Global Health: Prevention of Diabetic Foot Ulceration and Amputation

BME 200/300

October 9th, 2019

Client: Ms. Kayla Huemer

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Abstract

Diabetic patients often suffer from ulceration in their feet which can result in amputation of the foot. In order to detect ulceration, others have employed a thermal imaging system paired with image processing software in order to detect statistically significant changes in temperature due to ulcer development. The team has been tasked with designing an imaging device along with image processing software and an AI algorithm for early-stage detection of ulceration. The device proposed is an insulated box that is foldable in order to increase portability. Image processing software will comprise of a histogram for segmentation; the client has already performed calculations that will be implemented into the AI software to place individuals in a class based on risk level. Future work will consist of an Android app that employs the above software.

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I. Introduction

Motivation

Diabetes is a major epidemic in India; it is often referred to as the diabetic capital of the world, as over 60 million in the population suffer from the disease [6]. As many lack access to proper treatment, there are additional complications that arise that many do not typically associate with diabetes. Many who suffer from diabetes develop foot ulcers, which may go on to become infected, and ultimately end in the amputation of the foot. For this reason, it is desirable to create a device for early-stage detection. With the ability to detect the beginning of ulceration before the ulcer forms, physicians would better be able to advise and treat patients.

Competing Designs

Others have done similar work in this area. Thermal imaging devices as well as image processing programs have been fabricated and shown to have success [3]. Some have also performed case studies that analyze the success of their devices [2]. However, there has been a lack of data supporting competing designs coming from clinical trials. As our client has approval to continue clinical trials in India, as well as prospects for running clinical trials at the Veterans Affairs Hospital in Madison, this sets us apart from other similar designs. Others have also not gone so far to produce an AI algorithm for efficient analysis of images. There is also much greater funding in competing projects, and so expensive and high-tech systems have been designed; the team seeks to maximize cost efficiency

American biotechnology companies have developed products targeting the American diabetic population. One example is continuous temperature monitoring socks, which alert patients when certain areas of the feet reach temperature thresholds [5]. These products are not accessible to our target demographic due to cost and feasibility issues.

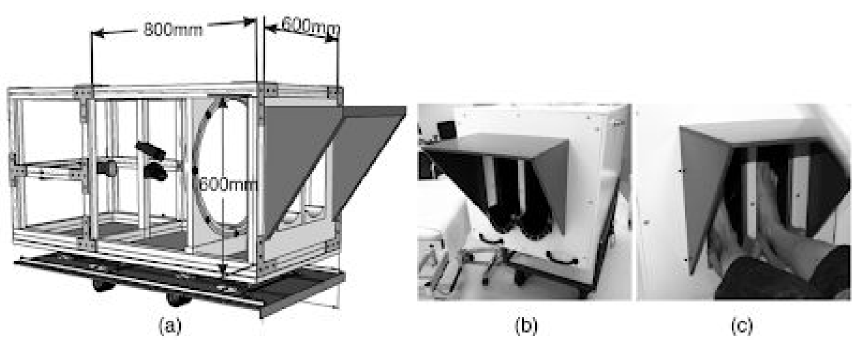


Figure 1. *competing design from [Liu, Netten]*

Problem Statement

Thermal imaging has proven to be an effective technique in early-stage ulcer detection in diabetic patients. However, a gap exists in the acquisition and analysis of thermal images by computation in order to streamline the process of ulcer detection. The team has been tasked with creating a thermal image acquisition device, as well as an AI algorithm that will be able to analyze thermal images and separate them into categories based on levels of risk for ulceration.

