Wearable Light Logger for the Treatment of Mood Disorders

Preliminary Report

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Abstract

A wearable light logger which is user-friendly and accurately measures light entering the patient's retinas in lux has been requested by the client Dr. Jean Riquelme. The scope of patients with mood disorders is on the rise worldwide, with current treatment solutions leaving patients with low response rates and lacking full remission of symptoms. Currently, there are no light loggers intended for use in clinical research for the treatment of mood disorders. Existing designs are used for the treatment of myopia outside of a research setting. The team aims to produce a research tool that satisfies the client's requirements. The design will consist of a circuit that will incorporate a light sensor and connect to a microprocessor which will be encoded to display the recorded signals in light intensity. The device will be tested for both accuracy, using a light source with known intensity similar to outdoor settings, and for usability with a questionnaire. A successful prototype will allow further research to determine more successful treatments for mood disorders like Seasonal Affective Disorder and will increase remission of symptoms for patients.

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Introduction

A. Impact and Motivation

Mood disorders constitute a category of psychiatric conditions characterized by disturbances in an individual's emotional state. Research indicates that approximately 21.4% of adults will experience a mood disorder at some point during their lifetime [1], with Seasonal Affective Disorder (SAD) impacting up to 16% of the population worldwide [2]. The effectiveness of first-line antidepressants is questionable, with a response rate of just 50-60% in adults, while only 35-40% experience remission symptoms [2]. Additional treatment apart from medication is necessary to increase response rates and remission. Analysis has revealed that a significant reduction in depression symptom severity was associated with bright light treatment and dawn simulation in seasonal affective disorder and with bright light treatment in nonseasonal depression [3]. Full-spectrum light therapy has shown efficacy in treating mood disorders, especially seasonal affective disorder, however patient response studies are lacking. Patient response studies are crucial in determining the exact treatment of mood disorders, as factors like light intensity should be determined for the ideal remission of symptoms. Research is needed to study the exact conditions of light therapy needed to best treat disorders like SAD. With data regarding the light intensity that best reduces symptoms of SAD, more concise prescriptions can be made for patients with SAD or similar mood disorders. Thus, a measurement device is warranted to characterize which conditions result in the most remission of symptoms of mood disorders. A wearable light logger would provide convenient research into what correct dosages for optimal patient response look like for patients suffering from mood disorders. A wearable sensor allows for an accurate representation of light intensities that reach the retina, the presumed site of action.

B. Existing Designs

There are currently no wearable light logging devices meant for clinical research on the market. There are a few similar competitive products that track and record light exposure through the retina. One of the most popular products is the Clouclip [4]. The Clouclip is a clip-on sensor that attaches to a standard pair of glasses. The device performs and collects long-term real-time data and monitoring. The Clouclip is currently marketed toward children for myopia-related behavior control. The device records reading distance, reading duration, outdoor sunshine duration, and illuminance in lux. The Clouclip does not precisely have the same function as a wearable light logger would, but it records illuminance in lux which is the main component of the wearable light logger this project aims to fabricate.

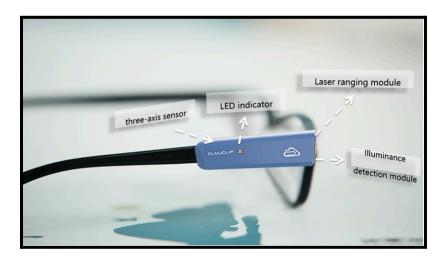


Figure 1: The Clouclip and its features [5].

C. Problem Statement

There are currently no clinical research devices that measure light intensity which reaches the retina. Consequently, patient response studies to bright light therapy are minimal. To provide more insight into what effective treatment of mood disorders like SAD looks like, a wearable sensor that records data of light intensities entering a patient's eyes during research is necessary. By knowing the levels of illuminance that best result in remission of symptoms of SAD and similar mood disorders, more effective treatment can be prescribed by professionals resulting in a decrease in patients who suffer from mood disorders. The device must be wearable during research trials, record light intensity in lux which reaches the retina, and display the data collected in a useful way, allowing researchers to make conclusions about the most effective treatment for mood disorders.

