UCL DEPARTMENT OF MEDICAL PHYSICS AND
BIOMEDICAL ENGINEERING

Undergraduate Project Tracking Sheet

Module Code:	MPHY0042		
Module Title :	**Medical Physics and Biomedical Engineering Research Project**		
Coursework Title :	**Final Report**		
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1) **Hand in a hardcopy to the main Reception Office (2nd Floor, MPEB).**

Coursework Deadline:	**26 April 2021**
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Mark (%):

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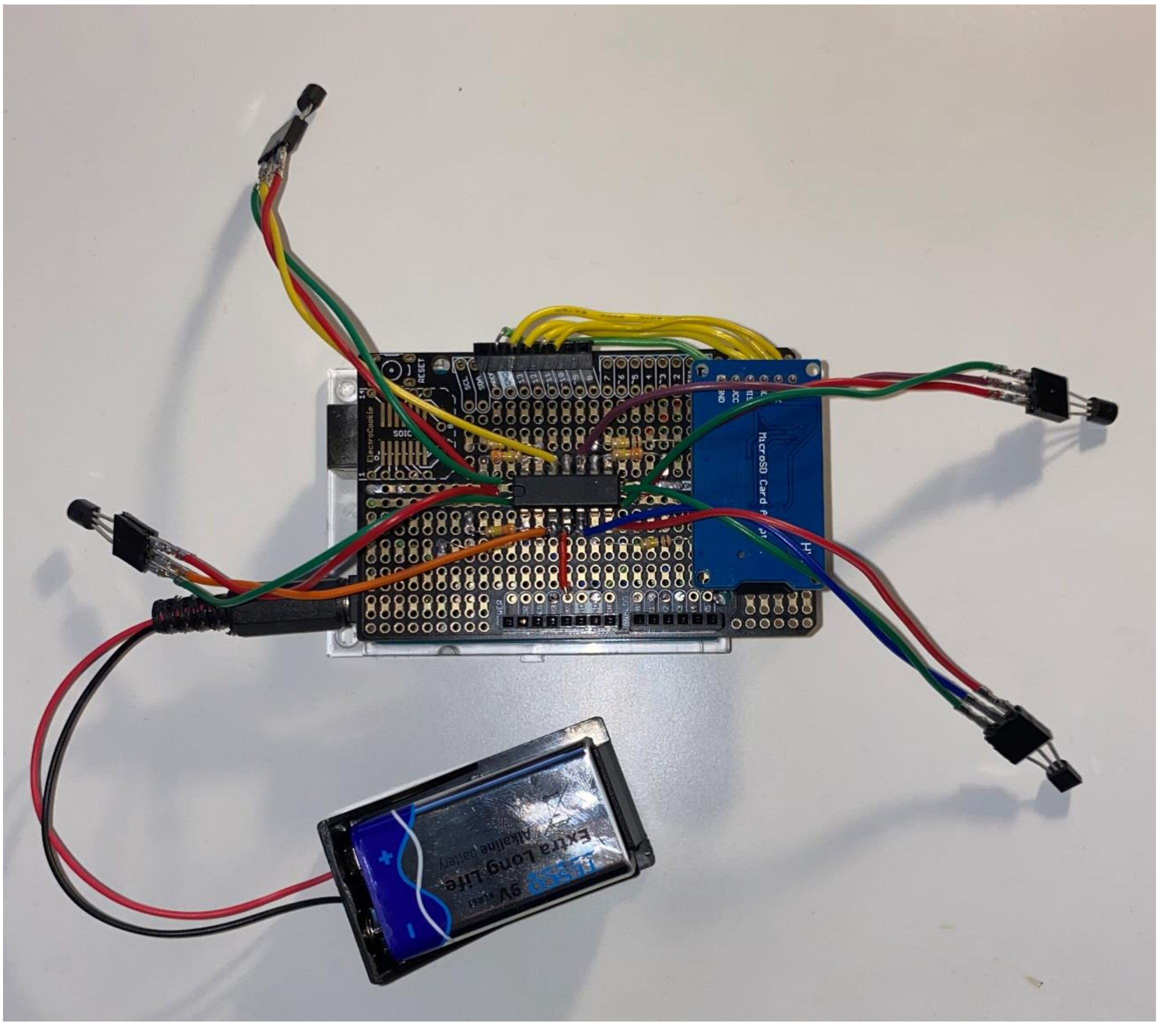
Reason for late submission of course work:

SYSTEM FOR IN-SHOE TEMPERATURE MONITORING OF FEET


MicroSD Card
Extra Long Life

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ABSTRACT

10% of the people that have diabetes suffer from diabetic foot ulcers. Diabetic foot ulcers are extremely difficult to treat and debilitating. They can lead to amputation and even death if not treated in time. They often lead to lengthy hospitalisation and high medical expenditure. It is important to predict the occurrence of diabetic foot ulcers before they happen. Measuring temperature is one way that can be used to predict the occurrence of diabetic foot ulcers. Studies show that areas of the feet that are more likely to get ulceration experience high temperatures compared to other parts. The aim for this project was to make an in-shoe temperature monitoring system that will be used to measure the temperature of feet. The system is compact, effective, and reliable further tests of the device is needed before it is used on patients, but the device works as intended.

