

SMART FOOTWEAR FOR TRACKING AND PRIMARY TREATMENT FOR DIABETIC FOOT ULCERS

Submitted in partial fulfillment of the requirements for the award of Bachelor
of Technology in B.Tech Biomedical Engineering

by

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**INSTITUTE OF SCIENCE AND TECHNOLOGY
(DEEMED TO BE UNIVERSITY)**

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APRIL – 2023



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BONAFIDE CERTIFICATE

This is to certify that this Project Report is the bonafide work of **AISHVARIYA SHIVANI.S (39240002)** and **BHAVANI SRI S (39240010)** who carried out the Project entitled "**SMART FOOTWEAR FOR TRACKING AND PRIMARY TREATMENT FOR DIABETIC FOOT ULCERS**" under our supervision from **October 2022 to April 2023**.

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We, **AISHVARIYA SHIVANI.S (39240002)** and **BHAVANI SRI S (39240010)**, hereby declare that the Project Report entitled “**SMART FOOTWEAR FOR TRACKING AND PRIMARY TREATMENT FOR DIABETIC FOOT ULCERS**” done by us under the guidance of **Dr.S.KRISHNAKUMAR M.Sc., Ph.D.**, (Internal) is submitted in partial fulfillment of the requirements for the award of Bachelor of Technology degree in B.Tech Biomedical Engineering.

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ACKNOWLEDGEMENT

We are pleased to acknowledge our sincere thanks to Board of Management of SATHYABAMA for their kind encouragement in doing this project and for completing it successfully. We are grateful to them.

We convey our thanks to Dr.T.Sudhakar, M.Sc., Ph.D, and Dr.J.Premkumar, M.Sc., Ph.D., Head of the Department, Dept. of Biomedical Engineering for providing us necessary support and details at the right time during the progressive reviews.

We would like to express our sincere and deep sense of gratitude to our Project Guide Dr.S.Krishnakumar, M.Sc., Ph.D., Associate Professor, Dept. of Biomedical Engineering for his valuable guidance, suggestions, and constant encouragement that pave the way for the successful completion of our project work.

We wish to express our thanks to all Teaching and Non-teaching staff members of the Department of Biomedical Engineering who were helpful in many ways for the completion of this project.

We would also like to express our gratitude to our parents for supporting us in completing this project successfully.

ABSTRACT

Diabetic foot ulcers (DFUs) are a serious complication among diabetic patients whose blood sugar levels are not efficiently controlled. Severe instances may entail amputations of the foot. With this in mind, we have come up with a solution that may help both in the diagnosis and therapeutic procedures for foot ulcers. The device helps to identify foot ulcers with the help of temperature and pressure sensors located in the various pressure points of the foot. This is detected and is automatically given a prescribed rate of vibrations with the help of a vibration motor. This not only helps in the healing of the ulcers but also enhances the blood flow in the area which may help in the prevention of the recurrence of these ulcerated wounds. Also, an accelerometer is attached in this device in order to monitor the treatment and mark its efficiency in curing these ulcers.

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Keywords- Diabetes mellitus; Diabetic foot ulcer; wound debridement; peripheral neuropathy

LIST OF ABBREVIATIONS

ABBREVIATION	FULL FORM
ABI	Ankle-Brachial Index
AVR	Alf And Vegard's Risc
CRP	C-Reactive Protein
DC	Direct Current.
DPN	Diabetic Peripheral Neuropathy
ESR	Erythrocyte Sedimentation Rate
LABVIEW	Laboratory Virtual Instrument Engineering Workbench
LCV	Local Continuous Vibration
LDF	Laser Doppler Flowmetry
LIV	Local Intermittent Vibration
MRI	Magnetic Resonance Imaging
PWM	Pulse Width Modulation
TCC	Total-Contact Cast
UV-LED	Ultra Violet Light Emitting Diode

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CHAPTER – 1

INTRODUCTION

1.1. BASIC INTRODUCTION

A critical and problematic condition of diabetes is diabetic foot ulcers, and it is the major cause of the formation of diabetic foot. Repair of broken tissues and wounds is the innate activity of the humoral and molecular mechanisms in the body regulated by our immune system. The healing process involves three parts- inflammation, proliferation, and remodeling (Tian et.al., 2021). The major constituent of the skin layer, the extracellular matrix undergoes repair, which is a significant process of the wound healing process, however, in some cases, certain maladies or physiological disorders affect the wound healing process. Diabetes mellitus is such an example that hinders the wound healing process.

Around 15% of people are affected by diabetic foot ulcers and out of which 84% tend to undergo lower leg amputations.

Risk factors involved in the development of diabetic foot ulcers include (Al-Rubeaan et.al., 2015):

- Oedema
- Foot deformities
- Callus formation
- Ischemia of blood vessels
- Foot ulcers
- Poor blood sugar levels
- Diabetic Neuropathy
- Peripheral vascular disease
- Age of the Patient
- Infections
- Smoking

Several metabolic and neurovascular factors lead to diabetic foot ulcers in diabetic people. Loss of pain and feeling in the lower and upper limbs due to nerve damage and low blood flow is a common symptom of peripheral neuropathy. Autonomic neuropathy causes Sudomotor dysfunction and dryness of the skin. Blisters and sores may appear on numb areas of the feet and legs, such as metatarsophalangeal joints and the heel region, as a result of pressure or injury which may go unnoticed and eventually become a portal of entry for bacteria and infection.

Doctors use the Wagner Grades to describe the severity of an ulcer. The purpose of the Wagner Grades is to allow specialists to better monitor and treat diabetic foot ulcers. This grading system classifies Diabetic foot ulcers using numbers, from 0 to 5 (Reyzelman et.al.,2022). Wagner Grades 0 through 5 are represented in the Table 1.1:

Table 1.1 Wagner Grade System for Diabetic Foot Ulcers

GRADE	STAGE NAME	DESCRIPTION
0	Intact Skin	No diabetic foot ulcer is present, but there is a high risk of developing one.
1	Superficial ulcer of the skin or subcutaneous tissue	A surface ulcer involves full skin thickness but does not yet involve the underlying tissues.
2	Ulcers extend into tendons, ligaments, or capsule	A deep ulcer penetrates past the surface, down to the ligaments and muscles. There is no abscess or bone involved yet.
3	Deep ulcer with osteomyelitis, or abscess	A deep ulcer occurs with inflammation of subcutaneous connective tissue or an abscess. This can include infections in the muscle, tendon, joint, and/or bone.
4	Partial foot gangrene	The tissue around the area of the ulcer (limited to the toes and forefoot) has begun to decay.

