

# Product Design Specification

10/1/2007

## Skin Color Monitor

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**Function:** Miniature device to be attached or adhered to the skin that will record changes in skin color during a hot flash. The device is designed to be fastened to the upper chest of a woman and be smaller than 6 cm x 6 cm x 1 cm. A LED within the device will shine light onto the skin to be reflected back to a photodiode. The photodiode within the device will record changes in color by affecting the voltage output of the device in relation to the amount of light it absorbs, which will be observed and collected as data. Device may be used to record relevant data during drug testing.

**Client Requirements:** Miniature size & weight, record color changes at least every 10 s, low-cost.

## Design Requirements:

### 1. Physical and Operational Characteristics

- a. *Performance requirements:* Must record changes in skin color every 10 s by displaying voltage changes proportional to the amount of light detected by photodiode.
- b. *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.
- c. *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.
- d. *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.
- e. *Shelf Life:* Must have a shelf life of at least one year when stored in original packaging.
- f. *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.
- g. *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.
- h. *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

- i. *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.