

Skin Color Monitor

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Client

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Abstract

Many menopausal women suffer from hot flashes, the symptoms include momentary sensation of heat, sweating, flushed face, and increased heart rates. In drug and other treatment development, developers use devices to record the accounts of hot flashes in women. Devices that accurately study hot flashes in women are especially useful in developing new drugs to help relieve the symptoms of hot flashes. Currently, the devices used to monitor hot flashes are big, bulky, and simply inconvenient to wearers. We hope to develop a device that will accurately monitor hot flashes by detecting the change in skin color during a hot flash. This device aimed to be small, comfortable, cheap, and effective. Our team has come up with three specific design ideas and after the evaluation of all three; a final design has been selected. The team plans to go forward in creating a working prototype in the near future.

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Problem Statement

Our client, Professor John Webster has presented us with the task of creating a device that uses changes in skin color to monitor and record hot flashes in women. The device is to be used in research and testing of experimental menopausal drugs. Traditionally, hot flashes have been monitored by use of a journal and or electrodes attached to the chest. However, our client indicated that the journal is extremely inaccurate and the use of current electrode devices is uncomfortable, inefficient, and expensive. Our device will detect when the skin becomes flushed using changes in skin color as an indicator. Our client has expressed interest in us creating a device that is capable of performing the said task using a small, comfortable, and relatively cheap design.

Background Information

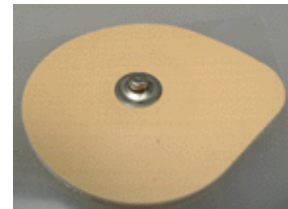
The most common symptom of menopause in women is hot flashes. Hot flashes are sensations of heat a woman experiences that are marked by excessive sweating and flushed appearance of the skin. During a hot flash, the capillaries near the surface of a woman's skin dilate in an attempt to cool the body (WedMD, 2007). This will give the skin a reddish appearance, similar to the flushed appearance one gets after exercise. Hot flashes often occur at night and can be very debilitating to sleep patterns (Stöppler, 2007). The length of a hot flash can fluctuate from several seconds to as long as an hour. Hot flashes occur in eighty five percent of women as they approach menopause and twenty to fifty percent have hot flashes that persist for years.

Currently there are many treatments for the onset of hot flashes. Hormone replacement therapy is a very common form of treatment for hot flashes. Also some antidepressants and other drugs have been found to help curb the symptoms (Wikipedia, 2007). Given these current options, there is still a great need for the development of drugs. For years, studies were performed with subjects using journals to record hot flashes (Webster, 2007). As stated before, this method is ineffective given their ambiguous and subjective nature.

Current Devices

Presently, research studies are often conducted with monitors that involve electrodes attached to the chest. These electrodes then run wires down the chest to a device kept on the belt. The electrodes measure differences in voltages across the wearer's skin indicating a hot flash. A hot flash causes the skin's sweat ducts to adjust which alters the difference in voltage across the skin (Webster, 2006).

An example of a current device on the market is the BIOLOG device, manufactured by UFI (UFI, 2007). While



the device does well to monitor hot flashes, it presents several problems we plan to address with our device. First of all, it



<http://www.ufiservingscience.com/HFMon1.html>

is too heavy (200 g) to be worn comfortably as well as too bulky (3.3 x 7 x 13 cm). The

device also requires wires be run from electrodes to the device which also reduces comfort levels. Moreover the device only has a 24-hour battery life, which greatly restricts how well drug tests can be performed and also the length of those procedures. The BIOLOG system also is very expensive; about \$2,200 USD and the software needed for it is about \$2,000 USD (UFI, 2007).

To the best of our client's and our knowledge, we will be the first to create a hot flash monitor based on changes in skin color (Webster, 2007).