5	Whole foot gangrene	Gangrene has spread from the localized area of the ulcer to become extensive. This involves the whole foot.
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Evaluation of foot ulcers is done by laboratory tests, radiological investigations and probe-to-bone tests. Laboratory tests involve sting blood sugar, glycated haemoglobin levels, a complete metabolic panel, a complete blood count, erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP). MRI, Arterial Doppler with ankle-brachial index (ABI), and X-ray are commonly used radiological investigative techniques (Novello and Pobre, 2022).

Treatment of diabetic foot ulcers should include: control of blood sugar levels, removal of dead tissue from the wound, wound dressings and removing pressure from the wound through techniques such as total contact casting. Surgery in some cases may improve outcomes. Hyperbaric oxygen therapy may also help but is expensive (Abid and Hosseinzadeh, 2022).

1.2 DIAGNOSIS AND EVALUATION

Diabetic patients must undergo an annual foot exam followed by a clinical assessment in order to prevent and manage ulcers efficiently. The clinical assessment should include vascular and neuropathic symptoms and consumption of tobacco (Boulton et.al.,2004). With the help of electro diagnostic studies, clinical and neuropathic symptoms are detected. The following are the customary methods to diagnose diabetic foot ulcers.

1.2.1 Physical Examination

The primary examination is visually inspecting the skin's surface for callus growth, elevated temperature, and cracks in the cutaneous barrier. Each time a patient interacts with a healthcare professional, a physical inspection could uncover new, unidentified foot lesions. Primary care clinicians increasingly acknowledge the

prognostic significance of foot ulcers and recommend individuals suffering from foot ulcers double as often for podiatric foot management and awareness than patients with bone anomalies or peripheral neuropathy (Mayfield et.al.,1998).

1.2.2 Musculoskeletal Assessment

Any inflexible deformities or contractures are found during this evaluation. Claw toe or distal phalangeal extension is two common forefoot abnormalities that have been linked to skin disintegration (hammer toe). Charcot arthropathy is another often misdiagnosed illness that may impair the midfoot. This would appear as a flat, bloated, red foot that is unilaterally deformed severely. A quick and timely referral to a specialist should be made for subsequent evaluation and treatment of a patient with suspected Charcot arthropathy.

1.2.3 Neurological Assessment

This assessment deals with the testing of peripheral nerves for loss of sensation, that is, peripheral neuropathy. Being the strong cause of foot ulcers, different screening processes are present in the market (Lanting et.al.,2020). Commonly used are Semmes-Weinstein monofilament, vibration using a 128 Hertz tuning fork, pinprick sensation, ankle reflexes, and Neurothesiometer/biothesiometer (McIlhatton et.al., 2021). The reliability and sensitivity of the monofilament screening could be boosted by analyzing 10-foot spots. The traditional test by 128 Hertz vibration tuning fork is a rapid and low-cost way to determine whether the first metatarsal head and lateral malleolus are vibrating (Doğruel et.al.,2022).

1.2.4 Skin Temperature and Vascular Measurements

Blood flow is done to diagnose and monitor peripheral artery disease, which in turn helps to manage the ulceration process. The popular and effective techniques for assessing peripheral artery disease are Laser Doppler flowmetry (LDF) and Doppler

ultrasonography (based on the toe-brachial and ankle-to-brachial indices). Microvascular impairment may manifest before macrovascular deficits in diabetic patients, according to research investigations. The initial tracking of a localized increase in skin temperature of the plantar region may be employed for the early recognition of these foot ulcers. According to scientific reports, this temperature examination has been employed as a substitute for measuring plantar blood flow (Galvão et.al.,2020).

1.2.5 Plantar pressure measurements

Increased plantar pressure has been correlated to ulceration and the risk of amputation. A Harris mat or a force plate with a polytechnic alteration can be used to monitor static plantar pressure whereas in-sole pressure transducers and pedobarographs are utilized to measure dynamic pressure and shear stress. Although they are more challenging to measure, shear and dynamic pressures are likely to be more insightful than static pressures (Menon and Bril,2022) .

1.2.6 Electrophysical Studies

Non-invasive and very reliable measurements that are applied to detect the progression of nerve damage are electrophysical tests. Nerve conductivity and electromyography seem to be the most popular electrophysical examination done on both non-diabetic and diabetic patients to identify the sensitivity of the nerves, nerve injuries, and severity of the lesions (Reyzelman et.al., 2022).

1.2.7 Accelerometer-based Assessment

Studies showed that abnormalities in the walking pattern of diabetic patients can be adopted as a valuable tool for the spotting of these foot ulcers. The detection of gait irregularities can be accomplished with the use of accelerometers and gyroscopes. This is due to the fact that they give the user options for independent movement and

fall detection. They are portable and affordable and can be used to track the effects of peripheral neuropathy (Brognara et.al.,2021).

1.2.8 Biopsy

An invasive procedure that detects the loss of sensation in the nerves. The main types include nerve and skin biopsy. The first one called nerve biopsy comes with several disadvantages especially the postop agony in the region where the procedure was performed, sensory disturbances, allodynia, and paresthesia at nerve distribution sites, especially with diabetic patients. Comparatively speaking, a skin biopsy is less intrusive than a nerve biopsy.

1.3 THERAPY AND MANAGEMENT

In order to control the ulceration moving to the next stage, various therapies are administered based on the patient's condition. Conventional techniques comprise surgical methods mostly. New procedures incorporating non-invasive remedies are becoming available as research and technology advance constantly. The advantages and disadvantages of each technique is described in table 1.2.

1.3.1 Wound Debridement

This method comprises various types namely autolytic, enzymatic, mechanical, non-mechanical, and so on. In order to make the foot ulcer bacteria-free and create the ideal environment for the ulcer to heal, this treatment entails eliminating the infected and dead tissues from the ulcer using special scissors or a scalpel.

1.3.2 Revascularization

Diabetic patients will gradually have ischemia, or reduced blood flow, in their limbs, which prevents ulcers from healing quickly. In order to facilitate faster healing either angioplasty or arterial reconstruction is done to increase blood circulation (Armstrong and Andros, 2012).

1.3.3 Negative Pressure Wound Therapy

After debridement, an open-aperture covering with an airtight dressing is applied to the wound. Then, a vacuum source that generates negative pressure is introduced to the wound. Through contraction, the negative pressure at the injured area diminishes the wound proportions. It also continuously cleans the area by sucking the debris and lowering the level of proteases by eliminating wound fluid. Despite the limited evidence, this therapy's effectiveness has been shown and it is a useful strategy for accelerating wound healing (Jones and Cooper, 2022).

1.3.4 Dressings

The purpose of dressing the wound is to keep the region clean, dry, and free from external irritants so that new tissue can develop and autolytic debridement can proceed. Commonly used dressing varieties include acrylics, hydrogels, foam adhesives, alginates, and hydrofibers.

