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VERSATILE INSOLE MONITOR

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ABSTRACT

The various disciplines of electronics such as the sensors, data transmission and processing are used in wearable systems on target applications. The insole contains a sensory array which provides a more distinct picture of the activity than a wrist worn monitoring device. A sensor laden insole is developed which can be used in any shoe to measure the pressure and temperature distribution as well as measure the pulse of the user. The project aims to use sensors, wireless data transmission modules and a software for data processing to perform physical activity monitoring and provide biofeedback especially for diabetics and peripheral arterial disease. It can be used to provide significant information about the status of health without undergoing elaborate tests in the hospitals. Wireless data transmission methods (Bluetooth (BLE)) is used to send the sensor readings to the application developed for monitoring. The proposed system involves the use of pressure, temperature and a heart rate sensor and pedometer to measure the various biological parameters. The insole can be used for regular health monitoring, training analysis and rehabilitation measures.

KEYWORDS

Bluetooth Low Energy (BLE), sensor-array, biofeedback.

1. INTRODUCTION

The foot-wear based system has a wide range of applications. It can be extended from a simple pressure balancing solution to a more progressive system which can be used in rehabilitation programs for subjects who are disabled. The shoe-based activity is applied in various fields and targets a wide range of population (Ivanov et al., 2019). They are used to measure the plantar pressure, ground reaction forces, gait analysis. It is effective for fall prevention in elders, Parkinson disease patients and post stroke rehabilitation.

We propose to develop a system which can be used for monitoring the physical activity of the user on a daily basis. It is capable of providing the user significant information about the status of health without undergoing elaborate tests in the hospitals and to make them aware of the minute changes that are happening within their body which if unattended may lead to serious health issues later (Hu et al., 2018; Roth et al., 2018). It is observed that the existing systems concentrate on a specific application. They need better sensor calibration schemes and the numbers of sensors used for foot load distribution are not appropriate. The manufacturing of these systems are not cost effective (Rescio et al., 2018).

The proposed system helps in regular monitoring and can be used to monitor the improvement or degradation in health. Afflictions that cause tissue inflammation and injury, such as tendon injuries and fractures, ulcers in persons with neuropathy can be predicted or identified by observing subtle changes in temperature, pressure and heart rate.

Around 85% of amputations in diabetic conditions are caused due to diabetic foot ulcers. According to the research study, more than half the

patients did not see an ulcer cure over a year (Martín-Vaquero et al., 2019; Yazdanpanah et al., 2015). This evidently shows the need for the prevention of foot ulcers. A major purpose of investigating the plantar pressure and skin injury in patients is to indicate the early detection of foot ulcers.

As diabetic is a major risk factor for peripheral arterial disease, the pulse rate is sensed. Neuropathy, peripheral arterial diseases and vascular alterations are the common causes of foot ulcer which can be prevented by monitoring the changes in temperature, pressure and heart rate (Lakho et al., 2019).

Diabetic foot ulcers mostly manifest as a combined effect of neuropathy, bone and tissue deformity which results in repetitive pressure on certain areas of the feet. High plantar pressure and deformity on the plantar foot are caused by insensitivity conditions and it leads to the ulcer development on the foot which is monitored by placing pressure sensors (Sazonov et al., 2011). Proper training can be given to patients to assimilate the behavior necessary to prevent the formation of ulcers.

The skin temperature on the bottom of the feet is another parameter that can be predictive of foot problems such as ulcerations and can indicate the presence of some inflammation on the foot. The presence of a wide variation in temperature between the feet or in various regions in the same foot can be considered to determine the health condition of the foot. Increase in temperature around the skin, decreases skin tolerance to superficial pressure making it vulnerable to ulcer formation (Bonato and Paolo, 2003; Najafi et al., 2017). When the increased temperature under the foot links with the absolute loss of sensation, it leads to ulceration. The foot thermal monitoring is essential for the detection of problems related to diabetic foot. Monitoring heart rate is a way to gauge the health of the user.

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It gives a real time snap of the heart muscle function This helps the users to keep track of cardiac conditions (Yamakawa et al., 2008).

