

Global Health: Thermochromic Imaging Surface For

Prevention of Diabetic Foot Ulceration and Amputation

BME 200/300 - Final Report, December 9th, 2020

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Abstract

Diabetes is a growing problem in India that can often lead to the formation of ulcers and even amputation of the feet. At-home monitoring of the temperature of the feet has been shown to effectively decrease the risk of ulceration for patients who consistently comply with the care regime specified by their health care provider. There are several devices in the United States designed for at-home monitoring of foot temperature through the use of special socks or shoes, but these devices are not as applicable to patients in India who often do not wear socks or close toed shoes. In order to create a solution to affordable at-home care for diabetic patients in India, a thermochromic liquid crystal (TLC) imaging surface was created and will be combined with a machine learning algorithm for analysis of the temperature data. Patients can step on the surface to generate a thermal image of their feet. The colors on the thermal map correspond to different temperatures, and can be analyzed directly by observing any major color differences between the right and left feet, or they can be photographed using a smartphone and uploaded to an app-based software to a machine learning algorithm for image processing. The software will output whether or not a patient is at risk of developing an ulcer based on any differences in temperature between symmetric parts of the feet. Although not enough data has been collected to adequately program a machine learning algorithm, a thermochromic imaging prototype was created and can be used to assess the temperature of the feet. Providing a simple and affordable device to measure foot temperature can allow diabetic patients to take control of their own health and make lifestyle changes when necessary.

Table of Contents

| Abstract | 1 |
|----------------------------------------------------------|----|
| Table of Contents | 2 |
| Introduction | 3 |
| Motivation | 3 |
| Existing Devices and Current Methods | 3 |
| Problem Statement | 4 |
| Background | 4 |
| Relevant Biology and Physiology | 4 |
| Development and Process Flow | 7 |
| About the Client | 9 |
| Design Specifications | 9 |
| Preliminary Designs | 10 |
| Design 1 - Insulated Thermochromic Color Changing Sheets | 10 |
| Design 2 - Mix of Thermochromic Color Changing Powders | 11 |
| Design 3 - IR Thermal Camera Smartphone Attachment | 12 |
| Preliminary Design Evaluation | 13 |
| Design Matrix | 13 |
| Summary of Design Matrix | 14 |
| Proposed Final Design | 15 |
| Development of Machine Learning Algorithm | 16 |
| Materials and Tools | 16 |
| Methods | 16 |
| Final Prototype | 17 |
| Testing | 17 |
| Fabrication of Thermochromic Imaging Surface | 17 |
| Materials | 17 |
| Methods | 19 |
| Final Prototype | 20 |
| Testing | 21 |
| Results | 23 |
| Discussion | 24 |
| Conclusion | 25 |

| References | 26 |
|------------------|----|
| Appendix | 29 |
| Appendix A - PDS | 29 |

Introduction

Motivation

Diabetes has recently become a prevalent problem in India. In the United States, 13.3% of the population has diabetes while India only 8.9%. However, due to its large population, this is still 77 million people compared to 30 million in the United States [1]. This increase is in part due to the number of people that lack access to healthcare. In fact, 50-90% of diabetic patients in rural areas are undiagnosed [2]. If left untreated, diabetes can lead to ulcers that worsen to a point where it is too late to save the foot when medical treatment is finally received. Several devices, such as different types of socks and shoes, exist in the United States in order to provide an accessible at-home treatment plan for diabetic patients, however, since many people in rural areas of India do not wear socks or closed toed shoes, these solutions are not as applicable. Many existing devices are also expensive, and therefore not accessible to low-income individuals. Thus, an inexpensive, at-home device that can effectively predict the onset of a foot ulcer before it is too late is necessary for the care and treatment of diabetic patients in India.

The need for such a device is also motivated by client Kayla Huemer, who originally started this project in 2017 while working directly with diabetic patients. During her time in India, she collected hundreds of thermal images of patients' feet in order to study the relationship between foot temperature and ulceration. After finding that many patients sought out treatment only after development of an ulcer, she was motivated to find a low-cost solution by taking into account the temperature of the foot in order to prevent ulceration in diabetic patients in India in order to prevent infection and amputation.

Existing Devices and Current Methods

Currently, there is a brand called Siren that produces socks that monitor the temperature of the patient's foot when worn daily [3]. These socks contain sensors that constantly measure temperatures of key points on the foot and send the information to the Siren app for the patient and even their doctor to see. A patient's healthcare provider then can notify the patient when there is any sign of inflammation or concerning changes in the state of the feet. The socks then are replaced every six months to avoid misleading data from wear and tear [3]. Socks like these are an example of an existing device that monitors the temperature of the foot in order to prevent ulceration. However, as the client, Kayla, observed during her time in India, many people do not wear socks on a daily basis. Thus, a device like this would clash with the daily life of many diabetic patients there, making enforceability difficult. These socks also come with a monthly cost rather than a one-time payment, making them a more expensive

option. Similarly, the Orpyx SI Insole, like Siren socks, continuously monitors foot temperature and reports findings to a smartphone app [4]. Adherence to a product like this has been found to be difficult in the United States, so a shoe insert would be even less effective for diabetic patients in rural India.

There are also several different brands of diabetic shoes that exist in order to take pressure off of the ball and heel of the foot, the areas that typically receive the most pressure and friction, and thus develop calluses and ulcers more often [5]. Often made of protective, nonbinding and stretchable material with enough depth to ensure a loose fit that eases pressure points, diabetic shoes and insoles have become a common sight in stores, and can even be custom ordered [6]. These shoes are particularly common in the United States, with brands like Dr. Comfort [7] selling a variety of padded shoes aimed at shifting the weight and pressure while walking. However, similarly to the Siren socks, these shoes are not the best option for patients who are not used to wearing close-toed shoes, and they can be very costly.

Another method for at-home temperature monitoring involves sending patients home with a thermometer that they can use to directly take the temperature of their feet, without having to wear an additional item of clothing [8]. This method provides quicker and more direct results without having to rely on a smartphone app for feedback. Solutions like this are more appropriate for diabetic patients in India, who may not want to change their daily routine by introducing new socks or shoes to their wardrobe, but this method is also much more expensive. Thus, an inexpensive way for diabetic patients to monitor the temperature of their feet is necessary in order to prevent ulceration and even amputation.

