Emory Periodic Limb Movement Monitoring System

<u>ECE4011 Senior Design Project</u>

Team Name: The Dream Team
Project Advisor: William Smith
Project Sponsor: Emory University Sleep Center

Mauricio Builes Zapata, mbuiles3@gatech.edu
Xavier Williams, xwilliams3@gatech.edu
James Grusy, jagrusy@gatech.edu
Isabel Anderson, ianderson7@gatech.edu

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Executive Summary

The purpose of the project is to improve and design a leg sleep monitor that is capable of detecting and recording continuous movement measurements while the patient is sleeping. Movement is a notable identifier of sleep related disorders, and is specifically relevant to Restless Leg Syndrome. By obtaining leg movements clinical professionals will be able to effectively diagnose and treat patients without the added expense of having them sleep at a sleep clinic. Such measurements will be detected by the use of accelerometers and gyroscopes that yield high quality and precise measurements, in conjunction with a microcontroller to process the raw values and save them into an SD card. The system must be able to record measurements for prolonged periods of time while holding battery charges so that it is viable for the device to be sent to a patient's home and have the data examined. Furthermore, the device must incorporate the Bluetooth communication protocol to transfer the data recorded wirelessly in a convenient medical setting. In order to save battery life, the device will only do this when it detects battery charging, namely using the newly commercially available wireless charging method. The data will then be analyzed and displayed in a custom made GUI. The goal of the project is to be able to incorporate all the aforementioned components into a printed circuit board (PCB) in order for the product to become feasible as a wearable device.

The expected cost of the device is $379. The main drivers for the cost are parts and manufacturing as well as testing and are justified by the compared cost of hosting a person at a sleep clinic overnight.

The expected outcome is that of a comfortable device, fully enclosed, printed circuit board device that is capable of recording and displaying accurate body movement signals that will aid a physician in the diagnosis of a patient’s pathology.

Emory Periodic Limb Movement Monitoring System

1. Introduction

The Dream Team is requesting $98.40 to continue the development of a sleep monitoring device for use in Emory University's sleep research lab. The device will be worn on a patient's leg for up to 5 days during sleep and will collect Periodic Leg Movement (PLM) data. The data will then be wirelessly transmitted to a nearby device (computer, smartphone, etc.) for processing and analysis.

1.1 Objective

The team will continue with the progress made by the previous sleep monitoring team. This will involve microcontroller software enhancement for better battery life, Graphical User Interface (GUI) and data processing enhancements, as well as PCB development. The team will utilize a new microcontroller, the Pyboard, which will be more compact and allow for development in Python. The wireless charger addition will activate the Bluetooth module and automatically connect to a device to begin data transfer. The device will run an application that will collect and render the data for physician use.

1.2 Motivation

This project is a joint effort between Emory University and Georgia Tech. The goal is to produce a sleep monitoring device that can collect and later transmit data that can be used to diagnose sleep disorders related to PLMs which are commonly linked to Restless Legs Syndrome [1]. The device will be used by patients of Emory sleep clinic. Patients will wear the device on their leg for up to 5 days for data collection. This project will improve upon the previous Georgia Tech senior design team's prototype which overall will improve upon an obsolete device. The PAM-RL, the device Emory University currently uses, is no longer on the market and costs approximately $800. The prototype designed by Georgia Tech's senior design team will cost a fraction of that to at $379.

1.3 Background

The original sleep monitoring product that Emory used was the PAM-RL. This device, now obsolete, had cost and performance limitations that affected its usability. The performance issues related to the data transfer and battery life. The battery only lasted for 72 hours and the data transfer took up to 37 minutes.

Previous senior design teams have constructed a prototype that allows for collection of data and Bluetooth transfer of data. The battery life, wireless charging, and GUI improvements have been target points of improvement for the current senior design team. Also, the current team aims to reduce the size of the device to make it unobtrusive and comfortable for patients to wear for long periods of time [2].

