Sleep-Monitoring Mask and Smart Alarm

Interdisciplinary Senior Design Project Proposal



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Executive Summary

The REM "Ready Every Morning" Mask is a sleep-monitoring device that actively senses the user's sleeping patterns, ultimately employing this data in the implementation of a smart alarm clock. The alarm maximizes the user's quality of sleep by waking them up at an individualized time when they are scientifically proven to feel the most energetic and refreshed.

Problem: The human body passes through multiple sleep cycles during a normal night of sleep. Waking up after rapid eye movement (REM) at the end of the cycle, when sleep is lightest, results in individuals awakening feeling the most well-rested. The sounding of an alarm when an individual is in a deeper state of sleep leads to *sleep inertia*, or grogginess and difficulty waking up. According to Valley Sleep Center, "there is a 45% chance that a fixed-time alarm clock will wake one up from REM sleep, and a 49% chance from non-REM sleep, [resulting in] sleep inertia... [Thus,] there is only a 9% chance [of being] awakened by alarm at the optimal moment of sleep stage transition" [1]. Sleep stages vary widely from person to person, so no single timing of sleep is suitable and healthy for everyone.

Solution: Modern smartwatches can track sleep, but these are unspecialized devices; their primary purpose is not sleep-tracking, and they use indirect, inaccurate methods such as heart rate data to make inferences about a user's sleep. Polysomnography techniques (involving electrode measurements on the head), although very accurate, are expensive, onerous to operate, and often require sleeping in unfamiliar environments that themselves can inhibit natural sleep. The REM Mask – employing a subset of polysomnography methods called electrooculography (EOG) – acts in the balance of these two extremes by filling the need for a specialized sleep-monitoring device that is both comfortable and

accurate. Thus, this solution is unique from existing market solutions in two key ways: it both can **accurately** identify sleep stages (ie. end of REM sleep) as well as actually **make use of the data**, benefiting users with "better" sleep.

Proof of Function: Proving the efficacy of the REM Mask is essential to its success. In this regard, there are three primary that must be met:

- 1) Prove that the device can *accurately* record the user's EOG data.
- 2) Prove that the integrated software can recognize REM sleep from the EOG data.
- 3) Prove via customer surveys that the device fulfills its goal of maximizing quality of sleep.

Project Scope: The REM Mask targets any and all individuals who need to wake up at a specific time but also want to prioritize their sleep (eg. students, workforce). The end goal is to provide users with a product that maximizes the quality of their sleep without jeopardizing the timeliness of their waking up, ultimately serving as a product that one can wear to sleep every night.

Proposed Cost: The estimated **total prototyping cost is \$270.08** (for four prototypes). On top of this, total projected labor costs (\$37,500.00) and five-year manufacturing costs (\$2,424,998,540.00) are also considered. Given these costs as well as the projected product sales revenue over five years, team Tired Techies expects **\$49.04 net profit per unit sold**, or 32.7% in expected profit, a **48.58% return on investment (ROI)** over the project timeline, and an 8.24% annualized ROI.

Acronyms and Nomenclature:

- AFE Analog Front End
- BLE Bluetooth Low-Energy

BOM	Bill of Material
CAD	Computer-Aided Design
DC	Direct Current
DMM	Digital Multimeter
EEG	Electroencephalography
EMG	Electromyography
EOG	Electrooculography
FCC	Federal Communications Commission
FDA	Food and Drug Administration
GUI	Graphical User Interface
I2C	Inter-Integrated Circuit
IC	Integrated Circuit
IEC	International Electrotechnical Commission
IMU	Inertial Measurement Unit
LDO	Low-Dropout Regulator
MCU	Microcontroller unit
nREM	non-REM
PCB	Printed Circuit Board
PLA	Polylactic Acid
REM	Rapid Eye Movement
RF	Radio Frequency
SD	Secure Digital
SPI	Serial Peripheral Interface
SVM	Support Vector Machine
USB	Universal Serial Bus

REM "Ready Every Morning" Mask

1. Introduction

1.1 Objective

Team Tired Techies is requesting support to develop a state-of-the-art smart sleeping mask, the REM "Ready Every Morning" Mask. The project scope is primarily to develop a wearable device that can actively monitor users' sleeping stages and patterns. The device will also be capable of transmitting the data to a smartphone, which will serve the purpose of an alarm clock that optimizes users' quality of sleep by waking them up at an individualized time when they are scientifically proven to feel the most energetic and refreshed.



Figure 1. A typical hypnogram showing sleep stages and cycles in adult sleep [2].

1.2 Motivation

During a typical night's sleep, the human body passes through multiple sleep cycles (Figure 1). Waking up after rapid eye movement sleep at the end of the cycle, when sleep is lightest, may be best to help an individual wake feeling more rested and ready to start the day [3]. An alarm going off when an individual is in one of the deeper stages of sleep may lead to grogginess or difficulty waking up, which is formally known as *sleep inertia* [4]. These stages vary from person to person, meaning that no single timing for sleep is right for everyone.

Thus, existing online "sleep calculators," which attempt to tackle the problem of sleep inertia, can be very ineffective. These programs simply spit out various potential times a user should target waking up based on a time they *plan* on going to sleep. According to the Sleep Health Foundation, the assumptions that these sleep calculators make are not based on scientific evidence. These programs take two scientific facts, firstly that humans have sleep cycles throughout the night of approximately 90 minutes in duration and secondly that waking from REM sleep is more likely to make one feel refreshed, and massively over-generalize. In truth, the duration of the sleep cycle changes throughout the night, and as mentioned above, varies between individuals. Additionally, these existing sleep calculators miss out on accounting for factors like the time it takes an individual to fall asleep and the instances throughout the night during which someone may wake up and interrupt their sleep.

With this in mind, there is an evident need for the creation and development of a smart sleep-specific wearable device that is capable of monitoring an individual's active state of sleep. This information can be used to determine the best time to "sound the alarm" and wake up individuals at a non-generalized, *individualized* time that makes them feel their freshest and most awake.

This project thus aims to address this specific problem: "when is the *healthiest* time for me to wake up?" Doubling down on what a "healthy" awakening means, various studies have proven that the stage in which one wakes up affects grogginess and exhaustion levels, even if one has slept an

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adequate amount of time [4]. Specifically, waking up in the middle of an REM cycle interrupts sleep and results in tiredness [5]. A reliable smart alarm is the obvious solution to this problem.

1.3 Background

While modern wrist wearables and smartwatches can track sleep, these are generalized devices whose primary purpose is not sleep-tracking. They also typically use relatively indirect methods such as movement and heart rate data to make inferences about a user's sleeping pattern. While they offer a somewhat viable solution, they do have their shortcomings in their accuracy and therefore helpfulness [6]. Polysomnography techniques, however, can be much more accurate. These methods involve several electrodes placed on the head and provide the most thorough sleep data; however, they are expensive, sometimes require experts to operate, and require sleeping in an unfamiliar environment which itself can inhibit natural sleep [7]. Wristwatches are too general to be the best smart alarm solution, and polysomnography is too specialized to be an at-home, comfortable solution; thus, a true opportunity exists for the creation of a specialized device that is both comfortable and more accurate than the average smart watch.

To focus on accuracy, polysomnography, which gathers electroencephalography (EEG), electrooculography (EOG), and electromyography (EMG) datapoints, has made it a known fact that the head is a more suitable source of sleep data than the wrist. However, for the specific purpose of a smart alarm clock, it is not necessary to maintain the whole gamut of sleep data that polysomnography offers [8]. Thus, the aim of this project will be to develop a low-power, rechargeable wireless sleep mask that simply gathers a users' electrooculography (EOG) data – essentially eye movement data – in order to classify their active state of sleep. To minimize onboard processing, this data will then be wirelessly communicated to a paired smart phone running a mobile phone application, which will provide a model and algorithm for deciding an optimal wake time, ultimately sounding the alarm. This alarm will be designed such that it sounds at or before a user-specified time, prioritizing that users wake up at the end of an REM cycle, therefore ensuring that they wake up feeling refreshed.

As alluded to above, the projected scope of the product is to serve as an at-home nightly wearable device that can be worn to bed by any and all individuals who need to wake up at a specific time but also want to prioritize their sleep. Whether this is for college students or for members of the workforce, the end goal is to provide users with a product that maximizes the quality of their sleep without jeopardizing the timeliness of their waking up.