Problem Statement

Diabetic patients often lose feeling in their extremities and cannot feel an ulcer which can then lead to amputation. To fight this lack of sensation, temperature monitoring is used to predict and prevent ulcers, however this is difficult in India. Many people in India don't have access to medical treatment and often don't wear socks and shoes which are the common products for diabetics. The goal of this product is to create an easy and affordable way for patients to monitor the state of their feet. The patients should be able to take the device home and effortlessly find out if they have an ulcer developing.

Background

Relevant Biology and Physiology

Type II diabetes affects the body's ability to use insulin to regulate glucose levels. This can either be due to the body not producing sufficient amounts of insulin or resisting the efforts of insulin to maintain a healthy blood sugar level [9]. Since diabetes affects the regulation of glucose in the blood, diabetic patients develop hyperglycemia, or high blood sugar [10]. Normally, sugar obtained from food is sent into the blood through the circulatory system. In response to the spike in blood sugar that follows eating, beta cells in the pancreas secrete insulin, a hormone that elicits the fat cells in the body to absorb the glucose and subsequently lower blood sugar levels [11]. This is a regulatory process that takes place whenever blood sugar levels increase, but when diabetes affects insulin function, this natural process cannot take place, leading to hyperglycemia.



Figure 1. Insulin and glucagon regulation of blood sugar. This figure shows how insulin is released in the presence of high blood sugar to return the blood to normal glucose levels [11].

High blood sugar can damage the walls of blood vessels, particularly smaller vessels in the extremities [12]. The damage of blood vessels from hyperglycemia, combined with the harmful effects of other factors such as hypertension, obesity, and even smoking, often leads diabetic patients to develop neuropathy, a condition where sensation in the hands and feet is lost as nerve cells are destroyed [13]. When the blood vessels connected to nerve cells in the peripheral nervous system are damaged, nerve terminals are no longer adequately protected by the perineurium outer layer and can be exposed to extracellular environments that cause injury or even death of the nerve cell, leading to neuropathy (see figure 2 below) [14].



Figure 2. Diagram of nerve fiber and the blood vessels that penetrate the perineurium to supply oxygen to nerve cells. These microvessels are easily damaged, which can in turn damage the nerve endings [14].

When diabetes progresses and is not properly managed, the layers of skin on the bottom of the foot can break down to form a foot ulcer. Diabetic foot ulcers can cause the skin to turn black and leak discharge, and when severe they can expose muscles and tendons [15]. Ulcers are also prone to infection since the open wound is difficult to keep clean and free of bacteria and other substances. Infected ulcers are more difficult to treat and often lead to amputation [15]. Neuropathy can cause ulcers to worsen. Lack of sensation prevents diabetic patients from feeling pain in their feet, often leading them to put more pressure on their damaged feet than they would if they had sensation [16]. Minimal wounds can easily turn into ulcers if a patient uses their feet too much, and an improper adherence to treatment strategies often results in amputation. For all diabetic patients, the lifetime risk of developing ulceration is 25%, the majority of which will lead to amputation within four years of the initial diagnosis. [16]

Several diabetic patients will begin to suffer severe pain despite the absence of any high stress impact after traversing long distances on rough ground. Travelling long distances, a consequence of restrained access to proper footwear amplified by improper modes of transportation, is endured most heavily by rural or marginalized stratas in India who are often geographically dislocated because of economic, environmental, or migrational push or pull factors. [17] Severe pain while walking is due to two distinct types of receptors, specifically nerve endings found in the skin, that are involved in the heightened pain that diabetic patients are subjected to throughout the course of the disease. The receptors found in healthy tissue that respond to relatively high levels of mechanical stress are referred to as High Threshold Mechano-Receptors (HTMs), or receptors that respond to high pressure impinging upon otherwise undamaged skin [18].

Conversely, in the situation that the patient has already damaged the foot, Poly-Modal Nociceptors (PMNs) begin responding to relatively low pressure stimuli due to chemical products of inflammation [18]. This means that the patient experiences extreme pain due to PMNs in response to very

minimal stimulation. A diabetic with a high risk for ulceration begins to feel severe pain despite the absence of high stress impacts, activating the response from PMNs caused by the pain from constant low stress. Tenderness from a consistent hard beating results in much greater pain from a much lower threshold of pressure, and after a certain duration of normal tissue responses to HTMs that report injury, inflammation induces the response of PMNs [18].

The imminent danger that the aforementioned receptors pose to diabetic patients in India is that the foot that is neuropathic or responsive to PMNs often bears more weight than the foot that is uninjured and contains healthy tissue that responds to HTMs, further increasing the patient's risk of ulceration [18]. This creates an indubitable need for a low cost and simplistic way to extrapolate a patient's risk of ulceration with careful and consistent at home monitoring.

A modality such as cost-effective home thermometry provides an option to diabetic patients for early monitoring of signs of ulceration, and serves as an preventative warning system for the development of diabetic foot wounds. In a pilot study published by the American Diabetes association, it was found that patients who actively practiced at home temperature monitoring of their feet had a very low rate of foot complications in comparison to the standard therapy group [19]. Signifying the efficacy of at home temperature monitoring, the enhanced therapy group using at home temperature monitoring had shown significantly better clinical outcomes in comparison to the standard group not practicing at home temperature monitoring. Furthermore, patients representing the standard therapy group were found to be 10.3 times more at risk for foot complications than their enhanced therapy group counterparts, indicating an urgency for the development of an affordable at home temperature monitoring device [19]. The aforementioned results of the pilot study create an imperative to provide diabetic foot patients with a modality that may prove effective in preventing both ulceration and the adverse risk for amputation. By interleaving affordability and convenience, home monitoring of foot skin temperature serves as a potential preventative solution to diabetic foot complications and facilitates the early detection of ulceration.