To improve upon the current prototype, the Dream Team aims to add further improvements to the GUI and enhance the data rendering capabilities. The Dream Team will use a new microcontroller called the MicroPython Pyboard which will decrease the size and add functionality such as a built in microSD card slot and built in accelerometer.

2. Project Description and Goals

The end goal of this project is to construct a functioning sleep monitor which is to be worn around a patient's leg. The entire monitoring system will be configured in a compact, anklet format. Within the anklet's structure, there will exist gyroscopes amongst sensors which will detect motion of the limbs throughout the day and night. The limb acceleration data will be exported into a corresponding GUI with a user-friendly interface for the clinicians. The device is meant for use only by the clinicians at the Emory Sleep Clinic and will display the collected limb acceleration data in a graphical (time) format. As shown in Table 2, the estimated cost of the equipment needed to fabricate the monitor is $98.40. The main functional goals will consist of the following:

- Data collection software of limb acceleration
- Collected data exportation via Bluetooth
- Wireless inductive charging
- Contained inside a discrete, sealed package
- Battery life of at least 5 days
- Low power "Sleep Mode"
- Contained on a PCB

3. Technical Specifications

TABLE 1

QUANTITATIVE SPECIFICATIONS OF THE PLM MONITOR

Feature	**Specification**
Physical Constraints	
Dimensions	Goal <= 9 cm x 5 cm x 1.5 cm
Weight	Goal <= 65 grams
Software Constraints	
Download Time	< 37 minutes (Lower than the PAM-RL's download time)
Sampling Rate	10 Hz
Durability	
Continuous Operation Time	> 5 days

Table 1 provides a list of quantitative specifications that must be met in order for the device to improve upon the PAM-RL [2]. The Dream Team will be building upon and improving the features that Team Five Year Journey finishes. Below are a list of qualitative requirements:

- Needs to be in wearable form factor.
- Unobtrusive to patient.
- Durable enough to last 5 days without being taken off.
- Completely sealed off and waterproof.
- Display data graphically (GUI).
- GUI will automatically detect patterns when data is loaded in.
- Have various options for filtering data.

- Still provide access to raw data.
- Data cannot be traced back to specific patient by anyone other than doctor.
- System miniaturization onto a PCB.

4. Design Approach and Details

4.1 Design Approach

The Dream Team will be working on the fourth generation of the Periodic Limb Movement monitoring system. During previous semesters, teams have focused on designing the hardware, firmware and software prototypes as proofs of concept for the device. Team Five Year Journey (Spring 2017) is currently working on solidifying the wireless charging capabilities of the device, interfacing with the MicroPython's Pyboard microcontroller in order to save battery life and is currently creating the GUI to interface with the device. Some of the key elements in The Dream Team's design is to optimize microcontroller firmware to allow for sustainable battery performance and data extraction, order, design, and interface with the required components to make wireless charging feasible, miniaturize the system to a printed circuit board since it is currently being prototyped in a breadboard, add features to the GUI as well as implementing pattern detection algorithms to aid in the interpretation of the data collected as well as to provide calibration set points. Figure 1 shows a concept for the design methodology of a miniaturized and fully concealed device.

