

Senior Design EE/CpE-423/424 Final Report

We pledge our honor that we have abided by the Stevens Honor System

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Executive Summary

In this age of innovation, we are focused on making our products smarter and smarter--fridges that tell you when you're out of eggs, cars that tell you when they're due for routine maintenance. These products are made to monitor and automate. These are items made to ease the mind of the consumer, but this idea of monitoring and automating could do so much more if applied in home healthcare. Bodies can seem fickle and unpredictable at times, but the truth is there are telling shifts before we even realize something is off. It is time for a product that starts to make our bodies smarter.

Workplace health is an ever pressing issues for all employers. When an infected employee comes in, they can spread what they have to their coworkers before they even know they are sick. By detecting when you are sick ahead of leaving the house, you allow more people to make the decision to stay at home earlier. This will allow for a reduced transmission rate not just in the workplace but universally--leading to a reduction in illness in our world.

This also has the capacity to catch illnesses before they become severe. With many terminal illnesses the key can be detecting it early on. This can lead to increased longevity and save so many hard decisions and so much suffering.

Doctors would also benefit from the information provided by a smart body monitor. Client input cannot always be reliable, and some clients are not very good at tracking their condition. Furthermore, without portable monitoring technology, much of illness tracking can be based on how the client felt at the time which can vary between individuals. Rock solid data would be invaluable to medical professionals and their clients.

A development such as this would change the lives of everyone with a chronic illness. Being able to monitor a disease's progress would be great for these people, but more than that, many people with chronic illnesses suffer from episodes that are inconvenient at the least and deadly at the most. The ability to predict when such an episode might occur and get assistance immediately. If it does would save people with chronic illnesses frustration and fear and allow them to live more independently.

The ChronoSTAT team imagines a healthier world for every individual. No one can know what is happening inside their body at any given moment, but ChronoSTAT can. This product will be revolutionary in its protection of mind and body.

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Section –I: Project Definition and Plan

1. Mission Statement

For the average individual, tracking health changes is a preventative measure--it helps keep themselves and others healthy. For doctors, health tracking helps them do their job better. But for those with chronic illness, health tracking is something that is vital to everyday life. These individuals are burdened with constant vigilance and the fear that an episode could put them in a life threatening situation is very real.

The ChronoSTAT will be a constantly wearable health tracking device that will learn a user's normal homeostasis pattern and detect outlying shifts and patterns. Once these abnormalities have been detected, the device will forward the data to a mobile application. This application will be capable of sending this information to a doctor, alerting users to a shift or irregularity in the pattern which could suggest an oncoming episode or a shift in their status, and in the event of an episode the app will not only alert emergency contacts, but also provide an emergency medical information notification for passerby on the screen of the mobile phone.

Unlike other attempts at such a device, ChronoSTAT will be capable of detecting all maladies, physical and mental. That range is something that is not offered by any other product. This is done by using a new approach with machine learning to learn usual patterns and identify abnormalities. The interface with a mobile phone application and the services provided by this application also makes the device a unique tool.

2. Background

Chronic health conditions can be difficult to categorize because they tend to be invisible to everyone except the person affected and perhaps a small number of others. A chronic illness is a long term medical condition, lasting for months or even years. These conditions can strike at any time of life in any system of the body, from digestive organs to immune system to neurons in the brain. Though the actual physical manifestations vary greatly from one illness to another, they all have the potential to be devastating to a person's daily life.

According to the CDC, approximately half of all adults in the United States in 2012 suffered from at least one chronic illness, while one fourth of the adult population had two or more diagnoses. Chronic conditions also account for around 86% of all health care expenditure in the US per year. Some chronic conditions, such as cancer, receive a lot of publicity and funding. However, there are many other conditions that are much more difficult to diagnosis. In some cases, getting an accurate diagnosis can take months or even years.

As part of either a diagnosis or treatment plan, chronically ill people may be asked to keep a record of their symptoms. Finding patterns can help identify triggers that exacerbate a person's illness, which may allow the person to take precautions that will lessen the severity of an episode. It can also be instrumental in establishing a treatment plan to improve the person's daily life. For many people, keeping such a log is a daunting task because it requires physical actions on their part. If a person's symptoms include fatigue or physical weakness, the act of recording their symptoms can be exhausting. Some illnesses and medications can cause forgetfulness, which is also detrimental to the person's ability to keep a record.

3. Stakeholder List

Stakeholder	Major Benefits	Attitudes	Win Conditions	Constraints
Project Team	Releasing the device.	Full attention.	The device is released, successful and fulfills all requirements placed by the team, or other stakeholders.	Device must be cheap, easy to manufacture, easy to repair.
Users with Illnesses	Warning for potential attacks, and inform user of vitals.	Enthusiastic.	Device is able to warn user of potential attacks, and allow the user to react. Monitor their vitals.	Device must be light, and must be conspicuous.
Users without Illnesses	Detect illnesses prior to any major symptoms.	Indifferent but Interested	Device is able to monitor vitals and alert the user of any abnormalities.	Device must be light, and must be conspicuous.
Health Professionals	Constant monitoring of user vitals and activity.	Interested	Device is able to accurately sense vitals, and record any abnormalities and attacks.	Device must be easy to use and read/record vitals.
Researchers	Provide data of users, their activities and vitals.	Enthusiastic.	Device is able to record activity overtime accurately, and sense activity patterns.	Device must be easy to use and read/record vitals. Also must limit the information released, privacy protection.

