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- (71) Applicant: SENSORIA INC [US/US]; 16225 N.E. 87th Street, Suite A-9, Redmond, Washington 98052 (US).
- (72) Inventors: ESPOSITO, Mario; 7429 - 152nd Court N.E., Redmond, Washington 98052 (US). MACAGNO, Maurizio; 13521 - 173rd Place N.E., Redmond, Washington 98052 (US). VIGANO, Davide Giancarlo; 16203 N.E. 43rd Court, Redmond, Washington 98052 (US). ESPOSITO, Victoria Ann; 7429 - 152nd Court N.E., Redmond, Washington 98052 (US).
- (74) Agents: SPECKMAN, Ann W. et al.; Speckman Law Group PLLC, 2014B East Union Street, Seattle, Washington 98122 (US).

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(54) Title: METHODS AND SYSTEMS FOR DATA COLLECTION, ANALYSIS AND FORMULATION OF USER-SPECIFIC FEEDBACK; USE OF SENSING SYSTEMS AS INPUT DEVICES

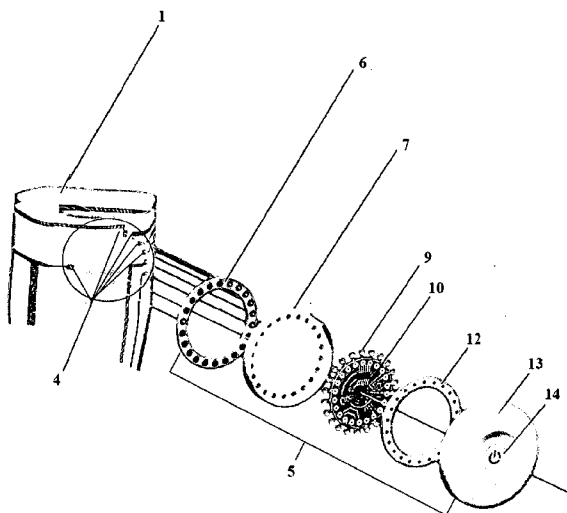


FIG. 4

(57) Abstract: Sensing devices including flexible and stretchable fabric-based pressure sensors, may be associated with or incorporated in garments intended to be worn against a body surface (directly or indirectly), or may be associated with other types of flexible substrates, such as sheet-like materials, bandages and other materials that contact the body (directly or indirectly), and may be provided as independently positionable sensor components. Systems and methods for storing, communicating, processing, analyzing and displaying data collected by sensor components for remote monitoring of conditions at body surfaces, or within the body, are also disclosed. Sensors and sensor systems provide substantially real-time feedback relating to current body conditions and may provide notifications or alerts to users, caretakers and/or clinicians, enabling early intervention when conditions indicate intervention is appropriate.





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**METHODS AND SYSTEMS FOR DATA COLLECTION, ANALYSIS
AND FORMULATION OF USER-SPECIFIC FEEDBACK; USE OF SENSING SYSTEMS
AS INPUT DEVICES**

FIELD

The present invention relates generally to sensors, including flexible and stretchable fabric-based pressure sensors, that may be associated with or incorporated in garments intended to be worn against a body surface (directly or indirectly). Sensors may also be associated with or incorporated in sheet-like materials, bandages and other accessories that contact the body (directly or indirectly), and may be provided as independently positionable sensor components. Systems and methods for storing, communicating, processing, analyzing and displaying data collected by sensor components for remote monitoring of conditions at body surfaces, or within the body, are also disclosed. Sensors and sensor systems provide substantially real-time feedback relating to current body conditions and may provide notifications or alerts to users, caretakers and/or clinicians, enabling early intervention when conditions indicate intervention is appropriate.

BACKGROUND

Various types of sensing systems have been incorporated in shoes, insoles, socks and garments for monitoring various physiological parameters for various applications, including recreational, sporting, military, diagnostic and medical applications. Medical applications for sensing pressure, temperature and the like for purposes of monitoring neuropathic and other degenerative conditions with the goal of alerting an individual and/or medical service providers to sensed parameters that may indicate the worsening of a condition, lack of healing, and the like, have been proposed. Footwear-related sensing systems directed to providing sensory data for patients suffering from neuropathy, for gait analysis, rehabilitation assessment, shoe research, design and fitting, orthotic design and fitting, and the like, have been proposed.

Potential causes of peripheral neuropathy include diabetes, alcoholism, uremia, AIDS, tissue injury and nutritional deficiencies. Peripheral neuropathy is one of the most common complications of diabetes and results in wounds, ulcers, etc., which may be undetected and unsensed by the individual. There are 25 million diabetics in the US alone, with a projected population of 500 million diabetics worldwide by 2030. In the presence of neuropathy, diabetic patients often develop ulcers on the sole of the foot in areas of moderate or high pressure and shear, often resulting from walking during normal daily activities. About 70% of diabetics have measurable neuropathy, and every year about 5% of those patients get foot ulcers, and about 1% requires amputations. Foot ulcers are responsible for more hospitalizations than any other complication of diabetes and result in at least \$40 billion in direct costs annually.

There is strong evidence that uncomplicated plantar ulcers can be healed in 6-8 weeks, yet current US clinical trials have reported a 76% treatment failure rate at 12 weeks. Many approaches to monitoring diabetic patients for the purpose of preventing ulceration from occurring, or to facilitate healing of existing ulcers, have been proposed, yet little or no improvement in ulceration or its complications has been observed. Off-loading may be an important aspect of ulcer prevention and healing. In "*Practical guidelines on the management and prevention of the diabetic foot*," the authors concluded that mechanical off-loading is the cornerstone of treatment for ulcers with increased biomechanical stress. *See*, Diabetes Metab Res Rev 2008; 24(Suppl 1): S181-S187. It has been demonstrated that the offloading capacity of custom-made footwear for high-risk patients can be effectively improved and preserved using in-shoe plantar pressure analysis as guidance for footwear modification, which should reduce the risk of pressure-related diabetic foot ulcers. *See, e.g.*, Diabet Med. 2012 Dec;29(12):1542-9.

