

Sensorized Insole for Diabetic Foot Monitoring [†]

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Abstract: Several wearable technologies for the prevention of diabetic foot ulcers have been developed by the scientific community. However, they are often very invasive and normally just one parameter between pressure loads or temperature is acquired. Moreover the amount of thermal reading points is lower than 5 and the accuracy of thermal sensors is greater than 0.5 °C. This work presents a low invasive and accurate smart insole in which both temperature and pressure data are acquired in 8 reading points and then transmitted to a gateway, through a wireless protocol, in order to communicate the foot health status to the caregiver.

Keywords: diabetes; smart insole; wearable devices

1. Introduction

The research literature have demonstrated a great correlation degree between the foot ulceration and higher plantar loads due to the diabetic neuropathy. Indeed, this disease induces insensitivity conditions that can cause high plantar pressure, deformity and ischemic wounds on the plantar foot up to the ulcers development [1–3]. This dramatic consequence of the Diabetic disease is widespread and has a very negative adverse effect on the patient's quality of life. For this reason several scientific works were developed about the prevention techniques and medical treatments of diabetes. When the ulcers appear, the treatment is challenging, expensive and a long term treatment is required. In this scenario the prevention of ulcers assumes a prominent rule. The prevention could forecast through the use of technologies for the monitoring of relevant vital parameters on the plantar, as temperature and foot load distribution. They may identify the prolonged and excessive pressure at a point of the foot or recognize anomalies in skin conditions and in blood circulation. Several methods have been developed to measure the pressures and stresses in the plantar tissue by using mainly sensorized mats and force platforms. These strategies are usually realized following pre-defined scheduled medical visits. This approach could be not very effective because it is desirable to continuously monitor and to detect high pressure values in timely way. Several systems for measuring plantar pressure in the foot are commercially available [4]. These systems are extremely expensive and aim at athletic activities and are not specifically designed for prevention of ulcers.

Another useful parameter for assessing the diabetic foot severity status is the temperature. Progressive degeneration of sensory nerve pathways affect thermoreceptors and mechanoreceptors. High temperatures under the foot coupled with reduced or complete loss of sensation can predispose the patient to foot ulceration. So, the foot thermal monitoring may facilitate detection of diabetic foot problems [5]. The most part of the temperature foot measurements for the diabetic foot is realized with non-invasive and accurate thermal images analysis or thermography inspections. However, as described for the pressure monitoring, the long-term and continuous measurements of temperature may allow for a more effective ulcers prevention.

The wearable technologies presented in literature, for the permanent monitoring of the diabetic foot show large dimensions and typically are able to monitor only one parameter, the pressure or temperature. Moreover the amount of thermal reading points is lower than 5 and the accuracy of thermal sensors is greater than 0.5 °C. This work presents a smart insole in which both temperature and pressure data in 8 reading points are acquired and then transmitted through a wireless protocol to a gateway in order to monitor foot conditions and inform the caregiver about the health status.

2. Materials and Methods

The hardware architecture of the developed smart insole system is shown in Figure 1. It consists of two main modules for (a) temperature and pressure parameters acquisition and (b) elaboration and transmission data.

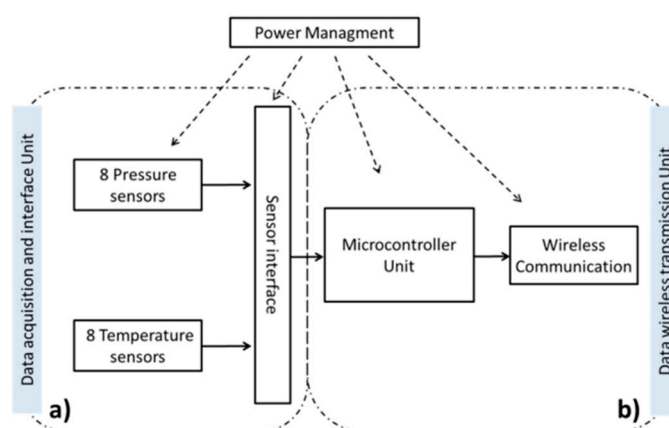


Figure 1. Overview of the Insole hardware architecture. (a) temperature and pressure parameters acquisition and (b) elaboration and transmission data.

To choose the sensors number and their insole positioning for the correct monitoring of the load foot distribution, the best trade-off between the active area and measurements accuracy at specific points of the plantar was studied and assessed. According to the R. Ferber et al. [6], the local load foot analysis, performed by using the BTS G-studio and the baropodometry P-Walk platform [7], eight sensors were used and placed as shown in Figure 2. The temperature sensors were located close the pressure sensor in order to monitor the main pressure point of the foot.

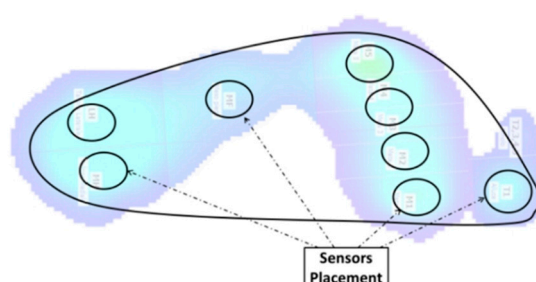


Figure 2. Temperature and pressure sensors positioning.