Background

A. Relevant Biology and Physiology

Mood disorders, also called affective disorders, can be divided into two categories: depressive disorders and bipolar disorders [6]. Mood disorders can be best described as prevalent occurrences of emotional disturbances. These disturbances impact negatively an individual's quality of life and increase the risk of suicide [6]. Depressive disorders are characterized by feelings of depression like a down mood, irritability, and a feeling of sadness or emptiness. Bipolar disorders are characterized by alternating mood episodes of depression and mania. Diagnosis of a mood disorder comes from a clinical evaluation by a psychiatrist who will look at past mood episodes, general medical history, and family medical history [6]. To treat depressive disorders, typically selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs) are the first recommendations. Depending on the evaluation of the patient, other types of medication can also be an option. Psychotherapy strategies such as cognitive behavioral therapy (CBT), interpersonal therapy, and behavioral activation, can also be used in combination with medication [6]. Bipolar disorders have a wide range of potential treatment options. A variety of medications can be used depending on many personal factors of the patient some examples being lithium, divalproex sodium, and antipsychotics. Other treatment methods such as CBT, several forms of therapy, and peer programs can be used in combination with medication [6]. Seasonal Affective Disorder (SAD) is a type of depressive disorder. SAD has many of the same symptoms as general depression however symptoms usually coincide with seasonal patterns. SAD typically occurs in individuals in the fall and winter months [7]. Approximately 5% of the U.S. population is affected by Seasonal Affective Disorder (SAD) annually, with symptoms occurring for nearly 40% of the year [7]. SAD is caused by several factors, mainly a result of a disruption in a person's circadian rhythm due to shorter daylight hours in the winter months. Diagnosing SAD requires an evaluation using clinical methods and tools [7]. When light passes through the eye, there are several different functions that pertain to each part of the eye. Light passes through the eye first through the cornea, then the pupil, and then the lens, and once it reaches the retina, it triggers electrical signals in the brain. When light hits the retina, special cells called photoreceptors turn the light into electrical signals. These signals travel from the retina through the optic nerve to the brain [8]. Once these electric signals reach the brain, the light signals the brain to produce serotonin, a neurotransmitter that can improve mood, energy, and focus[9]. It has been hypothesized that bright light therapy may function by either correcting the winter circadian rhythm phase delay or by increasing synaptic serotonin, possibly in the serotonin-rich midbrain[9]. Many systems are under circadian control, including sleep-wake behavior, hormone secretion, cellular function, and gene expression. Circadian disruption is associated with an increasing incidence of certain cancers, metabolic dysfunction, and mood disorders, including SAD [10].

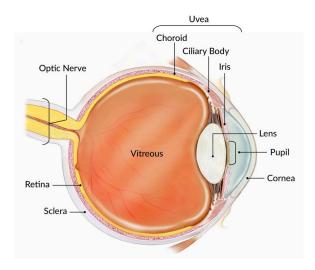


Figure 2: Anatomy of the eye [8]

B. Client Information

The client, Dr. Jean Riquelme, is a clinical professor at the University of Wisconsin-Madison's Department of Family Medicine and Community Health.

C. Design Specifications

The client has requested one functioning device that measures and records the light intensity in lux near the retina from a light therapy source used to treat mood disorders. The device should be comfortable for the user and be able to function for at least two hours in one day to allow adequate data collection. The electrical components must ensure operation on a low voltage to avoid hazardous conditions for the user. The open circuit should be operated on less than 6 volts to comply with UL 60601-1 [11]. The data recorded must be within a 5% range of the correct lux reaching the device to ensure accurate data collection. The device should be relatively lightweight to ensure patient comfort. The device must be fabricated, and tested within the client's budget of \$500.

Preliminary Designs

A. Glasses with Built-in Sensor

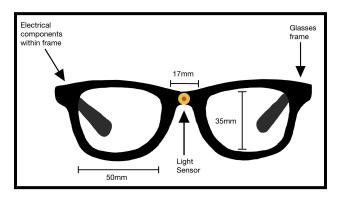


Figure 3: Glasses with Built-in Sensor

The Glasses with the Built-In Sensor design feature a photoresistor sensor attached in the middle of the bridge of the glasses frame. The electronic components of the design would be integrated into the frame of the glasses by cutting out a small subsection of the frame and implementing the circuitry. The electronic components would require an integrated circuit to fit within the frame and would be completely enclosed by the glasses frame for a cohesive design. The photoresistor attached to the center of the bridge of the glasses would be able to accurately sense the light reaching the retina.