Table 1: Stakeholder Table

4. Analysis of Stakeholder Needs

ChronoSTAT will have five stakeholders: the project team, users with and without illnesses, health professionals and researchers. For all stakeholders, the device itself must be able to function and provide accurate reading of their vitals as intended.

The project team will consist of developers and manufacturers and have a wide spectrum of needs. ChronoSTAT developers will need the device to be easy to manufacture, cheap in terms of material, as well be easy to repair and upgrade. The device itself must be able to create a profit from its sale, making its cheap manufacturing cost a priority in increasing its profit margins.

There are two types of users that are expected to use ChronoSTAT, users with a need to react to a potential attack, and users that want to monitor their own health. Both users have similar constraints on the device. Most people prefer not to be seen wearing a device in public, due stigmas against mental and neurological illnesses, therefore the device must be concealable. In addition, the

device will be worn by a person for a good portion of their day and must not restrict the movement of the wearer. The device must be light and comfortable so not to irritate the user.

Healthcare professionals and researchers have similar interest. Both groups would desire the device to be able to be accurate in its readings and be to record activity or abnormalities on the user. Healthcare professionals would be able to better diagnose and react to symptoms with the data it can provide. Researchers can also use the data to better progress along with disease research by having an accurate timeline of vitals over the course of days or weeks depending on the user. In addition, there will be numerous people using the device so sample sizes will not be miniscule.

5. Project Scope and Recourses

The scope of ChronoSTAT is to comprehensively track and monitor physical as well as mental issues that are most prevalent in society. ChronoSTAT will offer vital tracking along with pattern recognition and analysis to provide information to the user about how their body works normally. When this information is established it will then look for signs that the body is not in its hemostasis and alert the user to such developments. As the product develops, this warning system will be used to alter emergency contacts and doctors if the hemostasis shift is determined to be a severe health risk. This is not meant to replace a doctor but is intended as an aid for those who want to keep a healthy body.

The resources focused on this project are two CPE and Two EE students. The CPE students will focus on the programming application, and Bluetooth application of ChronoSTAT. The two EE students will focus on the sensors and hardware development of ChronoSTAT. A full breakdown of resources and tasks can be found in the appendix of this report.

Some other resources the team has at their disposal include their advisor Brian Ackland for technical consult and the campus counselling center for medical consult.

6. Project Plan

The project is divided into five phases as seen in Table 2. The Define stage is where the group researches and develops the overarching mission of the project. The Innovate phase is where the team comes up with solutions to problems found in phase 1. Phase 3 or the Design phase is where the team selects one realization of the solution and defines on how to implement the solution. Optimize and Demo phase is where the prototyping and physical testing will take place. The Documentation phase is present throughout the project plan with reports due at the specified dates in Table 2.

Throughout this the project will be monitored by management to ensure that the team is budgeting resources such as money, personnel, and time effectively as well as evaluating risks and assessing the past, present, and future of the project and the team.

Marketing is also something the team will work on throughout the project as they evaluate the best ways to fund the project and make it appealing to their stakeholders in addition to just getting the word out about the opportunities ChronoSTAT provides. This was done by setting up a website, blog, and social media pages in order to make as much information available to supporters. The team also set up streams of revenue by creating a fundraiser page for the project and setting up a shop where the public can buy ChronoSTAT themed souvenirs.

Although there are weekly reports on progress and surveys on team participation, the bi-semester reports (such as this one) are a good summary of the project as a whole as it moves along. The ultimate deliverable is the senior design expo where the team will be expected to present the finished ChronoSTAT product to their peers, professors, and interested investors.

Event or Deliverable	Target Date
Project Management	Wed 5/10/17
Phase I: Define	Mon 10/10/16
Phase II: Innovate	Mon 11/21/16
Phase III: Design	Mon 1/30/17
Phase IV: Optimize and Demo	Mon 3/27/17
Phase V: Document	Wed 5/10/17
Website	Mon 5/15/17
Reporting	Wed 5/10/17
Fall Midterm Report	Tue 10/18/16
Fall Final Report	Tue 12/6/16
Fall Presentation	Tue 12/6/16
Spring Midterm Report	Tue 3/28/17
Spring Final Report	Tue 5/2/17
Design Expo	Wed 4/26/17
Design Report	Wed 5/10/17

Table 2: Project Schedule

Section –II: Design, Evaluation & Optimization

1. Requirements

This product must be designed in a way that allows it to learn the user’s normal homeostasis pattern and predict and detect episodes defined by a sudden, dramatic change from that pattern. Once that goal has been accomplished the team can move onto developing it to detect shifts in the normal pattern that happen more slowly over time. This is the ultimate necessity of the device as it is its purpose.

In order to achieve this, the system will require carefully a carefully calibrated network of sensors because with health it is necessary that there are an extremely limited number of false

alarms. In order to handle this extensive network, the product will need to have a microcontroller with a large amount of inputs.

The software for this product will need to sort through the sensor's readings and compare it to standard patterns over time. It must log anomalies and shifts and forward that data to doctors. It must also be able to notify the user when a shift indicates an oncoming episode. It must also do the same for if it detects an episode is occurring in addition to notifying emergency contacts and/or passerby using an alert system.

In a best case scenario the product will prove to be capable of 24 hour use regardless of environment. This is why it is of the utmost importance that the product be wearable so that the user can bring it anywhere. The product must be light, compact, and nonintrusive on the user's lifestyle as we expect this product to expand their horizons, not limit them. For this reason it is also necessary that this device be wireless so as not to impede the user, therefore at the very least some kind of wireless communicator will need to be utilized to network with the user's phone. Furthermore, this goal will require long battery life or another mitigating continuous powering method. It also will require being able to withstand wet, heat, cold, and shock.