1.3.5 Hyperbaric Oxygen

For patients with severe infections in the soft tissue of the limbs and osteomyelitis who did not attain decent results by following traditional methods, hyperbaric oxygen can be administered as a supportive remedy. Pneumothorax, convulsions, and temporary alterations in visual acuity are some of the negative effects (Ehrenreich and Ruszczak, 2006).

1.3.6 Offloading

To boost the therapeutic healing of ulcerated areas, load redistribution is crucial. Even after the removal of ulcers, the patient will be prone to recurrent ulceration due to inadequate offloading. Devices such as half shoes, acorn cushioned slippers, removable cast walkers, therapeutic shoes with custom insoles, diabetic socks, and half shoes are used for load redistribution. The suitable strategy for this goal, as well as the benchmark, is the nonremovable total-contact cast (TCC).

Table 1.2 Analysis of Therapeutic Methods For The Effective Ulcer Management

Technique	Advantages	Disadvantages
Wound Debridement	It enhances healing by the removal of unwanted tissues and microbes as well as stimulates the development of new tissues.	The type of debridement purely depends on the patient's wound. Hence surgeries can cause severe bleeding at same time causing local pain.
Revascularization	Revascularization helps in promoting recuperation by improving the blood supply to the lower extremity. Thus liberating agony.	The chances of remedial depend on the patient's condition.
Negative pressure wound therapy	Effective recuperation is met even in gigantic ulcerated areas. It prevents the spread of ulcers.	Patients with anticoagulants experience bleeding. Dressing seems to be tiring to change and can also lead to skin discomfort.
Dressing	Dressing aids to manage ulcers and prevent foul odor Also provides relief from agony.	Dressing requires frequent changes in order to control the infection. It cannot be an alternative measure but always an adjunctive remedial treatment.
Hyperbaric Oxygen	This procedure minimizes wound tissue hypoxia, increases circulation, eliminates edema, inhibits inflammatory cytokines, and fosters fibroblast multiplication, collagen formation, and angiogenesis.	Pain in ears and sinuses, pneumothorax, convulsions, and temporary alterations in vision.

Offloading	It helps in the healing of foot ulcerations and is effective pressure reduction thereby easing the healing process.	Infection and maceration may have occurred due to the presence of exudate, improper treatment could aggravate and result in amputation, which is expensive, and involves lots of maintenance thereby increasing practical difficulty for patients.
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1.4 PARAMETERS WHICH AIDS TO TRACK INITIAL STAGES OF DIABETIC FOOT ULCERS

There are various parameters that help us track the initial stages of diabetic foot ulcers. By comparing the changes in these parameters with the reference values, we will be able to check for the presence of diabetic foot ulcers. A picture of the diabetic foot ulcer is shown in figure 1.1.

1.4.1 Plantar temperature

The initial tracking of a localized increase ($>4^{\circ}\text{F}$) in skin temperature of the plantar region may be employed for the early recognition of these foot ulcers. According to scientific reports, this temperature examination has been employed as a substitute for measuring plantar blood flow. Stages of ulceration can also be classified to a certain extent with plantar temperature detection (Bus et.al., 2021).

1.4.2 Plantar pressure

The increased plantar pressure ($>6\text{N}/\text{cm}^2$) can be correlated to ulceration and the risk of amputation. A Harris mat or a force plate with a polytechnic alteration can be used to monitor static plantar pressure whereas in-sole pressure transducers and pedo barographs are utilized to measure dynamic pressure and shear stress. Although they are more challenging to measure, shear and dynamic pressures are likely to be more insightful than static pressures (Allan et.al., 2022).

1.4.3 Gait assessment

Studies showed that abnormalities in the pattern of walking of diabetic patients can be adopted as a valuable tool for the spotting of these foot ulcers. The detection of gait irregularities can be accomplished with the use of accelerometers and gyroscopes. This is due to the fact that they give the user options for independent movement and fall detection. They are portable and affordable and can be used to track the effects of peripheral neuropathy.



Fig 1.1. Diabetic Foot Ulcer

CHAPTER- 2

LITERATURE REVIEW

Some of the recent research works done related to our project has been discussed as follows.

2.1. LITERATURE SURVEY

Kukreja et.al., (2020) used DHT1 and flex force sensors to measure temperature and pressure respectively. Thresholds are fed and if it is abnormal, an email alert is produced. The system was able to store data for up to 30 days. The results are monitored in UBIDOTS. Real-time tracking of these parameters is fed to the database. Email alert/ SOS are generated when thresholds don't match up and are sent both to patients and the hospital.

Prem Anand et.al, (2018) measured foot pressure at the pressure points using the pressure kit which consists of a Pressure mat, Force Sensing Resistor, LM35 Temperature Sensor, Amplification circuit (LM324), Data acquisition device(12 or 20 channel), personal computer with LABVIEW used to process data. The sensed signals are finally processed by Arduino and are represented using Lab VIEW. The foot ulcers were detected at an earlier stage itself compared to the prior detection methods. The sensor values in Lab VIEW indicated the risk of foot ulceration. But the foot pressure values differ according to the factors such as sex, age, weight, history of diabetes (HOD), and the pressure given to the sensors differs with individuals.

Soubache et.al., (2020) used Arduino Nano to control the system connected with the vibrator, UV -LED, Peltier monitor (to heat/cool the wound), and power supply to run the overall modules. To a certain extent, the ulcers in the early stage were treated using this method. A vibration motor provides vibrations to the foot, which makes the dead cells rejuvenate, and the Peltier device increases the recovery rate.

Ren Weiyan, et.al., (2019) applied Local continuous vibration (LCV) and local intermittent vibration (LIV) randomly to the middle metatarsal head of each subject's right foot in each test. The SBF was measured prior to intervention (Baseline), during Vibration, and during the Recovery Stage for each test. For diabetic subjects, the subcutaneous blood flow was significantly increased in both vibration and recovery stages with local intermittent vibrations (LIV1 and LIV2), but not with LCV. It was observed that LIV is better than LCV.

Mahran et.al., (2013), assessed wound size (length, width, and area) with by Visitrak device before and after the treatment by the vibrational motor. There was a significant difference between pre-treatment and post-treatment mean values. It can be concluded that low mechanical vibration may improve the healing of diabetic foot ulcers.

Brognara et.al., (2021) reviewed 104 articles in order to evaluate the accelerometer-based gait alterations in diabetic patients. They observed that the reproducibility rate was less when the wearable sensors are placed on the shank or tibia. Moreover, higher gait variability was seen in patients who have undergone the prescribed treatment like offloading and dressing. Other observations include a higher risk of falling, shorter strides, reduced double support and slower gait velocity witnessed in progressing diabetic neuropathic conditions.