Design Constraints

Our design must follow a specific set of constraints detailed by our client, Professor Webster. First, the device must provide detailed readings of skin color change every 10 seconds to indicate a hot flash. The device must be FDA approved for humans with low voltage and no issues with heating the skin. The attachment of the device to the skin must also be non-irritant. It must demonstrate accurate readings of voltages that demonstrate an ability to detect a hot flash. The device must have sufficient power to last for an overnight reading, and must also have an on/off switch to preserve battery life. The device may be disposed after multiple uses. It must also have a stored shelf life of at least 1 year in original packaging. The device is to be attached to the skin while the wearer is resting and may be removed for necessary daily activities. The maximum size of the monitor should be less than 1 x 6 x 6 cm and have only smooth edges to prevent skin irritation. The weight of the device must be less than 50 g. The device must be made of materials that are safe for human use and have a smooth, sleek appearance that is "user-friendly", and should be aesthetically pleasing. Finally, our target budget should be less

than seven dollars per device, making it a viable disposable device. (A full product design specification is available **Appendix A.**)

Design Alternatives

In generating different design possibilities, it is important to consider design requirements. After some preliminary research and brainstorming, the design process was initiated. Ideas were evaluated according to the customer specifications and the top three designs were selected: box & barrier, cave, and laser design. We will now discuss the three designs

Design 1: Box & Barrier

Overview

The box design is the first and most basic design of our skin color monitor designs. Its purpose is to successfully monitor the change in skin color during hot flashes. Since our client, Professor John Webster, has some specific demands on the way the monitor should work, he provided us the basis of the design. Perhaps the most important of his specifications is that the device should detect differences in the tone of a wearer's skin using light. He also requested that the design weigh no more than 50 g and the light be as close to the skin as possible. The design functions by shining light onto the skin and monitoring the differences in reflected wavelengths and intensities. This more basic design is what our other more sophisticated designs were based on.

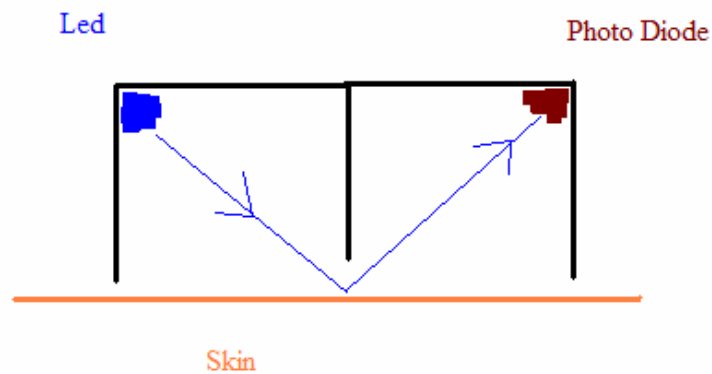


FIGURE I: THE BOX DESIGN

While picture is a poor indicator of the complexity of the design, it shows clearly how the design will function. It detects the difference in skin color by shining a light from the led on the skin and absorbing the reflected light with a photodiode. The resistance of the PD is dependent on the absorbed intensity. This means that the color of the skin can be quantified in terms of voltage across the photodiode. The above design may be the simplest of our designs, but it is the calibration and wiring that is required may be harder to implement compared to our other design ideas.

According to Kevin Elicieri of the University of Wisconsin—Maidson blue light is the best color to use because it is the wavelength that is absorbed the least by the skin (Elicieri, 2007). A report written by Elli Angelopoulou from the University of Pennsylvania, however, suggests otherwise. In that article, the studies suggest that red light spectrum reflects the best off skin (Angelopoulou, 1999). We are hoping that experimental data with differently colored LEDs in our prototypes will provide the determining factor in deciding on which wavelength to use. Also, the more important

property is the *change* in reflected intensity during hot flashes, not the intensity of one wavelength of light at one time.

Because of this importance, the distance and angle of light must be set carefully and kept constant at all times to produce accurate results. To make this easier, the design will be constructed of hard plastic. We will have to perform tests with the various conditions that a woman will experience to determine a way to keep the distance of the LED and PD (photodiode) from the skin from fluctuating. In the box design, the LED and PD are to be 2 mm away from the skin. 2 mm was chosen as the distance we want the system to be as close to the skin as possible, allowing the PD to receive as intense readings as possible while also ensuring the system will not be in contact with the surface of the skin. The angle will also be such that the light is able to reflect off the skin and hit the PD with the greatest intensity, however experimental data will determine how precise the calibrations will need to be. The purpose of the barrier in this design and the opaque walls in all designs are to minimize the amount of light reflected off the walls of the device and other ambient light that may hit the PD, since extra light picked up, not reflected from the skin, would reduce the accuracy of the device.