Development and Process Flow

Monitoring the temperature of the feet can be an important tool in preventing diabetic foot ulceration. Studies have found that enhanced therapy involving the addition of a skin thermometer for patients to measure their foot temperatures in addition to therapeutic footwear and education on health care for diabetes greatly reduces the risk of ulceration [19]. Patients who consistently measured the temperature in their feet and took preventative action, such as taking fewer steps each day, had a much lower rate of foot complications and ulcerations compared with patients who did not measure their foot temperature. This suggests that at-home monitoring of foot temperatures serves as an effective first step in preventative care. It has also been found that a temperature difference of 2.2 degrees Celsius (4 degrees Fahrenheit) or more in analogous areas of the right and left foot can indicate the onset of an ulcer [same as above], thus the at-home monitoring of these temperatures can be an important step in recognizing health concerns before the severity increases.

Diabetic foot screening usually involves frequent measurement of infrared skin temperature, but with small, cheap and easy to use devices. This includes electrical devices such as diodes or programmable electronic devices, and mechanical versions of temperature monitoring generally include glass thermometers with liquid [20]. Diabetic foot screening is also often achieved through devices

utilizing thermal radiation that employ infrared radiation or thermography. The use of color indicators such as pencils or paints, ultrasonic sensors, or thermochromic liquid crystals and powders are also beneficial for producing heat maps of the patient's feet, as the aforementioned methods provide a cost effective and accessible solution to at home monitoring of skin surface temperatures [21].

Furthermore, infrared thermography (IRT) by way of infrared cameras allows for effective determination of skin surface temperature, asserting the importance of infrared cameras and thermochromic materials in risk prediction of ulceration. Thermographic maps produced by IRT detect variations in plantar temperature, however, the plantar temperature distribution does not follow a particular pattern in diabetic patients, thereby making it difficult to measure the changes. Thus, an interest arises in ameliorating the analysis and classification methods used in image analysis algorithms involved in artificial intelligence and machine learning that operate with complex data structures [22].

Another method of producing thermal maps of a patient's feet is by using thermochromic liquid crystals (TLCs), a material that can change from smectic phase to nematic phase, thereby exhibiting a change in color [23]. The molecules in these crystals are aligned rather than facing in random directions. At low temperatures, while in the smectic phase, the molecules are arranged in layers that can slide past each other. In this phase, the material is typically either translucent or completely black because they either allow all or no light to pass through them. When the material experiences a higher temperature, the molecules shift phases by changing their orientation and distance from one another, thus changing the way light interacts with the material. This causes the crystals to exhibit a color change at these higher temperatures. Depending on the material, the color could either shift from one designated color to another, or show many colors during the phase change [23].

Thermochromic liquid crystals can be manufactured in the form of pigments, leucodyes, microscopic capsules, and even embedded into polymers [same as above]. The color changing abilities of these materials are completely reversible, and can be prepared from combination of cholesteryl oleyl carbonate, cholesteryl pelargonate, and cholesteryl benzoate [24]. Different ratios of these three compounds can produce materials that change color over different temperature ranges. For example, combining 0.65g cholesteryl oleyl carbonate with 0.25g cholesteryl pelargonate and 0.10g cholesteryl benzoate yields a transition range of 17-23 degrees Celsius [24]. Heating the mixture while combining the different chemicals activates the color changing ability of the material, which can last from several months to a year.

Producing accurate thermal images of diabetic patients' feet for analysis by machine learning algorithms involves active participation by the patient [25]. In the field of image analysis and pattern recognition, an image processing algorithm is able to produce a prediction of the classification of new images based on a prior data set with known parameters. The first of two main methods of machine learning is an algorithm for creating a data point or "feature vector" given an image. A feature vector consists of several numbers that are measured or calculated from the image [26]. These features are then used by the second part of the system, a machine learning algorithm, to classify unknown feature vectors given a large database of feature vectors whose classifications are known [26]. These images are then uploaded to an app-based software, written by code that is developed, tested, and frequently debugged, that outputs to the patient their risk for ulceration. Developing an image analysis algorithm to be more accurate in its machine learning recognition of hot spots for potential ulcers greatly increases the chance of preventing amputation.

About the Client

Kayla Huemer graduated from the University of Wisconsin - Madison in biomedical engineering. She is currently attending graduate school at the University of Stanford to study the intersection of healthcare data, AI, and global health. Kayla became involved with this project when she was a sophomore at the University of Wisconsin - Madison. She traveled to India in order to research the diabetes breakout that was occuring. While she was there she was offered the opportunity to collect data of patients at a hospital in India. She didn't have the funds in order to continue her research so she came back in 2018 and 2019. She was awarded the US Fulbright Fellowship in order to continue her medical device research in India. After working a year on pressure sensing footwear she started to realize that the footwear wasn't the best way to detect foot ulcers in diabetic patients. She shifted her focus and started using thermal imaging of patients feet to help detect early signs of foot ulceration. Now she is trying to integrate a more cost effective way and machine learning in order to improve the detection capabilities.

Design Specifications

To summarize the product design specifications, the device must be a low cost at home temperature monitoring device that is easily usinable by any patient. It also must be usable by patients that both use and don't use socks and sandals. It also must incorporate a thermochromic material in conjunction with an app based software and a machine learning algorithm to intake heat map images of the thermochromic material. This app will then output the risk factor of a patient's likelihood of developing a foot ulcer. One thing to note is that the machine learning algorithm must be accurate enough to recognize multiple thermal images whether or not a patient is in fact at risk of an ulceration. Also the product needs to be able to withstand multiple uses while still producing an accurate image and thermal map of the patient's feet for uploading to the app based software. See Appendix A for the full product design specifications.

Preliminary Designs



Design 1 - Insulated Thermochromic Color Changing Sheets

LC-2530 25-30°C Transition



The first design proposed by the team was chosen in order to minimize cost and maximize the ease of fabrication. Insulated thermochromic color changing sheets contain thermochromic liquid crystals (TLCs) which are molecules that can exist in a liquid state with some crystal-like order. TLCs change color due to variations in intermolecular forces at different temperatures and different molecules experience these variations within different temperature ranges [28]. Insulated thermochromic sheets usually display color changes over a 5°C range with a tolerance of ± 1.5 °C and can be customized to include protection from water and UV light. If the sheets are properly stored at room temperature with minimal UV exposure they can be reused and maintain the expected accuracy for over one year [29]. Despite the advantages of this design, complications arise from the small effective temperature ranges and mediocre accuracy of insulated thermochromic sheets. Due to the large variation in possible foot temperatures, consumers would need to buy multiple sheets, each effective over different temperature ranges, to guarantee a proper temperature profile can be collected and analyzed. This could also require the machine learning software to be trained to recognize areas of high ulcer risk for each sheet, which would prove challenging and require a large amount of data to be gathered.