To achieve this, the most vital performance aspect of the device is its ability to properly characterize user sleep data. This can be divided into both the ability to properly gather EOG data via electrodes as well as the ability of the algorithm to utilize such data in order to meaningfully decide whether the user is in REM sleep. As it is improbable that sleep quality can adequately be tested during the short 15-week time frame of this project, the product's proof of concept will involve demonstrating the system's ability to recognize REM sleep and determine an appropriate alarm time. If the product is successful in doing so, research indicates that the device will in fact improve sleep quality [9].

In short, given the tradeoffs of getting too little versus too much sleep, as well as evidence [5] that waking up at certain points in a sleep cycle can be beneficial, while others are detrimental, there is currently no viable solution on the market that is both accessible and effective... and the Tired Techies' goal is to change that with the REM Mask.

The remainder of this proposal will expand on the ideas introduced in this section, discussing customer requirements, project goals, technical specifications, design decisions, and development timelines. The proposal will be concluded with a discussion of the viability of the project as a true product, supported by accompanying market and cost analyses.

2. Project Description, Customer Requirements, and Goals

In order to successfully develop a sleeping mask that can be worn to bed every night, there are many requirements to satisfy. In addition to this, to fulfill the desired functionality of the product – that the data gathered by the sleep mask can be properly utilized by a mobile application to sound an alarm at a personalized time – the list of customer requirements grows lengthy. The following describes what must be required for ideal functionality and utility of the REM Mask:

- The mask must be adequately fashionable, convenient, and comfortable to wear to sleep.
- The mask must be affordable for the average user.
- The device must be reliable in waking users up at or before their specified times.
- The mask must be intuitive to use for a single individual.
- The application interface must not require much, if any, education to use effectively.
- The battery life of the device must last for an entire night on one charge.
- Wearing the mask must not inhibit proper sleep.
- The device, which will be battery-powered, must not pose an electrical shock or fire hazard.
- Any circuit board or hard component in the device must not pose a poking hazard.
- The mask and paired smart phone must be able to reliably communicate via Bluetooth.
- The mobile application must provide users with flexibility and the ability to customize their alarm, specifically the sound it will make, and the range of times during which they are prepared to be awakened.

Along with these more general customer requirements, there are technical specifications and more quantifiable needs that the product must fulfill as well:

- Maximum time for users to learn how to use the device: 5 minutes
- Maximum set-up time: 2 minutes
- Minimum battery life: 10 hours
- Maximum charge time: 2 hours
- Maximum weight: 0.5 pounds
- Head circumference (minimum and maximum): 21.5 inches to 23 inches
- Product lifetime: 3 years
- Cost of Production: \$90

Given these lists of customer and engineering requirements, it is important to consider the potential stakeholders of the product. It's obvious to consider the end-user – individuals who care about waking up on time while maintaining their sleep quality. This can be further broken down into various groups: students (of all ages and levels), everyday workers (of diverse fields), and even parents (who are stay-home, have infant/young children, etc.). Other groups besides the end user also have a stake in the product as well. Key examples include the engineering and design team behind the ideation and development of the REM Mask, medical experts/researchers who specialize in the sleep field, sleep therapists, school officials, doctors/general physicians, and government officials in charge of public health policy. Figure 2 outlines more specifically the *stake* each of these potential stakeholders will have in the product.



Figure 2. A stakeholder chart illustrating parties with interest and power regarding the product.

To meet the needs of stakeholders while simultaneously fulfilling the mask's desired functionality, it is important to outline some constraints and tradeoffs too. The mask's goal is to benefit a user's health and sleep. To achieve this, an adequate device battery is necessary in order to survive the entire duration of the night. This requirement highlights an important problem; the more capable a battery is, the larger it is, the more heat it gives off, and potentially the worse it is for a user's health (especially considering that the battery will be adjacent to the eyes and head). It would defeat the purpose of the REM Mask if the product was ultimately deemed unhealthy, not because it was ineffective in accomplishing its specific goal, but instead because its battery and power source were found to be detrimental to users' wellbeing. Despite this hefty constraint, solutions are plentiful. Small-scale low-power rechargeable batteries are both cheap and cost-effective, and these can easily accomplish a full night of charge and function, depending on the rate of data acquisition and transfer. If it's not needed to constantly perform active sensing and sending transactions between the mask and the paired smartphone (and instead carry this out in batches with larger packets of data), a smaller battery can more than satisfy the electrical requirements of the REM Mask.

Another constraint is the size (and thus comfort-level) of the mask. If the product is intended to maximize and increase users' sleep quality, it is vastly important that the sleep mask's size, bulk, and feel don't detract from users' sleep because it results in nightly discomfort and difficulty sleeping. Therefore, in designing the product, it is important to prioritize the selection of effective yet sleek parts and devices as well as soft, comfortable material for the mask's casing.

3. Technical Specifications

The House of Quality, depicted in Figure 3 below, shows that the most critical customer needs (highlighted in blue) are those directly relating to waking up the user at the correct time, as well as being suitable and practical. Relative weight identifies the importance of a specification. The engineering requirements with the highest relative weight which are outlined in red are accuracy, operation time, and set up time. This correlates with the customer needs as accuracy and operation time have a positive correlation and is necessary to wake the user at the correct time in the sleep cycle. Additionally, the lower the setup up time, the more convenient the product is. The roof of the House of Quality highlights the tradeoffs and synergies between engineering requirements; notable synergies include those between accuracy and set up time. Though set up time needs to be minimized, this could affect accuracy because the sensors need to be positioned properly. The least important engineering requirements are heat and mask lifetime. Because the product uses lower power components, heat should not be a concern. The mask lifetime is also not relatively important as the forces acting on the mask are minimal. A specification sheet for the product can be seen in Figure 4.



Figure 3. House of Quality for the REM Mask.

Changes	D/W	Requirement	Responsibility	Source
2/1/22		Wake User Up at the Most Optimal Time	Team	Team
		Geometry		
2/1/22	W	Prefered Dimensions: 8.2 in x 4.5 in x 1 in	Kai	Team - min form factor for comfort/convience
2/1/22		Min Head Circumference: 21.5 in	Kai	Average mininum size for one size fit all hats
2/1/22	W	Max Head Circumference: 23 in	Kai	Average maximum size for one size fit all hats
		Energy		
2/1/22	D	Battery Capacity: 1200 mAh	Nabid	Battery- For a night of sleep
2/1/22	W	Product Temperature: Room Temp	Nabid	Team - Low power components
		Software		
2/1/22	D	Min Data Collection Rate: 100 Hz	Andrew	Based on eye movement rate.
2/1/22	W	Data Collection Rate: 200 Hz	Andrew	Team - higher collection rate for accuracy
2/1/22	D	Min Accuracy: 70%	Ananth	Based on Competitors
2/1/22		Preferred Accuracy: 90%	Ananth	Team
2/1/22	W	Sleep Classication Algorithm: 30 Seconds	Andrew	Team
		Safety		
2/1/22	D	Number of Loose Parts: 0	Kai	Team
2/1/22	D	Voltage Outside Of Mask: 0 V	Kai	Team
		Sustanability		
2/1/22	W	Product Lifetime: 3 years	Kai	Team
		Operation		
2/1/22		Max Operational Time: 10 Hours	Nabid	Team - For a night of sleep
2/1/22		Max Set-up Time: 2 Minutes	Nabid	Team - Try to reduce for convenience
2/1/22	W	Max Charge Time: 2 Hours	Nabid	Team - Try to reduce for convenience
		Cost		
2/1/22	W	Max Cost of System: \$90	Andrew	Team
		Materials		
2/1/22		Max EOG Sensors: 2	Nabid	Team
2/1/22		Max Temperature Sensor: 1	Nabid	Team
2/1/22		Max Mircotroller: 1	Nabid	Team
2/1/22	W	Max Number of Batteries: 1	Nabid	Team
		Ergonomics		_
2/1/22		Wires Contained: 100%	Samin	Team
2/1/22	W	Aesthetic Appearance Jury: 95% concensus	Samin	Team
0 /1 /5 -5		Production		
2/1/22	W	Total Prototype Time: 10 hours	Kai	Team
0/1/5-5		Schedule		
2/1/22		Prenstation and Project Proposal: 02/09/22	Team	Project Requirement
2/1/22	D	Presentation and Report #2: 03/16/22	Team	Project Requirement
2/1/22	D	Final Presentation: 04/20/22	Team	Project Requirement
2/1/22	D	Final Report: 4/29/22	Team	Project Requirement

Figure 4. Specification Sheet for the REM Mask.

4. Design Approach and Details

4.1 Design Concept Ideation, Constraints, Alternatives, and Tradeoffs

The design functions foremost as a "smart" alarm clock, a system that wakes the user at a time informed by both the time they need to wake, and processed biometrics gathered by the system's

wearable device. Systematically, the device reacts to the alarm time the user sets as well as signals

gathered from wearing the device to create the single output, the alarm. Additionally, a charging cable

and simple power button inform the state of the system, which indirectly affects the alarm output. A symbolic representation of the high-level function is shown in Figure 5.