The exact dimensions and power source of the design are still somewhat in speculation, but we currently estimate that the monitor will be 5 by 5 by 2.5 centimeters. Ideally, we would like to use the smallest battery possible to keep the weight of the monitor under 50 g.

Advantages:

The first benefit of our first device is its simplicity. Another advantage is its firm, sturdy shape. Depending on when the device is to be worn, it is important that the monitor stays intact and produces accurate results despite the wearer's movements. This could mean sustaining a bump from a co-worker or withstanding a significant amount of pressure if the woman should roll over on it in her sleep. The size and weight of the monitor are also advantageous aspects of the box design. It is important that the woman be able to function normally throughout the day and that she not be hindered by a bulky piece of equipment.

Disadvantages:

One of the advantages of the box design is also a disadvantage. While the rigid plastic will be durable, it will also be uncomfortable. For example, when pushed on, the barrier and edge of the device, even if designed smooth, may press into the wearer's skin and cause discomfort. Also, if users decide that the device will be more useful in detecting hot flashes during the day instead of only while the woman is sleeping, it is important that the device go unnoticed. Wearers will most likely be deterred from using a product that does not appear to be natural or that is not easy to conceal. Alternatives to harder plastic may also be easier to work with.

The source of light for this design may not be the most efficient option. In one of our later designs, a laser, for example, would be capable of focusing light in ways an LED could not. Because of the relationship between the dispersion of an LED's light and its distance from the skin, a small change in distance could cause a large change in the intensity of light picked up by the PD.

Design 2: The Dome

Overview

The dome design is very similar to the box design. It is simply an improvement on the same principles on which the box design is based. While the outside design is not firmly set, once we build a working prototype, we will be able to modify the structure to make it more comfortable, less noticeable, and perhaps more appealing to the eye. After all, in today's world, customers and patients demand more than just results.

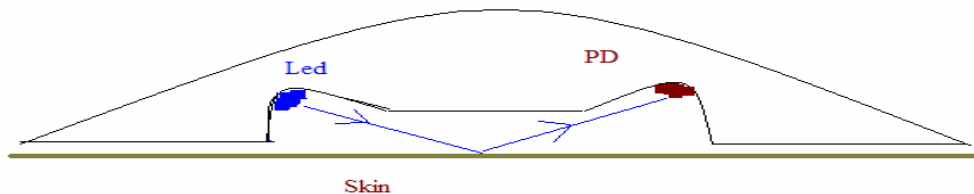


FIGURE 2: THE DOME DESIGN

The only differences between the above cave design and box design are the shape of the casing, the material from which it is constructed, and the way the barrier works. The dome design will be made of a softer material like rubber or some soft plastic. It will be just firm enough to avoid significant deformation while being subjected to realistic pressures. Currently, we are thinking of using something simple like a large eraser for the prototype of this design.

Instead of having rigid edges in contact with the skin, the design will have a larger surface area to greatly reduce the pressure applied to the skin when the device is pushed on. However, this means that the distance from the skin to the LED and PD may fluctuate. To prevent light from going directly from the LED to the PD, we plan to carve

“caves” for both into the case material instead of making a potentially uncomfortable barrier.

Advantages:

Like the box design, the dome design is cheap, lightweight, and small. The difference is that, we believe, the dome could be designed to be less noticeable. This makes it a much more appealing choice if the wearer is going to wear it in public. The most important difference that this device had over the box design is that it will be more comfortable, which is important in not causing additional stress to the wearer, especially if worn during sleep.

Disadvantages:

The only difference between the designs that is a disadvantage for the dome design is its softer material. There is a possibility of the monitor flexing while being subjected to varying pressures and producing less accurate results. The material from which the device is constructed, will determine how significant this flexing will be.

