

MedCap with Early Heat Illness Detection

ECE4012 Senior Design Project

MedCap
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Executive Summary

Heat-related fatalities among athletes have more than doubled since 1975. The Centers for Disease Control (CDC) estimates that there is an average of more than 9,000 heat illnesses among high school athletes annually, making it the leading cause of death and disability among high school athletes [1, 2]. The MedCap is an athletic cap fitted with sensors capable of measuring core temperature and mean arterial pressure which are connected to an embedded microcontroller housed on the hat. The MedCap aims to detect an early heat illness related event. The data from these sensors would be transmitted to a smartphone application using the Bluetooth communication protocol. If an early heat illness event is detected, the mobile application shall alert the user. The data shall then be stored in a cloud database and remain available as historical data.

This cap will be marketed to recreational athletes who want to monitor their body metrics and be alerted about potential heat illness. Additionally, the historical data can be used by the medical research field to better understand the physiological parameters and patterns of heat illness.

The sensors monitor core temperature and mean arterial pressure. The software is also capable of capturing the ambient heat index in order to use it as an additional data point. This data shall be compiled and used by a software algorithm to calculate whether the wearer is experiencing an early heat illness event. The algorithm shall compare real-time sensor data to predetermined temperature and artery pressure thresholds based on wearer characteristics (e.g. age, height, weight).

MedCap aims to reduce deaths due to heat-related events by identifying early heat illness events and notifying the user. Once the user is notified, he or she will be able to take steps to cool down including drinking water and leaving the direct sunlight.

MedCap with Early Heat Illness Detection

1. Introduction

Team MedCap shall develop a wearable device capable of detecting and alerting for early heat illness. The hat shall be accompanied by a data processing framework and user interface design to store, analyze, and present health data to the user. The team is requesting \$180.25 (see Table 5) to create a prototype of the product.

1.1 Objective

The team shall design a hat that captures relevant data metrics from the human body in order to detect early heat illness in recreational athletes. An infrared thermometer shall measure the body's core temperature from the ear cavity, and a pulse oximeter shall be used to measure mean arterial pressure directly under the temples of the head. These two measurements shall be combined with the heat index of the area in a weighted average in order to provide a reliable means of detecting heat related health issues in near real-time. The measurements shall be gathered by a microprocessor and sent via a Bluetooth communications device to a smartphone nearby. The smartphone shall then send the data to a cloud data analytics framework and the analytics shall store and return processed data back to the smartphone. The phone shall then display the data graphically as well as tabular form via a mobile web application.

1.2 Motivation

Heat-related illness is responsible for thousands of hospital visits annually by young athletes. In

fact, the leading cause of death and disability in high school athletes is due to heat-related illnesses. Heat-related fatalities that occurred during sports have more than doubled since 1975. The largest demographic group for heat-related illnesses is the youth. The youth account for approximately 47.6% of all heat-related illnesses. In fact, the Centers for Disease Control (CDC) estimates that there is an average of more than 9,000 heat illnesses among high school athletes annually [1, 2].

Heat illness manifests itself in three ways, in order of increasing severity: heat cramps, heat exhaustion, and heatstroke. Severe heat illness is largely preventable given enough warning and assuming precautionary measures are taken, however the market for a suitable wearable device which detects early heat illness is sparse.

1.3 Background

Wearable technology is rapidly becoming an integral part of modern society. Companies like Apple and Fitbit have developed wrist devices that contain a variety of functions from messaging and checking email to monitoring sleep cycles and heart rate. Professional sports teams in particular have embraced the idea of wearable technology to monitor and improve performance among their athletes. The most popular wearable device manufacturer on the market is currently Fitbit [3]. The Fitbit Charge 2 base model monitors heart rate, sleep patterns, cardio fitness levels, and provides call and text alerts.

Another, less popular wearable device is the LightBEAM Smart Hat. This hat monitors heart rate, steps taken, and number of calories burned and can transmit that information to a smartphone app or even another wearable such as a smart watch; it is also hand washable and weather tolerant [4].

A different Smart Hat website shows plans for the design of a smart helmet for cyclists. The

planned functionality includes a display with GPS and proximity sensing, as well as heart rate and temperature monitoring. It also has safety features such as brake lights and impact protection [5].

The key building blocks for the development of this technology are the: sensors, microprocessor, communications platform, data analytics framework, and user interface. The team has conducted research in these areas in order to gain an understanding of the current state-of-the-art technologies under each category. This information has been used to select the most appropriate and efficient platforms for the MedCap project.

