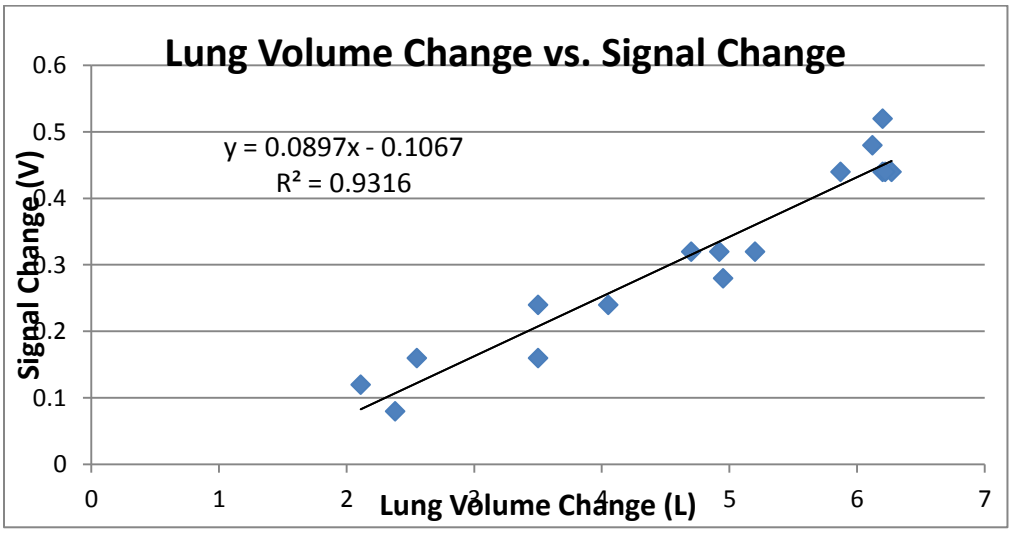

Figure 15: Signal-Lung Volume Testing Graph

Device Reliability Test

A critical aspect of the device's design is for the alarm to reliably sound when breathing has ceased in fifteen seconds. The amount of time that passes while an infant is no longer breathing is inversely related to the infant's survival rate, so the device must sound the alarm every time. In order to test the effectiveness of the alarm system in this regard, a test subject had the monitor's electrodes properly attached to their torso. The subject then engaged in normal breathing during the first thirty seconds of initialization and continued another thirty seconds to ensure the device did not sound the alarm prematurely. The subject held his breath for fifteen seconds, and started a stopwatch timer when he stopped breathing and stopped the timer when the alarm went off. Five successive trials were conducted, and then an average and standard deviation were calculated and were determined to be 14.30 ± 0.36 seconds. The discrepancy between the actual time of 14.30 seconds and the expected time of 15 seconds may be due to the microcontroller timer starting at the last significant delta, while the subject starting the timer mid-breath slightly later. In sum, the device reliably sounded an alarm every time 14.30 seconds after the subject stopped breathing; in mobile clinic settings, this would be sufficient time for a nearby caretaker to respond to an apneatic event.

Parts

The parts that are used for the construction of this prototype are listed in Figure **14** along with the expected price for bulk purchases of the components. The overall cost is reduced from the previous team's prototype, due to the cost of the PIC18F14K22, as well as the donated batteries that were obtained through donations. The total product cost comes to $30.06.

Parts List

Resistors……...…….……..$0.05

Capacitors……$0.36

Operational Amplifiers……..……..$0.38

Breadboard……..……$4.00

PIC18F14K22…….……...…….$1.71

Piezo Siren…….……$5.79

Housing…….……$4.49

Cell Phone Batteries……..…….…….Donations

LEDs…….……$0.04

Banana Plugs…….……..……$7.00

Electrodes……..……..$0.72

Power Switch……..……..…..……$0.52

Battery Charger…….…….……..$5.00

Total Cost……..…….$30.06

Figure 16: The final parts list with estimated bulk prices (Sources 21-28)

Safety and Ethics

Safety is an extremely important factor to consider for this device. Because it is intended to be used in a mobile clinic setting, the possibility of a false alarm (type I error) and undetected respiratory arrest (type II error) should be absolutely minimal. Fifteen seconds was chosen as the length of time to sound the alarm as a compromise between the client's requested length (20 seconds) and the conservative literature value (10 seconds). The device features a simple original code that can be easily altered if the user desired a longer or shorter interval for the alarm. It would not be difficult to implement an interface to make programming the sensitivity to a personally preferred value. This was not considered for the final design because it is not essential for the functionality of the device and would add an unnecessary expense.

