Diabetes Mellitus is a major concern in diabetes management all over the world. According to new findings by health researchers, every 30 s an extremity is amputated due to diabetic neuropathy. Furthermore, research shows that 15% of diabetic patients develop foot ulcers during their lifetime [1]. Unfortunately, early detection and treatment of foot ulcers are either infrequent or misdiagnosed. Due to this lack of awareness by both the primary caretaker and the patient, the complications are exacerbated and degrade to issues such as gangrene, Charcot's foot, foot ulcers and finally amputation [2].
Foot ulcers are developed in diabetes due to sensory neuropathy, trauma, and deformity. Foot deformities result in high pressure in local focal areas on the foot[3]. Therefore, an inshoe monitor is required to help in managing the formation of ulcers.
There has been a steady increase in awareness of tracking blood glucose level, healthy lifestyle etc. but unfortunately, complications such as foot ulcers caused due to diabetes are understated and ignored. This not only leads to physical agony and a decreased standard of living but also is an expensive financial affair in the long run. According to a few studies, it is one of the most common causes of hospitalization for a diabetic patient. Furthermore, these patients incur indirect costs such as the inability to attend work, premature retirement, and premature morbidity [5].
Currently, foot ulcers are diagnosed by doctors when the patient is affected by them. Solutions exist according to the risk that the patient faces. Table 2.1 describes the solution for various risk levels

Table 1.1: Current Solutions available in accordance with the risk level [3].

Risk Level	*Symptoms*	*Current Solution*
Low Risk	Normal Sensation No high pressure	Microcellular Rubber(MCR) Footwear
Moderate Risk	Loss of protective sensation	MCR Footwear with add-ons such wedges, straps etc
High risk	Loss of protective sensation Intrinsic muscle paralysis High-pressure areas	Braces AFO(Ankle/Foot Orthosis) Total Contact Cast

Other methods to treat diabetic foot complications are medical management and surgery. Medical management includes prescribing antibiotics and various gels. As can be seen in Table 2.1, current solutions are heavily dependent on clinical diagnosis. The footwear design also needs to be customized according to the foot structure of the patient. After extensive research, it has been concluded that therapeutic footwear is not effective because in most cases they are not modified according to the patient's needs [4]. Also, other subtle yet important factors such as material softness, plantar offloading etc. are not considered.

The other alternatives such as medical management and surgery are very expensive and time-consuming and other factors such as late diagnosis or procrastination due to expenses of early treatment leads to amputation.

Several papers have been studied to understand the different pressure focal areas of the foot. Ulceration is mostly susceptible in particular regions of the foot. This is discussed briefly in the paper by David G. Armstrong et. al This study was done by evaluating 360 medical reports of people suffering from diabetic foot ulcers and several parameters were tested such as sensory neuropathy, vascular insufficiency. In this study, the wound locations have been underlined using the Texas Diabetic Wound Classification system [6]. The wound severity has also been mentioned as shown in Fig 2.1. These wound locations have been used in determining the position of the sensors for this project.

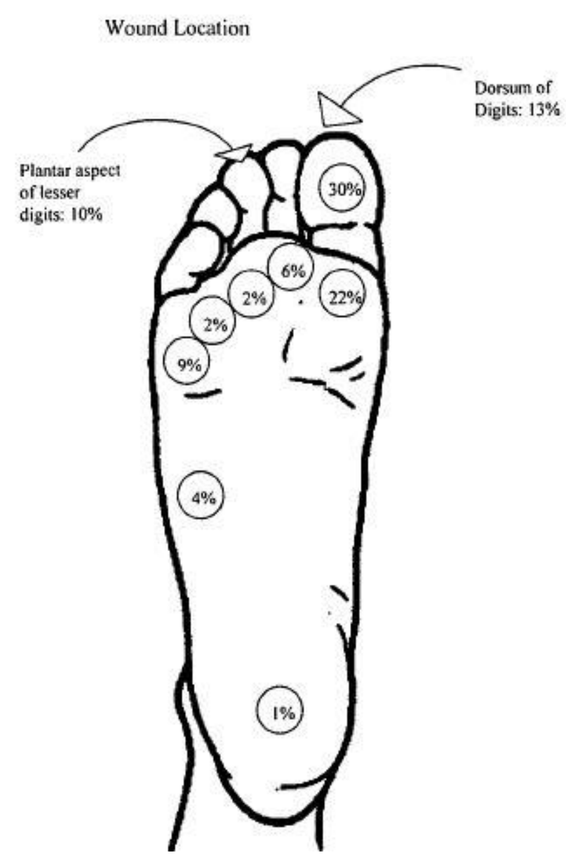


Fig 1.1: Wound locations and severity of wound [6]