Bagavathiappan et. Al., (2010) used infrared thermal imaging, to study the plantar foot temperatures of 112 subjects with type 2 diabetes selected from a tertiary diabetes centre in South India. They observed that patients with diabetic foot ulcers had a higher foot temperature of 32–35 °C compared to patients without neuropathy who were in the range of 27–30 °C. Diabetic subjects with neuropathy also had higher mean foot temperature compared to non-neuropathic subjects.

Abri et.al., (2019) compared the distribution of plantar pressure in diabetic patients with and without neuropathy. They found that patients with severe neuropathy had higher maximum peak plantar pressure at the midfoot, heel, and medial forefoot compared to those without neuropathy. Additionally, the peak pressure at the midfoot was significantly different among the following categories: patients without neuropathy (32.3 ± 17.9 kPa), mild neuropathy (24.0 ± 17.9 kPa), moderate neuropathy (21.5 ± 12.6 kPa), and severe neuropathy (22.9 ± 10.7 kPa) groups. They concluded that the progression of diabetic neuropathy would have been increased followed by the peak plantar pressure.

Alam et.al., (2017) concluded that abnormalities in gait occur in patients with DPN and are intimately linked to alterations in kinetics, kinematics and posture. Sarcopenia related to the severity of DPN also appears to play a pivotal role. These conditions may lead to an increased risk of falls and be a significant cause of morbidity and mortality in older people with diabetes.

CHAPTER 3

AIM AND SCOPE

3.1 AIM AND OBJECTIVES:

- To develop smart footwear that aids with the diagnosis, treatment, and monitoring of foot ulcers using various sensors, vibrational motors, and Arduino microcontroller boards.
- To develop a device that helps in the diagnosis and treatment of diabetic foot ulcers using sensors and Arduino.
- To analyze the efficiency of the vibrational treatment provided to patients.
- To infer the trends in GAIT patterns before and after treatment.

3.2 SCOPE:

The objective of the development of this device is to alleviate the patients from the discomfort by analysing the irregular plantar pressures on an individual with diabetic peripheral neuropathy. This would assist the patient in tracking and recuperating from the internal damage caused by this illness over the years. The pressure patterns help us understand how the load is distributed unevenly in the foot region of a diabetic patient over time, resulting in an increase in Neuropathic diseases. Consequently, these uneven stress patterns can cause serious nerve injury and constriction of blood flow and signals, finally culminating in the loss of feeling. A specific level of stimulation is delivered at the same time, resulting in a counteractive action that aids with balance and neutralizes the damage produced by the condition after extended use. This device can be enhanced by the application of various other wearable sensors like glucose sensors, blood flow meters, etc for the purpose of personalization. Doctors can effectively monitor the treatment suggested to their patients with this device and accordingly make corrections in order to eradicate or prevent the disease. Researchers can study the patterns provided by these wearable sensors with the purpose of conceptualizing an effective solution.

CHAPTER – 4

MATERIALS AND METHODS

4.1. COMPONENTS

The following components were used for development of the device

4.1.1 Power Board

A power board is used to provide electric power to the system and typically can be a battery, USB cable, adapter, or a regulated power source device. It can be used with any power adapter that gives 7 to 20 volts and will regulate the voltage down to a very clean 5 volts. The adapter must be DC (Direct current). A picture of power board is shown in Fig 4.1.



Fig 4.1.Power Board

4.1.2. Arduino Uno Rev3

Arduino UNO is a low-cost and easy-to-use programmable open-source microcontroller board that can be integrated into a variety of electronic projects for

automation. This board can be interfaced with other Arduino boards, Arduino shields, and Raspberry Pi boards and can regulate motors, relays, light-emitting diodes, and servomotors as an output. Arduino UNO has an AVR microcontroller Atmega328, 6 analog input pins, and 14 digital I/O pins out of which 6 are used as PWM output. Programming of the microcontroller is done using C/C++.languages. A picture of Arduino Uno Board is shown in Fig 4.2.



Fig 4.2. Arduino UNO REV3 SMD

4.1.3. DS18B20 Temperature Sensor

DS18B20 is a waterproof temperature-detecting device that can be interfaced with Arduino UNO to determine the plantar temperature of the user. It is a digital output sensor that can measure temperature in the range of -67°F to +257°F or -55°C to +125°C with +-5% accuracy. It has three pins, two pins for powering and grounding purposes and one for receiving the detected temperature output. A picture of DS18B20 Temperature sensor is shown in Fig 4.3.



Fig 4.3. DS18B20 Temperature Sensor

4.1.4. Force-Sensitive Resistor

The force-sensitive resistor is a piezoelectric sensor that detects plantar pressure by varying its resistance when a force/ mechanical stress is applied to it. They are available in many sizes and shapes according to the need. The most common ones are circular for high precision and rectangular for wide-area sensing. The harder the force applied, the lesser the resistance by which a voltage is produced at the output in the range of 0-5V (Khandakar et.al.,2022). A picture of Force sensitive sensor is shown in Fig 4.4.



Fig 4.4. Force-Sensitive Resistor

4.1.5. Vibration Motor Module

The vibration motor module is a small and compact device that provides the necessary rate of vibrations at ulcerated locations at the plantar surface. Vibrational Therapy improves the blood flow at the site along with the prevention of the recurrence of ulcers. A picture of vibration module is shown in Fig 4.5

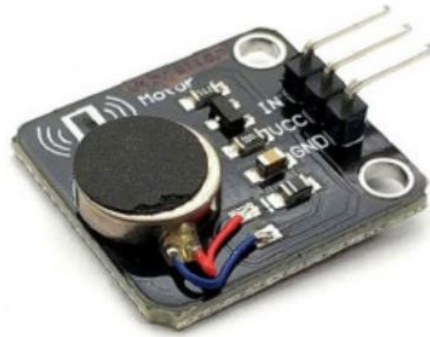


Fig 4.5. Vibration Motor Module

4.1.6. Accelerometer (ADXL345) Module

ADXL345 is a triple-axis accelerometer module that functions as a powerful MEMS device. It measures the position deviation along X, Y, and Z axes. The sensor comprises a micro-machined surface on a silicon wafer which alters the capacitance in response to the deflection produced. This difference in capacitance is proportional to the output voltage produced at the interfaced device (Ghazali and Rahiman, 2022). A picture of an accelerometer is shown in Fig 4.6.