Figure 5. A high-level functional representation of the REM Mask project.

The REM Mask device will be broken down into two main systems: a wearable device which is at its core responsible for collecting and transmitting the user's electrooculography data which can only be obtained when the user is wearing the device and the sensing system permits it. To discourage unwanted and unsafe use of the REM Mask, these functions are disabled while the charging cable is plugged in.

On the user's personal device, which will be a laptop or smartphone, they will be able to set an alarm time. Whether the design demands a preferred alarm time, a latest acceptable alarm time, or a range of acceptable alarm times is to be determined, but the alarm time input symbolically represents these options. The user's personal device does the algorithmic "heavy lifting" of parsing the EOG data from the wearable, running a classification algorithm to determine whether the user is in REM or nREM sleep, dynamically calculating the alarm time, and ringing the alarm. The most computationally-expensive tasks are performed outside the wearable in order to meet the device's low power consumption constraint.



Figure 6. A functional decomposition of the REM Mask project.

Some of these functions are intuitive and do not have a sizable design space which should be considered; for example, the "sense system status" function can be decided by simple logic (e.g., the system can be used when the power is on and the charging cable is disconnected). Other functions, such as the smart alarm algorithm and the REM/nREM classifier have many options for their designs, and we can discuss these at length.

For the biometric data collection function, we have already decided on the biometric to be used: EOG. However, there are many potential implementations of EOG concerning our electrical hardware and device form factor. We could use one or two EOG channels. One channel would simplify the layout of the device, reduce the traffic over our interconnect, and eliminate the need for our MCU to label the channel data before transmission. Two channels would produce higher quality results [10], so the number of channels is a crucial decision to be made. In addition to the number of channels, the placement of these channels must be discussed. Reliable electrode contact is critical to the success of our project, so we must pick locations accordingly. The specification of needing reliable contact makes an impact towards our decision to measure vertical or horizontal eye movement. We have not found any research indicating the suitability of any direction differs much. An additional tradeoff related to data collection is the sampling rate of our electrodes. More samples per second may contribute to better precision in REM/nREM classification but would increase power consumption and interconnect traffic.

For biometric data transmission, there are likewise many potential solutions. Considering the importance of power on the wearable, it is most sensible to use BLE as our means of wireless communication. The use of BLE will make a collateral impact of determining what the software on the user's personal device can look like, as we must make use of existing free-to-use BLE libraries for this project. Additionally, we must consider what our data transmissions will look like, and how frequently they will occur. These decisions will impact power consumption and the user's personal device's interface with the wearable. We will buffer EOG data on the wearable device; a larger buffer allows for fewer transmissions, but it could potentially influence the amount of RAM and ultimately footprint size of the MCU.

Another design decision is the format of the user-set alarm time. We could accept one desired time, a latest acceptable time, or a range of potential times. This decision will affect the smart alarm algorithm immensely. We want to simplify the interface and have no need for the user to understand our algorithm to favor user experience, but we also want the data that allows the smart alarm to minimize the need for wakeups during REM sleep. As we cannot know which option performs the best with the smart alarm algorithm until later, we can only pick an option we believe will perform best. We will start off by accepting the latest user's acceptable wake time and later deciding how much earlier we should allow the smart algorithm to wake.

For the REM versus nREM classifying function, a reasonable tradeoff to be made is complexity which may contribute to performance versus project time. Some of the research we have found classifies sleep stages using deep convolutional neural networks, and the approach was developed and refined by a team of professionals over a span longer than one semester [11]. We will have to make use of existing libraries and documented approaches, such as an SVM, to accomplish this project in time. The features we input into such a machine must be considered as well. Researchers found thirteen features which we can deduce on the user's personal device rapidly and input to our classifier model [12].

An ideal smart alarm function is in the best-case scenario outlook for this project, but we may have to revise our timeline eventually, in which case the logic of the algorithm can be quite simple; for example, do not wake the user in REM sleep unless it is as late as the user has have declared it acceptable to wake up.

The project design revolves around some overarching concepts. On the wearable device, minimal power consumption is vital; this specification affects hardware and software design. Dependability is important, and the design must consider how it will fail under certain circumstances. For example, if the device runs out of power or the BLE connection is dropped, the alarm clock on the user device must respond in a way such that the alarm still goes off. Simplicity is a concept that affects the application software user interface and mechanical design; no user should have to stick electrodes on themselves in an ideal design, and the software behind the algorithm must be abstracted away into a single alarm time setting in the user interface. A design factor for health and safety of wearing an electrical design on the face is overheating. The electronics the mask contains can not generate a great amount of heat, or it could potentially burn the user's face if an issue occurs. Since the product will involve a lot of physical contact with the user, the material that contains the electronics should ideally be an insulator, it must also have no exposed wiring or the potential of electrifying the user. For economic factors, the cost of the device is based on similar devices in the market for profit. A design factor to consider is the ethical aspect of personal data logging. People could have concerns of their data being misused, so a privacy policy must be written if the product were to hit the market. Global design factors include differences in standard compliance that should be looked at if the product enters the market in different countries. The design should be able to be manufactured anywhere in the world, so it should only use standard components and manufacturing techniques. The product should also be environmentally friendly to be seen more favorably by consumers. Polylactic acid (PLA) will be used to contain the electronics since it is a bioplastic, all natural, and degradable. PLA is also sustainable, because the material is made from fermented plant starch.

The computing aspects of this project, in hardware, are a small MCU on the wearable device and an application processor on the user's smartphone, or their laptop. A major tradeoff we have identified is between power consumption and processing power. We have decided to minimize the power consumption of the wearable device's MCU by pushing intensive processing, such as REM versus nREM classification onto the user's personal device. We are doing so because the MCU will be powered by a battery pack. Further actions may need to be taken to conserve power on the wearable, which may be done by designing the firmware to limit BLE transmissions and maximize sleep time while not compromising device function. An example of a design consideration already being made is

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the sleep/wake status of the MCU over the course of the night. This design choice also affects the link between the wearable device and the user application. Three approaches have been considered: 1) the MCU sleeps for most of the night and wake up 2 hours before the alarm for continuous operation; 2) the MCU sleeps for 5-7 minutes then sends 3-5 minutes of data, and this action is repeated over the course of the night to maximize odds of catching REM cycles, which are typically at least ten minutes in length; 3) additional hardware and connection from the sensing subsystem interrupts the processor upon observing a high-amplitude eye movement, setting a timer for three minutes to send data, and this timer is reset on every interrupt. These options are illustrated in Figure 7.



Figure 7. Three sequence diagrams depicting BLE interaction options.

4.2 Preliminary Concept Selection and Justification

Throughout the ideation and design processes, certain (sometimes unstated) questions had to be answered by the group to narrow in on a design concept to pursue and the specifications of the design. Some of those critical questions are listed in the evaluation matrix in Figure 8.

Evaluation Question	Methods for Answering Question
Which biometric should we utilize in the design?	 Consider where the sensor would have to be placed and how that interacts with undisturbed sleep. Research how well the biometric can classify sleep stages alone, especially compared to competitor performance.
	 Consider the width and depth of signal necessary to solve our design problem.
How should we connect the system?	 Evaluate how a method impacts the physical footprint of the system. Consider the low-power constraint of the wearable device.
How should we classify sleep?	 Consider engineering time and group expertise. Research how others have attempted to classify sleep using a particular biometric and how successful they were.

Figure 8. Evaluation matrix for the sleep mask design.

Referring to the question, "What biometric should we utilize in the design?", options were found to be those utilized in competitor approaches (i.e., heart rate, motion) and those utilized in formal medical techniques (i.e., electroencephalography [EEG], electromyography [EMG], electrooculography). EEG was ruled out as an approach due to how many signals would need to be used; this width of the signal would complicate making a comfortable hardware design and demand more power from the wearable device. Heart rate and motion were ruled out due to the documented accuracy of the approach, compared to electrooculography. Lastly, EMG was ruled out due to the awkward placement of electrodes on the chin. EOG is the design concept that will be pursued further as it has a manageable pair of signals, typically sampled around 200Hz [13]. Additionally, research shows that EOG signals can classify REM sleep with high accuracy [14].

The options considered to connect the system were Wi-Fi, Bluetooth, and wired connections. Wired connections were ruled out due to the inconvenient footprint and potential strangulation hazard. Bluetooth Low-Energy (BLE) was selected as the means of communication due to minimizing our power consumption compared to Wi-Fi.

