E-101/9579/2019

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Claims:

I claim,

1. An insole device for detecting changes in plantar pressure, temperature, skin dryness state and electrodermal activity of the foot of persons in need of monitoring the changes in foot plantar pressure, temperature, skin dryness state and electrodermal activity, comprising:
    a) a bottom layer having a first surface and a second surface;
    b) a plurality of pressure sensors implanted onto the first surface of the bottom layer;
    c) an upper layer having a first surface covering the said pressure sensors and attached to the bottom layer along the outside edges, and a second surface having sensors for measuring temperature, skin dryness and electrodermal activity, implanted onto the said second surface and in contact with the foot of the person in need of monitoring the changes in foot plantar pressure, temperature, skin dryness state and electrodermal activity;

wherein the plantar pressure, temperature, skin dryness and electrodermal activity sensors transmit the data through a connector cable to a data acquisition unit, and the said data acquisition unit processes the said data to provide an output, if peak threshold values of pressure are detected and are continuously maintained for more than 15 minutes of time and if temperature variations detected are abnormal and continuously maintained for more than 24 hours of time or if variations in skin dryness state and galvanic skin response values detected are abnormal and continuously maintained for more than 48 hours of time.

2. An insole device as claimed in claim 1, wherein the second surface of the bottom layer is in contact with the sole of a footwear.

3. An insole device as claimed in claim 1, wherein the second surface of the bottom layer is in contact with the receptacle of a pressure, temperature, skin dryness state and electrodermal activity testing mat.

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4. An insole device as claimed in claim 1, wherein the plurality of pressure sensors are located on strategic points such as toe, fore foot, middle foot, and heel areas that have maximum occurrence of foot ulcers due to excessive plantar pressure.

5. An insole device as claimed in claim 1, wherein the temperature sensors are located on the metatarsal area on the dorsal side and plantar side of the foot.

6. An insole device as claimed in claim 1, wherein the electrodermal activity sensor is embedded on a Velcro strap that can be affixed on middle foot pad area, toe area plantar side, big toe, or other toe areas.

7. An insole device as claimed in claim 2, wherein the footwear maybe selected from shoes, sneakers, flip-flops, sandals, chappals, boots and the like.

8. An insole device as claimed in claim 1, wherein the foot plantar pressure, temperature, skin dryness state and electrodermal activity sensors may range from one to thirty in number.

9. An insole device as claimed in claim 8, wherein each of the foot plantar pressure, temperature, skin dryness state and electrodermal activity sensors has a separate output alert indication.

10. An insole device as claimed in claim 9, wherein the said output alert indication is in the form of LED lights and a buzzer.

11. An insole device as claimed in claim 9, wherein the said output alert indication is attached on the dorsal side of footwear for ease of visibility and audibility purpose.

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12. An insole device as claimed in claim 3, wherein the foot plantar pressure, temperature, skin dryness state and electrodermal activity sensor output is displayed on the mat's display unit.

13. An insole device as claimed in claim 12, wherein the strength of the intensity range of pressure, temperature, skin dryness state and electrodermal activity of the foot skin is indicated in the form of color with RGB LED.

14. An insole device as claimed in claim 1, wherein the skin dryness state sensors indicate different states of skin such as wet skin, dry skin, callous skin, or broken skin.

15. An insole device as claimed in claim 1, wherein the temperature, skin dryness and electrodermal activity sensors may be a separate attachment that can be affixed whenever needed on the upper part of the insole and in contact with the skin of the wearer.

16. An insole device as claimed in claim 1, wherein the first and second layers are made of foam, leather, rubber, thick fabrics such as canvas, synthetic materials such as polyurethanes, and the like.

17. An insole device as claimed in claim 1, wherein the sensing units are selected from one or more of pressure sensors, flexible pressure sensors, force-sensing resistor, infrared temperature sensors, contact temperature sensors, thermistor temperature sensor, resistance temperature detector sensors, negative thermal coefficient thermistors, digital temperature sensors, semiconductor based temperature sensor, GSR sensors, and manually fabricated sensors.

18. An insole device as claimed in claim 1, which is customized according to the prescription values suggested by the physician.

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19. An insole device as claimed in claim 1, which is used to detect and control the risk of occurrence of foot ulcers in diabetic and non-diabetic persons.

20. A method for protection and control of risk of occurrence of foot ulcers in persons, the method comprising,

a) monitoring foot plantar pressure, variation in foot skin temperature, variation in skin dryness state and electrodermal activity of the foot plantar area;

b) assessing the changes detected in the measured values;

c) giving an alert indication in case of risk of probable foot ulcer due to either one or combination of changes detected in the measured values;

wherein the changes include a foot peak plantar pressure threshold that is maintained or more than 15 minutes at any specific part of the foot, abnormal temperature variations continuously maintained for more than 24 hours of time, difference in temperature between right foot and left foot is more than the acceptable rangeand is continuously maintained for more than 24 hours of time,abnormal variations in skin dryness state and electrodermal activity values continuously maintained for more than 48 hours of time.

21. A method as claimed in claim 20, wherein the said method can be used for protection and control of ulcers in diabetic and non-diabetic persons.

Dated this 5th day of July, 2019

Signature

Meeta Ruparel

Ruparel Meeta

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METHOD FOR DETECTION AND CONTROL OF DIABETIC FOOT ULCERS

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Technical field of the invention:

This invention relates to the method for detecting a predisposition to getting foot ulcers due to increased foot plantar pressure, variation in foot skin temperature and electrodermal activity of the foot skin in diabetic and non-diabetic patients. More specifically, the present invention relates to methods of controlling foot ulcers through monitoring of foot plantar pressure, temperature, skin dryness state and electrodermal activity of the foot skin in patients suffering from diabetes.

Background of the invention:

Diabetes is among the leading causes of death in the world today, with the impact of the disease rising phenomenally over the last 20 years. Foot ulcers are one of the major complications caused due to poorly controlled diabetes. Approximately 25% of diabetic patients experience an ulcer/wound at some point and get admitted to hospitals due to infected wounds. Foot ulcers can lead to increased morbidity, amputations, and mortality. Because of poor wound healing; amputation incidents resulting from ulcers in diabetic patients are 15 times higher than that found in general population. A planned foot care program can reduce amputation rates by 45 to 85%; early detection is the key to do so.

Literature studies reveal that foot plantar pressure is significant to detect probabilities of foot ulcers. However, peak foot plantar pressure alone cannot give accurate prediction, as foot morbidities resulting in foot ulcers are also due to various other pathogenic activities like foot infections, skin autonomic response activities, foot deformities like ulcers resulting from Charcot foot, etc. Hence it is important to measure other parameters of the foot pathogenesis like skin dryness, galvanic skin response (GSR) or skin conductance and foot skin temperature, in addition to peak foot plantar pressure to enable an accurate detection of risk of foot ulcers and prevent foot ulcerations and its associated morbidities and assure appropriate foot care.

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The largest organ of a human body is skin. The skin not only is a protective barrier to external environmental threats but also contains an extensive network of nerve cells that detect changes in the surrounding environment in various parameters such as pain, temperature, pressure, and moisture, and transmit these changes based on the receptor activities and regulate body temperature by peripheral blood circulation and sweat releases. The total body skin has over three million sweat glands, however density of sweat glands varies across the body and it is observed that sweat glands are the highest in number on the forehead, palms and feet soles. Whenever these sweat glands are triggered, they release sweat and result in electrical changes which are generally measured in terms of skin conductance further known as Galvanic Skin Response (GSR) or electrodermal activity (EDA). The sweat glands functioning cannot be consciously controlled it is regulated by the autonomic nervous system (Sympathetic and Parasympathetic) of which increase in sympathetic activity is associated with sweat gland activity. Measuring EDA (GSR) involves measuring the autonomic changes in the electrical properties of skin resulting due to autonomic sympathetic activities.

Diabetic foot problems and its related diseases are complex issues, which if left unaddressed, result in infections, ulcers and other grave complications that may result in amputations. Diabetic neuropathy results in lack of adequate blood supply in the affected area that in turn reduces oxygen supply to the tissues, further damaging the tissues and subsequently ingresses callous skin and further skin cuts making the area more susceptible to infections. The inadequate blood supply also causes damage to the sensory nervous system further affecting the autonomic nerves and sweat gland regulating activities. Diabetic neuropathy affects nerve fibres; of which nerve fibres responsible for motor actions like sense of temperature changes, pain and other related autonomic functions are involved early and are significant symptomatic observations in foot ulcerations. Lack of pain sensations, temperature change sensations and restricted immune response are the effects of diabetic neuropathy which result in ulceration due to missed or late detections of the resulting morbidities. Diabetic patients with foot ulcers have shown prevalence of severe autonomic neuropathy as compared to diabetic patients with no ulcers. Also, the diabetic patients with no ulcers but with

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autonomic neuropathy and abnormal GSR readings provide an indication of higher chances of foot ulcerations at a later stage, thus proving GSR to be an important parameter to be considered for risk detection of foot ulcers.

Improper sweat gland activities result in skin pathogenesis in terms of elasticity, local temperature, thickness, dryness or moisture level, etc. Moisture or wet skin reduces tissue strength, affects skin elasticity that further increases chances of mechanical damage and ulcers. Prolonged wet skin can also result in trench foot, further resulting in ingression of infections and tropical ulcers. On the other hand, dry skin or callous skin has more chances of skin break and cuts that can ingress infectious pathogenic agents. Hence it is equally important to measure skin wetness, skin dryness, detect skin breaks / cuts and callous skin.