II. Background

Biology and Physiology

Diabetes mellitus is a disease that affects the regulation of glucose in the blood. It is typically treated by administering synthesized insulin, a protein used in the regulation of blood-glucose levels. A common side effect that many diabetics suffer from is peripheral neuropathy, in which the individual loses sensation in their feet. This has detrimental effects, as the patient is unable to adjust their stride to distribute mechanical pressures on their foot. Repeated shear forces acting on tissue over time can cause inflammation and tissue damage, regardless of the magnitude of the force being minimal [1]. Without the ability to sense the pain associated with inflammation and tissue damage, a diabetic individual may then experience the formation of an ulcer without their noticing it. Left untreated, ulcers can easily become infected, and often require the amputation of a part of the limb. As inflammation is associated with increased blood flow, temperature measurement has proven to be an accurate marker of ulcer development. It has been found that an increase of 2.2 ℃ is associated with the beginning of ulceration [4]. This threshold provides a basepoint for analysis of risk through thermal imaging.

Client Information

Ms. Kayla Huemer is a recent graduate of the Biomedical Engineering Department at UW - Madison. After graduation she spent time in India on a Fulbright fellowship working on early-stage ulcer detection. She was able to collect about 250 images with the device that she created, and is now asking us to help with the continuation of the given project.

III. Preliminary Designs

Thermal Image Acquisition System

The thermal image acquisition system designs should include a mechanism to capture thermal data from the bottom of a patient's feet in addition to analyzing and running the data through predictive algorithms. The designs should also provide some way to gathering repetitive and consistent measurements of the thermal data as well as collecting the data in a way that is comfortable for the patient. All designs should be easy to operate and ergonomic for an Indian hospital setting and should be realistic and able to be fabricated.

Design 1 – Thermochromic Material System

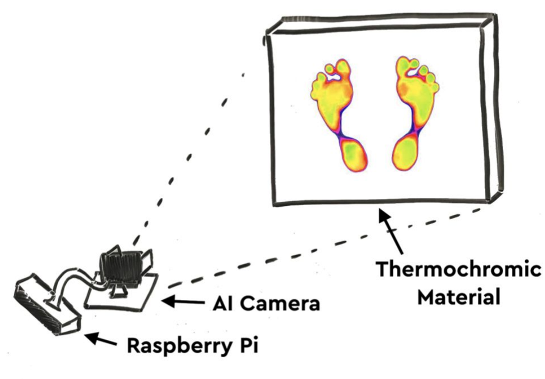


Figure 2. *Design 1, depicting thermochromic mat and AI camera + raspberry pi*

This design involves two main systems: a mat and a data analysis acquisition system. The mat is composed of thermochromic–liquid crystal layer that changes color in response to changes in temperature. The patient is meant to step on the mat for a period of time, leaving behind a color map that corresponds to the thermal distribution of their foot. The second part of the system is an AI camera connected to a processing system (Fig. 2 shows a Raspberry Pi), that will ultimately analyze the color map and translate it into data to be interpreted by diabetic ulcer predictive algorithms.

Design 2 – Heat Strip Box

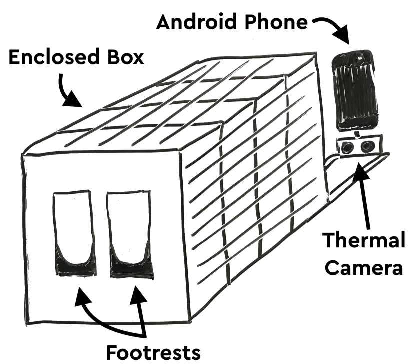


Figure 3. *Sketch of Heat Strip Box*

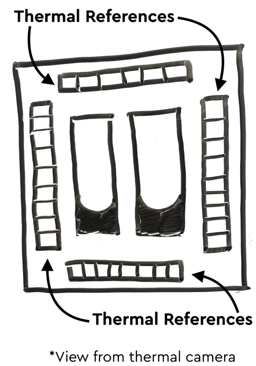


Figure 4. *Camera view showing the thermal references*

This design is broken up into 3 main parts: a foot positioning system, a thermal calibration mechanism, and a thermal camera with output display. The foot positioning system, shown in Figure 3, involves 2 foot rests enclosed in a long box providing minimal light entry. The patient is meant to place both feet on the rests with the openings able to fit a multitude of patient feet sizes. The thermal calibration mechanism, shown in Figure 4, and seen from the viewpoint of the camera inside the enclosed box, uses heated strips in addition to direct temperature measuring sensors that record the real temperature at the moment a thermal image is taken, in order to calibrate the color of the thermal image to the real temperature in the box. The last part is the thermal camera which is connected to a mobile device. The camera/mobile system is placed on a sliding track, connected to the enclosed box, that allows for a modular distance to be set between the feet and the camera.