Design 2 - Mix of Thermochromic Color Changing Powders



Figure 4: *The temperature profile of a hand as shown by three TLC powders each layered in a unique pattern* [30].

TLC powders can be applied to materials to create thermochromic color changing sheets. Combining powders that experience color changes at contiguous temperature ranges on one sheet would allow for consumers to purchase a single sheet that would be sensitive to a wider range of temperatures. Top coats would be used to increase the durability, and therefore reusability, of the final product. It has been shown that layering the TLC powders in unique patterns allows for significantly accurate temperature profiles to be obtained [Figure 4]. While the fabrication process of this design would be very involved, the increase in effective temperature range in comparison to the first design increases accuracy and keeps the cost low. Both designs one and two require the consumer to stand on a TLC surface, take a picture of the resulting temperature profile of their feet, and upload the image to an app with the machine learning software trained to recognize areas of high ulcer risk. The team will need to assess whether the time required to step off the sheet and capture an image will cause a significant loss in accuracy of the accuracy of the temperature profile or not.



Design 3 - IR Thermal Camera Smartphone Attachment

Figure 5: Circuit with thermal camera component and display using TFT Feather [31].

The third design the team proposed was an infrared thermal camera that could attach to a smartphone. This design would allow for digital thermal images to be taken and directly uploaded to the software based app for processing and classification by the machine learning algorithm. Such thermal cameras have the potential to be much more accurate than the other two designs. Although the accuracy of the temperature profiles is an important factor to consider, the comparatively large cost of thermal cameras to the TLC based designs outweighs the benefits of increased accuracy. It would also be difficult for a consumer to take a direct picture of the soles of their feet without assistance which would likely cause a decrease in the compliance of consumers.

Preliminary Design Evaluation

Design Matrix

Table 1. Design Matrix. Evaluation of feasible design ideas amongst different criteria.Highlighted areas indicate the highest score per category. Scores out of 10.*Displayed as: score out of ten | weighted score

| | | Design 1: Insulated color changing sheets | | Design 2: Mix of color changing powders | | Design 3: Thermal camera smartphone attachment | | |
|------|------------------------------|-------------------------------------------------|----------------------|--------------------------------------------------|----------------------|---------------------------------------------------------|----------------------|-------------------|
| Rank | Criteria | Weight | Score (10 max) | Weighted Score | Score (10 max) | Weighted Score | Score (10 max) | Weighted Score |
| 1 | Cost | 20 | 10 | 20 | 10 | 20 | 4 | 8 |
| 2 | Accessibility/ Compliance | 20 | 10 | 20 | 10 | 20 | 5 | 10 |
| 3 | Ease of Use (for patient) | 20 | 10 | 20 | 10 | 20 | 5 | 10 |
| 4 | Accuracy/ Sensitivity | 15 | 3 | 4.5 | 9 | 13.5 | 10 | 15 |
| 5 | Durability | 10 | 8 | 8 | 10 | 10 | 10 | 10 |
| 6 | Ease of Fabrication | 10 | 7 | 7 | 6 | 6 | 2 | 2 |
| 7 | Safety | 5 | 10 | 5 | 10 | 5 | 10 | 5 |
| | Sum | 100 | Sum | 84.5 | Sum | 94.5 | Sum | 60 |

Summary of Design Matrix

Our design matrix included 7 different points of criteria. These points of criteria in order of importance included cost, accessibility/compliance, ease of use, accuracy/sensitivity, durability, ease of fabrication, and safety. First, cost is one of the most important factors for our project because our main goal is to create a solution that is affordable to the average diabetic patient in India. This needs to be an affordable device that patients can purchase either directly from their healthcare provider or from an online source.

Next, compliance is a big issue for at-home medical care. Other products like temperature measuring socks would not be viable in India because the majority of people do not wear socks. Finding a solution that patients would be able and willing to comply with is important. This means the device cannot interfere with daily life, and must have a minimal amount of steps to use. Ease of use goes hand in hand with compliance. If the device is easier to use for the patient, then compliance is less of an issue. The device should be easy to use on a daily to weekly basis, and should not take up too much time. This is an important factor because if the device is not easy to use, it is not an adequate at-home solution.

Next, accuracy, it is necessary for the device to be accurate in order to properly diagnose individuals who are at risk of developing foot ulcers. The most important aspect of this criterion is not necessarily the accuracy of the temperature measurement, but of the differences in temperature of the foot. If temperature differences cannot be accurately measured, the machine learning software will not be able to accurately identify at-risk individuals. Durability is important because the device must be durable enough to take daily or weekly measurements for an extended period of time. This criterion is ranked lower than most as the materials the team are working with are reliable for over one year. Ease of fabrication is one of the least important factors because the team only needs to know if they have access to the materials and equipment required to accomplish the project. It does not matter if the product is easy to manufacture if it cannot accurately indicate the level of ulcer risk or if the patient does not comply. Safety is the least important factor because there aren't any known health concerns associated with the materials being used.

Using this criteria the team ranked each of the designs. Design 1: Insulated color changing sheets and Design 2: Mix of color changing powders received maximum points for cost, accessibility and ease of use. The team gave these two designs these scores because they are cheap compared to current options, and they are both easy to use and something the patient would comply with. Design 3: Thermal camera smartphone attachment on the other hand scored much lower in these three categories because it is less cost effective and would be more complicated for the patient to use. After researching our three designs the team came to the conclusion that designs 2 and 3 would be much more accurate than design 1 which is why design 1 scored much lower than the other two in this category. All three designs scored high in the durability category. Designs 2 and 3 received a full score for this category and design 1 scored slightly lower. Designs 1 and 2 are about the same when it comes to ease of fabrication which is why it scored so low. Lastly, each design received a full score in the safety category because there are no known health concerns associated with the materials that the team would use of any design.