In the embodiment, the force or pressure sensors are placed along with the temperature sensors to observe the variations. The observed values are compared with predetermined thresholds to check for abnormalities. Early warnings or predictions are provided to the user when some abnormality is observed. Target audience of the insole system includes patients and healthy persons (Guldmond et al., 2006). It helps in regular monitoring of the physical condition of the user. The pedometer used can help in keeping track of the daily activity of the user. Information such as frequency of application of pressure to specific areas of feet while walking, allows in the identification of any tendencies that are hindering the performance of the user. This can be applied to gait analysis, physical activity monitoring and provide biofeedback to the user (Sanfilippo et al., 1992; Pataky et al., 2012).

2. PROPOSED METHOD

We propose a system that helps in continuous monitoring of the health of the users and continuous data transmission. It can be used to monitor diabetic feet to prevent the formation of ulcers which leads to various complications. The insole can be employed in everyday monitoring of the users, measuring the rehabilitation activities and analyzing training in sports.

The design of the insole system embraces three subsystems: (1) Temperature, pressure and heart rate acquired through sensor system. (2) Transmission by wireless module (3) Aggregation and processing of data.

The first subsystem is an array of sensors which includes pressure sensors, temperature sensors and heart rate sensors. Second subsystem acquires the data and transmits them (liu et al., 2005).

Figure 1: Block Diagram of the insole monitor

NodeMCU is the microcontroller unit used in the insole system. The acquisition and communication of data were checked using an external NodeMCU board.

This enables the user to monitor the processed output in the application.

2.1 Sensor System

Pressure sensors are placed based on the distribution of foot pressure. The foot pressure is basically analyzed on the toe, metatarsal, midfoot and heel regions. Economic sensors include pressure sensors, temperature sensors and heart rate sensors. To measure the main pressure point, the pressure sensors are accompanied by temperature sensors.

The FSR (Force Sensing Resistor) is involved in measuring the pressure. FSR primarily has a resistor whose resistive value depends on the force applied. The resistance decreases as the force increases. This FSR basically has a spacer adhesive between the top most semiconductor substrate and the bottom most substrate with electrodes. When force is applied, the resistance changes as the particles that are present in the sensing film touches the conducting electrodes. FSR is used in the insole as it has a thickness less than 0.5mm which would be appropriate for its placement on to the insole and it has a good shock resistance (Caselli et al., 2002; Da et al., 2015).

A circuit holding FSR along with a pull down resistor is used to get the required output range of 0-5V by voltage division. The output voltage can be measured by using the voltage division formula,

$$V_{out} = V_{cc} \cdot R / (R + R_{fsr}) \quad (1)$$

The voltage increases with decrease in the FSR resistance. The output voltage is measured across the pull down resistor.

Supply voltage is 5V and the range of the FSR is 200 ohms to 1M ohm.

Assuming the pull down resistor to be 10K ohm and FSR is set to it's high resistance, then V_{out} is

$$V_{out} = 5V \cdot 10K \text{ ohm} / (10K \text{ ohm} + 10M \text{ ohm}) = 0.005V. \quad (2)$$

When FSR=200 ohm, the V_{out} is,

$$V_{out} = 5V \cdot 10K \text{ ohm} / (10K \text{ ohm} + 200 \text{ ohm}) = 4.9V. \quad (3)$$

The output value between 0.005V and 4.9V is appropriate.

Thermal values of the foot are measured using the temperature sensor TMP 36. TMP 36 is precise, does not wear out, works under many environmental conditions, and is consistent between sensors and readings. They are economical and easy to use. The output range provided by TMP36 is -40 to 150C. They require a power supply of 2.7 to 5.5V.

Analog pins of NodeMCU can measure up to 3.3V. NodeMCU analog pin resolution is 0-1023 thus it counts 1023 at 3.3V. TMP 36 maximum voltage output is 1250mV at 125C. TMP36 maximum voltage = 1.25 volts.

$$1.25V \text{ is counted by the analog pin in NodeMCU} \\ = (1.25 / 3.3) \cdot 1023 = 387.5 \quad (4)$$

$$\text{New NodeMCU-TMP36 Resolution} = 387.5 / 125 = 3.1. \quad (5)$$

1 degree in centigrade is changed for every 3.1 count in the analog pin. Temperature in degree Celsius = (Analog value of TMP36)/3.1

The Integrated pulse oximetry and heart-rate monitor module used in the proposed insole is MAX30102. The Standard I2C-compatible interface communication takes place in MAX30102 which is suitable for communicating with NodeMCU and can be operated through a 3.3V supply for the internal LED's communication.

The beats per minute of a person are measured using MAX30102 by interfacing it with a NodeMCU. The average BPM is measured to know the heart rate of a person.