INTRODUCTION

AIM:

The aim of this project is to create an in-shoe temperature monitoring device or system that will be used to measure the temperature change of feet for people with diabetes. The system must be effective, sensitive, and compact, portable, and easy to use and inexpensive.

WHY IS IT IMPORTANT?

Diabetic patients are more likely to suffer from diabetic foot ulcers. Studies show that measuring the temperature of feet can be an effective and simple way of predicting and reducing the occurrence diabetic foot ulcers[1,2] and is an accepted method in helping preventing occurrence of diabetic foot ulcers[3]. One of the most common symptoms of a disease is increased temperature at areas of inflammation[4]. Evidence suggest that monitoring plantar foot skin temperature at home is more effective than standard treatment procedures[1,5], such as ambulatory activity. Trials on measuring temperature shown that areas with increased temperature were likely to develop ulcers[6,7,8]. This could help with early prevention and reduce the incidence of diabetic foot ulcers.

In this report I will be going through how the system was designed; I how I picked the temperature sensors, the way I went through with the signal conditioning, the code I wrote for the device and the data storage and the future improvements. The system I have created is small and can fit anywhere. Results are provided to show that the device is working as intended. I will also discussion how temperature recordings will be used to predict the occurrence of the disease.

Current methods being used are either bulky, poor or must be replaced time and again and can be expensive. Sometimes the devices are not easy to use, and the patient can may find monitoring their temperature, a burden[9]. Patients prefer a system that is easily available to use. The in-shoe temperature monitoring device is small and will be placed comfortably in sole of shoes, which makes it very easy to use. The shoe with the device can be used daily, which will decrease the chance of the patient getting ulcers[10].

BACKGROUND

Diabetes affects a lot of people in the world. In 2019, roughly 463 million of adults (20-79) had diabetes and it is expected to rise 700 million cases in the world [11]. It is a major cause of blindness, kidney failure, heart stroke and lower limb amputation. Its symptoms are increased thirst, frequent urination, unexplained weight loss, slow healing sores, and frequent infections such as skin infections to mention a few.

In this project, I will be focussing on the slow healing of wounds and frequent infections of the skin that happen to patients with diabetes, which will lead us to diabetic foot ulcers. Since the body cannot produce enough insulin for to convert the glucose in the blood to glycogen, this results in excess sugar in the blood. Excess sugars can injure the walls of the capillaries that nourish the neurons, especially those in the legs[12]. It leaves the skin susceptible to diseases including bacterial and fungal infections[12]. This is called diabetic neuropathy and diabetic nerved pain. Diabetes can lead to diabetic foot ulcers (DFU), which when not treated, they may lead the patient with diabetes have their legs amputated and we do not want that. 10 % of people with diabetes develop DFU at some point because it damages the nerves in the feet[13] . Diabetic foot ulcers can lead to the patient dying if not treated well in time[14]. The mortality rates are estimated to be 5% in the first twelve months of having DFU and 42% in the 5-year mark[14].

To give a description of what DFU is; Diabetic foot ulcers happen when the wound on the feet takes longer to heal and can even get worse when the wound gets infected by bacteria or fungus or viruses. It happens to patients who have diabetes as said in the paragraph above and is often followed by amputation of the patient's leg/s if not treated fast enough. It estimated that in every 30 seconds somewhere in the world, at least one limb is lost due to diabetic foot ulcers[15]. It is a significant complication of diabetes mellitus[16]. The causes of DFU include neuropathy[17], trauma, high plantar pressures[51] to mention a few and study show that 60% of the DFU result from the causes that I mentioned[18]. It often leads to hospitalisation of the patients with diabetes and causes expensive medical expenditures if the patient has a lengthy stay in the hospital[11,12]. National health service(NHS) in England spends around £650 million every year on complications of diabetes[19,20] and $58.6 billion is spent yearly in US to combat diabetic foot ulcers[21,22].

Diabetic foot ulcers are difficult to treat and are extremely debilitating[23]. But can DFUs be prevented? Yes, and the simpler way is for diabetic people to take care of their feet and checking with the doctor at least once a month and wearing the right shoes to reduce pressure the feet[23]. Can you predict it? It is possible to predict the occurrence of diabetic foot ulcers and hence help prevent them. You can do this by measuring the temperature of the feet. Elevated temperatures can sure area of inflammation and can be an early warning sign of foot ulceration[24]. High temperature gradients may predict the onset of neuropathic ulceration and self-monitoring may reduce the risk of ulceration[25]. So, I want the aim of the project is to build a circuit that will measure the temperature of the feet with high sensitivity and specificity. The system will have an efficient algorithm for early detection of the ulcers.

The proposed method of measuring temperature comprises of four sensors, which will be placed on different parts of the foot, signal conditioning circuit, analog to digital converter which is a microcontroller, the data storage section, and the power supply for the entire system. The microcontroller is Arduino Uno. It has a lot of open-source code that can be used.