Diabetic pathogenesis also indicates temperature as a parameter that varies from case to case depending on the foot abnormalities. Infections cause inflammation and higher skin temperatures in the infected area. Lack of blood supply and callous skin can result in lower temperatures in that area, and on the other hand diabetic neuropathy cases with inflammation can show a higher than normal temperature depending on the weather and ambient temperature. Ulcers due to Charcot foot also show significantly higher temperature as compared to a normal variation. Hence, foot skin temperature also is an important parameter to monitor, for early detection of any abnormality in the foot pathogenesis.

US20140200486 describes a footwear that can detect pressure and erythema in regions of human foot and send data wirelessly to an electronic medical record via cloud computing and collate the readings to predict which region of the foot is prone to foot ulcers and the patient is accordingly notified.

US5566479 describes a shoe for use by diabetics and other people suffering from maladies caused due to increased foot pressure. Each sensor described has a separate electronic circuitry, so increasing the number of sensors will require that many multiples of circuitry, thereby increasing the weight of the shoe and also escalate the cost thereby making it inaccessible as well as impracticable to a majority of diabetic patients.

US5642096 describes footwear for detecting both pressure and temperature which can communicate to a wearer the changes in pressure and

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temperature in the foot. The footwear contains a device that includes a sensor disposed in a contained liquid mass of a hydrocell carried in the shoe inner sole, the sensor being one that detects both pressure and temperature values. However, a liquid mass is invariably soft and gets depressed on contact with the heel of the wearer so an accurate measurement of pressure may not be possible.

Most of the sensors described in prior art either have a complex method of collecting and analyzing data requiring advance technological methods or they are heavy on the pockets of the target population. Moreover, the prior art documents describe a cumulative foot plantar pressure and not the plantar pressure at specific points on the foot, and they, therefore, do not provide any indication of reducing the localized pressure at any specific point on the foot. Also, none of the prior art references describe galvanic skin response or electrodermal activity of the foot skin and skin dryness state in relation to foot ulcers.

The Applicant has surprisingly discovered that electrodermal activity of the foot skin along with skin dryness state, foot plantar pressure and temperature changes of the foot provide a more accurate method of analyzing the risk for diabetic patients getting foot ulcers, and thus, help in controlling the onset of the malady. The Applicant further has provided means to measure individual foot plantar pressure at four different points on the foot and thereby a method to alleviate the risk of occurrence of foot ulcers due to peak foot plantar pressure by offloading the pressure on those specific points.

Object of the invention:

It is an object of the present invention to provide a simple and economical device for monitoring changes in foot plantar pressure, foot skin temperature, skin dryness state and electrodermal activity of the foot skin of persons in need of monitoring these changes.

It is also an object of the present invention to provide a device for monitoring the foot plantar pressure at specific points on the foot and provide individual assessment thereby enabling the user to offload the foot pressure from that point and thus, reduce the occurrence of developing foot ulcers at each of the possible sensitive locations.

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It is also an object of the present invention to provide an assessment device to physicians for monitoring the changes in foot plantar pressure, foot skin temperature, foot skin dryness state and electrodermal activity of the foot skin of their patients.

It is also an object of the present invention to provide an assessment device to physicians for correlating the changes in foot plantar pressure, foot skin temperature, foot skin dryness state and electrodermal activity of the foot skin of their patients with conditions critical for onset of foot ulcers.

It is also an object of the present invention to provide a mechanism to control the damage caused due to increased foot plantar pressure, changes in foot skin temperature, foot skin dryness state and electrodermal activity of the foot in patients having a disease condition.

It is also an object of the present invention to provide a device to assist physicians in prescribing the parameter specifications for a customized device and, also, for calibration and performance check of the device.

These and other objects and features of the present invention will become apparent from the detailed description given below and the appended claims.

Summary of the invention:

In one aspect, the present invention provides a simple and economical device such as an insole device, for monitoring changes in foot plantar pressure, temperature, skin dryness state and electrodermal activity of the foot of persons in need thereof.

In another aspect, the present invention provides a mat having a receptacle for fitting the insole for monitoring the changes in foot plantar pressure, temperature, skin dryness state and electrodermal activity of the foot of persons in need thereof.

In yet another aspect, the present invention provides a mechanism for prevention and control of the changes in foot plantar pressure at individual points of the foot, temperature, skin dryness state and electrodermal activity of the foot of persons in order to avoid development or aggravation of foot ulcers.

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In yet another aspect, the present invention provides an insole device to assist physicians in prescribing the parameter specifications for a customized device for monitoring changes in foot plantar pressure, temperature, skin dryness state and electrodermal activity of the foot and, also, for calibration and performance check of the device.

Brief description of drawings:

Fig. 1 – Depicts a diagrammatic representation of the bottom layer of the insole device of the present invention with positions of the sensors.

Fig. 2 – Depicts the design of the insole device of the present invention.

Fig. 3 – Depicts another embodiment for the design of the insole device of the present invention.

Fig. 4 – Depicts the functional block diagram of the insole device of the present invention.

Fig. 5– Depicts the device block diagram of the insole device of the present invention.

Figs. 6 and 7 – Depict the prototype of the insole device of the present invention.

Fig. 8 – Depicts the functional block diagram of the mat fitted with the insole device of the present invention.

Fig. 9 – Depicts the device block diagram of the mat fitted with the insole device of the present invention.

Fig. 10 – Depicts the prototype of the mat with the insole device of the present invention.

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Detailed description of the invention:

As described herein, persons in need of monitoring changes in foot plantar pressure, temperature, skin dryness state and galvanic skin response include persons suffering from diabetes, neuropathy, those having poor blood circulation; athletes, persons having gait defects, overweight people, persons wearing ill-fitting footwear, and the like, or any combinations thereof.

As described herein, the term "foot ulcers" includes non-healing open wounds in the foot skin or skin wounds in the foot that are difficult to heal and may be caused due to any of the following conditions such as diabetes, blood circulation problem, damaged peripheral nerves, prolonged pressure on the feet, peripheral arterial disease, kidney failure, high blood pressure, smoking, high cholesterol or sedentary lifestyle, or a combination of one or more above-mentioned conditions.

Redness on the affected skin area is usually the first symptom of an ulcer, which eventually breaks down over time, resulting in an open wound in the skin that does not heal easily. The affected area of the skin may have a different elasticity or firmness or temperature than the surrounding skin. Stage I of an ulcer is similar to a blister and may be painful to touch. The skin breaks over time, exposing a shallow wound bed (Stage II), followed by Stage III that results in a layer of fat beneath the skin, until bones, tendons, or muscles are exposed which is Stage IV of an ulcer. Often the ulcer may be covered with discolored tissue ranging from yellow to green to brown or black, making it difficult to determine the extent of damage simply by looking at the ulcer. Tendency of foot ulcer is a high risk for a diabetic patient who is obese, has smoking habits, or has a posture and gait that results in high plantar pressure for long durations.

Foot plantar pressure is the pressure field that acts between the plantar surface of the foot and the support surface during everyday locomotor activities in other words it is the pressure exerted by the foot on a surface during daily routine activities. Information on foot plantar pressure with respect to duration of pressure, provides valuable insight on a variety of foot disorders, and also aids in diagnosing likely foot wounds at an early stage in order to provide appropriate treatment to prevent aggravation of wounds caused by high foot plantar pressure. Further, foot

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plantar pressure studies during a gait cycle provides insight to gait asymmetries and other lower limb dysfunction enabling physicians to identify root cause of problems and give appropriate line of treatment and care. The key sensitive areas of foot that have a tendency to get affected are toe, fore pad of foot, side pad of foot or the middle area of the foot and the heel. Foot peak plantar pressure for a prolonged duration has a high tendency to cause ulceration.

Accordingly, the Applicant has designed an insole device that has pressure sensors embedded in the insole in the toe, fore pad, side pad, and the heel area of the foot that can detect the foot plantar pressure at these four points, and underneath the toe; temperature at the foot metatarsal area dorsal and plantar side and galvanic skin response at plantar side and communicate to the wearer of any possible risk of development or aggravation of foot ulcers. The wearer can then re-position himself/herself to offload and reduce the plantar pressure on the foot and thereby reduce the chances of developing foot ulcers. Further, in case of foot skin temperature variations and skin dryness changes alert indications given by the insole device, the wearer can immediately visit the doctor for further care and thereby reduce the chances of developing foot ulcers. It has been noticed that the peak plantar pressure threshold varies from person to person and is dependent on various factors like gender, age, body weight, body mass index, height, geographical variations due to lifestyle, body structures, eating habits, etc.

The Applicant has also observed, based on interactions with diabetologists and podiatrists, that apart from foot plantar pressure, foot skin electrodermal activity or galvanic skin response, skin dryness state and foot skin temperature are other crucial parameters to monitor detection of ulceration. It is observed that ulceration happens when there is repeated friction due to high pressure, in an area where there is dry skin, dead skin and skin breaks (cuts) which if left open result in infections and other unhealthy foot outcomes. Also, the first initial symptom is change in skin temperature in the foot sole area which goes unobserved or not sensed by a diabetic patient and in cases of peripheral neuropathy (diabetic and non-diabetic). However, these parameters are best monitored by a clinical specialist on a regular basis but not necessarily required to be monitored on a real time basis by the patient i.e. the insole user. Hence, in certain embodiments of the

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present invention, the temperature sensor and GSR sensor may be optional features that are in an attachable form factor and can be attached to the insole if real time monitoring of these parameters are critical for a wearer and also for detecting these additional parameters a mat has been designed and made available for the physicians to enable proper monitoring of important foot health parameters and ensure efficient diagnosis and efficacy in appropriate foot care.