Not only is there an electrical current being passed into the child, but there are wires in the current design that pose a strangulation hazard. Therefore, before this device is used without

supervision, extensive testing must be done to ensure that the signal passed through the infant does not harm the infant for a projected eight hours of use overnight. We do not foresee any problems, because the device was originally designed with the safety protocol for electrical medical equipment issued by the International Electrotechnical Commission. The IEC's threshold current limit for the general public is 0.5 mA but do allow larger currents at higher frequencies. Additionally, the wires from the leads on the current design will be replaced with an electrode belt that will eliminate the current hazard. It was suggested to further reduce this risk by putting the electrodes in an all-encompassing suit, or a "onesie", and should be considered by future teams. The user (adult or caretaker) should also not be at risk during the normal operation of the device. To make sure of this, a manual was created and is intended to be distributed with the device to outline basic user protocol and any potential risks.

Extensive ethical considerations were taken into account with the design of this respiratory monitor. All engineers have moral responsibilities to society, their clients, and to the profession and this design project is no exception. Most importantly, the quality and reliability of the device should not be sacrificed at the expense of the cost-minimizing features included in the design. Failing to provide a reliable product would risk the lives of infants who use the device. Although this device is not intended for use in the United States, the more stringent US safety regulations and standards for medical devices were followed in the design of this monitor.

Future Work

There are a number of improvements that can still be made to the prototype to make it more effective and user-friendly before it can enter the market. Currently, the batteries are charged by a separate universal battery charger. A battery charging circuit should be integrated into the device itself, in order to both reduce the number of separate pieces required for device operation, as well as make it simpler to use. This charger could run off of a micro-USB plug in port, or a system such as a solar panel charger to increase the functionality in the case of unreliable power sources or generator failure. The current prototype uses disposable electrodes, which present a recurring cost as they must be replaced after each use. In order to eliminate this unnecessary cost, an electrode belt that can be sterilized and reused should be designed for use with the monitor. An alternative to a belt design that might be more comfortable for the infant

and easier to use would be a pajama-type suit that has the electrodes built into it. Testing of the device was all done using adult subjects, so testing must be conducted using infants to ensure that the device works with them, as well as to identify any problems that may arise as a result of using the device with infants that were not present for adults. The team would also like to see the breadboard circuit replaced with a printed board. This would help to both reduce the size of the device as well as reduce the potential for connection failures, which would lead to a malfunction of the device.

Although the device successfully monitors respiration of the subject and sounds the alarm when breathing ceases, the sensitivity of the device could be improved further. It was noted during testing that several times the device did not respond properly to shallow breathing, possibly due to the presence of cardiogenic artifacts in the signal. Testing was done using a digital Hanning filter as well as analog low pass filters, but neither sufficiently attenuated the heart artifact. Implementation of a more effective higher order analog filter or a digital low pass filter would improve the prototype's performance. In addition, with the adults used, the gain of the device sometimes had to be adjusted for different subjects, so improving the device sensitivity so that a lower set gain could be used with any subject would be desirable.

One requirement of the device that was not extensively tested was the robustness of the device. Fatigue testing should be done to test the durability of the device to ensure that it will be able to endure shipping and use in harsh environments. In addition, improved battery housing should be implemented in order to constrict battery motion and ensure a secure connection to the circuit.

As mentioned before, one of the benefits of using cell phone batteries to power the prototype is that they can be collected via recycling or donation for free. In order to support extensive production of these devices, a large scale collection of old cell phone batteries should be established to acquire a sufficient battery supply for use.

