Adaptive Wireless Wearable Neuro-Stimulator

PROJECT PLAN

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Contents

1 Introduction						
1.1 Project statement						
1.2 purpose						
1.3 Goals						
1.4 Intended Users and uses						
1.5 Assumptions and Limitations						
2 Deliverables						
3 Design						
3.1 Previous work/literature						
3.2 Proposed System Block diagram4						
3.3 Assessment of Proposed methods6						
3.4 Validation7						
4 Project Requirements/Specifications						
4.1 functional8						
4.2 Non-functional9						
4.3 Standards9						
5 Challenges9						
6 Timeline						
6.1 First Semester						
6.2 Second Semester						
7 Conclusions						
8 References						
9 Appendices						

1 Introduction

1.1 PROJECT STATEMENT

According to the Center for Disease Control, in 2015, there were 1,600 deaths due to SIDS alone. This accounted for almost half (43%) of infant deaths, leaving many parents not knowing why their children died (<u>https://www.cdc.gov/sids/data.htm</u>). There is currently no known reason as to why SIDS occurs, and many avenues are being explored to explain these sudden deaths. Our client, Adan Cervantes, has been studying the correlation between the low energy waves emitted from lightning and the rate of SIDS. He has found, that there is an inverse correlation between the amount of low frequency wave emissions from lightning and the rate of SIDS.

1.2 PURPOSE

Our device is aimed at helping researchers have a way to study the correlation between the low energy waves emitted from lightning during each season and its effects on the occurrence of SIDS in various geographical locations. The device and applications will provide various biometric and geographic data on the infant wearing the device. In the future, we hope to adapt the software and device to fit the needs of parents to give them a way to actively prevent an occurrence of SIDS.

1.3 GOALS

Our end goal is to either find data correlation backing the suspicion that SIDS is caused by energy (lighting resonance) using information provided by radio stations. Additionally, regardless of that research we will also be developing a wearable anklet to track infant health and infant motion. Similarly, there will be a vibration motor for stimulation.

1.4 INTENDED USERS AND USES

The intended user are parents concerned about monitoring and keeping track of their infant's health. The anklet will allow parents to be notified if the infant does not respond to the pulse from the anklet, as well as see other metrics in the application.

The other use is for researchers who may use data from the device in order to find correlations with SIDS rates.

1.5 ASSUMPTIONS AND LIMITATIONS

Assumptions:

- This device is intended to be used globally.
- Device will be used in research purposes. Data from device is to be sent to database which researchers may view in visualizations such as graphs. This also assumes enough parents would agree to have this (anonymous) data sent.

Limitations:

- Device must be small enough to fit on an infant's ankle. The device is designed to be a wearable on the ankle; the circuit design should lend itself to being able to made into a small enough board.
- Circuit needs to be done before the embedded code is developed. Embedded code relies on gathering data from sensors which depends on how sensors may be connected to the microprocessor.
- Due to schedule constraints and limited knowledge on PCB design, a custom PCB on a small scale was decided not feasible in the time frame. A prototype circuit is to be developed with an evaluation board as proof of concept.

2 Deliverables

End Product – Prototype of anklet: A prototype of the anklet able to connect to Android Application. Anklet should be configurable by application and send data back. Application should be able to visualize the data. Anklet needs to be able send pulse (vibrations) based on readings from sensors and the pulse periods based configuration (input from setup in application). Expected delivery is March-April 2018.

Analysis of Data: Client gave us data to investigate if the electrical energy in the atmosphere has any correlation the number of cases of SID. This will include graphs of data to provide visualization. December 2017.

Software source code: The source code for the application, as well as the embedded code for the anklet. Expected delivery for all complete code: March-April 2018

Flow chart: An overall design of the software. Showing both software and hardware interactions. December 2017.

System diagram: diagram of the anklet connection, circuit diagram, etc. December 2017.

3 Design

3.1 PREVIOUS WORK/LITERATURE

Infant monitoring is not a new concept, there have been many different forms of infant monitoring throughout the years. Most people are familiar with the baby monitor, there are many different companies making these, one example would be the audio and video monitors produced by VTech [1]. These types of monitors are very passive and hands off, they won't alert you, they only send whatever is being recorded and the rest is up to the parent. These types of devices however do not offer the level of data required to diagnose sleep apnea, a cause of SIDS (Ziganshin, Numerov & Vygolov, 2010).

