A Thermally Regulated Footwear & Alerting System

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***Abstract*—Diabetes can impair the circulation of blood in an individual suffering from said illness. Neuropathy, another medical complication of diabetes, inhibits the ability of a patient to sense pain and temperature changes, most often in their hands and feet. These medical complications together can be dangerous as an individual suffering from diabetes may be unable to detect a harmful change in the blood circulation of their feet. Undetected changes may lead to other medical issues such as calluses and foot ulcers. This study developed a prototype device for the insole of an individual's footwear that is capable of monitoring signs which gauge the health of a users feet. Based on the measured temperature of a users feet, a system issued alerts to indicate poor foot health. The insole system included a microcontroller, temperature and humidity sensors, a Bluetooth transceiver and an electrical heating pad. The Bluetooth module communicated with a smartphone application for event recording, alerts and communication with the user and other stakeholders. The prototype developed showed promise. However, further development and testing will be necessary toward deployment.**

***Index Terms*—Diabetics, Thermally unregulated, Temperature sensor, Heat pad, Arduino, Microcontroller**

I. Introduction

Individuals who suffer from diabetes make up nearly 10% of the US population [1]. Such individuals may develop impaired blood perfusion control, affecting tissue health and temperature regulation. Feet are particularly at risk for development of damage from impaired blood perfusion [2]. In many cases, loss of blood flow to the feet is indicative of a serious medical issue that should be addressed quickly [3]. Due to the prevalence of diabetes in the United States as well as its global rise, further improvements in the products available to those who suffer from its effects are necessary [4]. Diabetics as well as individuals with other ailments have reduced blood flow to their feet. The physiological control of their bodies cannot adequately detect and control the flow. Blood flow is essential for sufficient supply of oxygen and nutrients, and elimination of carbon dioxide and other chemical by-products from the peripheral tissue [5].

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Although some commercial products do exist to assess their condition, a device which is capable of alleviating their symptoms and alerting relevant parties on their condition is not commercially available. The purpose of our project was to develop and test a system for the insole of a users footwear to monitor temperature, provide heat as needed, and communicate status to an app on a smartphone.The necessary hardware and software components to develop such a prototype system are commercially available, including temperature sensors, electrical heating pads, Bluetooth modules for connectivity, and smartphone applications for emergency contact.

A system capable of warming a users feet automatically based on the temperature being read by a sensor was primarily aimed for diabetic patients, but such a system may also be beneficial for other groups of people, such as individuals who spend long periods of time in cold conditions. This broadens the relevance of the project as it becomes applicable to many people who live in winter climates and have trouble keeping their feet warm. Future improvements to the system that involve collection of user data to predict potential health risks before serious issues occur are also discussed.

Our proposed system integrated an Arduino microcontroller and a commercial electrical heating pad. The device monitoring the temperature of the foot with a sensor placed in an insole of the users footwear. The Arduino could then pair to a smartphone via Bluetooth. With the developed system, the user could monitor their foot temperature status through the smartphone application, allowing for ease of integration into the users lifestyle.

The paper is organized as follows: Section 2 introduces the proposed electrical, software and mechanical design. Section 3 presents our findings and Section 4 contains concluding remarks.

II. Methods

A. Design Overview

A custom insole and an Android application were developed as a prototype. A LilyPad Arduino 328 main board was utilized as the microcontroller system in the prototype. A DHT11 Temperature and Humidity sensor was employed to read the temperature from the users feet. Similarly, an HC-05 Bluetooth module was selected to wirelessly communicate between the Android smartphone and a device (foot) and, an NRF24L01 transceiver was employed to wirelessly communicate between the two devices (feet). The heating component for the system is a heating pad (5x15cm) and a MOSFET IRF520 transistor to regulate its voltage.

B. Hardware design

Our initial task was to design the circuit for the hardware. Three DHT11 temperature and humidity sensors are connected to the three-analog pins (A0, A1, A2) of LilyPad Arduino 328 Main Board. The Bluetooth and heating components are connected to the digital pins of the Arduino as show in Fig. 1.

A similar circuit diagram is utilized to create insoles for human feets. Insoles are designed to house the LilyPad Arduino, temperature sensors, transceiver, transistor, and heating pad. In order to communicate with Androids app, left foot insole has Bluetooth module. Right foot insole reads temperature data from right feet temperature sensors and sends it to the left foot insole via transceiver. Right foot insole reads right feet temperature and its temperature sensors data and sends it to the Android app over Bluetooth. Once the app receives the temperature data, it continuously monitors and check the temperatures changes and sends back heating pad voltage regulation signal to the insoles. If the temperature of the feet remains unstable, Android app dispatch emergency alert to health service provider.

