Adaptive Wireless Wearable Neuro-Stimulator

PROJECT PLAN

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1 Introduction

1.1 PROJECT STATEMENT

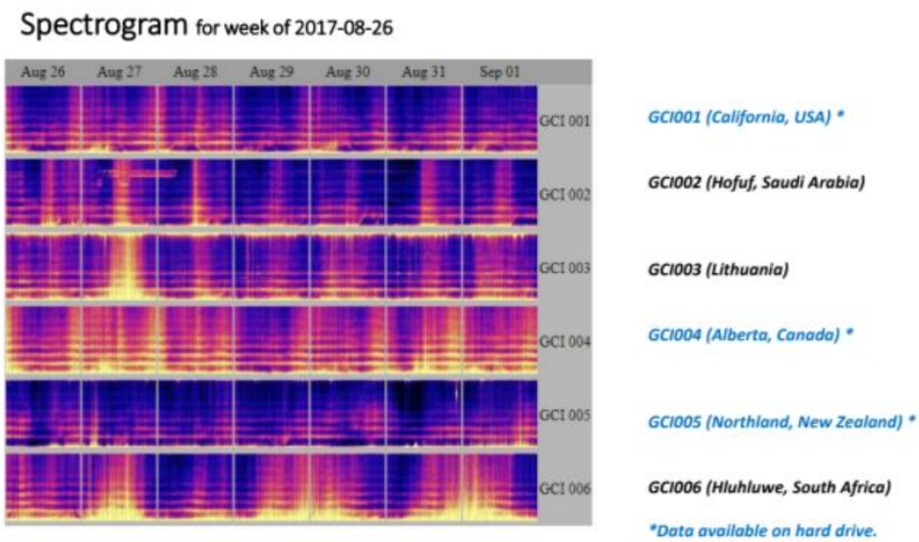

Figure 1.

According to the Center for Disease Control, in 2015, there were 1,600 deaths due to Sudden Infant Death Syndrome (SIDS) alone. This accounted for almost half (43%) of infant deaths, leaving many parents not knowing the cause of their child's death (https://www.cdc.gov/sids/data.htm). 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 sources like lightning, and the rate of SIDS.

1.2 PURPOSE

Our device is aimed at helping give researchers 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 of the user 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 main goal is to create a product that allows medical professionals or other interested parties to research any correlation between the data that we recorded and the rate of SIDS. This will involve creating a wearable to track the biometrics of infants and report it to a website where researchers can view historical trends. The device will also be used as a monitoring device for parents, and have a vibration motor the can stimulate the neurological system of an infant as an attempt to correct any dangerous situations.

The data that we collect will then be used to find if there truly is any correlation between energy around the globe and SIDS rates.

1.4 INTENDED USERS AND USES

The device will be worn by and keep track of information about the infants, but the intended user of the product are the parents. As we will have an app that allows parents to monitor their child and be alerted of any dangerous situations.

Another user would be researchers, who will not be involved on an individual product level, but rather looking at historical trends of data from all the connected devices.

1.5 ASSUMPTIONS AND LIMITATIONS

Assumptions:

- This device will be used by people around the world.
- Device will be used in research purposes. Data from device is to be sent to a database which researchers may view with 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

Wearable Prototype – An Arduino evaluation board that has the heart rate sensor, temperature sensor, accelerometer, and vibration motor. Embedded C code on the Arduino that interfaces with all sensors to pull data from them and store it. Once data is pulled and stored, the device must be able to communicate with the Android application to transmit it to the Android device.

Android Application – The Android application that is easy to use, and presents data that is easy to read in real time from the wearable device. The application will communicate with the wearable via Bluetooth, and it will be able to both send and receive information. Once raw data is received from the wearable, the Android application will process it, and then upload it to the secure database via internet or cellular data connection. April 2018.

Web Application – All data from the database will be viewable in the web application. Graphs of the various statistics read from the wearable device will be presented to the user. The data from the database will be available to the researcher to download in a .csv format so that it can be further analyzed in a different application if needed. April 2018.