Most of the research mentioned above utilizes machine learning to do the actual sleep stage classification. Currently, the design employs a similar method. For classifying sleep data, the EOG signals will be transmitted to the user's personal device. Then the data will be divided into timestamped epochs, relevant features such as energy in particular feature ranges, absolute mean differences, and standard deviation will be extracted. Lastly, these features will be input to a model that has been trained offline and deployed within the application on the user's device.

Because our primary sensing element is the EOG, it is the most critical aspect of our design. To address issues early on, we may breadboard the analog front-end for the EOG subcircuit to verify that eye movement is detectable. It may be wise to also prepare a discrete front-end using common op-amps rather than IC so that a backup is prepared in case of future failure. Prior literature has demonstrated the capability of using EOG signals as an identifier of various stages of sleep.

Once the EOG subcircuit is verified, we will construct a full breadboard of the expected electrical system that temporarily uses an MCU with BLE to test data acquisition and transmission. A power budget would then be prepared based on component datasheets and typical currents may directly

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be measured to anticipate expected runtime, addressing initial concerns of battery capacity. This will pave a path forward for determining any needed low-power techniques such as sleep modes and disabling unneeded peripherals on the MCU, which may also help thermals of the device.

Early mechanical prototypes should be constructed in parallel with circuit verification to address comfort for prolonged periods of time. The final PCB design of the full breadboard will need to align with mechanical structure in terms of board footprint and mounting while being easily accessed for powering and firmware programming.

Most biopotential sensors employ a similar analog front-end structure: an instrumentation amplifier for initial signal capture and noise rejection, a filter to isolate frequency range of interest, a second gain stage to further amplify, and an analog-to-digital converter for sending to a microcontroller for processing [prob source if want]. Because the structure is so common, the entire analog-front end can be encapsulated within a single IC and for that purpose, the ADS1292 as the low-power analog front end (AFE) for EOG. This selection was made based on documentation and resource availability, past project examples online, pin solderability, and current available stock. While a specific microcontroller has not been decided, our final selection of one will be based on BLE support, low power features, board footprint, serial communication peripherals, and team familiarity with toolchain, such as compatibility with the Arduino environment. At the moment, potential MCU candidates include the ESP32, Nordic nrf52840, or common ATMega328 with a separate Bluetooth serial module like the HC-05. For temperature sensing and IMU, the MCP9808 and the MPU6050 will be used, respectively. This is due to past use in prior projects, part availability locally, and occupation on the I2C bus for reduced wiring needed compared to SPI communication.

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A subsystem-level block diagram for the wearable device is shown in Figure 9. Overall, the wearable side of the system can be separated into five abstracted subsystems: power, sensing, user interface, compute, and transmission (provided this is not embedded in the selected MCU). The power is responsible for managing charging status and providing regulated DC power to all other subsystems. The "sensing" subsystem encapsulates all of the sensors needed for the device (i.e., EOG, temperature, and IMU), and provides a simplified interface to communicate with the MCU in the computer subsystem. The user interface is simple; it is merely a power button connected to the MCU.



Figure 9. Subsystem-level diagram for wearable device.

The firmware on the wearable device will exist in a bare-metal program. Because of anticipated constraints with code space, a real-time operating system is not currently planned to be utilized. If power consumption of the wearable becomes excessive, an RTOS may be deployed to help manage

power consumption. An organizational software architecture diagram is shown in Figure 10. The peripheral protocols required do inform the microcontroller component selected; the selected MCU must support two I2C interfaces and one SPI interface. Additionally, existing BLE library support is a must-have.



Figure 10. Organizational Software Architecture Diagram for Wearable Device Firmware To view gathered data and set desired wake-up time, an app or mobile site will be developed to host the user interface. A rough mock-up of the GUI is shown in Figure 11 with two primary screens

considered currently: one for viewing the night's sleep biometric data and another for setting the desired alarm. The device's battery life may also be potentially added to the app.



Figure 11. Rough Mockup of App GUI for Night and Day Screens.

The most critical risk factor to our design is failure of the EOG subcircuit since the key differentiating aspect of our design from current sleep wearables is the direct measurement of eye movement. In the event that the ADS1292 functionality is not achieved, the entire analog-front end stages will be recreated using common LM741 op-amps and the AD620 instrumentation amplifier found locally. A SPICE simulation setup for the discrete AFE is shown in Figure 12 using ideal op-amps for initial proof of concept.



Figure 12. Initial SPICE schematic for custom analog-front end for EOG sensing

Due to the multiple weeks required for a PCB to be fabricated and delivered, it is critical that the initial design accounts for potential issues and is designed for testing. If modifications are needed such as white wiring, the PCB design should incorporate signal and power test points, jumper wires to extra MCU pins, screw terminal access to peripherals like I2C, and ease of hand solderability with part selection and placement. It may also be desired for a team member to be trained on using the PCB fabrication machines so that rough, yet functional, boards can be prototyped and tested before a final design is sent for higher quality and quantity fabrication.

While our device is to be battery operated and rechargeable, in the event that our power subcircuit design fails, we may opt for wired power over USB as backup. To ensure safe operation, the

USB connection will go to either a laptop or portable power bank to ensure earth ground isolation. A USB isolator cable may also be used if connected to a laptop.

In the event that our machine learning model poorly classifies REM versus non-REM stages, we may opt for a more hard-coded algorithm that attempts to differentiate the stages of sleep based on the onset of rapid eye movement to indicate the presence of a REM cycle.

While we are fairly certain to be using BLE for small-distance, low-energy transfer of data packets to a personal device, we are uncertain of the exact procedure of transmission. For example, we still need to determine whether we will send packets regularly to the personal device or store locally within an SD card for larger time period transfers or single-time transfer at the end of a night's rest. Furthermore, the rate of data transmission needs to still be determined and tested. In terms of physical design, we have yet to decide on the exact form factor and choice of fabric. Though battery operation is intended, the exact type of battery is still firmly to be decided, which would affect the charge circuitry and components. Potential candidates include a 3.7V LiPo battery or coin cell batteries due to their voltage level and small form factor.

The current proposed cost for the electrical components needed for a single unit of the device is shown in Table 1. Additional components on the mechanical end for fabrication may include example fabric sleeping masks as baseline for prototyping and rapid prototyping material provided freely by on-campus makerspaces such as plastic filament for 3D printing and wooden panels for laser cutting.

<u>Part</u>	<u>P/N</u>	<u>Qty</u>	<u>Unit Cost</u>	<u>Order</u> <u>Link</u>	<u>Extra notes</u>
AFE, low pwr	ADS1292	1	\$11.08	link	Capable of 2-channel
Temperature sensor	MCP9080	1	\$4.95	<u>link</u>	
IMU	MPU6050	1	\$3.33	link	
3.7V LiPo	LP-503562	1	\$9.95	<u>link</u>	1200 mAh for now, subject to change
Battery Charger IC	MCP738	1	\$6.95	link	
SD card reader	PID:254	1	\$7.50	link	
SD card	PID:5252	1	\$4.95	link	
Gel electrodes	PID:2773	2	\$0.83	link	
Electrode cable	CAB-12970	1	\$5.00	link	
MCU	(TBD)	1	\$20.00		worst-case price
USB connector	54819-0589	1	\$2.04	<u>link</u>	mini or type-B?
FTDI uart-usb IC	FT260Q-T	1	\$2.06	<u>link</u>	Possibly not needed

Table 1. Bill of Materials for Single Unit.

РСВ		1	\$2.50		Expected price from JLCPCB
3.3V LDO regulator	TC1264-3.3 VDB	1	\$0.83	<u>link</u>	3.7V -> 3.3V = max 0.4V dropout
Barrier Diode	SBAT54SLT 1G	4	\$0.38	link	Transient voltage protection
Est. TOTAL UNIT COST		1	1	\$82.79	N

Table 1. Bill of Materials for Single Unit Continued.