Sensing devices and footwear having sensors incorporated for monitoring pressure and other body parameters have been proposed. These devices have generally not been successful in preventing ulceration or accelerating healing of wounds, in part as a result of poor patient compliance. Notwithstanding the existence of several pressure sensing systems, the incidence of, patient pain and costs associated with diabetic ulcers has not declined. In one aspect, the components and assemblies for collection and analysis of data from sites such as feet and other body surfaces described herein are directed to providing intermittent or continuous monitoring and reporting of body conditions (such as pressure) at body locations for purposes of reducing the incidence and severity of ulcers and other wounds and accelerating the pace and quality of wound healing. In other aspects, sensors, interfaces, systems and materials described herein for collection and analysis of physiological and biomechanical data from sites such as feet and other body parts may be used for a variety of sports-related, military, fitness, diagnostic and therapeutic purposes.

SUMMARY

In one aspect, sensor systems of the present invention comprise one or more sensor(s) mounted to or incorporated in or associated with a substrate material such as a wearable garment, a wearable band, an independently positionable component, or another substrate, such as a flexible and/or pliable sheet material. In one aspect, sensors are capable of sensing a physiological parameter of the underlying skin or tissue, or sensors are capable of sensing force or pressure exerted on or against an underlying skin or tissue. Each sensor is electrically connected, via one or more flexible leads, to a flexible conductive trace mounted to or incorporated in or associated with the substrate, and conductive traces terminate at conductive signal transfer terminals mounted to or incorporated in or associated with the substrate. Each sensor may additionally be connected to a ground trace terminating at a ground terminal. Sensor

systems and sensing devices described herein preferably comprise at least one flexible sensor (or means for sensing), and one or more of the sensor(s), flexible leads, and conductive traces may be stretchable and/or elastic as well as being flexible. In some embodiments, the sensor(s), flexible leads and conductive traces may all comprise flexible, pliable electrically conductive fabric materials. Garments incorporating such sensor systems and sensing devices may be comfortably worn by users under many conditions, providing real time monitoring of conditions at or near body surfaces to the user, a caretaker, coach, employer and/or clinician.

The signal transfer terminal(s) on the substrate may be matingly received in signal receipt terminals associated with a Dedicated Electronic Device (DED) that is attachable to the substrate and serves as a (temporary or permanent) data collection device. The DED may also (optionally) house batteries or other energy storage devices and serve as a sensor charging device. The DED may communicate with one or more external electronic device(s), such as a smartphone, personal computing device/display, host computer, or the like for signal transfer, processing, analysis and display to a user and/or others. In some embodiments, the external electronic device, and/or the DED, communicates with an external, hosted computing system (operated, *e.g.*, at a centralized, hosted facility and/or in the “Cloud”) that provides additional data analysis, formulates feedback, notifications, alerts, and the like, that may be displayed to the user, a caretaker, and/or a clinician through one or more computing and/or display devices. In alternative embodiments, the DED may itself perform signal processing and analysis, and display or otherwise communicate feedback directly to a user without interfacing with an external computing device.

In some embodiments, one or more sensor(s) detect changes in voltage or resistance across a surface area that is associated with force exerted on the sensor, which is related to pressure (as force per unit surface area) and/or shear. In some embodiments, FSR (Force Sensitive Resistor) or piezo-resistive sensors may be used. One type of piezoresistive force sensor that has been used previously in footwear pressure sensing applications, known as the FLEXIFORCE[®] sensors, can be made in a variety of shapes and sizes, and measure resistance, which is inversely proportional to applied force. These sensors use pressure sensitive inks with silver leads terminating in pins, with the pressure sensitive area and leads sandwiched between polyester film layers. FLEXIFORCE[®] sensors are available from Tekscan, Inc., 307 West First Street, South Boston, MA 02127-1309 USA. Other types of sensors may also be integrated in or associated with various substrate materials (*e.g.*, garments, sheet materials and the like), including sensors providing data relating to temperature, moisture, humidity, stress, strain, heart rate, respiratory rate, blood pressure, blood oxygen saturation, blood flow, local gas content, bacterial content, multi-axis acceleration, as well as locational positioning (GPS), and the like. A variety of such sensors are known in the art and may be adapted for use in sensing systems described herein.

In some embodiments, pressure sensors and/or associated leads and/or conductive traces incorporated in sensing systems of the present invention comprise non-silicon-based materials such as flexible, resistive and/or conductive “e-textile” fabric material(s). In some embodiments, sensors and/or associated leads and/or conductive traces incorporated in sensing systems of the present invention comprise flexible, resistive and/or conductive fabric materials that are substantially isotropic with respect to their flexibility and/or stretch properties. By “substantially” isotropic, we mean to include materials that have no more than a 15% variation and, in some embodiments, no more than a 10% variation in flexibility and/or stretch properties in any direction, or along any axis of the material. Suitable materials, such as piezoresistive fabric sensors, coated and/or impregnated fabrics, such as metallic coated fabric materials and fabric materials coated or impregnated with other types of conductive formulations, are known in the art and a variety of such fabric sensors may be used. In some embodiments, pressure sensors comprise flexible conductive woven fabric material that is stretchable and/or elastic and/or substantially isotropic with respect to their flexibility and/or stretch properties.

Fabrics comprising a knitted nylon/spandex substrate coated with a conductive formulation are suitable for use, for example, in fabricating biometric pressure sensors and in other applications requiring environmental stability and conformability to irregular configurations. One advantage of using these types of e-textile sensors is that they perform reliably in a wide variety of environments (e.g. under different temperature and moisture conditions), and they’re generally flexible, durable, washable, and comfortably worn against the skin. Suitable flexible conductive fabric materials are available, for example, from VTT/Shieldex Trading USA, 4502 Rt-31, Palmyra, NY 14522, from Statex Productions & Vertriebs GmbH, Kleiner Ort 11 28357 Bremen Germany, and from Eeonyx Corp., 750 Belmont Way, Pinole, CA 94564.