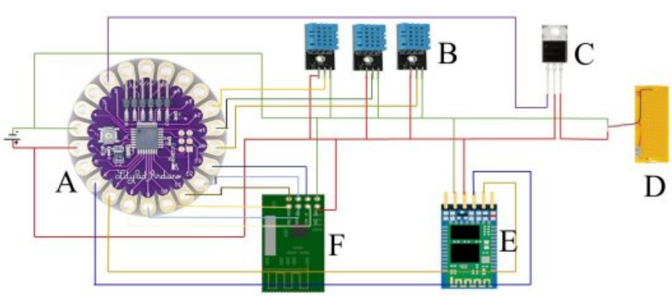

Fig. 1. Overview of the prototype hardware. Battery is connected to Arduino (A), temperature sensor (B), Bluetooth HC-05 module (E), NRF24L0 transceiver (F), MOSFET transistor (C) is connected to the heating blanket (D). All these components are connected to analog and digital pins of Arduino in order to stream data and instructions.

The insole was carefully designed to fit the hardware components of the prototype and still maintain comfort of the foot. The insole had a plug for the temperature sensors that could be placed anywhere on the foot as determined by the physician. Users could also use an elastic band to attach the temperature sensor to the foot.

TABLE I
THRESHOLD VALUES SET AFTER CONSTANT MONITORING AND ANALYSIS

Heating Level	Temperature Thresholds (°C)	Alert Thresholds	Duty Cycle
HIGH	Less than 28.99	Every 7 minutes	100%
MEDIUM	29.00 to 30.99	Every 13 minutes	66%
LOW	31.00 to 33.5	No Alert	33%

C. Software Design

An Android app was designed to view, analyze and regulate the heater connected to the Arduino. Also, a Kalman filter was implemented in Android app in order to tune to the incoming stream of temperature data and get better-quality temperature data. The Kalman filter is an effective method of reducing noise in a sensor [6]. Fig. 2 shows the overall design of the system along with the software architecture.

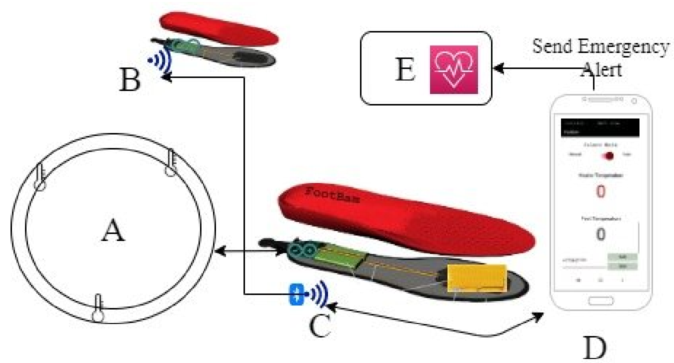

Fig. 2. Structure of the communicating and connected components. Android app (D) is connected with Arduino in Left insole(C) via Bluetooth module. Left insole(C) and right insole(B) communicates with transceiver. Arduino on both feet are connected to temperature sensors(A). Android app dispatches emergency alert via SMS to health service provider(E).

The temperature sensors used on the current design are not intended for use directly against the human skin. Given this factor the sensors read slightly lower than the expected body temperature of 37°C. After constant monitoring, the body temperature for the provided sensor is averaged to 35°C.

All the analyses and alert mechanism used 35°C body temperature implications. After monitoring the use of the device by various individuals, three timing thresholds and temperature thresholds were evaluated for the alert system and to trigger the heating pad. High, Medium and Low are the three heating modes implemented in the system.

When the temperature reading was less than 28.99°C, the foot was considered to be too cold. A 100% duty cycle signal was sent to the heating pad from the Arduino to turn the heater to the HIGH level. After a period of 7 minutes of monitoring of the foot temperature, if the temperature did not rise, an emergency alert was dispatched via SMS to a phone number saved in the system. MEDIUM level is less crucial, so the alert was only dispatch after a 13 minutes cycle and the heating pad is sent a 66% duty cycle. Similarly, no alert was dispatched on the LOW level and the heating pad is sent a 33%

duty cycle. The flowchart on the Fig. 3 shows the complete implementation of the monitoring and alerting system.

When the user launches the Android application, they were given the option between manually trigger the heating device or setting the application to automatic mode where heating and alerts are triggered automatically. Essentially the foot temperature was monitored actively, if it fell to one of the thresholds outlined then they are given the option to suppress an alert and apply heat or notify the appropriate contacts of their condition.