2. Project Description and Goals

The main objective of the MedCap is to provide the ability to detect a heat related illness early in recreational athletes. The system consists of several sensors attached to a microprocessor housed in an everyday baseball hat. The sensors include an analog front end pulse oximeter, infrared thermometer and an accelerometer. Features include:

- Real-time dynamic sensing of chosen physiological parameters
- Risk evaluation for a heat-related illness
- UI interface that allows for real time data and risk monitoring

3. Technical Specifications

The MedCap requires many design components which can be grouped into four major subsystems: Processing and Communications, Infrared Thermometer, Analog Front End Pulse Oximeter, and Data Processing and Software. The features listed in Tables 1-3 below show quantitative measurements, while Table 4 displays qualitative choices for the Data Processing and Software components of the design.

Feature	Specification
Microcontroller Voltage [6]	2.1-3.6 V
Microcontroller Operating Frequency [6]	16 MHz
Microcontroller Flash Memory [6]	128 kilobits
GPIO Availability [6]	0-7 pins
Battery Module [7]	2-3 V
Bluetooth Frequency Range [8]	2.400-2.485 GHz

Table 1. Processing and Communications Specifications

Feature	Specification
Resolution (bits) [9]	10
Output Channels [9]	1
Operating Voltage Range [9]	3-5 V
Cord Length [9]	24 in.

Table 2. Pulse Sensor (PPG) – SEN-11574

Feature	Specification
Operational Voltage [10]	2-3 V
Outside Temperature Range [10]	-40 to 80 Celsius
Object Temperature Range [10]	-70 to 380 Celsius

Table 3. Infrared Thermometer - MLX 90164

Feature	Specification
Data Transfer from App to Cloud Service	JSON
Data Transfer from Microcontroller to App	Bluetooth
UI/UX Components	React Native Built-In Components
Cloud Data Storage	Amazon DynamoDB
Heat Index Data	AccuWeather API

Table 4. Data Processing and Software Specifications

4. Design Approach and Details

4.1 Design Approach

4.1.1 Product Design

The MedCap shall be based on the classic baseball cap-style hat design. A 3-D printed apparatus shall be mounted to the side of the hat to allow positioning of the sensors over the wearer's ear. Wires will go through the cloth of the hat and into a compartment just above the bill, containing the battery, microprocessor, and accelerometer.

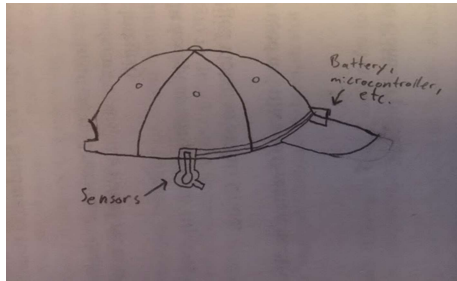


Figure 1. Side view of MedCap prototype concept.

4.1.2 Sensors

The system will detect and evaluate conditions for heat illness using three sensors. The first sensor will be the SEN-11574 (see Appendix A) Pulse Sensor for pulse oximetry. This sensor uses a filter and an amplifier to normalize the signal around a reference point. This makes the peaks and troughs easier to identify. The goal of the SEN-11574 is to take the photoplethysmography technique which is normally used to measure oxygen saturation in the skin, and instead use it to measure mean arterial pressure [9]. The SEN-11574 will be mounted on the side of the head using a 3-D printed apparatus. This is to ensure accurate local temporal artery pressure measurements.

The other sensor will be an infrared thermometer, the Spark fun MLX90614 (see Appendix B) [10]. This sensor will be mounted in parallel with the SEN-11574 and directed into the ear. Having the MLX90614 taking temperature readings in the ear canal allows for non-invasive core temperature readings.

After the two sensors are mounted, their ends will be soldered to wires and connected to a microprocessor located on the brim of the hat. The wires will be electrically taped and shielded using electrical shrink wrap. This is to isolate the circuit as much as possible from the body, reducing the risk of an unexpected wire-body coupling.

The MedCap will be used in the field, giving rise to the need for dynamic physiological measuring from devices. To combat movement artifacts as much as possible, an accelerometer will be included in the brim along with the microprocessor; the team has chosen the three axis accelerometer, LIS3DH (see Appendix C). The LIS3DH will control the rate at which the microcontroller will pull data from the sensors. If the LIS3DH detects that the user has stopped moving, the microprocessor will pull data and begin the signal processing and data beaming.

The final parameter used in the device will be local heat index. The heat index will be pulled using locality services on the paired Bluetooth phone and will be used in the evaluation of a heat-related event.

