



Senior Design EE/CpE-423/424 Midterm 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.

Figure 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 usgjers 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 to 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.

6. Project Plan

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

Figure 2 Project Schedule

The project is divided into five phases as seen on Figure 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 state 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 Figure 2.

Section –II: Design, Evaluation & Optimization

1. Requirements

ChronoSTAT has several requirements that it needs to fulfil. These requirements include understanding the homeostasis of the end user. With this information it will be able to predict patterns that are out of the ordinary and warn the end user accordingly. ChronoSTAT will also have to be fully environmental resistance so I can work outside and in many conditions that people find themselves in. That being said ChronoSTAT needs to have a long battery life to sustain prolonged activity.

2. Constraints and Assumptions

The constraints on ChronoSTAT are that it has to be a wearable device with no intrusive portions. It also has to be light weight so people don't think they are carrying something heavy around with them all the time.

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 Detail Design

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.

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 figures 3 and 4.

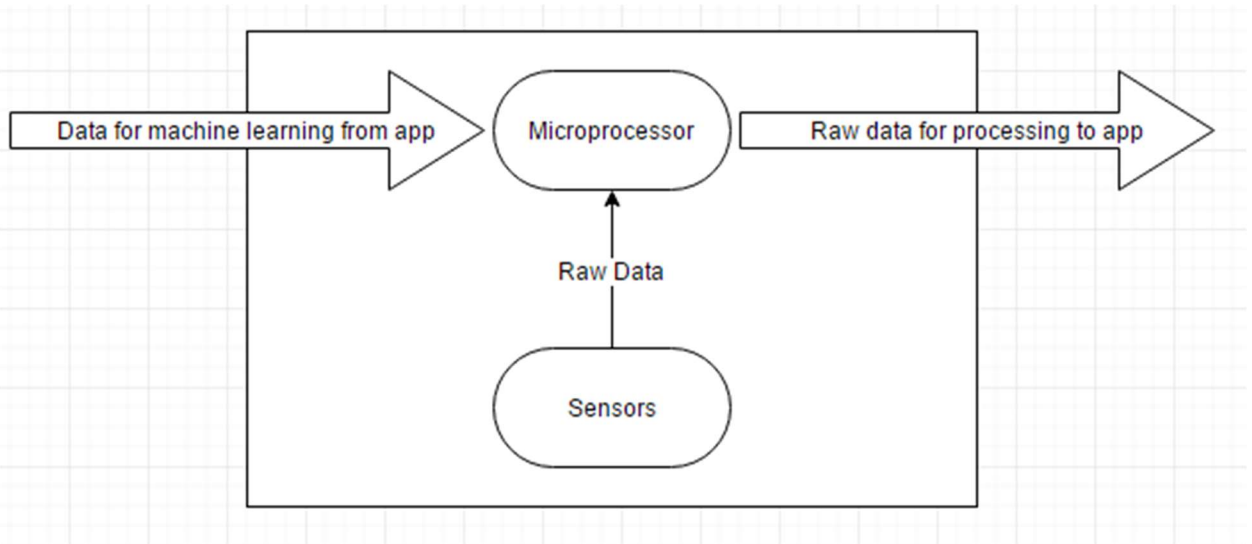


Figure 3 Wearable Device Information Flow

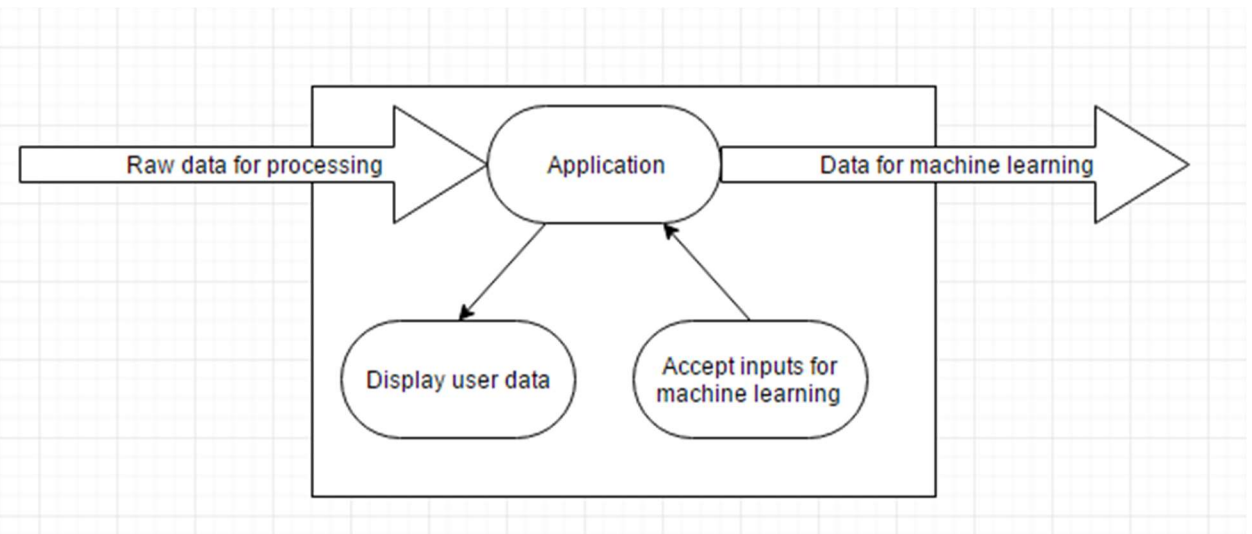


Figure 4 App Information Flow

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.

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.

b. **Physical Prototyping: Plan and Budget**

Because the project still in the concept development phase, there is no physical design yet. This section will be updated in a future report.

c. **Prototype Build and Test Report**

A prototype has not yet been built, so the team has no comments for this section. It will be updated as the project progresses.

7. Design Evaluation Report: Performance, Reducibility and Cost

Once the team begins to build the product, their critique on the physical design will go here. Since there is no physical manifestation of the product at the time the team has no comments to make on the performance, reducibility, or cost of the product.

8. Design Revisions and Optimization

Since the team is still developing the concept of the design, there have been no design revisions to the project as of yet. Once a concept has been settled, the team will begin to design the system. 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.

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.

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, 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 within the given time.

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.

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

Although some research has been done on similar products that exist, the team has found that many of these products are not on the market and available to the public. At this time the team finds it difficult to compare their product to any other that has been developed as the team is still

generating the concept of the product, and therefore even a theoretical analysis is difficult to pin down.

3. Lean Canvas Business Model

Problem:

Chronic illnesses have many associated patterns, but there is currently no passive way to collect data to identify them.

Customer Segments:

The target population segment will ideally be anyone with a chronic illness, or any other reason to find patterns in symptoms. For this project, the target population will be limited to people with anxiety and mood disorders.

Solution:

Combine conventional applications with a wearable device to gather a more complete data set.

Key Metrics:

1. Creating a system to detect abnormalities
2. Creating a system to track abnormalities over time.

Unique Value Proposition:

The combination of a wearable app will allow for a more complete dataset than other systems currently offer.

Unfair Advantage:

Using physical sensors gives us a huge advantage over other products

Channels:

The path to the customer will be through a wearable device with an accompanying application

Cost Structure:

At this point in time, a specific cost structure has not been identified.

Revenue Streams:

Since this project is still in the conceptual development phase, these details have not yet been worked out.

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

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:

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