Techniques for deriving force and/or pressure measurements using e-textile fabric materials are known in the art and various techniques may be suitable. *See, e.g.,* <http://www.kobakant.at/DIY/?p=913>. Techniques for measuring other parameters using e-textile fabric materials, such as humidity and temperature measurements, are also known and may be used in sensing systems of the present invention. *See, e.g.,* <http://www.nano-tera.ch/pdf/posters2012/TWIGS105.pdf>. Fabric sensors of the present invention may thus be capable of monitoring various parameters, including force, pressure, humidity, temperature, gas content, and the like, at the site. Additional monitoring capabilities may be available using fabric sensors as innovation in fabric sensors proceeds and as nano-materials and materials incorporating nano-structures are developed and become commercially feasible.

Flexible (and optionally stretchable or elastic) conductive fabric sensor(s), leads and/or traces may be mounted to/in/on, or associated with, an underlying substrate such as fabric or sheet material that’s non-conductive and flexible. The term “fabric” or “sheet material” as used

herein, refers to many types of pliable materials, including traditional fabrics comprising woven or non-woven fibers or strands, as well as fiber reinforced sheet materials, and other types of flexible sheeting materials composed of natural and/or synthetic materials, including flexible plastic sheeting material, pliable thermoplastic, foam and composite materials, screen-like or mesh materials, and the like. The underlying substrate may comprise a sheet material fabricated from flexible fabric material that is stretchy and/or elastic. The sheet material forming the underlying substrate may be substantially isotropic with respect to its flexibility and/or stretch properties. By “substantially” isotropic, we mean to include materials that have no more than a 15% variation and, in some embodiments, no more than a 10% variation in flexibility and/or stretch properties in any direction, or along any axis of the material.

For garment applications, for example, one or more sensor(s) and/or sensing devices may be mounted to (*e.g.*, sewn or otherwise attached or connected or fixed to) an internal surface of a garment for contacting an individual’s skin, directly or indirectly, during use, and detecting pressure exerted against an individual’s skin, or other parameters sensed at or near a skin surface. In situations where pressure or other parameters are desired to be measured as they impact an outer surface or fabric layer, one or more sensor(s) may be mounted (*e.g.*, sewn or otherwise attached or connected or fixed to) an external surface of a garment. For applications such as bands, bandages and independently positionable sensing components, sensors may likewise be mounted to/in/on, or associated with (*e.g.*, sewn or otherwise attached or connected to or fixed to) an underlying substrate that may be conveniently positioned as desired by the user, a caretaker or clinician. In alternative embodiments, conductive yarns and/or e-textile fabric sensors may be knitted into, sandwiched between substrate layers (as in compression socks) or otherwise incorporated in fabric substrates.

In some embodiments, conductive and/or resistive fabric sensors may be partially or fully enclosed in a flexible barrier material or envelope. Conductive fabrics employed for the sensors, leads and/or traces are generally water resistant and water resistant fabrics are suitably used, without the use of a barrier, for many applications. In cases where the sensor is frequently exposed to body fluids, natural liquids or other solutions (*e.g.*, water, sweat, other bodily fluids) however, the e-properties (*e.g.*, electrical conductivity) of the material can be negatively affected by fluid contact and build-up of biological or other debris. To mitigate this condition, a substantially liquid impervious barrier may be provided to protect the sensor(s), leads and/or traces from direct contact with liquids or other materials. In some embodiments, a sandwich approach in which a conductive sensor is enclosed in a substantially liquid impervious barrier may be employed to protect the sensor from contact with liquids and preserve the core resistive features (e-properties) and functions of the sensor(s). Providing a protective barrier covering and/or enclosing the sensor(s) may also be particularly useful in cases when the sensor(s) cannot be exposed directly to an open wound or to a particularly sensitive area of human skin. The

barrier may be placed to seal the sensor(s) alone, or the leads and/or traces may be sealed as well. When protected sensing components are used, external surface(s) of the barrier layer(s) may be attached to the underlying substrate (e.g., garment, skin or the like) via adhesive materials or in other ways.

Each sensor is generally associated with two conductive leads, and each of the leads is electrically connected to a conductive trace conveying electrical signals to a signal transfer terminal. Conductive e-textile fabric sensors as previously described may be electrically connected to conductive leads, or may have a flexible fabric lead associated with or incorporated in the fabric sensor footprint. In general, flexible, conductive e-textile leads may comprise conductive fabric materials having high electrical conductivity. Other types of flexible leads, including conductive yarns, fibers, and the like may also be used. The conductive leads are electrically connected to flexible conductive traces, which may comprise a variety of flexible conductive materials, such as a conductive fabric, conductive yarn, or the like. In some embodiments, the conductive traces are stretchable and/or elastic, at least along the longitudinal axis of the conductive trace. In some embodiments, conductive traces comprise a conductive e-textile fabric having high electrical conductivity, such as silver coated e-textile materials, and may be bonded to the underlying substrate material using adhesives, heat bonding or non conductive threads. Suitable e-textile materials are known in the art and are available, for example, from the vendors identified above.

Sensor(s) as described herein and sensor systems, including fabric e-textile pressure sensors and a variety of other types of sensors, with conductive leads and traces, may be associated with a variety of substrates including, without limitation, garments intended to be worn (directly or indirectly) against the skin of an individual, such as a shirt or tunic, underwear, leggings, socks, footies, gloves, caps, bands such as wrist bands, leg bands, torso and back bands, brassieres, and the like. Sensors and sensor systems may additionally be associated with wraps having different sizes and configurations for fitting onto or wrapping around a portion of an individual's body, and with bands, bandages, wound dressing materials, as well as with other types of accessories that contact a user's body surface (directly or indirectly) such as insoles, shoes, boots, belts, straps, and the like. Conductive leads associated with each sensor are electrically connected to conductive traces, as described, which terminate at signal transfer terminals associated with the underlying substrate garment, band, wrap, bandage, or the like.