4.1.3 Microcontroller and Communications

The team has selected the RFduino Simblee DIP as the microcontroller for the MedCap. The RFduino is approximately the size of a quarter and can handle between 2.1V and 3.6V. It has a Bluetooth 4.0 Low Energy module built in. Additionally, the RFduino has seven GPIO ports which can be used to connect to the sensors monitoring the user [6].



Figure 2. Top view of the RFDuino microcontroller showing the available pins (e.g. GPIO) [6].

The microcontroller will be powered by a 3V coin battery (part number CR2032) which is easily accessible by the end user. The battery power will power the microcontroller through the RFDuino CR2032 Coin Battery Shield [7]. The hardware modules are dual inline package and therefore can be wired and soldering together in order to make electrical connections.

The microcontroller and the associated hardware (e.g. battery module) will reside inside the bill of the MedCap. Since the RFDuino microcontroller and the battery module are both about the size of a quarter [6, 7] they should be able to easily fit within the lining of the cap. The wires will all be insulated as well as all the electronics will be covered in waterproof plastic in order to protect the hardware from the user's perspiration. The battery module has a power switch that can be mechanically extended to reach the outside of the hat, so the user can control when the MedCap is operating.

The microcontroller will be programmed using the RFDuino IDE. It will be programmed in a language which is similar to C/C++ [11]. The program will have to sample the accelerometer in order to determine when the user is not moving. Movement causes extreme inaccuracies in the measurements which is avoided by taking measurements only when

the user is not moving. The program will then sample sensors signals every 30 seconds the user is not moving, and the data will then be transferred through the built in Bluetooth module to the user's cell phone. The Bluetooth module will have to pair with the user's cell phone before any communication can occur. Once the cap and the cell phone are paired, the data can then be transmitted using Bluetooth protocol from the microcontroller to the cell phone.

4.1.4 Data Processing

After receiving packets of sensor readings from the MedCap, the Bluetooth paired smartphone shall upload the data packets to the Amazon DynamoDB database tables allocated for preprocessed data storage. After the data sets are available in the database, the data analytics platform, powered by Amazon EC2 Compute services, shall perform calculations on the captured data. The algorithm shall be a weighted average of the three gathered metrics: mean arterial pressure, core temperature, and relative heat index. The varied weights allow for highly correlated metrics to have a greater impact on the prediction of heat illness. The metric offering the greatest correlation to heat illness is the mean arterial pressure, and the second most correlated factor is body core temperature. The heat index carries the least weight since an increase in heat index does not directly correlate with an increase in likelihood of heat illness.

Before utilizing the weighted function to determine heat illness, the data must first be converted to likelihoods based on the acceptable thresholds. Since each of the three variables has acceptable thresholds, the recorded values will be measured based on these thresholds, and the severity of each value will be recorded as a number within a discrete range. The function relating the raw data to finalized heat illness likelihood is as defined in Equation 1:

$$\begin{aligned}
& \text{weights: } 0 < w_3 < w_2 < w_1 < 1 \\
& m_1: \text{mean arterial pressure} \\
& m_2: \text{core temperature} \\
& m_3: \text{heat index} \\
& \sum_{i=1}^3 w_i * m_i
\end{aligned}$$

Equation 1. Definition of the weighted average to calculate likelihood of heat illness.

4.1.5 User Interface

The mobile application will be built using React Native, a free and open-source framework designed by Facebook to allow developers to build native applications using ReactJS, and will be targeted for both Android and iOS markets. The application will leverage open source React-Native Bluetooth libraries to gather data from the microcontroller and sensors. Upon receiving this data, the data shall be transferred to a cloud service via API requests. The data shall be processed using the data analytics provided by the cloud service and sent back to the application. The application shall consume this data and present it in an informative, easy to use, and intuitive manner to the user as shown in Figure 3.