After the team completed the design matrix there was a clear winner. Design 2: Mix of color changing powders scored the most points and was chosen as our proposed final design.

Proposed Final Design

The proposed final design consists of a thermochromic imaging surface which will work in conjunction with a machine learning algorithm to analyze the data. The imaging surface will contain a layer of thermochromic powders mixed with a liquid or acrylic base so that it can be painted or spread over the solid surface. The thermochromic layer will be secured with a top coat that will prevent the lower layer from exposure to water or dirt so that it maintains its color changing properties. Preliminary testing will help the team determine the best solid material to apply the thermochromic powder mixture to (e.g. wood, plastic, fabric secured over wood, etc.). When fully assembled, the imaging device will have dimensions of 14 in. by 14 in. and will be a solid surface that the patient can stand on with their bare feet to generate a thermal map (Fig X below). The thermal image generated from the temperature sensitive color changing powder layer will last several minutes before fading, ensuring that the patient can take a picture of the imaging surface with their smartphone to upload to the app-based software.

Once the image is fed to the software, the machine learning algorithm will process it and analyze the colored regions. Each color will be associated with a certain temperature range, so the software will identify the different temperatures in different regions of both feet. It will assess whether or not there is a temperature difference of four degrees fahrenheit or greater in symmetric parts of the feet (e.g. the difference in temperature between the right and left heel). If there are any temperature differences that meet or exceed this threshold, the software will output an 'at-risk' result, indicating that the patient is at risk of developing an ulcer. An 'at-risk' output would mean that the patient should reduce the number of steps they take daily and the amount of time they spend on their feet.



Figure 6. Top view of solid surface with thermochromic material showing a thermal image of two feet.



Figure 7. Side View of solid surface with thermochromic material showing a thermal image of two feet.

Development of Machine Learning Algorithm

Materials and Tools

A machine learning algorithm will be created in order to analyze the thermal maps generated after a patient steps on the thermochromic material and takes a photograph with a camera or smartphone. This algorithm will be a type of artificial intelligence program that will be trained to classify images. In order to create this algorithm, open source code will be used to train a model using Python, a coding language. The model will require a collection of data, of which approximately 200 thermal images of diabetic patients' feet have already been taken with an infrared camera by the client, Kayla Huemer, in India. At least 800 more photos will be needed to adequately program the algorithm. These images will serve as the data that the machine learning model will be trained to recognize and classify. A model such as ImageAI [35] or TensorFlow 2.0 [36] will be used and imported into Supervisely, a collaborative workspace to compile and edit data and open source software [37]. Currently, not enough thermal images have been collected to begin the machine learning process, which typically requires a minimum of one thousand images in order to begin to recognize patterns in the data. Due to restrictions from Covid-19, it is unknown when Kayla's team will be able to return to India to continue to collect patient data.

Methods

In order to create the machine learning algorithm after enough thermal images have been collected, an open source machine learning model will be used, such as ImageAI. These open source models are written in Python, and are built to import an RGB (color) image file, then classify the image type so that it can be processed. Images can either be interpreted one by one or as a dataset. For large amounts of images, like the set of thermal images provided by the client, a dataset is the best method for organizing the data. An iterator in the Python code will allow the program to run through each photo. Processing the images will involve creating a set of parameters to classify the images [36]. The team will determine a temperature scale and assign temperatures to color values. Based on these temperatures associated with colors, the code will be modified to assign temperatures to different areas of the foot. If

the algorithm recognizes that there is a temperature difference of four degrees Fahrenheit or more between any symmetric parts of the foot, it will classify the image as at-risk of an ulcer.

Final Prototype

The final prototype will be a functioning code that will take an input thermal image, process it by analyzing the color of each pixel and assigning a temperature value, then outputting whether or not the patient is at risk of ulceration. 'At risk' will be defined as containing at least one area of the foot with a temperature difference of at least four degrees Fahrenheit (2.2 degrees Celsius) compared to the analogous section of the other foot.

Testing

In order to test the accuracy of the machine learning algorithm, more thermal images that the team takes will be input into the software. The output will be compared to actual data collected with a thermometer to test how often it correctly classifies the image as at-risk or not. Inputting these images will help to further teach the algorithm to properly identify the images it is fed. This testing cannot take place until enough data has been collected to begin the machine learning process.

Fabrication of Thermochromic Imaging Surface

Materials

| ltem | Description | Manufacturer | Date | QTY | Cost Each | Total |
|----------------------|--------------------------------------------------------------------|------------------|-----------|-----|--------------|--------|
| Category 1: Thermocl | Category 1: Thermochromic Materials (powders, sheets, paints, etc) | | | | | |
| | Blue to Violet | | 11/6/2020 | 1 | ¢0.09 | ¢0.09 |
| | Powder 22 degrees | | 11/0/2020 | | \$9.98 | \$9.98 |
| THERMOCHROMIC | Black to Green | ATLANTA CHEMICAL | | | | |
| POWDER PIGMENT | Powder 25 degrees | ENGINEERING® | 11/6/2020 | 1 | \$9.98 | \$9.98 |
| | Red to Yellow | | 11/6/2020 | 1 | ¢0.09 | ć0.00 |
| | Powder 28 degrees | ENGINEEKING® | 11/6/2020 | | \$9.98 | \$9.98 |
| THERMOCHROMIC | Black to Pink Powder | ATLANTA CHEMICAL | | | | |
| POWDER PIGMENT | 31 degrees | ENGINEERING® | 11/6/2020 | 1 | \$9.98 | \$9.98 |

Table 2. Materials and Costs Spreadsheet.

