Sleep-Monitoring Mask and Smart Alarm

Final Report

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Submitted
May 4, 2022

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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.

Motivation: 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 6% 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.

Approach: 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 Concept: Proving the efficacy of the REM Mask was essential to its success. In this regard, there are three primary criteria that the device met:

1) Proving that the device can *accurately* record the user's EOG data.
2) Proving that the integrated software can recognize REM sleep from the EOG data.

3) Proving that the smart alarm algorithm adapts to users' sleep stages and wakes them during the transition from REM to nREM sleep.

The team, throughout the course of the project, achieved the completion of these three criteria, and by doing so created an effective project.

Nomenclature

2D	Two Dimensional
3D	Three Dimensional
ABS	Acrylonitrile Butadiene Styrene
AFE	Analog Front End
BLE	Bluetooth Low-Energy
BOM	Bill of Material
CAD	Computer-Aided Design
DC	Direct Current
EEG	Electroencephalography
EMG	Electromyography
EOG	Electrooculography
FCC	Federal Communications Commission
FDA	Food and Drug Administration
GUI	Graphical User Interface
HMM	Hidden Markov Model
IC	Integrated Circuit
IEC	International Electrotechnical Commission
LDA	Linear Discriminant Analysis
LDO	Low-Dropout Regulator
LED	Light-Emitting Diode
MCU	Microcontroller unit
nREM	non-REM
PCB	Printed Circuit Board
PLA	Polylactic Acid
REM	Rapid Eye Movement
RF	Radio Frequency
SPI	Serial Peripheral Interface
SVM	Support Vector Machine
USB	Universal Serial Bus

Introduction and Background

Team Tired Techies has developed a state-of-the-art smart sleeping mask, the REM Mask. The project scope was primarily to develop a wearable device that can actively monitor users' sleeping stages and patterns. The device is also capable of transmitting this data to a smartphone or computer, which will serve the purpose of an alarm clock that optimizes users' sleep health by waking them up at an individualized time when they are scientifically proven to feel the most energetic and refreshed. In other words, the REM Mask was designed with the goal of waking user's up on time, ensuring they feel less tired, more refreshed, and **R**eady **E**very **M**orning.

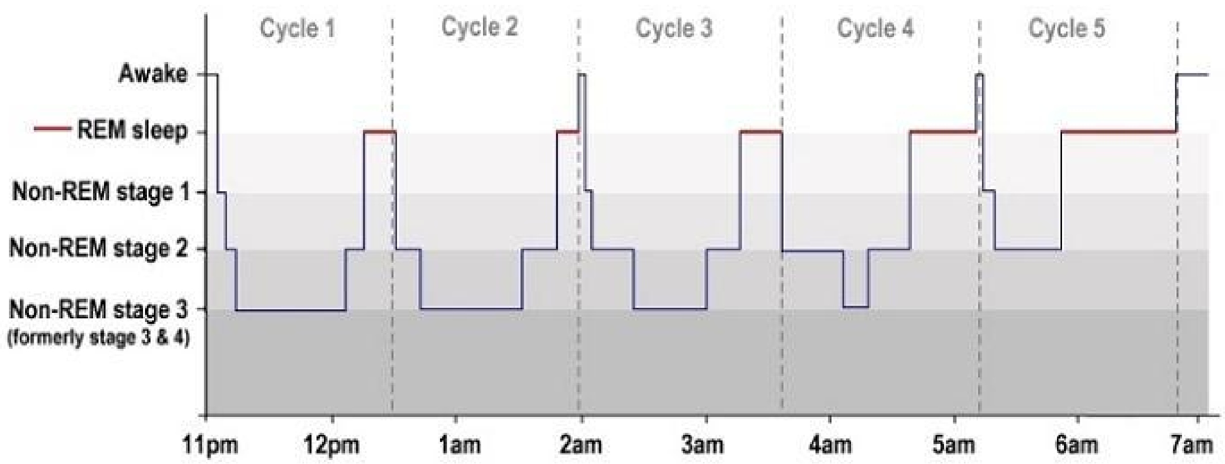


Figure 1. A typical hypnogram showing sleep stages and cycles in adult sleep [2].

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 aforementioned, 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 ultimately 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 was aimed at addressing 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 adequate amount of time [4]. Specifically, waking up in the middle of an REM cycle interrupts sleep and results in sleep inertia. A reliable smart alarm that avoids waking users during sub-optimal periods of their sleep is the obvious solution to this problem [5].

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 was instead 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 was then wirelessly communicated to a paired computer (laptop) running a software application, which provided a model and algorithm for deciding an optimal wake time, ultimately sounding the alarm. This alarm was designed such that it sounded at or before a user-specified time, prioritizing that users would 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 was 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 was to provide users with a product that prioritizes healthy yet timely waking up.

To achieve this, the most vital performance aspect of the device was its ability to properly characterize user sleep data. This was 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 a user is in REM sleep. As it was improbable that sleep quality could adequately be tested during the short 15-week time frame of this project, the product's proof of concept involved demonstrating the system's ability to recognize REM sleep and determine an appropriate alarm time. Since the product was successful in doing so, cited research indicates that the REM Mask will in fact benefit user's sleep health [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 was to change that with the REM Mask.

The remainder of this final report will expand on the ideas introduced in this section, discussing customer requirements, project goals, existing products, technical specifications, design decisions, market research, product analysis/testing, development timelines, and final design prototype. The report will be concluded with a discussion of the future commercialization of the product, supported by accompanying market, risk, and cost analyses.

Existing Products, Prior Art, and Applicable Patents

As mentioned above, there are existing products and applications that perform similar functions. However, none compare directly to the scope and overall functionality of the REM Mask. A comparison between the REM Mask and existing products is highlighted in the product comparison table below:

FEATURES	POLYSOMNOGRAM	SMART WATCHES	SLEEP CALCULATORS	REM MASK
< $100 Cost	✗	✗	✓	✓
Direct Eye Measurement	✓	✗	✗	✓
Comfort	✗	✓	✓	✓
Visible Live Data	✓	✓	✗	✓
> 70% Accuracy	✓	✗	✗	✓
Sleep Stage-Dependent Alarm	✗	✗	✗	✓

Figure 2. Comparison chart between existing sleep solutions.

Outside of these more functionally analogous competitors, it is also interesting to look at more direct, visually-similar competitors and existing patents. One example is “Chesma,” an eye mask that “can capture pulse, eye movement, and sleep signals when worn in an everyday environment.” [28]. The Chesma is primarily meant to aid in sleep and psychosocial studies. Another example is the Neuroon, a Kickstarter product, which is the “world’s first system that allows [users] to modify [their] sleep patterns with patented light therapy.” [31].

These products all differ from the REM Mask on many accounts. Some are meant for during-the-day use, whereas the REM Mask is a *consumer product* meant for nightly use.

Others are meant to help users fall asleep or for clinical studies, but the REM Mask ultimately serves to *wake users up* in the form of an individualized smart alarm.

Finally, a few patents do exist that claim to use EOG or other polysomnography for monitoring sleep, but none of these combine to match the user-specific utility of the REM Mask. Namely, the REM Mask's novelty and uniqueness comes from its ability to actively sense a user's sleep stages during the night, finally employing this data via an alarm that wakes users up at an optimized time that is specifically based on their sensed and classified sleep patterns.

Codes and Standards

As the device is to be worn on the head, there are certain health and safety standards it should comply with. One of the most critical of these standards is the IEC 60601 standard for electrical safety of medical devices. There are different requirements for passive and active devices. An active device is one using a technique that sends some current through the tissue, such as measuring bioimpedance. The device measures potentials created by the human body, thus making it a passive device. Standard practices for passive devices 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].

A standard to be followed in conjunction with IEC 60601 is IEC 62133, which applies to lithium-ion batteries. The device uses a rechargeable 3.7 V lithium-ion battery, which was confirmed to be compliant with the standard [29].

Were the device to be commercialized, the product would be marketed as a general wellness device, which removes the need for FDA approval. A requirement to market the device this risk is to be low-risk, which the group has decided is appropriate. Additionally, the product cannot make claims to treat or detect specific diseases, such as sleep apnea in our case. The scope of this project did not involve such medical aspirations, so this additional requirement is satisfied [16].

Because the device utilizes a form of wireless transmission in BLE, it 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, allows the wearable device to meet the RF requirement [17]. The microcontroller board used in the device, the Seeeduino XIAO, is a pre-certified module for wireless transmissions [30].

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.

Customer Requirements and Design Specifications

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 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 is battery-powered, mustn't pose an electrical 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: 225g
    - Battery: 34g
    - Microcontroller: 9g
    - PCB board: 2.5g
    - Sleep mask body: 150g
- 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 3 outlines more specifically the *stake* each of these potential stakeholders will have in the product.

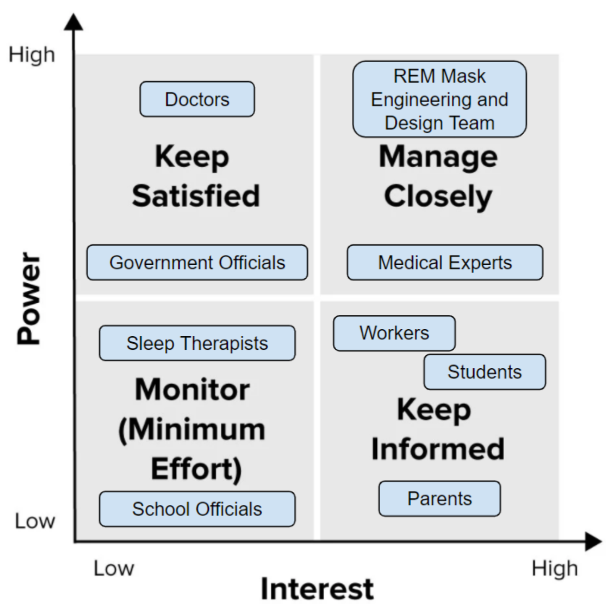


Figure 3. A stakeholder chart illustrating parties with interest and power regarding the product.

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.

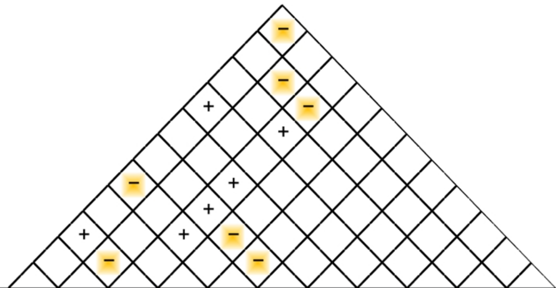
Another constraint is the size (and thus comfort-level) of the mask. If the product is intended to maximize and increase users' sleep quality, it is vastly important that the sleep mask's size, bulk, and feel don't detract from users' sleep because it results in nightly discomfort and difficulty sleeping. 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.

The House of Quality, depicted in Figure 4 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 5.