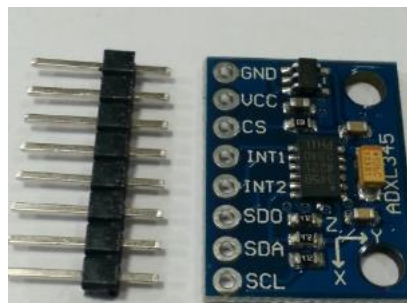


Fig 4.6. Accelerometer Module (ADXL345)

4.2. BLOCK DIAGRAM

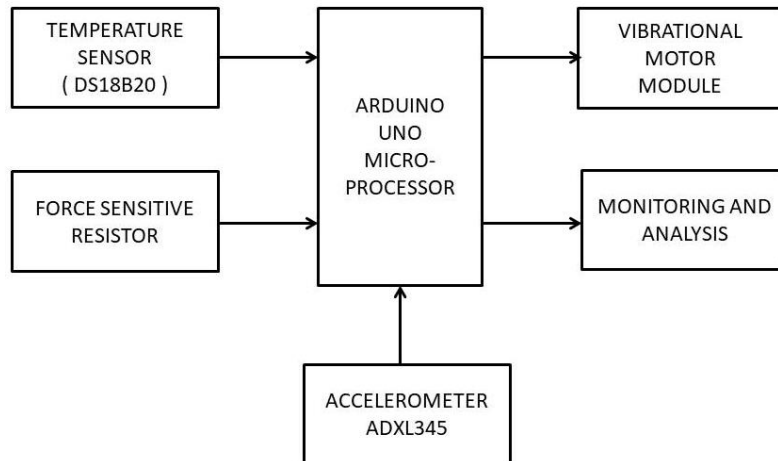


Fig 4.7 Block Diagram of The Circuitry

4.3. WORKING

The proposed system consists of an Arduino UNO as a microcontroller that diagnoses temperature and pressure differences at the ulcerated areas (foot pressure points) with the help of DS18B20 and a Force-Sensitive Resistor respectively. After the detection of these parameters, a particular number of vibrations is given at the detected areas to heal them by increasing the blood flow at the site. This is done using a DC motor Vibration Module. The ADXL345 Accelerometer Module helps in the monitoring of the gait alterations before and after the treatment to measure its efficiency. The block diagram of the circuitry is depicted in Fig 4.7 and a labelled picture of the proposed model is shown in Fig 5.1.

CHAPTER – 5

RESULTS AND DISCUSSION

5.1 RESULTS

The sample size was a total of 50 participants that included 10 healthy individuals (control group) and 40 who had type 2 diabetes mellitus. Out of 40 patients who had diabetes with an average history of six years, 15 were males and 25 were females. The participants were included only if they had a long history of diabetes/ peripheral neuropathy/ foot ulceration. We first examined the feet of the participants and classified the severity of the disease in order to provide a correct number of vibrations at the ulcer. The patients were included to participate only when there is a sign of ulcer or inflammation that is yet to be formed or formed but had not started decaying. Demographics such as age, gender, history of diabetes, history of foot ulcers, smoking and alcohol abuse, neuropathic symptoms, Hemoglobin A1c, diabetic retinopathy, and body mass index.

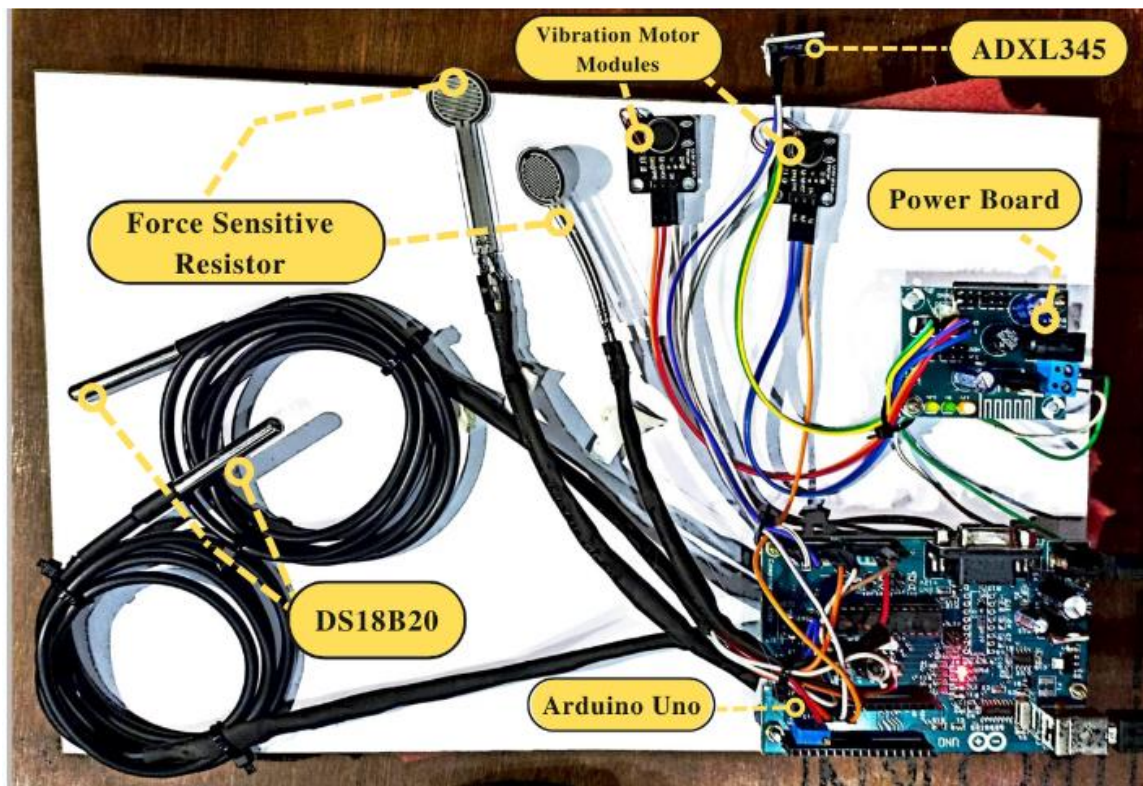


Fig 5.1 Prototype Model of the Smart Footwear

5.1.1 Sensor Locations

We chose to split the plantar surface into three main divisions namely, forefoot, midfoot, and rearfoot from which temperature and pressure readings were taken both before and after an effective therapeutic session. The sensor locations from which the data was acquired is shown in Fig 5.2.

SENSOR LOCATIONS



Fig 5.2 Representation of Sensor Locations for Data Acquisition

5.1.2 Plantar Temperature

The initial tracking of a localized increase ($>2^{\circ}\text{C}$) in skin temperature of the plantar region may be employed for the early recognition of these foot ulcers. According to scientific reports, this temperature examination has been employed as a substitute for measuring plantar blood flow. Stages of ulceration can also be classified to a certain extent with plantar temperature detection. The process of measuring temperature is shown in Fig 5.3.