2. Constraints and Assumptions

ChronoSTAT will have critical restrictions. The device itself will be used to monitor health on a person, and therefore will be worn for long periods of time. The wearer will need the device to be very light, not restrict movement. Movement restriction will also interfere with motion sensing on the person and generate false readings. In addition, the device cannot have any intrusive sensors, such as needles and deep electrodes. Since it will be carried by a person, wireless technology will be needed, but will need to be low cost and can be short range.

For the wireless technology, it can be assumed that Bluetooth technology will be used. The component will be designed and built in CPE 490 Information Systems as part of the final project for the class. The design and software built will be used in ChronoSTAT.

<u>Constraints:</u> <i>Constraints limit what you can do</i>	<u>Assumptions:</u> <i>assumptions may brush aside some constraints.</i>
Bluetooth must be used for wireless technology.	CPE 490 Information systems final project will be using Bluetooth technology, this will be used in the device.
Device must be light and non-restrictive.	
Device must be inconspicuous and non-intrusive.	

Table 3: Constraints and Assumptions

<i>Dimension</i>	<i>Constraint (state limits)</i>	<i>Driver (state objective)</i>	<i>Degree of Freedom (state allowable range)</i>
Features (Vitals Sensors)	<i>Must include sensors needed for sensing mental and neurological health by release of prototype. Intrusive sensors cannot be used.</i>		<i>0 to 100% of additional sensors for other illnesses can be released with the prototype.</i>
Quality			<i>90-95% of user acceptance tests must pass for release 1.0, 95-98% for release 1.1</i>
Cost	<i>Prototype must be built with \$400 budget.</i>		<i>Additional spending is allowed, but will be out of pocket.</i>
Schedule		<i>Design and Logistics must be done by late November 2016.</i> <i>Prototype to be finished by March 2017.</i>	
Wireless Technology Information Systems CPE 490	<i>Must include one short range, low cost wireless technology. Bluetooth is assumed technology.</i>	<i>Will be built and tested by the end of Fall semester, used in Information Systems as final project.</i>	

Table 4: Specific Constraints

3. Applicable Codes/Standards/Regulations

ChronoSTAT will be a wearable medical device and will have to conform to CFR (Code of Federal Regulations) Title 21 parts 800 - 1299 in regard to a medical device. Other codes that apply to the device are CFR Title 47 which is the FCC regulations.

a. Professional and Ethical Issues

ChronoSTAT has a professional responsibility to ensure that all personal data is secure and communicated only to those who the consumer has authorized to see such data. Another responsibility is to ensure that the device does not interfere too much in the normal everyday actions taken by the user.

4. Concept Development and Selection

After doing some research, it quickly became apparent that the scope of this project needed to be narrowed in order for it to be feasible. Chronic illnesses can affect any system in the body, and the relatively small scale of this project makes it impossible to cover all of them. Instead, the team decided to focus on a single type of illness.

Once it was decided to narrow the focus of the project to one family of disorders, the next question was which one to pick. One of the major factors in this decision was the sensors required. For instance, blood pressure is an important thing to measure for many conditions, but at this point in time there are no affordable, convenient sensors to measure it. This ruled out some illnesses, such as diabetes and many cardiac conditions. Another basic medical sensor used for many types of conditions is a blood-oxygen monitor. However, blood-oxygen sensors must be placed on a part of the body that is thin enough to shine a light through, such as a fingertip or earlobe. One of the purposes of this project is to make something that can be comfortably worn during normal activities, making this sensor less than ideal. Eliminating blood-oxygen monitors ruled out respiratory illnesses as the focus of this project. The team also considered applying the project to neurological illness, but this also quickly proved to be impractical because it would require the device to be worn on the user's head.

The most promising focus for this project was mental illnesses. Behavioral patterns are very important to the diagnosis and treatment of mental illnesses because there is so much possibility for variance between people. Applications have been developed to help people keep track of their behavioral symptoms, but they are not always effective because mental health symptoms can be very difficult to quantify. Another symptom in many mental illnesses, particularly anxiety disorders, is an accelerated heart rate, which can easily be monitored by a wearable device.

One of other considerations for mental illness as the focus of this project is the lack of resources currently available. Even with the applications developed to help people with mental illnesses, finding an accurate diagnosis or effective treatment plan can take months or even years. Learning the body's patterns is incredibly important for improving quality of life for people with mental illnesses. All of the applications currently in use rely on user input and not passive data collection. Based on conversations with professionals in the Stevens Counseling Center, the team came to realize that this project could have a very big impact on the lives of people with mental illnesses.

5. Preliminary and Detailed Design

There are two primary components in this design: a mobile application and a wearable device. The wearable device can be further broken down into sensors, a microcontroller, and a Bluetooth transmitter. The overall system architecture is shown in Figure 1. The sensors will be connected to the microcontroller in the wearable, which will process the data. The wearable will be

connected to the application via Bluetooth. The application will provide the primary interface between the user and the wearable. The design process for this semester has mostly focused on the hardware aspect of the wearable; further development of the app will take place over break and during the spring semester.