Studies also point at the inappropriate footwear used by diabetic patients which increase the risk of infection and new ulcer formation. Customized footwear is absolutely necessary for diabetic patients. These types of footwear are also known as medicated footwear and are developed considering the offloading principle. In offloading, the aim is to remove the pressure from the site of the ulcer. The present footwear includes rocker bottom and wedges. The examples of these types of footwear are shown in Fig. 2.2.

Fig 1.2: Rocker Bottom and wedges shoes [7]
(Courtsey: indiamart.com/supad/diabetic-footwear.html- Open Source)

Many researchers have also used pressure sensors to measure the pressure applied by the patient. They have been calibrated using the weight of the patient. The sensors are taped on the insole of the shoe or on the sock and the patient is made to walk. Such studies revealed that the pressure applied is maximum under the heel and forefoot areas [8].

Therefore, our idea is to provide a real-time diagnostic-cum-therapeutic wearable shoe-insole. This smart insole tracks the pressure on the foot that is caused by either foot deformities or trauma.

The idea of tracking the pressure is to warn patients when pressure is applied on the existing wounds in order to avoid further complications. Also, foot deformities disturb the normal gait of the patient. Our device aims at representing these changes visually either on a smartphone or through simple light (LEDs) or a sound alarm system. Various readings of the sensors will be sent from the insole to the smartphone or cloud by using wireless technology such as Bluetooth modules.

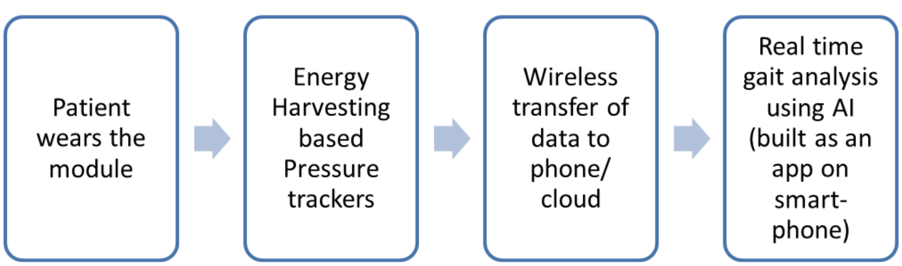


Figure 1: schematics of the device

The unique feature of our smart diabetic shoe is the biomechanical design of the insole. Our technique is to provide off-loading of the plantar region while the person is walking. The design is novel as the material used for the insole will consist of constant force springs or other nonlinear force springs. This feature would only allow a constant force over a range of motions hence restricting excess pressure in wounded regions.
Another unique selling point of our device is the use of energy harvesting mechanisms. Which means that the electronics in the insole will be powered by using the energy generated while the patient is walking hence obviating the need for a bulky conventional battery.
We plan to integrate all this information on a smartphone using an app. It will analyze the patient's foot and act as a tool for patients to understand their gait and modify it according to the suggestions given by our app. This would be done by using different machine learning and artificial intelligence techniques.
An example of a sample analysis would consist of placement of the rocker for better offloading, placement of wedges for decreasing shear stress, an appropriate degree of softness of the material used for the footwear. By saving the patient's data, clinicians can give better counseling to their patients.