References

1. Sudden Infant Death Syndrome. Retrieved 3/8/12 at http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0002533/

2. Sudden Infant Death Syndrome. Retrieved 3/8/12 at http://www.nichd.nih.gov/health/topics/sudden_infant_death_syndrome.cfm

3. Mortality Statistics > Sudden Infant Death Syndrome (most recent) by Country. Retrieved 3/8/12 at http://www.nationmaster.com/graph/mor_sud_inf_dea_syn-mortality-sudden-infant-death-syndrome

4. How Reliable are SIDS Rates?. Retrieved 3/8/12 at http://adc.bmj.com/content/90/10/1082.full

5. International Trends in Sudden Infant Death Syndrome and Other Sudden Unexpected Deaths in Infancy: Need for Better Diagnostic Standardization. Retrieved 3/8/12 at http://www.ispid.org/fileadmin/user_upload/textfiles/articles/CPR17_Hauck_SIDS_Trends.pdf

6. Lawn et al. 4 Million Neonatal Deaths: when? Where? Why?. The Lancet: Volume 365, Issue 9462, 5–11 March 2005, Pages 891–900

7. Engineering World Health. Retrieved 3/10/12 from www.ewh.org

8. Grenvik et al. Impedance Pneumography: Comparison between chest impedance changes and respiratory volumes in II healthy Volunteers. Chest 1972: 62:439-443.

9. Home Monitoring for SUDC Siblings. Retrieved 3/10/12 at http://www.sudc.org/Portals/0/medical/HomeMonitoringForSUDCSiblings.pdf

10. Norman et al. Detection of Respiratory Events during NPSG: Nasal Cannula/Pressure Sensor versus Thermistor. Sleep 20 (12): 1175-1184

11. Babysense. Retrieved 3/10/12 from http://www.hisense.co.il/catalog.php?id=16

12. AC 201 – Movement and Sound Monitor. Retrieved 3/10/12 from http://www.angelcare-monitor.com/International/en/products/angelcare-monitor-AC201

13. Respisense. Retrieved 3/10/12 from http://www.respisense.com/en/index.php

14. Durante, Caleb et. Al. 2011. EWH: Infant Apnea Monitor. University of Wisconsin-Madison Department of Biomedical Engineering.

15. Cypress Electronics. Products Catalog [Online]. http://www.cypress.com/?rID=38235 [Mar. 12, 2012]

16. Microchip. Products Catalog [Online]. http://www.microchipdirect.com/ProductSearch.aspx?Keywords=DM180021 [Mar. 12, 2012]

17. Atmel Corporation. Products Catalog [Online]. http://www.atmel.com/devices/atxmega32a4u.aspx?tab=tools [Mar. 12, 2012]

18. Battery Bundle. Retrieved 3/10/12 from http://w.batterybundle.com/sizes/9v-batteries/energizer-en22-72/.

19. All-Battery.com. Retrieved 3/10/2012 from http://www.all-battery.com/4piecesso9v250mahnimhhighcapacityrechargaablebatter.aspx.

20. Over-stock.com. Retrieved 3/10/2012 from http://www.overstock/com/Electronics/Kyncera-TXBAT10099-Standard-Battery-Bulk-Packaging/457738/product.heml?recmndsrc=2.

21. Online. Retrieved May, 1, 2012, from http://search.digikey.com/us/en/products/ERD-S2TJ301V/P300BATB-ND/503284.

22. Online. Retrieved May, 1, 2012, from http://search.digikey.com/us/en/products/ECA-1HM3R3B/P10391TB-ND/268476

23. Online. Retrieved May, 1, 2012, from http://www.mouser.com/ProductDetail/Texas-Instruments/LM2904D/?qs=3pnr37ZAbK%2fuflQSGuUuDMzEn5jQ88Ll

24. Online. Retrieved May, 1, 2012, from http://www.newark.com/jsp/search/productdetail.jsp?SKU=25R0654&CMP=AFC-GB100000001

25. Online. Retrieved May, 1, 2012, from http://www.mouser.com/ProductDetail/Kingbright/WP3A8GD/?qs=DkZGzo4b%252bTIVVzNJYUy5tero32SfE7ZsPV54u%2ffhz3E%3d

26. Online. Retrieved May, 1, 2012, from http://www.aliexpress.com/product-fm/545926785-Disposable-Electrodes-For-ECG-EKG-machine-patient-monitor-50pcs-bag-wholesalers.html

27. Online. Retrieved May, 1, 2012, from http://www.mouser.com/ProductDetail/CW-Industries/NAA-211-BI31-00/?qs=4EnmSMTL3HNVzbvPbUjKdVFFWCyDXuVa