Each of the conductive traces terminates in a signal transfer terminal that is mounted to/in/on, or associated with, the underlying substrate and can be associated with a mating signal receipt terminal of a dedicated electronic device (DED) having data storage, processing and/or analysis capabilities. In general, conductive traces and terminals are arranged in a predetermined arrangement that corresponds to the arrangement of signal receipt terminals in the DED. Many different types of signal transfer and receipt terminals are known and may be used in this

application. In one exemplary embodiment, signal transfer and receipt terminals may be mounted in cooperating fixtures for sliding engagement of the terminals. In another embodiment, signal transfer terminals may be provided as conductive fixtures that are electrically connected to the conductive trace (and thereby to a corresponding sensor) and detachably connectible to a mating conductive fixture located on the DED. The mating terminals may comprise mechanically mating, electrically conductive members such as snaps or other types of fasteners providing secure mechanical mating and high integrity, high reliability transfer of signals and/or data. In some embodiments, easy and secure mating of the terminals may be enhanced using magnetic mechanisms or other types of mechanisms that help users to properly connect/disconnect the mating terminals with minimal effort. For example, the mechanism may allow an overweight diabetic patient to reach down to his own legs or feet and easily snap or unsnap the DED to/from the wearable device without excessive effort. In some embodiments, mating terminals on the underlying substrate (e.g., a garment, sock, sheet, band, etc.) and on a DED are provided in a predetermined arrangement, or are keyed, to ensure that the DED is mounted to the terminals provided on the substrate in a predictable and pre-determined orientation.

The DED, in addition to having data recording, processing and/or analysis capabilities, may incorporate an energy source such as a battery providing energy for data recording, processing and/or analysis, as well as providing energy for operation of one or more of the sensor(s). The energy source is preferably a rechargeable and/or replaceable battery source. The DED generally provides a lightweight and water-tight enclosure for the data collection and processing electronics and (optional) energy source and provides receiving terminals that mate with the transfer terminals connected to the sensor(s) for conveying data from the sensors to the dedicated electronic device. In some embodiments, the DED is provided as a bendable or partially bendable device that can be shaped, as desired, to fit comfortably on and closely to body surfaces having different configurations and sizes. A DED provided in the form of a curved band for mounting to an ankle, for example, may be at least partially flexible so that it fits, comfortably and functionally, on men's and women's ankles and on ankles having different sizes and shapes, providing connection to the sensor transfer terminals provided in a sock or anklet form. In some embodiments, a partially or fully bendable DED may be used in both a curved and a straightened (e.g., flat or substantially flat) form, depending on the location of sensor transfer terminals provided in an underlying substrate.

In some embodiments, a partially or fully bendable DED may be used in different configurations with sensor transfer terminals provided in different form factors. A common DED may be shaped to fit comfortably on a user's ankle and mate with sensor transfer terminals provided on an underlying sock or anklet; it may also be shaped to fit comfortably on a user's arm and/or wrist and mate with sensor transfer terminals provided on an underlying sleeve. The same bendable DED may additionally be shaped to fit comfortably, in a generally curved or a generally

flat configuration, and mate with sensor transfer terminals provided on garments or substrates having other form factors.

Dedicated electronic devices having signal receipt terminals that mate with the signal transfer terminals associated with the substrate may take a variety of form factors, depending on the form factor of the underlying sensing substrate and/or the conditions and location of the device during use. When sensors are incorporated in a sock-like form factor for monitoring conditions sensed at the foot, for example, the signal transfer terminals may be arranged in proximity to one another in an ankle region of the sock, and the DED may have the curved form factor of a band that extends partially around the ankle or lower leg and attaches to the underlying signal transfer terminals and sock substrate along a front and/or side portion of the user's ankle or lower leg. When sensors are incorporated in a shirt-like garment and signal transfer terminals are arranged on a sleeve along the arm or wrist area, the DED may have similarly have the curved form of a band that extends partially around the arm or wrist. When sensors are incorporated in a shirt-like garment or tunic and signal transfer terminals are arranged on a front or back surface of the garment, the DED may have a generally medallion-like form factor, or a linear or another form factor, depending on the placement and type of the signal transfer terminals, the underlying conformation of the body surface, and the like.

When sensors are incorporated in a wrap or band or sheet-like substrate, the signal transfer terminals may be arranged at or near an exposed end of the wrap or band or sheet, following its application to an underlying anatomical structure or body surface or substrate, and the DED may be provided as a band or a tab or a dongle-like or capsule-like device having aligned signal receipt terminals. The DED may be provided as a substantially flexible or a substantially rigid component, depending upon the application, and it may take a variety of forms.

In some embodiments, the DED communicates with and transfers data to one or more external computing and/or display system(s), such as a smartphone, computer, tablet computer, dedicated computing device, medical records system or the like, using wired and/or wireless data communication means and protocols. The DED and/or an external computing and/or display system may, in turn, communicate with a centralized host computing system (located, e.g., in the Cloud), where further data processing and analysis takes place. Substantially real-time feedback, including data displays, notifications, alerts and the like, may be provided to the user, caretaker and/or clinician according to user, caretaker and/or clinician preferences.

In some embodiments, the DED may store the data temporarily to a local memory, and periodically transfer the data (e.g., in batches) to the above mentioned external computing and/or display system(s). Offline processing and feedback, including data displays, notifications and the like may be provided to the user, caretaker, and/or clinician according to user, caretaker and/or clinician preferences.

In operation, an authentication routine and/or user identification system matches the DED and associated sensing system (e.g., the collection of sensor(s) associated with an underlying substrate) with the user, caretaker and/or clinician, and may link user information or data from other sources to a software- and/or firmware-implemented system residing on the external computing system. The external computing device may itself communicate with a centralized host computing system or facility where data is stored, processed, analyzed, and the like, and where output, communications, instructions, commands, and the like may be formulated for delivery back to the user, caretaker and/or clinician through the external computing device and/or the DED.

Calibration routines may be provided to ensure that the DED and connected related sensor system are properly configured to work optimally for the specific user. Configuration and setup routines may be provided to guide the user (or caretaker or medical professional) to input user information or data to facilitate data collection, and various protocols, routines, data analysis and/or display characteristics, and the like, may be selected by the user (or caretaker or medical professional) to provide data collection and analysis that is targeted to specific users. Specific examples are provided below. Notification and alarm systems may be provided, and selectively enabled, to provide messages, warnings, alarms, and the like to the user, and/or to caretakers and/or medical providers, substantially in real-time, based on sensed data.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows an exemplary sensing device having a sock form factor and having one or more sensor patches electrically connected to one or more terminals by means of conductive pathways.