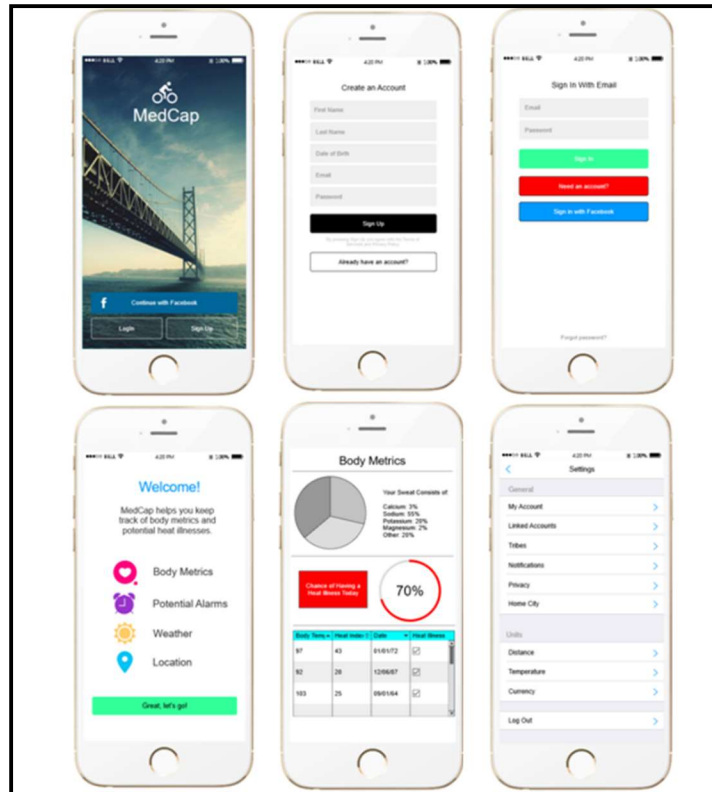


Figure 3. Candidate UI diagrams for MedCap.

The mobile application development process will consist of three stages:

1. Frontend – Bluetooth Integration and UI
2. Backend – Connection with Cloud Services
3. User Profile – Facebook or Email Login

4.1.6 Critical Path

The critical path, as shown in the PERT chart in Appendix E, is almost identical to the entirety of the PERT chart itself, with one exception. The critical path would separate when testing and building the hardware and software components, respectively. Equal time has been

allotted for the hardware and software branches of the chart, however practical variance in either branch would define the critical path as the longer of the two branches. In the case that one of the two branches requires more time, the 40 day buffer period before the Capstone Expo would be used as contingency to ensure sufficient completion time.

4.1.7 Success Criteria

The user shall wear the MedCap and obtain body metrics, open the MedCap mobile application on a mobile phone, and remain within ten meters of the device to listen for any warning notifications. The communication protocol has the ability to reach 100 meters to accommodate long-range activities. Based on power consumption, the batteries shall last 9 hours. As with other standard commercial devices, the operating temperature range shall be between 0°C and 70°C. These are the input requirements of the system. The system shall analyze the data gathered from the user by taking PPG measurements and from the PPG waveform the analysis platform shall estimate systolic and diastolic blood pressure by contour analysis [12]. Changes in blood pressure will correlate to changes in mean arterial pressure and be used along with core temperature measurements and local heat indices to determine whether a heat stress event is imminent.

The system shall then output visual and audible indicators of the user's level of heat stress, placing the data in distinct green (good/stable), yellow (warning), and red (danger) regions. The system shall notify the user of a dangerous level of heat stress by additionally giving audible signals from the mobile phone. A graph shall also be displayed in the MedCap mobile application to track trends in levels of heat stress, and a database shall be populated with historical data for analysis.

The MedCap mobile application shall have adjustable thresholds to allow the user to adjust the green, yellow, and red heat stress regions for various levels of alerting. These thresholds shall be predefined and set to default expected values with the option for the user to adjust the alerting sensitivities and the thresholds of the three stress regions.

If time permits we will accomplish the following tasks. The MedCap itself will be able to directly alert the user after two-way communication is available between the mobile phone and the cap. Also, the data on the cloud will be encrypted for safety. A login to access the data will be protected with two factor authentication. Additionally, the Bluetooth pairing will be restricted so that only the cap and smartphone can transmit data.

If the team were to bring this device to market, it would require FDA approval as a Class II medical device.

4.2 Codes and Standards

IEEE 802.15.1 is the standard which governs Bluetooth wireless communication between the embedded processor and mobile device. Bluetooth networks can include one master device and up to seven slave devices. Also, Bluetooth networks traditionally have a 100 meter range for data transfer. Unlike other wireless protocols (e.g. Zigbee) Bluetooth does not occupy the WiFi signal. This allows data to be received from the MedCap through Bluetooth and transferred to the data processing cloud through the WiFi/4G network communication [8].