28. Online. Retrieved May 1, 2012 from http://www.cellphoneshop.net/univbatcharger.html?CAWELAID=550030630&gclid=CPXpqeDC5a8CFU3UKgodoXe11g

Appendix

Testing Data

Table 3: Electrode Placement Testing Data

Electrode Placement	Bottom	Top	Delta
Original Placement: Ventral/Dorsal Right Side 1	1.69	2.06	0.37
2	1.65	2.02	0.37
3	1.65	2.02	0.37
4	1.69	2.02	0.33
5	1.74	2.02	0.28
Ventral Coronal (Lateral Arrangement) 1	1.33	1.74	0.41
2	1.33	1.74	0.41
3	1.33	1.74	0.41
4	1.37	1.78	0.41
5	1.41	1.78	0.37
Ventral Coronal Upper Chest 1	2.22	2.5	0.28
2	2.34	2.54	0.2
3	2.42	2.66	0.24
4	2.5	2.7	0.2
5	2.66	2.74	0.08
Ventral Coronal (Vertical Arrangement) 1	1.98	2.46	0.48
2	2.02	2.5	0.48
3	2.06	2.58	0.52
4	2.22	2.7	0.48
5	2.06	2.5	0.44
Ventral (Left Side)/Dorsal (Right Right) 1	2.26	2.5	0.24
2	2.42	2.58	0.16
3	2.18	2.42	0.24
4	2.34	2.5	0.16
5	2.22	2.5	0.28