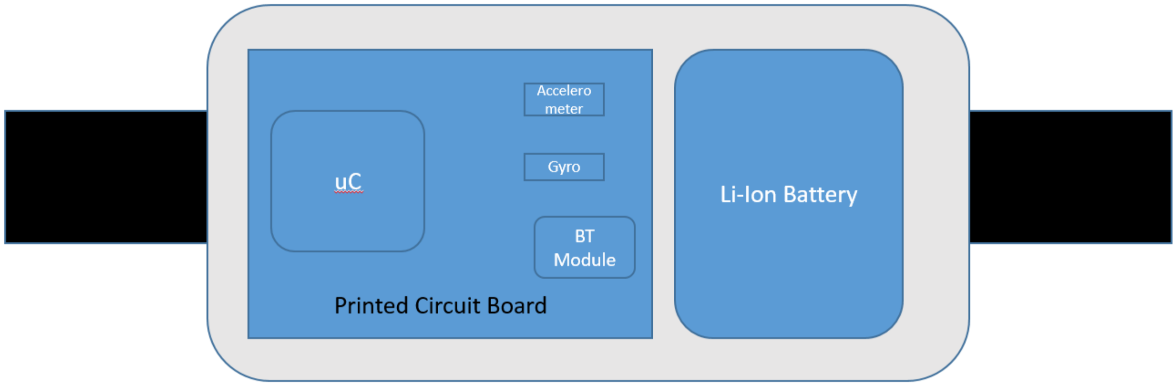

Figure 1. Packaging Schematic for PCB.

The design approach put forward focuses and relies on the team's ability to interface with the already existing components from previous semesters and pick up where the previous team left off. Purchasing or replacing components due to incompatibilities or change in direction from previous teams is a technical critical path limiting factor, as time required to identify, purchase and ship the components will put a halt on progress made in firmware development, as well as system miniaturization and integration as these components will have to be prototyped.

As a parallel task, the necessity to design a printed circuit board with the appropriate dimensions for traces, the correct electromagnetic properties for RF transmissions, the necessary power supply noise reduction as well as proper placement of the components will need to be made. Maintaining good design practices such as 45 degree trace turns, plane assignments for power supplies and grounding are planned to be the norm in the design. The team has two members that have experience with PCB design and relies on their past experiences in order to provide a feasible design with enough time to demonstrate the results.

Furthermore, GUI changes and additions will largely depend on Emory's Sleep Clinic's requests, and design implementations to the GUI will have to accommodate to the sponsor's petitions. Since the GUI is being developed using Octave and QT, and Team Five Year Journey is in the process of generating a code repository to host all the required documentation/versions of the software, The Dream Team's ability to generate change early enough will depend on both the previous' team's ability to create the repository and The Dream Team's ability to get trained and familiarized with the ongoing project. Given the importance of an early start in order to reach the miniaturization stage, the team will commit to understanding the workings of the current development of the summer.

Miniaturizing the system will pose as one of the most challenging aspects of the project. It will require for a stable, reliable and functional prototype that is capable of consistently measuring movements with the added Bluetooth, wireless charging capabilities and battery life efficiencies that are currently being designed and that will probably need refinement by the time The Dream Team starts working on the project. At the same time, the product needs to be consolidated into a small package in order for it to be a feasible device to be worn while sleeping, which is why hardware packaging and miniaturization will remain the main emphasis even if the hardware components have already been selected and tested.

Faults in the design will occur if the components that make up the device pose difficulties in interfacing with each other, if there are code or firmware roadblocks that interfere with the device basic performance, if the GUI presents glitches and finally if the process of miniaturizing the prototype poses new issues to the intended functionality of the device. In order to account for these possible faults, the best course of action is to identify early in the project what the requirements for each component are in both the current prototypes and the planned miniaturized design, and work in parallel with the proposed alternatives to provide a safety net in the implementation.

4.2 Codes and Standards

- Bluetooth Wireless Technology Standard: Communication standard that operates at 2.4GHz bandwidth. Necessary for obtaining the data from the monitoring device into a computer for interfacing and data processing.
    - Provides a unique address in each module that the previous team has taken advantage of as a patient identification number [3].
- Qi Wireless standard: Inductive charging standard being used in the smartphone industry. It is a powerful standard to have due to extensive documentation and proven viability. Will be used due to the monitoring device's necessity to be a fully enclosed product [4].
- QT: Open license GUI development framework which is already being used by the current team and will be maintained as the GUI development tool.
- Octave: Open source scripting and calculation based software with considerable similarities to MATLAB. Current code is being developed using this software by the Five Year Journey Team.
- The IEEE P360 Standard on wearable technology is a current working project by the Wearable Working Group that outlines basic safety and suitableness to wear wearable devices. It provides with technical requirements such as battery duration and optimization that help provide for guidelines in the project's technical considerations [5].
- FCC regulations on class B devices: No radio interference is allowed to happen within a 10 meter radius. Given that the microcontroller and the Bluetooth module are commercially bought, they are already compliant with all necessary regulations [6].
- HIPAA Regulations: Require all information to be encrypted when concerning patient health records [7].