Design 3 – Insulated Folding Studio

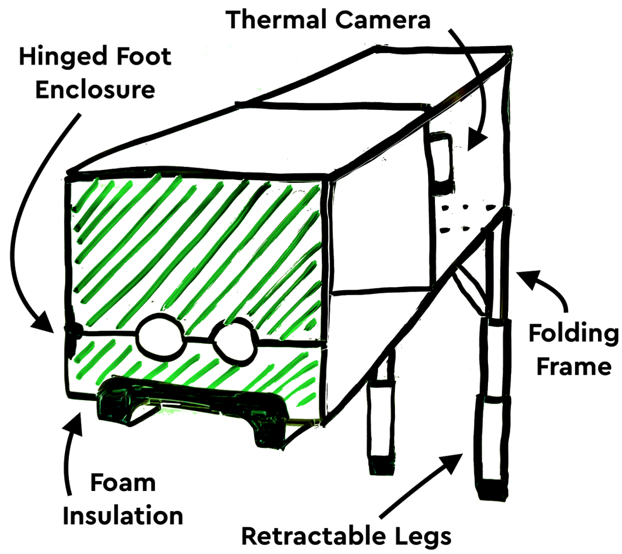
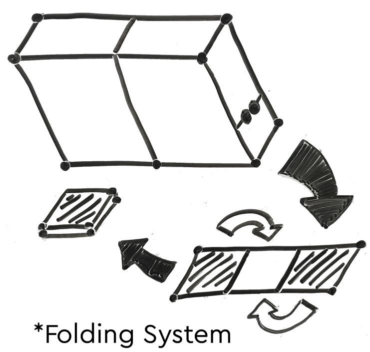


Figure 5. *Sketch of Insulated Folding Studio*



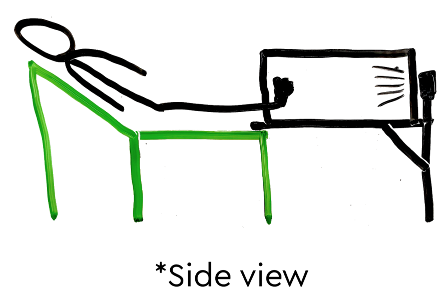


Figure 6. *Depicts the proposed folding process* ***Figure 7.*** *Side view of the design folding process*

The last design has similar main parts to design 2: a foot positioning system, a thermal calibration mechanism, and a thermal camera with an output display. The main difference is in the first two parts, with the thermal camera being similar to design 2. The foot positioning system is composed of an open box with structural rods. The foot rests functions similar to Design 2 with 2 holes, modular to fit multiple patient sizes. A cloth would be draped over the open box to minimize the amount of light entering the box. When finished the box would be able to fold into a smaller system, depicted in Figure 6. The thermal calibration system is a 3 layer cover, composed of 2 layers of foam with air in between, which will provide a consistent temperature for the background of the thermal images. Figure 7 shows how the patient will interact with the system, which involves laying on a bed and placing their feet in the foot rests.

Software

Language and Platform Decision

The software that will interface with and power the thermal acquisition system will require multiple parts: an image processing algorithm, machine learning/pattern recognition/artificial intelligent predictive algorithm, and finally a mobile display interface.

The software platforms that will be used to develop the different parts are limited to the FLIR Camera software development kit (SDK) which is inherent to the thermal camera that the team currently has and what the client already captured images with. The FLIR software development kit (SDK) is written to be used with the mobile Android Java environment, which limits what languages can be used in the software design. While it is possible to integrate other image processing/machine learning platforms, such as Python, MATLAB, or Tensorflow, into the mobile Java environment, this would require multiple 3rd party extensions lowering the feasibility of having a substantial software that integrates into the mobile form in the time frame provided. As a result, the software chosen as the starting point for development is the mobile Android Java environment for the display interface, and OpenCV; a real time computer vision platform that can be written in Java and is easily integrated into the mobile Android Java environment in addition to interfacing easily with the FLIR SDK. A proof of concept preliminary Android application was created to validate that the FLIR SDK could be used in the mobile Android Java environment, the MainActivity.java file is provided in Appendix A. OpenCV can be used for image processing and implementation of machine learning algorithms needed at this stage of development and provides a great starting point for development.

