Abstract — The diabetic foot present many complications if it is not supervised. Statistics shows that 25% of diabetics that develop peripheral neuropathy will develop a foot ulcer and more than a half of them will become infected and 80 % require non-traumatic amputation which are performed yearly. This paper shows a daily instrumented shoe for the monitoring of diabetic foot to reduce the risk of ulcers and others complication due to many effects of the shoe’s environment. The system contains an insole pressure distribution sensor to monitor the pressure of critical point of high risk to prevent ulcers. Also, it contains temperatures sensors placed in critical contact points to give feedback of the friction rate, and a humidity sensor to give feedback of the sweating rate. Since the aim of the system is to be used daily by any diabetic person, the different sensors communicate wirelessly thought Bluetooth with an Android based phone application. In addition to a real-time sensor’s data visualization, the application contains different alerts set according to medical preconization to give feedback such as the maximum time recommended to wear a shoe.

Keywords — diabetic foot, instrumented shoe, plantar pressure

I. INTRODUCTION

Diabetic ulceration foot increase every year and the principal cause is the missed information of the pathology and how to prevent [1]. Even if a diabetic person monitor their feet every day, the risk is high due to the difficulty to be alerted by signs of an ulcer beginning. Unfortunately, 15 percent of diabetic people had a foot ulcer in their life, and 24 percent of them require a lower extremity amputation. This make the diabetes the leading cause of amputation of the lower limb [2]. For these reasons, the importance of identifying individuals at risk is critical for eventual prevention. This is priority of a trained staff (Doctor, Nurse, etc.) and should be often evaluated, yearly for people at low risk and monthly for those at high risk [1]. Sadly, not all Doctors inspect feet at every visit, and not every diabetic person respect a normal visiting planning, especially when they have no skills to practice a visual inspection for themselves.

The First reason of these traumas is a peripheral artery disease caused by poor blood flow and nerve’s damage caused by an excessive glucose in the diabetic blood [3]. It results in a losing feeling in the sole that lead to a poor or inexistent feel of pain, heat or cold in the lower limb. The legs may not feel a fold in the socks, an exterior body in the shoes or another thing, provoking an excessive friction between the skin and the sock or shoes, which increase the risk of infections and ulceration.

The type and quality of shoes are critical for healthy diabetic foot. A bad environment where the foot is, can affect the gait [4], for that, the shoes must be taken into account and must be chosen carefully according to the physiology of the foot [5]. Unfortunately, the shoes available in the market are made into standards that do not match the foot form of everyone. Consequently, patients are often forced to wear shoes that do not fit their feet forms, that may cause several problems, among them ulcer development. Bad quality may cause corn and callus, too much rubbing on high-pressure area, making the foot at high risk of infection. Blisters are also due to excessive friction and temperature elevation. Their size increase with humidity which increase the risk to damage and expose them to infection [6].

In addition to the classical foot examinations done yearly by a doctor for a normal low risk diabetic foot, the patient need a self-monitoring to have a feedback about his feet environment in real time. Fig. 1 shows an example of an ulcer which can be done by a bad shoe.

A bad plantar pressure distribution, an excessive humidity and a high temperature are factors depending of the quality of shoes that affect feet and may cause disease like ulcer. A hot and humid environment are factors for the development of virus and microbes. A high rate of pressure in specific point of the sole increase the risk of these pathologies. There is a need to measure all these parameter simultaneously in a daily shoe for feet’s disease prevention.

Taketoshi Mori et al [4] demonstrate the importance of the plantar pressure and shear force measurement in the prevention of diabetic ulcer and the effect of the presence of callus in patient’s foot. SHU Lin et al. A. Perrier et al. [7] developed
washable socks for diabetic foot prevention using wireless sensors which communicate with phone. Many other papers [8], [9], [10] and [11] talk about the importance of these parameters in the diabetic foot ulcer prevention, principally the analysis quantifying of the plantar pressure repartition during the different phases of gait.

The aim of our system is to give a real-time active feedback data to prevent risk of ulcer in a diabetic person. It consists in a daily embedded shoe with a foot pressure distribution insole, a coupled moisture/temperature sensor and 3 temperature sensors in high friction area. The pressure distribution system consists in an insole developed in the laboratory, which contains six Force Sensing Resistor (FSR). The temperature sensors are localized in high-risk area and the moisture sensor are under the sole and record the humidity thought a small hole between the sensor and the skin.

The sensors data are sent to an Android based phone thought Bluetooth. The Android application should be easy to use which contains the different data and medical recommendations. Alerts will be set according to the sensors’ values to prevent the user about an eventual risk of disease caused by these parameters.

The sensors used to build the insole are the 402 FSR from Interlink Electronics. Flexibility, size and easiness to use were the criteria of choice as it is mainly used in biomechanics to map and monitor foot pressure distribution [12].

To maximize the result accuracy, a uniform force distribution on the active area have to be provided [13]. For this, a rigid coating dome made of epoxy and metal were used. The dome is glued to the FSR using a thin double sided tape. This form allows us to distribute a pressure from a little surface to the entire active area of the sensor.

![Fig. 3. Applied force and its distribution on the active area with the conditioner circuit](image)

The FSR are conditioned using a voltage divider with a reference voltage of 5V and a resistance $R_m$ of 470 $\Omega$. Each voltage divider is followed by an Op Amp, connected as follower to achieve impedance matching with the microcontroller. The output voltage is given by,

$$ V_{out} = \frac{R_m V_{ref}}{R_m + R_{FSR}} $$

All outputs are connected to a Multiplexer and then fed an Analog/Digital Converter (ADC). The pressure data are then sampled by an ATmega328p microcontroller mounted on an Arduino Mini Pro Board where the digitalized data pressures are calibrated according to the results of the calibration process. The final data are sent to an Android phone thought a HC-06 Bluetooth module using the Serial Port Profile (SPP).