With reference to Fig. 1, **A1** is the bottom layer of the insole, **S1** is sensor 1 that is placed on the toe area, **S2** is sensor 2 that is placed on the fore foot area, **S3** is sensor 3 that is placed on the side foot area, here termed as middle foot area, and **S4** is sensor 4 that is placed on the heel area.

Referring to Fig. 2, the insole **A** comprises of the bottom layer **A1** of a thin foam sheet. The four sensors **S1**, **S2**, S3 and **S4** are implanted on layer **A1** which is then covered with a top layer of thin foam sheet **A2.** The temperature sensor **S9** and GSR (EDA) sensor **S11** are placed on upper side of **A2** layer.

In certain embodiments, the Fig. 3 provides a design wherein the temperature and GSR monitoring is optional. In this design there are two temperature sensors and one GSR sensor, and these sensors are embedded in velcro straps which are attachable to the insole **A**. Sensor **S9** is the contact temperature sensor for the foot plantar side and Sensor **S10** is the non-contact temperature sensor for the foot dorsal side (both located generally near the 5^{th} metatarsal phalangeal joint area) and Sensor **S11** is the GSR sensor which can be placed wherever the foot area needs to be checked for its electrodermal activity and the skin dryness state (Generally placed on the foot plantar side middle foot pad area or the big toe or other toes area).

The insole device is the device that acquires the sensor readings from insole **A** and processes the data to analyse the pressure implied on the sensors and the foot skin temperature, the foot skin dryness state and the foot's galvanic skin response. The device further gives an alert when a particular threshold of peak plantar pressure is measured and detected to be prevailing for specified time duration on a continual basis. The time duration may be fifteen minutes and above. The device also gives an alert if the foot skin temperature is abnormally

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high or low than the normal variation or if there is a noticeable difference in temperature between the right foot and left foot that is more than 3°C and is detected to be prevailing for specified time duration on a continual basis. The time duration may be 24 hours and above. The device also gives an alert if the foot skin is very dry or wet or broken and is detected to be prevailing for specified time duration on a continual basis. The time duration may be 48 hours and above.

Referring to Fig. 4 which is the functional block diagram of the insole device of the present invention, **I1** is where the sensors measure the pressure applied, foot skin temperature and skin dryness state, **I2** is the data acquisition system wherein the readings from the sensors are acquired, **I3** is where the acquired data is processed and analysed. In **I4** an initial alert with an LED (Light Emitting Diode) is given if a specified peak pressure threshold or abnormal temperature or abnormal skin dryness state is detected in any of the sensors. This is achieved by turning its respective LED to ON state. **I5** is a second alert which is indicated with a buzzer if the peak plantar pressure threshold is continuously detected for next 15 minutes even after LED alert indication is ON for its respective sensor or if abnormal variation in foot skin temperature is continuously detected for next 24 hours even after its respective LED alert indication is ON or skin dryness state changes is continuously detected for next 48 hours even after its respective LED alert indication is ON.

Referring to Fig. 5, the insole device block diagram, **A** is the insole with the array of sensors, **B** is the device board that comprises of the data acquisition system, microcontroller for data processing and analysis and the power supply unit that supplies regulated power to the insole device.

The microcontroller processes the data received, computes the sensor reading values and analyses the readings to detect specified peak pressure thresholds and continuous peak pressure for a specific duration of time based on physician's prescription or pre-decided research analysis results. On detecting a peak pressure threshold on a particular pressure sensor the microcontroller triggers an alert indication by switching its respective LED to ON state, if no pressure off-loading activity observed even after the alert LED indication and

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peak pressure continues to be detected for next 15 minutes then the buzzer is triggered to ON state.

On detecting abnormal temperature changes (Higher or lower than normal temperature) in the foot plantar or a difference in temperature between the right foot and left foot of more than 3°C the microcontroller triggers an alert by switching its respective LED to ON state, if the temperature change continues to be abnormal for the next 24 hours even after the LED indication alert then the buzzer is triggered to ON state.

On detecting abnormal skin dryness state in the foot plantar being very dry, wet, callous or broken skin state then the microcontroller triggers an alert by switching its respective LED to ON state, if the skin dryness state change continues to be abnormal for the next 48 hours even after the LED indication alert then the buzzer is triggered to ON state.

The power supply unit provides a regulated power supply to the insole device and it comprises of a regulated power supply circuitry that, a rechargeable battery with a low battery indicator and a battery charging with isolation protection circuitry.

C is a flexible flat cable connector connecting insole **A** to the device board **B**".

D is the alarm indicator board and comprises of an array of LEDs and a buzzer. The alarm indicator board comprises of 5 LEDs and one buzzer. Each of the LEDs represent specific sensors and an LED of a pressure sensor is turned ON when peak pressure threshold for continuous specified time interval is detected by any of its respective pressure sensor (**S1, S2, S3, S4**) and LED of temperature sensor is turned ON when foot skin temperature is higher or lower than the normal skin temperature or if the foot skin temperature between the right foot and left foot is varying with a difference of more than the specified variation or if the difference is more than 3°C continuously for a specified time interval and is detected by **S9** and **S10** that is placed on the foot. The LED for skin dryness state is turned ON when the foot skin is very wet / dry / callous / broken and is detected by GSR sensor **S11**.

The buzzer is turned ON when no pressure-offloading happens even after an alert is indicated with its respective LED and peak pressure threshold continues

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to be detected by any of the sensors for 15 minutes after indication of the LED alert or if abnormal temperature changes continues to be detected by its sensors for 24 hours after indication of its respective LED alert or if skin dryness state changes continues to be detected by its sensors for 48 hours after indication of its respective LED alert.

Any of a variety of materials can be used to make the insole parts **A1** and **A2**, including but not limited to foam, leather, rubber, thick fabrics such as canvas, synthetic materials such as polyurethanes, and the like.

The sensors used in the present invention may be selected from one or more of pressure sensors, flexible pressure sensors, force-sensing resistor (FSR), Infrared (IR) temperature sensors which are non-contact temperature sensors, contact temperature sensors, thermistor temperature sensor, Resistance Temperature Detector or RTD, negative thermal coefficient (NTC) thermistors, digital temperature sensors, semiconductor based temperature sensor, GSR sensors or sensors measuring galvanic skin response, GSR sensors and pressure sensors which may be fabricated manually, and the like.

The insole of the present invention and its device design is such that it can be attached to any type of footwear that the person/patient wears on a daily basis. The footwear may be shoes, sneakers, sandals, flip-flops, chappals, boots, and the like.

With reference to Fig. 6, the insole device prototype design shows how the insole and its device can be attached to any type of shoe or a sandal that a person maybe wearing on a regular basis. **A** is the insole with array of sensors which is placed inside the shoe. In certain embodiments, embedded on upper side of insole **A** is the GSR sensor **S11** and the temperature sensors **S9** and **S10** which are hidden and cannot be seen in Fig. 6. In certain other embodiments, the temperature and GSR sensors are attachable and hence, not visible on the upper side of the shoe as depicted in Fig.7. **B** is the insole device which is fitted on top of the shoe (foot dorsal side), **C** is the connector that connects the insole to its device, and **D** is the alarm indicator board and comprises of an array of LEDs and a buzzer.

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D is placed on the upper cover case of insole device **B** for proper vision of an indication of LEDs in the top line and an audible buzzer placed in the centre of the upper cover case. Each LED is labelled to indicate the sensor location it represents, to enable the wearer appropriate pressure off-loading in foot area indicating high plantar pressure and for suggesting the wearer to visit a doctor in case of abnormal temperature or skin dryness state indication.

T: is LED for sensor **S1** (Toe area)

F: is LED for sensor **S2** (Fore Foot area)

M: is LED for sensor **S3** (Side Foot area or Middle Foot area)

H: is LED for sensor **S4** (Heel area)

ST: is LED for sensor **S9** and **S10** (Temperature)

SD: is LED for sensor **S11** (GSR)

The above figures show right foot insole device and a person skilled in the art will understand that similar set of sensors are present on the left foot insole and are numbered sequentially though not visible in the above figures. The alarm indicator comprising of LEDs and buzzer get triggered to ON state in a similar manner as described above.

The insole device is designed such that it is easy to attach, easy to use and easy to understand. It is also comfortable, user-friendly and has an aesthetic appearance.

Since, the peak threshold pressure varies from person to person and is dependent on various factors like gender, age, body weight, body mass index, height, geographical variations due to lifestyle, body structures, eating habits, etc., it would be inaccurate to ambiguously state a peak pressure threshold value based on literature. Hence, to ensure accuracy and efficacy in quality of monitoring and care, the threshold value of peak plantar pressure and time duration for detection and alert is designed to be prescription based which is given by the patient's physician, based on the patient's physical and lifestyle factors, clinical parameters and medical history; i.e. the peak plantar pressure threshold is prescribed by the patient's physician and the time duration of continuous peak plantar pressure after which the alert is to be given is also prescribed by the physician. Similarly, the temperature variation to be monitored, the foot skin's dryness state to be

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monitored, and the foot's electrodermal activity (GSR or skin conductance) to be monitored with respect to the identified regular time intervals are also prescribed by the physician for efficacy in foot care.