Fig 5.3 Measurement of Plantar Temperature using DS18B20

5.1.3 Plantar Pressure

Studies show that the distribution of plantar pressure is different for accelerated neuropathic conditions. Plantar pressures are a reflection of the severity of the disease and can be used to detect ulcers in the primary stage. Here we placed the force-sensitive resistors on these locations mentioned while gait and static states. This showed a high disparity when the readings before and after the vibrational treatment were compared. The process of measuring Pressure is shown in Fig 5.4.



Fig 5.4 Measurement of Plantar Pressure using force-sensitive resistors

5.1.4 Provision of Vibrational Therapy

After diagnosing the location of the ulcers through temperature and pressure at the plantar surface. The device is automated to provide a certain number of vibrations for 30 minutes with an interval of 1 minute. Since local intermittent vibrational therapy is far better than local continuous vibrational therapy. The process of providing vibrational therapy is shown in Fig 5.5.

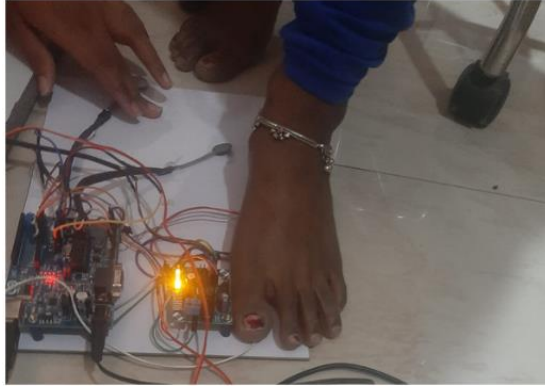


Fig 5.5 Provision of Vibrational Therapy using Vibration Motor module

5.1.5 Gait Assessment

Studies showed that abnormalities in the pattern of walking of diabetic patients can be adopted as a valuable tool for the spotting of these foot ulcers. The detection of gait irregularities can be accomplished with the use of accelerometers and gyroscopes. This is due to the fact that they give the user options for independent movement and fall detection. They are portable and affordable and can be used to track the effects of peripheral neuropathy. The process of measuring Gait parameters is shown in Fig 5.6.



Fig 5.6 GAIT Assessment using Accelerometer

5.1.6 Inference

Table 5.1 indicates the temperature and pressure readings before and after the vibrational therapy.

Table 5.1 Temperature and Pressure readings before and after the vibrational therapy

Region	Forefoot		Midfoot		Hindfoot	
Parameters	Temperature [°C]	Pressure [kPa]	Temperature [°C]	Pressure [kPa]	Temperature [°C]	Pressure [kPa]
Control Group	28±2.1	332±120.2	27±1.3	179.4±89.4	28±3.6	328.7±92.1
Before treatment	32±6.2	390.7±182.7	30±4.4	282.8±244.5	33±5.1	350.2±130.4
After treatment	30±1.2	205.3±118.7	27±2	205.3±118.6	30±2	356±101.2

Table 5.2 represents the gait variations observed for the control group, ulcerated patients before and after the therapy. The risk and fear of falling were found to be higher in diabetes patients with neuropathy. Gait speed, stride length, gait patterns such as shuffling, and sensory gait were all significantly improved after therapy. Retropulsion and festination changed just noticeably, as did gait freeze.

Table 5.2 GAIT variations observed for the control group, ulcerated patients before and after the therapy

Gait Parameters	Control Group	Before Treatment	After Treatment
Stride Length (metre)	0.97±0.03	0.85±0.08	0.90±0.03
Gait Speed (metre/second)	1.17±0.16	0.98±0.10	1.10±0.05
Cadence (steps/minute)	104±16	95±10	104±10
Retropulsion	None	Severe	Mild
Foot drop	None	Yes	Yes
Double support time (%)	28.7-32	36.4-43.2	35.6-41.1
Festination	Normal	Slow or None observed	Moderate
Body symmetry	Good	Mild	No change
Gait Freeze	None	Yes, several times	Mild
Changing Direction	No difficulty	Very difficult	No change
Shuffling Gait	None	Yes	Less dragging gait
Sensory Gait	None	Yes, severe	Yes
Steppage Gait	None	Yes, severe	Yes

5.2 DISCUSSION:

The smart footwear for tracking and primary treatment for diabetic foot ulcers helps to measure the plantar temperature using DS18B20 temperature sensor, measure pressure using the FSR and acceleration using ADXL345 accelerometer. We provided Vibrational therapy when the temperature was greater than 32°C and Pressure greater than 150 kPa. Then we analysed the patterns in temperature, pressure and gait before and after provision of vibrational therapy.

5.2.1 Pattern in Plantar Pressure and Plantar Temperature Before Treatment

The patterns due to varied pressure aids us to discern uneven distribution of load in a foot of a patient with diabetic patient over a span of time, engendering an increase in neuropathic diseases. Consequently, these uneven stress patterns can cause serious nerve injury and constriction of blood flow and signals, finally culminating in the loss of feeling. A diversified sample size between the age group of 18-74 was taken into consideration for diagnosing plantar temperature and plantar pressure. The plantar temperature and pressures were recorded at five different locations of the foot. A temperature range of 32 ± 6.2 °C and a pressure range of 390.7 ± 182.7 kPa was observed in people with diabetic neuropathy. These values coincide with study conducted by Bus et.al., (2021) where they meta analyzed the effectiveness of at-home skin temperature monitoring in reducing the incidence of foot ulcer recurrence in people with diabetes.

5.2.2 GAIT Pattern Before Treatment

Gait parameters such as Stride Length, Gait Speed, Cadence, Retropulsion, Foot drop, Double support time, Festination, Body symmetry, Gait Freeze, Changing Direction, Shuffling Gait, Sensory Gait, and Steppage Gait were measured. The gait patterns were observed for all the participants and it showed a higher gait variability between the control group and patients with diabetic neuropathy. The common parameters included a higher risk or fear of falling, worsened body symmetry, difficulty in changing direction, and increased double support time. The study of Alam et.al., (2017) provided the ranges of neuropathic and non-neuropathic patients, which was the base paper for our observation.

5.2.3 Pattern in Plantar Pressure and Plantar Temperature After Treatment

After providing vibrational therapy to the patients, we measured their plantar temperature and pressure to assess the treatment's effectiveness. The results showed a 1-3°C drop in plantar temperature and a reduction of more than 200 kPa in plantar pressure. The post-treatment plantar temperature range was 30 ± 1.2 °C, which correlates with the control group's temperature range of 28 ± 2.1 °C. The post-treatment

plantar pressure ranged from 205.3 ± 118.7 kPa. The values which we obtained coincided with that of Bus et.al., (2021).