4.3 Engineering Analyses and Experiment

Throughout the design of the product, subsystems will be tested individually as they are developed to ensure proper functionality and will be followed by integration events to combine subsystems. First, a breadboard will be designed to test the EOG subcircuit, the most vital concept of the project. When electrode placement on the eyes and oscilloscope waveforms indicate correspondence to eye movement, a critical aspect of the design will have been verified. Additional sensing elements such as IMU and temperature will then be tested on the breadboard before integration with the EOG for completion of sensing elements. From here, the firmware team can verify wireless transmission of data by quickly creating a rough app using MIT App Inventor tooling for setting up BLE communications without coding. In parallel to this, a battery charging subcircuit can be tested by charging and discharging the selected battery and examining typical runtime under load. While our worst-case analysis should allow for the minimum hours of runtime, permitting a live test of battery discharge may give a more accurate depiction of typical runtime in a realistic use case. Once these elements have been verified, a complete system breadboard can be assembled and handed off for further firmware development while design of the PCB can take place. This ensures that upon arrival, pinout test, and fabrication of the PCB, the software can progress independently using a breadboard with identical setup. Collaboration between the PCB designer and CAD designer will take place to properly size the board after iterating through various mechanical designs of the mask for comfort and accessibility, utilizing rapid prototyping techniques such as 3D printing, sewing, and existing mask products as a baseline.

To ensure that the design meets specifications, several experiments will be performed to validate the device. For electrical testing, a power budget will be designed for worst-case analysis of device runtime. When the full system is actually fabricated or at least completely breadboarded with firmware loaded, several battery discharge tests under expected load may be done and averaged to verify typical runtime in addition to worst-case analysis. Once the PCB is fabricated, pinouts will be verified to assure proper net connections using a digital multimeter (DMM) and ensure no short circuits exist. The EOG subcircuit in particular will be verified by electrode on placement on a user and viewing under an oscilloscope to validate opposite peak waveforms corresponding to eye movement and lead-off detection. Wireless transmission of sensing data to a personal device will be tested by doing long-period transmission of data. Data may be stored locally, such as on internal memory or SD card, to be later compared to data sent wirelessly and stored on the personal device to examine any lost packets.

For mechanical testing, visual inspection can be done initially to verify hidden wires and ensure other exposure. Dimensions can be verified to be within specification by measuring with a ruler. The weight can be tested on a scale to ensure it's below threshold. Users' surveys can be used to test aesthetics and appearance.

Based on Table 2, a worst-case analysis of power consumption was calculated using the datasheets for major components in the system.

Component	Voltage (V)	Max Current (mA)	Power (mW)
MCU	3.3	50	165
IMU	3.3	4	13.2
Temperature Sensor	3.3	0.2	0.66
EOG front-end	3.3	0.4	1.32
Battery charger	3.3	-	-
LDO operating	3.7	0.08	-
LDO heat dissipation	0.4	(total system current)	-

Table 2. Max Power Consumption

An early experiment regarding REM versus nREM classification has already been performed. A Python script which parses polysomnography data with hypnogram annotations verified that the dataset found is sufficient in size and content. Furthermore, a third-party machine library was utilized to create a support vector machine (SVM) to attempt to naïvely classify single-channel EOG signals into REM or nREM sleep. This experiment elucidated the difficulty of this project, as no simple measure of EOG data (mean, energy, or standard deviation) was able to classify even the training data it was fitted with, nor were any combinations of the used metrics. The Python code is listed in Appendix 1.

4.4 Codes and Standards

As a wearable device with potentially clinical usages, the product must comply with several health and safety standards. Most essential would be the IEC 60601 standard for electrical safety of medical devices. Because our device involves passive measurement, unlike methods such as bioimpedance that send current to stimulate tissue, less strict protocols may apply to our device. Standard practice would still include protection circuitry from the skin interface electrodes such as a high series resistor to limit current and diode bridges to suppress transient voltages [15]. Because lithium-ion batteries will be used in the product, the IEC 62133 standard regarding secondary, or rechargeable, battery safety must also be adhered to in conjunction with IEC 60601.

To avoid the need for FDA approval in the sale of the product, the device must be marketed as a low risk, general wellness device rather than a clinical device [16]. Essentially, the product must be sold as a device to improve lifestyle and assist with sleep management but cannot make claims to treat or detect specific diseases, such as sleep apnea. For the marketing and design of the project, the idea of addressing sleep apnea or other sleep disorders was thus excluded for this iteration of the product. Instead, the device will have a sole focus on sleep tracking and improving energy upon wakeup to fit within the general wellness device category. Because there will be wireless transmission of data from our wearable to another device for processing, the product must meet FCC compliance for radio frequency (RF) transmission. To meet more loose criteria for compliance, utilizing a pre-certified module that adheres to normal use case without any modification of the unit, such as antenna, would allow the wearable to meet the RF requirement with the tradeoff of higher unit cost [17].

In general, all relevant standards can be encapsulated in the IEEE P360 draft standard for wearable consumer devices [18]. The IEEE standard serves as a hub of references to all other standards, including the aforementioned, in regards to use case and safe design of the device such as charge rate, operating temperature, and materials. For the most part, due to the rigor of formal testing within the capstone timeline, pre-certified modules and batteries will be used to meet the requirements of wearable device standards.

5. Project Demonstration

Due to the nature of this project and the fact that actual testing occurs when one is asleep overnight, recorded and classified data will be used to validate that the final device functions the way that it was designed to do so. Various metrics will need to be evaluated in order to demonstrate proof of function for different project specifications. The core functionality of the device is to be able to wake up the user and keep track of REM cycles of sleep versus non-REM cycles overnight. This entails that the device must be active while the user sleeps. For this to happen, the rechargeable battery must be able to survive the length of the entire night. Furthermore, accurately monitoring and acquiring data overnight for the various biometrics specified must also be validated. The primary biometric that serves as the basis for the project is the EOG data transmitted from the electrodes connected to the temples. Classifying the EOG data into REM versus non-REM will be based on various features and measurements such as waveform peaks and magnitudes, rate of change of the waveform, relative energy of eye movement, etc. Figure 13 demonstrates a desired EOG signal waveform in which the magnitude of the waveform becomes larger when REM sleep occurs. This waveform will be compared against data collected via EOG signals from other sleep study databases in order to confirm whether the data that is being collected correlates to other studies and research. With a waveform like this, amplifying the larger magnitude will allow the REM cycle to be easily pinpointed during a full night of sleep.



Figure 13. Typical EOG waveform showing transition to REM cycle with presence of eye movement.
Other biometrics to test and validate include temperature sensors and accelerometers to ensure that they function as needed. These are common biometrics used in various other wearable devices that may prove useful in classifying when REM may occur.

Classifying the data and distinguishing between REM and non-REM stages of sleep with EOG signal waveforms will serve as a proof of function, validating the initial purpose of this project. All of the data collected will be monitored and stored with an associated GUI on an external device such as a smartphone or a laptop via Bluetooth. This will operate as a hub for all the data collected for a user on a night-to-night basis. Being able to transmit data from the EOG electrodes to the external device will also be an important proof of function that must be tested, validated, and seen for different data captures to ensure overall system functionality. In order to get a sufficient quantity of data samples, the testing procedure must occur over several weeks with various people in order to collect unbiased data to compare to desired results.

In terms of live demonstrations, the focus will be primarily directed to EOG sensor functionality. For instance, a user may be able to put the product on and move their eyes left and right at a rapid pace at any given time to simulate REM sleep, and the data will be transmitted on a screen, pinpointing exactly when the rapid eye movement occurs. Another live demonstration, although not as core to overall device functionality, would be demonstrating how accurately our product can use and interact with EOG signals. For instance, having "smart" controls via Bluetooth could be an application for a demonstration in which a person may move one or both of their eyes in a certain manner while the EOG electrodes are collecting data, and this muscle contraction would allow an external device such as a smart plug with a lamp to turn on. In summary, demonstrating the full use and purpose of this project is not feasible as it requires a person to use it overnight when sleeping; therefore, demonstrations regarding this project involve classifying collected data that verifies the initial purpose stated for the device. This includes verifying that separate subsystems and components function properly and work when integrated together. Moreover, demonstrations can also include live user tasks in which EOG signal collection will be the key subject for the demonstration. It is imperative to create a functional design that operates as needed and desired, specified by design and customer requirements.

6. Schedule, Tasks, and Milestones

Tasks will be split up into several categories: Electrical, Firmware, Software, Mechanical, and Full System Integration. Team members will get tasks based on their majors, experiences, and estimated time consumption of tasks. Below are tables indicating each of the tasks in their categories as well as the members that will be involved with them.