Accordingly, in another embodiment, the insole device of the present invention can be fitted on to a mat specifically designed to enable the physician to give a prescription for the insole. In order to ensure no doubts of calibration and variation in device from unit to unit, the mat is such designed that it has a set of insoles that are detachable, so that it can be replaced by the patient's insoles and its readings monitored to enable the physician to give appropriate prescription that is patient specific and user centric and also to check the insole sensors performance for calibration needs if any. Thus, the mat with its insole device indicates the current foot plantar pressure for each sensor area. The insoles of Right foot (R) and Left foot (L) both can be attached to the mat and it displays the plantar pressures of all the four sensors of both the feet; i.e. total eight pressure sensor readings, in one glance. The Temperature sensors and the GSR sensor can also be attached to the mat and it displays the temperature parameters of both the feet in one glance. In addition to the skin dryness state the mat device also indicates the foot skin conductance with the GSR sensor. For safety purpose it is advised to use GSR sensor of one foot at one given time, hence only one foot's GSR sensor is attached at a time, after which the physician can detach it and attach the GSR sensor of the other foot to assess the electrodermal activity of the foot skin. As an alternative for device portability and user comfort the temperature sensors and GSR sensors are also provided with a separate OLED display, in order to enable the physician with ease of mobility and detachable application of these sensors in other foot areas. This embodiment of the insole device fitted into a mat is for the physicians' use only. The insole device of the mat provides an insight to the plantar pressure, temperature and GSR parameters (Skin Conductance and Skin dryness state) of a patient's foot and thus supports the physician in analysing the foot health state and further enable an appropriate line of care and treatment.

The readings of Pressure are generally stated as Force per unit area perpendicular to the surface. The International System of Units of Pressure is

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"Pascal" (Pa) and when Pa is prefixed with "k"; i.e. the unit is "Kilopascal", it is termed as "kPa". Electrodermal activity (EDA) is the continuous variation in the skin's electrical characteristics. EDA is also known as galvanic skin response (GSR), skin conductance response (SCR), skin conductance level (SCL), electrodermal response (EDR), sympathetic skin response (SSR) and psychogalvanic reflex (PGR). GSR is the ability to conduct electricity in a given area of skin and the unit for GSR is microSiemens (μS). Skin dryness is nominally rated as "Wet", "Dry", "Callous", "Broken".

Referring to Fig.8, the functional block diagram of the insole device in the mat, **I6** are the sensors of both right (R) foot and left (L) foot that measure the pressure applied, **I7** are the temperature sensor and GSR sensors, **I8** is the data acquisition system wherein the sensors readings data is acquired, **I9** is where the acquired data is processed and analysed, and **I10** displays each sensor readings on an OLED (organic light-emitting diode) display or a TFT LCD (thin-film-transistor liquid-crystal) display and indicates its value strength or intensity range in terms of an LED color.

Referring to Fig.9, the device block diagram of the insole device placed in the mat, showing the following.

L: is the Left side Foot Insole

R: is the Right-side Foot Insole

A: is the insole with the array of sensors comprising of Right side insole **A** pressure sensor arrays (**S1**, **S2**, **S3, S4**), Left side insole **A** pressure sensor arrays (**S5**, **S6**, **S7**, **S8**), attachable temperature sensors and GSR sensors.

S9: is the Contact Temperature Sensor placed on the 5th metatarsal phalangeal joint area (Right foot plantar side)

S10: is the Non-Contact Temperature Sensor placed on the 5th metatarsal phalangeal joint area (Right foot dorsal side)

S11: is the GSR Sensor (Right foot plantar middle foot pad area or toes)

S12: is the Contact Temperature Sensor placed on the 5th metatarsal phalangeal joint area (Left foot plantar side)

S13: is the Non-Contact Temperature Sensor placed on the 5th metatarsal phalangeal joint area (Left foot dorsal side)

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S14: is the GSR Sensor (Left foot plantar middle foot pad area or toes)

C: is the connector connecting the insole "A" to the device board "E".

E: is the device board that comprises of the data acquisition system, microcontroller for data processing and analysis and the power supply unit comprising of a rechargeable battery along with a low battery indicator and a battery charging with isolation protection circuitry that supplies regulated power to the insole device in the mat.

The microcontroller processes the data received, computes the sensor reading values and analyses the readings to display the parameters measured on an OLED display or a TFT LCD display. The parameters displayed are: Foot plantar pressure, foot skin temperature, foot skin dryness and foot skin conductance. Based on the parameter range the RGB (Red Blue and Green) LED is also triggered to ON state in the colour with respect to the parameter intensity range from "Low to Highest".

G: is the Display unit comprising of two displays which display each sensor readings on an OLED display or a TFT LCD display

J: is the Display unit which displays each sensor reading in terms of its strength or intensity range indicated by colour of RGB LED.

LED OFF: No reading

LED ON: Blue Colour (Range 1)

LED ON: Green Colour (Range 2)

LED ON: Yellow Colour (Range 3)

LED ON: Red Colour (Range 4)

LED ON: Purple Colour (Range 5)

where range 1 to 5 are ranges from lowest to highest.

All Pressure values are given in kPa, Skin temperature in °C, Skin Dryness in score of "Wet, Dry, Callous, Broken", and Skin Conductance in µS.

Referring to Fig.10, the prototype of the mat with the insole device of the present invention, showing how the Right Foot insole and Left Foot insole can be attached to the mat.

K: is the mat.

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R: is the Right Foot insole attachment side of the mat.

L: is the Left Foot insole attachment side of the mat.

A: is the insole with array of sensors which is mounted on the mat as shown

E: is the Mat Device which is fitted on top side of the mat

C: is the connector that connects the insole to the Mat Device

G: is the OLED or TFT LCD display comprising of two displays G1 and G2

G1: is the display for the foot plantar pressure readings

The pressure measured by **S1** is the pressure value of Toe area of Right foot and is displayed as "**Tr**"

The pressure measured by **S2** is the pressure value of Fore Foot area of Right foot and is displayed as "**Fr**"

The pressure measured by **S3** is the pressure value of Middle Foot area of Right foot and is displayed as "**Mr**"

The pressure measured by **S4** is the pressure value of Heel area of Right foot and is displayed as "**Hr**"

The pressure measured by **S5** is the pressure value of Toe area of Left foot and is displayed as "**Tl**"

The pressure measured by **S6** is the pressure value of Fore Foot area of Left foot and is displayed as "**Fl**"

The pressure measured by **S7** is the pressure value of Middle Foot area of Left foot and is displayed as "**Ml**"

The pressure measured by **S8** is the pressure value of Heel area of Left foot and is displayed as "**Hl**"

G2: is the display for the foot temperature and GSR readings

The temperature measured by **S9** is the skin temperature value of the metatarsal area of the right foot plantar side and is displayed as "**STpr**"

The temperature measured by **S10** is the skin temperature value of the metatarsal area of the right foot dorsal side and is displayed as "**STdr**"

The skin dryness measured by **S11** is the skin dryness level value of the right foot plantar skin and is displayed as "**SDr**"

The skin conductance measured by **S11** is the skin conductance value of the right foot plantar skin and is displayed as "**SCr**"

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The temperature measured by **S12** is the skin temperature value of the metatarsal area of the left foot plantar side and is displayed as "**STpl**"

The temperature measured by **S13** is the skin temperature value of the metatarsal area of the left foot dorsal side and is displayed as "**STdl**"

The skin dryness measured by **S14** is the skin dryness level value of the left foot plantar skin and is displayed as "**SDl**"

The skin conductance measured by **S14** is the skin conductance value of the left foot plantar skin and is displayed as "**SCl**"

J: is the LED indicator comprising of an array of RGB LEDs. It is placed on the top side of the mat for proper vision of an indication and its colour indicating the parameter range. Each LED is labelled to indicate the sensor location it represents, to enable the wearer and the physician; proper diagnostic display of parameter ranges in one glance for all sensors that were in use during the foot health check process.

Tr: is LED for sensor **S1** (Right foot plantar pressure Toe area)

Fr: is LED for sensor **S2** (Right foot plantar pressure Fore Foot area)

Mr: is LED for sensor **S3** (Right foot plantar pressure Middle Foot area)

Hr: is LED for sensor **S4** (Right foot plantar pressure Heel area)

Tl: is LED for sensor **S5** (Left foot plantar pressure Toe area)

Fl: is LED for sensor **S6** (Left foot plantar pressure Fore Foot area)

Ml: is LED for sensor **S7** (Left foot plantar pressure Middle Foot area)

Hl: is LED for sensor **S8** (Left foot plantar pressure Heel area)

STpr: is LED for sensor **S9** (Right Foot Plantar Skin Temperature)

STdr: is LED for sensor **S10** (Right Foot Dorsal Skin Temperature)

SDr: is LED for sensor **S11** (Right Foot Skin Dryness)

SCr: is LED for sensor **S11** (Right Foot Skin Conductance)

STpl: is LED for sensor **S12** (Left Foot Plantar Skin Temperature)

STdl: is LED for sensor **S13** (Left Foot Dorsal Skin Temperature)

SDl: is LED for sensor **S14** (Left Foot Skin Dryness)

SCl: is LED for sensor **S14** (Left Foot Skin Conductance)

It is to be noted that for health safety reasons, the GSR sensors on both right and left feet insole devices on the mat may not be used simultaneously.