B. Glasses with Clip-On Sensor

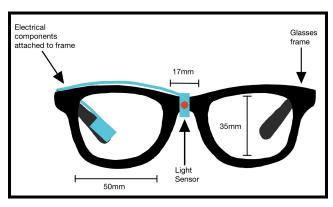


Figure 4: Glasses with Clip-On Sensor

The Glasses with the Clip-On Sensor design feature a clip-on photoresistor sensor that would attach to the middle of the bridge of the glasses and clip-on electrical components attached to the frame of the glasses. The photoresistor clipped onto the glasses would be able to replicate the light reaching the retina. This design would be able to attach to any standard pair of glasses and could be removed and reattached. The electronic components attached to the frame of the glasses would feature an integrated circuit covered in a 3D-printed box that can clip onto the side of the frame of the glasses.

C. Headlamp

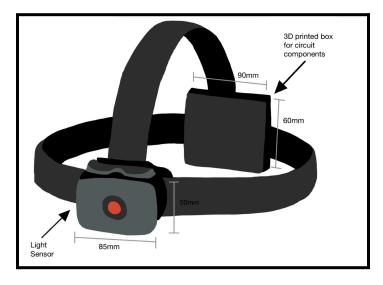


Figure 5: Headlamp

The Headlamp design features several different components. The light from the original headlamp would be removed and the photoresistor sensor would be attached to the tilting plate of the headlamp. The electronic components would be attached to the anterior of the headlamp by being positioned into a 3D-printed box that would be attached to the back strap. The electronic components would feature a breadboard circuit, Raspberry Pi, and a battery to power the circuit. The tilting aspect of the headlamp with the sensor would be able to accurately replicate the light reaching the retina.

Preliminary Design Evaluation

A. Design Matrix

Table 1: Design Matrix

Criteria:	Gla t	esign 1: asses with built-in Sensor	Design 2: Glasses with clip-on Sensor		Design 3: Headlamp Design		
Usability (20)	3/5	12	2/5	8	5/5	20	
Accuracy (20)	5/5	20	4/5	16	3/5	12	
Durability (20)	2/5	8	1/5	4	4/5	16	

Ease of Fabrication (15)	1/5	3	3/5	9	3/5	9
Safety (10)	5/5	10	2/5	4	3/5	6
Cost (10)	1/5	2	3/5	6	3/5	6
Total: 100		55		47		69

Usability:

Usability refers to the ease of data collection for the clinician, the comfort level of the patient during data collection, and the inclusivity of the design. Usability was ranked highly due to the client's emphasis on these components of the design. The headlamp design scored the highest due to its inclusive design, which allows the device to adjust to any patient's head size, and its comfortable design which easily fits over one's head. The two glasses designs require the patient to be able to wear glasses despite potential deformities a patient may have, and are not adjustable making the two designs less comfortable and inclusive than the headlamp design. Additionally, the glasses with clip-on sensor design place the electronics on one side of the glasses frames, which could tilt the glasses to one side or cause the glasses to fall off of the face during data collection.

Accuracy:

Accuracy refers to the device's ability to record data which correctly represents the intensity of light entering the eyes. The sensor should be placed between the eyes on the bridge of the nose to best represent the light reaching the retinas. The glasses with a built-in sensor scored the highest in accuracy since the sensor is placed directly on the client's desired site of action, the bridge of the nose. The glasses with a clip-on sensor scored just below the first design since the clip could potentially fall off or change angles during data collection and slightly skew the data. The headlamp scored the lowest in accuracy since the design places the sensor just above the desired site of action.

Durability:

Durability accounts for the device's necessary time of use, ease of electronic component maintenance, and the fact that the entire device should be reusable for multiple trials without replacement. The headlamp design scored highest in durability since it has easy access to the electronic components via the circuit box at the posterior of the patient's head. The electronic components could be easily replaced if needed with no destruction to the other components of the design. The two glasses designs would require more difficult replacement of electronic components, and have a more fragile design which could break more easily than the headlamp design. The glasses with clip-on sensor design scored lowest since the clip could fall off of the frames and the wire connecting the sensor to the other electronic components would be difficult to keep intact during the movement of the device.