Correlations	
Positive	+
Negative	−
No Correlation	

Relationships	
Strong	●
Moderate	○
Weak	▽

Direction of Improvement	
Maximize	▲
Target	◇
Minimize	▼



Weight	Column #	1	2	3	4	5	6	7	8	9	10	11
	Direction of Improvement	▼	▼	▲	▼	▼	▲	▼	▲	◇	◇	◇
Weight	Customer Requirements (Explicit and Implicit) / Engineering Requirements	Dimension	Charge Time	Operation Time	Setup Time	Total Cost	Accuracy	Power Consumption Rate	Weight	Mask Lifetime	Heat	Light Level
9	Comfortable	○									▽	▽
10	Reliable Alarm			▽	▽		●					
8	Easy-to-use		▽		●							
4	Aesthetically Pleasing	▽										
9	Convenience	▽	●	▽	○				○			
5	Affordable					●				▽		
8	Safety							▽				
6	Durable	▽								○		
10	Wake User Up Refreshed			●			●					
7	Intuitive				●							
7	Track User Sleep		○	●				●				
7	Reliable Mask											
3	Nondisruptive						●				▽	▽
6	Sleep Inducing											○
7	Light Weight	▽							●			
	Target	8.2 in x 4.5 in x 1 in	2 hours	10 hours	2 minutes	90 dollars	99%	120 mAh per hour	0.5 lbs	3 years	Room Temperature	0%
	Max Relationship	3	9	9	9	9	9	9	9	3	1	3
	Technical Importance Rating	7	11	20	22	9	27	10	12	4	2	5
	Relative Weight	5%	9%	16%	17%	7%	21%	8%	9%	3%	2%	4%
	Weight Chart											

Figure 4. House of Quality for the REM Mask.

Changes	D/W	Requirement	Responsibility	Source
2/1/22	W	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	W	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	W	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	W	Max Operational Time: 10 Hours	Nabid	Team - For a night of sleep
2/1/22	W	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	W	Max EOG Sensors: 2	Nabid	Team
2/1/22	W	Max Temperature Sensor: 1	Nabid	Team
2/1/22	W	Max Mircotroller: 1	Nabid	Team
2/1/22	W	Max Number of Batteries: 1	Nabid	Team
		Ergonomics		
2/1/22	W	Wires Contained: 100%	Samin	Team
2/1/22	W	Aesthetic Appearance Jury: 95% concensus	Samin	Team
		Production		
2/1/22	W	Total Prototype Time: 10 hours	Kai	Team
		Schedule		
2/1/22	D	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 5. Specification Sheet for the REM Mask.

Market Research

Sleep is an important part of a person's daily routine. Everyone has to go to sleep and wake up at different times. The focus groups that were considered to be primary customers or the target audience for the REM Mask would include those who need to wake up at a specific time every morning such as students or the working class. However, anyone that uses an alarm clock would be able to benefit from the device as normal alarm clocks have no knowledge of an individual's unique sleep stages in order to wake them up at the most optimal time. In order to evaluate the utility and viability of the REM Mask, customer surveys were conducted to gather market statistics. The survey included over 60 respondents, primarily being college students, answering questions regarding how they normally feel when waking up. Although results from this small population may be slightly skewed, 73.8% of respondents said that they always use an alarm clock or some form of wake up aid, while 16.4% stated that they sometimes use alarm clocks or wake up aids. Generally, 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 approximately 226.747 million.

From the initial customer surveys, over 93% of respondents declared that they wake up feeling groggy often with 61.7% stating that they feel groggy even with more than 8 hours of sleep. On the other hand, 65% of respondents stated that they have felt refreshed and fine while having less than 8 hours of sleep. These responses upheld the initial problem that the REM Mask would address being that people feel groggy when waking up depending on the sleep stage that they wake up during. In order to validate that the REM Mask would have a market audience and use if it were to be able to accurately wake a user up at the correct stage to prevent grogginess, the survey also asked the following question: "If you could wake up earlier and it meant NOT feeling groggy, would you do it?" 72.1% of respondents replied with "Yes" and 18% of respondents declared "Maybe." Over 53% of respondents stated that they would consider wearing a sleeping mask. An additional fraction of 5.40% of those people would wear a sleep-tracking wearable. Thus, the serviceable, obtainable market size is 4.731 million. From this small sample of respondents, there does in fact exist a market for sleep wearables that can classify sleep stages and use that data to wake up users at the most optimal time to reduce grogginess.

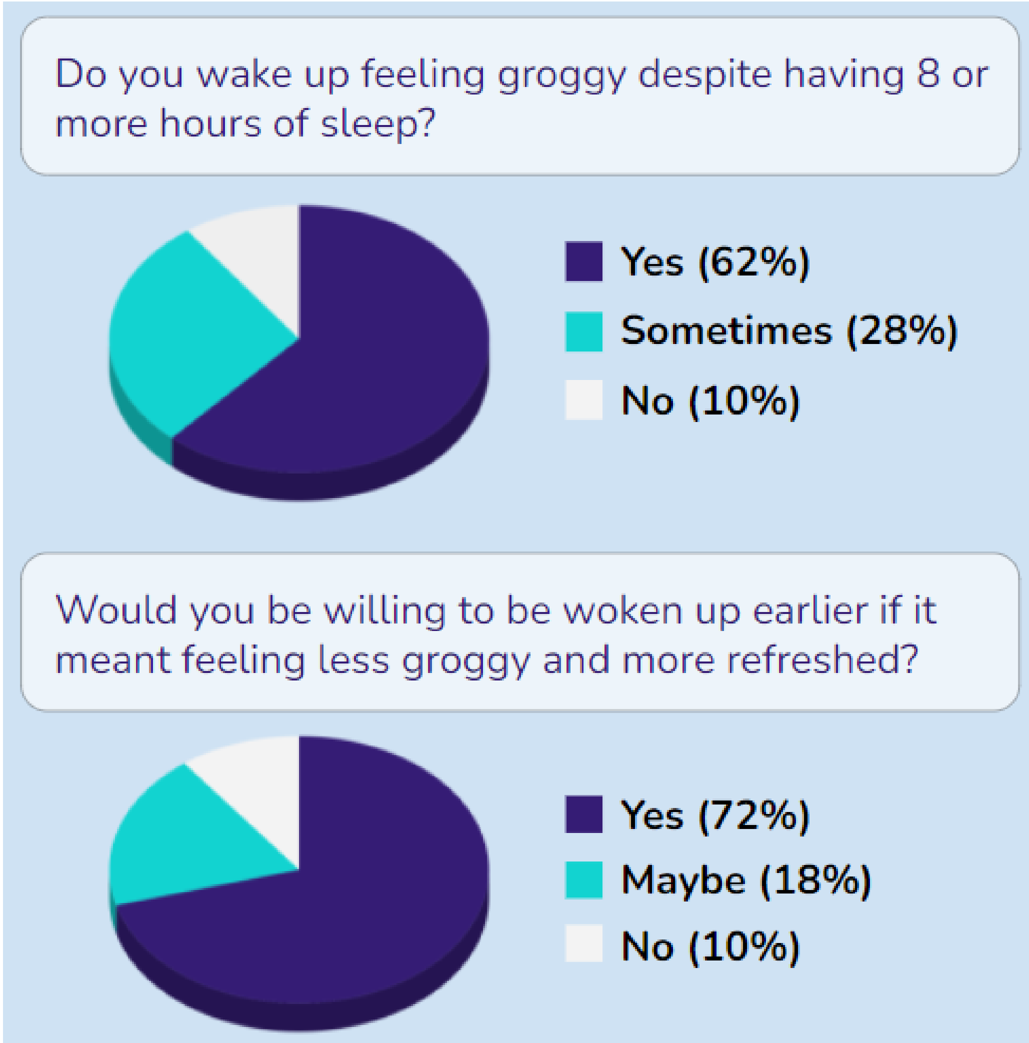


Figure 6. Results from Initial Customer Market Research Surveys

Table 1. Revenue Analysis based on market research.

Revenue	
Timeline (years)	5
Serviceable Obtainable Market Size	4,731,889
- 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	72.10%
- Fraction of those people that would use a sleep-tracking wearable	5.40%
Unit price	$100.00
Total revenue over period	**$2,365,944,624**

The product costs about $78 per unit to manufacture. However, this cost is for low-volume production (<10 units) and would be reduced by about 25% to $56 when we reach mid-volume production for orders of 100 units. Therefore, when mass produced, the device could be reasonably sold for approximately $100 per unit. This is much cheaper when compared to alternatives and competitors such as smartwatches and full sleep studies that use polysomnography [25].

Due to the fact that the REM Mask utilizes the sleeper's direct eye movement measurements to classify REM versus nREM sleep, it is much more accurate at classifying sleep stages than devices such as smartwatches that use other biometrics such as movement, breathing, and heart rate data. Therefore, because the REM Mask is able to accurately classify individual user's sleep stages and use that data to wake the user up at the correct time, the REM Mask will be able to compete with other, more expensive, alternatives at a much lower price, influxing a large market audience.

When conducting initial customer surveys and after presenting the idea of the REM Mask and its utility to see if the REM Mask would be a viable product, there seemed to be a lot of interest in the idea behind the REM Mask and it's functionality; therefore, it is important that the device is designed to be comfortable, lightweight, and fully functional in order to retain its existing market audience as well as pull in new customers for the future. The REM Mask currently weighs just under 125 grams which is relatively light on the face. After trying the mask on and feeling it directly, we received positive feedback about the comfort and the weight. Most people do not wear any form of sleeping masks, but a lot of people do wear smartwatches when they sleep. Thus, there are a lot of people open to wearing devices while they sleep as long as those devices are functional. Taking this into consideration, the REM Mask must be designed in order to be a fully functional and comfortable sleeping wearable.

Design Concept Ideation

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 the Figure 7 below.

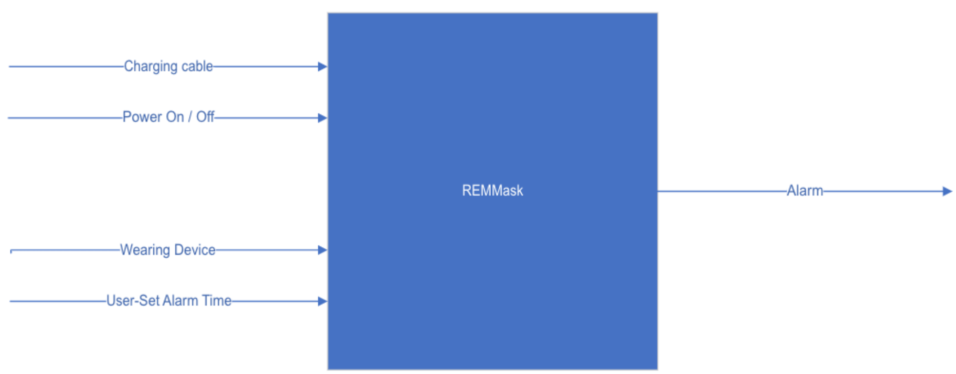


Figure 7. A high-level functional representation of the REM Mask project.