METHOD

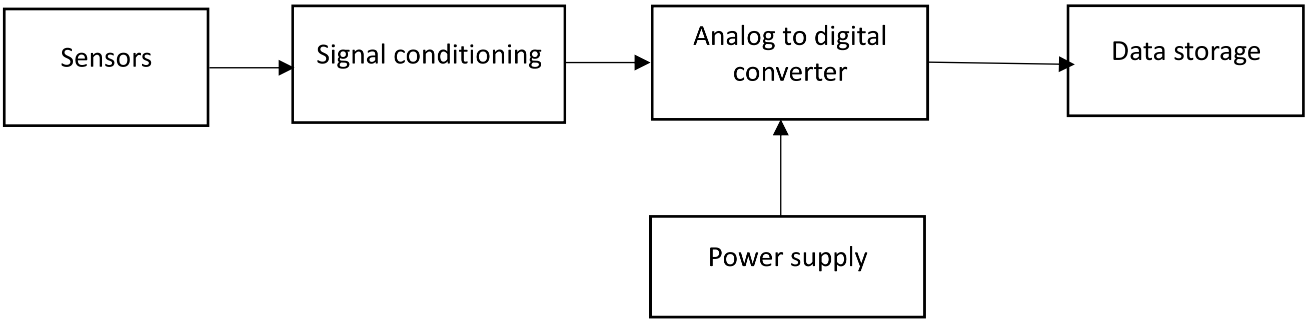

Figure 1: schematic flowchart of proposed method

Sensors

The device I created makes use of a total of four temperature sensors. To choose the sensors, was looking at the size of the sensors, the linearity, sensitivity, and the ease to make the signal conditioning circuit and ability to be used with Arduino and the availability of the sensors in the lab.

First, I looked at the different types of temperature sensors that available. There are four types of different types of temperature sensors[26]:

Negative temperature coefficient- (NTC) thermistors: I did the project before and I used a thermistor by then and from that project, even though are small, they require calibration and the don’t have linear sensitivity.

Resistance temperature detectors (RTDs).

Thermocouples: I could not use them because of their size alone.

Semiconductor-Based sensors**:** The come in different packaging styles and I looked at the sensors with TO-92 package as they are small and cost less and have a low power consumption compared to other packaging[27]. They have low self-heating and will not in anywhere present burning sensation to patients. The sensors also offer linear response[111].

I choose to work with TMP36, see figure 2.

Size: the reason why I was picking a temperature sensor looking at the size, is because the sensors are to be embedded in the sole of a shoe and small sensors will not cause discomfort to the wearer of the shoes.

Tmp36 is small and has the following dimension: 4mm x 4mm x 3mm.

Sensitivity: TMP36 has a sensitivity of 10mV/°C and directly calibrated in °C which makes them much easier to work with[28].

Linearity: the temperature sensor I wanted to work with had to have linear, so it is easy to get then temperature readings. TMP36 has ±0.5°C and gives 750mV at 25°C and has a temperature range of −40°C to +125°C[28]. The linearity makes it easier to come with equation to calculate the temperature after the signal conditioning. See figure 3.

The voltage operation TMP36 is between 2.7V to 5.5V. from this, I know it can be used with Arduino as the supply voltage from is 5V. The sensor draws very small current, maximum of 50µA and this is important as the system will be powered with a battery and I want the battery to last longer.

SIGNAL CONDITIONING

As stated above the sensor's description, the voltage output of the TMP36 at 25°C is 750mV. But I want to amplifier even the subtle voltage changes due to temperature change. The sensor doesn't need any noise filtration. To consider the amplification, I looked at the resolution given when I measure the temperature without it:

Arduino analog to digital voltage range is 0V to 5V and there are 1024 levels at 10 bits in Arduino uno.

Voltage per division for the levels: $\frac{5}{1024}$ = 4.88mV

And the resolution is: voltage divided by the sensor sensitivity, 10mV/°C: $\frac{4.88}{10}$ = 0.488°C. The resolution is low, so amplification is needed.

First, I choose the temperature range between which I wanted to amplify the voltages. Which is 15°C to 40°C. The reason for this temperature range is because feet temperatures can range from 15.6°C in the winters to 37.5°C in the summer, independent of sex and age[33].

The temperature gives a voltage range of 650mV and 900mV and by amplifying these voltages, the resolution will increase. They amplified voltages fall between 0V and 5V.

Using this formula, $V_{OUT} = A(V^{+}-V^{-})$, where A is the gain, I calculated the max gain to be 5.556; 5V = A(0.9V). I used a non-inverting amplifier: $A = 1+\frac{R1}{R2}$. R_1 = 330kΩ and R_2 = 100kΩ giving a gain of 4.3. I choose the resistors looking at then availability and the closest I could get to the maximum gain required. To get the resolution, divide the voltage per division with the gain and the sensitivity: $\frac{4.88}{4.3*10}$=0.11°C and this resolution is sufficient.

