

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

The Foot-O Booth

Team Members: Jarett Jones, Thor Larson, Jan Wodnicki, Kelson Rauser, Carson Gehl

Function: Our client has provided us with an IR camera that she has used to take images of over 250 diabetic feet. We are tasked with developing an artificial intelligence program that has the ability to detect patients that are at low risk for ulcerations from those that are at a high risk. A mobile application should also be developed for easy patient access. Additionally, a prototype needs to be designed and fabricated to mount the camera and provide for an area of consistent temperature measurement of the patient's feet.

Client requirements:

- Mobile application to accurately detect formation of ulcers
- Application should automate image analysis
- Additional testing apparatus to standardize thermal imaging
- Low budget devices for hospital and at-home use
- Utilize variables such as typical ulcer location, typical ulcer size, etc to improve accuracy
- Crowded hospitals require the product to be easily maneuverable and small in size

Design requirements:

- While the client has not specified a budget, it should be low cost as it is being implemented in a third world country where money is limited.
- The device needs to be able to travel overseas to India.
- Device needs to be accurate for early-stage detection of 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 longer battery life as well as durability. 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: No safety concerns aside from typical electrical hazards from IR camera and telephone. Radiation is at a low enough wavelength to not be of concern.

c. Accuracy and Reliability: Our analysis of thermal foot images should precisely detect temperature differences of 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 likely be operating in a hot and dry environment with possible accumulation from dust as well as significant noise levels.

g. Ergonomics: The device should include a position for the patients' feet to ergonomically fit into in order to correctly position the feet for image acquisition.

h. Size: The device needs to be relatively portable to move quickly around the hospital. Small enough to be carried by hand, possibly foldable or retractable. Currently, the client uses a tripod for the camera; 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 \$100. This figure does not include the thermal camera that has provided to us. Most of our team's expenditures will be materials costs for the fabrication of the "Foot-O-Booth".

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 patients' main priority is to minimize time away from work, as their livelihood depends on daily income. Shoe or sock related devices are viewed as unnecessary in India.

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 product.