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Design and Implementation of Smart Therapuetic and Monitoring Insole for Diabetic Foot Ulcer Using Embedded System and Iot

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Abstract: According to the World Health Organization (WHO), Diabetes is defined as chronic disease occurred when pancreas not producing required insulin to the body or the body can't effectively use the insulin it produced. Insulin is the inevitable hormone which regulates the blood glucose level. The word hyperglycaemia called as raised glucose or sugar in the blood is a general effect of uncontrolled diabetes to the human society. This often collapses the functional system of the body mainly the blood vessels and injuries to the nerves. The raise of percentage of diabetes in the world is rapidly increasing and become the direct cause of deaths for millions. Due to various awareness programs introduced in the world against diabetes resulting, probability of dying from non communicable diseases are decreased said by WHO with statistical data. Even after so many guideline based remedial measures taken by medical and social professionals in the world ,diabetes still exists because of improper food culture, less work than the food intake, high stress level, sleep culture ,social pressure and anthropological changes in the world. Diabetes often makes injuries in nerves, the damage on nerve could be the significant reason to occur foot ulcers and if it is uncared neuropathy will be the result, it is a long time or term complications for diabetes. It is essential to find foot neuropathy in early stage using scientific approach could lower the effect and makes the life easier. The diabetic patient start suffering from foot ulcer, they must learn to manage and overcome. Once they go beyond the level ,they may find drop in sensation called neuropathy situation which always appears in foot ulcers. To manage this, a diabetic shoe could be the perfect option to decrease peak planter force exerted on their foot. The commercially available shoes doesn't match to all because ,humidity ,abnormal pressure and temperature levels are not concentrated which can increase the level of wounds. In this proposed research we emphasized the vital parameters to be considered like SPO2, pressure, Temperature ,Humidity and Body position sensor during walking with the shoe designed called Smart Shoe .The proposed device (Plug and play With Mobile Interface) have numerous built in features like Wi-Fi data transmission, internal power backup ,Embedded Controllers and Stimulation Vibrators to provide effective solution to foot ulcer and keep the user comfort to overcome various tough situations.

Keywords: EMC-Embedded Micro Controller, MEMS-Micro Electro Mechanical System, FSR-Force Sensible Resistor, WHO-World Health Organization, USART-Universal Synchronous Asynchronous Receiver Transmitter, ADC-Analog to Digital Converter.

I. Introduction

Smart shoes are essential to keep the patients more comfort in all aspects like walking, moving around, slow running and make them stress free mindset. The evolution of shoe for diabetes from a simple to advanced technologies have been introduced after invention and adopting sensors embedded within it for analysis of pressure equality in all areas, humidity ,temperature changes inside the shoe while wearing. The chart (Figure 1) mentioned below shows that the present and projected increment of various foot ulcer from year 2020 to 2030. Based on the chart, there is a possibility of increase in foot ulcer in almost all the regions of the world and people have to manage the same with scientific approach or they have to overcome by changing the life style. If life style, habits or environment is not meeting the standards ,adopting these kinds of modern sensing techniques with shoes are inevitable for safer life.

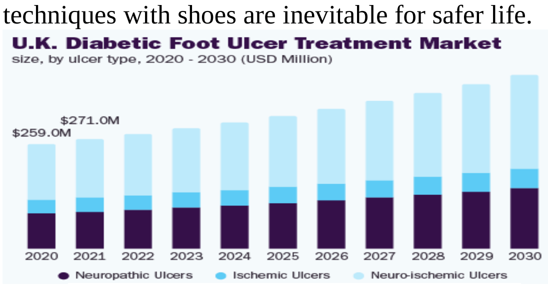

Figure 1 Diabetic foot ulcer present and projections upto 2030

In general Diabetic foot ulcer is an open sore or can be a wound that occurs in approximately 15 – 20% percent of patients with common diabetes, it is always located on the bottom of the foot. When the foot ulcer is at an advanced stage, it should be obvious condition. A foot ulcer looks like a round red crater in the skin bordered by thickened callused skin. Severe ulcers like shown in the Figure no 2 below can be deep enough to expose tendons or till bones is experienced by the diabetic patients.