For the load pressure acquisition, the IEE CP151 force resistive sensor (FSR) has been chosen for the low invasive integration into a flexible thin-film layer (0.43 mm thick) [8]. Their responses are limited to 100 N maximum load onto an active area of 113 mm², so it is appreciated for dynamic and static foot load pressure measuring. To allow an higher accuracy level, a calibration step was performed through a quasi-static analysis technique. The full custom set-up realized for the calibration is shown in Figure 3. The system is able to apply controlled force to the sensors area with different frequency, in order to obtain the characteristic curve of sensors.

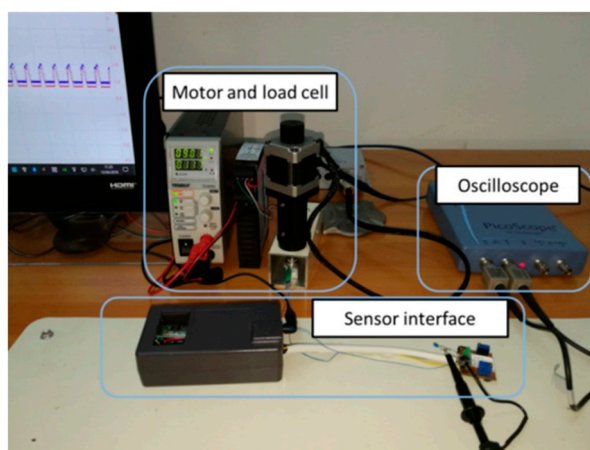


Figure 3. Measurement Set-up for IEE CP151 force resistive sensors calibration.

For the temperature analysis, the Maxim MAX30205 sensor was chosen since it presents a state-of-the-art temperature accuracy ($0.1\text{ }^{\circ}\text{C}$) [9] and a low current consumption ($600\text{ }\mu\text{A}$ in operative mode and 5 nA of leakage current), useful for the long-term monitoring. Low-power, low-dimensional, low-profile and high-precision electronic components were identified to enhance the battery autonomy and accuracy level, reducing the size of the system. The sensors and their interface circuits were integrated on the insole. A dual-layer circuit board was realized and all components were integrated on the bottom side (apart the flat and very thin FSR sensors) to avoid asperities potentially harmful for the diabetic foot. To measure the foot temperature, a via hole has been realized on the board in correspondence of the sensing pad of each temperature sensor, assuring an optimal thermal transfer between the bottom and the top of the insole, through the application of a silver-based conductive paste. The flexible circuit was incorporated between two antibacterial polyurethane-based layers assembly, designed in accordance with the typical requirements of diabetic foot insoles. The elaboration and wireless transmission of data were realized using a minimally invasive Arduino-based board, equipped with the Bluetooth Low Energy 4.2 technology. This board was integrated into the polyurethane-based layers together with the battery and the power management circuit.

3. Results

The developed smart insole is shown in Figure 4. The prototype results lightweight and minimally invasive. To evaluate the performance, preliminary laboratory testing were performed in order to compare the temperature values measured by the proposed system and an accurate infrared thermometer on the top of insole.

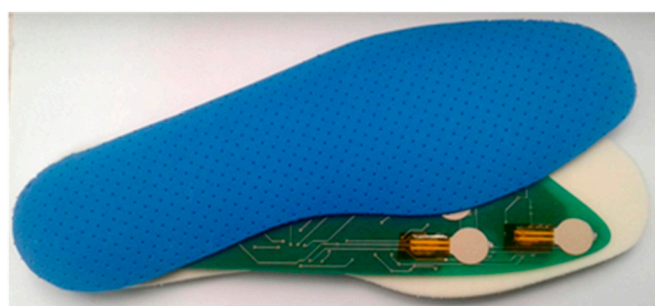


Figure 4. Prototype of smart insole. The flexible PCB is integrating between two antibacterial polyurethane-based layers.

To evaluate the performance laboratory tests were performed. For the temperature distribution monitoring the insole was inserted between two aluminum plates with accurate ($0.01\text{ }^{\circ}\text{C}$) temperature gradient control. For the load pressure acquisition, 5 subjects simulated static and dynamic actions

on the baropodometric BTS Pwalk platform, wearing the insole. The comparison between the data acquired with the two systems were analyzed. Based on results, reported in Table 1, the developed system shows a very good performance in temperature/pressure detection.

Table 1. Main features of the developed smart insole.

Features	Smart Insole System
Temperature accuracy	0.21 °C (range 25–40 °C)
Pressure accuracy	8% (range 40 to 298 kPa)
Power consumption	Max 46.3 mW (Data transmission mode)

4. Conclusions

In the presented work a smart insole system for foot ulcerations prevention in diabetes patients was described. Temperature and pressure parameters were acquired from eight different points on the foot plantar. The preliminary laboratory tests validate high accuracy level in temperature data acquisition. Moreover good performance was obtained for the foot load distribution evaluation by using minimally invasive and calibrated pressure sensors. Ongoing studies are focused on the integration of a low-power elaboration and transmission unit to allow the final coupling with antibacterial socks.

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