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Claims:

I claim,

1. An insole device for detecting changes in plantar pressure, temperature, skin dryness state and electrodermal activity of the foot of persons in need of monitoring the changes in foot plantar pressure, temperature, skin dryness state and electrodermal activity, comprising:
    a) a bottom layer having a first surface and a second surface;
    b) a plurality of pressure sensors implanted onto the first surface of the bottom layer;
    c) an upper layer having a first surface covering the said pressure sensors and attached to the bottom layer along the outside edges, and a second surface having sensors for measuring temperature, skin dryness and electrodermal activity, implanted onto the said second surface and in contact with the foot of the person in need of monitoring the changes in foot plantar pressure, temperature, skin dryness state and electrodermal activity;

wherein the plantar pressure, temperature, skin dryness and electrodermal activity sensors transmit the data through a connector cable to a data acquisition unit, and the said data acquisition unit processes the said data to provide an output, if peak threshold values of pressure are detected and are continuously maintained for more than 15 minutes of time and if temperature variations detected are abnormal and continuously maintained for more than 24 hours of time or if variations in skin dryness state and galvanic skin response values detected are abnormal and continuously maintained for more than 48 hours of time.

2. An insole device as claimed in claim 1, wherein the second surface of the bottom layer is in contact with the sole of a footwear.

3. An insole device as claimed in claim 1, wherein the second surface of the bottom layer is in contact with the receptacle of a pressure, temperature, skin dryness state and electrodermal activity testing mat.

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4. An insole device as claimed in claim 1, wherein the plurality of pressure sensors are located on strategic points such as toe, fore foot, middle foot, and heel areas that have maximum occurrence of foot ulcers due to excessive plantar pressure.

5. An insole device as claimed in claim 1, wherein the temperature sensors are located on the metatarsal area on the dorsal side and plantar side of the foot.

6. An insole device as claimed in claim 1, wherein the electrodermal activity sensor is embedded on a Velcro strap that can be affixed on middle foot pad area, toe area plantar side, big toe, or other toe areas.

7. An insole device as claimed in claim 2, wherein the footwear maybe selected from shoes, sneakers, flip-flops, sandals, chappals, boots and the like.

8. An insole device as claimed in claim 1, wherein the foot plantar pressure, temperature, skin dryness state and electrodermal activity sensors may range from one to thirty in number.

9. An insole device as claimed in claim 8, wherein each of the foot plantar pressure, temperature, skin dryness state and electrodermal activity sensors has a separate output alert indication.

10. An insole device as claimed in claim 9, wherein the said output alert indication is in the form of LED lights and a buzzer.

11. An insole device as claimed in claim 9, wherein the said output alert indication is attached on the dorsal side of footwear for ease of visibility and audibility purpose.

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12. An insole device as claimed in claim 3, wherein the foot plantar pressure, temperature, skin dryness state and electrodermal activity sensor output is displayed on the mat's display unit.

13. An insole device as claimed in claim 12, wherein the strength of the intensity range of pressure, temperature, skin dryness state and electrodermal activity of the foot skin is indicated in the form of color with RGB LED.

14. An insole device as claimed in claim 1, wherein the skin dryness state sensors indicate different states of skin such as wet skin, dry skin, callous skin, or broken skin.

15. An insole device as claimed in claim 1, wherein the temperature, skin dryness and electrodermal activity sensors may be a separate attachment that can be affixed whenever needed on the upper part of the insole and in contact with the skin of the wearer.

16. An insole device as claimed in claim 1, wherein the first and second layers are made of foam, leather, rubber, thick fabrics such as canvas, synthetic materials such as polyurethanes, and the like.

17. An insole device as claimed in claim 1, wherein the sensing units are selected from one or more of pressure sensors, flexible pressure sensors, force-sensing resistor, infrared temperature sensors, contact temperature sensors, thermistor temperature sensor, resistance temperature detector sensors, negative thermal coefficient thermistors, digital temperature sensors, semiconductor based temperature sensor, GSR sensors, and manually fabricated sensors.

18. An insole device as claimed in claim 1, which is customized according to the prescription values suggested by the physician.

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19. An insole device as claimed in claim 1, which is used to detect and control the risk of occurrence of foot ulcers in diabetic and non-diabetic persons.

20. A method for protection and control of risk of occurrence of foot ulcers in persons, the method comprising,

a) monitoring foot plantar pressure, variation in foot skin temperature, variation in skin dryness state and electrodermal activity of the foot plantar area;

b) assessing the changes detected in the measured values;

c) giving an alert indication in case of risk of probable foot ulcer due to either one or combination of changes detected in the measured values;

wherein the changes include a foot peak plantar pressure threshold that is maintained or more than 15 minutes at any specific part of the foot, abnormal temperature variations continuously maintained for more than 24 hours of time, difference in temperature between right foot and left foot is more than the acceptable rangeand is continuously maintained for more than 24 hours of time,abnormal variations in skin dryness state and electrodermal activity values continuously maintained for more than 48 hours of time.

21. A method as claimed in claim 20, wherein the said method can be used for protection and control of ulcers in diabetic and non-diabetic persons.

Dated this 5th day of July, 2019

Signature

Meeta Ruparel

Ruparel Meeta

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E- 101/ 9576/2019

Abstract:

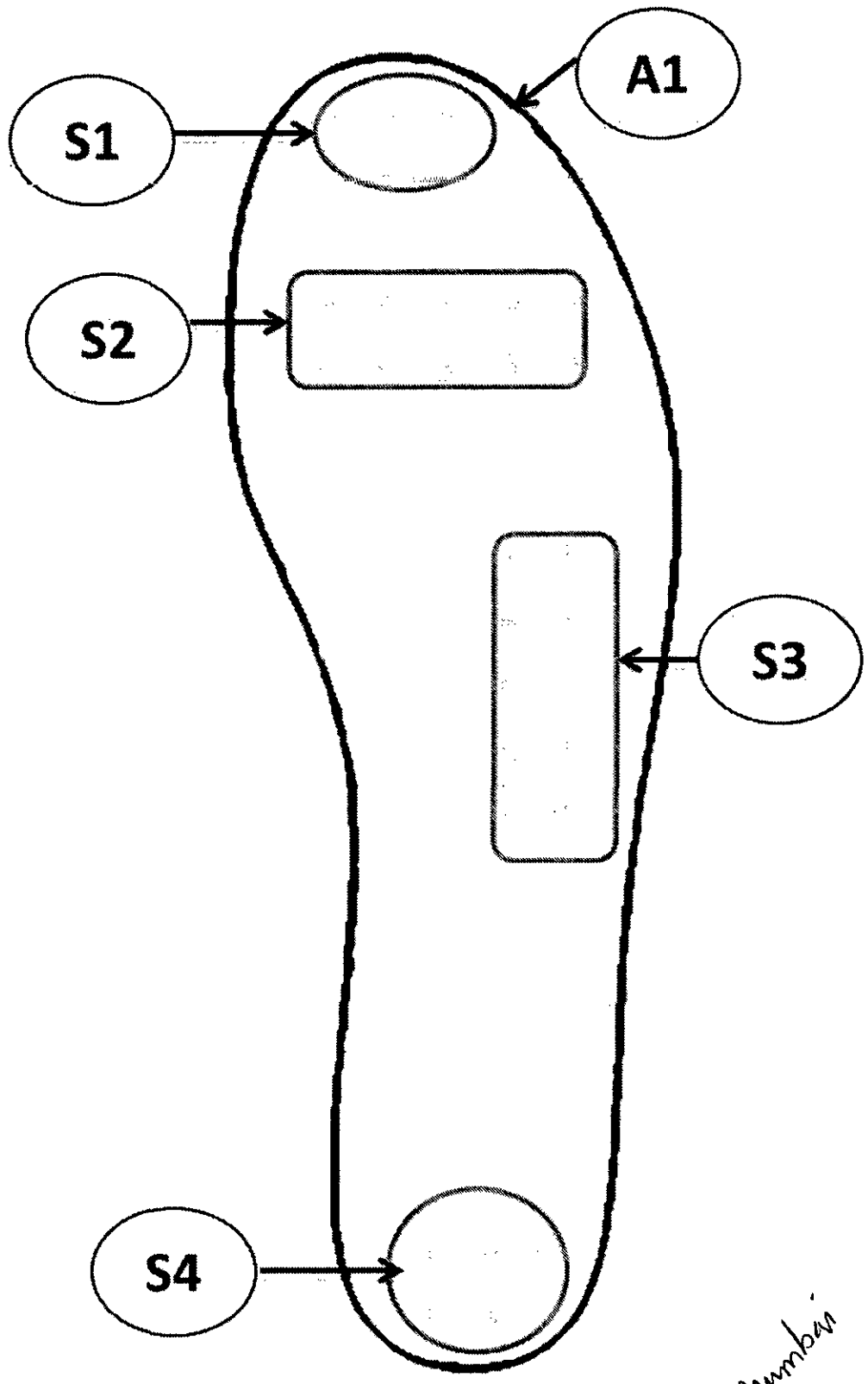
Provided is a device and method for detecting a predisposition to getting foot ulcers due to increased foot plantar pressure and variations in foot skin temperature, skin dryness state and electrodermal activity of skinof the foot in diabetic and non-diabetic patients (Fig. 7).