In order to detect sleep apnea, which is pauses in breathing during sleep, a better monitoring system would be required. Some of the proposed ideas by Ziganshin, Numerov & Vygolov are a sensor pad to detect movement, a motion sensor to attach to the body, or a type of radar system to monitor the infant (2010). A version of this is the NanoPulse Baby SleepGuard, which monitors respiration, heart-beat, and general movement while the infant sleeps, and parents are alerted if any of these are abnormal. Another such device is the Sproutling Wearable Bay Monitor [2], which has a similar design to what our proposed idea is. This device monitors the infants heart rate and movement to let the parent know if the child is asleep, waking up soon, or sleeping on their stomach.

One of the major problems with these devices is the parents have to be alerted and then are the ones to correct the action. Ideally, the device would automatically fix the problem, or attempt to fix it before parent intervention was required. This is the new area that our device is moving into, there currently are not products on the market that will take action other than alerting when the infant enters a dangerous state. Our device is able to take this action and attempt to correct the problem before alerting the parents to the danger.

3.2 PROPOSED SYSTEM BLOCK DIAGRAM

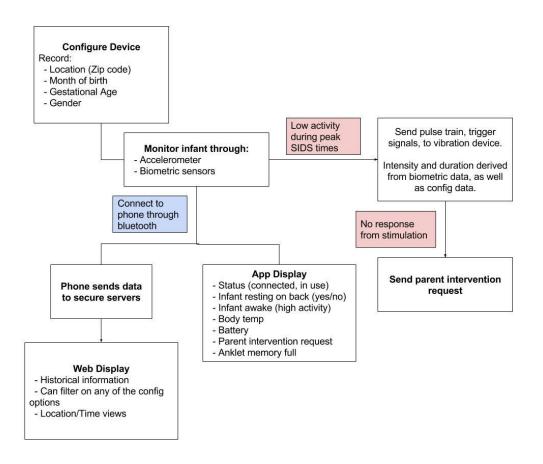
Our system will consist of three separate sections. The device itself, which will do the monitoring and pulse actions. The android app, which will be accessible for the parents, that will display active information, with options to view historic data for their child. And finally, the web app, which will primarily be used by researchers to view historic data for all devices, filtered by any criteria necessary.

Each different part has its own design, as each is used for a different action. To start with the monitoring anklet itself, there are a number of different solutions to consider. The design of this part in broad terms is to allow input parameters to be set that define the subject, and then monitor biometric data and take action if needed. The input data is mostly set through the research given to us, we need the gender, birth month, gestational age, and location of the infant, as these all account for the variable action we need to take.

The other two parts of this design, the action and biometric data are more up for interpretation. First, the action that the device takes has to be aggressive enough to get a response from the infant, yet gentle enough to not wake it. Some design options here were a vibration applied to sensitive area such as a nerve, a small electric shock that has the benefit of being applied anywhere, or a shake of the environment, such as a crib, that the infant is sleeping in. A small electric shock was ruled out as we did not feel that parents would enjoy a device that seems to cause harm to their child, and also the fact that this option would require more power, which we are trying to keep the unit low powered to prevent more charge times. The environment shake was ruled out as this would require much more infrastructure than just a wearable device, as we would have to create an entire crib or such that can move the infant safely. So, we decided on a vibration to a nerve in the ankle, a small enough one to garner a response, but not aggressive enough to wake the child.

Biometric data recorded from the child must serve two purposes, it must be accurate enough to give us enough data to make decisions off of, and it must be able to be recorded from an extremity such as the ankle, as that is where we must send the vibration. This information could include, temperature, heart rate, movement, blood pressure, or even perspiration levels. The decision to go with heart rate and movement for recording was based of the research that we received, as well as past literature, where devices today were recording this same information [2]. And the temperature sensor is used to detect if the device is being worn currently so we can switch between low and high-power mode.

The other two visual parts of the product were mostly determined by who was looking at them, for the app we wanted to create a parent-friendly interface. Something that could easily get the relevant information across and not go into detail unless requested. So, we decided for a simple alerting page, where the parent could see at a glance what was going on with their child, as seen in the App Display section below. The web display on the other hand is meant for researchers, so this will be more data-intensive and customizable, allowing researchers to obtain the necessary data they need.