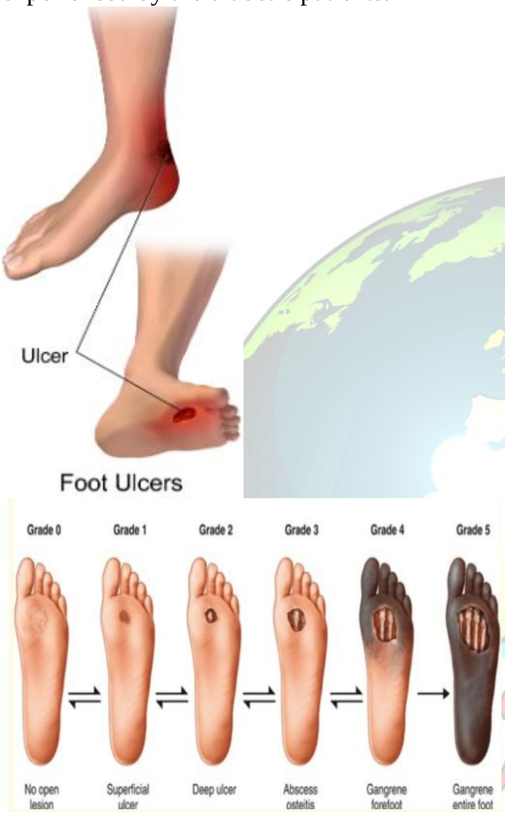

Figure 2 Diabetic foot ulcer causes damages till bones

The process of foot ulcer is clearly mentioned and well explained in the above figure, how it starts from simple to complex grade 5 foot ulcer which causes severe damage to the foot.

Figure 3 Spectrum of Diabetic Foot Ulceration process

Figure 3 indicates the spectrum of diabetic foot ulceration process for patients with diabetic foot ulcer wound that is not at all improving with standard treatment and medicines must be carefully evaluated for peripheral arterial disease analysis in early stage. **The majority of foot wounds will have some component of ischemia (lack of blood flow to the foot).** Failure to correct blocked arteries from peripheral arterial disease can result in prolonged wound healing or worse, amputation.

Figure 4 Detailed Nerve, ulcer and blood flow diagram of foot ulcer

Figure 4 indicates how the ulcer, dry cracked skin looks like, reduced blood flow, damaged nerves happens to most of the patients all over the world and in precise Asian continent. As per the IDF (International Diabetic Federation) statistics published and accepted by WHO more than 463 million diabetic patients at the age group of 20 – 79 up to year 2019 and this number may be increased to 700 million by 2045. Among the above statistics almost 80% of the population lives in low and middle income countries. Further the statistics added that in Southeast Asia more undiagnosed diabetes, which is more alarming to the global medical emergency after some years. India has the highest in the statistics of diagnosed and undiagnosed diabetics in the Asian continent with high mortality rate with huge medical expenditure.

II. Proposed System

It is essential to create a date driven analysis approach for early detection and warns the affected to understand their health condition towards diabetics. A Non- Invasive Embedded Diagnostic Tool with data driven Approach is essential with built in features. A device to be developed with Communication methodology to manage, reduce the foot ulcer in very early stage by wearable device like Smart shoe.

The proposed research block diagram (Figure no 5) mentioned below could solve the problems mentioned above. The proposed system uses the state of art sensor technology to find the variables of the foot like temperature, humidity, SPO_2, pressure(Figure no 6) at various points of the foot and in final the walking style analysis in XY direction. Appropriate sensors embedded on the shoe in a systematic manner to get the valid data at a higher speed with good repeatability are organized in this research. The data collected are processed using signal conditioners to amplify the low level signals and to remove the unwanted signals using low pass filters of desired frequency. The processed signals are fed to an

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Embedded controller to make use of the signals in a digital way and to pre-fix the limits of actuator relays to stimulate the nerves using vibrators located in the various spots in the foot.

A critical medical condition called diabetic neuropathy can be avoided by spotting aberrant pressure patterns under the foot early on. Although there is technology to measure foot pressure distribution in India and other countries, it is still difficult for a huge portion of the people to access it since it is too expensive to acquire and too large to be portable. Additionally, there is a lack of accessibility to the foot pressure monitors in less developed nations, which are home to numerous communities with a high prevalence of diabetes.

