Skin Color Monitor—Product Design Specification

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Function: A skin color monitor that records color changes that occur during hot flashes, which could be used to provide the objective measurement needed for therapeutic drug testing for menopausal women. The device is to be capable of discerning color changes while remaining small and at a low cost. The device adheres to the skin in the upper chest region. An LED will shine light onto the skin and a photodiode will register the change and that will affect the output voltage. The changes in the voltage are recorded every 10 seconds.

Client Requirements:

- Small size, Maximum of 6 cm x 6 cm x 1cm, ideally 3 cm x 4 cm x 0.5 cm.
- Aesthetically pleasing, smooth design.
- Elimination of specular reflection.

Design Requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The device must record "skin color" every 10 s by displaying voltage proportional to light detected by photodiode, which will vary according to skin color.

b. *Safety*: The device must be FDA approved for humans. The LED and photodiode will be powered with a small voltage input and low duty cycle which will not overheat the skin, making the device safe for continual use. The method of attachment must not irritate skin.

c. *Accuracy and Reliability*: The output voltage must be recorded at least every 10 s. Changes in normal pattern will be flagged and measured to determine the intensity of skin color change. Accuracy will be improved by adjusting the position of the photodiode in order to reduce specular reflection, and by improving the circuit in order to provide larger voltage differences with skin color change. Multiple persons of different ethnicities must be tested in order to find the accuracy of the device when applied to varying skin colors at normal body temperature.

d. *Life in Service*: The device must survive the minimum duration of an overnight recording and retrieval of data before recharging battery. There will be an On/off switch to preserve power when recording is not needed. It is designed to be a disposable device.

e. *Shelf Life*: The device must have a shelf life of at least one year when stored in original packaging.

f. *Operating Environment*: The device will be attached to the wearer's chest daily at home and work, and during sleep. The device should be taken off during daily activities such as during shower in order to prevent damage to device. When unattached, the device should be stored and safe from outside exposure.

g. *Ergonomics*: The device will be fabricated with no sharp edges in order to prevent irritation or possible injury of the wearer. The on/off button will be contoured with the smooth casing of the device.

h. *Size*: The device will be a maximum of 6 cm x 6 cm x 1cm including all possible attachments. The preferred size of the device by itself would be 3 cm x 4 cm x .5 cm

i. *Weight*: The device must be lighter than 50 g.

j. *Materials*: The device must not be fabricated with materials that would irritate or otherwise harm human skin. It should be soft and smooth to be comfortable while attached to wearer.

k. *Aesthetics, Appearance, and Finish*: The device must be small, smooth, and comfortable in order to avoid obvious detection and to provide the wearer optimal comfort. The LED within the device will also act as an "on" signal.

2. Production Characteristics

a. *Quantity*: Although we will only be making one prototype, if it is a successful design it may be produced in the thousands or hundreds of thousands.

b. *Target Product Cost*: We need to make a prototype that costs less than $7.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval is required for this device.

b. *Customer*: The customer requires a device that is comfortable to wear and is able to be concealed under clothing. If these specifications are not met, the motivation for the customers to wear the device (and thus the utility of the device) will be negatively affected.

c. *Patient-related concerns*: The device will be able to be thrown away after approximately two week's use. Therefore, depending on the method of attachment to the skin, adhesive may need to be cleaned off the skin after each use, and an adhesive may need to be re-applied to the device before subsequent uses. Hot flash occurrence data will be stored in the device, which may need to be safeguarded for the patient's confidentiality.

d. *Competition*: There are other skin color monitors available, but due to their large sizes, heavy weights, and high costs, are not able to monitor a person constantly during their normal, everyday activities without being obtrusive and very expensive.

There are several small hot flash monitors being designed and tested that measure hot flashes by changes in skin resistance due to sweating. Although these monitors have similar size and weight requirements as our design project, the method of detecting hot flashes is different.