3.3 ASSESSMENT OF PROPOSED METHODS

Our solution is a divided one, it is very good at giving the parents the basic information they need, and letting researchers obtain all of the information. The device itself is also monitoring some of the most important factors in determining the sleep health of an infant. Because we need to keep the device running on low power, we do have to make sure the phone is in range at all times in order to alert and upload the data, otherwise the device will just be acting on its own with no backup of parental alerts. This is also a benefit though, in that the device can function and be useful even if the parents are not around.

A possible weakness of this device however is the fact that if the device cannot correct the problem, then essentially the danger alert to the parent is delayed, by however long the device was trying to fix it itself. This is balanced out, we believe, by the amount of times the device fixes the problem and does not have to send an alert. But, being cognizant of this weakness, the device tries a small number of times, with short intervals between attempts, in order to decrease the time before parents are alerted of the problem if they need to be.

Obviously, the biggest strength of this device is the fact that it can take corrective action when it sees the infant has entered into a dangerous state, even when alerting the parents is not possible. This brings a higher sense of safety to parents, knowing that their child is being monitored autonomously, which relieves some burden from the already burdened parents.

3.4 VALIDATION

For the device itself these tests include, code tests to verify that with the expected inputs, such as no movement for 30 minutes, and based on all the different combinations of input parameters, the device sends the appropriate length of vibration pulse. These tests are based on the research our client provided us, of how much stimulation an infant requires, based on gender, age, location, etc. Outside of the code tests, which are automated and run every time we need to apply a firmware update to make sure we did not break any of the action logic, we also manually test the hardware components of the device, verifying the sensors record data correctly and the vibration device can send pulses. This is manual testing that we do whenever changing parts in the circuit.

The two apps that we create have automated tests for every part of the code. Asserting that the path taken is what we expect, such as data being sent to the server, when the server responds with a success, the device continues, and an error causes it to retry. Since these are both software components much of these tests are similar in nature. We also have functional tests, that verify that when the user takes an action, such as pressing a button, or inputting arguments to the web app, the correct data is displayed. Again, all of these tests are automated and run every time we release new versions of the code, to assert that the code is correct.

4 Project Requirements/Specifications

4.1 FUNCTIONAL

Ankle Device

- The device can tell when it is on an infant
- The device has a temperature sensor
- The device has a heart rate sensor
- The device has an accelerometer
- The device can store at least 1 day's worth of data
- The device runs in a very low power mode when not attached to an infant in a "sleep mode"
- ✤ The device is rechargeable
- The device administers up to 3 pulses of vibration to infant's ankle when algorithm deems it necessary
- The device communicates with an android device via Bluetooth low energy
- The device can accurately tell what time it is
- The device can determine its own geographical location
- The device knows when it is attached to an infant or not
- The device "wakes up" when attached to an infant
- The device sends data to the paired android device via Bluetooth low energy

Android Application

- The android application communicates with the database via internet connection
- The android application requires a login
- The android application communicates with the device via Bluetooth low energy
- The android application creates time dependent graphs
- The android application uploads information from the device to the secure database
- The android application displays real-time updates from the device
- * The android application will only display information pertinent to the current user

Web Application

- The web application requires a login
- The web application will display at least 6 months of data
- The web application will only show the data relevant to the current user
- * The web application will communicate with the database via internet connection
- The web application will get its data from the database
- The web application allows the user to download a .csv copy of the currently displayed information

Database

- The database will store the information in a secure way
- The database will only allow access from authenticated users
- The database will hold all information in such a way that preserves the integrity of the information

4.2 NON-FUNCTIONAL

- Data presented in application focuses on researcher needs
- All information is stored securely
- Pulse is administered when device deems it necessary
- Created circuit can read all necessary metrics and provides a good proof of concept for an actual device
- All applications are user friendly easy to use
- All graphs are labeled with titles and units
- * Data displayed on web is downloadable in a format that can be opened in Microsoft Excel
- The parents/researcher is notified after the third attempt of stimulation from the device fails

4.3 STANDARDS

Standards are important to deliver a quality product that will do what it is supposed to without issue. It is important for us to have standards for our processes because our device is intended to be put on children. As such, it is important for us to design a device that is well packaged and performs as expected. Our process could not be considered unethical because the device will be tested on ourselves before it goes on anybody else. Nothing we create will be allowed to be used unless we are certain it is safe to be worn.

We will be following the Agile organizational process in order to efficiently complete our coding tasks. All code that is submitted will need to be approved and looked over by at least two additional people. All hardware purchase decisions will need to be approved by the client and be as cost efficient as possible.