AI/Machine Learning

Due to being early in the process, many of the AI/Machine Learning decisions with regards to what algorithms will be used and what platform they will be developed on will be made as we develop as deciding on one pathway at this stage in development is not beneficial. The team expects to try out many different pathways including, but not limited to: supervised and unsupervised learning, K-means clustering, and support vector machines. If time allows, the team hopes to test a multitude of these methods and taylor the methods under the data amount and time constraints that we have.

IV. Preliminary Design Evaluation

Design Matrix

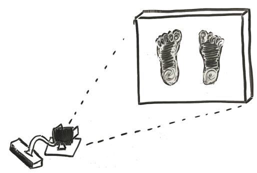
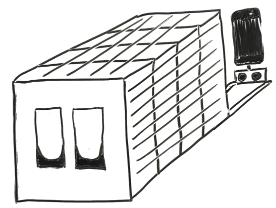
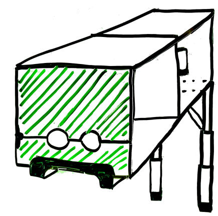
Design Criteria	Weight	Thermochromic Material 		Heat Strip Box 		Insulated Folding Studio 	
Ease of Fabrication	(10)	5/5	**10**	3/5	6	2/5	4
Cost	(30)	2/5	12	3/5	18	4/5	**24**
Portability	(20)	4/5	16	2/5	8	5/5	**20**
Consistency	(30)	1/5	6	5/5	**30**	4/5	24
Longevity	(10)	2/5	4	5/5	**10**	4/5	8
Totals	**(100)**	48		72		**80**	

Figure 5. *Design Matrix Evaluation of methods to standardize thermal imaging of diabetic foot. Each design was graded in each category on a scale of 1 (worst) to 5 (best), and was evaluated with weighted categories. Total points displayed at bottom out of 100.*

Ease of Fabrication

Ease of Fabrication is defined as how easily the design can be physically constructed using accessible fabrication machinery and materials. This category received the lowest weight of 10. According to our product design specification we foresee all aspects of our design having a long shelf life. For this reason, frequent refabrication should not be necessary and thus the difficulty associated with fabrication will be of little concern.

Cost

Cost is defined as how much it will cost us to purchase the necessary camera equipment as well as materials for design fabrication. Cost received the highest weight as its minimization serves as a large aspect of the project motivation and was emphasized by our client in the product design specifications. Many preliminary designs for early detection of diabetic foot ulceration exist however one that can be cost effectively implemented into an Indian hospital is of utmost importance.

Portability

Portability is defined as how easily the design will be able to move from one location to another. This category received the second highest weight, as the device will be transported overseas as well as frequently within the hospital. Components of portability include packed size, weight, and the amount of time it takes to collapse and construct. Other designs that have been constructed to detect diabetic foot ulceration have been designed to be stationary. However, our aim is to create a device that can fit in a suitcase.

Consistency

Consistency is defined as how effectively the design can standardize the thermal image of the foot. Consistency received the highest weight along with cost. Image consistency will allow us to create a better artificial intelligence system for early detection of ulcers. Ulcer detection occurs through observation of only 2.2 degree celsius difference; therefore, the image quality is crucial.

Longevity

Longevity is defined as the length of time the design is built to endure. We gave this category the lowest score, as the device will be used indoors, constructed with durable materials, and won’t need to be replaced very often. We expect this device to be used for several months to years, and expect longevity will not be a primary concern.