The REM Mask is 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, users will be able to set an alarm time. Specifically, this will be in the form of a *range* of alarm times during which the user prefers to be woken up. 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.

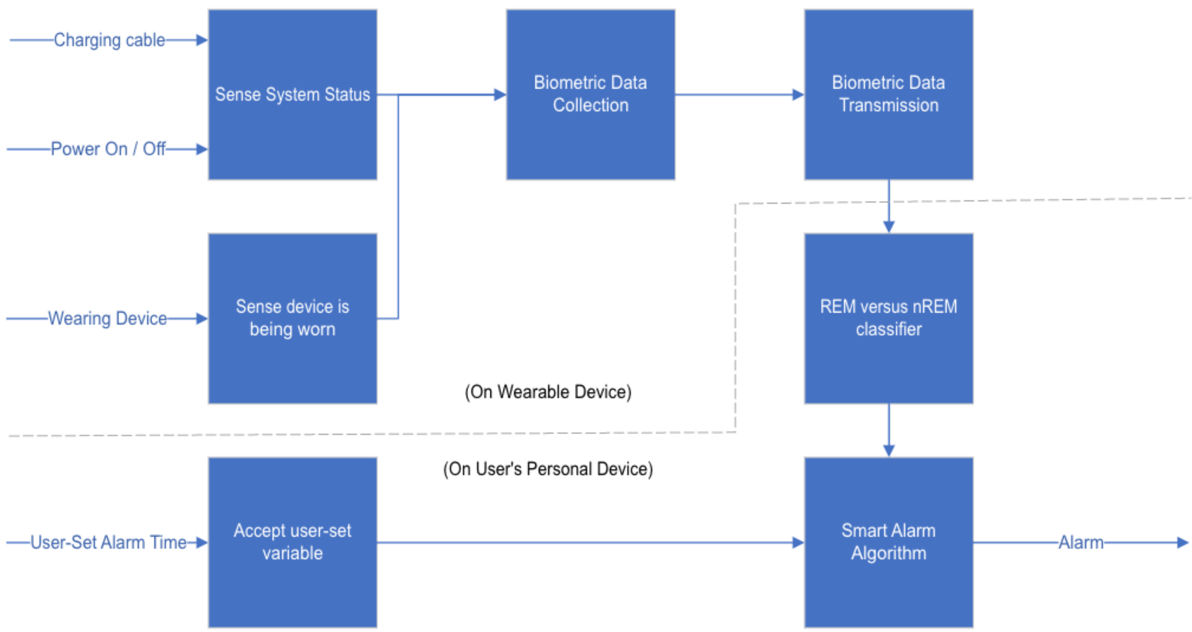


Figure 8. A functional decomposition of the REM Mask project.

Some of these functions are intuitive and do not have a sizable design space; for example, the "sense system status" function is ultimately decided by simple logic (e.g., the system is only 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 had many options and iterations for their designs, both of which are discussed in further depth in the following sections of the report.

For the biometric data collection function, the biometric used and decided on was: electrooculography (EOG). However, there are many potential implementations of EOG concerning our electrical hardware and device form factor. We had to decide between 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, which is what was used on the actual REM Mask, produced higher quality results [10], so the number of channels is a crucial decision to be made. Another important consideration that had to be made was the placement of these electrodes. Reliable electrode contact is critical to the success of the project, so we must pick locations accordingly. The electrodes were placed on the user's temples, next to their eyes. REM sleep involves eyes moving in all directions; however, left to right movement is predominant. Furthermore, the electrodes are placed on velcro in order to be adjustable. For better eye movement measurements, the electrodes could be placed slightly diagonal to get better measurements of up and down movement as well to aid with the classification of REM sleep.

For biometric data transmission, the project opted to connect wirelessly via BLE. The use of BLE made a collateral impact of determining what the software on the user's personal device can look like, as we made use of existing free-to-use BLE libraries for this project. Additionally, we considered what our data transmissions will look like, and how frequently it would occur. The device ended up transmitting 125 samples or 500 bytes of data every second. This decision wimpacted power consumption and the user's personal device's interface with the wearable. We buffered EOG data on the wearable device; a larger buffer allows for fewer transmissions, but it influenced the amount of RAM and ultimately footprint size of the MCU.

Another important design decision that was made was the format of the smart alarm. The REM mask prioritizes waking up users at the most optimal time which is when a person's sleep stage transitions from REM to nREM. The user must enter a time range in which they are okay with waking up. If this transition occurs in the window, the alarm will sound. However, depending on the size of the time range, this transition may not always occur; thus, we want to make sure the user does not risk waking up during REM sleep. If the user is in nREM 30 minutes before the latest wake up time, the alarm is sounded.

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 made use of existing libraries and documented approaches, such as an SVM, to accomplish the project in time. The features we input into such a machine were 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].

A design factor for health and safety of wearing an electrical design on the face is overheating or heat emitted from the battery. 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 is so close to the user's face, the material that contains the electronics have been placed so that they are separated from the face. Between the hardware and the face exists a cotton sleeping mask. Furthermore, battery and power consumption tests have been to ensure that the device will not overheat. 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 is also designed to be environmentally friendly to be seen more favorably by consumers. Polylactic acid (PLA) was 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 laptop or desktop. 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 is powered by a battery pack. An initial concern was that the battery would not survive the course of the night and would need to start data collection 2 hours before the earliest user-specified time range. However, after testing the battery and monitoring how much current the device draws at full load, we discovered that the battery could actually last up to seven nights per charge.

Throughout the ideation and design processes, certain questions were 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 9.

Evaluation Question	Methods for Answering Question
Which biometric should be utilized in the design?	1. Consider where the sensor would have to be placed and how that interacts with undisturbed sleep. 2. Research how well the biometric can classify sleep stages alone, especially compared to competitor performance. 3. Consider the width and depth of signal necessary to solve our design problem.
How should the system be connected?	1. Evaluate how a method impacts the physical footprint of the system. 2. Consider the low-power constraint of the wearable device.
How should sleep be classified?	1. Consider engineering time and group expertise. 2. Research how others have attempted to classify sleep using a particular biometric and how successful they were.

Figure 9. 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 [EOG]). 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. These eliminations determined EOG to be the design concept that was pursued.

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.

For classifying sleep data, the EOG signals are transmitted to the user's personal device via BLE. The data is filtered and segmented into thirty second epochs. A feature of the epoch is input to a model that has been trained offline and deployed within the application on the user's device.

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. Because the structure is so common, the entire analog-front end can be encapsulated within a single IC and for that purpose, the ADS1292 was chosen 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. The selected MCU for the project was the Seeeduino XIAO BLE Sense; this decision was based on the board's BLE support, low power features, small footprint, serial communication peripherals, and team familiarity with toolchain (Arduino environment).

A subsystem-level block diagram for the wearable device is shown in Figure 10. Overall, the wearable side of the system can be separated into five abstracted subsystems: power, sensing, user interface, compute, and transmission. The power subsystem is responsible for managing charging status and providing regulated DC power to all other subsystems, and is implemented already by the XIAO board. The "sensing" subsystem encapsulates all of the sensors needed for the device (i.e., three EOG electrodes), and provides a simplified interface to communicate with the MCU in the computer subsystem. The user interface is comprised a power switch connected to the MCU and a button used to initiate calibration sequence once connected to the app.

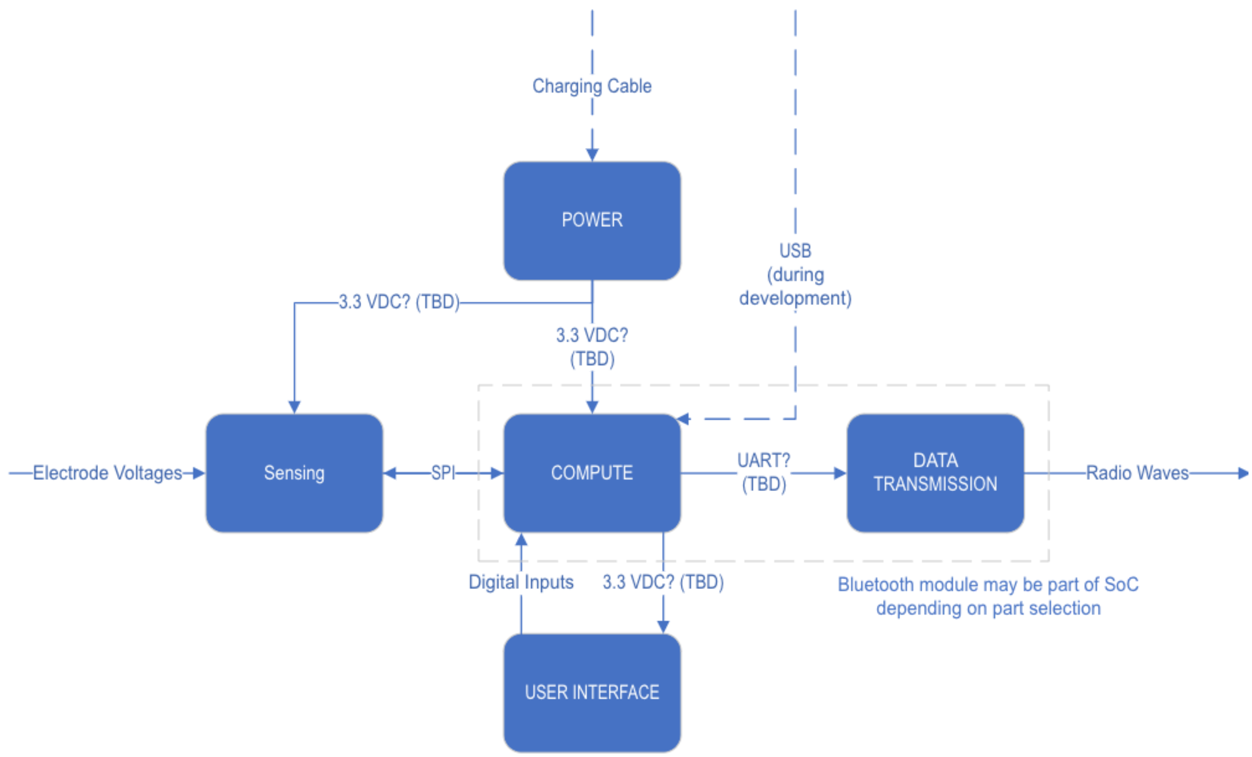


Figure 10. Subsystem-level diagram for wearable device.

The firmware on the wearable device exists in a bare-metal “event loop” program. Event loop programs are typically driven by delays and interrupts, and the device’s firmware is no exception. SPI communications with the AFE are triggered via interrupt, as well as BLE events such as connection and disconnection. The total delay of the event loop was devised to be maximized and yet still below the needed sample rate of the AFE. Fortunately for power-saving endeavors, the delay function call automatically shuts down most hardware, which contributes to the device’s 60-hour battery life. The software for the project is integrated entirely with a GUI desktop application, which manages BLE connections, the smart alarm algorithm, and the sleep-stage classifier.