Ease of Fabrication:

Ease of fabrication focuses on the time constraint of one semester and the available resources the team has access to, so it was rated slightly lower than the previous three criteria since the team has access to a sufficient amount of resources. The designs scored similarly in this category with the glasses with built-in sensor scoring lower than the other two designs. This is mainly due to the need for hollow glasses frames which would require more time to fabricate, and incorporating the electronics into the small hollows of the frames which would be difficult. The other two designs have fairly similar designs regarding how the electronics are fabricated on the exterior and would be about the same amount of difficulty to fabricate.

Safety:

Safety should be considered when designing the prototype. However, the device will be used in a controlled research setting and presumably treated with great care as a research tool, so safety is ranked lower than the previous criteria. The glasses with built-in sensor design scored highest since all electronics are internal and pose the least risk of shocking the patient. The other two designs have electronic components that are less internally contained and could pose a hazard to the user if the device is not handled carefully.

Cost:

Cost is ranked low on the matrix since our budget of \$500 should cover the costs for all of our design. The only significant difference in cost may be the size differentiation of electronic components, with smaller components costing more than the components already on hand from Sparkfun kits. The glasses with a built-in sensor would need the smallest components, so it scored the lowest in the cost category.

B. Proposed Final Design

Based on the criteria above, the proposed final design will most similarly resemble the headlamp design. This is mainly due to its high score in the usability and durability categories of the design matrix. The headlamp design can be simply fabricated to be adjustable to any patient's needs and features padding to maximize the patient's comfort. The circuit box allows for easy maintenance of electrical components that may wear out with excess use like resistors and op amps. The accuracy of the headlamp design will be improved by allowing the sensor to sit lower on the forehead, closer to the bridge of the nose. The electronic components will be comprised of a circuit board containing a Wheatstone bridge with a piezoresistive sensor incorporated to measure light intensity in lux, which will feed into two comparators to reduce noise and lower output impedance, then pass the signals through a differential amplifier to amplify the signal before sending the signal to a raspberry pi microchip which will be coded and use wifi to display the signal lux for easy interpretation by the researcher. The exact values of the electronic components are still being calculated, but a circuit diagram is included, with R4 as a photoresistor.

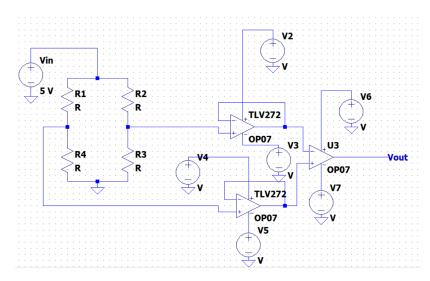


Figure 6: LTSpice circuit schematic of a photoresistor instrumentation (R4 as a photoresistor)

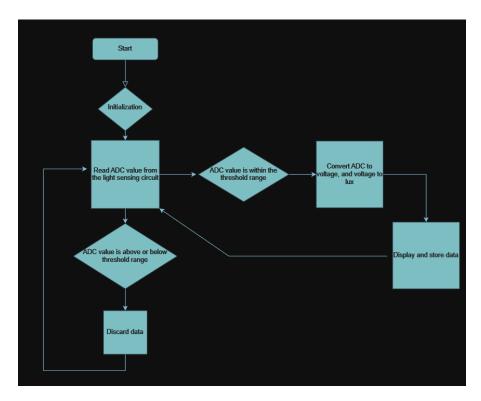


Figure 7: Block diagram of the light sensor system

Fabrication

A. Materials

The device will feature an elastic headlamp design as it offers a cost-affordable option compared to a more expensive integrated electronic pair of glasses. The headlamp also has better accommodation for users of all head shapes and sizes. The measurement device will be a photoresistor, which will be necessary to measure the light intensity received between the eyes. To receive the circuit output, the Raspberry Pi will be connected to a breadboard that will connect the necessary circuitry pins to the chip. The device will be powered by a CR2450 lithium coin battery. The battery was determined to be a better option compared to a wired connection as the client requires the device to be free-standing. The CR2450 also features a longer power life compared to average lithium coin batteries - about fourteen to twenty days of operation time. The design will also have an external battery holder such that users have an easy method of battery replacement. The circuit will contain resistors, op-amps, and voltage followers. The resistors will be arranged in a Wheatstone bridge to measure the unknown electrical resistance. The device will then measure the resistance difference and amplify the signal using a differential amplifier. The operational amplifier will measure the voltage difference between the non-inverting and inverting terminals. The voltage will then be used in a given equation to calculate the measured light intensity in lux. Voltage followers will also be connected to the circuitry, as they are vital to reducing the output impedance without changing the voltage. A Raspberry Pi Pico W will be the microchip that is coded to collect, convert, and export the light intensity values to a website via a stable wifi connection. Finally, a happy light that has precise and measured light intensities of up to ten thousand lux will be used to test the sensor to ensure its functionality.