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Fig.1

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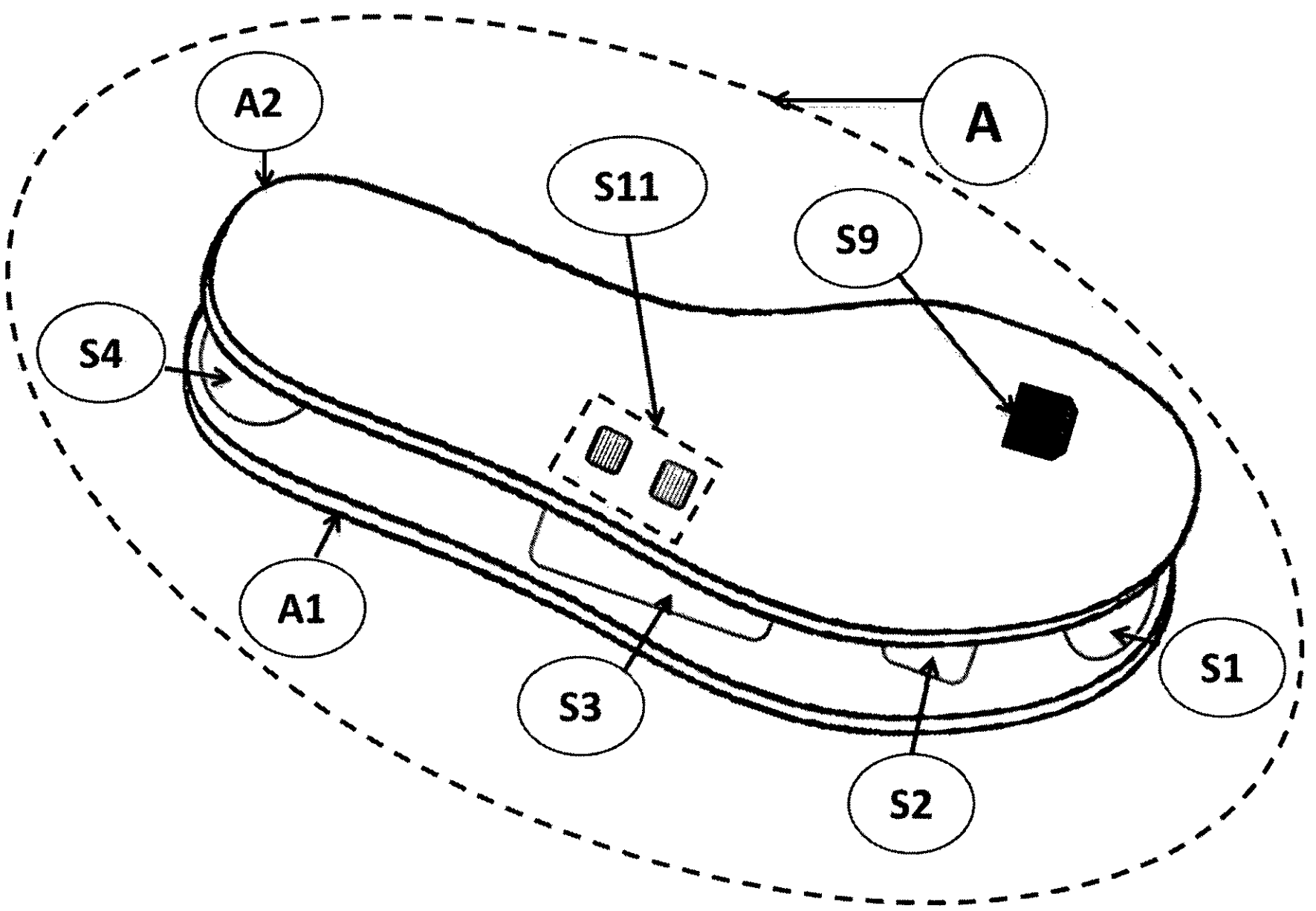


Fig. 2

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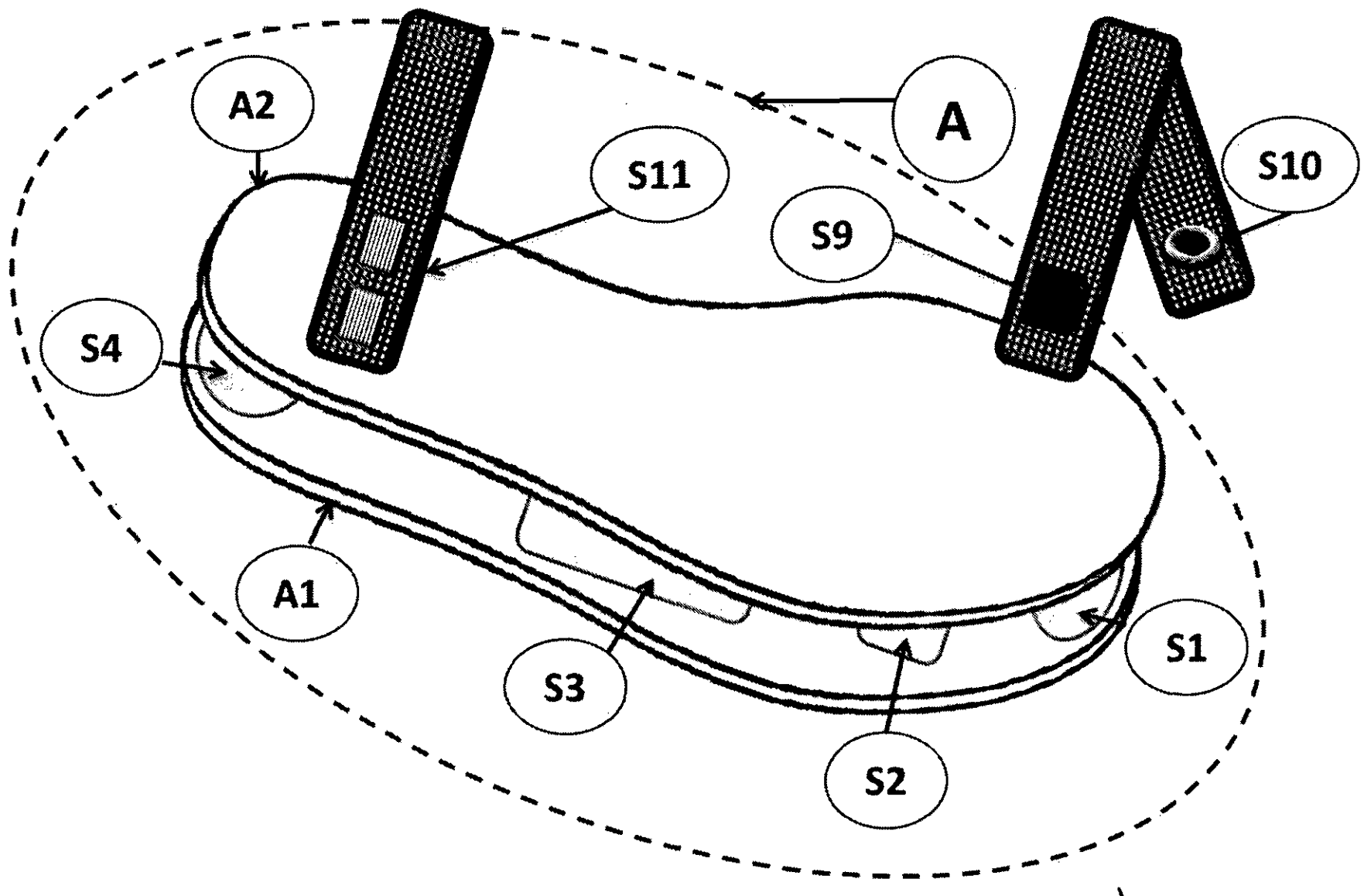


Fig. 3

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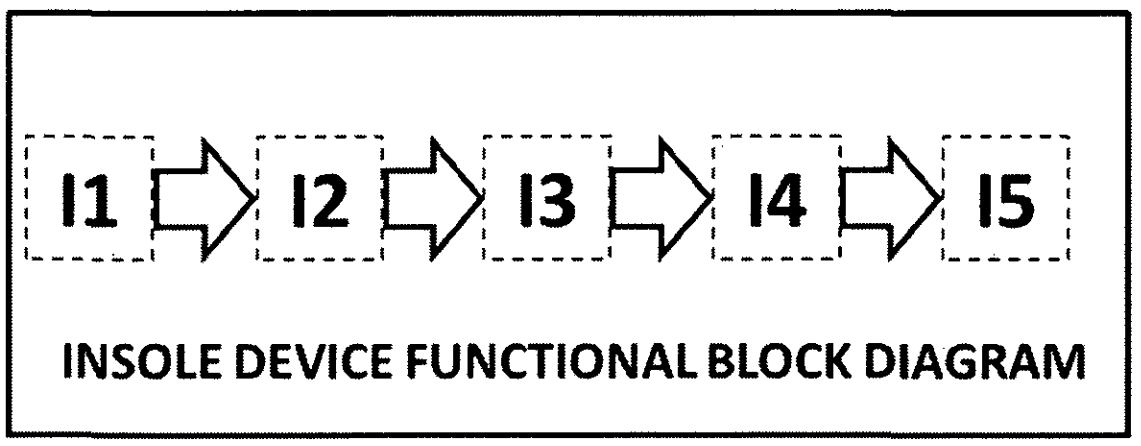