Since I have four sensors, looked for a quad op-amp and I landed on LM324AN.Quad op-amps have four amplifiers in one package and hence make the circuit smaller. Any quad op-amp can be used. The op-amp requires very low supply current and has power supply voltage range of ±1.5V to ±15V, which makes it easier to power with Arduino. Having a quad op-amp reduces the PCB footprint making the signal conditioning as small as possible. The circuit was tested using a myDAQ to make sure everything was working as intended. After building the amplifying circuit on a breadboard, the circuit was then soldered onto a PCB.

See figure 4 in appendices

ANALOG TO DIGITAL CONVERTER.

Arduino UNO is used as the brains of the device. It converts all the voltage readings to temperature and stores them in an SD card.

The code:

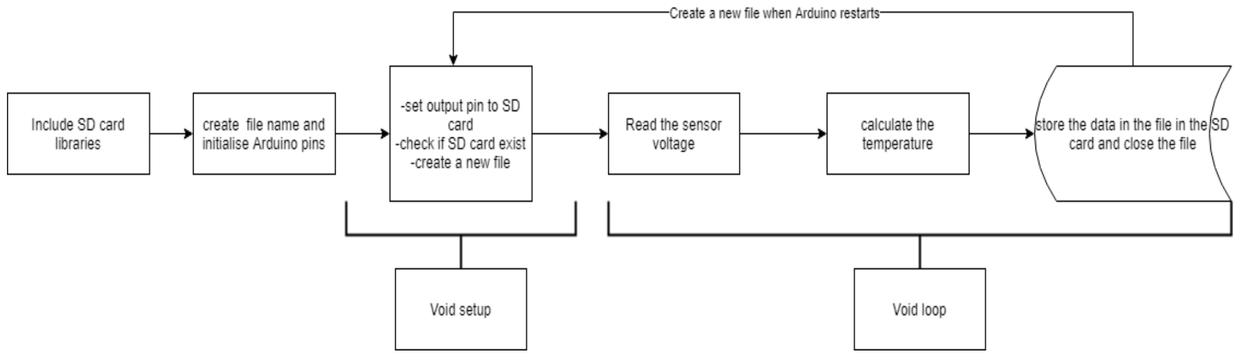

Figure 5 code flow diagram

Since I will be saving to an SD card, I included the SD card libraries. The SD card inserted in Arduino SD card module which is solder to the PCB with the amplifying circuit and the sensors. When picking the SD card module, I looked its ability to be used with Arduino and the one I used, requires a minimum voltage supply of 3.3V and hence can be used with Arduino. The module is also cheap and if the device is ever commercialised, it will not be expensive to make. To save the temperature to the SD card is important, because we want it to be accessible when we need to check for the temperature changes. In the SD card, the code creates a new filename each time Arduino is powered, and the temperature readings are recorded in that file. The makes sure that every time, the recording starts, the previous recording is not overwritten. The files created are csv files. This makes it easy for anyone with the data to visualise it with excel. In the future, I will add real time clock, to make sure the date and time which the data was recorded is also recorded. This will make the data tracking much easier. And I will add lines of code and a beep to alert the user to insert an SD card in case they forgot.

Sensor voltage reading: in the code I made sure that 50 readings are taken for every reading. The readings are then averaged. This makes the readings stable and reduces fluctuations in the readings. It acts as some form of filtering. The code makes use of a for loop, to avoid code repetition for averaging:

```
for(int i = 0; i < 50; i++) { // Average 50 readings for accurate reading
  reading += analogRead(sensorA);  // reading from sensor 1
  reading2 += analogRead(sensorB);  // reading from sensor 2
  reading3 += analogRead(sensorC);  // reading from sensor 3
  reading4 += analogRead(sensorD);  // reading from sensor 4
  delay(1); // there is 1 millisecond between each of the 50 readings.
}
```

The voltage readings are then converted to temperature readings:

Arduino reading x 5/1023 to convert the readings to voltage.

Temperature = 1000/43 x voltage reading – 50:

The readings are taken at sampling rate of 1 temperature reading per minute. There is a delay between taking one reading and the next. As part of future aims, I will write part of the code such the code commands the device does not start recording for 10 seconds after power supply has been attached to the device. This gives the sensors time to reach the body temperature and saves space in SD card. Another part of the code runs the code for 1 hour then terminates the recording of the temperature data to the SD card and stops the coding from running by putting Arduino to sleep, until the battery reattached again. This saves power and makes the battery last longer. This will make it easier for patients to use the device without with having a burden to always check if the device is switched off to save power.

DATA STORAGE:

The device makes use of 14.5 GB SD card. After recording the data for an hour, the file size is 8KB, which is very small. It will take 1812500, which is a lot. So, we do not worry about the memory ever running out. Storing the data in microSD card makes very easier to read the data at any time, when its needed. Its convenient and cheap to replace.

BATTERY

The device makes use of 9V battery with a capacity of 1200mAh. To calculate how the battery will last, I first calculated the current drawn by each Arduino pin I used.

The input/output pins of Arduino: 40mA max

I used 4 analog pins and 4 digital pins giving a total of 320mA. This is the maximum current that all the pins can draw from the power supply. This gives a total time of battery usage of 3 hours 45 minutes.

The temperature sensors draw: 50uA X 4.

The amplifier draws a maximum current of: 375uA.