4.3 Constraints, Alternatives, and Tradeoffs

The most notable constraints for the device are those that are characteristic of wearable technology. Size and weight, battery life and efficient data management are constraints that are seen in industry and replicated on the project. Size and weight are factor that limit the comfortability of a monitor being worn on a patient's ankle, and hence need to be kept to a minimum. Battery life is critical in any mobile device, especially for the project's monitor and its intended 5 day on time period of data collection. Given then that battery life and the physical dimensions of the device are pivotal to the design, the data collection needs to be adjusted in such a way that minimizes battery consumption but that is still reliable and accurate enough. Moreover, a simple increase to battery size and charge would increase the size and weight of the device, so an optimal point needs to be found where all three characteristics are at acceptable values.

The device physical properties and layout will be limited by the electronics manufacturing company that will handle the production of the printed circuit board, and design constraints established by PCB manufacturer will be need to be kept under consideration.

Tradeoffs in the project are visible through each of the modules chosen to be part of the device:

- The Bluetooth module is a powerful data transfer tool, however it drains the battery at a much faster rate, meaning it will only be enabled when the device is charging.
- Data sampling will have to be limited in order to preserve battery life. A higher sampling rate will produce a signal with a higher confidence signal however the Teensy 3.2 microcontroller will draw more current at higher sampling frequencies, therefore reducing battery life.
- A larger battery will cause an increase in weight and hence diminish the comfort of the device.

Alternatives for the device include replacing Bluetooth connectivity with a Wi-Fi module, although this poses more complications regarding security issues such as logins and passwords. Further, supercapacitors could be added to the device in order to hold a substantial amount of charge for high demand as they contain higher power densities than batteries. The reason supercapacitors haven't been considered is due to the excess circuitry needed to implement a reliable system around them.

5. Schedule, Tasks, and Milestones

The main tasks in this project will be divided up between two teams, with one team will mainly focus on hardware tasks and the other team focus on software tasks. There will be overlap between the two teams. It will be important for both teams to understand the project from a hardware and software standpoint before the system miniaturization PCB design phase begins. The overall project timeline with the specific tasks, milestones, and critical paths is shown as both a GANTT chart and PERT chart in Appendix B. The PERT displays the critical path with optimistic and pessimistic estimates for the time required to complete each task. Software development will be an important task because it needs to be done before the team starts on the PCB design for system miniaturization.

6. Project Demonstration

The Sleep Monitor prototype will be demonstrated by placing the device on a subject and having them sporadically move over a set amount of time. This will demonstrate the ability for the device to sleep whilst motionless, as well as the ability for the device to wake up and record the motions in real time. The GUI will be viewed to demonstrate the accuracy of the data collection software. The software will be tested in partnership with the hardware for a device calibration. A total of six measurements will be taken to record the corresponding gravitational forces that the sensors are measuring. Each axis of the device will be placed face down to record and determine whether or not the sensors are calibrated (ex. the top of the packaged device should have an equal but opposite gravitational measurement as the bottom of the device). The prototype will subsequently be tested at the Emory Sleep Clinic to investigate the longer-term functions. These lengthier functionalities include a battery life of at least five days, the continual collection and storage of data, and the Bluetooth exportation of said collected acceleration data once the device reaches a certain proximity to a Bluetooth receiver. This calibration check will then be performed once the monitor has been returned to the clinic. This final calibration measurement will used to determine any potential errors or inconsistencies in the collected motion data.