Analysis of Data: Client gave us data to investigate if the low frequency waves from lightning in the atmosphere has any correlation the number of cases of SIDS. 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 wearable. Expected delivery for all complete code. April 2018

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

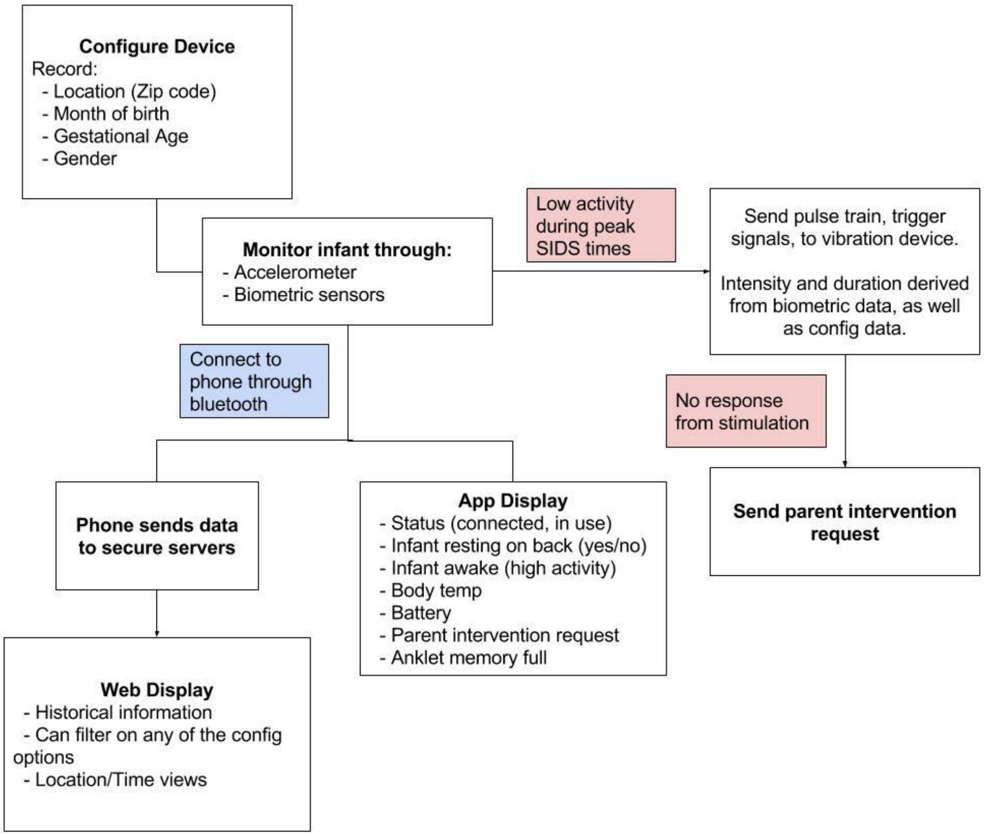

Figure 2

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 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/TEST PLAN

For the device itself, which is a combination of hardware and software, we will have multiple different types of tests to verify that our parts work to our specification and that our code can correctly identify dangerous situations, respond accordingly, and report to the Android application. Our performance and compatibility tests will be used to verify the correctness of our parts, this will include things like testing that our vibration motor can send a strong enough pulse, and verifying the biometric sensors record data at a rate that is fast enough to be useful. Moving to the embedded code, we will have more system tests for things such as making sure the device will turn on and off when it is attached to a user, and that after a period of time, and based on the initial set up config, a vibration pulse of varying length is sent to the motor. These tests will have their acceptance values based on the research our client has provided us, so we know that a certain gender, in a certain location, that is a certain age, should receive one length pulse, while another user will receive a different length. We can also write some lower level integration or unit tests to verify things such as the config data can be entered and it is stored correctly and can be accessed. There should be a large amount of these tests, and should cover all of the associated requirements we have for the device itself.