The microSD card draws a current of: 13mA when not in use[29].

This gives a current of 13.575mA that is drawn by the whole device. And total time the battery last is 88.39779006 hours. Given that the recordings are done for only 2 hours daily, this the battery will for 44 days from the day of use.

SENSOR PLACEMENT

Diabetic foot ulcers can occur on any part of the foot, either the plantar or dorsal of the foot. Approximately half of Dfu happen on the plantar of the foot[30], hence the sensors of the device are on the shoe in sole, to measure the temperature of the plantar of the foot. The sensors are placed on certain areas of the insole, the feet pressure points. These are areas prone to getting ulcers over time[31] and where foot comes in contact with the ground or the shoe insole, and this will mean good contact between the sensors and the foot.

Sensor 1: toe, Sensor 2: first metatarsal, Sensor 3: fifth metatarsal and Sensor 4: heel.

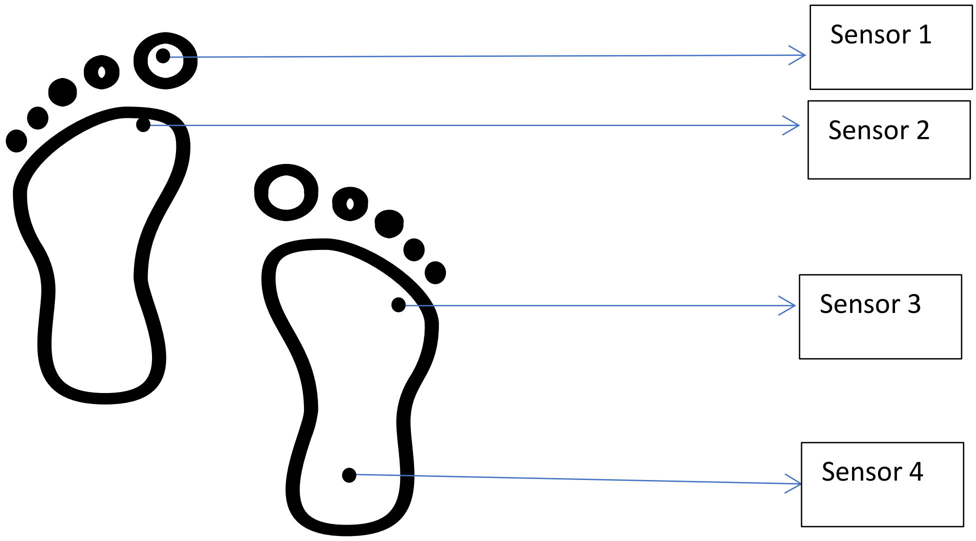

Figure 6 placement of sensors

RESULTS

All the temperature data is saved to the microSD card with different filenames, as said above. Figure 7 shows how the data is stored in the file. The way the files are named helps keep track of which data was recorded first. After an hour of recording, this is what the temperature data look like: figure 8 in appendices. I recorded the temperature of my room for 1 hour, at two different times of the week. The first graph, figure 9 shows sensor 4 with temperatures going to 36°C, which indicates when the wiring in the circuit is broken. The graphs show different temperature for the sensors because the sensors, when recording the temperature, have a different placement on the table and the temperature of the table influences the difference. The data is plotted in excel to see how the temperature changes over time. The second graph, figure 10, shows less fluctuations because I resoldered all the wires, creating secure connections.

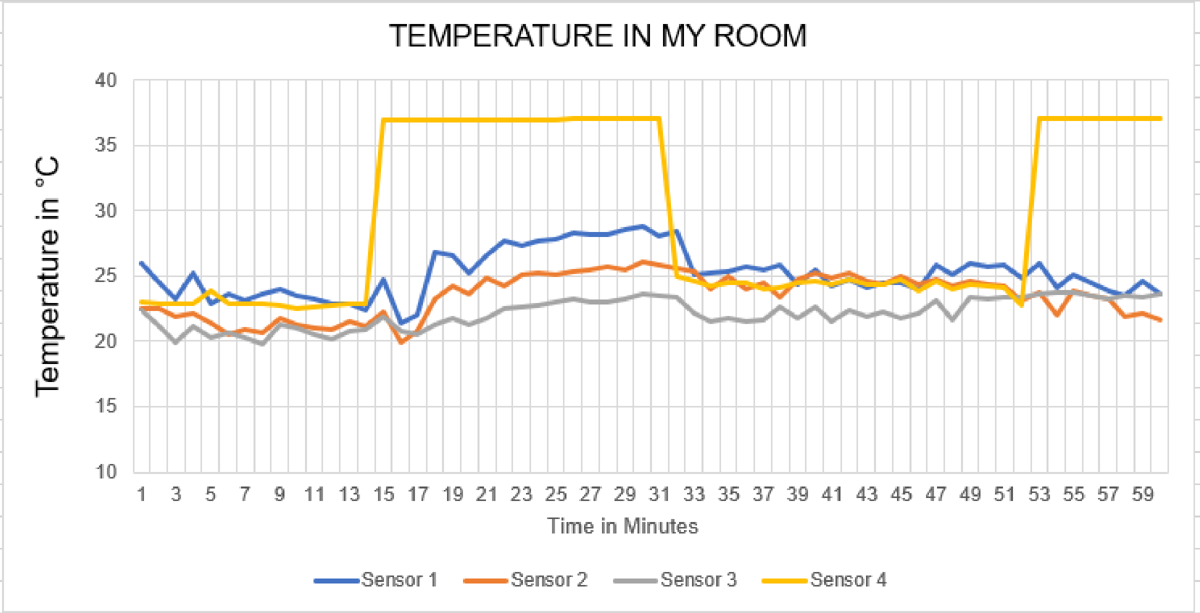

Figure 9 Sensor 4 shows that the wire connection in broken.