Fig. 2 shows another exemplary sensing device similar to that shown in Fig. 1 and having a different arrangement of sensor patches electrically connected to terminals by means of conductive pathways.

Fig. 3 shows another view of an exemplary sensing device similar to that shown in Figs. 1 and 2.

Fig. 4 shows a view of terminals of the sensing device and an exploded view of a detachable dedicated electronic device that, when attached to terminals on the sock, captures and optionally processes, stores and/or analyzes sensed signals or data.

Fig. 5 shows an enlarged, exploded view of an exemplary detachable electronic device similar to that shown in Fig. 4.

Figs. 6A and 6B show schematic illustrations of exemplary sensors having leads provided in different configurations.

Fig. 7 shows an image illustrating a sensor of the type illustrated in Fig. 6A mounted on a fabric substrate, with each of the leads connected to a conductive trace.

Fig. 8 shows an image illustrating two exemplary conductive traces mounted on an internal surface of a fabric substrate in a sock-like form factor, terminating in conductive signal transmit terminals that penetrate the fabric substrate.

Fig. 9A shows an image illustrating two exemplary sensors of the type illustrated in Fig. 6A mounted on a fabric substrate, with each of the leads connected to a conductive trace and each of the traces terminating in a conductive signal transmit terminal. Fig. 9B shows an image illustrating the external surface of a fabric substrate in a sock-like form factor, showing multiple conductive terminals for mating with terminals of an intermediate device. Figs. 9C and 9D show drawings from underneath and above (respectively) another sock-like form factor having a different arrangement of sensor devices, leads and traces.

Figs. 10A-C show exemplary embodiments of sensors provided in other garment-like form factors, each showing multiple conductive terminals for mating with terminals of an intermediate device. Fig. 10A shows an inner surface of a shirt or tunic having a plurality of sensors, with associated leads and traces, positioned (directly or indirectly) on the back interior surface of the shirt-like garment; Fig. 10B shows an inner surface of the exemplary shirt of Fig. 10A having a plurality of traces terminating in terminals at the interior front of the shirt-like garment; and Fig. 10C shows an exemplary DED in a medallion-like form factor mounted to mate with the sensor terminals provided on front of the shirt. Fig. 10D shows a highly schematic exemplary embodiment of a different arrangement of sensors associated with a shirt-like garment. Fig. 10E shows yet another highly schematic exemplary embodiment of another arrangement of sensors associated with a shirt-like garment.

Figs. 11A and 11B show images illustrating one embodiment of a dedicated electronic component for connecting to signal transmit terminals having a curved form factor for mounting at an ankle or lower leg portion (or arm or wrist) of a user. Figs. 11C and 11D show images illustrating another embodiment of a dedicated electronic component having a curved or curve-able form factor for mounting to a curved body surface and having a keyed arrangement of terminals for connecting to signal transmit terminals. Fig. 11E shows a schematic image illustrating a DED that is bendable and flexes. Fig. 11F shows a schematic image illustrating an exemplary charging device for the DED.

Figs. 12A and 12B show schematic diagrams illustrating one embodiment of mating mechanical and magnetic fasteners providing a mechanical and electrical connection between the dedicated electronic component and the signal transmit terminals, via mating magnetic snaps. Fig. 12A shows a schematic exploded diagram illustrating exemplary components of the male connector; Fig. 12B shows a schematic exploded diagram illustrating exemplary components of the female connector. Figs. 12C and 12D show schematic diagrams illustrating another embodiment of mating mechanical and magnetic fasteners

Fig. 13 shows an image illustrating a sensor-activated device of the type shown in Figs. 7-10 having a sock-like form factor in place on a user's foot, with an intermediate device having an ankle-like form factor as shown in Figs. 11A and 11B connected to the external terminals for data collection and, optionally, analysis.

Fig. 14 shows a block diagram illustrating basic components of an exemplary data collection device and illustrating its interface with sensors provided in a substrate, an external computing device, and a centralized host system maintained, for example, in the Cloud.

Fig. 15 shows an image illustrating an independently positionable sensor mounted to conductive leads and signal transmit terminals for placement at the discretion of a patient or care provider.

Fig. 16A illustrates the placement of an independently positionable sensor device of the type illustrated in Fig. 15 at a location (e.g., on the bottom of a patient's foot or between layers of bandages) where the patient and/or caretaker would like to monitor conditions (e.g., pressure and/or shear), and Fig. 16B illustrates signal transfer terminals connected to conductive traces connected to the sensor that are positionable, for example at the top of a patient's foot or on the exterior of a bandage, for connection to a dedicated electronic component.

Fig. 17 shows an image illustrating one view of a sensing system using a sensor device as illustrated in Figs. 15-16B in combination with a versatile wrap, with the conductive signal transfer terminals exposed for connection to an electronic intermediate such as a Dedicated Electronic Device (DED).

Figs. 18A and 18B show images schematically illustrating an exemplary textile sensor employing a protective, substantially liquid impermeable barrier. Fig. 18A shows one face of the assembled sensor system and Fig. 18B shows the opposite face of the assembled sensor system.

Fig. 19 shows an image schematically illustrating a sensing system having one or more sensors with leads and conductive traces terminating in terminals in a bandage or wrap form factor.

Fig. 20 shows an image schematically illustrating a fabric-based sensing system having multiple sensors with leads and conductive traces terminating at signal transmit terminals for connection to an intermediate electronic device for data collection, storage and/or processing.

Fig. 21 schematically illustrates a patient setup protocol, clinician dashboard and patient offloading data display for monitoring wounds such as foot ulcers.