The two applications we create, Android and web, which are the software only parts of the project, will have unit and integration tests to assert that the applications are accessible and work correctly. These types of tests will depend on the actual implementation of the applications, but in general will be asserting things such as data received on a Bluetooth connection is stored and then sent wirelessly to a database, or when a user has defined bounds on their web interface, the correct query is executed to give them the graph that they want. The goal of these tests is to cover as much of the code base as possible to ensure that any updates we make do not break existing workflows. The Android application also has UI tests associated with it, so we can verify that a user can hit the overview button and be shown the overview page, for all of the pages of the app. These tests will then be run on every software update, and will cover all of the requirements in the requirements section.

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 days' 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

One of the biggest challenges that we faced was our lack of experience in circuit design. We started out the semester looking into designing a PCB, but after running into road blocks we felt it was out of our scope of knowledge. Due to our limited experience in circuit design and analysis, we felt we would not be able to complete a full PCB design in the time allotted for the project. After discussions with our faculty advisor and client, we concluded that a proof of concept would be more feasible to do than a full PCB design. Our focus then switched to getting the technological connections between the website, app and wearable to function properly. The client, then, in the future may ask another senior design group to work on the wearable PCB. If the hardware design gets delayed for too long, our embedded code design will be delayed until we are able to get a working proof of concept. Without the embedded code, we will be unable to fully test the Android application as we need to.

Android development has been a source of challenges due to our limited Android development experience. We have been working with our faculty adviser to properly develop our application. Additionally, we have done research into various Android development practices so that we may quickly learn as much as possible in the restricted time period we have.

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

Android Application

- Finalize UI design.
- Create backend logic to enable Bluetooth and internet connections.
- Test the connection between wearable and Android application.
- Test the connection between the database and Android application.

Web Application

- Create the user interface.
- Write the backend logic to display the information desired by the user.
- Write logic to interface with the database securely.

Wearable

- Add sensors to Arduino.
- Develop embedded code to interface with sensors and enable Bluetooth connectivity.
- Test connectivity between Android application and wearable.