The area of high pressure were chosen according to a study were 87 patients with 103 existing foot ulcers [14]. Six sensors placed in 1: Toe (T), 2: Medial Forefoot (MF), 3: Lateral Forefoot (LF), 4: Medial Med-foot (MM), 5: Lateral Mid-foot (LM) and 6: Heel (H) was decided to use as shown in Fig 3.

![Fig. 5. Plantar pressure distribution insole](image)

**II. SYSTEM DESCRIPTION**

**A. The foot plantar pressure distribution**

Many sensors can be used for the foot pressure plantar such as piezoelectric sensors, load cells, strain gages and FSR. The latter was chosen for this purpose [5], as it is an easy to use technics based on a polymer sensing film where its resistance decrease with the applied pressure. Each sensor measures the dynamic weight in a specified point and display the result in a Graphic User Interface (GUI) Android custom application.

![Fig. 2. System architecture](image)

**B. Temperature of high friction area**

As temperature is an important parameter which affects the skin condition, three temperature sensors are placed in areas where the friction between the skin and the shoe is the highest.
These frictions can cause skin damage and may end with injuries which increase the risk of ulcer. Studies shown that a difference of 2.2°C between two risky areas may become an ulcer [15].

Our system use TMP35 temperature sensors placed under a layer of fabric present in the shoes. These sensors are placed so that they will be not felt by the patient.

C. Humidity and temperature of the shoe

In addition to the three temperature sensing points, a coupled Temperature/Humidity SHT1X sensor is placed under the insole. The humidity plays an important role in the skin condition, a high sweating rate is very useful for diagnosis and evaluation of the feet environment in the shoes [7]. Mainly, footwear prevent sweat from evaporating. Socks may also act as a sponge and lock moisture in. It can become dangerous due to the suitable environment for bacteria’s development and increase the risk of skin injury with infection. For these reasons, the system collect the humidity rate through data of the sensor and gives an alert if the humidity exceed a certain rate during a predefined time set by a doctor or the patient itself. The temperature it also a factor which play an important role in the humidity rate due to the necessity of the body to cool itself thought sweat. This parameter must be monitored seriously and gave alert when a certain rate is exceeded.

D. Central unit

All sensors are connected to the Arduino Mini pro board through a motherboard. The board contains two LM324 chips (each one contains four Operational Amplifiers), 4051 multiplexer to connect the 6 FSR to the ADC input and the HC-06, SHT1x, TMP35 connections.

Two Li-Ion batteries provide the power supply with a TP4056 charge controller. A connection was added to select between two modes, the first connects the batteries in parallel to be charged and the second connects them in series to supply the regulator mounted on the Arduino Board.

E. The Android application

The aim of our system is to be accessible by everyone. For this, we chose to use an Android based phone as the Human-to-Machine interface for his popularity and simply to use. The developed application is structured into four screens with a “Main Menu” where we can switch between them. The first one is about the temperature and the humidity of the shoe collected by the SHT1X sensor. It displays the data and gives an alert if predefined high rates are detected. The second screen gives the six plantar pressure distribution points collected by the FSRs. The pressures are represented by a colour variation from the blue for a low load weight to the red colour for a maximum load. The data are also stored in a text file to be accessed for a better analysis. It gives alert if dangerous pressure is detected during a predefined time. The third is about the temperature of high friction areas. Finally, a fourth screen connects the application to a website to give recommendations and advices from professional doctors of different fields concerning diabetes and the way to prevent complications.

The application was coded and designed using “App Inventor” supported by Google and the MIT.

III. SYSTEM CALIBRATION

The temperature and humidity sensors (TMP35 and SHT1X) are factory calibrated, but FSR needs calibration. Each FSR gives different output voltage and calibrating one by one is necessary. Adding to this, the dome on the active area change the sensors’ response and not all domes are the same. Fig. 9 gives four examples of calibration data.
These graphs shows that the FSR is nonlinear over the whole range and each FSR gives different results. An fourth degree polynomial function was calculated to approximate the data given by the FSR by a microcontroller, thus,

\[ F(V) = b_0 + b_1V + b_2V^2 + b_3V^3 + b_4V^4 \]  

The polynomials are implemented into the Android application because the calculation speed of a smartphone processor is greater than the speed of an ATmega328p microcontroller.

IV. TESTS AND RESULTS

To demonstrate the feasibility of the system and an example of the results, a test on normal person were performed. Then, the data are recorded and collected by the foot pressure distribution insole during 10 tests as shown in Fig. 11.

![Fig. 10. Foot wearing the footwear system](image1)

![Fig. 11. Tests of the plantar pressure distribution](image2)

1: Stand-up, 2: Sit-down, 3: Stand-up, 4: Walk 6 steps forward, 5: Walk 3 steps backward, 6: Walk 3 steps forward, 7: Stand, 8: Lean forward, 9: Lean backward, 10: Lean Leftward.

The risk of ulceration is not the same for all person, it depend of the anatomical proprieties of the patient’s foot (bones curvature, thickness of the soft tissues, etc.) [16]. The System must be tuned according to these parameters by a trained staff before using the shoe. It also permits to the clinician to keep an eye on the patient feet state evolution and adapt the alerts triggering.

V. CONCLUSION

A daily shoe equipped with specified sensors for monitoring temperature, humidity, plantar foot pressure distribution and high friction temperature area has been developed and transformed into an intelligent footwear in order to prevent ulceration of diabetic persons. Tests on normal persons to demonstrate the feasibility of the system are carried out. The data are visualized on an Android application, so that the system is easy to use by every patients. The system will give feedback about the variables of the shoe and will alert if anomalies are detected according to predefined data’s limits.

REFERENCES