Electrode Placement Pictures

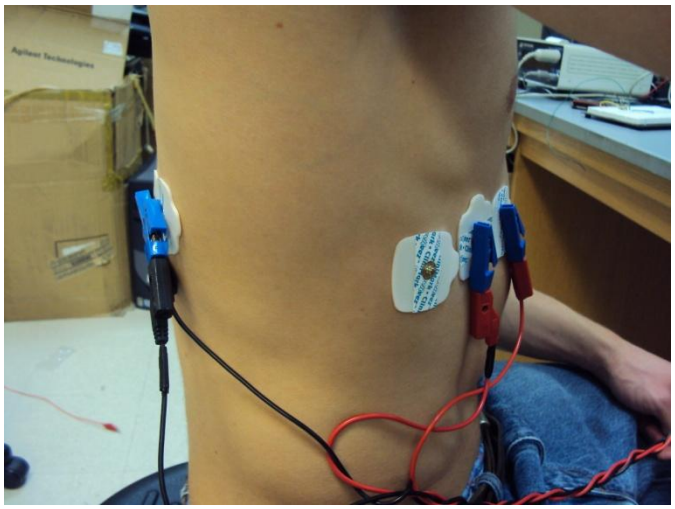

Figure 17: Ventral/Dorsal Right Side

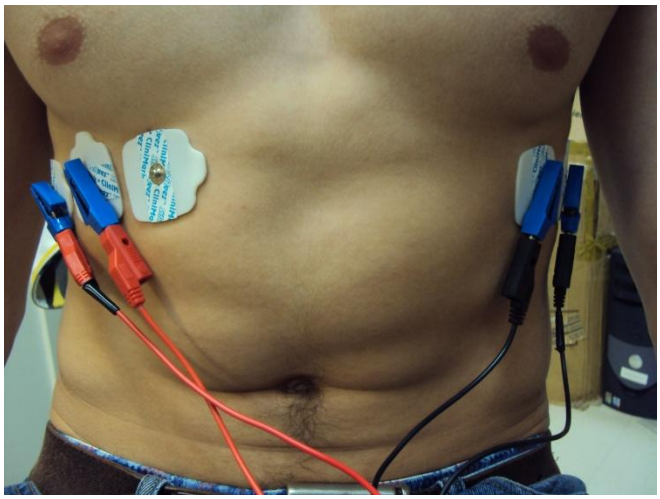

Figure 18: Ventral Coronal Lateral Placement

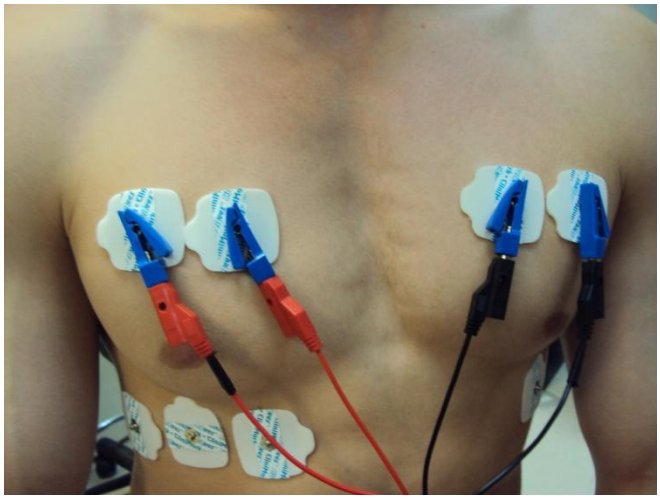

Figure 19: Ventral Coronal Upper Chest Arrangement

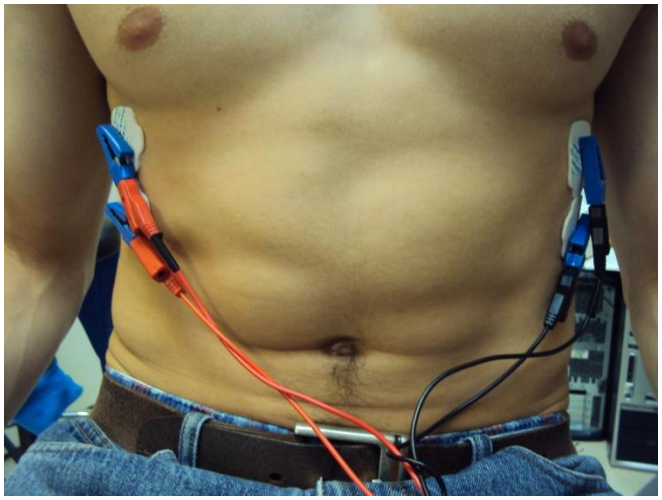

Figure 20: Ventral Coronal Vertical Arrangement

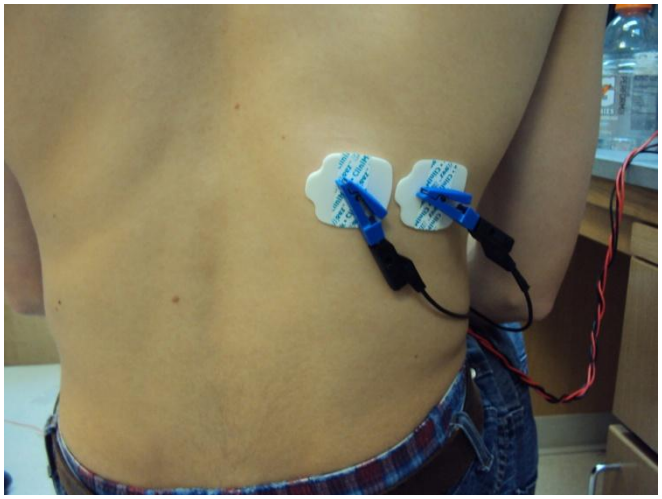

Figure 21: Ventral left/Dorsal Right Placement – Back View

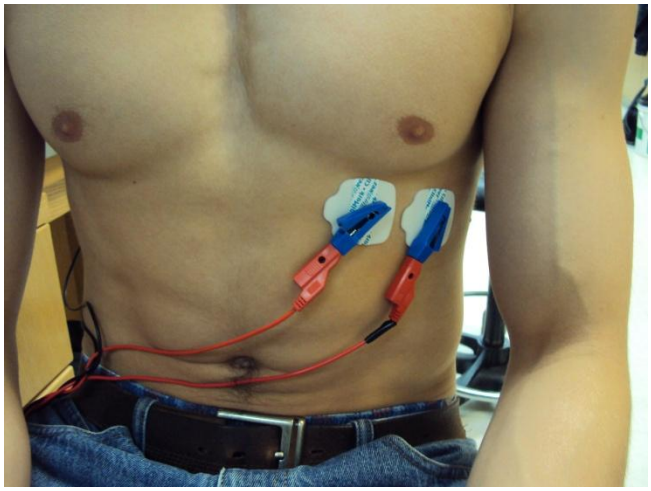

Figure 22: Ventral left/Dorsal Right Placement – Front View

Table 4: The raw data collected for our lung volume- voltage change testing.