Concept Selection and Justification

After comparison with existing sensing methodologies, it was established that EOG would be a feasible compromise between direct measurement and comfort for the end user due to its lower required electrode count compared to traditional polysomnogram but closer correlation to REM sleep using eye movement compared to heart rate utilized in smart watches.

To isolate EOG signals from other bands and noise such as motion, the data would be bandpass filtered between 0.5 Hz and 60 Hz.

Originally, the team proposed developing a mobile application for the user to input their alarm preferences, connect to the mask, and be awakened by. While this decision was made with the intent to provide maximum value to the end user, it soon became apparent with the team’s experiences and timeline that developing a functional mobile application would be overextending the team’s time commitment. The team had more experience with Python and more specifically Python GUI libraries, so the decision was made to re-scope the project to include a desktop application, but not a mobile app. As discussed later in the document, a mobile application is a vital component of proposed future work.

The classifier aspect of the design went through two major iterations. The first iteration attempted to utilize the intuition that REM sleep eye movement has different features than nREM sleep. The first ML model utilized for classifying the sleep stages was a support vector machine (SVM). The dimensions the SVM was to fit included several features: statistical measures such as mean, variance, kurtosis, and skew; signal measures such as power, flatness, and spectral entropy; and statistical measures of the STFT such as mean and variance. Test methodology is discussed below in the section “Technical Analysis and Experimentation”. The results of this implementation were woeful, yielding accuracy below 55%. The next steps taken were analyzing the value of each individual feature by being able to demonstrate a separation between sleep stages in that feature space. Notably after this step, it was found that spectral entropy can distinguish REM from nREM significantly. As shown in Figure 11, the distributions of spectral entropies for REM and nREM sleep stages show little overlap.

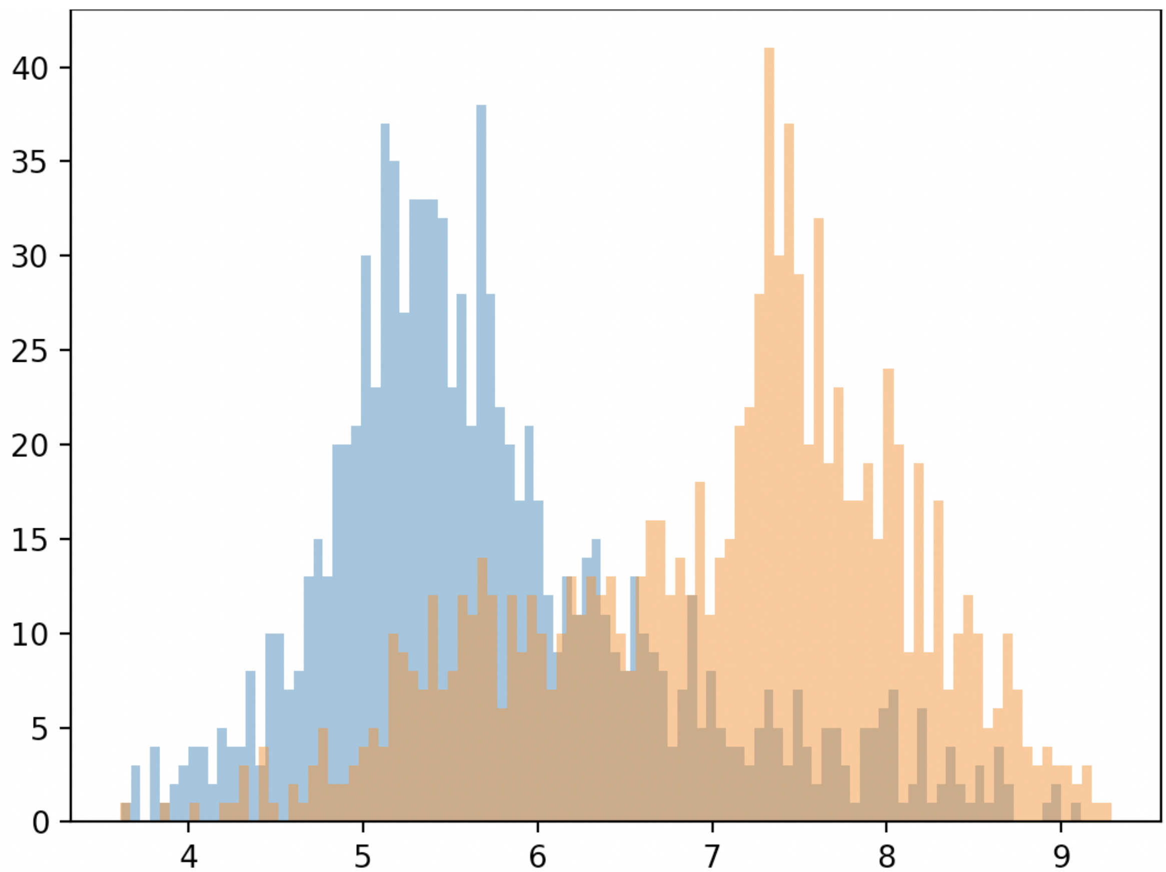


Figure 11. Distribution of full-band spectral entropy for 1000 REM sleep epochs (blue) and 1000 nREM epochs (orange).

Following the observation of the distributions of full-band spectral entropy, a linear discriminator was trained using only this feature. Testing this approach resulted in accuracy nearing the goal outcome of 70%, but still not very impressive.

The second iteration of the classifier utilized both the intuition described above as well as the fact the REM sleep stages typically last a certain duration, meaning there is a learnable heuristic probability of a transition between sleep stages. These two pieces of intuition led to the design of a Hidden Markov Model (HMM) filtering algorithm, utilizing the “forward algorithm”. A Hidden Markov Model predicts the “belief” of a hidden current state utilizing the belief of the previous hidden state, an observation resulting from the current state (emission model), and an understanding of the likelihoods of transitions between states (transition model). Upon training and testing this model, it was found that an overall accuracy of over 90% could be achieved, and 85% overall accuracy while still meeting the requirement of 70% accuracy (recall) of REM.

Manufacturing

At the start of the manufacturing process, a vector graphic software was used to create a 2D layout of where all the necessary components of the mask will fit into the mask before spending an extensive amount of time using a 3D Computer Aided Design software. The overall mask size and components location was determined from the layout before using SolidWorks to create a 3D mock up. For prototyping, 3D printing was used for its availability as well as its speed. 3D printing allows for the customized part to be manufactured and tested in as little time as possible. Since design changes were inevitable, 3D printing was chosen so the design could be modified without adversely affecting the speed of the manufacturing process. Figure 12 shows the software used for 3D printing. For potential future mass production, injection molding will be used as it is very efficient. A part can take hours in 3D printing while it takes minutes in injection molding. The downside of injection molding is the high initial investment as well as design change costs. However, once the design is finalized in the prototyping stage, there should not be any more design changes going into mass production.

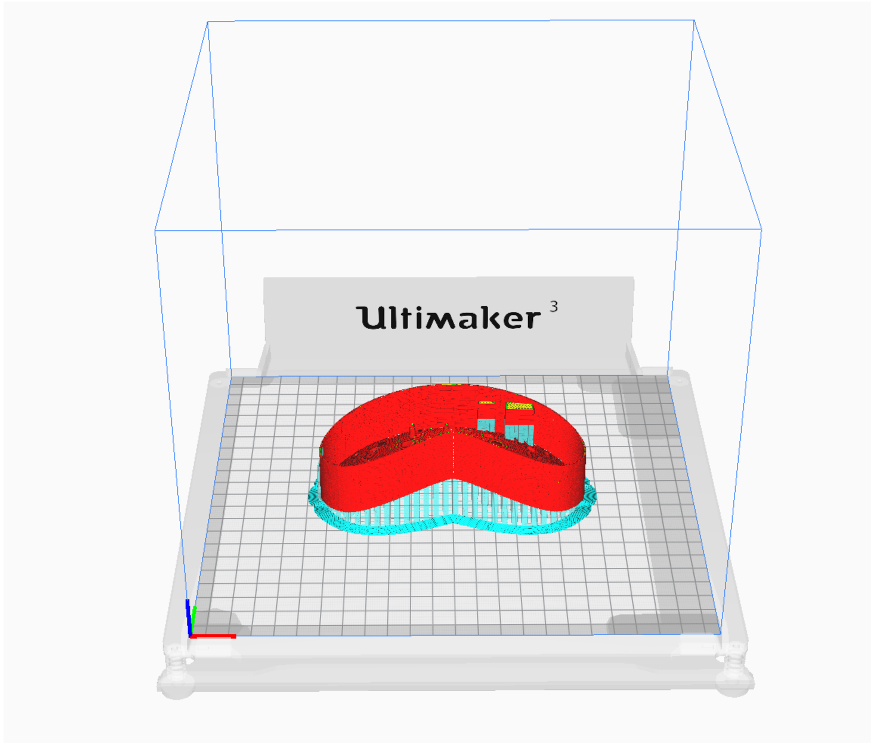


Figure 12. 3D print preview of the electronic casing in Cura.

For both 3D printing and injection molding, PLA plastic will be used instead of traditional ABS plastic. PLA is chosen as it has a lower cost while being a biodegradable plastic made from renewable resources. Therefore,it will create a cheaper and more environmentally friendly product. The advantages of heat resistance and mechanical properties from ABS do not apply to the mask as the electronics stay at room temperature and are subjected to heavy loads [26].

There are no issues with tolerances in the two physical manufacturing processes as the smallest feature that the plastic enclosing has is 6.6 mm. 3D printing and injection molding can produce parts with tolerance well below 0.5mm [27]. In addition to manufacturing the plastic encasing for the electronics, additional sewing is needed to enclose the encasing in cloth. Since this is an electronic product, it should be packaged and stored with water resistance in mind. The current BoM to produce 1 mask cost $77.71. The Budget Appendix may be referred to for a comprehensive breakdown of the budget. However, this is a cost for buying individual components. If the product was to be mass produced and the components were bought in bulk, the cost to bill of material for 1 mask is estimated to drop by 25% or $58.28. Taking into account labor cost, the final production cost is estimated to be around $63.79.

Technical Analysis and Experimentation

As discussed above, the smart alarm aspect of the software performs as follows. First, the user's current sleep stage is classified by the Hidden Markov Model. Then, this classification is maintained and recorded by a "window" that keeps track of the past five classifications over the past five epochs of the user's sleep (150 seconds). The novelty of the smart alarm algorithm is in its ability to accurately determine an optimal sleep stage transition during which to wake the user. The software does this by evaluating the five-sample window; if a majority (three out of five) of the samples have the same classification and this classification *matches* the classification of the last two (most recent) samples, the software concludes that *this classification* describes the user's *current sleep*. If this is determined to be REM sleep, the alarm algorithm will wait for the next stage transition away from REM and select this as the user's wake-up time.