7. Marketing and Cost Analysis

7.1 Marketing Analysis

The target market will be patients of the Emory sleep clinic and any other sleep clinics who currently use the PAM-RL monitoring device. The PAM-RL monitoring device is currently the only comparable device on the market and it is no longer in production. The device proposed will be sold for $379 which is a fraction of the cost of $800 cost of the PAM-RL. In addition, the proposed device will have higher performance specifications with faster data transfer and better battery life.

7.2 Cost Analysis

The total cost for the parts will be approximately $98.40. Table 2 shows a breakdown of the components that will be used in the prototype.

TABLE 2

EQUIPMENT COST.

Product Description	**Quantity**	**Unit Price ($)**	**Total Price ($)**
MicroPython Pyboard lite v1.0 with accelerometer and headers [8]	1	$35.51	$35.51
MicroSD card 32GB [9]	1	$15.99	$15.99
Qi Wireless Charging Transmitter [4]	1	$26.95	$26.95
Bluetooth Module [3]	1	$19.95	$19.95
Total Cost ($)			**$98.40**

The development costs will be approximately $10,898.40. The number of labor hours was estimated based on the Gantt chart in Appendix B. The labor cost was calculated assuming an entry level engineer salary of $40 per hour. There are various software tasks that consume 110 hours in total. The biggest challenge will be in designing a PCB effectively to manufacture the product.

TABLE 3

DEVELOPMENT COST.

Project Component	**Labor Hours**	**Labor Cost**	**Part Cost**	**Total Component Costs**
Software Development				

Data Extraction/Organization	30	$1,200.00		$1,200.00
Pattern Recognition	30	$1,200.00		$1,200.00
Sleep Mode	20	$800.00		$800.00
Testing and Debugging	30	$1,200.00		$1,200.00
Hardware Development			$98.40	$98.40
PCB Design	60	$2,400.00		$2,400.00
Testing and Debugging	30	$1,200.00		$1,200.00
Team Meetings	50	$2,000.00		$2,000.00
Demo Preparation	20	$800.00		$800.00
Total Labor Costs	270	$10,800.00		
Total Part Costs			$98.40	
Total Cost ($)				**$10,898.40**

The total development costs were calculated using a value of 30% for fringe benefits and using 120% for overhead of material, labor and fringe. Table 4 shows the total development costs to be $45,242.88.

TABLE 4

TOTAL DEVELOPMENT COSTS.

Parts	**$98.40**
Labor	**$10,800.00**
Fringe Benefits, % of Labor	$3,240.00
Subtotal	$14,138.40
Overhead, % of Material, Labor, and Fringe	$16,966.08
Total	**$45,242.88**

Assuming a production of 5,000 units, Table 5 shows a breakdown of what the selling price and profit per unit of the device would be. The assembly and testing labor assumes a technician works for 30 minutes assembling the device and 30 minutes testing the device at a pay rate of $20 per hour. The fringe benefits of labor assume the 30% figure used in Table 4. Likewise, the overhead is calculated with the same 120% figure used in Table 4. The sales expense will cover the cost to advertise the product and will represent 4% of the selling price. At a price of $379 per unit, 5,000 units of sale will generate $1,895,000 of revenue. This translates to a profit of $78.90 per unit and $394,000 overall profit.

TABLE 5

SELLING PRICE AND PROFIT PER UNIT
(BASED ON 5,000 UNIT PRODUCTION).

Parts Cost	**$98.40**
Assembly Labor	**$10.00**
Testing Labor	**$10.00**
Total Labor	$20.00
Fringe Benefits, % of Labor	$6.00
Subtotal	$124.40
Overhead, 120% of Material, Labor, and Fringe	$149.28
Subtotal, Input Costs	$273.68
Sales Expense	$16.42
Amortized Development Costs	$10.00
Subtotal, All Costs	$300.10
Profit	$78.90
Selling Price	**$379.00**

8. Current Status

The current status of the project is concentrated in what team 5 Year Journey will be able to accomplish by the end of the Spring 2017. The team has been focusing on finishing a prototype that is able to modulate its sampling frequencies, be compatible with wireless charging and have a functioning GUI that is able to zoom into specific timeframes of the data.