4.3 Constraints, Alternatives, and Tradeoffs

There were two communication technologies that were considered in order to transmit data between the microprocessor and the external mobile device. These two communications were Bluetooth and Zigbee. Zigbee is able to transmit data over longer distances while Bluetooth traditionally limited to 100m. Bluetooth connects to smartphones through Bluetooth module that is pre-installed in most current smartphones. Zigbee connects to the smartphone through the WiFi adapter. If Zigbee is occupying the WiFi connection, the software will not be able to relay the data up to the cloud for data processing and storage through the WiFi communication. Bluetooth, on the other hand, can receive data from the MedCap while leaving the WiFi network open to transmit data to the cloud. Due to the connectivity constraints Zigbee would place on the design, Bluetooth was chosen even with its limited communication range.

A tradeoff between the physical size of the microcontroller hardware and the amount of data the MedCap can collect from the wearer arises due to the available space in an athletic hat. While the algorithm will be more accurate with more input parameters, there is not enough space in the hat for the sensors nor are there are enough I/O pins in a small microcontroller for these sensors to connect to

the microcontroller. Because smaller size is more important than a surplus of sensor readings, only a few sensors will be used.

5. Schedule, Tasks, and Milestones

The Gantt Chart in Appendix D gives a specific timeline for tasks to be accomplished by the team over the rest of this semester and next semester. Task lengths have been assigned according to the estimated complexity. Project deliverables such as presentations and papers shall be completed collaboratively by all team members. Research has been completed by each individual group member, and two sub-teams have formed to make development, testing and prototyping modular. One sub-team is responsible for designing and building the cap hardware system, and the other team shall be responsible for most of the software development, including UI development and data processing.

The PERT chart in Appendix E gives the critical path, which was estimated to be 165 days. This timeline allows for significant delay in part delivery and testing and also includes Christmas holiday. The most difficult part of the design will be the correct choice of sensor for detecting early heat illness. None of the team members has a background in biology or medicine, so choosing an appropriate sensor requires significant front-end research.

6. Project Demonstration

The MedCap shall be designed to detect early heat illness while the wearer is participating in physical activity. The following steps will be followed using either a prototype or the final product. In order to create the appropriate conditions for testing, the user will do the following:

1. The user shall turn the MedCap on.
2. Then the user shall put the MedCap on his or her head with the bill facing forward and pull the cap down until it touches the ears. Also, the user must ensure the ear piece fits snug to the ear lobe and sits across the ear opening. This ear fitting will allow for accurate readings.



Figure 4. Model shows proper fit of a baseball cap [13].

3. Either the user or a spectator shall enable the Bluetooth connection on his or her cellphone, pair with the MedCap, and open the mobile application.
4. The user will then participate in an outdoor physical activity. An example activity would be a recreational soccer game.

In order to see results, the user will have to participate in enough activity such that his or her vital signs (core temperature and arterial pressure) rise to the point the algorithm determines an early heat illness warning. When this occurs, the mobile application shall alert the user. During the time the mobile application is receiving data, it stores these readings in a database that the user can access later. This historical data can be used at a later time.

The project specifications will be met if the user's vital signs exceed the limit, the user exhibits symptoms of early heat illness, and the mobile application notifies the user of the early heat illness. Symptoms of early heat illness include fatigue, nausea, headache, cramps, drenching sweats, dizziness and fainting [14]. Additionally, the project specifications can fail to be met if the user experiences a heat illness event but the mobile application does not notify the user before it occurs. The other requirement is that historical data is stored. If the user is able to navigate the mobile application and display the historical data, then this specification will be met.

7. Marketing and Cost Analysis

7.1 Marketing Analysis

The market for wearable devices is growing rapidly, but is still relatively small and dominated by only a few products that do not have the same functionality as the MedCap. The MedCap will be marketed to athletes who are concerned about the possibility of heat illness. This device will be unique because there are no other retail products with the capability to warn an athlete about impending heat stroke. The LightBEAM SmartHat costs \$99.90 but it only provides fitness data [4]. Typical consumer wearable devices range from about \$90 to about \$500 for very high-end models with extensive functionality.

7.2 Cost Analysis

The total component cost for a single MedCap prototype is approximately \$180.25. Table 5 displays detailed information about the cost per component. The most expensive items are the RFduino processor and the accelerometer, while the least expensive items are the watch batteries to power the device.