5.2.4 Pattern in GAIT after Treatment

After a certain amount of vibrational therapeutic sessions, the patients showed a significant improvement in terms of cadence, gait velocity, and pattern of walking. A decrease in gait freeze, double support time overall, and moderate festination was observed after several sessions. The parameters measured after the treatment corresponded to that of Tian et.al., (2021) who they constructed wearable Gait Analysis System used for studying the Gait parameters of neuropathic and non-neuropathic type 2 diabetes patients.

The therapy proved to be effective for early-stage ulcers. A specific level of stimulation is delivered at the same time, resulting in a counteractive action that aids with balance and neutralizes the damage produced by the condition after extended use.

CHAPTER – 6

SUMMARY AND CONCLUSION

6.1 SUMMARY

The objective of the development of this device is to alleviate the patients from the discomfort by analyzing the irregular distribution of plantar pressures. This would help the patient track and recuperate from the destruction caused by the illness over time. The pressure distributions give us insight into how the load is dispersed unequally in the plantar surface of a diabetic patient over time, resulting in an increase in Neuropathic diseases. Consequently, these uneven stress patterns can cause serious nerve injury and constriction of blood flow and signals, finally culminating in the loss of feeling. A diversified sample size between the age group of 18-74 was taken into consideration for diagnosing plantar temperature and plantar pressure. The gait patterns were observed for all the participants and it showed a higher gait variability between the control group and patients with diabetic neuropathy. The common parameters included a higher risk or fear of falling, worsened body symmetry, difficulty in changing direction, and increased double support time. After a certain amount of vibrational therapeutic sessions, the patients showed a significant improvement in terms of cadence, gait velocity, and pattern of walking. A decrease in gait freeze, double support time overall, and moderate festination was observed after several sessions. The therapy proved to be effective for early-stage ulcers for more than half of the patients. A specific level of stimulation is delivered simultaneously, resulting in a counteractive action that helps with steadiness and nullifies the injury produced by the illness after extended use.

6.2 CONCLUSION

The device was developed to analyze the uneven distribution of plantar pressures in diabetic patients and alleviate their discomfort while helping them track and recover from the disease. The study used a diverse sample size and found that the uneven stress patterns caused by diabetes could result in serious nerve injury and loss of feeling. Patients with diabetic neuropathy showed higher gait variability, an increased risk of falling, worsened body symmetry, and difficulty changing direction. However, after several vibrational therapeutic sessions, patients showed significant improvements in cadence, gait velocity, and walking pattern. The therapy was effective for early-stage ulcers for more than half of the patients and delivered a specific level of stimulation that helped with steadiness and nullified the injury produced by the illness after extended use. Overall, the device has the potential to be an effective tool for managing the complications of diabetes and improving the quality of life for patients.

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APPENDIX

```
#include <OneWire.h>
```

```
#include <DallasTemperature.h>
```

```
#include <Wire.h>
```

```
#include <Adafruit_Sensor.h>
```

```
#include <Adafruit_ADXL345_U.h>
```

```
#define ONE_WIRE_BUS_1 2
```

```
#define ONE_WIRE_BUS_2 3
```

```
OneWire oneWire_1(ONE_WIRE_BUS_1);
```

```
OneWire oneWire_2(ONE_WIRE_BUS_2);
```

```
DallasTemperature sensor_1(oneWire_1);
```

```
DallasTemperature sensor_2(oneWire_2);
```

```
#define FORCE_SENSOR_PIN_1 A0 // the FSR and 10K pulldown are connected to  
A0
```

```
#define FORCE_SENSOR_PIN_2 A1 // the FSR and 10K pulldown are connected to  
A0
```

```
float temp_1, temp_2;
```

```
int analogReading=0, analogReading_1=0;
```

```
/* Assign a unique ID to this sensor at the same time */
```

```
Adafruit_ADXL345_Unified accel = Adafruit_ADXL345_Unified(12345);
```

```
void displaySensorDetails(void)
```

```
{
```

```
    sensor_t sensor;
```

```
    accel.getSensor(&sensor);
```

```

Serial.println("-----");
Serial.print ("Sensor:   "); Serial.println(sensor.name);
Serial.print ("Driver Ver: "); Serial.println(sensor.version);
Serial.print ("Unique ID: "); Serial.println(sensor.sensor_id);
Serial.print ("Max Value:   "); Serial.print(sensor.max_value); Serial.println("
m/s^2");
Serial.print ("Min Value:  "); Serial.print(sensor.min_value); Serial.println(" m/s^2");
Serial.print ("Resolution: "); Serial.print(sensor.resolution); Serial.println(" m/s^2");
Serial.println("-----");
Serial.println("");
delay(500);
}

```

```

void displayDataRate(void)
{
    Serial.print ("Data Rate:  ");

    switch(accel.getDataRate())
    {
        case ADXL345_DATARATE_3200_HZ:
            Serial.print ("3200 ");
            break;
        case ADXL345_DATARATE_1600_HZ:
            Serial.print ("1600 ");
            break;
        case ADXL345_DATARATE_800_HZ:
            Serial.print ("800 ");
            break;
        case ADXL345_DATARATE_400_HZ:
            Serial.print ("400 ");
            break;
    }
}

```

```
case ADXL345_DATARATE_200_HZ:
    Serial.print ("200 ");
    break;
case ADXL345_DATARATE_100_HZ:
    Serial.print ("100 ");
    break;
case ADXL345_DATARATE_50_HZ:
    Serial.print ("50 ");
    break;
case ADXL345_DATARATE_25_HZ:
    Serial.print ("25 ");
    break;
case ADXL345_DATARATE_12_5_HZ:
    Serial.print ("12.5 ");
    break;
case ADXL345_DATARATE_6_25HZ:
    Serial.print ("6.25 ");
    break;
case ADXL345_DATARATE_3_13_HZ:
    Serial.print ("3.13 ");
    break;
case ADXL345_DATARATE_1_56_HZ:
    Serial.print ("1.56 ");
    break;
case ADXL345_DATARATE_0_78_HZ:
    Serial.print ("0.78 ");
    break;
case ADXL345_DATARATE_0_39_HZ:
    Serial.print ("0.39 ");
    break;
case ADXL345_DATARATE_0_20_HZ:
```

```

    Serial.print ("0.20 ");
    break;
case ADXL345_DATARATE_0_10_HZ:
    Serial.print ("0.10 ");
    break;
default:
    Serial.print ("???? ");
    break;
}
Serial.println(" Hz");
}