Figs. 22A-22L illustrate exemplary device set ups, calibration and monitoring criteria input and routines, along with an exemplary clinician dashboard, a graphical representation of patient offloading data, and an exemplary sample of acquired pressure data. Fig. 22A shows exemplary setup and calibration steps; Fig. 22B shows an exemplary patient data input routine; Fig. 22C shows an exemplary device setup routine; Fig. 22D shows an exemplary device setup routine; Fig. 22E shows another exemplary device setup routine; Fig. 22F shows another

exemplary device setup routine; Fig. 22G shows an exemplary monitoring routine setup; Fig. 22H shows another exemplary monitoring routine setup; Fig. 22I shows an exemplary user calibration routine; Fig. 22J shows an exemplary clinician dashboard presenting patient status information for a plurality of patients using a sensing device of the present invention; Fig. 22K shows an exemplary patient offloading data display; and Fig. 22L shows exemplary pressure data collected using an exemplary sensing system of the present invention.

Fig. 23 shows schematic drawings illustrating an exemplary sensing system having sensors located in a sock, with one or more sensors electrically connected to one or more terminals, and subsequently to a dedicated electronic device located in a shin guard.

Figs. 24A and 24B show a conceptual flow diagram illustrating exemplary fitness output data, graphical user interfaces, and the like, presenting data and analytics to a user based, at least in part, on data collected from a sensing systems employing sensors located in a sock-like form garment.

Figs. 25A-D illustrate exemplary presentations (displayed as graphical user interfaces or GUIs) showing the type of data and analytical information presented to a user in a fitness context using a system of the present disclosure.

It will be understood that the appended drawings are not necessarily to scale, and that they present simplified, schematic views of many aspects of systems and components of the present invention. Specific design features, including dimensions, orientations, locations and configurations of various illustrated components may be modified, for example, for use in various intended applications and environments.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Sensors and sensor systems used in a sock-like form factor

In one embodiment, systems incorporating sensors, leads, traces and terminals may be mounted to and/or incorporated in or associated with a garment having a sock-like form factor. One version of this embodiment is illustrated in Figs. 1-5. In general, a substrate material in the form of a sock may be equipped with one or more sensors, leads, traces and connectors that provide signals and/or data to a dedicated (and preferably detachable) electronic device that gathers data from each sensor and communicates to an external computer and/or mobile device. Sensors used in footwear and sock applications typically include pressure sensors capable of detecting levels of pressure (and/or force and/or shear) at one or more areas of the foot and may include other types of sensors, including temperature, accelerometers, heart rate monitors and/or moisture sensors, and the like. Based on the detected pressure, force and/or shear at one or more areas of the foot, and trends in those parameters over one or more monitoring period(s), conclusions relating to the lack of proper offloading and related conditions of the underlying skin or tissue, healing progression (or lack of healing), discomfort, extent and seriousness of injury,

and the like, may be drawn and may be communicated to the user, caretaker and/or clinician, essentially in real time. In addition, notifications, alerts, recommended actions, and the like may also be communicated to the user, caretaker and/or clinician based on the data analysis, essentially in real time. These systems are suitable for use in medical and patient adherence monitoring applications, diabetic (and other) foot monitoring, sports and fitness applications, footwear fitting applications, military applications, etc.

One embodiment of a sensor system embodied in a sock-like form factor is illustrated in Figs. 1-5. In this embodiment, a flexible and preferably stretchable fabric substrate in the form of a sock 1 has one or more sensors, shown as sensor patches 2, optionally including one or more pressure sensors constructed from flexible and conductive fabric as disclosed herein. Each of the sensor patches 2 has leads and conductive traces or threads 3, each terminating in a conductive signal transfer terminal 4. The sensor patches 2 and conductive traces or threads 3 may be woven into the fabric forming the sock, or may be applied to a surface of the fabric forming the sock. In one embodiment, e-textile fabric pressure sensors are applied to an internal surface of the fabric that contacts a user's skin (directly or indirectly) when the sock is worn. Additional fabric sensors may be used in connection with the sock, and other types of sensors, including heat sensors (e.g., thermocouples), moisture sensors, and the like, may also be incorporated in the sock with leads and traces terminating in additional signal transfer terminals. In general, the conductive traces may be applied to an internal or external surface of the underlying fabric substrate, and the terminals preferably have a conductive transfer interface accessible to the external surface of the fabric substrate. In the embodiment illustrated in Figs. 1-5, the signal transfer terminals 4 are positioned in proximity to the top of the sock, although it will be appreciated they may be positioned elsewhere.

The signal transfer terminals 4 that connect to the sensor(s) in the sock are connectible to mating signal receiving terminals of a detachable electronic device (DED). Simplified diagrams illustrating exemplary DEDs are shown in Figs. 4 and 5. Detachable electronic device 5 receives signals from each of the signal transfer terminals, and thus collects data from each of the sensors. As shown in Fig. 4, the DED may comprise mechanical interface(s) 6 for attaching the DED to terminals 4 located on the sock (or another sensing device); a housing component 7 protecting internal DED components and providing signal transfer from the sensing device (e.g., terminals on the sock) to internal DED components; electronic and communications components 10 and conductive terminals 9 receiving signals from terminals 4 in the sock sensing device; a mating ring 12, and an external housing lid 13 having a power button 14 for activating the DED. An alternative, simplified DED is shown in Fig. 5, comprising mechanical interface(s) 6 for attaching the DED to terminals 4 located on the sock (or another sensing device); an integrated component 15 providing a housing, electronic and communications components, and an external housing lid

13. It will be appreciated that many other types and styles of DEDs may be provided for interfacing with and downloading signals and/or data from the underlying sock sensing device.