| THERMOCHROMIC | Black to Purple | | | | | |
|---------------------|---------------------------|----------------------------|-----------|---|---------|----------|
| | Powder 35 degrees | | 11/6/2020 | 1 | \$9.98 | \$9 98 |
| | Three Color | | 11/0/2020 | | Ş5.50 | Ş5.50 |
| | Changing | | | | | |
| | Thermochromic | | | | | |
| TLC sheets | Sheets | Amazon | 11/6/2020 | 1 | \$28.40 | \$28.40 |
| Category 2: Other M | aterials (for building th | e imaging surface, testing | g, etc) | 1 | 1 | 1 |
| Wooden Craft | | | | | | |
| Rectangles | Wooden Boards | Amazon | 11/6/2020 | 1 | \$17.99 | \$17.99 |
| | Foam to glue onto | | | | | |
| 1 inch thick foam | wooden board | Amazon | 11/6/2020 | 1 | \$9.99 | \$9.99 |
| | Acrylic paint base to | | | | | |
| Acrylic paint base | mix with pigments | Amazon | 11/6/2020 | 1 | \$11.12 | \$11.12 |
| | Epoxy Resin top coat | | | | | |
| Epoxy Resin and | to secure the TLC | | | | | |
| Hardener | material | Amazon | 11/6/2020 | 1 | \$13.99 | \$13.99 |
| | Fabric to paint the | | | | | |
| | pigments onto and | | | | | |
| Black fabric | secure over fabric | Amazon | 11/6/2020 | 1 | \$4.99 | \$4.99 |
| | | | | | TOTAL: | \$136.38 |

Table 2, shown above, is a compilation of all of the materials ordered for this project. Five different thermochromic liquid crystal powder pigments were ordered from Atlanta Chemical Engineering. Each of these pigments (changing from blue to violet at 22 degrees Celsius, black to green at 25 degrees Celsius, red to yellow at 28 degrees Celsius, black to pink at 31 degrees celsius, and black to purple at 35 degrees Celsius), were intended to be mixed with a white acrylic base to form a paint that would change colors at their respective temperatures. Two white acrylic bases were used to mix with the thermochromic pigments, including one that was purchased (Table 2 above) and a second that did not need to be purchased.

Four wooden boards were also purchased to use as a hard base for the imaging surface, as well as 1-inch thick foam that was intended to serve as cushioning and provide a surface that would conform to the contours of the foot, thus allowing the thermal map generated from the thermochromic paints to show the entire three dimensional surface of the foot rather than just the flat footprint. Black fabric was also ordered to cover this foam and layer the thermochromic paints. A clear coat of epoxy resin was ordered to apply in between each layer of paint on the fabric to secure the color changing abilities of the thermochromic paint. In addition to these materials that were ordered to fabricate the color-changing imaging surface, a set of thermochromic temperature sensitive sheets were also ordered with the intention of fabricating a second prototype based on the first preliminary design so that comparisons could be made between the pigments and the sheets. This set came with three sheets with different temperature ranges

(20-25, 25-20, and 30-35 degrees Celsius). Additional materials not listed in the table include glue, staples, paint brushes, and plastic cups, which did not need to be purchased.

Methods

In order to fabricate the proposed final design, each pigment was added to a separate container and mixed with two different acrylic bases, a white Liquitex acrylic medium, and a Craftsmart white acrylic paint. Swatches of each pigment-paint mixture were painted onto both wood and fabric to test their color changing abilities and assess their vibrancy. Several layers of these swatches were built up, and once each pigment dried completely, heat was applied to qualitatively test the color-changing abilities. A detailed fabrication plan for the intended prototype using these pigments can be found in Appendix B.

Unfortunately, the fabrication process did not go as planned. When the pigments were mixed with the Liquitex acrylic medium and applied to wood, the color change observed when heat was applied was very weak in two of the five pigments, and no color change was observed in the other three. The same results were found with the Craftsmart acrylic base as well when applied directly to wood. Both the Liquitex and Craftsmart pigment mixtures were also applied to black fabric, but no color change was found in these swatches either when temperature was applied.

After unexpectedly finding no color change when the pigments were applied to both wood and fabric, the same process was repeated after first applying a white base coat to both materials, then painting the thermochromic mixtures. However, like the first experiment, no color change was observed when heat was applied to these swatches. This meant that fabrication of the prototype could not proceed as outlined in the fabrication plan (Appendix B).

In order to continue fabrication, the team modified plans for the final prototype to resemble the first preliminary design idea rather than the proposed final design, and ordered a set of three thermochromic sheets that change color from 20-25, 25-30, and 30-35 degrees Celsius respectively. Each sheet was cut into strips 0.5cm wide and 4in long. These dimensions were chosen because each of the three sheets were originally 4in x 4in, and they were cut into strips approximately 0.5cm wide because, when combined, the three strips of different temperature ranges had a total width of 1.5cm, which is approximately the width of the average foot ulcer [32]. These strips were glued onto a wooden board in order of increasing temperature range so that repeating groups of three strips covered the board. The strips were labeled on the board with their temperature ranges.

This design was chosen so that when heat is applied to the surface, lower temperatures cause color change in only the 20-25°C strips, mid-range temperatures cause change in the 25-30°C strips, and only high temperatures cause any change in the 30-35°C strips. Different areas of the foot have different temperature ranges, the toes having an average temperature of 26.2°C and the sole an average temperature of 29.3°C [33]. These fall within the 25-30°C temperature range, however, foot temperatures can be as much as 5°C higher or lower than these averages, thus the need for the combination of thermochromic strips with different temperature ranges so that higher foot temperatures can be sensed by the device. The final surface with the thermochromic strips had dimensions 8in x 8in, which is not as large as the intended design due to lack of materials and time constraint caused by the unexpected change in design.

Final Prototype

The final prototype consists of a flat wooden surface with thermochromic liquid crystal sheets of different temperature ranges arranged in repeating groups of three strips, with the lowest temperature range (20-25°C) starting at the top of each group of three, the mid-range (25-30°C) in the middle, and the highest temperature range (30-35°C) at the bottom of each group (figures 8 and 9 below). Each group of three strips is labeled on the side of the board with their corresponding temperatures so that each strip's temperature range is easily legible. Unlike many infrared cameras, the warmer colors (red, orange, and yellow) in this prototype correspond to lower temperatures in each range, and the cooler colors (blue and green) correspond to higher temperatures in each range. Thus, the blue areas on each strip coincide with the high end of the corresponding temperature range.