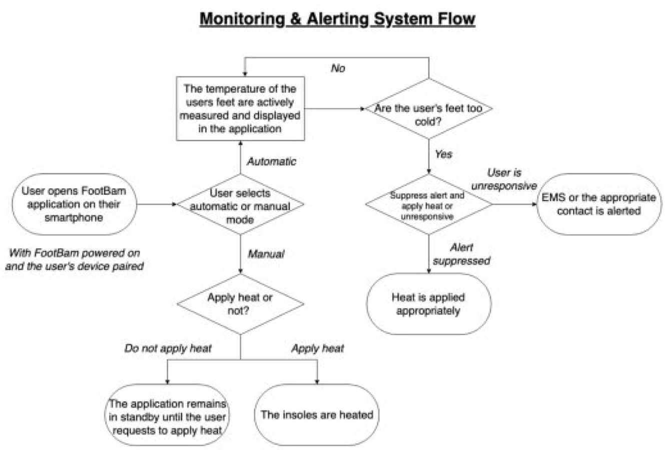

Fig. 3. Smartphone application flowchart to decide if alerts should be sent to EMS or if the heating pad should be triggered. Note the first step selecting automatic or manual mode is made by the user in the application UI.

D. Fabrication and Assembly

The physical prototype device itself is wired together in the fashion illustrated in Figure 1. The insole was modeled for a users shoe and printed on a 3D printer. The components were mounted accordingly.

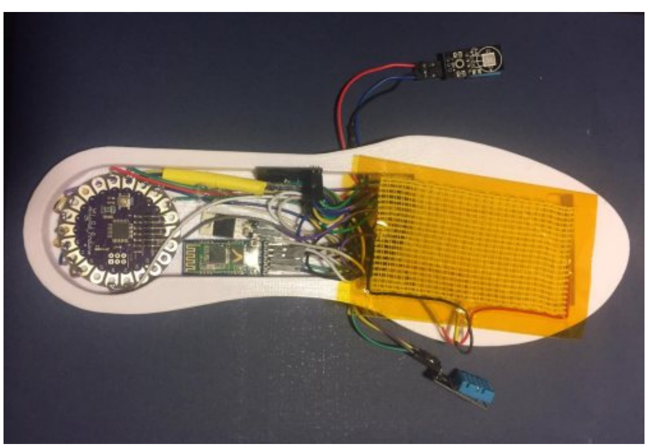

Fig. 4. Depicted is the physical prototype of the device. All hardware components are connected and adjusted to fit within the 3D printed insole.

E. Testing Procedures

The prototype device has been preliminary tested on few select users. The test consists of having the user manipulate the temperature and observe the changes displayed on the smartphone application. When the device is not sensing heat from a human body the device automatically triggers the heated insole and emergency alert as expected.

III. Results

The prototype developed based on the details outlined in this paper was tested on multiple users, and was met with overall positive feedback by those evaluating it. The prototype was able to successfully measure the temperature of a users foot and trigger both the heating pad and alerting system accordingly via an Android smartphone. Ultimately, the project achieved its goals as a prototype but will require further adjustments in order to make it a robust and commercially viable product.

IV. Conclusion

While the prototype has achieved its objectives, further improvements to the design of the system are planned. One fundamental improvement is to incorporate temperature sensors better suited for measuring the temperature of a person's skin. The DHT11 temperature and humidity sensor used in the prototype is not designed to measure body temperature. It was selected as an economical alternative for the proof of concept prototype. Furthermore, better sensor readings and calibration would allow for an individual to have personalized alert triggering thresholds. This would increase the viability of the device to be deployed as a commercial product as personalized thresholds would mitigate false alerts, increasing accuracy and reliability. Moreover, in order to make the device commercially viable, custom hardware would have to be developed to ensure consistent device functionality and ease of use.

Given that the device could be worn by the user for the majority of their day, and the device would be continuously transmitting data on the health of their feet, it presents an opportunity for predictive healthcare analytics to be implemented. Remote monitoring systems designed prevent diabetic foot ulceration [7] could benefit from such data and improve patient outcomes in healthcare. Such application would involve collecting data from users devices and analyzing it in such a way which may allow for medical professionals or algorithms to predict medical issues in patients before they arise or become severe [8]. This could allow the system described to potentially serve as a means to improve medicine.

Ultimately the system and prototype developed were effective in monitoring the temperature of a user's feet and taking action accordingly. This fact could potentially improve the lives of over 400 million people with diabetes globally [9]. Conclusively, by applying predictive analysis on the data collected by the system, the scope of this project could allow for medical professionals to take action even before the alerting system notifies users and third parties of a serious health risk.

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