Product Design Specifications: Analysis of Insulating Properties of Skin (Rodent)

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BME 200/300

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Function:

The insulative properties of mouse skin prompt significant changes in the rodents' energy metabolism. Heat-permeable skin allows for increased heat dissipation, improving the metabolic health of mice and preventing diet-induced obesity. In order to explore these relationships by monitoring and quantifying skin insulation, a biomedical device which can sense said skin thermal insulation from a patch of ex-vivo mouse skin is necessary. An easy to use, reusable device will be developed to detect these measures within a specified sensitivity and display the results. This device will improve efficiency and accuracy in the testing of rodent skin.

Client Requirements:

1. The device must measure the heat transmitted through a sample of mouse skin as a way of quantifying insulative properties.
    a. Included in the device must be a heating element that uses pulses of 37℃ to heat the sample periodically.
    b. The temperature on the dorsal (top) side of the skin must be detected.
    c. The heat transmitted that is measured should only be a result of conduction and convection, not evaporative cooling.
2. The temperature measurements relative to time must be displayed to the researcher in a graphical form.
3. The device must be easy to use, reusable, and a cost effective alternative to competition.

Design Requirements:

1. Physical and Operational Characteristics:

a. Performance Requirements:

- The biomedical device will quantify the thermal insulation of mouse skin by measuring the temperature on top of the skin in relation to time.
- The device will provide a heat source to heat the skin from the bottom and sensors/circuitry for temperature measurement.
- The product will be reusable, allowing for the testing of multiple skins and able to be reset, calibrated, and sanitized.

- The researcher should have the ability to easily move and operate the device.

b. Safety:

- The device's heating element will be programmed to heat to specifically 37℃. Code and electronic hardware will ensure the heating element is off when the device is not in use.
- Electrical connections will be securely fastened to avoid short circuiting.
- The product must be kept in a dry environment away from liquids.
- The temperature sensor component of the device will allow for cleaning and sterilization after each use to prevent infection and contamination as laboratory protocols outline.

c. Accuracy and Reliability:

- To ensure the data collected is useful to the researchers, the device should record with a precision of 0.1℃ and be within 0.5℃ of the actual temperature within the range of 30-40℃.
- Data should be collected at a rate of 0.2 Hz.
- Per the client, the samples will be a maximum size of 4 x 6 cm and a minimum thickness of 0.05 mm.
- The device should maintain accurate performance after hundreds of repeated uses over the course of at least 5 years.

d. Life in Service:

- Both the heating element and temperature sensor will need to operate using skin that is with and/or without fur.
- The device will need to handle repeated use in quick succession. Each test is short, but many could be conducted at a time.
- The device will heat to standard body temperature of ≈37℃, so the materials used should be resistant to temperatures of at least 40℃.

e. Shelf Life:

- The average heating element has a lifespan of about 10 years, pending proper use and storage [1].
    - Heating elements have resistivity properties on their plates to make sure that they aren't damaged by samples while simultaneously making the surface easy to clean.
    - Based on the type of heating element and its electrical connections, non-corrosive features will increase the lifespan.
- Both plastic and copper are viable options to be used throughout the design. Both need to be able to withstand an increase in temperature as they will be near the heating element.

    - Copper has many positive attributes because it is corrosion resistant, has an extremely high melting point, and is malleable [2]. Based on the project's requirements it should have an indefinite life span [3].
    - Plastic has a lower melting point than copper, but it is still well above 37°C. Most plastics have a shelf life of about three years [4].

f. Operating Environment:

- The device will be utilized and stored in a laboratory at room temperature, 20°C, and standard pressure, 1 atm.
- The presumed conditions for the device will be in an indoor laboratory setting, meaning the device will have limited exposure to dust, humidity, and corrosion.
- People handling and operating the device will be researchers and other laboratory staff.

g. Ergonomics:

- There are many different sizes of workbenches and laboratory space. Most workbenches range from 24-36 inches in width, 30-120 inches in depth, and 30-36 inches tall [5].
    - The device should fit easily on all laboratory workbenches and thus should be designed with small benches in mind (24 x 30 x 30 inches).
    - The device will need to be operated from an angle that allows for easy placement of the rodent skin. Depending on the height of the researcher and/or the laboratory work space, a chair or stool may be necessary to use. Accessibility to the heating element and other components will be included in the design.
    - Due to the heating element being incorporated into the design, it will be important to have an external power source nearby.

h. Size:

- The heating element should be able to accommodate a 2 x 4 cm patch of skin.
    - Most heating elements such as hotplates sold commercially include a wide range of dimensions with moderate sized hotplates ranging from 20.8 x 36 x 10 cm and large hotplates ranging from 28.8 x 43.8 x 20 cm [6].
    - Due to the size of the sample, a smaller heating element with dimensions such as 14 x 14 x 5 cm and a plate with a radius of 5 cm would be better equipped to fit the researcher's needs [7].