Max 30102 uses photoplethysmography (PPG) technique which is sensing the change in light absorption or reflection by blood as it pulses through the arteries. The rising and falling of light is considered as a pulse and the heart rate is measured. Reflection from the arteries produces an AC component whereas that from bones and tissues produces a DC component.

The photo-diode in the sensor then converts the light to current that can be used to analyze the data. We aim to measure the heart rate alone, so we only require the AC component thus a sensor with one LED is sufficient for this purpose

The beat count in milliseconds is obtained through the function millis(). There are 60,000 milliseconds in a minute. So the formula to calculate the Beats Per Minute (BPM) is,

$$BPM = 60000 / (\text{one beat in milliseconds}) \quad (6)$$

It can be used effectively to sense the heart rate of the user. All the sensor data is sent to the application with a wireless data transmission method. Pedometer is added in the system in order to count the number of steps taken by detecting the movement of the feet. The pedometer contains a low power high performance MCU.

The MCU is capable of analysing the sensor data obtained from the physical movements. When there is a walking step or running step, the module provides the step information in the form of a high level pulse and it is very easy to use. It can be used to determine the distance covered and the calories burnt by the user. It helps in monitoring the physical activity of the user.

Distance = number of steps $\times$ step length (7)
 All the sensors are interfaced together into a microcontroller. NodeMCU is the microcontroller which we have used to interface all the hardware components.

Figure 2: Hardware Architecture

2.2 Wireless Data Transmission

Placement of sensors were studied and optimized in an effort to obtain precise foot monitoring. To enhance the accuracy and reduced system size in the 37-40 shoe size range, low dimensional and highly accurate electronic components were identified and integrated. The circuits were integrated close to each other on the insole in order to reduce the system noise.

Data acquired from the sensors can be transmitted to the user interface with the help of ESP8266 and Bluetooth. ESP8266 which is available in the NodeMCU provides a networking facility (Wi-Fi) which helps in the wireless streaming of data into the Application developed for monitoring the measured parameters.

Wi-Fi is basically the back and forth communication between two radios. It uses lower power and broadcasts over a much shorter distance. NodeMCU is opted as it supports Wi-Fi, I2C communication and consumes low energy. It also has a reduced size of board which makes it convenient to use. The wireless nature of the network allows the user to get connected easily. Through Wi-Fi the data is transmitted faster. Wi-Fi channels are spaced 5 MHz apart. 20MHz bandwidth is typically used by the channel for its operation. The acquired data is transmitted from the insole through NodeMCU board to the application developed for monitoring.

Wireless data communication can also be established by using a Bluetooth module HC 05. Bluetooth Module is used for wireless communication over a short distance. This module is used for wireless transmissions and receptions over a distance less than 100 meters. The module is preferred where power consumption is an issue.

The Bluetooth device is connected to the mobile Bluetooth. The Bluetooth module is the master and the mobile is the slave. The Bluetooth sends the collected data from the sensors to the mobile. The Bluetooth module transmits the data measured by the sensor at regular intervals to the application developed for monitoring.

2.3 Data Integration and processing module

The visualization and graphic user interface (GUI) subsystem. It consists of an app developed in order to retrieve the data read by the sensors. This application is useful in analyzing the body parameters and provides accurate results. The versatile insole monitor can be potentially used in the ambulatory monitoring of physical activity and gait analysis in free living conditions.

The app shows the continuous reading of the parameters from the point the system is ON. It provides a caution message when the measured values exceed a particular threshold. It is capable of showing the dynamic readings of the sensor

The values measured by the sensors are sent to the application as soon as the system is ON. The application is capable of monitoring every change in

the measured parameters. The data can be transmitted to the app with the help of Wi-Fi and Bluetooth.

The microcontroller can be connected to the mobile hotspot enabling the wireless streaming of data into the application or the mobile Bluetooth can be activated and connected to the Bluetooth module in the insole in order to transmit the data.

The Bluetooth module transmits the data measured by the sensor at regular intervals to the application developed for monitoring. The application is designed in such a way that it intimates the user if there are any abnormalities observed.

The app is made informational, reliable and easy to use. The pressure-sensitive insoles are capable of measuring the direct interaction between the feet and the ground. If there is any foot abnormality detected the user will be automatically notified, so that the appropriate action can be taken on time.

Having continuous monitoring allows the foot's physiological signals to become a powerful line of defense against the development of foot ulcers or other foot related issues.