In one embodiment, mechanically mating snaps are used as terminal interfaces and operated as mechanical switches that are switched on and off abruptly by an external driving force from one switch position (attached) to a second position (detached). In another embodiment, conductive, magnetic snap switches are used as mating terminals for transferring signals and/or data from the sock to the DED. Figs. 12A and 12B show one specific design of such snaps: an external magnetic ring may be used on the male (DED) snap to attract and maintain solid connection with a magnetically attractable component of a female portion of the snap located on the underlying substrate. Figs. 12C and 12D illustrate another specific design of conductive, magnetic snaps that may also function as activation switches, in which a metallic (or other magnetically attractable material) component having a configuration shown in Fig. 12C is mounted on and interfaces with conductive terminals on/in a substrate material and a mating, magnetic receiving component having the configuration shown in Fig. 12D is mounted on a DED. The conical interface surfaces provide convenient, sure and reliable magnetic attachment of the terminals and high fidelity signal transmission. It will be appreciated that while these magnetically and mechanically mating snaps are disclosed herein for use with the sensing systems described herein, they additionally have utility and may be used in a variety of applications and for a variety of uses in addition to those disclosed herein.

In this exemplary embodiment, properties of the magnetic field may be used to create snaps that can only connect in one orientation: in this way, the user is guided to properly connect the DED to the sensor system(s) associated with the underlying substrate. Circuitry in the DED may provide the ability to automatically turn the data collection on and off, for example, based on the presence of the magnetic connection between the DED and the sensor system. It will be appreciated that many other types of mechanical and non-mechanical interfaces may be used to attach and detach the DED from the signal transfer terminals, and to transfer signals and/or data from the sensing system to the DED.

Circuitry in the DED may be provided for reading the sensor signals; firmware may be provided for processing signal data, applying post processing algorithms and formatting the data for communication to an external computing and/or display device. The DED may incorporate firmware and/or software components for collecting, filtering, processing, analyzing data, or the like. In one embodiment, the DED hosts firmware subroutines that apply at least some of the following: low pass filtering algorithms to reduce incoming signal noise; pull up resistors logic to avoid shorting of the device and additional noise filtering.

In one embodiment, the DED may be physically attached to the sensing substrate (e.g., sock, shirt or other sensing substrate) for data collection and then detached from the sensor terminals and physically mounted (e.g., through a USB or another wired connection), to an

external computing and/or display device such as a phone, personal computing device, computer, or the like to download data. In other embodiments, the DED preferably has wireless communication capability (e.g., using Bluetooth, WiFi, or another wireless standard) and transmits signals and/or data to a computing and/or display device wirelessly. The DED is thus connected through a communication system to an external electronic device having computing and/or display capabilities. The external computing and/or display device generally hosts client firmware and/or software and processing firmware and/or software for processing, analyzing, communicating and/or displaying data. It will be appreciated that the division of functions and processing, such as data processing, analysis, communications and display functions as between the DED and the external computing and/or display device may vary depending on many factors and is, to at least some extent, discretionary.

In some embodiments, client software and communications systems are hosted on the external computing device (e.g., a computer or a mobile device such as a tablet or smartphone), and provide feedback to and interact with the user, communicating through an Internet connection via web services, to push collected data and retrieve processed data from the service and display (or otherwise communicate) it to the user. The client software may comprise a set of applications that can run on multiple platforms (not limited to personal computers, tablets, smartphones) and sub-components (diagnostics, troubleshooting, data collecting, snap and match, shopping) to deliver a rich and complete user experience. The experience can be also delivered through an Internet browser.

For some applications, server software components that apply crowdsourcing logic and/or machine learning technologies may be implemented to identify, profile, and cluster user data. The data may be stored in a database and may be continuously or intermittently updated with incoming user supplied and/or sensor supplied data. An optional software component that provides image and pattern recognition capabilities may also be implemented. This feature may allow a user to input data (e.g. images, external data accessed from databases, etc.) without entering any text input.

While this specific example of sensor systems has been described with reference to a sock form factor, it will be appreciated that e-textile fabric sensors may be used with (and/or applied to) other types of wearable garments (e.g., underwear, t-shirts, trousers, tights, leggings, hats, gloves, bands, and the like), and dedicated electronic devices having different configurations may be designed to interface with a variety of sensor systems embodied in different types of garments. The type of sensor(s), garment(s), placement of sensor(s), user identification, and the like, may be input during an authentication and initial device calibration set up protocol.

Another exemplary embodiment of a sensor system using e-textile fabric sensors in a sock form factor is shown in Figs. 6A-13. Fig. 6A shows an exemplary fabric sensor S with leads L1 and L2. In this example, sensor S1 comprises a rectangular piece of e-textile resistive and/or

conductive fabric, and conductive leads L1 and L2 are positioned on opposite sides of sensor S1. Conductive leads L1 and L2 are shown as integral extensions, or pieces, of the same fabric of sensor S1, but alternative types of leads may also be used. Fig. 6B shows a similar fabric sensor S2 having integral leads L3, L4 extending from a common side of the sensor. It will be appreciated that although rectangular sensors are illustrated, fabric sensors having a variety of sizes and configurations may be provided. Conductive leads having the same properties as the sensors may be used, or other types of conductive leads may be employed. It will also be appreciated that the arrangement of leads with respect to sensor(s) may vary, depending on the properties, size and configuration of the sensor and lead components.

E-textile fabric sensors, conductive leads and conductive traces may be mounted to, or associated with or integrated in, the underlying fabric substrate (e.g., a stretchable, knit fabric) in a variety of ways, including sewing, adhesive bonding, thermal bonding, weaving, and the like. Fig. 7 shows an e-textile fabric sensor S1 having the configuration shown in Fig. 6A attached to the inside of a stretchable, knit sock. Sensor leads L1 and L2 are sewn or bonded to the underlying sock, and conductive traces T1 and T2 are mounted and electrically connected to leads L1 and L2, as shown. In this embodiment, conductive traces T1 and T2 are fabricated from e-textile fabric materials having different properties from the materials of the sensor S1 and leads L1 and L2.

The conductive traces T1, T2 terminate in conductive terminals CT1, CT2, as shown in Figs. 8-10. In the embodiment illustrated, conductive terminals CT1, CT2 are provided as conductive mechanical snaps, illustrated in Fig. 8, that penetrate the substrate sock material from the interior to the exterior surface of the sock. The interior of the sock, where the sensor/lead/trace/terminal arrangement is positioned, is illustrated in Fig. 9A. Multiple fabric sensors may be implemented, resulting in multiple conductive terminals communicating data collected from multiple sensors located in different areas of the foot. It will be appreciated that other types of sensors may be integrated in this sock format sensing device (and in other formats of sensing devices), and that additional conductive terminals may be provided for transmission of signals and/or data from other types of sensors. The exterior of the sock having signal transfer terminals CT1, CT2 corresponding to a first sensor, and signal transfer terminals CT3 and CT4 corresponding to a second sensor, is illustrated in Fig. 9B. In this embodiment, the signal transfer terminals are aligned along a upper circumference of the sock, shown in this embodiment as an anklet.