Subject	Top Voltage (V)	Bottom Voltage (V)	Change in Voltage (V)	Volume (L)
Chris	2.25	1.81	0.44	5.87
	2.33	1.81	0.52	6.2
	2.25	1.81	0.44	6.27
	2.17	1.93	0.24	3.5
	2.01	1.93	0.08	2.38
	2.53	2.09	0.44	6.2
	2.57	2.13	0.44	6.22
	2.33	2.17	0.16	2.55
	2.25	2.13	0.12	2.11
	2.33	2.09	0.24	4.05
	2.25	2.09	0.16	3.5
	2.53	2.05	0.48	6.12
	2.37	2.05	0.32	4.92
	2.37	2.09	0.28	4.95
	2.41	2.09	0.32	4.7
	2.41	2.09	0.32	5.2

PDS

Function:

The purpose of this device will be to prevent Sudden Infant Death Syndrome (SIDS) in third world countries by providing a reliable detection mechanism that alerts nearby caretakers. The monitor should sound its alarm after breathing ceases for more than 20 seconds. This will allow the caretaker to properly resuscitate the infant.

Client Requirements:

1) Device must cost under $50.
2) Device must be *highly* reliable and consistently alert caretakers when breathing has stopped for more than 20 seconds.
3) Device must be simple and easy to operate with minimal training.
4) Device should be suitable for use in third-world countries.

1. Physical and Operational Characteristics

a. Performance Requirements: The device must be capable of monitoring an infant's breathing pattern and alerting nearby caretakers if there is a 20 second or more cessation in respiration.

b. Safety: The device cannot interfere with healthy electrical signals in the infant. Or present a shock risk to an operator. Any external wiring must not present a strangulation risk. There should be no small, easily breakable parts that can prevent a choking hazard. The device must meet all regulatory demands outlined by government or other agencies.

c. Accuracy and Reliability: The device must have reliable accuracy, and cannot allow for a false negative in the detection apparatus.

d. Life in Service: The device must be able to withstand reasonable wear due to use. It must be designed to minimize the risk of broken parts.

e. Shelf Life: The device will require batteries that should be easily replaced.

f. Operating Environment: The device should be designed to function in a mobile hospital setting.

g. Ergonomics: The device should not interfere with comfortable sleep.

h. Size: The device should have a maximum size of 10x10x10 cm.

i. Power Source: The device will be battery powered and should maximize power efficiency.

j. Weight: The device must be lightweight, not exceeding 3.0 kg.

k. Materials: The device will include basic circuitry including microprocessors, amplifiers, and wiring.

l. Aesthetics, Appearance, and Finish: The device should fit in a hospital setting

Product Characteristics:

a. *Quantity*: One
b. *Target Product Cost*: $40- 50.

Miscellaneous

a. *Standard and Specification*: Device must meet medical device and legal standards. Must comply with HIPPA and patient disclosure standards and must receive FDA approval.
b. *Customer*: Engineering World Health
c. *Patient-Related Concerns*: Device components in contact with the infant must receive sterilization between uses. Must not pose risk of shock or infant entanglement.
d. *Competitio*n: Devices on the market include the products made by Babysense, Respisense, AngleCare, and Snuza.