The temperature increases between the 17th minute and the 31st minute because the heater was turned on. And the shows a decrease and becomes steady after the 31st minute. The heater was turned off.

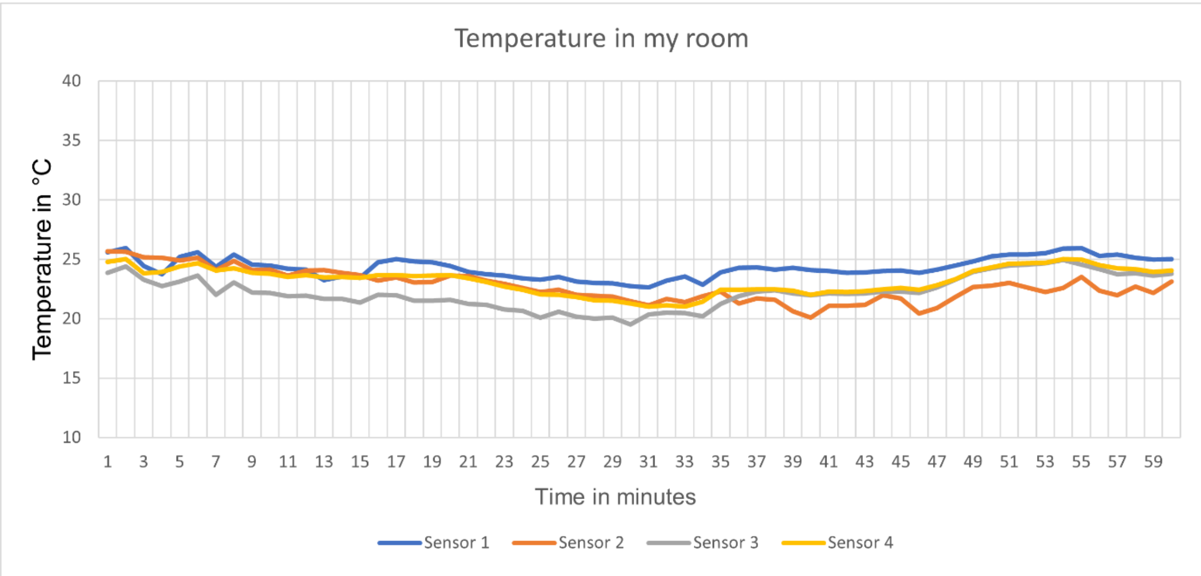

Figure 10

DISCUSSION

From the results, the temperature measured in my room remains steady. The device measures temperature accurately when the temperatures are compared to the one on the thermostat. But the sometimes the temperature was lower when compared to the one on the thermostat, which can sure that, the thermostat is not really that accurate in measuring the temperature of the room.

After measuring the temperature of the feet, compare the temperatures to a reference temperature from a healthy foot . The reference temperature can be around 30.6±2.6 °C for healthy feet[32], the average awake temperature of feet. A temperature difference of 2.2 °C or above between then feet, and the reference temperature, this is a sign that foot ulcers might be developing[33,34,35], given the temperature difference stays consistently above 2.2 °C. This was shown in a study, that found that a week prior to formation of an ulcer, the areas will ulcerate had a temperature 4.8 times greater than their contralateral counterpart[36].

An increase in temperature, indicates an inflammation and risk of ulceration, as mentioned in the introduction. One of the factors that lead to the formation of diabetic foot ulcers is, autonomic neuropathy: it causes increased peripheral blood flow and distended foot veins and warm foot[37]. Thus, this will mean the temperature of the feet increase significantly. Studies sure that monitoring temperature can reduce the incidence of diabetic foot ulcers by 62%[38], also as mentioned above. In a clinical study, patients who did temperature monitoring had a significant decrease in ulceration occurrence[4].

After getting this information, early prevention methods can proceed. 50% of the patients who monitor temperature are less likely to develop ulcers[9]. The patient can be referred to a healthcare professional or people who are best qualified to help the patient. Further tests can be done, such as assessment of diabetic peripheral neuropathy (DPN) [39], to check for the presence of DPN. The test is made by determining the presence or absence of sensation in the foot. A risk assessment can then be carried out to identify the areas where the prevention strategies can be focussed. International Working Group on Diabetic foot(IWGDF) guidelines on risk assessment can be followed[40]:

Category	Ulcer risk	characteristics
0	Very low	No LOPS and No PAD
1	low	LOPS or PAD
2	Moderate	LOPS + PAD, or LOPS + foot deformity or PAD + foot deformity
3	High	LOPS or PAD, and one or more of the following: • history of a foot ulcer

LOPS: Loss of protective sensation, PAD: peripheral artery disease.