- The device will include a second component that presses down on the dorsal side of the patch of skin. A copper or aluminum sheet should be used in order to minimize heat adsorption [8].
  - Most cost-efficient copper sheets are sold 15 x 15 cm with a gauge of 18 [3].
  - The metal sheets should be fabricated to fit the size of the heating plate, equating to a radius of about 5 cm.

i. Weight:

- The device must be within certain weight criteria as those operating and transporting the device will ideally carry it at chest height close to their body for easiest transportation. According to legal guidelines, this means that laboratory staff should only carry a device that is 16 kg or less [9].
  - A relatively small copper sheet (15 x 15 cm, 18 gauge) will weigh a little less than 0.15 kg per sheet [3].
  - A relatively small heating element will weigh around 0.6 kg including the weight of the heating plate itself [7].
  - The device should weigh under 3 kg which is well within the given lifting requirements for the workplace.

k. Materials:

- The final product should be made of a rigid material enabling reusability and invoking a professional, clean look.
- The heating element will be made of a material that withstands frequent temperature changes and temperatures of 37℃, allowing for the use of most metals and hard plastics [10].
  - A material that does not absorb heat or act as insulation from the heating component to prevent heat loss and allow for greater efficiency is optimal, such as copper [11].
  - For prototypes, cost-effective plastics and resins compatible with 3D printers will be used. Such materials are safe in short-term use at 37℃ [12].

l. Aesthetics, Appearance, and Finish:

- The final appearance of this product should be a relatively small and space-efficient device.
- Controls and other user interfaces on the device should be simplistic and intuitive.
- The final product and all electrical circuitry should be contained in a sleek, well-constructed exterior that is professional and able to withstand laboratory use.

2. Product Characteristics:

a. Quantity:

- One fully functional design will be developed and manufactured for the client by the end of the semester.
    - Multiple iterations of prototypes will be essential in the design process.

b. Target Product Cost:

- A firm budget has not yet been provided. However, the total cost of the device should be affordable as the prices of current commercial alternatives was cited as a hurdle by the client.
    - The necessary variation of microprocessors to operate the electronic circuit range from $20-$30 [13].
    - For the measurement of heat, K-type thermocouples cost $5.50, and thermopiles can be purchased for under $40 [13].
    - Wires, resistors, and other minor electronic items cost under $1.00 per unit [13].
    - All stock metal and plastic for the final design of the product cost under $35 [3]. However, prototypes can be constructed using scrap material available in the UW-Madison TeamLab.

3. Miscellaneous:

a. Standards and Specifications :

- This device must comply with National Safety Standard IEC 61010-031 Ed. 20 b: 2015, which specifies specific safety standards that electrical devices must follow in order to be utilized [14].
    - Under IEC 61010-031, the device should be able to be utilized without risk of electrical shock and burn, excessive temperature and mechanical hazards [14].
- Most specifically, IEC 61010-2-010 Ed. 4.0 b:2019 discusses safety and accuracy of measurement surrounding devices that are heating materials, which should be easily applicable to the device as the temperature is not getting extremely hot [15].

b. Customer:

- The target customer for this product is our client and her laboratory staff. However, this device could be useful to other research labs or for materials testing.
- Laboratory staff will be the primary users of this device, so it should seamlessly integrate into the lab environment and work well with other devices they currently use.

c. Patient-Related Concerns:

- This device will be used for an ex-vivo research application on surgically removed samples of mouse skin, thus patient-related concerns are minimal.
- Prior to being used for animal testing with this device, the mice should be humanely euthanized according to lab protocols.
- Sterlilzation of the device between tests is necessary to uphold researcher health and safety.

d. Competition:

- The temperature sensor market is quite saturated with products like the Total-Range Traceable Thermometer [16], or the Extech TM500 [17].
    - Both models are thermocouple thermometers and are limited in their ability to automatically transfer data. More importantly, they are affected by surface evaporation.
- The main competition that is specialized in ex-vivo skin temperature measurement while ignoring evaporative cooling is the Thermtest Measurement Platform MP-1 [18].
    - This device pulses heat and automatically calculates thermal conductivity for samples of a minimum size 5 mm x 5 mm and a minimum thickness of 0.01 mm [18]. The limit for this device is that it’s out of the client’s budget.

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