PIC 18F14K22 Microcontroller Operating Code

```
/* EWH Respiratory Monitor Operating Code
 Ben Smith, Don Weier, Matthew Bollom
 3/24/12
 BME 301 Design class*/
#include <p18f14k22.h>
#include <usart.h>

#define TRISA_MASK 0x09
#define TRISB_MASK 0xA0
#define TRISC_MASK 0x00

#define ALARM LATCbits.LATC0
#define LED LATCbits.LATC1
#define LED2 LATCbits.LATC2

 /*set timer start value*/
#define timer0_highbyte 0x3C
#define timer0_lowbyte 0xB0
#define timer0_overflow INTCONbits.TMR0IF

void transmitASCII(int result);
int hanning (int result1, int result2, int result3);
int initialize(void);
void alarm(void);
void high_isr(void);
void boss(void);

int wait = 0;
int result3; //these integers will store raw data to be filtered
int result2;
int result1;




int max; //these will store the current min and max values
int min;

int delta; //these will store the current delta

int deltaave; //this will store the initialized average gathered from 5 waves

int count = 0; //this will keep track of the time to determine if breathing has ceased for to long
```

```
int first = 1;



#pragma code high_vector = 0x08
void high_ISR(void) {
   _asm
   goto high_isr
   _endasm
}
#pragma code

#pragma interrupt high_isr
void high_isr(void) {
   if(timer0_overflow) { /* check to make sure it was the timer that interrupted */
      TMR0H = timer0_highbyte; /* reset timer */
      TMR0L = timer0_lowbyte;
      timer0_overflow = 0; /* clear the overflow flag */
      boss();

   }
}

void main() {
   OSCCON = 0x76;
   OSCCON2 = 0x00;
   OSCTUNE = 0x00;

   INTCON = 0x20;
   INTCON2 = 0x84;
   INTCON3 = 0x00;

   PIR1 = 0x00;
   PIR2 = 0x00;

   PIE1 = 0x00;
   PIE2 = 0x00;

   IPR1 = 0x00;
   IPR2 = 0x00;

   RCONbits.IPEN = 1;

   TRISA = TRISA_MASK;
   TRISB = TRISB_MASK;
   TRISC = TRISC_MASK;
```

```
    ADCON0 = 0x00;
    ADCON1 = 0x00;
    ADCON2 = 0xA5;
    ADCON0bits.ADON = 1;

    OpenUSART( USART_TX_INT_OFF &
            USART_RX_INT_OFF &
            USART_ASYNCH_MODE &
            USART_EIGHT_BIT &
            USART_CONT_RX &
            USART_BRGH_HIGH,
            34
            );

        baudUSART(BAUD_IDLE_CLK_LOW &
            BAUD_16_BIT_RATE &
            BAUD_WAKEUP_OFF &
            BAUD_AUTO_OFF       );

/* Timer code*/

       T0CON = 0x02;
       timer0_overflow = 0;
       TMR0H = timer0_highbyte;
       TMR0L = timer0_lowbyte;
       T0CONbits.TMR0ON = 1;     /* turns timer on*/

       ALARM = 0;
       LED = 0;
       LED2 = 0;

   deltaave = initialize();



   INTCON = 0xA0;

    while(1){
       OSCCONbits.IDLEN = 1;
       OSCCONbits.SCS1 = 0b1;
       OSCCONbits.SCS0 = 0b0;
       Sleep();
    }
}
```

```
void boss(){
      /*start conversion*/
      ADCON0bits.GO = 1;

      while(ADCON0bits.GO == 1){/*wait for conversion to complete*/}

      ADCON0bits.GO = 0;

      result3 = result2;
      result2 = result1;
      result1 = (((unsigned int)ADRESH) << 8|ADRESL);


   if(first){
      max = result1;
      min = result1;
      first = 0;
   }

   if(filtered > max){      //these will store the min and maxes
      max = result1;
      }
   if(filtered < min){
      min = result1;
   }

   delta = max - min; //recalculate delta

   if(delta >= (deltaave * .4)){
      max = result1;
      min = result1;
      count = 0;
   }

   else{
      count++;
   }



   if(count >= 150){ //at count = 150, there has not been an acceptable delta in 15 seconds
      INTCONbits.GIE = 0;
      alarm();
      INTCONbits.GIE = 1;
   }
}
```

```
int initialize(void){

    int first = 1;

    int stored = 0; //this will tell the program if the value is already stored

    int max1; // these will store our max and min values over the fifteen second period
    int max2;
    int max3;
    int max4;
    int max5;

    int min1;
    int min2;
    int min3;
    int min4;
    int min5;

    int avedelta; //this is the value the function should return

    int time = 0; //this will count to 15 seconds

    LED = 1;



        result3 = result2;
        result2 = result1;
        result1 = (((unsigned int)ADRESH) << 8|ADRESL);



        if(first){
            first = 0;
            max1 = result1;
            max2 = result1;
            max3 = result1;
            max4 = result1;
            max5 = result1;

            min1 = result1;
            min2 = result1;
```

```
    min3 = result1;
    min4 = result1;
    min5 = result1;
}
if(result1 >= max1 && !stored){
    max1 = result1;
    stored = 1;
}
else if(result1 >= max2 && !stored){
    max2 = result1;
    stored = 1;
}
else if(result1 >= max3 && !stored){
    max3 = result1;
    stored = 1;
}
else if(result1 >= max4 && !stored){
    max4 = result1;
    stored = 1;
}
else if(result1 >= max5 && !stored){
    max5 = result1;
    stored = 1;
}
else if(result1 <= min1 && !stored){
    min1 = result1;
    stored = 1;
}
else if(result1 <= min2 && !stored){
    min2 = result1;
    stored = 1;
}
else if(result1 <= min3 && !stored){
    min3 = result1;
    stored = 1;
}
else if(result1 <= min4 && !stored){
    min4 = result1;
    stored = 1;
}
else if(result1 <= min5 && !stored){
    min5 = result1;
    stored = 1;
}
stored = 0;
```

```
        if(time >= 297){
            avedelta = (max1+max2+max3+max4+max5-min1-min2-min3-min4-min5)/5;
            LED = 0;

            return avedelta;
        }

    }
}

void alarm(){
    int time = 0;

    int odd = 0;

    while(1){
    while(!timer0_overflow) {/*wait for timer overflow*/}

        TMR0H = timer0_highbyte;
        TMR0L = timer0_lowbyte;
        timer0_overflow = 0;
        time++;
        ALARM = 1;
        if(time == 10){ // this will pulse the alarm in one second intervals
            time = 0;
            if(odd){
                LED = 1;
                odd = 0;
            }
            else{
                time = 0;
                LED = 0;
                odd = 1;
            }
        }
    }
}
```