Figure 8 - Final Prototype. Image of layered thermochromic liquid crystal (TLC) strips layered in order from 20-25°C, 25-30°C, and 30-35°C. Brackets on the side show repeating groups of three strips, with the lowest temperature range starting at the top of each group of three and the highest temperature range at the bottom of each group. Pictured is a thermochromic heat map left from pressing a hand to the surface for five seconds before removing. The surface has dimensions 8in x 8in.



Figure 9. Image of hand pressed onto thermochromic imaging surface and subsequent heat map produced.

In order to use the prototype, a patient must stand on the surface, allowing their foot to press against the temperature sensitive strips for at least five seconds. After stepping on the surface, a heat map will be generated and the patient can take a photograph with a camera or smartphone for further analysis after the image fades. After using the device, the patient can take the time to observe which strips experienced a color change. Since the average foot temperature ranges from 26.2°C at the toes and 29.3°C at the toes, any color change in the 30-35°C strips indicates a slightly above-average foot temperature, and may be reason to contact a health care provider. In addition, since a 2.2°C temperature difference in symmetric areas of the feet (for example, between the heel on the right and left feet) can serve as an indicator of potential ulceration [34], a noticeable difference in colors in the temperature maps of the two feet can also be cause for concern, potentially leading a patient to take fewer steps each day and get in touch with a doctor about preventative health care.

Testing

In order to test the accuracy of the final prototype, a temperature comparison test was performed in order to compare temperatures estimated from the device and actual temperatures. A container full of water heated to an unknown temperature was used to apply heat to the thermochromic imaging surface for five seconds. After removing the heat source, the color of the different strips was used to estimate and record the temperature. Meanwhile, the actual temperature of the water was recorded with a thermometer as well. This comparison was performed eight different times, recording both the actual and estimated temperatures in table 3 below. After collecting this data, a two sample t test was performed.

| Trial | Estimated temperature based on color shift (Celsius) | Actual temperature from thermometer (Celsius) | Difference (Actual - Estimated) |
|--------------------|---------------------------------------------------------------|-----------------------------------------------------|------------------------------------|
| 1 | 36°C | 38.1°C | 2.1°C |
| 2 | 34°C | 33.2°C | -0.8°C |
| 3 | 27.5°C | 28.4°C | 0.9°C |
| 4 | 24.5°C | 23.2°C | -1.3°C |
| 5 | 19°C | 17.8°C | -1.2°C |
| 6 | 27°C | 29.5°C | 2.5°C |
| 7 | 29°C | 28.9°C | -0.1°C |
| 8 | 31.5°C | 31.3°C | -0.2°C |
| Average | 28.5625 | 28.8 | 1.1375 |
| Standard deviation | 5.4145 | 6.1542 | 1.31 |

 Table 3. Temperature Comparison Data. This table shows the estimated temperatures and actual temperatures found during the temperature comparison test, as well as the difference between the estimated and actual values.

A second test was performed to test the amount of time an accurate thermal map lasted on the device before fading. This test was performed to quantify the approximate amount of time someone using the product would have to take an image of the thermal map while it is still sufficiently accurate. To determine this, a clear plastic bag was filled with water of known temperature and used to heat the thermochromic imaging surface for approximately thirty seconds. The heat source was then removed and the amount of time that passed until the outermost thermochromic strip lost all color change was recorded. Although the color changes were more persistent at the center of the thermal map, the disappearing time of the colors at the edges was used to quantify thermal map retention because the color differences become more ambiguous at the center of the map as time passes.

| Temperature (°C) | 25-30°C Sheet Time to Color Loss (seconds) | 30-35°C Sheet Time to Color Loss (seconds) | |
|------------------|-----------------------------------------------|-----------------------------------------------|--|
| 25 | 1 | - | |
| 26 | 9 | - | |
| 27 | 11 | - | |
| 28 | 27 | - | |
| 29 | 50 | - | |
| 30 | - | 3 | |
| 31 | - | 4 | |
| 32 | - | 5 | |
| 33 | - | 6 | |
| 34 | - | 6.5 | |
| 35 | - | 7 | |
| 36 | - | 9 | |
| 37 | - | 10 | |
| 38 | - | 11 | |
| 39 | - | 22 | |
| Average | 19.6 seconds | 8.35 seconds | |

Table 4. Thermal Map Retention Data. This table shows how much time passed until all color change waslost in a strip of thermochromic material at the edge of the thermal map after removal of a heat source ofknown temperature.

Results

After collecting the temperature data, a two sample t test was performed in order to compare the means of the estimated and actual temperatures and determine if the temperatures were significantly different. A significance value of 0.05 was used, and the result of the t test was a t-value of -0.082 and a p-value of 0.94, which was not less than the significance level, indicating that the color-estimated temperature is not significantly different from the actual temperature. This means that the final prototype consisting of groups of thermochromic sheets is a successful and accurate visual depiction of the



temperature of a patient's feet. Figure 10 below shows a plot of the estimated and actual temperatures and the difference between the two.

Figure 10. Graph of actual temperature (red) compared with the color-estimated temperature (blue) for each of the eight trials from the temperature testing. The average difference between these two temperatures was 1.13°C.

The results of the fading-time test found that the 25-30°C thermochromic strips fade after an average of 19.6 seconds, while the 30-35°C strips fade after an average of 8.35 seconds. No average was found for the 20-25°C strips because the test was conducted at an ambient temperature of 23.2°C, so these strips were perpetually yellow and green during the test with no fading to black. Data was not collected at temperatures above 29°C for the 25-30°C thermochromic material because the time to lose color change at the edges was longer than one minute.

Discussion

A thermochromic imaging surface was created from TLC sheets. Temperature testing found that the temperature estimated from the device was not significantly different from actual temperatures, meaning that the device is accurate and successful, despite the change in designs that followed the failed tests of the thermochromic pigments. The surface is easy to use, and simply needs to be stepped on with bare feet in order to generate a thermal map. The brackets on the side of the thermochromic strips provide information about the temperature range of each strip so that the colors on the surface can be easily interpreted. Although the first attempt at fabrication using thermochromic pigments mixed with an acrylic base resulted in no color change with applied heat, the thermochromic sheets showed vibrant colors that changed at the correct temperatures, lasting long enough for a patient to step off of the surface and take a photograph for later interpretation.