B. Methods

To create the prototype, the first step is to build the appropriate circuit board and solder the pins to the board. Then, compute a code to interpret the illuminance reaching the sensor within the headlamp in lux into digital values. The device will then need a 3D-printed box to hold the electronic components. The circuit board and components will then be attached to the box. After that, the light from the purchased headlamps must be removed and the sensor purchased will attach to the tilting aspect of the headlamp to accurately replicate the light reaching the retina. Finally, the 3D-printed box will be attached to the posterior of the headlamp.

C. Final Prototype

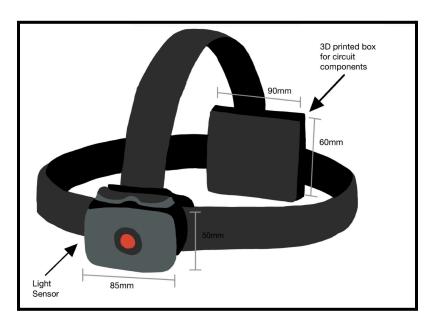


Figure 8: Proposed Final Prototype

Testing and Results

To ensure that the device meets the client's specifications, thorough testing will be conducted, focusing on both light intake accuracy and patient and doctor usability. To test the accuracy of the light sensor, the Happy Light [12], a portable light source emitting 10,000 lux will be used. Data transmitted by the device to a laptop will be analyzed to verify that the appropriate amount of lux is being measured. This process will be repeated several times to guarantee accurate measurements. If errors or discrepancies are identified, the device will be examined to determine what part of the device could have caused the error, and how to fix the issue.

For usability testing, several participants will wear the device and provide feedback on comfort, weight distribution, and stability. It is essential that the headlamp does not cause discomfort, is not too heavy, and stays securely in place without shifting. Additionally, the design must conform to various head shapes and sizes. All feedback will be considered, and design adjustments will be made based on the observations.

Discussion

A. Ethical Considerations

The device needs to be inclusive and be able to function for all patients regardless of race, ethnicity, and disability. Inclusivity is achieved by allowing the head straps to be adjustable to any patient's head size, regardless of deformities, and is comfortable to address any sensitivities a patient may have.

B. Future Work

The current design features a photoresistor which measures a maximum of 100 lux. In order for the design to measure more realistic levels of light intensity, around 10,000 lux, a different light sensor must be used in place of the photoresistor. When used with the Happy Light, and other light sources, the sensor will output around 2 $K\Omega$ according to the datasheet [13]. This is not useful for research that utilizes light intensities exceeding 100 lux, as the sensor would output the same resistance for all values exceeding 100 lux. The ideal sensor would measure between 100 and 130,000 lux to adhere to the client's needs [14]. Research needs to be done to locate this ideal sensor so that the design functions during clinical research as it is intended. The values of the resistors in the Wheatstone bridge, the operational amplifiers used, and the supplied voltage need to be calculated before testing begins.

Conclusions

Mood disorders are prevalent worldwide, and effective treatments are lacking. Therapies like bright light therapy are known to reduce rates of seasonal affective disorder, although research on the most effective treatments is needed. This warrants the need for a light sensor that detects light intensities related to the highest patient response to treatments. The device needs to be wearable during research trials, accurately detect light intensities that a patient would experience during treatment, and include a comfortable and inclusive design. The final design will resemble a headlamp and will feature electronics contained in a 3D-printed encasement at the rear of the design, connecting to a sensor which is located on the bridge of the nose that will detect light intensities reaching the site during research. The proposed circuit design is modeled as a Wheatstone bridge and includes a piezoresistive sensor, which feeds voltage into two voltage followers to clean up the signals, which then connect to a differential amplifier that communicates the output voltage to a Raspberry Pi, encoded to display the light intensity in lux to a monitor. This project will focus on creating a wearable research tool that detects light intensities reaching a patient's eyes during research which will advance the treatments of mood disorders like seasonal affective disorder to become more successful.