Of course, testing the accuracy of this process was very important. This was done in two phases. The first involved feeding both random and pre-selected chains of existing test data from the Physionet Sleep EDF Database (referenced below) in order to not only test the accuracy of the classifier, but also the algorithm's ability to recognize a *stable* "REM-to-nREM" transition. Stability in the transition (having a constant period of a single classification) was important because this implied certainty with regards to the user's current sleep stage; oscillating between two different classifications could be taken to mean that a user was in the process of undergoing a stage transition. The algorithm passed these initial tests without issue.

The second phase of algorithm testing involved using non-database data, either in the form of live data taken from an awake individual or in the form of true sleeping data that was actively gathered from individual team members wearing the mask to sleep. Tactics like printing out live classification results to a file that could be reviewed later (i.e. the following morning) allowed for further testing of the smart alarm's efficacy. Mapping sleep stage classification transitions from this "classification labels" file and the times at which these classifications occurred to the eventual alarm time effectively confirmed that alarm's ability to reliably sound at the end of REM sleep, just as was intended.

To test the average runtime of the product, an absolute worst-case power budget analysis was conducted using the voltages and max current from each component's datasheet in our prototype. At its absolute worst draw, a 200 mA peak current was expected, which would allow about a six-hour runtime on a single charge of a 1200 mAh lithium ion battery. However, because all unused peripherals on the processor, the major power consumer, could be disabled in its power management unit (PMU), the actual power draw was measured using a benchtop supply and monitored during full load. This saw an occasional peak current at 10 mA. Assuming a derated and continuous 20 mA current, our true typical runtime would instead be around 60 hours on a single battery charge. This greatly supersedes our written requirement of lasting a single night for about eight hours, allowing almost a week of nights without charge instead.

Because the major sensing component of our product is the EOG measurements, the analog front-end (AFE) IC was tested on a breadboard before soldering to the PCB. The IC was soldered to a breakout board and basic firmware functions for enabling SPI communication between the microcontroller and AFE were written. By probing the data input and output lines using an oscilloscope, we could decode the binary packets being sent and received to ensure that the packets matched those that were expected according to the datasheet. Furthermore, testing the ability to blink an LED through the AFE IC were validated to prove proper register-level communication. Our test setup for SPI communication and power measurement can be seen in Figure 13**.**

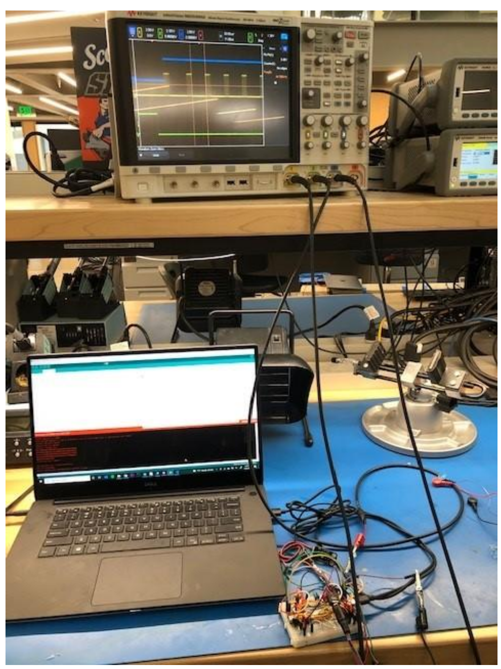


*Figure 13***.** Set up to validate SPI communication between MCU and AFE

Before integration with the EOG data, early Bluetooth transmission between the microcontroller and host computer was verified by transmitting “dummy” data wirelessly and verifying that the identical data was received without packet loss and the set rate. To actually test the voltage changes with eye movement, an assembled PCB was attached to electrodes with proper firmware and monitored over live plots in the Arduino serial monitor, which showed a direct peak transition with each direction of eye movement as shown in Figure 14. When moving to Bluetooth, the data pipeline was sent to the GUI application wirelessly for both live plotting and file writing to be monitored overnight and discover any halts in data transmission.

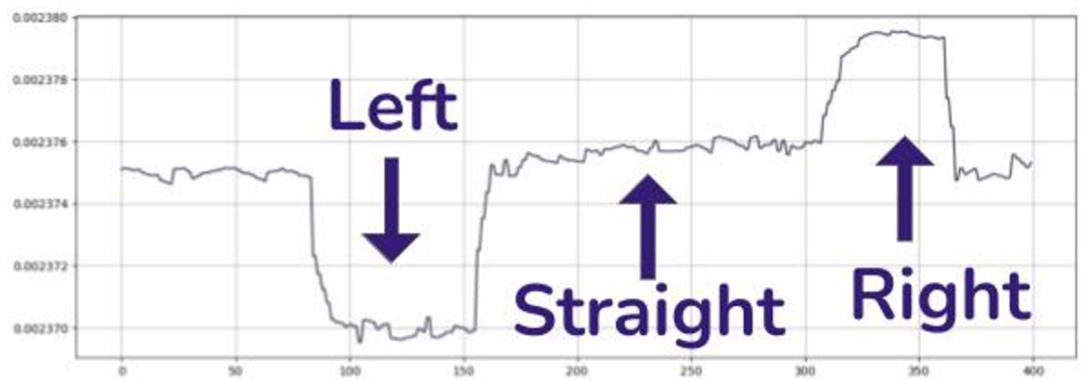


*Figure 14***.** EOG signal plot showing eye position correlation.

The REM classifying ML model was tested using a standard technique in the research field. Professionally-gathered EOG and hypnogram data were obtained from the PhysioNet Sleep-EDF database. A section of the database was used for training, and the other part for testing. The transition model was derived from the transitions between REM and nREM sleep stages, and the emission model was trained by thresholding the full-band spectral entropy into low or high. Testing was done by initializing the Markov model’s belief to 100% nREM at the beginning of the night, as is typical, and then recording the predicted beliefs throughout the night. Testing across over 70,000 epochs showed 85% overall accuracy at distinguishing between nREM and REM using the HMM technique. Additionally, tests revealed above 72% recall specific to the REM stage, which is in accordance with intended project outcomes.

After both software and hardware integration proved successful, we conducted full night tests on members of the team. The first two nights, data was gathered continuously and processed at the end with basic filtering and selection of a section of the data to be classified.

The final night saw a full test showcasing the full extent of the design: battery life, data acquisition, live BLE transmission, sleep stage classification, and the smart alarm algorithm. The test was run just as a hypothetical user would use the device, by setting an alarm window, attaching electrodes, calibrating the mask, and falling asleep. This test was successful; the smart alarm rang in the morning after detecting a transition from REM to nREM sleep during the user-specified wakeup interval. Qualitatively, the duration and frequency of REM sleep stages was in accordance with theoretical values, with the longest REM stage at the end of the night and lasting twenty-five minutes [32]. The team member who partook in this test claimed to have felt “better than usual” upon waking up, but this claim is subject to bias, and a more extensive clinical trial would be necessary were this project to progress further, especially into the medical or commercial realms.

Final Design, Mockup, and Prototype

The overall project is split into two main aspects: the hardware and the software. The hardware consists of the physical mask that the user wears and its internals which includes the processor board PCB that has a Xiao Microcontroller, EOG circuit, and power circuit. There is also a USB-C charging port, calibration button, power button, and LiPo battery located within and on the mask case. Electrodes also come from this case and are used to actually measure EOG eye movement data. The software of this project includes a desktop Graphical User Interface developed in python for the user to set their alarm time ranges, playback alarm audio when it is time to wake up, and view EOG data as live data acquisition from the mask or overall data from when the user was sleeping the night before.

The overall process is as follows. The user launches the application and turns on the mask. Once the user hits connect, the application will attempt to connect to the device. Once a connection is established, the user will be prompted to choose between a “Time to Sleep button” or a “Live Data” button. The “Time to Sleep” button is how the user actually inputs their alarm window range in which they are okay to wake up. After the user does this, they click the calibration button located on the top of the mask. The application will prompt the user to look straight, left, and right. Once the user does this, they are ready to sleep. While they sleep, EOG data is being classified and transmitted to the application. When the time reaches the user-specified time window, the smart algorithm will be constantly checking for a REM to nREM transition. Because data might vary with outliers, the device checks for a window of the past five stages. If the most recent two stages are the same as the majority in that window, the device is conclusively in that stage. If the device detects a REM to nREM transition, the alarm will sound to wake the user up. If the alarm reaches 30 minutes before the end of the window, the device will wake the user up if they are currently in nREM sleep to make sure that they don't fall under REM sleep soon. Once the user wakes up, they are able to stop the alarm and view the entire plot of EOG data from the night before. The "Live Data" button displays EOG eye movement data in real time.

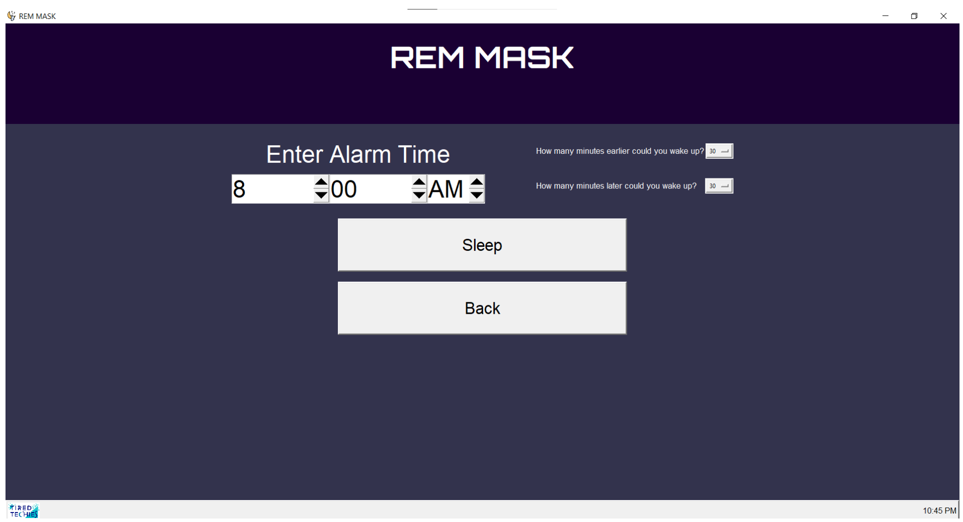


Figure 15. Screenshot of Application GUI of User inputting alarm range

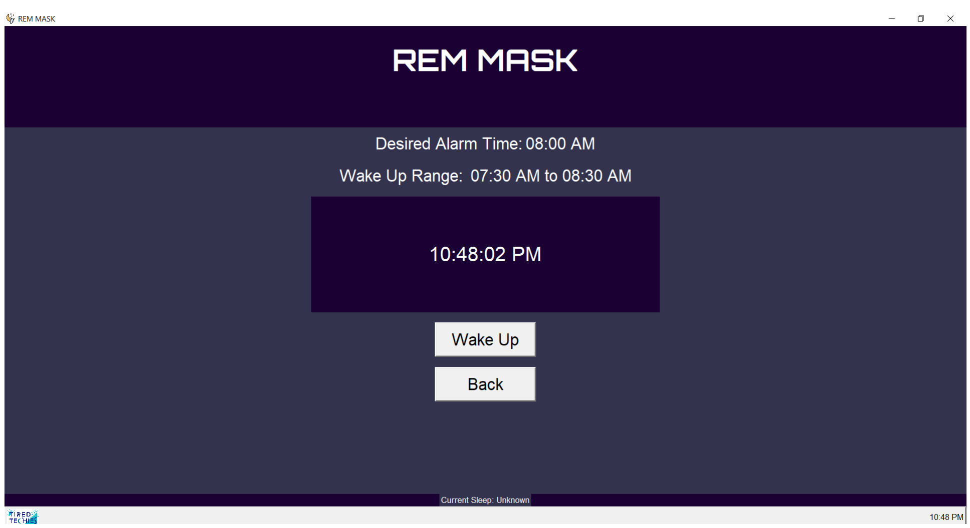


Figure 16. Screenshot of Application GUI once user is asleep

The final design can be seen in the exploded view below:

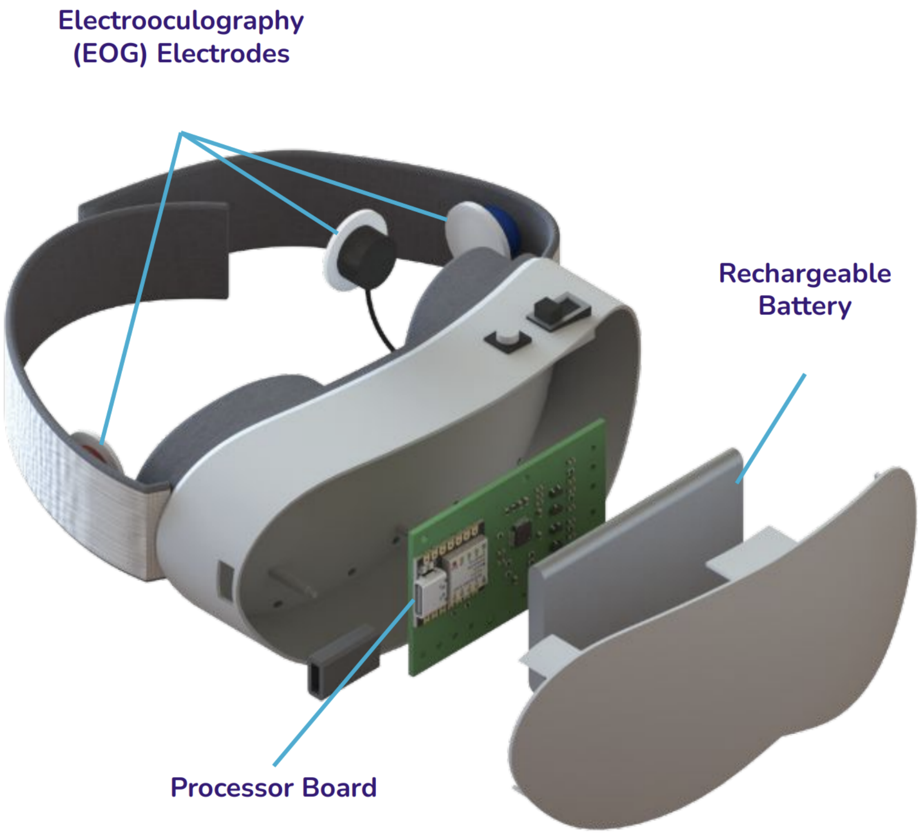


Figure 17. Final electronic casing design with overall dimension of 5.0in x 2.2in x 1.0in

The electrodes are positioned on the interior of the mask to be connected to the user's head. The electrodes and eye muffs are adjustable by velcro to accommodate the different head sizes of the user. A power switch and calibration button are placed on top to turn the mask on and off, as well as calibrate the specific user. A processor board and rechargeable battery is enclosed by a PLA case. The engineering drawings for the case and cover are in Appendices A. A USB-C charging port is placed on the side of the mask to charge the battery. The weight of the prints were 33g, putting the final assembly at 125g or 0.275lbs. A detailed bill of material can be seen in the budget appendix. The first iteration of the electronic encasing can be seen below:

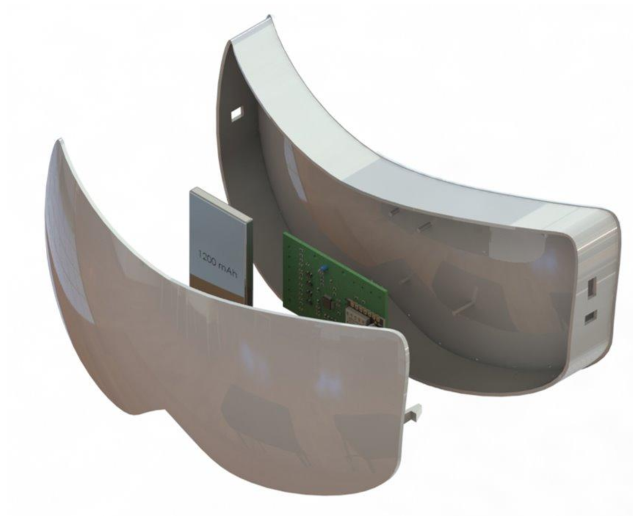


Figure 18. Design 1 with dimensions of 8.3in x 3.75in x 1.1in

From this initial iteration, it was clear that the overall dimension of the mask had to be reduced drastically. It was uncomfortable to put over a user face not very compact. The weight of the prints were 116g, putting the final assembly at 208g or 0.46lbs. Although this was under the weight in the design specification, improvements could definitely be made. The battery, which produced the most weight, was positioned toward one side of the mask resulting in a very unbalanced weight distribution. The actual sleeping mask that was used also needed to be changed. There was not enough fabric between the encasing and the user face. As a result, it was uncomfortable for the user to put on as they could feel the hardness of the plastic. In the second iteration, seen in Figure 19, the size has been drastically reduced. Weight of the prints were 35g, putting the final assembly at 127g or 0.28lbs. This was a huge improvement from the previous iteration. The PCB and battery are going to be stacked at the center to reduce space and have an even weight distribution. However, it did not account for power switches and a calibration button. The USB-C charging port was also located in a position that does not fit well with the PCB board. These changes are made in the final iteration.

Figure 19. Design 2 with dimensions of 5.0in x 2.2in x 0.9in

Societal, Environmental and Sustainability Considerations

Two primary lifestyle stages are considered when analyzing the potential societal and environmental impacts of our sleeping mask product as outlined in Table 2**.** When it comes to production, the primary concern is with the workers and their labor for manufacturing a unit. Specifically, child labor, work life hours, and the health of the workers must be considered. Quantification of such conditions can be done based on percentage or rates of incidents. From the consumer perspective, communication is of importance. Feedback mechanisms on state of the product and areas of improvement could be conducted over online satisfaction surveys as a low-carbon method of feedback. Our product should include proper instructions for disposal since the fabric and electronics could be recycled while LiPo batteries must be disposed of safely. The overview of these impacts can be found in Table 3**.**

Table 2. Goal and Scope

Objective of Assessment	Design Function	Functional Unit	Lifecycle Stages Considered	Associated Activities
Assess social impacts of a sleeping mask	Wake users up at best time to feel wakeful each day	1 sleeping mask	Production	Fabrication of electronics and raw material components
			Daily Use	Nightly wearing and use

Table 3. Inventory Analysis

Product Lifecycle Stage	Stakeholder Group	Social Impact Category	Impact Indicators
Production	Workers	Child Labor and Hours of Work	% of children working in country/sector
		Health and Safety	Accident rate by country/sector
Daily Use	Consumer	Health and Safety	Number of reported injuries or complaints
		Feedback Mechanisms	Satisfaction survey results
		End-of-Life Responsibility	Annual incidents of non-compliance

Risk Assessment, Safety, and Liability

A formalized risk assessment can be seen in Table 4**.** From the electronics aspect, since passive sensing is used, safety concerns are typically minimal and unlikely at the operating electrical conditions. Nonetheless, standard safety mechanisms were implemented in the circuit design including diode ladders for voltage suppression, series capacitors for blocking DC current, and series resistors to limit any potential increases in current from poor electrode contact. Since the current emphasis of the semester timeline was on proof of function, disposable gel electrodes were opted for due to their reliable signal integrity from adhesive contact to the face. Likewise, battery and signal circuitry were isolated through placement such that a ground plane would separate the two for signal integrity.

From physical aspects, the most concerns were on placement of electronics near the face. To avoid any potential impact with electronics or the battery, an enclosure was designed that would be sewed onto the mask fabric with additional fabric sewn over the enclosure, allowing a layer of cushion such that the user would not feel the items. The enclosure had an inner space margin to prevent any pressure on any of its internals. Velcro straps were used to properly fit the mask to individual faces and place the electrodes in proper locations to meet the needs of each customer's face size.

Table 4. Risk Assessment and Mitigation

Item / Function	Potential Failure Mode(s)	Potential Effect(s) of Failure	Sev	Potential Cause(s)/ Mechanism(s) of Failure	Prob	Current Design Controls	Det	RPN	Recommended Action(s)
Electrode	Improper location for measuring eyes, contact	Poor signal acquisition for classification	4	Face size mismatch	6	Gel electrodes to stick on skin	2	**48**	Add velcro straps for permanent size fit for user, calibration step
Battery	Run out of charge	Device power loss	5	Lack of charging, electronic contact loss	5	Snap plug and charging mode LED	2	**50**	Battery level indicator, low power functionality
Bluetooth connection	Connection loss	Loss of packet transmission	4	Long distance, latency	2	Software reconnection	4	**32**	Distance testing
Battery	Random voltage spikes caused by environmental noise and power lines from battery	Poor signal acquisition for classification	4	Battery proximity to signal lines	5	Twisted pair	2	**40**	Flip board and battery on back to isolate signals and power with ground plane
Enclosure	Slipping off mask	Dangling electronics	9	Poor adherence to fabric	5	Sewed on directly to fabric	4	**180**	Sewed on to fabric, pull testing
Battery	Punctured battery or leaK	Flammable	9	Sharp objects, exposed battery	1	box enclosurere with margin space for battery, onboard charge protection circuit	1	**9**	Hardwire power switch, over-voltage/current power off or reset
Mask	Slipping off	Fit on face	3	Oversized fit	3	Velcro strap	5	**45**	Velcro strap and calibration
Enclosure	Facial pressure	Discomfort	3	Rigid structure	3	Contour with fabric cushion	2	**18**	Contour design, multiple iterations
Electrode	Over-voltage or current	Improper measurements	7	Lack of protection circuitry	1	Suppression diodes, blocking caps, series resistors	2	**14**	Suppression diodes, blocking caps, series resistors

Commercialization

Due to both the total fulfillment of the planned scope of the project and the overwhelmingly positive feedback received at the Capstone Expo, the team believes that the REM Mask has a certain degree of commercial viability. To commercialize the product, the team sees three important steps of future work before scaling production: creating a mobile application, conducting formal clinical trials of the device, and further improving the classifier.