Production Description	Quantity	Unit Price	Total Price
Cap	1	\$10.00	\$10.00
RFduino Simblee DIP	1	\$30.00 [6]	\$30.00
RFduino Coin Battery Shield	1	\$17.00 [7]	\$17.00
USB Programming Module	1	\$26.00	\$26.00
Watch Battery	2	\$7.00	\$14.00
Infrared Thermometer	1	\$20.00	\$20.00
Pulse Oximeter	1	\$8.25	\$8.25
Accelerometer	1	\$30.00	\$30.00
AWS Subscription	1	\$25.00	\$25.00
Total Costs			\$180.25

Table 5. Component Costs for Prototype

Table 6 shows development costs for MedCap, calculated for labor costs of \$40 per hour. The assembly of all hardware and software components on the final cap requires the largest time commitment due to sizing and fitment constraints for the user and for the peripheral devices on the cap. Conversely, the Bluetooth integration will require the least time commitment as the microcontroller encompasses the communications technology and would simply require setup.

Project Component	Hours	Labor Cost
Product Design		
Assembly	100	\$4,000.00
Testing	40	\$1,600.00
Microcontroller/Communication		
Algorithm Coding	45	\$1,800.00
Sensor Integration	35	\$1,400.00
Bluetooth Integration	25	\$1,000.00
Testing and Debugging	40	\$1,600.00
Sensors		
Signal Extraction	20	\$800.00
Signal Filtering	50	\$2,000.00
Testing	40	\$1,600.00
Data Processing and User Interface		
Data Processing	30	\$1,200.00
App Development	50	\$2,000.00
Testing	40	\$1,600.00
Total Labor	515	\$20,600.00

Table 6. Development Costs of Prototype

The fringe benefit is calculated as 30% of the total labor, and the overhead is calculated as 120% of the material, labor, and fringe costs. The total development cost of the prototype is \$59,312, and all total cost information is displayed in Table 7.

Item	Amount
Parts	\$180.25
Labor	\$20,600.00
Fringe Benefits, % of Labor	\$6,180.00
Subtotal	\$26,960.25
Overhead, % of Matl, Labor & Fringe	\$32,352.30
Total	\$59,312.55

Table 7. Total Development Costs of Prototype

The production cycle for MedCap will yield 5,000 units over 5 years, to be sold at a price of \$400 per unit. The parts production will be purchased with a 40% discount, reducing the parts cost from \$180.25 to \$108.15. Additionally, advertising accounts for 6% of the sale price, while the profit margin is 8.07% of the sale price; the expected revenue is \$2,000,000 for the 5 year production run. Table 8 displays the details for the 5,000 unit production cycle.

Expense or Income Component	Dollar Amount
Parts Cost	\$108.15
Assembly Labor	\$20.00
Testing Labor	\$10.00
Total Labor	\$30.00
Fringe Benefits, % of Labor	\$9.00
Subtotal	\$147.15
Overhead, % of Material, Labor, & Fringe Benefits	\$176.58
Subtotal, Input Costs	\$323.73
Sales Expense	\$24.00
Amortized Development Cost	\$20.00
Subtotal, All Costs	\$367.73
Profit	\$32.27
<i>Selling Price</i>	\$400.00

Table 8. Price and Profit per Unit (Assuming 5,000 Unit Production Cycle)

8. Current Status

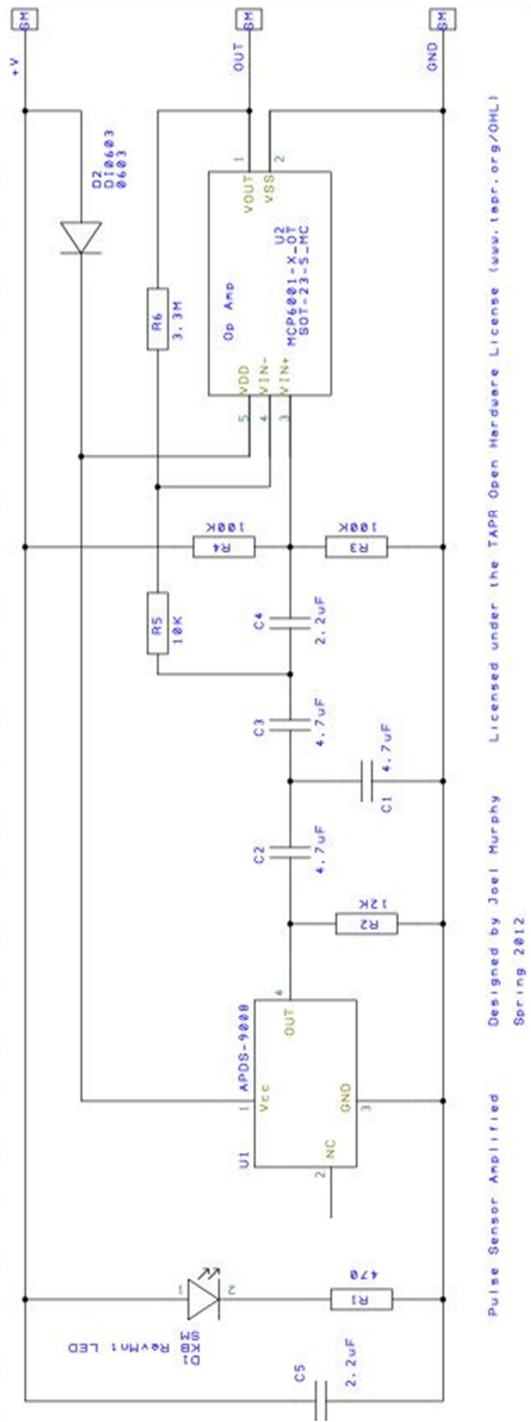
Currently, the team has identified all parts, components, and software development kits needed for the development of the cap. However, the team is awaiting confirmation of the project scope to begin ordering the components. The team has also conducted research to determine several effective methods of gathering and processing body metrics in order to determine and correlate heat illness events. Lastly, the designs of the physical device and the mobile application have taken shape. As the designs are finalized and the parts arrive, the team will begin the process of integrating subsystems, assembling, and prototyping the device.