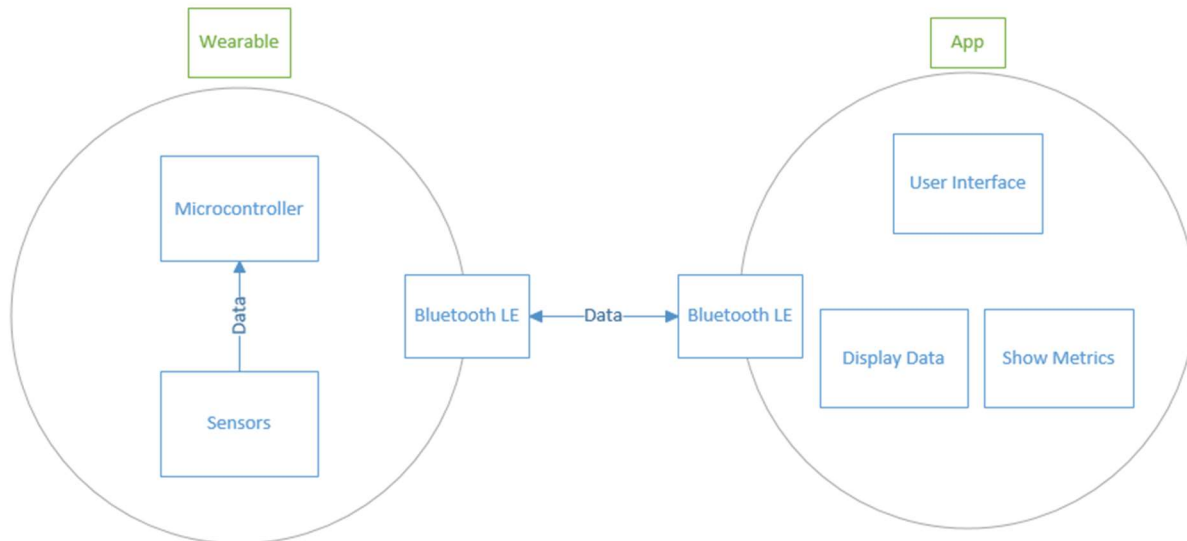


Figure 1: Overall System Design

a. Mobile Application

The mobile application will be primarily used to display user data and to provide an interface with the wearable device, since no significant interface has been planned for the device itself. At this point in time, there has not been much design work done on the application itself. The main focus of this semester has been on hardware selection and prototyping. More work on laying out and developing the application will be done over Christmas break and during the spring semester.

b. Wearable Sensors

The types of sensor that will be used are a blood oximeter, several motion sensors, and a custom muscle sensor. The blood oximeter that will be used is Nellcor MAX-N Neo-Adult Disposable Oximax Sensor and for development the MAXREFDES117 will be used. The motion sensor used for this project is going to be at least two IMUs. The muscle tension sensor will be a custom made sensor that will be based on research already done.

The blood oximeter the team order for development was made specifically for wearable device research and prototyping. The Nellcor MAX-N Neo-Adult Disposable Oximax Sensor is a medical grade blood oximeter the team got for free after ordering the other blood oximeter.

The IMU MPU-9250 is the motion sensor chosen for the project because the team had this originally on hand when development started. It provides nine degrees of freedom for accurate motion sensing.

The muscle tension sensor that the team has decided on for this project will be a custom build sensor that technology that can sense the type of muscle contractions.

c. Wearable Microcontroller

Selecting a microcontroller was more complicated than initially anticipated due to the large number of microcontroller platforms available for development. A decision matrix was constructed to select the best option. The decision matrix is shown in Table 5. The criteria for the microcontroller were derived from the project requirements and weighted as necessary. Each of the considered microcontrollers was given a rating based on how they met each requirement. A zero meant that the microcontroller satisfied all requirements, while a negative one meant that it did not satisfy the requirements, and a positive one meant that it exceeded the requirements.

The most important requirement for the microcontroller was that it needed to have sufficient analog inputs for all the sensors to be used. All of the sensors to be used by this project are analog, so being able to process those inputs is critical. Some of the considered microcontrollers, such as Raspberry Pi, do not natively have analog-to-digital conversion (ADC) and require additional hardware to perform this function. More analog inputs and high ADC resolution received a score of 1, while microcontrollers with few or no ADC pins received a score of -1.

The next criterion was storage. Having the ability to store data will become important as the project progresses into the machine learning phase. Some machine learning algorithms require past data samples to be stored, and while an algorithm has not been selected yet, this may be a major requirement as the project progresses.

The team also wanted to be able to program the microcontroller in a relatively low level programming language. Higher level languages, such as Arduino, are suitable for hobby electronics projects, but waste memory and processing power for embedded systems such as the one being designed here.

The rest of the criteria were not as heavily weighted because they were less important than those discussed above. Cost was an important factor primarily because of the limited budget provided by Stevens. Size of the microcontroller will be a bigger concern if this becomes an actual product, but the team is aware the prototype will probably be fairly cumbersome. Portability, or the ability to move from the development environment to a custom circuit board, will also only become a concern much later in the project. Finally, the available peripherals, such as Arduino Shields or Raspberry Pi Hats, were only important for certain controllers - Raspberry Pi, for instance, needed additional hardware for ADC.

Completing the hardware decision matrix immediately eliminated some of the options - all Raspberry Pi models were immediately out. The matrix showed that the Teensy series microcontroller was the best one for our purposes. The Teensy 3.6 has over 20 ADC pins with 13-bit resolution, as well as a built-in MicroSD port [4]. It can be programmed in Arduino or C.