Transitioning from a desktop application to a mobile app would be a non-negotiable decision. When assessing the project from the perspective of a potential consumer, multiple respondents at the Capstone Expo stated that they do not have their laptop near their bed before going to sleep.

Formal clinical trials would be necessary to fully justify our claims of classifier accuracy and improved perceived quality of sleep. While the classifier was tested against a professionally-labeled dataset, and the data filtering was done in the same manner as the dataset used, there is still potential discrepancy from the data the device measures versus that measured on the EOG channels of a PSG machine. Additionally, issuing surveys to sleep study participants would offer a less biased result than those of our own personal testing.

Further improvement to the classifier is still a possibility. One of the key value propositions of this product is improved accuracy. While application-specific accuracy is improved over that of potential competitors, further improvement would likely be necessary to justify our value to the potential consumer, contingent upon further market research. Given the current classifier design’s efficacy, such changes would involve tuning hyperparameters such as STFT window size, transition probabilities, and the “bins” used for the emission model. This work was not done within the course of the semester as it is both tedious and computationally intensive.

Team Member Contributions

Nabid Farvez: Electrical Lead, Financial Manager

The initial proposition of the idea for the wearable sleeping mask came from Nabid after preliminary research on sleep stage effects and prior coursework on biomedical sensing. Nabid handled the electronics development including selecting components, testing prototypes on a breadboard for early firmware communication, and design of the final PCB for fabrication and hardware integration.

Ananth Kumar: Expo Coordinator, Software Lead

Ananth's primary responsibility for this project was designing, implementing, and testing the smart alarm algorithm. Additionally, Ananth contributed to the GUI application and worked on the BLE software as well as its integration with the device firmware. Ananth led the creation of media for the team, including the expo poster and video.

Andrew Lang: Webmaster, Firmware Lead

Throughout the course of the project, Andrew oversaw the engineering of the sleep stage classifier pipeline, doing research into prior attempts to solve the problem as well creating multiple iterations of a classifier to ultimately reach the final project. Andrew also contributed to the development of BLE and AFE firmware and the application software.

Syed Samin: Documentation Coordinator

Syed primarily focused on working on developing a frontend Graphical User Interface for a user to interact with before and after sleeping. Furthermore, a key feature of the GUI that Syed worked on was to be able to view live EOG plotting and data acquisition from the REM Mask and being able see the entire waveform of collected data once the user wakes up.

Kai Vong: Group Leader, Mechanical Lead

Kai focused on the design and manufacturing of the actual mask. He produced CAD models, reworking multiple iterations to reach customer requirements and design specifications. Kai fabricated the electronic enclosure and assisted with hardware integration. He used a variety of methods to produce an aesthetic pleasing mask for the expo.

Conclusions and Future Work

At its current stage, the REM Mask is able to transmit live data from the device to an external desktop application over bluetooth. The mask itself is currently using position adjusting gel electrodes that are placed on the user's temples in order to collect and transmit EOG data. Before the user sleeps, they enter a window of time in which they are okay with waking up, and they calibrate the device by looking straight, left, and right. While the user is asleep, eye movement data using EOG is transmitted to the desktop app. A machine learning classifier is able to dictate whether the user is in REM sleep or nREM sleep. If the user transitions from REM sleep to nREM during the user-specified time window, the alarm will sound. However, if the time is currently 30 minutes before the end of the time range, the device will check if the user is in nREM sleep, and if they are, then the alarm will sound regardless. Currently, the device is prioritizing a REM to nREM transition, which is when sleep is the lightest and when a person would feel the least groggy when waking up. However, if this is not possible, the REM Mask would want to ensure that the user is still waking up during nREM sleep and does not want to risk them falling into REM sleep and waking them up during REM later on.

After some self tests and data collection, the fully functional prototype seemed to be effective. In the windowed time range, it would state what sleep stage the user is in, and once the stage switches from REM to a constant stream of stable nREM stages, the alarm sounds. At its core, the alarm algorithm is fully functional. Given the accuracy of the classifier, we can claim that the device is able to correctly distinguish between sleep stages and wake up users at the most optimal time.

However, there is work that still needs to be done before the REM Mask is able to become a commercial product. For instance, the core functionality of the device is to allow users to feel more refreshed and less tired when they wake up. In order to validate this claim, the device would have to be tested with people of all demographics including age, gender, race, BMI, etc. The device must have several nights of testing with unbiased subjects to ensure that it does in fact help people wake up feeling more refreshed and less groggy. This can be done by having people wear the mask to sleep and fill out customer satisfaction surveys regarding how they feel when they wake up. Furthermore, to further test the algorithm, a double blind study may need to be conducted of users wearing REM Masks but only half the masks are actually running the algorithm and the other half using a normal set alarm time. The subjects would be unaware which group they are in, and when they wake up, they would fill out a satisfaction survey describing how they feel when they wake up.

As the REM Mask is going to be a sleep wearable device, it is important that the overall aesthetic and accessibility of the device is further improved. For instance, the device currently weighs 125 grams; however, this can be decreased further by making the hardware compartment case even smaller. This can be done by using a flexible PCB to dramatically decrease enclosure height by allowing contour on the electronics board. Moreover, instead of using a flat LiPo battery, the device could use multiple coin cell batteries in parallel. The LiPo battery takes up most of the weight in the case, so by reducing this with coin cell batteries, and using a contoured flexible PCB to reduce the enclosed case's height, weight would be significantly decreased as well. Another design change would include using haptic feedback to wake up the user. Currently, the software sounds an alarm from the computer; however, having some sort of tactile component in waking the user up embedded into the mask may also be useful to make sure the user wakes up at the correct time. The wet gel electrodes would also be removed with dry electrodes to remove sticky residue after being removed. Moreover, dry electrodes do not constantly have to be replaced. Additional add-ons to the mask may also include LED indicators to indicate battery status, bluetooth connection status, etc. Research for this project showed that sleep stages are important to consider when choosing the most optimal time to wake up; however, another important factor is circadian rhythm, which is a user's own internal indicator of when it is the right time to wake up. Most people associate waking up with sunlight during the morning. Therefore, ambient LEDs with warm colors may be used to simulate sunrise, allowing the users to wake up easily.

Due to the overwhelming positive feedback regarding the idea behind REM Mask, the device may need to be designed to be a bit more user-friendly before it is fully produced and ready to sell. This includes aspects of the project that can be altered for user convenience and a better user experience. Currently, the device uses a desktop application; however, a phone application would be more convenient and easier to use while a person is sleeping in bed. While working on this project and acquiring live EOG data, filters were used to remove DC offsets and calibrate a user's eye movements. From this, depending on the EOG voltage, one can tell when a user is looking straight, left, or right. By classifying this further and solidifying these calibrated thresholds, the device could also have IoT applications and smart home controls using eye movements such as being able to turn on or off the lights while in bed.

The product is currently set to be a daily commercial product to help users feel better when they wake up; however, the product may have clinical applications as well. Common sleeping disorders include sleep paralysis and sleep apnea. Eye movement and eye controls using EOG may be useful to alert the user or wake the user up fully when they are facing one of these sleep disorders. If the REM Mask was to pursue clinical applications, however, FDA approval would be required.

This project is able to successfully determine sleep stages and differentiate between REM and nREM sleep, and by using this data, a user is able to be woken up at the best time to reduce grogginess and sleep inertia when woken up. Currently, the classifier is using sleep data from a PhysioNet database; however, everyone's sleep patterns are different, so a future improvement may include shifting the classifier to be trained using a user's specific sleep pattern. The mask would be more accustomed to every specific user's individual sleeping pattern and would be able to better classify individual sleep stages.

During the Capstone Design Expo, we received a plethora of compliments and overall positive feedback for our project, its utility, and the overall idea and presentation behind the REM Mask. People believe that the REM Mask definitely has future commercial uses, and we have been extremely proud of the functional final prototype of the REM Mask as well as the reactions from people when hearing about the product. The REM Mask's first prototype seemed to be a great success from its concept and problem being addressed, test results to prove that it can provide a solution, and overall customer feedback.

