Global Health: Prevention of Diabetic Foot Ulceration and Amputation
Final Product Design Specifications

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Function:

The device will be a preventative solution to India's diabetic foot ulcer problem by developing a low-cost way to measure temperature from the feet of diabetic patients using thermochromic material and an app-based software to further interpret the images and thermal maps. A machine learning algorithm will be incorporated to analyze the data collected and determine whether or not a patient is at-risk of developing a foot ulcer.

Client Requirements:

- Obtain a thermal image or map of the patients' feet
- Upload the thermal images to a software/app
- Use a machine learning algorithm that we will train to recognize whether an image is of an at-risk patient or not

Design Requirements:

1. **Physical and Operational Characteristics**
    a. ***Performance requirements:*** *The performance demanded or likely to be demanded should be fully defined. Examples of items to be considered include: how often the device will be used; likely loading patterns; etc.*
        i. The machine learning algorithm must be accurate enough to recognize whether or not a patient is at-risk of developing an ulcer based on the thermal image of a patient's foot.
        ii. The device could be used anywhere from monthly to daily. It must be able to withstand several uses in one day and still accurately display a thermal map of the patient's feet that can be uploaded to the app.
        iii. The app/software must be able to withstand the process of uploading an image several times a day, potentially by multiple different mobile devices. It cannot crash during usage.

b. ***Safety:*** *Understand any safety aspects, safety standards, and legislation covering the product type. This includes the need for labeling, safety warnings, etc. Consider various safety aspects relating to mechanical, chemical, electrical, thermal, etc.*
    i. The material used to collect temperature data and thermal maps must be safe for the patient. This includes thermal cameras and thermochromic material, neither of which can include any harmful side effects for the patient [1].
c. ***Accuracy and Reliability:*** *Establish limits for precision (repeatability) and accuracy (how close to the "true" value) and the range over which this is true of the device.*
    i. The machine learning algorithm must be very accurate and reliable, therefore it must go through a long enough "learning process" before it is used clinically.
    ii. It must be accurate enough to recognize when a patient is at-risk of developing a foot ulcer.
d. ***Life in Service****: Establish service requirements, including how short, how long, and against what criteria? (i.e. hours, days of operation, distance traveled, no.of revolutions, no. of cycles, etc.)*
    i. Liquid crystal thermochromic material can retain its properties for several months if handled properly. Soaking the material in hot water baths can cause the material to deteriorate faster, as well as exposure to UV light [2].
e. ***Operating Environment****: Establish the conditions that the device could be exposed to during operation (or at any other time, such as storage or idle time), including temperature range, pressure range, humidity, shock loading, dirt or dust, corrosion from fluids, noise levels, insects, vibration, persons who will use or handle, any unforeseen hazards, etc.*
    i. The thermochromic material will be used to obtain a thermal map of the patient's feet when the patient steps on the material. This can be used in any indoor setting with a controlled climate.
f. ***Ergonomics****: Establish restrictions on the interaction of the product with man (animal), including heights, reach, forces, acceptable operation torques, etc..*
    i. The thermochromic material must be easy to use by both the doctor and the patient. All that will be required of the patient will be to step on the material to collect the thermal map, and the person looking to analyze the thermal map should be able to easily take a picture of the generated thermal map with their phone camera and upload it to the app-based software, which will generate an output. This should be an easy process for the user.