Criteria:	Analog Inputs	Data Storage	Program on Low Level	Cost	Size	Portability	Available Peripherals	TOTAL
Weights:	10	7	7	5	3	3	5	
Arduino								
Uno	0	0	0	0	0	1	1	8
Mega	1	0	0	-1	-1	1	1	10
Mini	1	0	0	1	1	1	1	26
Micro	0	0	0	1	1	1	1	16
Raspberry Pi								
Pi 3 Model B	-1	1	1	-1	-1	-1	1	-2
Pi Model A+	-1	1	1	0	0	-1	1	6
Pi Zero	-1	1	1	1	1	-1	1	14
Beagle								
Rev C	-1	1	1	-1	-1	-1	0	-7
FPGA								
Mojo v3	0	0	1	-1	0	0	0	2
mbed								
Cortex-M3	0	1	1	-1	1	0	0	12
PIC								
IOIO-OTG v2.2	1	1	1	0	1	1	0	30
Teensy								
Teensy 3.6	1	1	1	0	1	1	1	35
Teensy 3.5	1	1	1	0	1	1	1	35
Teensy 3.2	0	1	1	1	1	1	1	30
Teensy LC	1	0	1	1	1	1	1	21
Teensy++ 2.0	1	0	0	0	1	1	1	21
Feather								
32u4 Bluefruit LE	0	0	0	0	1	1	1	11
M0 Bluefruit LE	0	0	0	0	1	1	1	11

Table 5: Microcontroller Design Matrix

d. Wearable – Bluetooth

The RedBearLab's BLE Nano is chosen to be the Bluetooth module for ChronoSTAT

One major criterion for choosing the Bluetooth module is the size of the board itself. ChronoSTAT is a wearable device; therefore most retain a small form to be fitted on a person. To help with the size reduction, a small wireless module can be fitted providing crucial wireless capabilities yet keep its size small. While most boards are fairly small (smaller than 50.0 mm by 50.0 mm boards, the BLE Nano has a small form, 18.5mm by 21.0mm, smaller than a standard US quarter. A comparable Bluefruit SPI Friend, Adafruit's BLE board, has a small size of 23.0 mm by 26.0 mm, slightly larger size.

Powering the module is the second criterion that is considered. Mobile devices run on a battery and must have a low power consumption lest the the device have a short battery life. The Nano is a Bluetooth Low Energy device as technology developed by Bluetooth SIG. Like most BLE devices, the Nano has a less than 0.5 power consumption with a peak current of 15mA, allowing it to save battery life. On the downside, the data rate and throughput compared to traditional Bluetooth devices is much lower limited to 1Mbit/s.

While it is not as important as power and size constraints of the Bluetooth module, the ease of use and support for developing the device is preferred. The Nano has an nRF51822 ARM core that allows it support Bluetooth. The core has a large library of prebuilt and user made programs from Mbed and the use of those programs. The hex files can be uploaded to the board through the MK20 USB dongle.

e. Mobile Application

The microcontroller, the Bluetooth module, and the application will all require software development. However, since the primary focus of this semester has been hardware, most of the software development is still at a very high level. The plan at the moment is to program the Bluetooth module and microprocessor in C. The team has had some trouble setting up an environment for compiling C in Windows, so most of the development will take place in Linux since it has a native C compiler. A basic flowchart for the microcontroller is shown in Figure 2 (a).

The microcontroller will classify incoming data based on the machine learning algorithm, and notify the mobile application when something out of the ordinary is detected. The mobile application, meanwhile, will need its own software to help classify the data. This flowchart is shown in Figure 2 (b) .

At this point in time, all the software is still in the planning stages. Fleshing out software will become a primary focus in the coming months.