Having measured an elevated temperature change, and if the patient is at category 2 or 3, different interventions for the prevention of the formation of the ulcers are used. These include regular inspection and examining the foot[41], education about the disease[42,43,44], the proper foot care[45], recommending the right footwear[46], wearing the right footwear proves to be very effective in preventing the occurrence dfus[47] and treating the risk factors. Pre-ulcerative signs, increase in temperature in this case, can be strong indicators of the possibility of DFU happening in the future[48,53].

I managed to achieve the aims of the project except, I did not manage to calculate the specificity and sensitivity, due to lack of resources, an accurate thermometer to compare the values with. In the future, I would measure temperature and compare to the ones measured by the device, so I can calculate the accuracy, sensitivity, and specificity.

During the design of the device, the wires tended to break even after soldering them. This was because the wires are too stiff, and this can be solved by using very flexible wires.

Also, to lack of resources, I did not manage to add a switch to cut the power off. I included this as part of future work.

The total cost of the device is: £36.93. This is cheap compared to other methods used to measure temperature.

CONCLUSION

Diabetic foot ulcers can lead to amputation and even death[49]. Temperature is a good way of predicting the occurrence of diabetic foot ulcers, as studies show. I have created a device that is both reliable and sensitive to temperature change as one way that can be used to measure temperature of feet. Temperature difference of 2 °C or above ,can be a sign of inflammation and patient may need early prevention or not. Prediction can help with early prevention and treat, which saves money and time. After the prediction of the occurrence of the ulcers, further steps can be taken that will to stop the ulceration from occurring. Steps like recommending appropriate footwear, education of the disease, offloading and proper foot care. The device I made is cheap to make and easy to use, for patients and can be used to at home to measure temperature, which proves effective in predicting occurrence of DFU[50].

FUTURE WORK

- Make it wireless and create a phone application for live monitoring[51]. The wireless system will make use of Bluetooth module.
- Temperature sensors on both feet and synchronise them. That way you can compare temperatures on both feet and see which foot is more likely to develop foot ulcers.
- Make it less bulky by using a smaller size Arduino. This will make the device even more appealing and easy to place in shoes.
- Include a switch on/off button to control when the data starts being recorded. Together with a switch, include a LED light that indicates when the device started recording.
- Make it water resistant. This that, given that the patient sweats, the sweat does not cause a short circuit in the device.