g. ***Size****: Establish restrictions on the size of the product, including maximum size, portability, space available, access for maintenance, etc.*
    i. The thermochromic material needs to be large enough for both of the patient's feet, but small enough so that there is not too much excess material. One sheet needs to be able to accommodate people of many different foot sizes.
    ii. The size of the images must be compatible with the software/app. The app must be able to analyze images of different sizes and still generate a result.
h. ***Weight****: Establish restrictions on maximum, minimum, and/or optimum weight; weight is important when it comes to handling the product by the user, by the distributor, handling on the shop floor, during installation, etc.*
    i. Liquid crystal thermochromic material weighs about the same as a piece of printer paper. The weight of the paper will not be an issue for the user or distributor.
    ii. The thermochromic material must be able to withstand the weight of the patient and still generate and accurate thermal map of the patient's feet.
i. ***Materials****: Establish restrictions if certain materials should be used and if certain materials should NOT be used (for example ferrous materials in MRI machine).*
    i. The thermochromic material will be the only physical material used in the project. This will either be thermochromic liquid crystal sheets, or leucodyes that can be printed on another material. The liquid crystal sheets are more accurate than leucodyes [3], so it is likely that will be the only material used.
j. ***Aesthetics, Appearance, and Finish:*** *Color, shape, form, texture of finish should be specified where possible (get opinions from as many sources as possible).*
    i. The user interface of the app/software must be user friendly and aesthetically appealing. It needs to be accessible to everyone eventually, so text must be readable and the image uploading process should be easy.
    ii. The output generated by the app should be easy to read and non-offensive if a non-desirable (at-risk) outcome is generated.

2. Production Characteristics
    a. ***Quantity****: number of units needed*
        i. Only one application needs to be created.
        ii. While testing the device, only a few sheets of thermochromic material need to be used to ensure the accuracy of the device and system.
        iii. If the product is marketed to the public, each individual using the device will require their own sheet(s) of thermochromic material.

b. ***Target Product Cost****: manufacturing costs; costs as compared to existing or like products*
    i. There is no set budget for this project.
    ii. One 12x12in liquid crystal sheet is $25.95 [4].

3. Miscellaneous
    a. ***Standards and Specifications****: international and /or national standards, etc. (e.g., Is FDA approval required?)*
        i. There are several FDA regulations on temperature sensing devices, although most apply to electronic devices. The team's thermochromic imaging surface will not include any electronic components that will need to comply with FDA guidelines, but if the project progresses to the point of human subject testing and involvement, FDA guidelines and regulations will need to be followed [5]
    b. ***Customer****: specific information on customer likes, dislikes, preferences, and prejudices should be understood and written down.*
        i. There are no specific requests from customers since there is no one customer. The client wants the device to be applicable to all customers/patients in India.
    c. ***Patient-related concerns****: If appropriate, consider issues which may be specific to patients or research subjects, such as: Will the device need to be sterilized between uses?; Is there any storage of patient data which must be safeguarded for confidentiality?*
        i. The reusable thermochromic imaging surface will need to be easily usable by the patient.
        ii. The imaging surface must be big enough to accommodate a variety of patients' feet.
        iii. Images of the patient's thermal maps that are uploaded to the app will not include any personal data, so no personal or sensitive data will be collected or saved.
    d. ***Competition****: Are there similar items which exist (perform comprehensive literature search and patents search)?*
        i. There is a brand called siren that produces socks that are worn daily and monitors the temperature of the patient's foot. These socks have sensors that constantly measure temperatures of key points on the foot and send the information to the siren app. The doctor then can notify the patient when there is any sign of inflammation or something concerning. The socks then are replaced every six months to avoid misleading data from wear and tear [6].

References

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[2]Hallcrest, "Thermosmart thermocolor sheets", Lcrhallcrest.com, 2020. [Online]. Available: https://www.lcrhallcrest.com/wp-content/uploads/2019/12/Labels-RE-Thermosmart-Stresssheet-SalesLit.pdf. [Accessed: 07- Oct- 2020].

[3]C. Woodford, "Thermochromic color-changing materials", explainthatstuff.com, 2020. [Online]. Available: https://www.explainthatstuff.com/thermochromic-materials.html. [Accessed: 18- Sep- 2020].

[4] [7]Educational Innovations, "Liquid Crystal Sheets (12x12 inch)", Teacher Source - Educational Innovations inc., 2020. [Online]. Available: https://www.teachersource.com/product/liquid-crystal-sheets-12x12-inch/chemistry. [Accessed: 07- Oct- 2020].

[5] FDA, "Temperature Sensors in the Regulated Industry", U.S. Food and Drug Administration, 2020. [Online]. Available: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-technical-guides/temperature-sensors-regulated-industry. [Accessed: 07- Oct- 2020].

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