Although there are several products on the market that are geared towards aiding diabetic patients in self-monitoring their feet to prevent injury or ulceration, many of these products involve components that would decrease compliance for diabetic patients in India. Siren is a growing company in the United States that uses temperature sensing technology built into a pair of socks so that patients can monitor the temperature of different areas of their feet and modify their daily activities if they notice significant temperature changes. Products such as diabetic socks and shoes are not as applicable in rural communities in India, however, where the average person often may not wear socks and close-toed shoes, but rather go about their daily lives in sandals or bare feet. The team's design of a thermochromic imaging surface that patients simply need to step on briefly bridges this gap because patients will not have to interfere with their daily routine to monitor the temperature of their feet. Instead, patients simply need to stand on the surface once a day to see a visual representation of the temperature of their feet. This removes the need for an extra piece of clothing or a costly infrared skin thermometer. The total cost of this final prototype was about \$36.40, but the individual cost of this device would be significantly lower if materials were purchased in bulk. The overall expenses of this project were much higher at \$136.38 including all of the materials for the failed thermochromic pigment design.

Overall, the results from the testing of the prototype show that it is successful in indicating when there are significant differences in the temperature of the feet, and thus when there is potential for the formation of an ulcer. This means that the product will provide a much more accessible method for diabetic patients in India to monitor the state of their feet so that they can be proactive in making decisions that will benefit their health. After observing any major color differences in the right and left foot, a patient can take steps to limit the number of steps each day and, when possible, meet with a health care provider about further treatment of an ulcer. This will create an avenue for at-home treatment that will benefit patients who have obstacles that keep them from accessing standard and consistent health care, such as money or distance.

In the future, the team would like to modify the imaging surface so that it is more precise when extracting data and see if the colors fade quicker at different ambient temperatures. The team would also like to incorporate a machine learning algorithm that will analyze a picture of the imaging surface and definitively tell the patient whether there is cause for concern for ulceration. In order to do this, the team will have to acquire more data to train the machine learning algorithm. This data would consist of thermal maps of both healthy feet and ulcerated feet. The algorithm will then learn to identify the difference. This algorithm is a long-term goal that the client, Kayla Huemer has begun, but has not been able to collect enough data to move forward due to the current situation with the Covid-19 pandemic. The device will also be tested under different conditions in order to learn the lifespan. The data taken from the imaging surface will also be compared to existing products such as Siren socks to learn the efficiency and effectiveness of the device and where improvements can be made.

Conclusion

The final prototype uses thermochromic liquid crystal sheets of different temperature ranges. These sheets are arranged into repeating groups of three strips with varying temperature ranges and placed on top of a flat wooden surface. The team came about with this final prototype based off of tests that were done in order to decide the most accurate way to generate the thermal map of a patient's feet. This final prototype allows the patient to step on the surface and generate a thermal map of their feet, which successfully and accurately displays the temperature of the feet. In the future, the color-coded thermal map that is generated would be photographed and uploaded to a software for classification by a machine learning algorithm. This software would output whether or not the patient is at risk of an ulcer.

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Appendix

Appendix A - PDS

Global Health: Prevention of Diabetic Foot Ulceration and Amputation Preliminary Product Design Specifications Date: 09/18/2020

| Team Members: | Cade Van Horn Team Leader | | | |
|---------------|---------------------------|--------------|--|--|
| | Matt Voigt | Communicator | | |
| | Emma Kupitz | BSAC | | |
| | Carter Rupkey | Co-BWIG | | |
| | Will Nelson | Co-BWIG | | |
| | Anvesha Mukherjee | BPAG | | |

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].

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Appendix B - Fabrication and Testing Plans

Intended Fabrication Plan:

Initial Qualitative Testing of Pigments:

- 1. In five separate containers, add about a teaspoon of each pigment
- 2. In each of the containers, add the Liquitex white acrylic medium in a 2:1 acrylic to pigment ratio and mix with a stir stick to fully combine the pigment and acrylic medium
- 3. With a paint brush, paint a swatch (about 2 inches long, 1 inch wide) of each pigment range onto a wooden board to test the color changing abilities
 - a. When the swatches dry completely, apply heat to each to test if the color changes at the desired temperature. If the color does not change as desired, apply more coats to the swatch until the desired color change is observed.
- 4. Repeat step 3 on the black fabric to test the color changing ability of each pigment on the fabric compared to the wood
- 5. Compare the swatches on the wood and the fabric and qualitatively determine if the color change is more vibrant on one or the other
- 6. Repeat steps 1-5 with the Craftsmart acrylic paint as a base for the pigments

a. Compare the Liquitex and Craftsmart swatches and qualitatively determine if the color change is more vibrant with one base versus the other

Fabrication of Fabric-Foam Imaging Surface:

- 1. Cut a square of black fabric that is 16in x 16in.
- 2. Lay the square of fabric out and paint an even layer of the lowest temperature pigment. Wait for the layer to dry completely and paint another layer until the pigment is opaque.
- 3. Once the first layer has dried, apply a thin, even coat of the clear epoxy resin over the thermochromic layer.
- 4. Repeat steps 2-3 with each successive temperature pigment until all pigments have been layered in between clear coats. Apply one final clear coat.
- 5. Cut a 14in x 14in square of 1in thick foam and wrap the fabric around the foam, securing it with glue.
- 6. Glue the foam onto a wooden board for a solid base to the imaging surface.

Testing of Imaging Surface - Temperature Comparison:

- 1. Using a container full of water heated to an unknown temperature, apply heat to the surface and let sit for five seconds.
- 2. Remove the heat source and use the colors to estimate and record the temperature (22 degrees Celsius = violet, 25 = green, 28 = yellow, 31 = pink, 35 = purple)
- 3. Measure the actual temperature of the water with a thermometer and record
- 4. Repeat step 2-3 eight times, recording the actual and estimated temperature
- 5. Calculate the mean, and standard deviation of both the estimated temperatures and the actual temperatures.
- 6. Perform a two sample t test to compare the means with a significance value of alpha = 0.05 to see if the actual vs estimated temperatures are significantly different