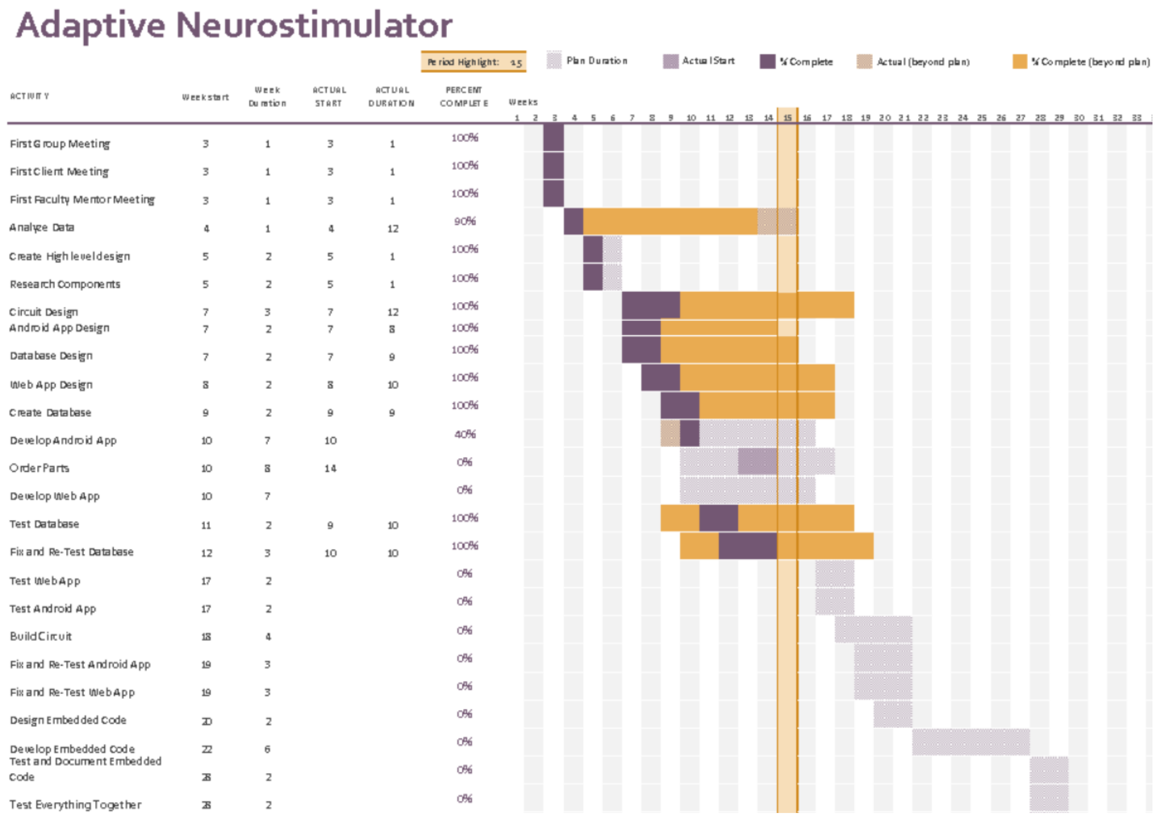

Figure 3

7 Conclusions

Our client is investigating the correlation of SIDS and low frequency energy waves. We have analyzed data from geomagnetic stations to investigate this claim, as well as design a proof of concept device that may have potential in assisting with research. The device is designed to be a health monitoring device that has the additional capability to provide an action.

Our end goal is to provide the client with a set of applications and a proof of concept device. The proof of concept device will be used by the client for future development into a full product that can be used for research. The software components created this year will be able to communicate with the wearable to be created in the future.

The wearable prototype will be Arduino device with sensors attached and embedded C code loaded on. Sensors/actuators will include a heart rate sensor, temperature sensor, accelerometer, and vibration motor. The sensors are used for checking if device is attached, monitoring biometrics, movement and position of infant. The wearable will use the vibration motor to send a small pulse to induce reflexive movement from the infant. To interface with the device, we plan on developing an Android application which will receive data from the wearable and alert the users when the infant may be at risk. The web application will be the interface aimed at researchers to view collected data.

8 References

[1] Baby Monitor | Official VTech® Audio and Video Baby Monitors. (n.d.). Retrieved December 05, 2017, from https://www.vtechphones.com/products/baby-monitors

[2] Sproutling Wearable Baby Monitor. (n.d.). Retrieved December 05, 2017, Retrieved from http://fisher-price.mattel.com/shop/en-us/fp/sproutling-sleep-wearable-fnf59

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9 Appendices

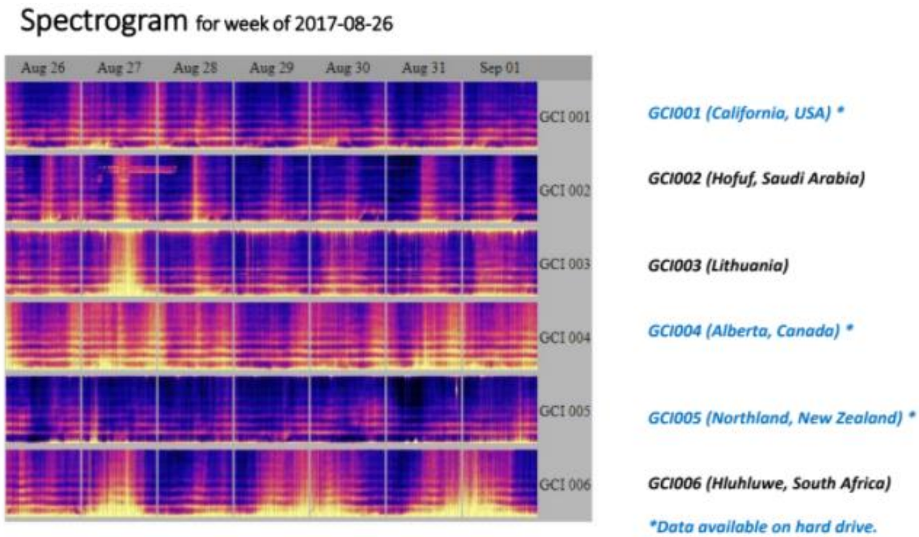


Figure 1. Data from magnetic field detectors in different locations of world.