9. References

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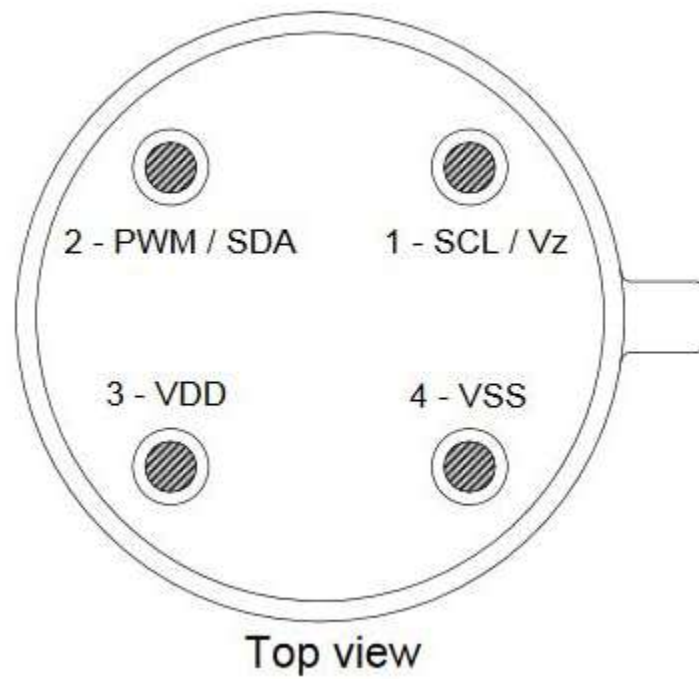
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Appendix A – SEN-11574 Schematic (Pulse Sensor) [9]

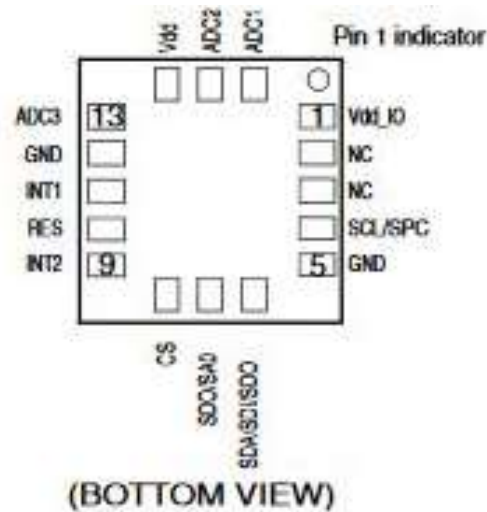


Pulse Sensor Amplified Designed by Joel Murphy Licensed under the TAPR Open Hardware License (www.tapr.org/OHL)
Spring 2012

Appendix B – MLX90614 Pinout (Infrared Thermometer) [10]



Appendix C – LIS3DH Pinout (Accelerometer) [15]