Fig. 4

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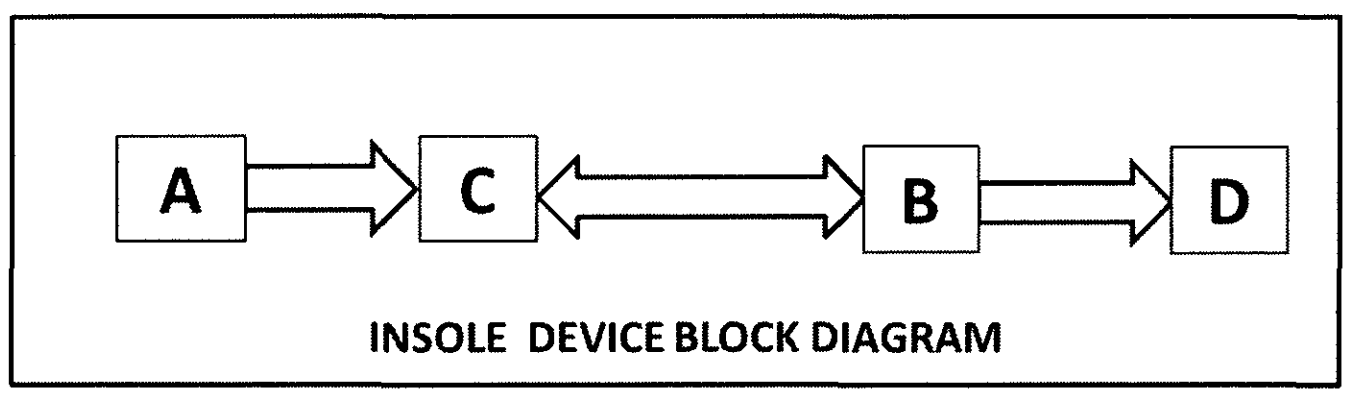


Fig. 5

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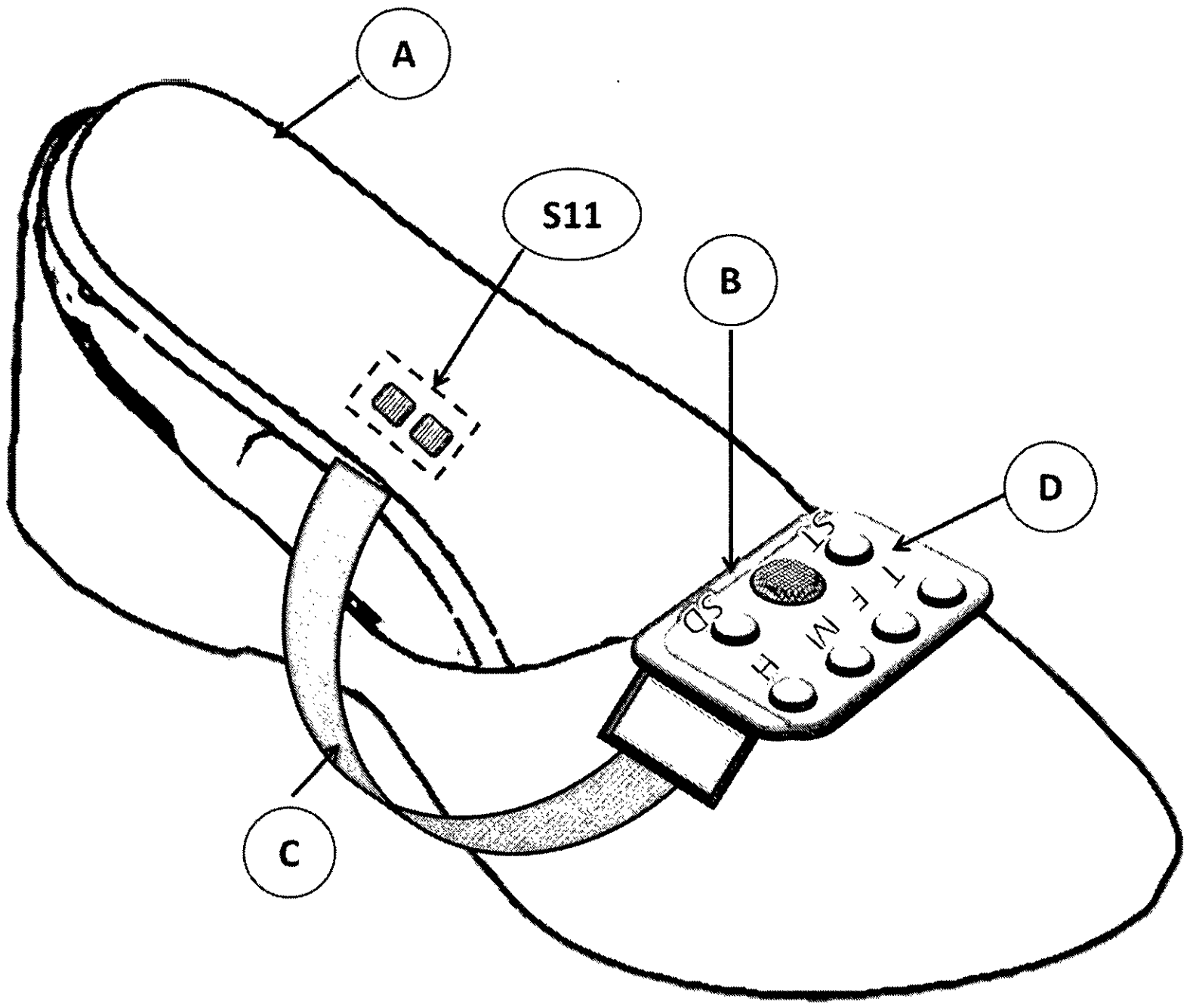


Fig. 6

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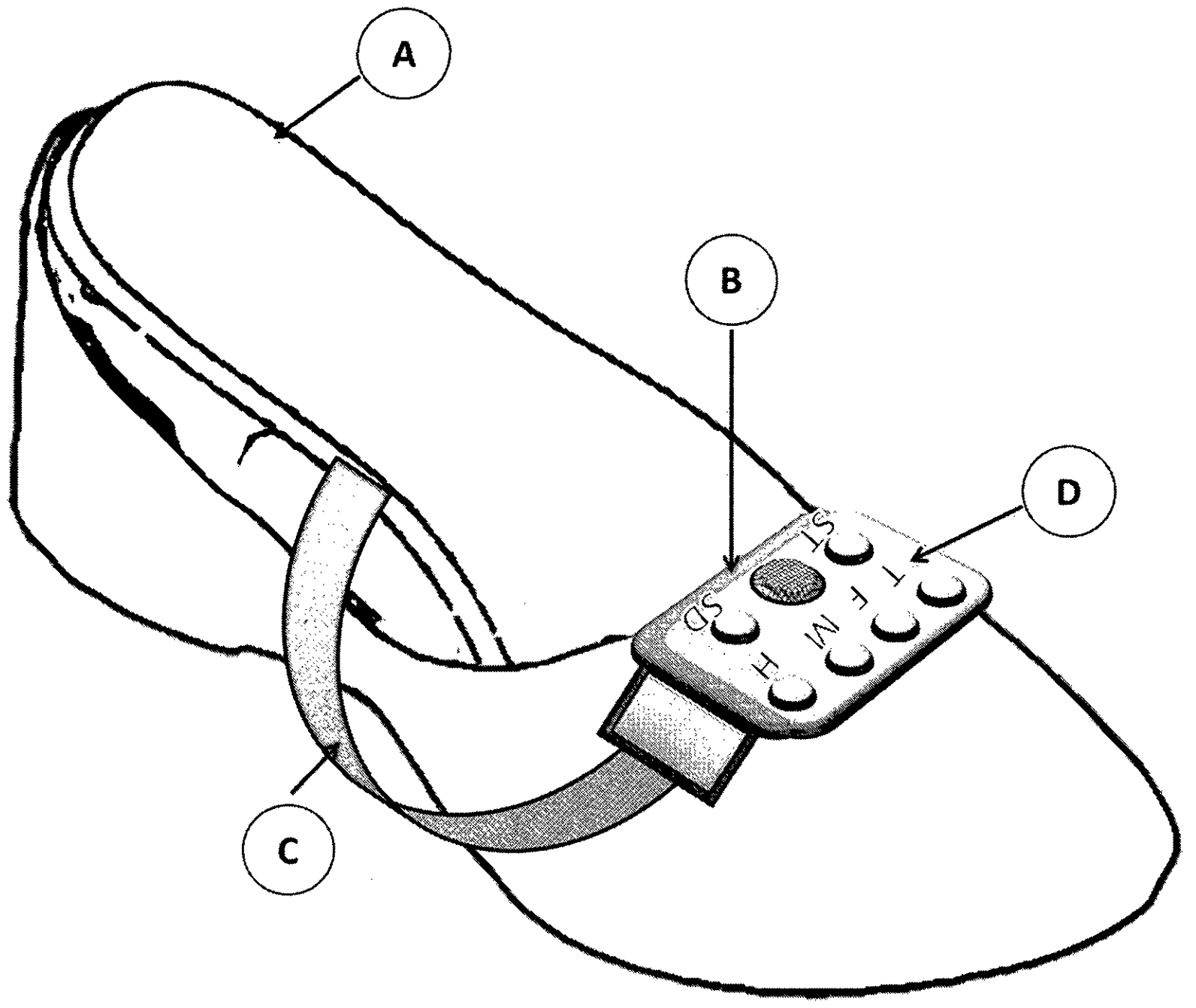