```

```

void displayRange(void)
{
    Serial.print ("Range:      +/- ");

    switch(accel.getRange())
    {
        case ADXL345_RANGE_16_G:
            Serial.print ("16 ");
            break;
        case ADXL345_RANGE_8_G:
            Serial.print ("8 ");
            break;
        case ADXL345_RANGE_4_G:
            Serial.print ("4 ");
            break;
        case ADXL345_RANGE_2_G:
            Serial.print ("2 ");
            break;
        default:

```

```

        Serial.print ("?? ");
        break;
    }
    Serial.println(" g");
}

void setup() {
    Serial.begin(9600);
    pinMode(4, OUTPUT);
    digitalWrite(4, HIGH);
    delay(1000);
    digitalWrite(4, LOW);
    pinMode(5, OUTPUT);
    digitalWrite(5, HIGH);
    delay(1000);
    digitalWrite(5, LOW);
    Serial.println("Dallas Temperature IC Control Library Demo");

    Serial.begin(9600);
    Serial.println("Accelerometer Test"); Serial.println("");

    /* Initialise the sensor */
    if(!accel.begin())
    {
        /* There was a problem detecting the ADXL345 ... check your connections */
        Serial.println("Ooops, no ADXL345 detected ... Check your wiring!");
        while(1);
    }

    /* Set the range to whatever is appropriate for your project */
    accel.setRange(ADXL345_RANGE_16_G);

```

```

// accel.setRange(ADXL345_RANGE_8_G);
// accel.setRange(ADXL345_RANGE_4_G);
// accel.setRange(ADXL345_RANGE_2_G);

/* Display some basic information on this sensor */
displaySensorDetails();

/* Display additional settings (outside the scope of sensor_t) */
displayDataRate();
displayRange();
Serial.println("");

delay(5000);

// Start up the library
// Start up the library
sensor_1.begin();
sensor_2.begin();

TCCR1A = 0;// set entire TCCR1A register to 0
TCCR1B = 0;// same for TCCR1B
TCNT1 = 0;//initialize counter value to 0
// set compare match register for 1hz increments
OCR1A = 15624;// = (16*10^6) / (1*1024) - 1 (must be <65536)//100ms timer(15624
for 1 second)
// turn on CTC mode
TCCR1B |= (1 << WGM12);
// Set CS10 and CS12 bits for 1024 prescaler
TCCR1B |= (1 << CS12) | (1 << CS10);
// enable timer compare interrupt
TIMSK1 |= (1 << OCIE1A);

```

```

    sei();//allow interrupts
}

/*
 * Main function, get and show the temperature
 */
void loop(void)
{

    // Serial.print("Requesting temperatures...");
    sensor_1.requestTemperatures();
    sensor_2.requestTemperatures();

    // Serial.print("1: ");
    temp_1 = sensor_1.getTempCByIndex(0);
    // Serial.println(temp_1);
    //Serial.println(analogReading);

    // Serial.print("2: ");
    temp_2 = sensor_2.getTempCByIndex(0);
    // Serial.println(temp_2);
    //Serial.println(analogReading_1);
    if((analogReading > 100) andand (temp_1 > 32))
    {
        // Serial.println("success");
        digitalWrite(4, HIGH);
    }
    else
    {
        digitalWrite(4, LOW);
    }
}

```

```

}
if((analogReading_1 > 400) andand (temp_2 > 32))
{
// Serial.println("success_2");
digitalWrite(5, HIGH);
}
else
{
digitalWrite(5, LOW);
}
sensors_event_t event;
accel.getEvent(&event);

/* Display the results (acceleration is measured in m/s^2) */
Serial.print("X: "); Serial.print(event.acceleration.x); Serial.print(" ");
Serial.print("Y: "); Serial.print(event.acceleration.y); Serial.print(" ");
Serial.print("Z: "); Serial.print(event.acceleration.z); Serial.print("
");Serial.println("m/s^2 ");
// delay(500);
}

ISR(TIMER1_COMPA_vect)
{
analogReading = analogRead(FORCE_SENSOR_PIN_1);
analogReading_1 = analogRead(FORCE_SENSOR_PIN_2);
}

```

Acceptance Letter of Review Paper:

ICECONF -2023 Conference –Decision – Reg Inbox x 🖨️ 🔗

 **ICECONF St. Joseph's Institute of Technology** <iceconf@stjosephstechnology.ac.in>
to aishvariyaashvani123, me, drkrishnakumar_phd ▾

Mon, Nov 28, 2022, 6:38 PM ★ ↶ ⋮

Dear Author,

On behalf of the conference committee, we are happy to inform you that your paper id: ICECONF-23-T3-447 and title " Conspectus of techniques to monitor and control diabetic foot ulcers " is accepted.

We invite you to present your research work at the International Conference on Artificial Intelligence and Knowledge Discovery in Concurrent Engineering (ICECONF -2023).

Registration Information available at

<http://iceconf.org/register.php>

After the payment, kindly send the final paper and payment proof to iceconf@stjosephstechnology.ac.in on or before 30th Nov, 2022.

Conference Date: 5th - 7th January 2023.

While sending your manuscript, mention your paper id in the subject line and rename your file name as paper id without fail.

Best regards,
Organizing Committee,

Acceptance letter of Research Article:

**7th International Conference on
Intelligent Computing and Control Systems
(ICICCS 2023)**
May 17-19, 2023 - Madurai, India
iciccs2023@jstce.ac.in

Letter of Acceptance

TO

Aishvariya Shivani, S, Bhavani Sri S, Krishnakumar, S
Department of Biomedical Engineering, Sathyabama Institute of Science and Technology, Chennai, India.

Paper ID- ICICCS446

Subject: Acceptance to the International Conference on Intelligent Computing and Control Systems [ICICCS 2023], May 17-19, 2023, Madurai, India.

Dear Author,

We are happy to inform you that your paper titled "Smart gadget for tracking and primary treatment of diabetic foot ulcers" has been accepted for the oral presentation at the 7th International Conference on Intelligent Computing and Control Systems [ICICCS 2023] to be held on 17 – 19, May 2023 at Vaigai College of Engineering, Madurai, Tamil Nadu, India.

With the evident of its previous publications, ICICCS 2023 is also dedicated for the publication in IEEE Xplore Digital library. As a result of the peer review process, the technical conference program committee is pleased to inform you that your paper is shortlisted and accepted for the presentation in conference event and formally accepted for inclusion in IEEE Xplore. We appreciate if you could submit the final version of manuscript at your earliest convenience, in order to ensure a novel and timely publication of your research paper.

Once again, on behalf of the conference committee we extend our warm gratitude to welcome you at our conference.

Yours' Sincerely,

Dr. R. Sivaraj,
Conference Chair,
ICICCS 2023

Proceedings by



ICICCS Previous Publications
2022 2021 2020 2019 2018 2017