This project not only permits early identification and also offers diabetic neuropathy therapy with prevention. The shoe unit may accommodate sensors and actuators, and the monitoring unit is a straightforward handheld device that is inexpensive and portable. As a result, our project will be more affordable and easily accessible in less developed nations. The system can continually save data from the smart shoe for a number of weeks thanks to the big external memory.

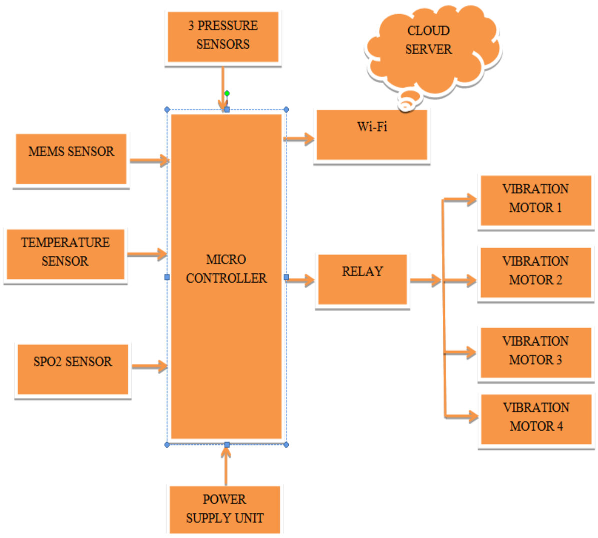

Figure 5 Block diagram of the proposed Smart Shoe Embedded Device – Transmitter Side

The proposed block diagram Figure no 5 indicates that the temperature sensor used here is to collect temperature while wearing the shoe with various conditions like walking, jogging and idling. The sensor used here is LM35 series are precision integrated-circuit temperature devices with an output voltage linearly-proportional to the Centigrade temperature. These device does not require any external calibration or trimming to provide typical accuracies of ±¼°C at room temperature and ±¾°C over a full −55°C to 150°C temperature range. The low-output impedance, linear output, and precise inherent calibration of the LM35 device makes interfacing to readout or control circuitry especially easy. These device is used with single power supplies, or with plus and minus supplies.

As the LM35 device draws only 60 µA from the supply, it has very low self-heating of less than 0.1°C in still air. The LM35 device is rated to operate over a −55°C to 150°C temperature range.

Figure 6 Sensors used in the Proposed Research

A pressure sensor is employed which shown above is used to collect the pressure created by the foot during the process of walking and idling, the differential pressure will be analyzed using Analog to Digital convertor device to identify foot pressure. The below Figure no 7 shows the pressure vs Resistance characteristics of FSR, the formula for force is an object's mass multiplied by its acceleration (or, F=M*A), or, applied pressure multiplied by the contact area (F=P*Area). There are several engineering units to represent "F" in these equations, such as Newtons (N), pound-force (lbf). The formula is employed in our proposed research to calculate the foot pressure.

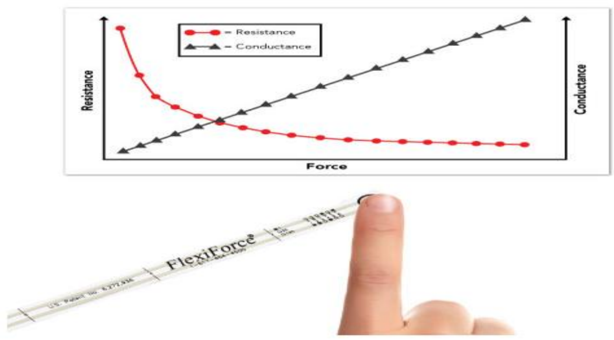

Figure 7 Foot Pressure Vs Resistance Graph

The MEMS sensor is employed here to find out foot behavior during diabetics at all stages, collects position value of the foot respect to the head to be found for perfect walking with smart shoe. It is essential to collect XYZ variable coordinates to calculate efficiency of walking and tilting angle.Various values collected from sensors are co-related with other parameters are presented below at various activities.(Figure no 8a,8b,8c)