In this project to measure the pressure at the focal points, piezo-electric sensors are used. The motivation to use these sensors is its inherent properties that it possesses. Piezoelectric materials are those materials which produce an electric voltage due to mechanical stress applied to the material. Exploiting this property of the piezoelectric material, we use these sensors to measure the pressure in terms of voltage.
The piezoelectric material can be used as both sensor and actuators. Usually, polymer piezo films are used in sensors [9]. Piezo ceramic discs can also be used as both sensors and actuators. The main features of piezoelectric materials are compactness, sensitivity over a wide bandwidth and ease of use [9].
PZT's are most commonly used piezoceramic sensors; they constitute of a solid solution of lead zirconate titanates. These are formed by mixing lead, zirconate and titanium oxide powders at a temperature of 800-1000 ^{0}C. While it cools down the material transforms from a paraelectric to ferroelectric phase. This changes its shape to being tetragonal [9]. At this point, there are still no piezoelectric characteristics, due to random orientation of the dipoles. When a high voltage electric field is applied, the dipoles align. Even after the removal of the high D.C. voltage electric field the dipoles remain aligned due to the strong dielectric property of the ceramic [10]. The orientation of the dipole is in the upward direction.

Piezoelectric sensors

The piezoelectric pressure sensor has two leads; one is the positive lead which is depicted in red in Fig 3.3 and the negative lead is depicted in grey in Fig 3.3. The positive lead is soldered in the ceramic area of the sensor and the negative lead is soldered on the outer ring of the disc.

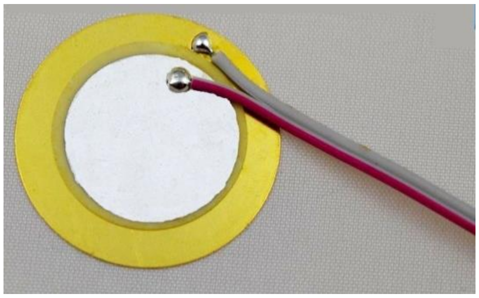


Fig 1.3: Piezoelectric Ceramic disc
(Courtsey: www.alibaba.com- Open Source)
Other parameters are for motion, gait analysis and temperature.

such as pressure,accelerometer, galvanic skin response, flex, piezo-electric film and temperature sensors. These sensors can provide continual physiological measurements as well as environmental measurements, even when people are operating in hazardous environments.

The prototype consists of piezoelectric sensors that are used to obtain the pressure applied in terms of voltage when the patient is walking. These sensor values are processed by a microcontroller which maps the voltage values of 0-5V in a different range which are as follows; 0-1023, 2000-3023, and 4000-5023. These ranges are integer values, which are whole numbers. These represent the voltage values ranging from 0- 5volts.
The limitation of mapping is that the voltages values are rounded off and hence don't provide accurate and precise readings

1 Component specifications

3.2.1.1 Piezoelectric sensors
The piezoelectric pressure sensor has two leads; one is the positive lead which is depicted in red in Fig 3.3 and the negative lead is depicted in grey in Fig 3.3. The positive lead is soldered in the ceramic area of the sensor and the negative lead is soldered on the outer ring of the disc.

Bluetooth Module- HC-05
The HC-05 is an SPP (Serial Port Protocol) device. The Bluetooth module in the project is a slave. The master is the android device. The module can act as a slave or a master, but not at once. The range of the sinking current is 30-40mA. After pairing, the sinking current is 8mA. This is an off the shelf module which has a breakout board for direct usage in a circuit.
Other specifications of HC-05 are as follows:
2.4 GHz radio transmitter
Low power 1.8V-3.3V
Programmable I/O control
Default baud rate 38400
Data bits:8, Stop bit:1,Parity:No parity

3.2.1.3 Development board- Arduino Uno
The Arduino Uno development board is built around the microcontroller ATMEGA 328. The motivation of using this board is the fact it's open source. Embedded C++ is used for this project.
The other specifications are as follows:
USB interface
16 MHz clock

32 KB Flash memory
In-built voltage regulator
13 digital pins
6 analog pins

3.3 Justification for components used

3.3.1 Piezoelectric sensors

The PZT sensors are made of materials that deform under pressure resulting in providing a voltage output. When the patients walk with the sensors which are placed on the sole deform under pressure providing a corresponding voltage value. Hence, these sensors can give an approximate range of the amount of pressure being applied in different focal areas on the plantar surface of the foot.

3.3.2 Bluetooth HC-05

This module is used for wireless communication between the sensor and the app module on an android device. The characteristics of HC-05 mentioned in Section 3.2.1.2 are compliant with the features of Arduino Uno and therefore was considered to be the best choice. Another reason for selecting this component is the power consumption is low and therefore is apt for this application.