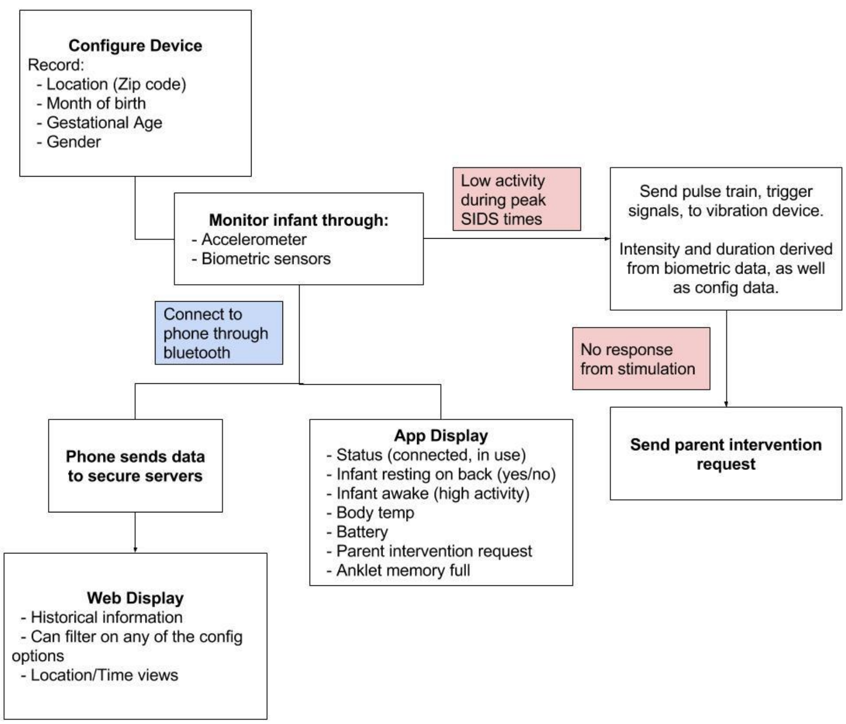
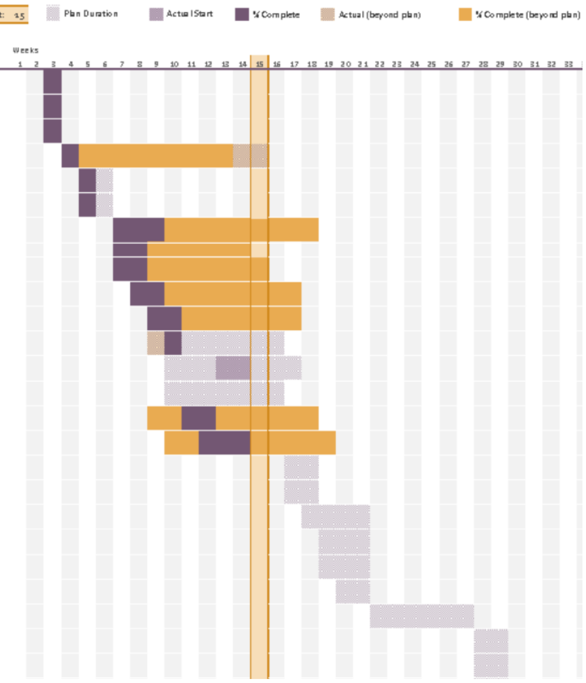


Figure 2 – Diagram of system interactions and actions

Adaptive Neurostimulator

Period Highlight: 15



ACTIVITY	Weekstart	Week Duration	ACTUAL START	ACTUAL DURATION	PERCENT COMPLETE
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	12	90%
Create High level design	5	2	5	1	100%
Research Components	5	2	5	1	100%
Circuit Design	7	3	7	12	100%
Android App Design	7	2	7	8	100%
Database Design	7	2	7	9	100%
Web App Design	8	2	8	10	100%
Create Database	9	2	9	9	100%
Develop Android App	10	7	10		40%
Order Parts	10	8	14		0%
Develop Web App	10	7			0%
Test Database	11	2	9	10	100%
Fix and Re-Test Database	12	3	10	10	100%
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	22	6			0%
Test and Document Embedded Code	28	2			0%
Test Everything Together	28	2			0%

Figure 3 – Gantt chart for group progress