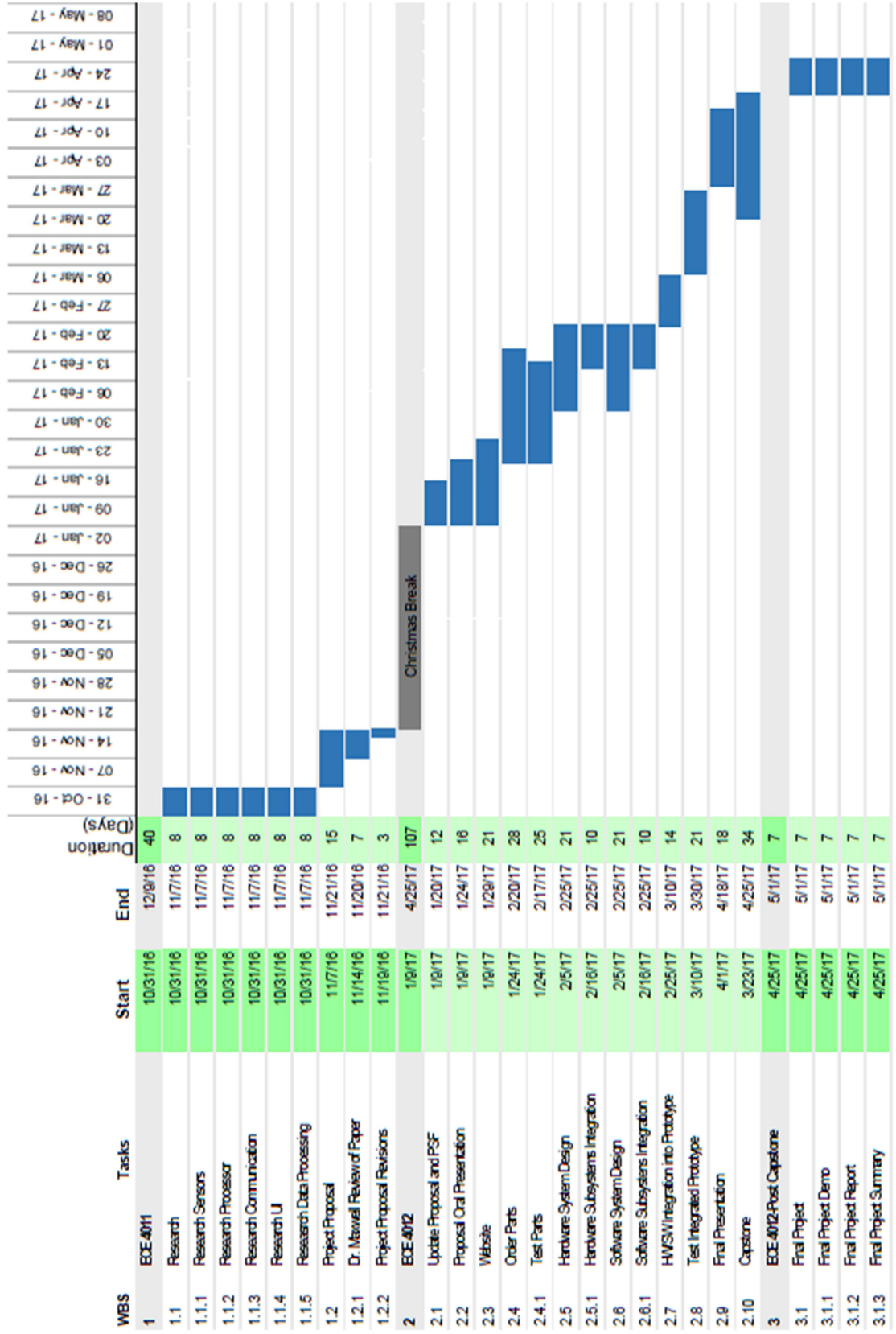
Pin#	Name	Function
1	Vdd_IO	Power supply for I/O pins
2	NC	Not connected
3	NC	Not connected
4	SCL SPC	I ² C serial clock (SCL) SPI serial port clock (SPC)
5	GND	0V supply
6	SDA SDI SDO	I ² C serial data (SDA) SPI serial data input (SDI) 3-wire interface serial data output (SDO)
7	SDO SA0	SPI serial data output (SDO) I ² C less significant bit of the device address (SA0)
8	CS	SPI enable I ² C/SPI mode selection (1: I ² C mode; 0: SPI enabled)
9	INT2	Inertial interrupt 2
10	RES	Connect to GND
11	INT1	Inertial interrupt 1
12	GND	0 V supply
13	ADC3	Analog to digital converter input 3
14	Vdd	Power supply
15	ADC2	Analog to digital converter input 2
16	ADC1	Analog to digital converter input 1

Appendix D - Project Gantt Chart

See next page for project Gantt Chart

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Start Date: 10/31/2016 Monday



Appendix E - PERT Chart

See next page for project PERT Chart