9. Leadership Roles

Team Leader: Mauricio Builes Zapata

Lead Backend Developer: Alan Grusy

Lead Frontend Developer: Xavier Williams

Lead Hardware Integrator: Isabel Anderson

Lead Data Analyst: Mauricio Builes Zapata

Webmaster: Isabel Anderson

Expo Coordinator: Mauricio Builes Zapata

Communications Chair: Xavier Williams

Documentation: Isabel Anderson

10. References

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Appendix A

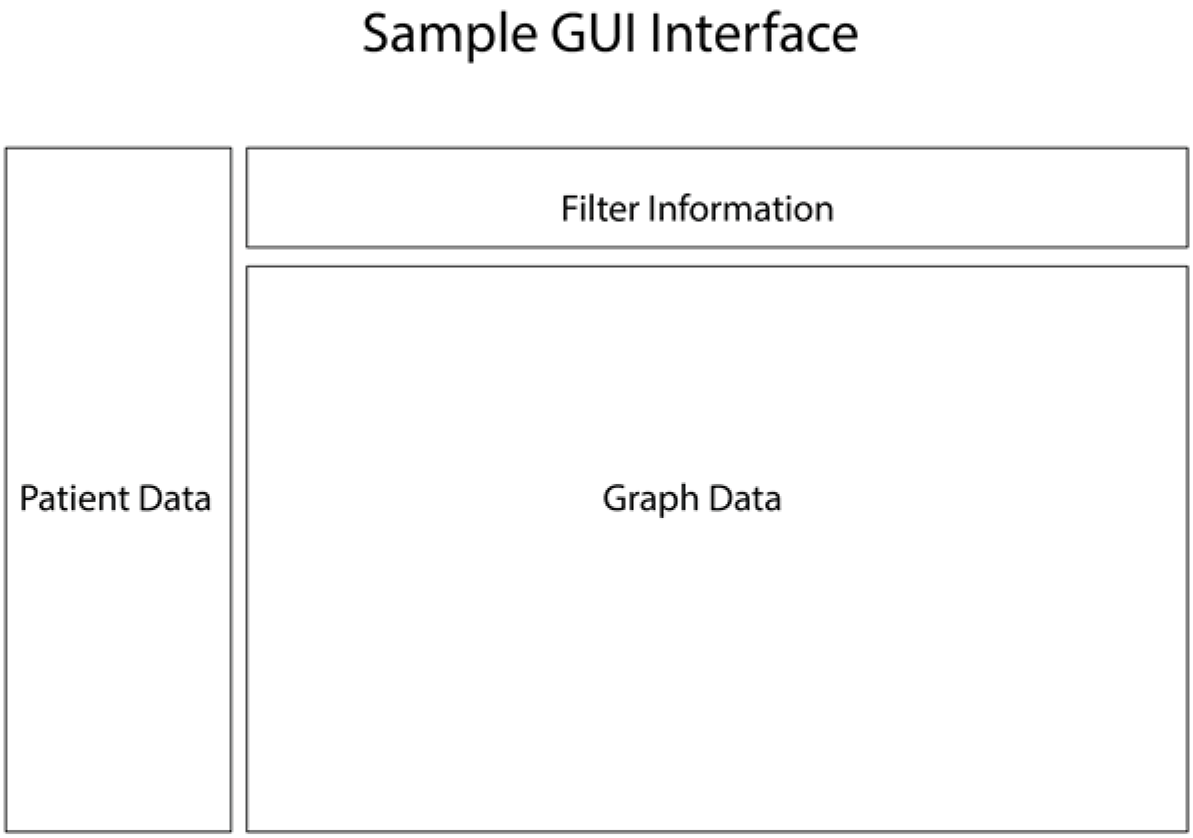

Figure 2. Sample GUI layout.[2]