3.3.3 Development board- Arduino Uno

The Arduino platform is an open source with the capacity to provide several hundred libraries. The availability of resources online is also strong.

The development board, Arduino Uno also has several capabilities such as an inbuilt analog to digital converter, voltage regulator, and USB plug and play interface. It also provides a very easy and simple way of burning code multiple times on microcontroller.

Circuit connections

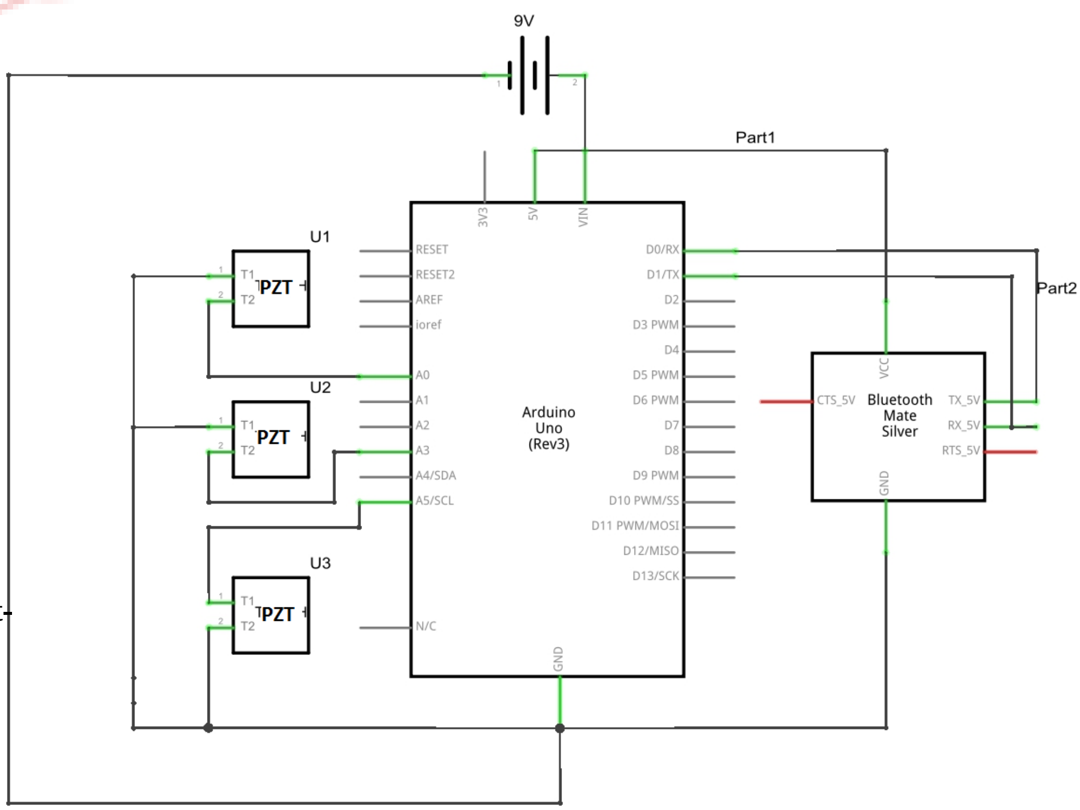
Table 3.1: Bluetooth HC-05 to Arduino Board connection

Bluetooth	Arduino Board
Rx	Tx
Tx	Rx
Vcc	5V
Ground	Ground

Table 3.2: Piezoelectric sensor to Arduino board connection

Piezoelectric Sensor	**Arduino**
Positive electrode x 3	A0, A3, A5 (Analog pins)
Negative electrodes x 3	GND

The Fig 3.4 below shows the final setup of the project using the connections stated in the above Tables 3.1 and 3.2.



Cost-

The cost of the total device £26.04 with preliminary components.

Component Name	Price(£)
Piezo-electric sensor	3.44
Arduino (Microcontroller)	17.29
Bluetooth Module	5.31
Total	26.04

Competition Analysis-

Name of Company	Podimetrics	SurroSense Rx®	Our product
Product	Foot monitoring device	Foot monitoring device	Foot monitoring device
Price(pounds)	100	200	26

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