Engineering World Health: Infant Respiratory Monitor

Midsemester Report

Christopher Besaw (Team Leader)

Stephen Young (BWIG)

Benjamin Smith (BSAC)

Donald Weier (Communicator)

14 March, 2012

Table of Contents

Abstract 3

Background Information 4

Client Description 5

Current Devices 5

Design Requirements 8

Current Prototype 9

Design Alternatives: Microcontrollers 10

Design Matrix: Microcontrollers 11

Design Alternatives: Batteries 13

Design Matrix: Batteries 14

Future Work 16

References 17

Appendix 19

PDS 19

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 yearly, 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. In order to be for this device to be used in the real world, power consumption and cost need to be reduced, so it is affordable to implement in developing countries. The PIC18F14K22 has been selected to replace the current microcontroller to reduce current draw and a rechargeable phone battery will be integrated into the design along with a charging circuit to decrease power consumption and allow for easy recharging of the device. Throughout the remainder of the semester, the microcontroller will be programmed to monitor the infant's breathing, the charging circuit will be incorporated into the monitor, and a reusable electrode belt will be made to decrease recurrent costs even more.

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].

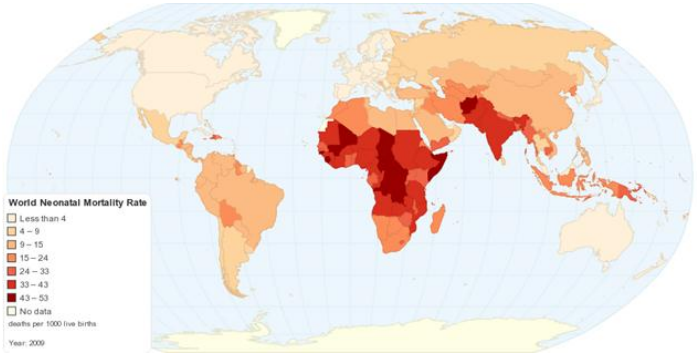

Figure 1: Neonatal deaths worldwide [5]

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. 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 [7].

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 [8]. 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 [9]. 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 [10]. 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 [11].

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 [12].

Figure 2: 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 [13].

Figure 3: The Angel care Respiratory Monitor. [13]

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 [14].

Figure 4: 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. In addition, they are all too expensive for widespread use in third world countries [13].

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.

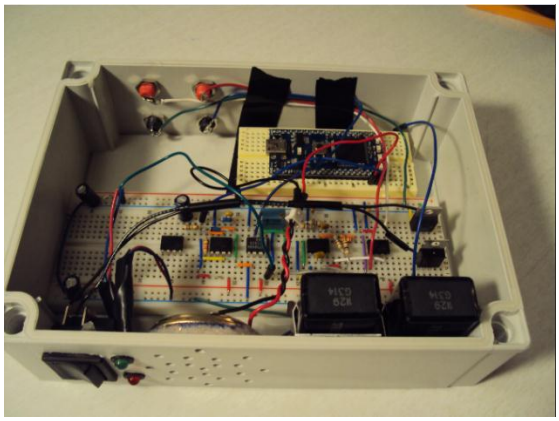

Figure 5: The current prototype with the top cover removed, exposing the circuitry. [14]

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 [1].

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 6. 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]

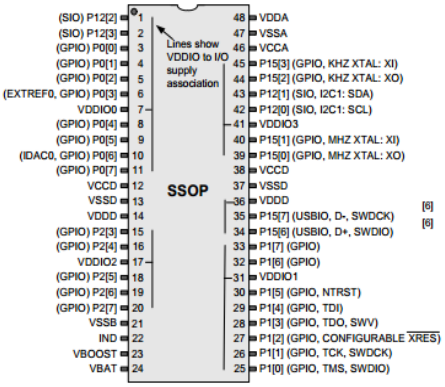

Figure 6: The Cypress microcontroller pinout diagram. [15]

Microchip PIC18F14K22-I/P

The second microcontroller considered is a product of Microchip Technology, which can be seen in Figure 7. 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]

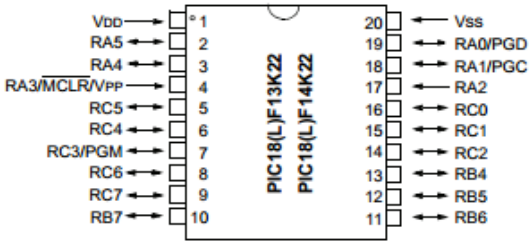

Figure 7: The pin out diagram of the microchip product. [16]

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 [17].

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 [18]. 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 8: 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 [19]. 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.

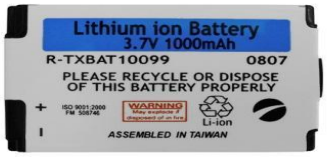

Figure 9: A 3.7 V Kyocera Phone battery [20].

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 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.

Future Work

The Microchip PIC18F14K22-I/P microcontroller has already been ordered and received by the team, so one of the first actions the team will take will be to begin programming the microcontroller. This will begin with members of the team becoming more familiar with C++, the language which will be used to program the microcontroller. The team will also conduct a close inspection of the algorithms used by the last team in order to make any improvements or changes to produce a more effective device. A particular point of interest will be finding a way to remove cardiac artifacts from the signal. Once an algorithm has been determined and the team is familiar enough with the process of programming microcontrollers, the microcontroller will be programmed for use in the device.

Work will also be needed to be done to add to and improve the circuit used in the device. An important addition that must be made in order to accommodate a rechargeable phone battery is to build a charging circuit. A schematic for such a circuit has been obtained by the team, although it requires several alterations for adaptation for implementation in this project. In addition to this charging circuit, the circuit used for signal processing in the prototype will have to be modified to accommodate the change from using +/- 9 V to using a 3.7 V/earth ground system. Along those same lines, the microcontroller will have to be powered by the battery, as opposed to powering it via computer as was done in the prototype.

The final change to be made to the old prototype is the development of a reusable electrode belt to replace the disposable electrodes used in the current model in order to reduce recurring costs of the device. Once the new prototype is complete, testing must be done to ensure the effectiveness, reliability, and safety of the device. The testing will expose any remaining unaddressed or unforeseen flaws in the device design, and appropriate changes can then be made to fix them.

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.

Appendix

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.