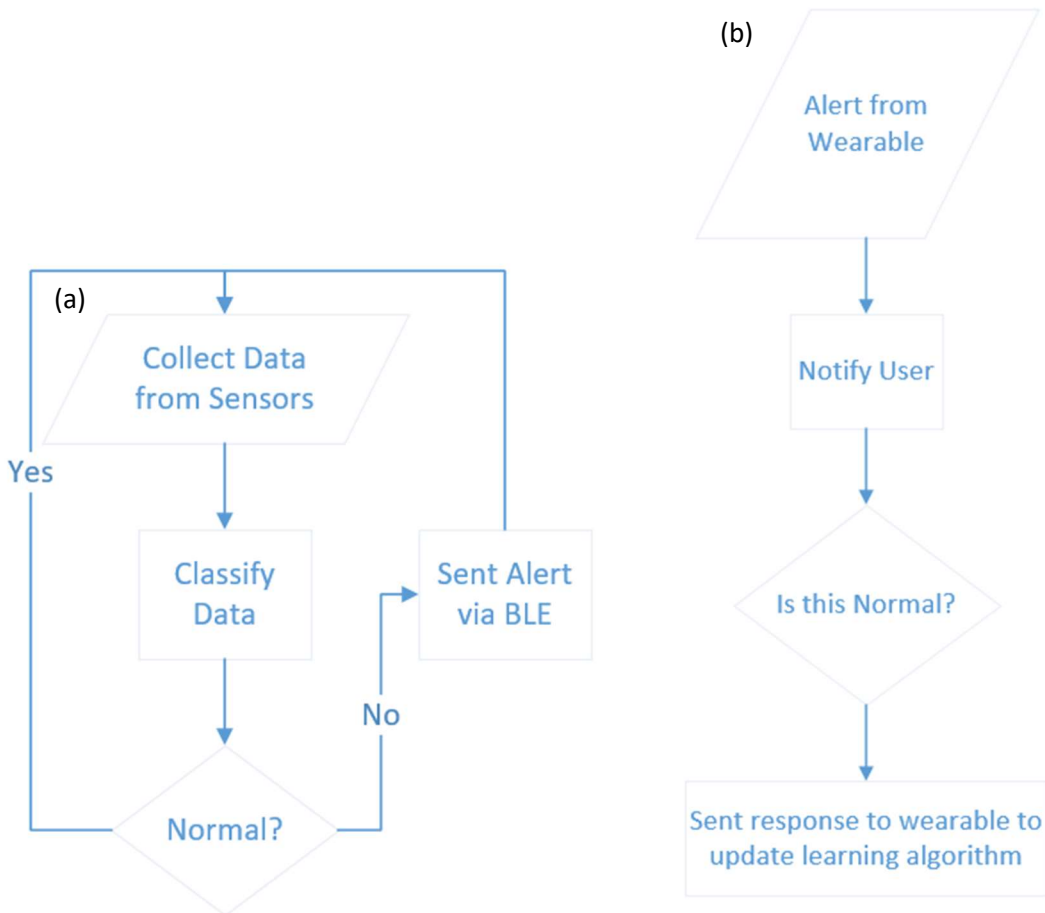


Figure 2: (a) Microcontroller Software Flowchart (b) Application Flow Chart

6. Design Evaluation

The initial design for this project involves two primary components: a wearable device with sensors to monitor the condition of the user and an application used to track their condition over time. At this point, most of the details have not been worked out yet. The current plan is to have the wearable be made up of the target sensors, a microcontroller, and a Bluetooth unit. It will also be paired with an application that will display user data over time to help identify patterns. The exact sensors that will be used in the wearable have not yet been set in stone; however, it is probable that they will include an accelerometer, gyroscope, and heart rate sensor at least. The initial iteration of the application will be programmed in Android, because it has the most accessible software development kit. A basic architecture for the two planned sections of the project are shown Figure 3 and Figure 4.

As of the writing of this report, the exact materials needed for this project have not yet been resolved. However, this section will be updated as the project progresses.