User's Manual

Electrode Placement

Note: Make sure to keep the device turned OFF until the electrodes are properly placed on the body and connected via wires to the monitor box.

1. Plug the red banana plug with the black electrical tape into the carrier wave indicated insert on the monitor box.

2. Plug the other red banana plug without tape into the other red insert.

3. Plug the black banana plug with the tape into the black carrier insert.

4. Plug the other black banana plug without the tape into the other black insert.

5. Wind the cords together.

6. Remove proper electrodes from the packaging.

7. After applying a small amount (penny-size) of conductive gel to the electrode, place it right under the right chest muscle just in front of the arm on the side of the torso.

8. Do the same on the left side of the body.

9. Place another electrode just under each of the other two electrodes.

10. Hook the opposite end of the taped red cord to the upper, right side electrode.

11. Connect the opposite end of the taped black cord to the upper, left side electrode.

12. Connect each of the same colored cords to the electrodes right under the already connected electrodes.

Initialization

After the electrodes are placed, the device can be turned on. (If the electrodes were placed after the device was turned on, toggle the power off and then back on). The device goes through a 30 second period after being turned on where it determines a baseline for future breathing to be compared too. In the initialization period, at least 5 full breaths must be made to ensure proper function of the device. After 30 seconds, the device can operate until turned off.

When the alarm sounds, it means that the patient has not taken an acceptable breath in the last 15 seconds, and needs medical attention.

Upkeep

To ensure that the device will perform as expected, it should be tested weekly. The testing procedure is outlined in this section.

Step 1: Turn the device on, without any electrode attachment. The device should initialize in the normal fashion, and sound the alarm after 45 seconds (30 for initialization, and 15 for the failure to be detected)

Step 2: With the device attached to a patient, toggle the switch into the on position, and wait for the device to be initialized. As long as the wearer is breathing normally, the device should not emit any alarms.

Troubleshooting

Problem	Possible Causes	Solution
The power light is not on when the switch is toggled to the on position.	The battery may be dead, or the LED malfunctioning.	If the LED is the problem, the secondary LED should still signal the end of the initialization phase. If the secondary LED still lights up, the device should function normally. If neither lights will illuminate, the battery may be dead, and should be recharged. If neither of these fixes the problem, a more serious issue has occurred, and the device will not be reliable for respiratory monitoring.
The secondary LED is not signaling the completion of the initialization phase, and/or the device does not emit a noise at the completion of initialization.	The LED or speaker may be expired. If only one is absent, this is likely the case. If both fail to signal, then something more serious may be wrong with the device.	If the speaker does not emit a noise, then the device will not be able to audibly signal a cessation of breathing, and the device should not be used. If only the LED is non-functional, the device should still emit an audible alarm and can be used. If both the LED and speaker fail simultaneously, the device should not be used, because the internal computer is not operating.