Design 3: The Laser

Overview

Both the box design and dome design involve some type of barrier between the light source and receiver to ensure the light detected is fully reflected from the skin. The barrier may cause discomfort to the patient, and it also takes extra time to fix the barrier into the case. To get rid of the barrier, a laser diode is used as the light source. Light emitted from laser diode is narrow and low-divergence, so light will be more focused and

as a result, the signal received from the photodiode will mainly be the light reflected from the skin.

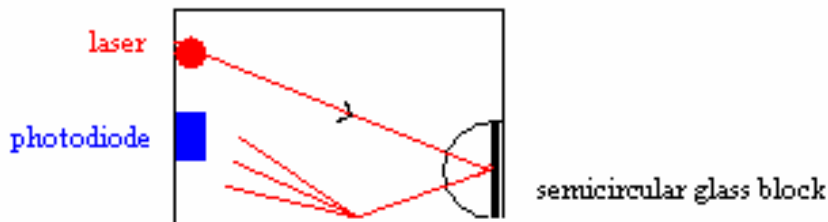


FIGURE 3: THE LASER

It may be easier to construct if all the electronic components are on the same side. To achieve this, a glass block is used to induce a total internal reflection of the laser emitted. The reflected light would then shine on the skin and back to the PD. A stiffer case would have to be used because if laser diode moves slightly out of place, it may affect the result.

Advantages:

The benefit of this design is that there is no barrier. This could decrease the manufacturing time and cost. Both the light source and receiver are on the same side. The firm, sturdy shape of the casing allows the device to take consistent measurements. Since the light source is more focused, the intensity of light picked up by the photodiode will be higher.

Disadvantages:

The laser diode is very expensive (>USD 15) which exceeds our budget (DigiKey, 2007). Moreover, using a laser is potentially dangerous. Inappropriate use of the laser diode, such as accidentally shining into the eyes, could cause hazardous damage.

Design Matrix

A design matrix was developed for the three unique designs to rate advantages and disadvantages based on several criteria: comfort, cost, light detection, safety, ease of construction, and durability. The criteria were weighted according to their importance. The ability of the pick up as much light as possible has the highest weight, as that is the main goal of our design. Cost comes next, as our budget is limited. Comfort and ease of

	Box	Dome	Laser
Comfort (0.15)	6	9	6
Cost (0.2)	8	7	2
Ease of construction (0.15)	6	7	6
Light Detection (0.25)	5	7	6
Safety (0.15)	7	9	5
Durability (0.1)	8	7	6
Total	6.45	7.6	4.75

construction are also put into high consideration.

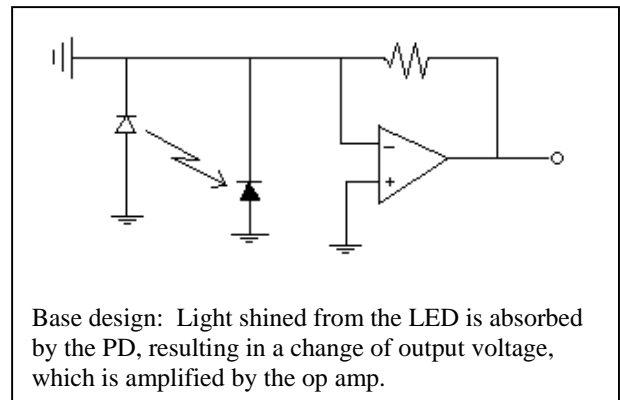
We believe the dome design will have better light detection ability than the box, since the light would be dispersed more broadly and give the greatest chance for detection in all possible conformations of the device. For the cost, the laser is the most expensive one while

others can be made in a reasonable price. The laser is also potentially more dangerous compared to the LED's. The dome design is the most comfort one as it will be made of

soft rubber, in contrast to the harder, firmer cases of the other two designs. It is also the most feasible to construct as we already have ideas to use a large eraser as the soft case material.

Circuitry

Our team decided to separate the design process of this part of the device since the circuitry can be applied to whichever device design we choose. The circuitry used in our device is based on the properties of a photodiode. When light is absent, the photodiode acts as a barrier, or an open circuit, preventing any current through it. When light is present, photons will strike the diode creating a charged electron hole and producing a current across the device (Wikipedia, 2007).