Proposed Final Design

Thermal Image Acquisition System

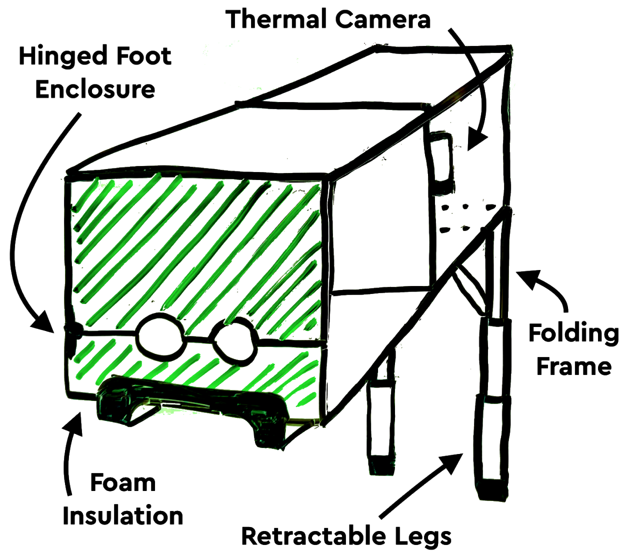
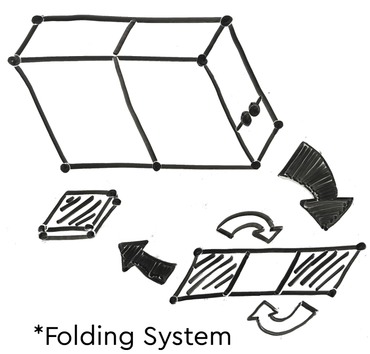


Figure 8. *Sketch of Insulated Folding Studio*



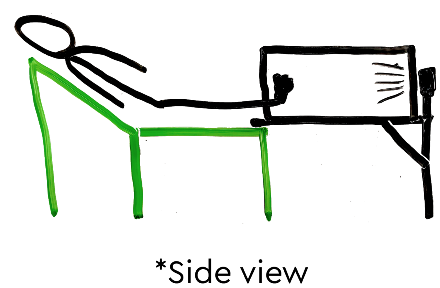


Figure 9. *Depicts the proposed folding process*

Figure 10. *Side view of the design folding process*

The proposed final design is Design 3: the Insulated Folding Studio with retractable and folding components to aid in its portability overseas as well as within a busy hospital environment. The end of the studio housing the feet will be constructed from a pair of insulating foam boards enclosing a layer of air. This will reduce any temperature bleed or distortion caused by other heat-emitting surfaces. Preventing heat from the rest of the patient's body to contaminate any images taken.

Software
In the initial stage of development, the mobile display will be created using the Android Studio environment written in Java with the image processing and AI algorithms being written in Java through the OpenCV platform.

V. Fabrication/Development Process

Materials

As the support stakes for the device will be 3D printed, these will be made of plastic. The camera being used is a FLIR camera attached to an android phone, both of which have been provided by the client. The rest of the box will be made of wood or a thin sheet metal so that it is lightweight and portable. Foot inserts will also be plastic as they will be 3D printed; they will have foam attached on the inside for comfort. Foam will also be used for insulating the feet from outside heat sources that would increase the difficulty and accuracy of image processing.

Methods

We will use Solidworks to model the initial prototypes; SolidWorks drawings can be directly transferred into 3D printed materials in the case of the support stakes and foot inserts. The support stakes will have threads in them in order to screw in to the mainframe of the device. This will allow the device to be taken apart for easy transportation. The mainframe of the device will be cut down to size and shaped in the ECB workshop. Foam can be cut to length with a razor blade.

Software will be developed over the course of the semester by rapid prototyping of new features. The team expects to try multiple different machine learning solutions within the feasibility of the semester time frame.

IX. References

[1] BRAND PW (1989). Repetitive stress in the development of diabetic foot ulcers. The diabetic foot./4th edition./edited by ME Levin, LW O'Neal p83-90.