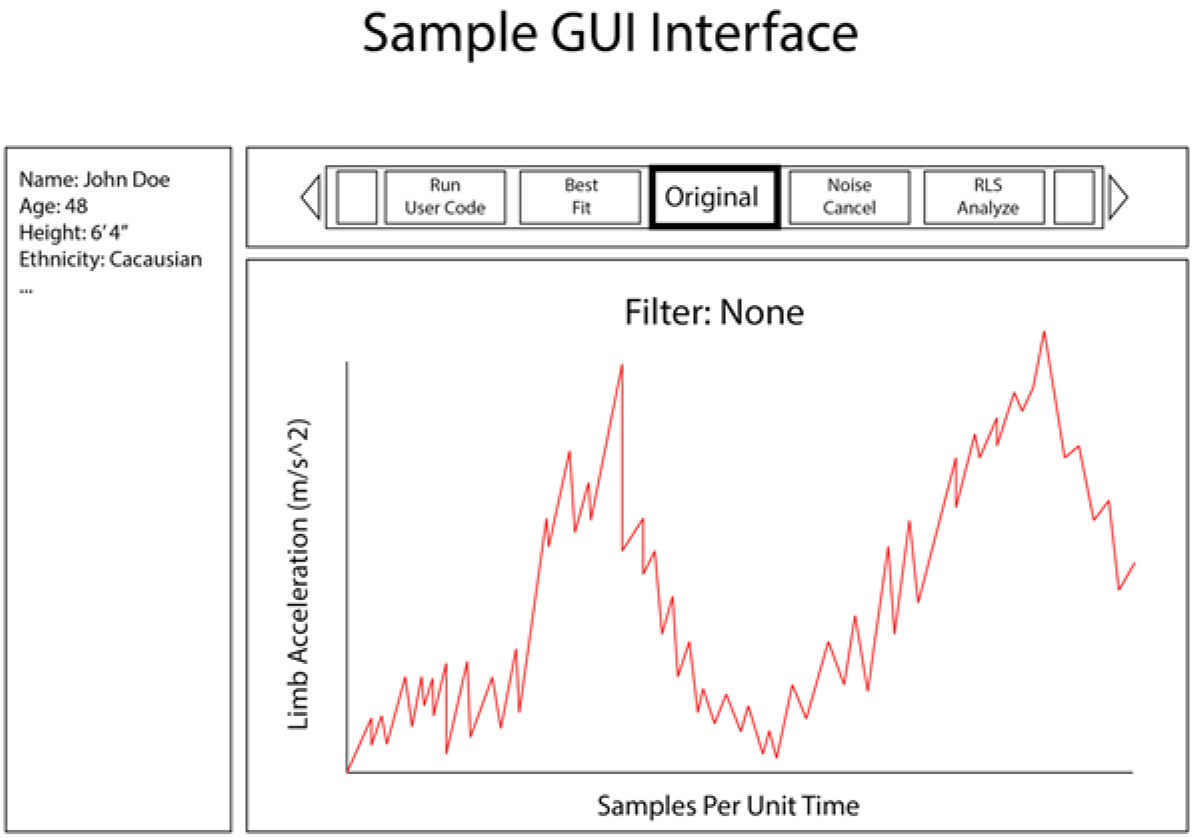

Figure 3. Sample GUI interface with sample data.[2]