3. HARDWARE IMPLEMENTATION

Figure 3: Connection setup for the proposed system

The connections are made according to figure 3. The pressure sensors are connected to the ADC and its output is provided to the digital pins of the NodeMCU. Each pressure value is printed separately in the application.

The temperature sensor is connected to the analog pin of the microcontroller and its output is converted into Celsius and displayed.

The pulse rate sensor two inputs are connected to the digital pins and the beats per minute are displayed and the average BPM is measured and displayed in the application developed.

The Bluetooth is connected to the receiver and transmitter pin of the microcontroller and the measured values are sent to the mobile connected to the Bluetooth

Figure 4: Insole monitor

4. RESULT

A insole monitoring system capable of continuous measurement of the foot planar pressure, temperature, heart rate and distance covered by the user is developed and these measured parameters are presented to the users.

For temperature, pressure and pulse monitoring, the data was taken from different points on the plantar foot.

The force sensors with the capacity of 0–150 kilopascal with 0.5" 14.7mm sensing area were used to observe the plantar pressure variations. The pressure sensors were placed on the insole in the toe, metatarsal, mid foot and heel regions.

Foot Regions	Mean Pressure (KPa) normal	Mean Pressure (KPa) foot ulcer
Toe	68	78
Metatarsal 1	87.82	92.7
Metatarsal 2	93	105.5
Metatarsal 3	76.63	80.25
Mid-foot	36	98

Figure 5: Table to observe the plantar pressure variations in various regions of the foot.

Figure 6: Graph that shows the plantar pressure variations

The variations in the foot plantar pressure are observed to provide warning to the user if there are any drastic changes in the pressure values. As the above observed values are plotted under erect standing conditions, wide variations are observed in the hind regions of the foot.

The pressure values increase when there is any foot abnormality. The thresholds are taken according to the values observed from the normal condition and by continuous monitoring, the user can take the appropriate precaution in case of any deviation.

Each foot, the system consists of insole pressure distribution sensors, with three coupled temperature sensors. The plantar temperature was observed to be in the range of 27–30°C for normal healthy humans. The temperature values increase when there are any foot abnormalities. The two temperature sensors are used to measure the internal temperature and one sensor is placed to calculate the external temperature.

Studies show that a difference of 2.2°C between two risky areas or a difference of 3°C between the two foot can lead to the development of ulcer. High rate of temperature leads to faster formation of ulcer in the high friction points. High increase in temperature leads to decrease in skin tolerance making it vulnerable to pressure induced ulcer formation. The variation in the foot temperature can be observed in the application.

User	Temperature (°C) internal	Temperature (°C) external	Condition
User 1	31	31	Normal
User 2	31	32	Normal
User 3	31	31	Normal
User 4	37	32	Abnormal
User 5	29	31	Normal
User 6	27	29	Normal
User 7	34	30	Abnormal

Figure 7: Temperature variation in the foot plantar

Figure 8: Graph that shows the variation in temperature

Pedometer provides the number of steps taken by the user daily. It enables the user to determine the distance covered. The pedometer acts as an everyday exercise counter and it can also be used to determine if the user is erect standing or having a gait. It is used to monitor the physical activity of the user. Studies show that a total of 10,000 steps per day is approximately equal to 8 kilometers and is considered as a benchmark for an active lifestyle. From the examination pedometer the posture of the person is determined. The user is supposed to be in an erect standing position when there are no fluctuations in the observation.

The heart rate sensor uses the optical method to determine the heart rate of the user. As per the pulse rate sensor, the BPM collected is between 60 and 100 when observed in a normal adult. But the risk alert is sent when it crosses above 100BPM as it may cause Tachycardia condition or when heart rate drops below 60BPM as it may result in Bradycardia. The message can help the user monitor his health.

Figure 9: Output of the versatile insole monitor

5. CONCLUSION

An instrumented insole with specified sensors has been developed for monitoring the various vital parameters. The system can be used for regular health monitoring, gait analysis and avoiding ulcers. The insole developed will be convenient to use, compact and comfortable to wear. Ongoing studies are concentrated on the integration of a low-power consumption. The insole is flexible and portable for field activities. The insole developed is light and very little invasive. Good performance is obtained for the evaluation of foot load distribution by the insole. The system is advantageous as it allows dynamic recording of readings and make the user aware of the minute changes that are happening within their body which if unattended may lead to serious health issues later.

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