References

- [1] "Any Mood Disorder," National Institute of Mental Health (NIMH). https://www.nimh.nih.gov/health/statistics/any-mood-disorder#:~:text=An%20estimated%2021.4%25%20of%20U.S.
- [2] Julia Maruani, Pierre Alexis Geoffroy, 2019. "Bright Light as a Personalized Precision Treatment of Mood Disorders," Front Psychiatry. 2019; 10: 85. doi: 10.3389/fpsyt.2019.00085
- [3] R. N. Golden et al., "The Efficacy of Light Therapy in the Treatment of Mood Disorders: A Review and Meta-Analysis of the Evidence," American Journal of Psychiatry, vol. 162, no. 4, pp. 656–662, Apr. 2005, doi: https://doi.org/10.1176/appi.ajp.162.4.656.
- [4] "Clouclip," Clouclip.com, 2024. https://www.clouclip.com/webCarbon/pc.html (accessed Sep. 20, 2024).
- [5] S. Jon and H. Bechtel, 2004. Accessed: Sep. 19, 2024. [Online]. Available: https://patentimages.storage.googleapis.com/05/0f/96/8cc94d8b41487b/US6737629.pdf
- [6] S. Datta, U. Suryadevara, and J. Cheong, "Mood Disorders," CONTINUUM: Lifelong Learning in Neurology, vol. 27, no. 6, pp. 1712–1737, Dec. 2021, doi: https://doi.org/10.1212/con.00000000001051
- [7] S. L. Kurlansik and A. D. Ibay, "Seasonal Affective Disorder," American Family Physician, vol. 86, no. 11, pp. 1037–1041, Dec. 2012, Available: https://www.aafp.org/pubs/afp/issues/2012/1201/p1037.html
- [8] National Eye Institute, "How the Eyes Work | National Eye Institute," Nih.gov, Apr. 20, 2022. https://www.nei.nih.gov/learn-about-eye-health/healthy-vision/how-eyes-work
- [9] P. D. Campbell, A. M. Miller, and M. E. Woesner, "Bright Light Therapy: Seasonal Affective Disorder and Beyond," The Einstein journal of biology and medicine: EJBM, vol. 32, pp. E13–E25, 2017, Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6746555/
- [10] T. A. Bedrosian and R. J. Nelson, "Timing of light exposure affects mood and brain circuits," Translational Psychiatry, vol. 7, no. 1, pp. e1017–e1017, Jan. 2017, doi: https://doi.org/10.1038/tp.2016.262.
- [11] UL Standard for Safety for Medical Electrical Equipment, Part 1: General Requirements for Safety, UL 60601-1, 2003. Underwriters Laboratories Inc. https://u.dianyuan.com/bbs/u/46/1160116752.pdf
- [12] https://a.co/d/eUdQzvC
- [13] https://cdn.sparkfun.com/datasheets/Sensors/LightImaging/SEN-09088.pdf
- [14] C. Lanca et al., "The Effects of Different Outdoor Environments, Sunglasses and Hats on Light Levels: Implications for Myopia Prevention," Translational Vision Science & Technology, vol. 8, no. 4, p. 7, Jul. 2019, doi: https://doi.org/10.1167/tvst.8.4.7. Available: https://tvst.arvojournals.org/article.aspx?articleid=2738326

Appendix A: PDS

Wearable Light Logger to Facilitate Full Spectrum Light Dosing for Mood Disorders

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Kate Briesemeister: BWIG Neel Srinivasan: BPAG

Client: Dr. Jean Riquelme Advisor: Dr. Brandon Coventry

Lab 304

September 19, 2024

Function:

Mood disorders are a category of mental illnesses in which the underlying problem primarily affects a person's emotional state. An estimated 21.4% of adults experience any mood disorder at some point in their life [1], with Seasonal Affective Disorder impacting up to 16% of the general population worldwide [2]. With only 50-60% of adults responding to first line antidepressants, and 35-40% experiencing remission symptoms[2], additional treatment is needed. Analysis has revealed that a significant reduction in depression symptom severity was associated with bright light treatment and dawn simulation in seasonal affective disorder and with bright light treatment in nonseasonal depression [3]. Full spectrum light therapy has been proven to be successful in treating mood disorders, especially seasonal affective disorder, but patient response studies are lacking. There are currently no wearable light logging devices meant for clinical research on the market. A wearable sensor allows for accurate representation of light intensities which reach the retina, the presumed site of action. A wearable light logger would provide convenient research into what correct dosages for optimal patient response look like for patients suffering from mood disorders.