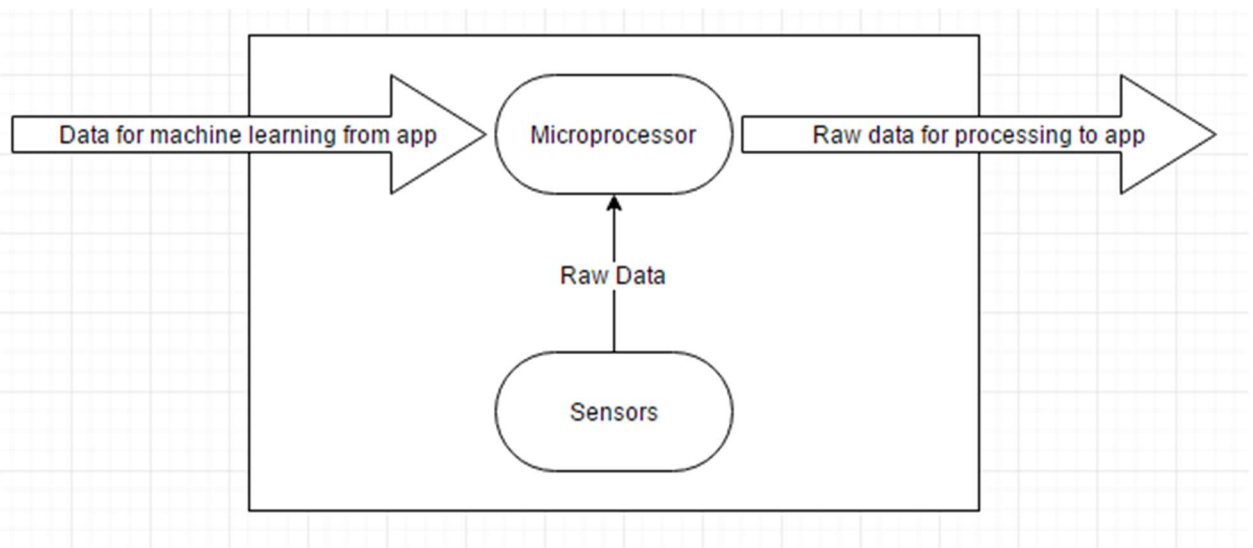


Figure 3: Wearable Device Information Flow

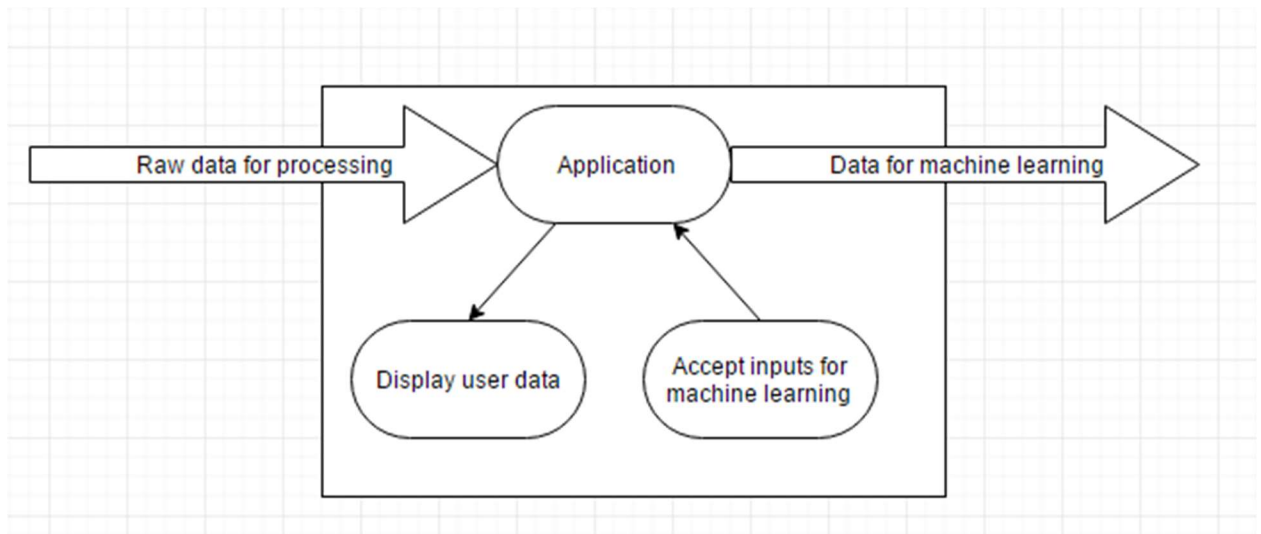


Figure 4: App Information Flow

a. Methods: Analytical, Simulated, Physical Tests

This project is still in the planning phases, so these methods have not been the focus of the project so far. This section will be updated in future reports. Tests predicted for the prototype are described in the section below.

b. Physical Prototyping: Plan and Budget

The team's plan for the initial prototype to be assembled over winter break was greeted with a goal of testing rather than the results the team intends to obtain at the end. For this initial prototype the team intends to connect one of the sensors through the microcontroller and Bluetooth to deliver the sensor data to a phone application. The sensor selected for this first test is the medical grade blood oximeter. The team finds it important to test a single sensor and then build the prototype up from there in order to minimize where to look for errors during this critical first assembly.

In this form, the prototype will not be wearable yet and will certainly not be environmentally proofed. These features are expected to be developed later once the configuration of the sensors has been modified into the final configuration. The application will be rudimentarily functional for this initial prototype and it will increase in functionality as the project proceeds.

The learning algorithm will also start to be developed over break but there is no current estimation on when it might be able to start the testing phase.

The expenses and budget for the prototype are listed in Table 6.

BOM	Date	Price	Quantity	Amount	Total
MAXREFDES117 + shipping unknown at this time	10/28/2016	\$21.40	1	\$21.40	\$91.27
RedBearLab BLE Nano - nRF51822	10/7/2016	\$26.36	1	\$22.55	
Teensy 3.6	11/25/2016	\$23.40	1	\$23.40	On Budget
IMU Breakout	11/25/2016	\$11.96	2	\$23.92	

Table 6: Material list for ChronoSTAT

c. Prototype Build and Test Report

Most of the parts for the initial prototype have already been ordered, including the microcontroller, the Bluetooth module, and several sensors. A basic schematic for the Bluetooth sensor has been created, and the environment for programming everything in C is set up. At this point, the plan going forward is to start working on the prototype before group members leave for winter break, and to continue the work over the break.

7. Design Evaluation Report: Performance, Reducibility and Cost

The designed initial prototype has not yet been built as it will be assembled over winter break--therefore the performance of even the sensors has yet to be evaluated.

The initial prototype design is extremely simplified; to remove any further components would make it impossible for the device to perform the most basic of functions. As a result it is the current assessment that nothing could or should be removed from the design.

However it is safe to say that the team is currently doing very well with their budget. This is because almost all of the hardware for this project has actually been assembled so far. No reductions to reduce cost are expected.

8. Design Revisions and Optimization

The initial prototype will consist of a microcontroller, a Bluetooth module, two motion sensors, and an oximeter sensor. After a prototype design has been made it will be designated as revision “-” and all subsequent design modifications will be recorded below as incremented alphabetical revisions as is industry standard.

Name	Date	Reason For Changes	Version
ChronoSTAT	12/1	Initial Prototype	0.1

Table 7: Prototype Version Table

9. Final Design Specification with BOM

The final design is still to be determined, since the project is still in the conceptual design phase of the project. Once the design has been finalized and tested will the team consider a final design specification with a corresponding BOM. As of right now the prototype BOM is shown in Table 8.

BOM
MAXREFDES117
RedBearLab BLE Nano - nRF51822
Teensy 3.6
IMU Breakout

Table 8: Final BOM

Section –III: Entrepreneurship & Business Development

1. Business Objectives and Risks

At the moment the team has no interest in bringing the finished product to the market. They have agreed that if a backer could be found for funding reasons the project could eventually be picked up by another senior design team, but there is no current active interest in finding such an entity. As a result the current goal of the project is to make it successfully to the products current set goals within the given time. The team also hopes to set up a good foundation for the next team to pick up the project by setting up excellent marketing strategies to get the word out and creating a solid platform technology.

As a result the most likely risk to the project is time itself. The product will be ambitious to make within the given time due to the large amount of testing and calibration that it will need. It is very likely that this could cause the project harm either through not having the time to finish the project or by rushing to meet deadlines have having sloppily done work as a result. The best way to mitigate this risk is to get the prototype built as soon as possible so that troubleshooting can begin.

A risk to the hardware of the system is the decision for the team to create their own muscle sensor. Should the team decide to take that risk and create their own muscle sensor it will require a large amount of time to be dedicated by the electrical engineers to set up the sensor both physically and in software. It will likely take some time to get the calibration to a point where the readings are fairly accurate. The best way to mitigate this risk is to get the other sensors sorted out first, and then spend the time and attention needed on this sensor, that way if the sensor falls through the rest of the network will not be compromised.