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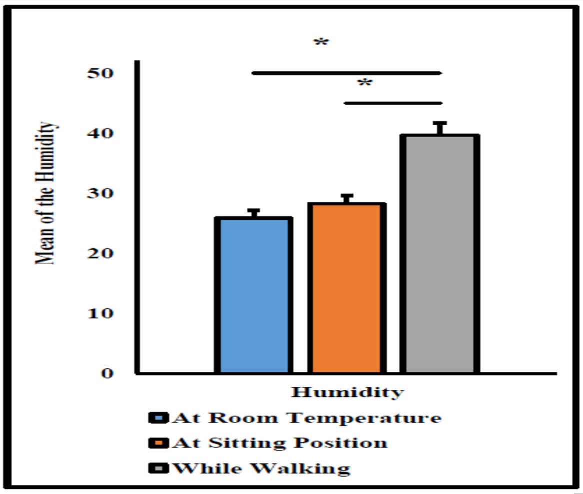

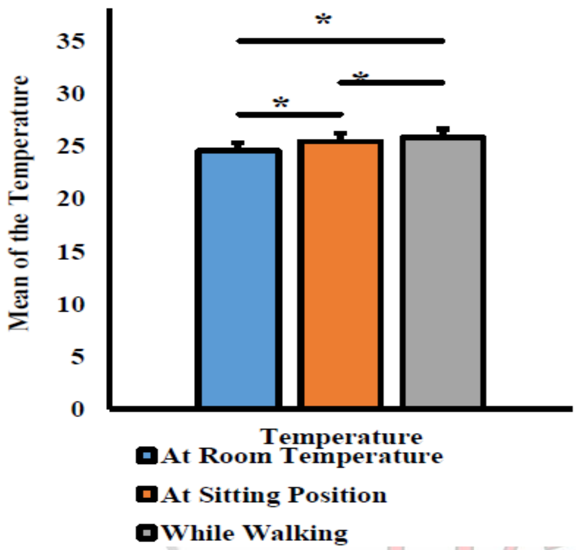

Figure No.8a

Figure No.8b

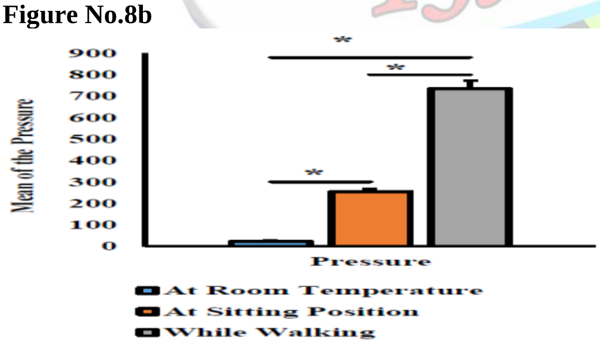

Figure No. 8c

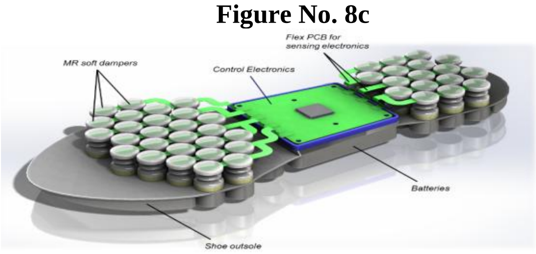

Figure No.8d

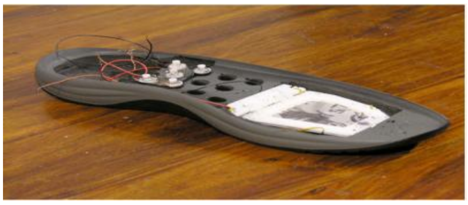

Figure No. 8e

The Proposed Research have been examined with diabetic patients with our smart shoe, we found that the temperature increased during walking time due to that humidity variations are high. The pressure at various points has been noted(Figure no 8d,8e), found significant variations between place to place. The more pressure is found during walking, jogging and humidity significantly increases at all levels. All the collected inputs are fed to an Arduino board(Figure no 9a and 9b) for processing information to transmit over IoT.