Client requirements:

• Functional wearable device that can record the amount of illuminance in lux near the retina

• The device must be able to be used up to once a day for a maximum period of 2 hours

• Must be comfortable and wearable for the user

Must accurately interpret the lux the device is intaking

• Budget must be within \$500

Design requirements

1. Physical and Operational Characteristics

a. *Performance requirements* - The device should be able to accurately measure and record the

amount of light measured in lux receiving from a light therapy source used for mood disorders.

The device must be wearable on the user and comfortable to avoid discomfort and strain. The

device must be able to be used up to once a day for a maximum time of 2 hours. The device must

be able to be used multiple days in a row and be able to be put on and removed easily by the

user.

b. Safety - The device must be used in the parameters of safety outlined with exposure to light

therapy. The device must not be used more than once a day for a maximum time of 2 hours to

reduce light therapy harm to the user. The device must be lightweight on the user to not cause

harm to the user's eyes. All attachments on the device must be securely connected to avoid

breakage and sharp edges. The electrical components connected to the device must be properly

concealed for use on the body of the user. For electrical components, the device should ensure

operation on a low voltage to minimize the risk of electric shock. The device must adhere to

relevant safety standards for machinery safety and risk management in medical devices. Clear user instructions should be given to the user to ensure safe and effective use.

- c. Accuracy and Reliability The device should be able to properly sense and record the amount of light recorded in lux coming through its sensor. The device must accurately record the lux data daily upon use, for up to multiple days in a row. The data recorded must be within a 5% range of the correct lux amount implemented upon the device from the light used.
- d. *Life in Service* The device should be able to be used periodically based on the user's needs. The device must be able withstand use once a day or less. The device should be able to be on and in use for a range of 15 minutes 2 hours based on the user's needs and personal preferences.
- e. *Shelf Life* As our device's intended use is based on clinical testing, the device is intended to have an extended shelf life and/or rechargeable batteries such that our client and others have ease of operation. While in storage, we intend for the device to be turned off and stored at room temperature to preserve the integrity of the sensors, wiring, and chips. We intend to avoid leaving the device on to stop chip overload and to protect battery life.
- f. *Operating Environment* The device is intended to be used in a clinic, and will be mainly indoors. It's operation will take place at 70° F or 20° C($\pm 5^{\circ}$), and a standard pressure of 1 atmospheres. While the part specifications haven't been decided yet, we intend to have the

device stored in a dry and dust-free environment to preserve the devices functionality. The material of the device hasn't been chosen, however, we intend to make it durable such that a tester or testee could use it without an abundance of caution.

- g. *Ergonomics* The device should be functional for ages 18+. Due to the undetermined measurements of the device, we are unable to provide exact numbers or a hyper-specific target audience. However, the device is intended to be used on adults in a clinical testing setting, so clinicians will be able to properly instruct patients on safe and careful handling procedures. The exact method of logging light has not yet been determined once this occurs, other ergonomic factors will be addressed.
- h. *Size* The device has not been prototyped yet, so we are unable to provide exact size specifications, portability details, and space availability. We intend for the device to be wearable, inconspicuous, and convenient to clinical patients. While there isn't a maximum size, the device will require patients to be at least 18+ or have similar features to an adult to fit properly. As we have not decided on the technological specifications for the device, it is impossible to assess the device's accessibility to maintenance.
- i. Weight The device needs to be fairly lightweight although specific requirements have not yet been determined. The optimal weight will vary based on the ultimate design chosen, however in each case, it needs to be assured that the weight of the device will be comfortable for the user, and will not cause them any harm.

j. *Materials* - The device is proposed to be in contact with the skin so metal should be avoided in order to make sure that there is no skin irritation caused by the device. Using materials such as plastic, or elastic will be acceptable as long as they do not cause irritation or cause the device to be uncomfortable to wear.

k. *Aesthetics, Appearance, and Finish* - There are no requirements in terms of visual aesthetic and appearance. Because the device will be used for clinical purposes as opposed to for commercial use, appearance is not a critical factor in its design.