The goal of the device is to have the LED shine light onto the skin, which is then reflected back at the PD. When the PD absorbs the light, current leakage will occur and a change in output voltage will be detected. Use of op amps provide a multitude of ways to fine-tune the circuitry such as changing linearity, offset, noise, and bandwidth, but most importantly amplify the change in output (Texas Instruments, 1995). The changes in output will then be recorded by the device for later analysis.

Future Work

While there is still a long way to go in the design process, we're optimistic about our chances to make a viable working device by the end of the year. Since such a device has never been created, the design specifications supplied by the client and the PDS (see Appendix) will be our most important guide. Our first task is to discuss and go over our designs with the client and finalize the proposed design, from there we can work on the circuitry and work to integrate the circuit into the design. Further knowledge and research will be needed for developing the device circuitry. We currently are in contact with Amit Nimunkar, a grad student here at the UW-Madison, and having his help and insight will aid us greatly. Method of attachment is also something the team will be continually brainstorming on. Hopefully we can fabricate a testable device within the coming weeks and begin testing the effectiveness and ability of the device. As of now, we plan to simulate hot flash by performing strenuous exercises to mimic the effects of a hot flash and see if the device will perform properly. From there, we'll fine-tune it and hopefully have a viably usable prototype by the end of the semester.

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Appendix A

Product Design Specification

Client Requirements:

- Miniature size & weight.
- Record color changes at least every 10 s.
- Low cost.

Design Requirements

1. Physical and Operational Characteristics

- Performance requirements:* Must record changes in skin color every 10 s by displaying voltage changes proportional to the amount of light detected by photodiode.
- Safety:* Must be FDA approved for humans. Small voltage and low duty cycle that powers the LED and photodiode will be safe for continual use without overheating the skin. Method of attachment must not irritate skin.
- Accuracy and Reliability:* Must output varying voltage levels corresponding to amount of light reflected from the skin at least at an interval of 10 s. Changes will be measured to study skin color changes.
- Life in Service:* Must last for the minimum duration of an overnight recording and retrieval of data. There will be an On/off switch to preserve power when recording is not needed. Will be disposed of after multiple uses.
- Shelf Life:* Must have a shelf life of at least one year when stored in original packaging.
- Operating Environment:* Will be attached to wearer's chest while he/she is at home and/or asleep. May be taken off during daily activities such as during shower to prevent damage to device. When unattached, the device will be stored away from outside exposure.
- Ergonomics:* Will be fabricated with no sharp edges in order to prevent irritation or injury to the wearer. On/off button will be contoured with the smooth casing of the device.
- Size:* Maximum size of 6 cm x 6 cm x 1cm including device and all possible attachments. "Device only" size goal of 3 cm x 4 cm x .5 cm
- Weight:* Must be lighter than 50 g.

- j. *Materials*: Fabricated with no materials that irritate or otherwise harm human skin. Must be soft and smooth to prevent discomfort while attached to wearer.
- k. *Aesthetics, Appearance, and Finish*: The texture and finish should be small, sleek, comfortable, and smooth for optimal comfort and minimal notice. LED within the device will also act as an “on” signal.

2. Production Characteristics

- a. *Quantity*: Working prototype. Likely to be mass produced, determined based on demand, in future if prototype meets all desired specifications.
- b. *Target Product Cost*: < \$7 USD

3. Miscellaneous

- a. *Standards and Specifications*: FDA approved for normal human use.
- b. *Customer*: Women aged 45 to 55 will be the primary wearers. The device will be small and concealable. It should be as unobtrusive and comfortable as possible, especially since it will be worn continuously. Women are more apt to wear tight fitting clothing as well so the device should not be noticeable given reasonable attire.
- c. *Patient Related Concerns*: The device should have no issues with sterilization, as it will be external and disposed of as desired. The data collected must be stored confidentially, both for the patient’s rights and to preserve the objectivity of the study.
- d. *Competition*: A device shown to us by our client Professor Webster used two electrodes to sense changes in skin resistance. The advantage to our device is the measure of color change is less obtrusive than attaching electrodes directly to the skin. All other monitoring devices found were large and obtrusive.