Task #	Task	Relative Importance, Level of Importance	Predecessors	Members involved
E1	Simulate discrete EOG circuit backup	7, 7		Nabid
E2	Assemble and test EOG AFE chip	10, 6		Nabid
E3	Wire temperature, IMU, SD card	5, 2		Nabid
E4	Full breadboard sensing test (EOG, temp, IMU, SD)	10, 5	E2, E3	Nabid, Syed
E5	Battery charge circuit test	7, 4		Nabid
E6	Power analysis/measurement	8, 3	E4, E5	Syed
E7	PCB schematic design	9,9	E4, E5	Nabid
E8	PCB board layout and ordering	10, 2	E7	Nabid
E9	PCB pinout test	7, 4	E8	Syed
E10	PCB fabrication	7,	E8	Nabid
E11	PCB power-on test	8, 4	E10	Nabid
E12	Full PCB sensor test	10, 6	E11	Nabid

Table 3. Electrical Tasl	ζS
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Table 4. Firmware Tasks

Task #	Task	Relative Importance, Level of difficulty	Predecessors	Members involved
F1	Read IMU data	7,4	E3	Andrew
F2	Read EOG data over SPI and buffer it	10, 5	E2	Andrew
F3	Read temperature sensors	4, 3	E3	Andrew
F4	Establish a BLE connection – wearable side	10, 5	E4	Andrew, Syed
F5	Send EOG data over BLE	10, 5	F2, F4	Andrew
F6	Send IMU data over BLE	7, 5	F1	Andrew
F7	Send temperature data over BLE	4, 5	F3	Andrew
F8	User interface development and integration	8, 8	E4	Andrew
F9	Refactor to minimize power	8, 8	E6, F5, F6,F7, F8	Andrew, Nabid
	consumption			

Table 5. Software Tasks

Task #	Task	Relative Importance, Level of difficulty	Predecessors	Members involved
S1	Establish a BLE connection – application side	10, 7	F4 (concurrent)	Syed
S2	Parse EOG data from BLE	10, 5	S1, F5	Ananth, Syed
S3	Parse IMU data from BLE	7, 5	S1, F6	Ananth, Syed
S4	Parse temperature data from BLE	4, 4	S1, F7	Ananth, Syed
S5	Subdivide EOG data and extract features	10, 5	S2	Ananth, Andrew
S6	Classify REM versus nREM using data	10, 6	S5, S7	Ananth, Andrew
S7	Create a model which classifies REM vs nREM sleep	10, 6		Syed, Ananth
S7.5	Make the classification model loadable, not created every time the application is launched	4, 5	S7	Ananth
S8	Create visualization tools to aid debugging and demonstration	4, 5	S2	Ananth
S9	Smart Alarm Algorithm	4, 8	S6	Ananth
S10	Mobile Application – User Interface	8,6		Syed
S11	Mobile Application – Integrate algorithm and sleeping data with user interface	8, 7	S6, S9	Ananth
S12	Mobile Application – Implement Bluetooth module fo data transfer between phone and mask	10, 6	S2, S3, S4	Syed
S13	Mobile Application – Integrate data classifier in backend of application	10, 6	S12	Ananth
S14	Mobile Application – Develop easily-customizable alarm that will "go off" at time determined by algorithm	10, 5	S9, S11	Ananth

Table 6. Mechanical Tasks

Task #	Task	Relative Importance, Level of difficulty	Predecessors	Members involved
M1	BOM for mask	6, 2		Kai, Nabid
M2	Create General Layout	6, 4		Kai
M3	Material Selection (EDUPACK)	7, 4	M1	Kai
M4	CAD Design	6, 8	E8, M3	Kai
M5	3D Printing/Resin Printing	6, 5	M4	Kai
M6	Prototyping Form Factor	8,7	E8, M5	Kai
M7	Prototyping Wearable Mask	8, 10	E10, M5, M6	Kai
M8	Obtain Customer Feedback for Mask	9, 2	M7	Team
M9	Iterate Design/Aesthetic adjustments (repeat M1 to M8 as necessary)	10, 8	M6, M7	Kai

Table 7. Integration of Full System Tasks

Task #	Task	Relative Importance, Level of difficulty	Predecessors	Members involved
		Level of difficulty		
I1	Ensure electronics fit the form factor	9,4	M6, E5, E12,	Kai, Nabid
I2	Confirm connection between wearable and app	9, 5	I1, F9, S12	Syed
I3	Full System testing	9, 8	M7, S10, S14, I2	Team
I4	Full System debugging	9,9	I3	Team
15	Final System Integration	10,9	I4	Team

Note: Milestone tasks are highlighted in yellow. Relative Importance and Level of difficulty are tentative estimates and may not reflect the actual scope of the project.

Due to the plethora of tasks for different subsystems for the project, separate PERT charts were created to reflect critical paths of each of these categories. It is important to note that the times associated with these tasks are estimates and may take much longer or shorter than listed, altering what the actual critical paths may be for the project. TBD time estimates depend on outside sources, and "agg" time estimates are the aggregate time estimate of that task and its predecessors.



Critical Path: $E3 \rightarrow E4 \rightarrow E7 \rightarrow E8 \rightarrow E10 \rightarrow E11 \rightarrow E12 = >13$ hrs

Figure 14. Electrical PERT chart



Critical Path: $E2 \rightarrow E4 \rightarrow F8 \rightarrow F9 =$ Approximately 13 hrs

Figure 15. Firmware PERT chart



Critical Path: aggregate $F4 \rightarrow S1 \rightarrow S2 \rightarrow S5 \rightarrow S6 \rightarrow S9 \rightarrow S11 \rightarrow S14 =$ Approximately 30 hrs

Figure 16. Software PERT chart



Critical Path: aggregate E8 \rightarrow M4 \rightarrow M5 \rightarrow M6 \rightarrow M7 \rightarrow M8 = Approximately 29 hrs

Figure 17. Mechanical PERT chart



Critical Path: aggregate $S14 \rightarrow I3 \rightarrow I4 \rightarrow I5 = 130$ hrs

Figure 18. Integration of Full System PERT Chart

Overall Critical Path:

 $E2 \rightarrow E4 \rightarrow F4 \rightarrow S1 \rightarrow S2 \rightarrow S5 \rightarrow S6 \rightarrow S9 \rightarrow S11 \rightarrow S14 \rightarrow I3 \rightarrow I4 \rightarrow I5 = \textbf{130 hours}$

Note: Critical paths are shown with the bigger arrows in each of the PERT charts. Paths that do not depend on predecessor tasks from a different subsystem can be done concurrently.

Task Categories	Associated Task Numbers
Electrical Design	E1, E2, E3, E4, E5, E6
Electrical Integration	E7, E8
Electrical Testing	E9, E10, E11, E13
Electrical Design	F1, F2, F3, F4
Firmware Integration	F5, F6, F7, F8
Firmware Testing	F9

Table 8. Task categories and the associated task numbers.

Software Design	S1, S7, S7.5, S8, S9, S10
Software Integration	S2, S3, S4, S5, S6, S11, S12, S13
Software Testing	S14
Mechanical Design	M1, M2, M3, M4, M5, M6
Mechanical Integration	M7
Mechanical Testing	M8, M9
Full System Integration	I1, I2
Full System Testing	13, 14, 15

Based on the current tentative task scheduling on a weekly basis and estimation of each of these tasks, the project will be designed, integrated, tested, debugged, and fully prototyped and ready one week before the expo.

Projected Schedule:

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16
Task	w/e 1/15	w/e 1/22	w/e 1/29	w/e 2/5	w/e 2/12	w/e 2/19	w/e 2/26	w/e 3/5	w/e 3/12	w/e 3/19	w/e 3/26	w/e 4/2	w/e 4/9	w/e 4/16	w/e 4/23	w/e 4/30
Team Formation																
Project Bidding																
Problem Statement																
Project Summary																
Project Proposal																
Project Research																
System Decomposition																
Part Selection/BOM																
Electrical Design**																
Firmware Design**																
Software Design**																
Mechanical Design**																
Electrical Integration**																
Firmware Integration**																
Software Integration**																
Mechanical Integration**																
Redesign																
Electrical Test**																
Firmware Test**																
Software Test**																
Mechanical Test**																
Full System Integration**																
Full System Testing**																
Data Collection																
Data Analysis																
Poster Design																
Final Report																
Ехро																

Figure 19. Gantt Chart

7. Marketing and Cost Analysis

7.1 Marketing Analysis

Customer surveys and gathering information from the internet were used in the market research plan. As stated previously, the customers are people who must wake up at a specified time. 68.2% of people use some type of alarm clock or wake up aid [19]. The U.S. Population is around 332.473 million [20]. Thus, the total addressable US market is 226.747 million. Based on an initial survey, a fraction of the market that would consider wearing a sleeping mask is 53.60%. From that fraction, 73.2% would trade off less sleep for a better wake up. An additional fraction of 5.40% of those people would wear a sleep-tracking wearable. Thus, the serviceable, obtainable market size is 4.804 million. Based on similar products in the vein of sleep-tracking wearables, a unit sale price of \$150 has been set [21]. This gives the product a revenue estimate of 3.6 billion dollars, as shown in Table 9.

