Wearable Light Logger for the Treatment of Mood Disorders

BME Design 200 & 300: Product Design Specifications

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Project title: Wearable Light Logger to Facilitate Full Spectrum Light Dosing for Mood Disorders

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Function

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 could 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.

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 3.3V 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 to 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 the device is intended for clinical use, extended shelf life and/or rechargeable batteries will be utilized to ensure ease of operation for the client and other users. During storage, the device is designed to remain off and stored at room temperature to preserve the integrity of its sensors, wiring, and chips. To prevent chip overload and protect battery life, the device will not be left on unnecessarily.
    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℉ or 20℃(±5°), and a standard pressure of 1 atmospheres. While the part specifications haven’t been decided yet, the device is intended to be stored in a dry and dust-free environment to preserve the devices functionality. The material of the device hasn’t been chosen, but is intended to be durable such that a subject/patient 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, no exact numbers or a hyper-specific target audience can be provided. 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 exact size specifications, portability details, and space availability are unable to be provided. The device is intended 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. The technological specifications for the device have not yet been decided so it is currently not possible 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 -** The client, Dr. Jean Riquelme, a clinical professor in the Department of Family Medicine and Community Health at the University of Wisconsin School of Medicine and Public Health, has requested that the device be non-obstructive to users. Her specifications include a lightweight, non-metallic, and comfortable design. Flexibility has also been provided regarding 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.