APPENDICES

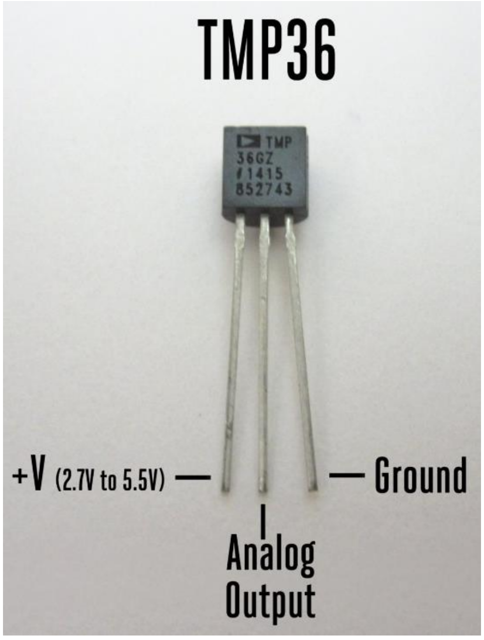

Figure 2

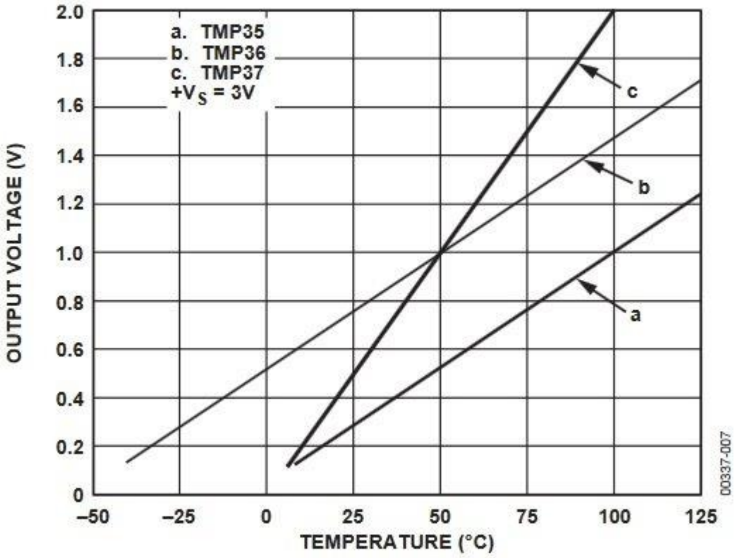

Figure 3 graph showing the linearity of TMP36

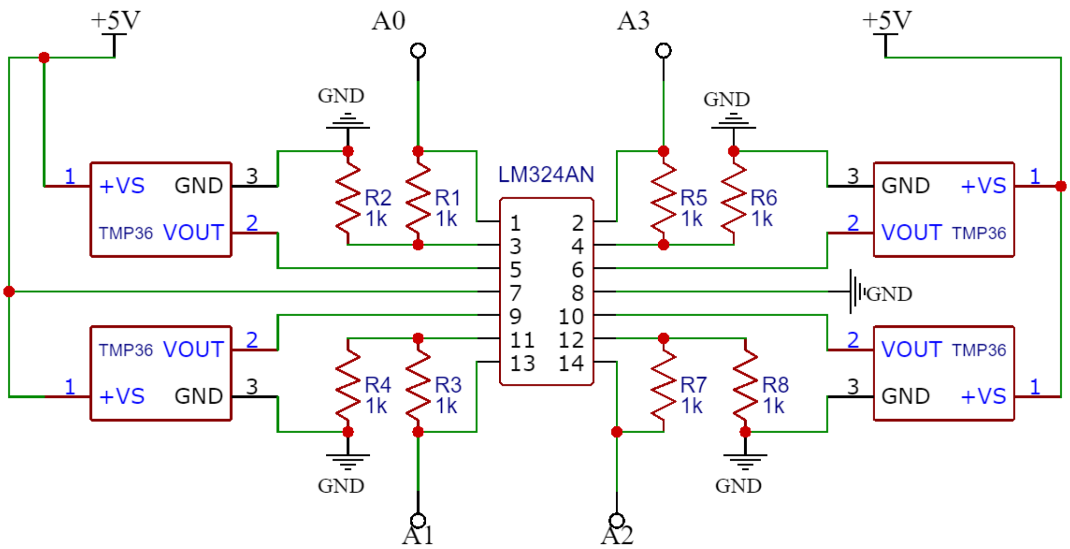

Figure 4

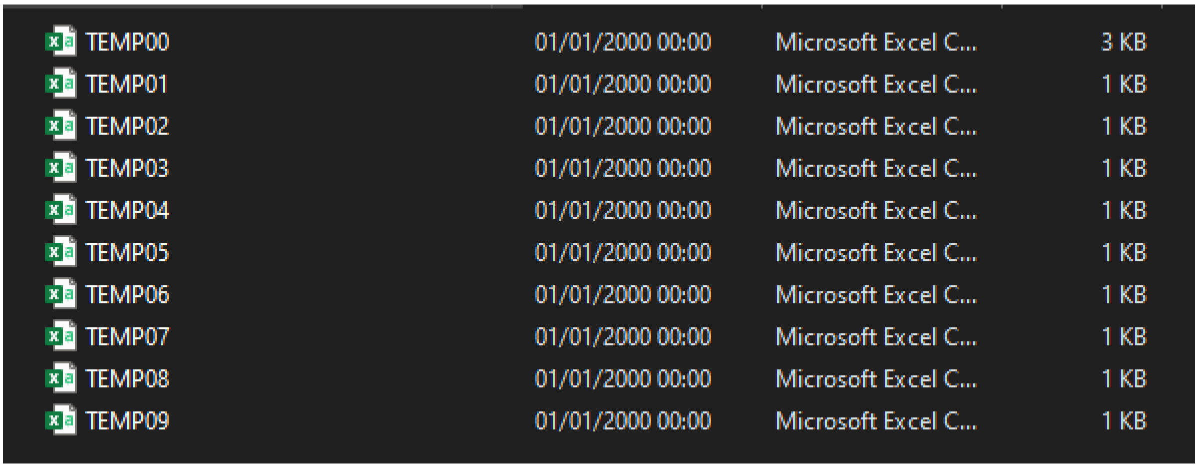

Figure 7 folder with different temperature data.

Sensor 1	Sensor 2	Sensor 3	Sensor 4
23.18	22.06	20.93	21.95
22.96	21.95	20.48	21.5
22.73	21.83	20.37	21.61
23.52	22.17	20.15	21.72
23.18	22.06	20.82	21.83
22.84	21.95	20.15	21.61
22.17	21.83	20.48	21.61
22.39	21.83	20.15	21.5
22.51	22.06	20.26	21.38
22.96	21.95	20.37	21.61
23.29	21.95	20.6	21.61
22.84	21.72	20.6	21.38
22.96	21.83	20.93	21.5
23.07	21.61	20.48	21.61
22.96	21.72	20.37	21.5
20.82	20.93	20.26	21.05
23.29	21.72	20.37	21.38
22.62	21.61	20.37	21.38
22.73	21.5	19.47	21.38
22.84	21.83	20.37	21.27
22.84	21.61	20.37	21.61
21.95	21.16	19.13	21.27
22.06	22.06	19.36	21.27
22.84	21.61	20.37	21.27
23.07	21.61	20.15	21.27
22.39	21.16	20.03	21.16
23.07	21.61	20.26	21.38

Figure 8

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