Revenue					
Timeline (years)	5				
Serviceable Obtainable Market Size	4,804,082				
- Total addressable US Market (US residents who use an alarm clock)	226,746,586				
- Fraction of market which would consider wearing a sleep mask	53.60%				
- Fraction of those people that would tradeoff less sleep for a better wake up	73.20%				
- Fraction of those people that would use a sleep-tracking wearable	5.40%				
Unit price	\$150.00				
Total revenue over period	\$3,603,061,299				

Table 9. Revenue Analysis based on market research.

7.2 Cost Analysis

A cost analysis for this semester's work is shown below in Table 10. The costs for this semester are broken down into labor costs and prototyping costs. The labor cost is calculated under the assumption our compensation is on-par with that of an entry-engineer in the United States [22]. Additionally, average weekly hours worked has been estimated based on the mean expected time contribution of group members. The prototyping costs take the unit purchase prices of the components currently listed on our BOM, and are scaled with the expectation that the group will make four prototypes using these parts or similarly-priced parts. For convenience, the components have been separated into their respective subsystems as shown in Figure 9.

Further, manufacturing costs account for the estimated total production cost of our product over the timeline of five years. These costs include manufacturing engineers, facilities, machines (with cost amortized over the time period), and raw parts. These costs were based on estimations by comparison with other groups and costs [23, 24]. The parts cost is taken from the prototyping cost under the assumption that the parts need do not change drastically in function or quality; additionally it is assumed that a bulk purchase of these components can lend us a 20% cost reduction from individual part purchases done in the prototyping phase. Lastly, the total manufacturing cost is scaled to the expected purchases derived from the market research in Section 7.1.

LABOR COST FOR THE SEMESTER (PRODUCT DEVELOPMENT)		
TOTAL SALARIES	\$30,000.00	
- Total Engineering Hours	750	
- Team Members	5	
- Weekly Hours Worked	10	
- Project Duration (weeks)	15	
- Hourly Engineering Rate (\$)	\$40.00	
EMPLOYEE BENEFITS	\$5,000.00	
REIMBURSED EXPENSES	\$2,500.00	
TOTAL LABOR COST	\$37,500.00	
PROTOTYPING COSTS		
SENSING SUBSYSTEM	\$25.19	
- EOG electrodes	\$5.83	
- Analog Front End for EOG data	\$11.08	
- IMU Chip	\$3.33	
- Temperature Sensor Chip	\$4.95	
COMPUTING SUBSYSTEM / TRANSMISSION SUBSYSTEM	\$20.00	
- ESP32 microcontroller	\$20.00	
USER INTERFACE SUBSYSTEM	\$0.50	
- Power Button	\$0.50	
POWER SUBSYSTEM	\$21.83	
- LiPo rechargeable battery	\$9.95	
- Power management	\$9.82	
- Charging Cable and Power Brick	\$2.06	

Table 10. Cost analysis of both prototyping and production phases of the project.

TOTAL PROTOTYPE COST	\$67.52
Anticipated Number of Prototypes	4
TOTAL PROTOTYPING COSTS	\$270.08
MANUFACTURING COSTS	
MANUFACTURING ENGINEER COSTS	\$260,000
- Yearly Salary	\$52,000
- Manufacturing Timeline (years)	5
TOTAL PRODUCTION COST FOR ALL UNITS	\$2,420,488,540
- Parts Pricing	\$60.77
- Manufacturing labor cost for one unit	\$40.00
- Total Expected Units Sold	24,020,408.66
- Yearly Expected Units Sold	4,804,081.73
- Product sales timeline (years)	5
OVERHEAD COST	\$4,250,000
- Facility cost	\$2,750,000
- Amortized Machine Cost over 5 years	\$1,500,000
- Total machinery cost	\$3,000,000
- Average machine lifespan (years)	10
Total Manufacturing Costs	\$2,424,998,540

Table 10. Cost analysis of both prototyping and production phases of the project continued.

Using both the revenue and cost analyses, the estimated net profit and unit profit can be determined. Over the project timeline of five years, over one billion dollars in net profit is projected, equating to nearly \$49 profit per unit, a 32.7% profit. This amounts to a 48.58% return on investment (ROI) over five years and an 8.24% annualized ROI. The profit analysis is presented in Table 11.

Table 11. Profit analysis over a five year project timeline.

PROFIT		
Product Sale Revenue	\$3,603,061,299	
Engineering Cost	(\$37,500.00)	
Manufacturing Cost	(\$2,424,998,540)	
TOTAL PROFIT	\$1,178,025,259	
PROFIT PER UNIT	\$49.04	

8. Current Status

Much research has gone into understanding a person's sleep cycle overnight as well as research into how to implement and understand EOG to collect data. Tasks for each subcategory have been delegated between members with a rough timeline for members to gauge their progress. Most of the team's work thus far has been dedicated to creating a design as well as a plan to execute all needed tasks in time for the project, so many development tasks are yet to have started as design is still being finalized.

Some preliminary tasks have been completed in order to aid with more critical future tasks on both the hardware and software ends. For the electrical subsystem, an initial SPICE circuit for EOG sensing has been made which will eventually be turned into a PCB. EOG sensors and electrodes have already been purchased to be used on a breadboard circuit to make sure EOG data can be properly collected. Furthermore, there exist sleep cycle databases which also contain REM sleep data using EOG sensors, which have been evaluated in order to have a basis for the REM mask's EOG data to compare with. This project will heavily depend on the device firmware and its interactions with a software application on an external device. Due to the fact that this device will be wireless, bluetooth connection will be necessary to collect data. MIT App Inventor may prove useful as it can be a useful tool to create a rough application software due to it having a built-in bluetooth module. As of now, MIT App Inventor seems to be the tool that is being considered to be the primary candidate for very rough mobile application development that will establish a connection to our device. Two possible graphical user-interfaces have been created for a "concept app" which basically show what the app is projected to look like when a user is going to sleep and when they wake up. Core functionalities of the app will include having the user set their desired alarm wake-up time with leniency for the REM alarm to actually wake the user up before going to sleep, and a summary of biometric data when the user was sleeping such as when REM occurred, overnight body temperature, and overnight movement.

On the mechanical end, preliminary 3D designing and prototyping on Solidworks have been done for a rough form factor for the mask. Electrodes will be placed on the temples of the user's head; therefore, the mask must be designed in order to prevent any unnecessary pressure being applied to and interfering with the electrodes and altering or disturbing data collection.

Category	Task	Completion
Design	Hardware Design	65%
Design	Firmware Design	60%
Design	Software Design	15%
Design	Mechanical Design	15%
Development	S6 - Classify REM versus nREM using data	15%
Development	M4 - CAD Design	30%

9. Leadership Roles

Nabid Farvez: Electrical Lead, Expo Coordinator

Nabid will be leading the electrical design of the product. This will involve designing subcircuits for the final PCB, making sure electrical tasks meet the timeline and specifications. He will also be responsible for the logistics of this semester's senior design expo.

Ananth Kumar: Financial Manager, Software Lead

As financial manager, Ananth will be in charge of ensuring the proper steps are being taken to source parts for prototypes. As software lead, he will be responsible for developing the alarm clock mobile application on the user's personal device.

Andrew Lang: Webmaster, Firmware Lead

Andrew will serve as webmaster for this project, serving as the primary means of communication to advisors. Additionally, he will be responsible for the completion of design, development, and testing for the firmware on the wearable device.

Syed Samin: Documentation Coordinator

Syed will serve as the documentation coordinator, making sure that all written material is completed in a timely manner by everyone in the group. There will be many iterations of prototyping and testing on both the hardware and software ends, and valuable information must be properly documented.

Kai Vong: Group Leader, Mechanical Lead

Kai is the group leader who will make sure everybody does their tasks. Kai will also be leading the designing and prototyping of the actual mask itself. He will create the CAD models, making sure it is within the specifications, and construct the product.