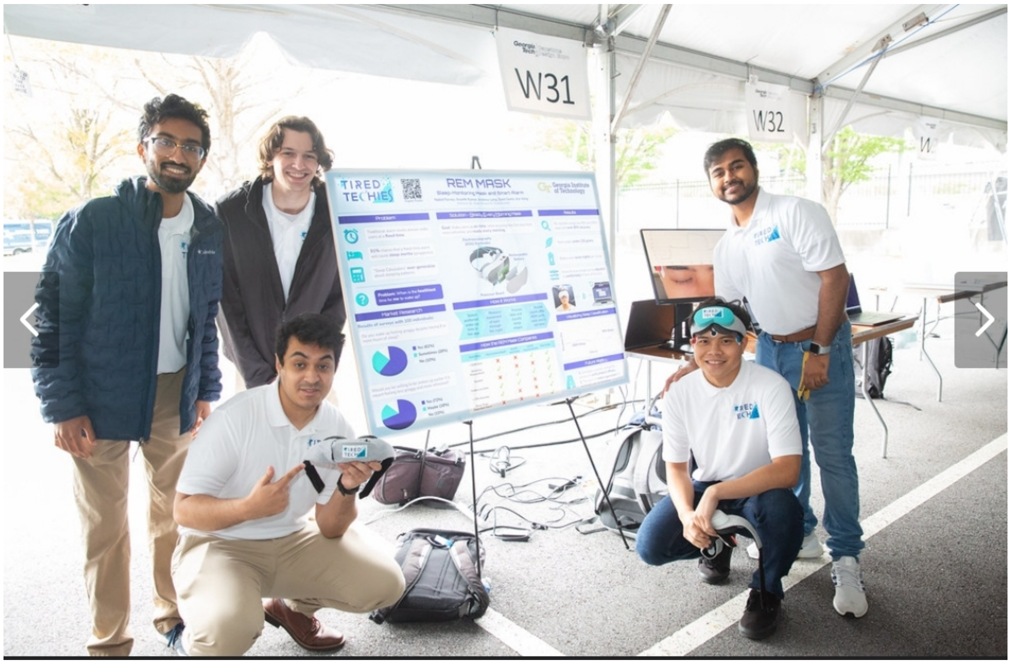


Figure 20. Team Tired Techies at the Spring 2022 Capstone Design Expo

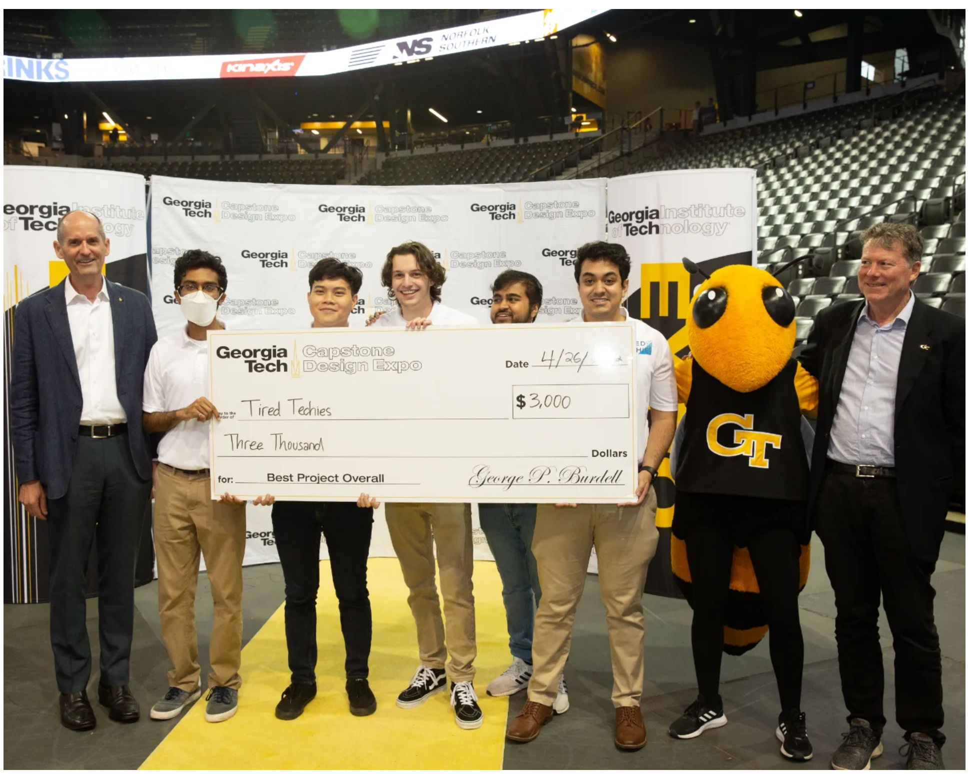


Figure 21. Triumphant Tired Techies at the GT 2022 Capstone Design Expo!

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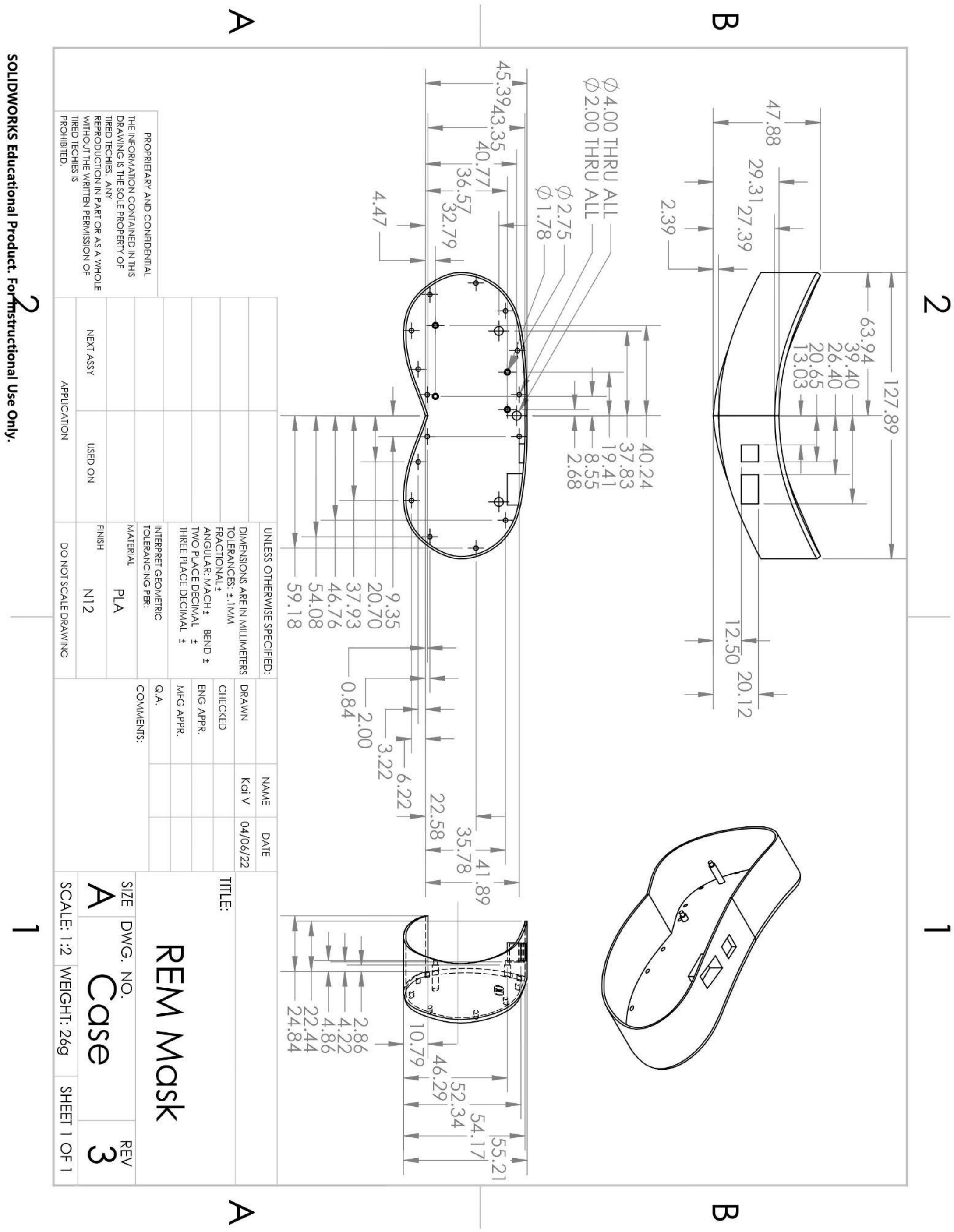
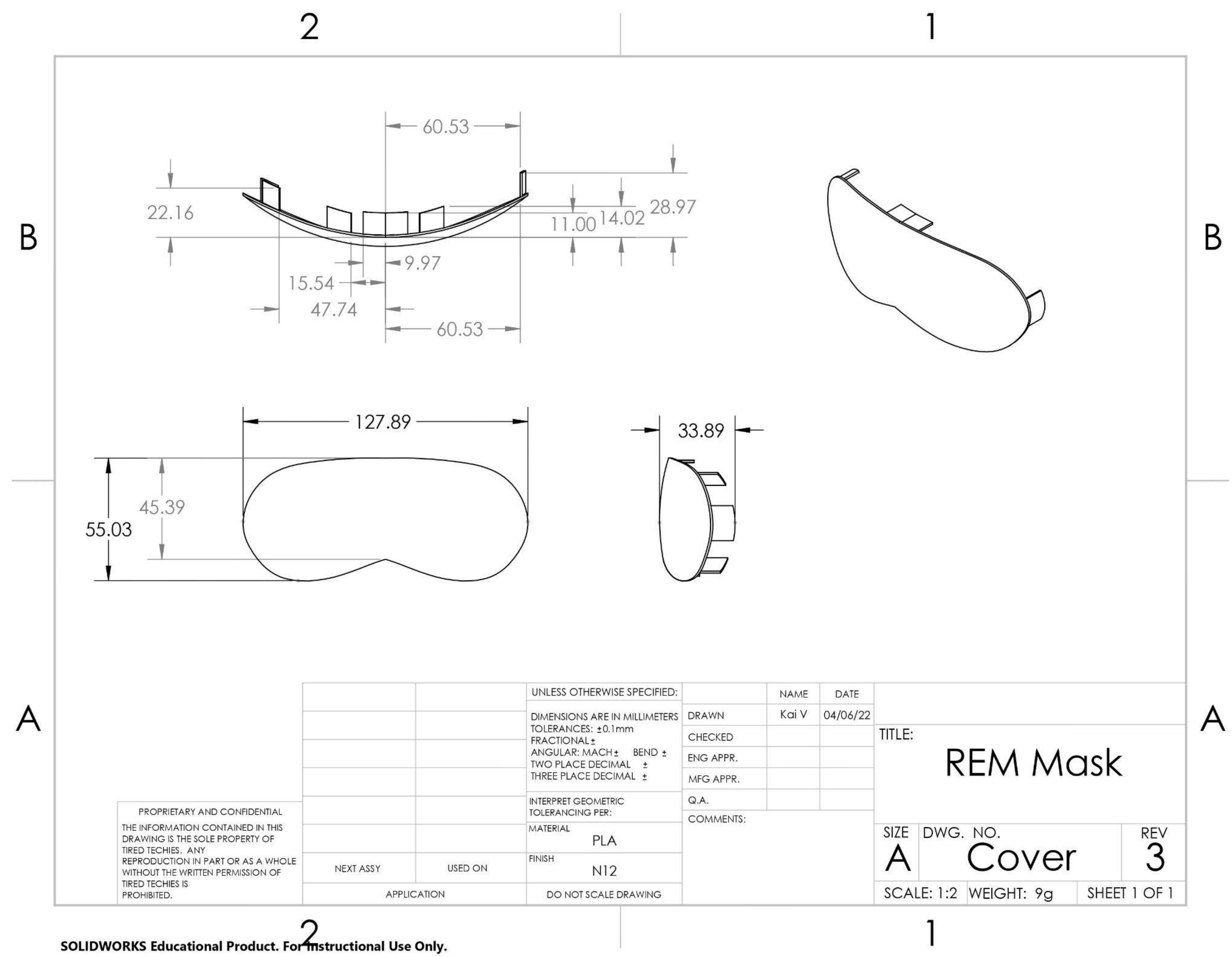
Appendices

Appendix A - Engineering Drawings

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SHEET 1 OF 1
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Budget Appendix

Part	**P/N**	**Qty**	**Unit Cost**	**Order Link**
AFE, low pwr	ADS1292	1	$11.08	link
3.7V, 1200 mAh LiPo battery	LP-503562	1	$9.95	link
Gel electrodes	PID:2773	3	$2.53	link
Electrode cable	CAB-12970	1	$3.00	link
XIAO MCU	SKU 102010448	1	$9.90	link
Barrier Diode	SBAT54SLT1G	4	$1.52	link
Button	95C06C3RAT	1	$0.47	link
Power Switch	EG1201A	1	0.76	link
USB-C extender	B07MBWH7QG	1	$3.50	link
Sleeping Mask	B07PRG2CQY	1	$35.00	link
Est. TOTAL UNIT COST	**$77.71**			