5 Challenges

With our group being mainly Computer Engineers, designing something that works with the human body would be a new struggle. If the hardware design gets delayed for too long, our app and later design goals will be delayed until we are able to get a working pcb. All parts need to be through hole design parts in order to fit on a pcb.

Is it feasible to fabricate a custom pcb and if we create a bad pcb it could take weeks to get a new one.

There is also the challenge of researching the parts needed for the design, as well as putting these parts together in order to create something that has these parts working together.

One of the big challenges that we had to do was Decide whether or not we could do This Project in two semesters or settle with a proof of concept. We decided to go with a proof of Concept So that we could focus on getting it right.

6 Timeline

6.1 FIRST SEMESTER

- Meet with group, client, and faculty advisor for first time
- Analyze data received from client
- Create a high-level design for each piece of the project
- ✤ Order parts for the circuit
- Develop at least half of the desired functions for the android application and web application
- Create the database

6.2 SECOND SEMESTER

- Build circuit designed first semester when parts arrive
- Design and implement embedded code
- Do iterative testing on each project piece: android application, web application, circuit, and embedded code
- * Tests all parts together and ensure that everything does what it is supposed to
- Present final product to client

					Period Highlight:	8 Plan Duration Actual Start 🖉 % Complete Actual (beyond plan)	
ΑCTIVITY	Week start	Week Duration	ACTUAL	ACTUAL DURATION	COMPLETE	Weeks 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36	
First Group Meeting	3	1	3	1	100%		
First Client Meeting	3	1	3	1	100%		
First Faculty Mentor Meeting	3	1	3	1	100%		
Analyze Data	4	1	4		20%		
Create High level design	5	2	5	1	100%		
Research Components	5	2	5	1	100%		
Circuit Design Android App Design	7 7	3 2	7 7		0% 0%		
Database Design	7	2	7		0%		
Web App Design	8	2			0%		
Create Database	9	2			0%		
Develop Android App	10	7			0%		
Order Parts	10	8			0%		
Develop Web App	10	7			0%		
Test Database	11	2			0%		
Fix and Re-Test Database	12	3			0%		
Test Web App	17	2			0%		
Test Android App	17	2			0%		
Build Circuit	18	4			0%		
Fix and Re-Test Android App	19	3			0%		
Fix and Re-Test Web App	19	3			0%		
Design Embedded Code	20	2			0%		
Develop Embedded Code Lest and Document Embedded	22	6			0%		
Code	28	2			0%		
Test Everything Together	28	2			0%		

Adaptive Neruostimulator

7 Conclusions

We are looking to find out if supporting evidence exists for correlation between SIDS and energy of lightning resonance. The goal is be able to come up with a design and deliverable in the form of a wearable device which monitors the status of an infant which may serve in alerting if something may be wrong and in data collection.

In order to achieve these goals, we plan to first look through the data given by the client and research information to gather a base of knowledge. From this base, we can come up with requirements and begin our design around this. Designs will be have to checked closely with thorough research on materials.

Testing will involve covering different cases of inputs to make sure the output (such as vibration or alert) is what is as expected.

8 References

- [1] https://www.vtechphones.com/products/baby-monitors
- [2] http://fisher-price.mattel.com/shop/en-us/fp/sproutling-sleep-wearable-fnf59
- Ziganshin, E. G., Numerov, M. A., & Vygolov, S. A. (2010, September). UWB baby monitor. In Ultrawideband and Ultrashort Impulse Signals (UWBUSIS), 2010 5th International Conference on (pp. 159-161). IEEE.
- "Sudden Unexpected Infant Death and Sudden Infant Death Syndrome." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 17 Apr. 2017, <u>www.cdc.gov/sids/data.htm</u>.

https://www.heartmath.org/research/global-coherence/gcms-live-data/

9 Appendices

Spectrogram for week of 2017-08-26

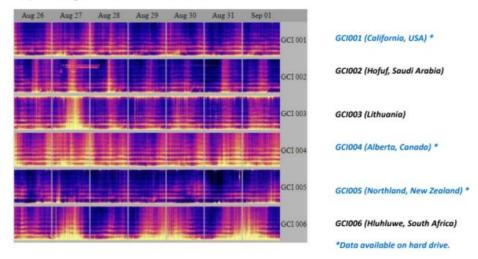


Fig 1. Data from magnetic field detectors in different locations of world.