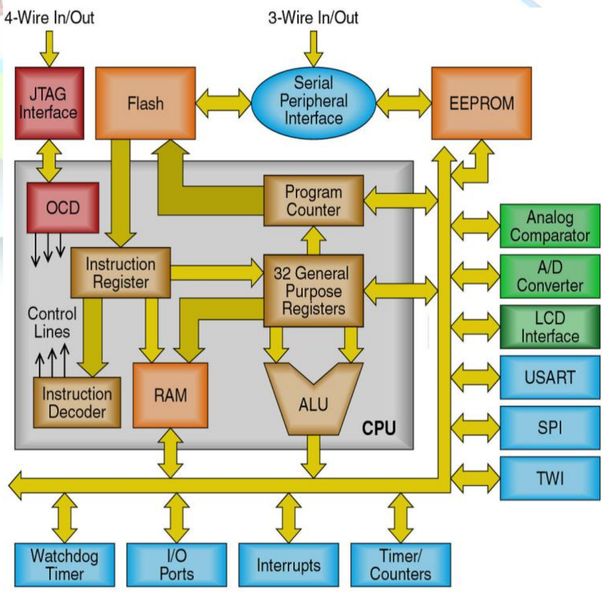

Figure No. 9a Arduino Board
Figure No. 9b Arduino Architecture

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The proposed research have been developed as a prototype for various case study analysis using above mentioned sensor with foot stimulator vibrator motors. The prototype model(Figure no 10) consist inbuilt relay module, Battery backup and associated circuits needed. The results like tabular ,individual and stimulated motor outputs shown in figure (11a,11b,11c).

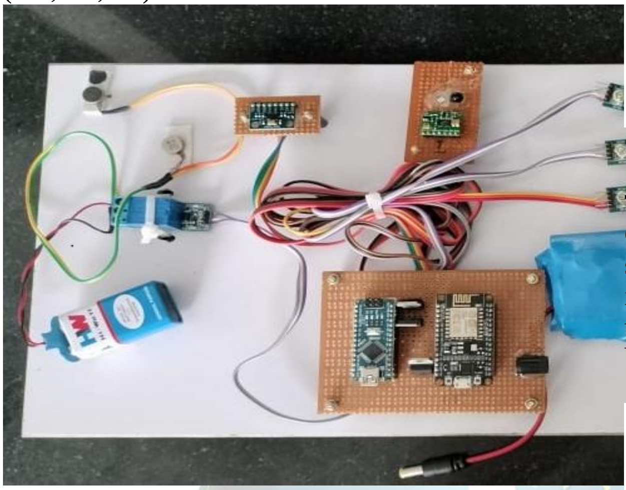

Figure no 10 Prototype model

Bank

S.no	Pressure1	Pressure2	Pressure3	Leg position	Temperature	Spo2	Date And Time
1	0	0	0	Checking	32	0	2023-05-03 12:06:18
2	0	0	0	Checking	32	0	2023-05-03 12:06:16
3	0	0	0	Checking	32	0	2023-05-03 12:06:14
4	0	0	0	Checking	32	0	2023-05-03 12:06:11
5	0	0	0	Checking	32	0	2023-05-03 12:06:08
6	0	0	0	Checking	32	0	2023-05-03 12:06:06
7	0	0	0	Checking	32	0	2023-05-03 12:06:03
8	0	0	0	Checking	32	0	2023-05-03 12:06:01
9	0	0	0	Checking	32	0	2023-05-03 12:05:59
10	0	0	0	Checking	32	0	2023-05-03 12:05:56
11	0	0	0	Checking	32	0	2023-05-03 12:05:54
12	0	0	0	Checking	32	0	2023-05-03 12:05:51

Figure no 11a Table of Results

Figure no 11b Results individual parameters

Figure no 11c Results with motor status

The results obtained from the smart shoe have to be Communicated to the cloud using strong computing system with associated software required for better informative system. Figure no 12a and 12b indicates the process involved in real-time communication between smart shoe and mobile phone or computer.

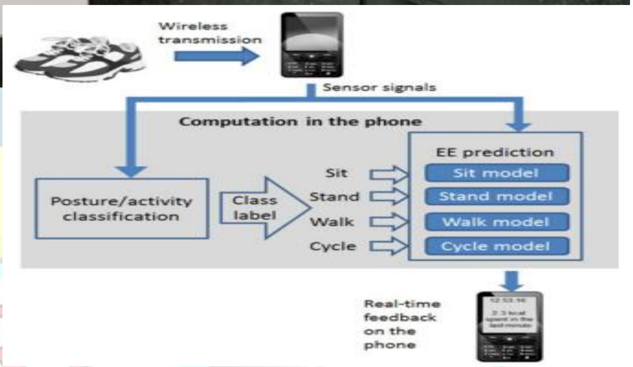

Figure no 12a Communication and Computing system for mobile phone((IoT)

Figure 12b Block diagram of the proposed Smart Shoe – Receiver Cloud Server Side

Figure no 12c System Configuration for IoT

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III. Conclusion

This technique has been put forth to offer people with diabetes disorders a quick, low-cost cure. It is made to produce vibrations of various frequencies along the muscles of the user's feet in order to manage the high pressure areas of his feet. This gadget is portable and available at all times. Future improvements can be achieved by reducing the size of the components used within the shoe to give the wearer the impression that it is more comfortable. The shoe unit can be linked to a smart phone as well.

