Product Design Specifications

Title: Development of a diagnostic device and mobile app for the early detection of ulcer formation in the diabetic foot

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Function: Our client has provided us with an IR camera (FLIR $315) that she previously used to take images of 250+ feet in India, all somewhere on the spectrum towards ulceration. We are tasked with developing an artificial intelligence program based on these images that has the ability to discern patients at low high risk for ulceration from those at high risk. A mobile application should also be developed for easy patient access. Additionally, a camera-mounting prototype needs to be designed and fabricated to allow for consistent measurement of patients' feet.

Client requirements:

- Mobile application to score thermal images for likelihood of ulcer formation
- Application should automate image analysis
- Apparatus to standardize thermal imaging
- Low-cost use in rural Indian hospital (<$150)
- Utilize variables such as typical ulcer location, typical ulcer size, temperature location etc to improve accuracy
- Crowded hospitals require portability of the imaging device (easily carried with 2 hands)

Design requirements:

- Imaging device: ~$150 to be implemented in a rural hospital where cost is a main concern. May be achieved with validation of low-cost thermal camera in comparison to $315 gold standard (FLIR).
- The device needs to be able to travel overseas to India.
- Device needs prioritize sensitivity over specificity in detecting patients early-stage diabetic foot ulcers.

1. Physical and Operational Characteristics

a. Performance requirements: As diabetes is an epidemic in India, this device will be used very frequently throughout a typical day, therefore it should have a battery life that lasts at least one day. It will be exposed to hot temperatures, which it needs to be able to withstand while still providing accurate measurements and data outputs.

b. Safety: Patients falling may be a concern if a patient is made to stand on top of an imaging device. Many patients who are at greatest risk for ulceration are elderly. Thus the device should allow for pictures to easily be taken either from a sitting (wheelchair) or lying down position (hospital bed). No safety concerns aside from typical electrical hazards from IR camera and telephone. Radiation is at a low enough wavelength (~750-1000 nm) to not be of concern.

c. Accuracy and Reliability: Our analysis of thermal foot images should precisely detect temperature differences of 2.2 degrees Celsius. It is not necessary for the temperature readings to be particularly accurate, but they must be precise. A component of our project is to reduce cost and experiment with lower quality thermal cameras that will test the necessary bounds of precision for our device to accurately identify ulcers. Therefore, the required temperature precision is to be determined.

d. Life in Service: The hospital device will be used 30+ times per day and needs to last several months to years. The physical components of our project include a portable phone rig, phone, and thermal camera attachment. Each of these components need to last at least a day without charge and withstand regular to heavy use. Longer battery life would be desired, but a single day allows for time to charge overnight.

e. Shelf Life: Life-time warranty. The IR-camera is equipped with a rechargeable battery giving it longevity in terms of shelf-life.

f. Operating Environment: The device will be used primarily in the hospital where temperature and humidity are relatively constant (~20 C, ~50%). There may be times during its transportation in which the device will be exposed to a hot and dry environment with possible accumulation of dust as well as significant noise levels. Temperature ranges in India regularly are between 25-50 C, or 77-122 F.

g. Ergonomics: The device should include a position for the patients' feet to stabilize for the imaging device while the patient is either seated or lying down in a hospital bed. Creating a consistent background (via a wet cloth or other material) needs to be inherently part of the design.

h. Size: The device needs to be portable to move quickly around the hospital. Small enough to be carried by hand, possibly foldable or retractable, and able to either be shipped in a suitcase or built upon arrival. Currently, the client uses box holder which has 2 degrees of freedom for taking photos. Sizing this down to make it more portable would be of interest.

i. Weight: The end goal is for patients to be able to self-monitor their disease from home. For this reason, nothing should be too heavy or bulky, as patients have varying health and physical strength, and it is necessary to be inclusive to all patients regardless of this. We will limit the weight to 35 lbs.

j. Materials: In the design of the "photo booth" device, there should be no heat-emitting materials as this would significantly affect the images being taken. All materials should be durable to aid in expanding the lifetime of the product. No particular materials have been determined or ruled out.

k. Aesthetics, Appearance, and Finish: As this is an application to be taken to a third world country in which healthcare does not receive the funding that it does in the United States, we are solely concerned about functionality, and not about aesthetics. The mobile application should be user friendly.

2. Production Characteristics

a. Quantity: We have been asked for just one device, although producing numerous products after the original has been tested may be of interest.

b. Target Product Cost: Our team would like to keep total product cost under $150 for use in hospital, and eventually reducing the cost to under $50 for in-home use. This figure does not include the thermal camera that has been provided to us. Most of our team's expenditures will be materials costs for the fabrication of the box.

3. Miscellaneous

a. Standards and Specifications: Our client has IRB permission through the Christian Medical Hospital in India that was used to obtain preliminary study images. Currently, in collaboration with our client we are seeking IRB approval through the Veterans Administration hospital in Madison WI, to image diabetic feet locally.

b. Customer: The main priority is to minimize patients time in-clinic, as their livelihood depends on daily income and missing even a day of work produces a great burden for the patients. Shoe or sock related devices are viewed as ineffective in India as most of the population does not wear shoes.

c. Patient-related concerns: Patient data will be stored on the mobile device for use in clinical trials. The patients information is not linked to the images being taken, and the patients will not be identifiable from the images alone. Additionally, client has gotten IRB approval to collect images from patients.

d. Competition: There are many products that are nearly identical to the product we have been asked to develop. The main improvement our client is hoping for us to achieve is the implementation of a clinical trial to test the validity and viability of the AI algorithm and product.