[2] C. Liu, F. V. D. Heijden, M. E. Klein, J. G. V. Baal, S. A. Bus, and J. J. V. Netten, "Infrared dermal thermography on diabetic feet soles to predict ulcerations: a case study," *Advanced Biomedical and Clinical Diagnostic Systems XI*, 2013.

[3] C. Liu, J. J. V. Netten, J. G. V. Baal, S. A. Bus, and F. V. D. Heijden, "Automatic detection of diabetic foot complications with infrared thermography by asymmetric analysis," *Journal of Biomedical Optics*, vol. 20, no. 2, p. 026003, Nov. 2015.

[4] L. Fraiwan, M. Alkhodari, J. Ninan, B. Mustafa, A. Saleh, and M. Ghazal, "Diabetic foot ulcer mobile detection system using smart phone thermal camera: a feasibility study," *BioMedical Engineering OnLine*, vol. 16, no. 1, Mar. 2017.

[5] Reyzelman AM, Koelewyn K, Murphy M, Shen X, Yu E, Pillai R, Fu J, Scholten HJ, Ma R "Continuous Temperature-Monitoring Socks for Home Use in Patients With Diabetes: Observational Study", 2018.

[6] S. Kaveeshwar, "The current state of diabetes mellitus in India," *Australasian Medical Journal*, vol. 7, no. 1, pp. 45–48, 2014.

X. Appendices

A. Product Design Specifications

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

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

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) and in-home use (<$5)
- 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 likely be operating in 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 $5 for in-home use. 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 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 IAI algorithm and product.

B. Preliminary DFUDetect Mobile Application

MainActivity.java file that integrates the FLIR SDK into the mobile Android Java environment, used as a proof of concept of connecting the FLIR SDK to a mobile application. Application is very preliminary but just allows for connection of the FLIR camera which is recognized by the application and begins outputting frames from the camera in real time. Will build upon this app but provided a great starting point at this stage in the development process.

```java
package com.example.dfudetect;

import androidx.appcompat.app.AppCompatActivity;

import android.graphics.Bitmap;
import android.os.Bundle;
import android.widget.ImageView;
import android.widget.TextView;

import com.flir.flironesdk.*;

import java.nio.ByteBuffer;
import java.util.EnumSet;

public class MainActivity extends AppCompatActivity implements Device.Delegate, FrameProcessor.Delegate {


    private FrameProcessor frameProcessor;

    @Override
    protected void onCreate(Bundle savedInstanceState) {

        super.onCreate(savedInstanceState);

        setContentView(R.layout.activity_main);
        frameProcessor = new FrameProcessor(this, this,
                EnumSet.of(RenderedImage.ImageType.BlendedMSXRGBA8888Image));
    }

    Device flirDevice;

    @Override
    protected void onResume() {
        super.onResume();
        Device.startDiscovery(this, this);
    }
```

```
    @Override
    protected void onPause() {
        super.onPause();
        Device.stopDiscovery();
    }

    @Override
    public void onTuningStateChanged(Device.TuningState tuningState) {}

    @Override
    public void onAutomaticTuningChanged(boolean b) { }

    @Override
    public void onDeviceConnected(Device device) {
        TextView textView = findViewById(R.id.textView2);
        textView.setText("Connected");

        flirDevice = device;

        device.startFrameStream(new Device.StreamDelegate() {
            @Override
            public void onFrameReceived(Frame frame) {
                frameProcessor.processFrame(frame);
                System.out.println("processing");
            }
        });
    }

    @Override
    public void onDeviceDisconnected(Device device) {

    }

    @Override
    public void onFrameProcessed(RenderedImage renderedImage) {
        final Bitmap imageBitmap = Bitmap.createBitmap(renderedImage.width(),
                renderedImage.height(), Bitmap.Config.ARGB_8888);
        imageBitmap.copyPixelsFromBuffer(ByteBuffer.wrap(renderedImage.pixelData()));

        final ImageView imageView = findViewById(R.id.imageView2);
        runOnUiThread(new Runnable() {
            @Override
            public void run() {
                imageView.setImageBitmap(imageBitmap);
            }
        });
    }
}
```