Another risk to the team is the lack of biomedical expertise. The team is well aware that as electrical and computer engineering biology is not their element and that what they plan to develop is undeniably a biomedical project. It is likely that through misunderstanding the team may not take the best routes to sense what they are looking for which could impact project scheduling as they pursue dead ends. To mitigate this risk the team has had multiple consultations with medical professionals and engineers who have agreed to consult with the team for the duration of the project and have even offered test subjects.

2. Competitive Intelligence: Market Analysis

When the idealistic design of a device with near-infinite diagnostic capabilities is incomparable to anything on the market. There exist diagnostic devices and even wearable diagnostic devices but nothing with the range and possibility that the ChronoSTAT has the potential for.

The easiest thing to compare the senior design version of the ChronoSTAT to is the FitBit and other vital monitoring wearable devices. The ChronoSTAT has several advantages over these devices. This includes a greater range of sensors, due to the fact that it currently is planned to work as a specified unit to detect fluctuations of mental health specifically. The greatest advantage that ChronoSTAT has to offer over any competitor is its ability as a learning device. The idea of a vitals monitor that is unique to the biorhythms of the user is something that no product on the market has to offer..

3. Lean Canvas Business Model

The problem addressed by this project is the difficulty people experience in keeping track of physical symptoms and patterns. Identifying patterns in symptoms can be crucial to improving quality of life for someone who suffers from a chronic illness. Ideally, this product would target people with all kinds of different illnesses by having modular sensors that could be used to detect different symptoms. However, for the scope of this project, the illnesses being considered have been limited to anxiety and mood disorders.

The proposed solution is to combine a wearable with a mobile application to ensure a more complete dataset. The initial goal is to have the system be able to correctly classify and warn the user of unusual data readings. In the long term, the system should be able to track and display patterns over time using the mobile application that will be developed.

Applications have been developed to help people keep track of their symptoms. The unique value in this solution is the wearable device, which will allow the user to have access to far more data, and with a more objective perspective. Right now, there are no similar products on the market. The wearable will be available through normal retailers, while the application will be on the Google Play app store. If sufficiently requested, an application may be developed for iOS, but at the moment the development costs are significantly lower for Android.

4. Financial Analysis

The team has not reached the point where a financial analysis is needed

5. Intellectual Property

The team has not yet developed any intellectual property yet.

Section –IV: Results

1. Conclusions

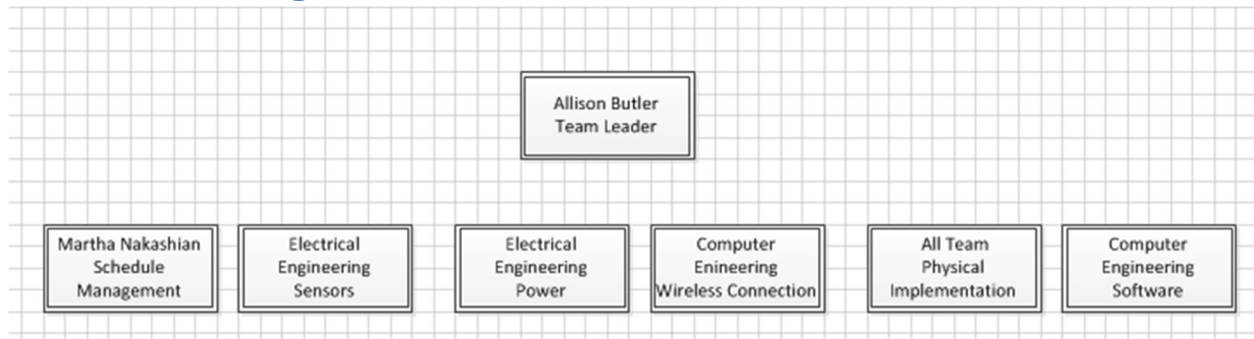
The team so far has done a tremendous amount of research into illness along with symptoms and how to track these symptoms. The team decided to focus on a wearable device that will focus on mental illnesses. This device will collect data and send the information to an application on a smartphone to be analyzed.

2. Recommendations

The team will continue working on researching mental illnesses and corresponding symptoms. The team is recommending a start to preliminary design solutions and evaluations. This will allow the team to stay on track and meet deadlines.

Appendices

A. Team Organization Chart



B. Project Gantt Chart



ChronoSTAT.mpp

C. Data Sheets

Teensy 3.6:

<https://cdn.sparkfun.com/datasheets/Dev/Arduino/Boards/K66P144M180SF5RMV2.pdf>

RedBearLab BLE Nano: <http://redbearlab.com/blenano/>

9DOF Sensor:

https://cdn.sparkfun.com/assets/learn_tutorials/5/5/0/MPU9250REV1.0.pdf

MAXREFDES117

https://www.maximintegrated.com/en/design/reference-design-center/system-board/6300.html/tb_tab1

References

- [1] Goodman RA, Posner SF, Huang ES, Parekh AK, Koh HK. Defining and Measuring Chronic Conditions: Imperatives for Research, Policy, Program, and Practice. *Prev Chronic Dis* 2013;10:120239. DOI:
- [2]"Code Of Federal Regulations (CFR)". *Fda.gov*. N.p., 2016. Web. 12 Oct. 2016.
- [3]"Chronic Disease Overview." *Centers for Disease Control and Prevention*. Centers for Disease Control and Prevention, 2016. Web. 13 Oct. 2016.
- [4] Teensy 3.6. (n.d.). Retrieved December 02, 2016, from <https://www.sparkfun.com/products/14057>