2. Production Characteristics

- a. *Quantity:* One device will be needed for research. The device should be reproducible for other researchers.
- b. *Target Product Cost*: The target cost for this product is a budget of \$500.

3. Miscellaneous

a. *Standards and Specifications* - US6737629B2[4] presents a patent for a standard light sensor which is used in the rearview mirrors of cars. This patent details some internal components of a light sensor that may be useful in designing our prototype.

- b. Customer Our client, Dr. Jean Riquelme, is a clinical professor in the Department of Family Medicine and Community Health at the University of Wisconsin School of Medicine and Public Health. She requests that our device is non-obstructive to users. Her idea includes a lightweight, non-metal based, and comfortable device. We have also been given flexibility over the target age range and aesthetic appeal.
- c. *Patient-related concerns* The device will need to be able to stay on the face or body appropriately without tilting to one side, or falling off. The device not being fastened appropriately could be concerning not only for patient safety, but also for the safety of the device. Additionally, if only one prototype is built for clinical use, the device will need to be sterilized between patients. A simple disinfectant wipe should suffice to appropriately clean the device between users.
- d. *Competition* There are a few similar competitive products that track and record light exposure through the retinas. One of the most popular products is called the Clouclip [5]. The Clouclip is a glasses clip that attaches to a standard pair of glasses. The device performs and collects long term real-time data and monitoring. The Clouclip is currently marketed toward children for myopia related behavior control. The device can record reading distance, reading duration, outdoor sunshine duration, and for the concern of our device, illuminance in lux. The Clouclip does not precisely have the same function as the wearable light logger, but records illuminance in lux and records which is the main component of wearable light logger.

References

[1] "Any Mood Disorder," National Institute of Mental Health (NIMH).

https://www.nimh.nih.gov/health/statistics/any-mood-disorder#:~:text=An%20estimated%2021.4%25%20of%2

OU.S.

[2] Julia Maruani, Pierre Alexis Geoffroy, 2019. "Bright Light as a Personalized Precision Treatment of Mood Disorders," Front Psychiatry. 2019; 10: 85. doi: 10.3389/fpsyt.2019.00085

[3] R. N. Golden et al., "The Efficacy of Light Therapy in the Treatment of Mood Disorders: A Review and Meta-Analysis of the Evidence," American Journal of Psychiatry, vol. 162, no. 4, pp. 656–662, Apr. 2005, doi: https://doi.org/10.1176/appi.ajp.162.4.656.

[4] S. Jon and H. Bechtel, 2004. Accessed: Sep. 19, 2024. [Online]. Available: https://patentimages.storage.googleapis.com/05/0f/96/8cc94d8b41487b/US6737629.pdf

[5] "Clouclip," Clouclip.com, 2024. https://www.clouclip.com/webCarbon/pc.html (accessed Sep. 20, 2024).

Appendix B: Expenses

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link		
Component 1	Component 1									
Happy Light	Light for testing sensor	Verilux	N/A	9/13/24	2	\$49.99	\$99.98	<u>Link</u>		
Component 2	Component 2									
Battery	Battery for chip	PGSONIC	CR2045	9/19/24	1	\$1.15	\$1.15	<u>Link</u>		
Component 3					•					
Head Lamp	Light that attaches to head	Fire Supply Depot	FL8210-6S MD	9/26/24	1	\$11.92	\$11.92	<u>Link</u>		
Component 4										
Raspberry Pi	Chip for coding	Raspberry Pi	Raspberry Pi Pico W	10/4/24	1	\$7.20	\$7.20	<u>Link</u>		
Component 5	Component 5									
Comparator	Building circuit	Texas Instruments	LM393PE4	10/4/24	2	\$0.25	\$0.50	<u>Link</u>		
Component 6	Component 6									
Battery Holder	Holder for coin battery	Digikey	BS-2450	10/4/24	1	\$3.84	\$3.84	<u>Link</u>		
Component 7	Component 7									

ОРАМР	Building circuit	Digikey	AD8276AR Z	10/4/24	1	\$7.37	\$7.37	Link
Component 8								
IC DAC 12BIT V-Out	Building circuit		MCP4726A 0T-E/CH	10/4/24	3	\$6.48	\$6.48	<u>Link</u>
TOTAL:								\$138.44