Fig. 7

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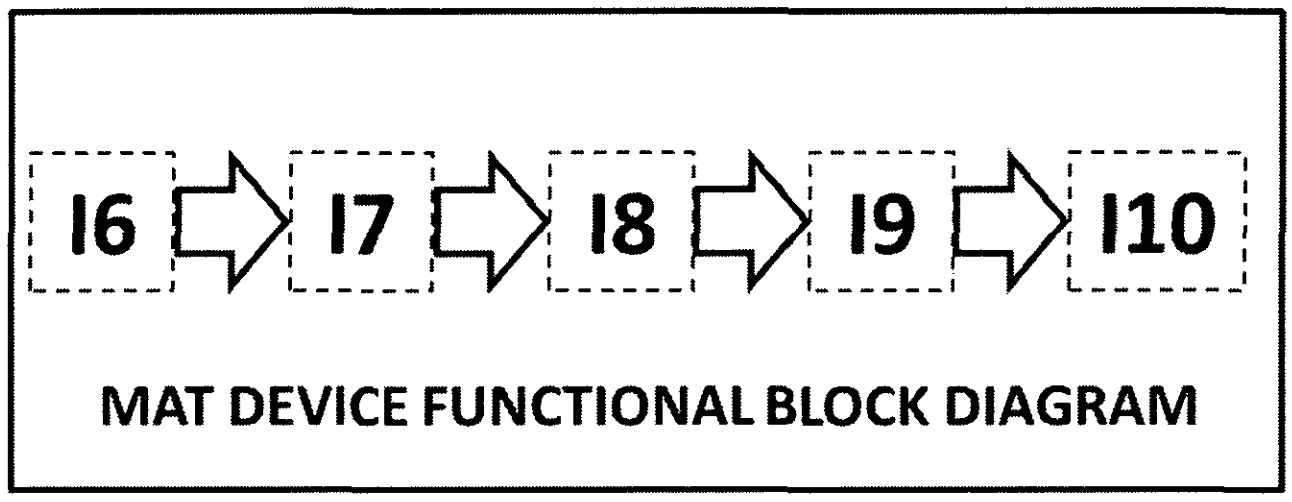


Fig.8

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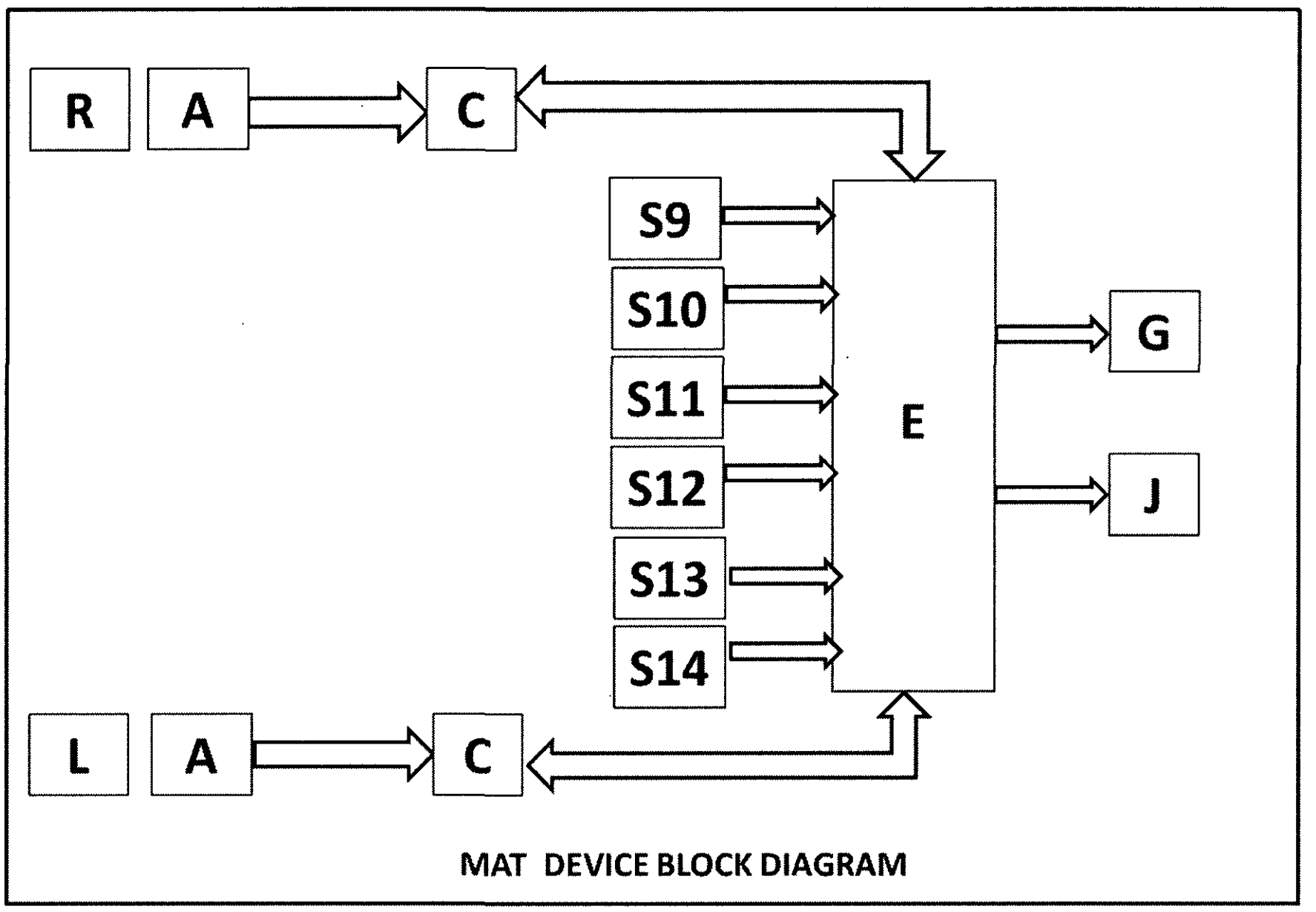


Fig. 9

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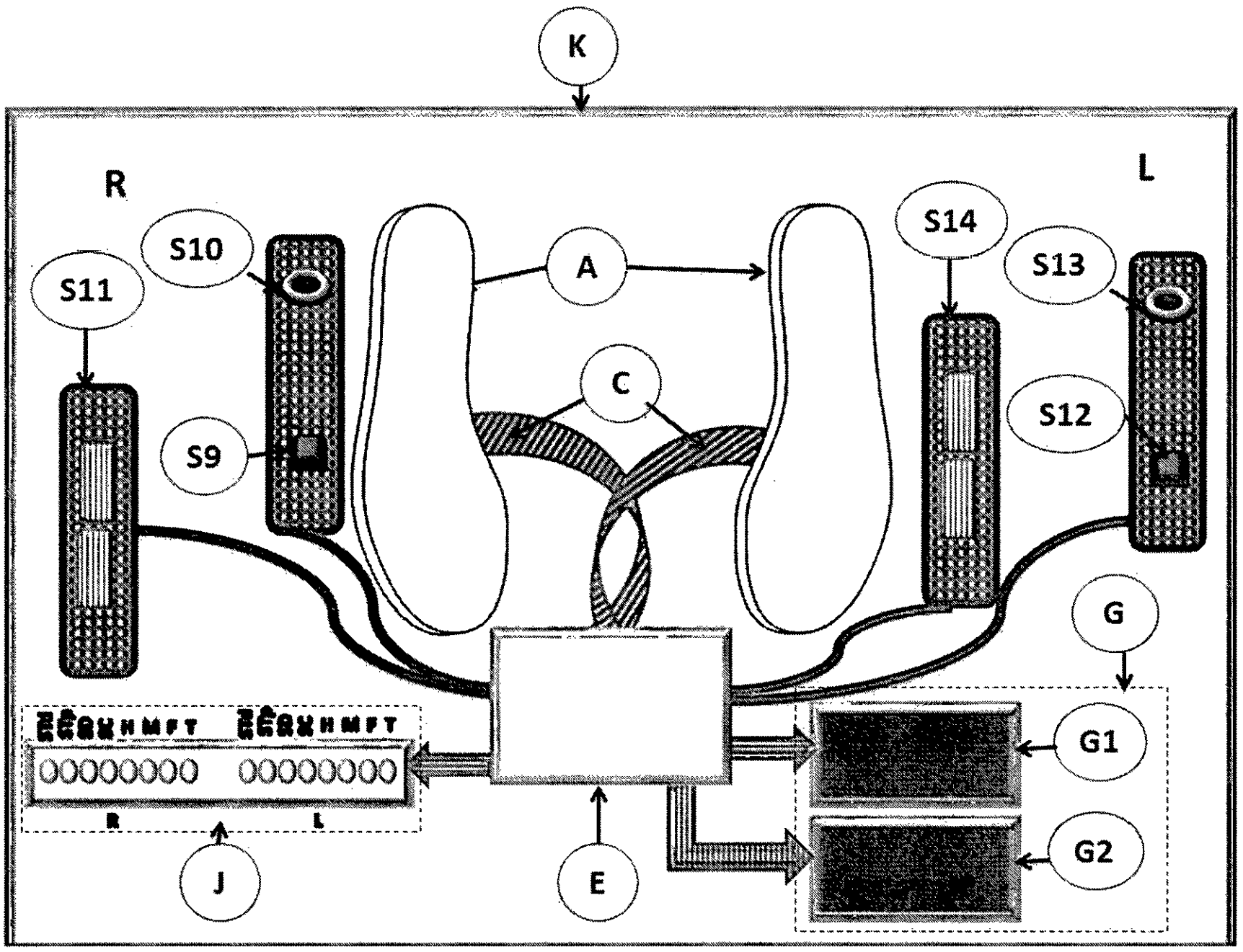


Fig. 10

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