References

1. Shadi Al-Sarawi, Mohammed Anbar, Kamal Alieyan, and Mahmood Alzubaidi. 2017. Internet of Things (IoT) communication protocols. In 2017 8th International conference on information technology (ICIT). IEEE, 685–690.

2. David G Armstrong, Katherine Holtz-Neiderer, Christopher Wendel, M Jane Mohler, Heather R Kimbriel, and Lawrence A Lavery. 2007. Skin temperature monitoring reduces the risk for diabetic foot ulceration in high-risk patients. The American journal of medicine 120, 12 (2007), 1042–1046.

3. T Bernard, C D'Elia, R Kabadi, and N Wong. 2009. An early detection system for foot ulceration in diabetic patients. In 2009 IEEE 35th Annual Northeast Bioengineering Conference. IEEE, 1–2.

4. A. J.M. Boulton, A. I. Vinik, J. C. Arezzo, V. Bril, E. L. Feldman, R. Freeman, R. A. Malik, R. E. Maser, J. M. Sosenko, and D. Ziegler. 2005. Diabetic Neuropathies: A statement by the American Diabetes Association. Diabetes Care 28, 4 (April 2005), 956–962. https://doi.org/10.2337/diacare.28.4.956

5. Antonella Caselli, Hau Pham, John M Giurini, David G Armstrong, and AristidisVeves. 2002. The forefoot-to-rearfoot plantar pressure ratio is increased in severe diabetic neuropathy and can predict foot ulceration. Diabetes care 25, 6 (2002), 1066–1071.

6. James Coates, Andrew Chipper"eld, and Geraldine Clough. 2016. Wearable multimodal skin sensing for the diabetic foot. Electronics 5, 3 (2016), 45.

7. Maria do Carmo dos Reis, Fabiano A Soares, Adson F da Rocha, João LA Carvalho, and Suélia SFR Rodrigues. 2010. Insole with pressure control and tissue neoformation induction systems for diabetic foot. In 2010 Annual International Conference of the IEEE Engineering in Medicine and Biology. IEEE, 5748–5751.

8. T Duckworth, AJ Boulton, RP Betts, CI Franks, and JD Ward. 1985. Plantar pressure measurements and the prevention of ulceration in the diabetic foot. The Journal of bone and joint surgery. British volume 67, 1 (1985), 79–85.

9. Marjorie Fierheller and R Gary Sibbald. 2010. A clinical investigation into the relationship between increased periwound skin temperature and local wound infection in patients with chronic leg ulcers. Advances in skin & wound care 23, 8 (2010), 369–379.

10. Carlos Gonçalves, Alexandre Ferreira da Silva, João Gomes, and Ricardo Simoes. 2018. Wearable e-textile technologies: A review on sensors, actuators and control elements. Inventions 3, 1 (2018), 14.

11. Aoife Healy, Philip Burgess-Walker, RoozbehNaemi, and NachiappanChockalingam. 2012. Repeatability of WalkinSense® in shoe pressure measurement system: A preliminary study. The Foot 22, 1 (2012), 35–39.

12. Nagaraj Hegde and Edward S. Sazonov. 2015. SmartStep 2.0 - A completely wireless, versatile insole monitoring system. In 2015 IEEE International Conference on Bioinformatics and Biomedicine (BIBM). IEEE, Washington, DC, USA, 746–749. https://doi.org/10.1109/BIBM.2015.7359779

13. Jason Gums. 2018. Types of Temperature Sensors. https://www.digikey.com/en/ blog/types-of-temperature-sensors

14. William J. Jecoate and Keith G. Harding. 2003. Diabetic foot ulcers. The Lancet 361, 9368 (2003), 1545 – 1551. https://doi.org/10.1016/S0140-6736(03)13169-8