10. References

- [1] "12 Facts about Sleep Inertia: Sleep Study, Sleep Clinic: Valley Sleep Center: Arizona." Sleep Study, Sleep Clinic | Valley Sleep Center | Arizona, 26 June 2012, https://valleysleepcenter.com/12-facts-about-sleep-inertia.
- [2] A. P. Babich, "Stages of sleep," *Mattress Advisor*, 22-Apr-2021. [Online]. Available: <u>https://www.mattressadvisor.com/sleep-stages/</u>.
- [3] C. J. Hilditch and A. W. McHill, "Sleep Inertia: Current insights," *Nature and Science of Sleep*, vol. Volume 11, pp. 155–165, 2019.
- [4] P. Tassi and A. Muzet, "Sleep inertia," Sleep Medicine Reviews, vol. 4, no. 4, pp. 341–353, 2000.
- [5] K. Slyusarenko and I. Fedorin, "Smart alarm based on sleep stages prediction," 2020 42nd Annual International Conference of the IEEE Engineering in Medicine & Biology Society (EMBC), 2020.
- [6] S. Haghayegh, S. Khoshnevis, M. H. Smolensky, K. R. Diller, and R. J. Castriotta, "Accuracy of wristband fitbit models in assessing sleep: Systematic review and meta-analysis," *Journal of Medical Internet Research*, 28-Nov-2018. [Online]. Available: <u>https://www.jmir.org/2019/11/e16273/</u>.
- [7] "Testing," *Apnea*, 11-Feb-2011. [Online]. Available: <u>https://healthysleep.med.harvard.edu/sleep-apnea/diagnosing-osa/testing</u>.
- [8] J. Fan, C. Sun, M. Long, C. Chen, and W. Chen, "EOGNET: A novel deep learning model for sleep stage classification based on single-channel EOG Signal," *Frontiers*, 01-Jan-1AD. [Online]. Available: <u>https://www.frontiersin.org/articles/10.3389/fnins.2021.573194/full</u>.
- [9] K. Slyusarenko and I. Fedorin, "Smart alarm based on sleep stages prediction," 2020 42nd Annual International Conference of the IEEE Engineering in Medicine & Biology Society (EMBC), 2020.
- [10] A. Coskun, S. Ozsen, S. Yucelbas, C. Yucelbas, G. Tezel, S. Kuccukturk, and S. Yosunkaya, "Detection of REM in sleep eog signals," *Indian Journal of Science and Technology*, vol. 9, no. 25, 2016.
- [11] A. Bulling, D. Roggen, and G. Tröster, "Wearable EOG goggles: Seamless sensing and context-awareness in everyday environments," *Journal of Ambient Intelligence and Smart Environments*, vol. 1, no. 2, pp. 157–171, 2009.
- [12] A. Coskun, S. Ozsen, S. Yucelbas, C. Yucelbas, G. Tezel, S. Kuccukturk, and S. Yosunkaya,
 "Detection of REM in sleep eog signals," *Indian Journal of Science and Technology*, vol. 9, no. 25, 2016.

- [13] M. Tripathi, "Technical notes for digital polysomnography recording in Sleep Medicine Practice," *Annals of Indian Academy of Neurology*, vol. 11, no. 2, p. 129, 2008.
- [14] J. Fan, C. Sun, M. Long, C. Chen, and W. Chen, "EOGNET: A novel deep learning model for sleep stage classification based on single-channel EOG Signal," *Frontiers*, 01-Jan-1AD. [Online]. Available: <u>https://www.frontiersin.org/articles/10.3389/fnins.2021.573194/full</u>.
- [15] A. López, F. Ferrero, J. R. Villar, and O. Postalache, "High-Performance Analog Front-End (AFE) for EOG Systems," Electronics, Jun. 2020.
- [16] "General wellness: Policy for low risk devices guidance ...," 27-Sep-2019. [Online]. Available: https://www.fda.gov/media/90652/download. [Accessed: 07-Feb-2022].
- [17] C. Chaduc, "How to Certify Your Bluetooth Product," Texas Instruments Application Notes, 2021.
- [18] "IEEE Draft Standard for Wearable Consumer Electronic Devices Overview and Architecture," in P360/D8, December 2021, vol., no., pp.1-33, 7 Dec. 2021.
- [19] M. F. G. CTO, "Almost 60% of 16-34 year olds use a phone as their primary timepiece," YouGov, 05-May-2011. [Online]. Available: https://today.yougov.com/topics/lifestyle/articles-reports/2011/05/05/brother-do-you-have-time. [Accessed: 07-Feb-2022].
- [20] "U.S. and World Population Clock," *United States Census Bureau*. [Online]. Available: https://www.census.gov/popclock/. [Accessed: 07-Feb-2022].
- [21] E. Team and R. Posts, "5 best Garmin watches for Sleep Tracking (top picks)," SmartwatchCrunch, 29-Dec-2021. [Online]. Available: https://smartwatchcrunch.com/garmin-watches-sleep-tracking/. [Accessed: 07-Feb-2022].
- [22] CollegeSimply, "Salaries for Georgia Institute of Technology Main Campus Graduates," CollegeSimply. [Online]. Available: <u>https://www.collegesimply.com/colleges/georgia/georgia-institute-of-technology-main-campus/salarie</u> <u>s/</u>. [Accessed: 07-Feb-2022].
- [23] "Factory, 1 story commercial construction costs per square foot," *RSMeans Construction Cost Database*. [Online]. Available: https://www.rsmeans.com/model-pages/factory-1-story. [Accessed: 07-Feb-2022].
- [24] "How to estimate injection molding cost?," *Formlabs*. [Online]. Available: https://formlabs.com/blog/injection-molding-cost/. [Accessed: 07-Feb-2022].

Appendix A

Appendix 1. Experimental REM versus nREM classifier.

```
1. import numpy as np
2. import mne
3. import itertools
4. import matplotlib.pyplot as plt
5. from sklearn import svm, metrics, linear model
6.
7. # All training data stored in "./training data/" subdirectory
8. # Only training data listed, many more edf files in dataset
9. psgs_and_edfs = {'ST7011J0-PSG.edf' : 'ST7011JP-Hypnogram.edf',
        'ST7012J0-PSG.edf' : 'ST7012JP-Hypnogram.edf',
'ST7021J0-PSG.edf' : 'ST7021JM-Hypnogram.edf',
'ST7022J0-PSG.edf' : 'ST7022JM-Hypnogram.edf'}
10.
11.
12.
13.
14. all eog metrics = []
15. all rem = []
16. for psg_edf_filename in psgs_and_edfs.keys():
        psg_edf_file = './training_data/' + psg_edf_filename
17.
        eog edf = mne.io.read raw edf(psg edf file).pick channels(['EOG horizontal'])
18.
19.
        eog data samples = eog edf.get data()[0]
20.
        stage at epoch = []
        hypn_edf_file = './training_data/' + psgs_and_edfs[psg_edf_filename]
21.
22.
        hypn_edf = mne.read_annotations(hypn_edf_file)
23.
24.
        # Get REM versus non-REM data from hypnogram EDF
25.
        for i in range(len(hypn edf.duration)):
26.
            stage_at_epoch.extend([hypn_edf.description[i][-1]] \
27.
                * int(hypn_edf.duration[i] / epoch_length_s))
28.
        for i in range(len(stage at epoch)):
29.
            all_rem.append(stage_at_epoch[i] == 'R')
30.
31.
        # Get EOG samples per epoch, then align them with rems
32.
        epoch_start_sample = 0
33.
        epoch_end_sample = eog_sample_rate_hz * epoch_length_s
34.
        eog_samples = []
35.
        while epoch_end_sample <= sum(hypn_edf.duration) * eog_sample_rate_hz:</pre>
36.
            eog_samples.append([eog_data_samples[epoch_start_sample:epoch_end_sample]])
37.
            epoch_start_sample = epoch_end_sample
38.
            epoch_end_sample += eog_sample_rate_hz * epoch_length_s
39.
40.
        # Extract features from EOG signals, epoch by epoch
        np_eog_data_samples = np.array(eog_data_samples)
41.
42.
        for eog epoch in eog samples:
43.
            np_eog_epoch = np.array(eog_epoch)
44.
            metric_list = []
45.
46.
            # Metric 1: Absolute mean of signal
47.
            metric_list.append(np.mean(np_eog_epoch))
48.
49.
            # Metric 2: Energy of Signal
            metric_list.append(np.sum(np_eog_epoch**2))
50.
51.
            # Metric 3: standard deviation of the signal
52.
            metric list.append(np.std(eog epoch))
53.
```

```
54.
55. all_eog_metrics.append(metric_list)
56.
57. # Train a model to predict REM / NREM using the EOG channel over the first 2/3 of epochs
58. rem_classifier = svm.SVC()
59. rem_classifier.fit(all_eog_metrics, all_rem)
60.
61. # For now, try to see a success classifying training data.
62. all_predictions = rem_classifier.predict(all_eog_metrics)
63.
64. # Construct a confusion for each test and calculate accuracy.
65. print("\nTRAINING RESULTS\n=========="""""")
66. print("CONFUSION MATRIX:\n==========\n", \
metrics.confusion_matrix(all_rem, all_predictions))
67. print("ACCURACY:\t", metrics.accuracy_score(all_rem, all_predictions))
```