Appendix B

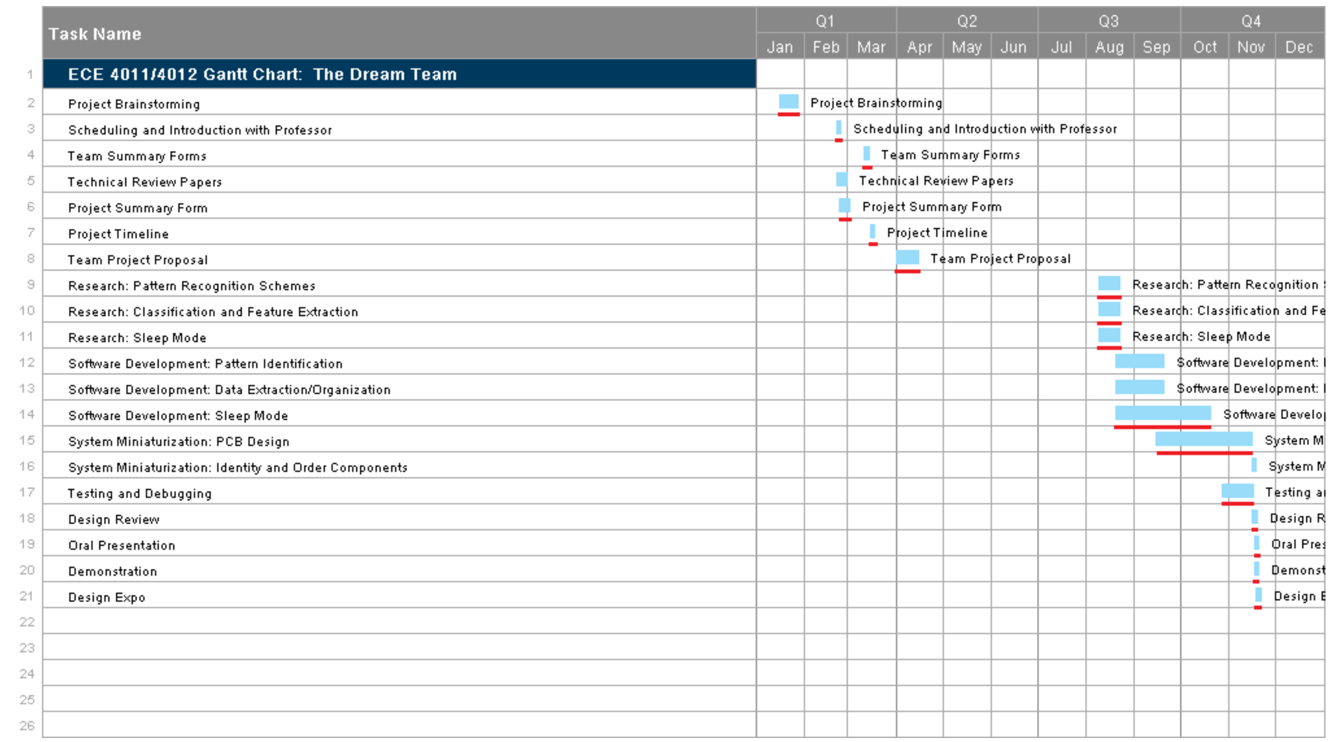

Figure 4. The project schedule in the form of a GANTT chart, the critical path is underlined in red.

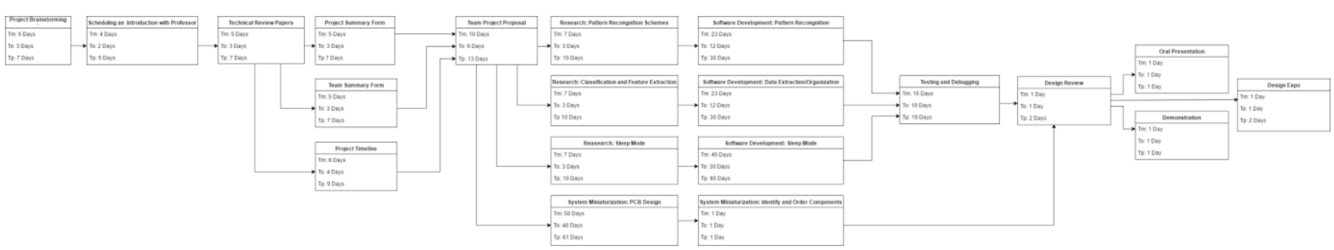

Figure 5. The project's critical path displayed as a PERT chart with optimistic and pessimistic time estimates for each task.