Figs. 9C and 9D illustrate alternative arrangements of e-textile sensors, conductive traces, a ground trace, and conductive terminals provided in a sock or anklet form factor. Figs. 9C and 9D illustrate one exemplary layout of sensors, ground and conductive traces and conductive terminals on a surface of (or otherwise incorporated within) a sock form factor garment. Fig. 9C illustrates an exemplary sensing system associated with a bottom interior surface of a sock-like or

anklet form factor substrate, with sensors arranged to contact (directly or indirectly) different locations on the bottom of the foot. Fig. 9D illustrates a top perspective view of a top interior surface of a sock-like or anklet form factor substrate, illustrating exemplary ground and conductive traces and their terminations.

The embodiment illustrated in Figs. 9C and 9D includes three e-textile sensors (S1, S2, S3), one located at the heel portion of the substrate, and two provided in different locations under the forefoot portion of the substrate for contacting different regions of the ball of the foot. A ground trace (G) is connected to ground leads extending from and electrically connected to each of the sensors S1, S2, S3, and the ground trace G terminates in at least one ground terminal (GT). In some embodiments, a second ground terminal, or a second terminal associated with a ground trace, may be provided for accomplishing auxiliary functions such as sensing mating or detachment of the terminal with an associated DED and triggering activation or inactivation of the DED, respectively. Auxiliary ground traces may be provided independently of other ground traces, or may be electrically connected to one or more other ground traces.

Conductive traces T1, T2 and T3 are connected to conductive leads L1, L2 and L3 of each sensor and terminate in conductive terminals CT1, CT2 and CT3. A DED is connectible to the conductive terminals CT1, CT2 and CT3, as well as ground terminal GT for collecting signals and data from the sensors and for grounding. It will be appreciated that additional textile (and other types of sensors) may be provided, and that different sensor, lead and trace layouts may be used. In one embodiment, for example, socks having individual toes may be provided as the substrate, with sensors provided in a heel region and/or a forefoot region and/or on the bottom(s) or top(s) of one or more toe regions.

The pliable substrate (shown in this exemplary embodiment in a sock form factor) comprises multiple layers of substrate material(s), which may be two or more layers of the same material, or layers of materials having different compositions and/or properties. In one example, a double layer garment (e.g., a sock, shirt, glove, or another garment) may be provided having one or more e-textile sensor(s) mounted to or associated with an intermediate location between the exterior surfaces of the fabric layers, such as mounted to (or otherwise associated with) an inner surface of one layer of the garment. Conductive leads and traces may be similarly provided at an intermediate location between the exterior surfaces of one or more fabric layers. In this embodiment, the sensor(s), conductive leads(s), and conductive trace(s) or portions of trace(s) may be provided on (or associated with) a substrate layer, such as an inner substrate layer, so that they (directly) contact neither the user's body surface nor are they exposed to the outside environment. In alternative embodiments, the sensor(s) may be provided on an interior surface for contacting a body surface directly, while sensor leads and/or sensor traces may be associated with an inner substrate layer, or with an exterior substrate layer. Conductive terminals may be

provided spanning one or multiple fabric layers, with conductive and ground terminals exposed, as desired, for interfacing with mating terminals of a DED.

Figs. 10A-10D illustrate an alternative exemplary embodiment of a garment incorporating e-textile sensors as described herein. Figs. 10A and 10B schematically illustrate an inside surface of a shirt form factor garment, showing a placement of sensors, leads, traces and terminals on different surfaces of the shirt. In this embodiment, three (3) e-textile sensors S1, S2, S3 are mounted to (or associated with, directly or indirectly) the back inner surface of the shirt substrate and are located at different locations that, when the shirt is worn, correspond to different locations along a user's spine. In the schematic and illustrative embodiment shown in Fig. 10A, sensors S3, S2 and S1 are located, respectively, near upper, middle, and lower locations along the spine. Conductive leads are associated with each sensor, as previously described, and sensor traces T1, T2 and T3 are electrically connected to each of the sensors and routed to the front of the shirt. Each sensor is also associated with a ground lead, as previously described, and a common ground trace GT is connected to each of the sensor leads. Sensor traces T1, T2, T3 terminate in conductive terminals CT1, CT2, CT3, respectively, located in a central region of the front of the shirt, and ground trace GT terminates in conductive terminal GCT1, near the sensor terminals, as shown schematically in Fig. 10B.

Fig. 10C shows a schematic drawing of a DED in the form of a medallion M having conductive terminals, shown in dashed lines, that interface and mate with terminals CT1, CT2, CT3 and GCT1 of the underlying shirt for data collection, transfer and/or analysis, as otherwise described herein. While the DED in this exemplary embodiment is illustrated in the form of a medallion that mounts on the front of a shirt, it will be appreciated that DEDs having many different form factors may be provided.

Figs. 10D and 10E show rudimentary sketches illustrating different sensor placement in connection with a shirt garment, and different trace routes and conductive terminal locations. Fig. 10D schematically shows a shirt having sensors S1, S2, S3 (shown in dashed lines, on the inner surface of the shirt) located in arm regions and an abdominal region of a shirt, respectively, with conductive leads and conductive traces T1, T2, T3 routed to conductive terminals CT1, CT2, CT3 provided in a central region of the front of the shirt. Fig. 10E schematically shows sensors S1, S1', S2, S2' located in the arm and shoulder regions of each side of a shirt, respectively. Conductive traces T1, T2 and T1', T2' are routed to conductive terminals CT1, CT2, CT1', CT2' provided in cuff regions of the shirt. Ground traces GT and GT' are associated with conductive leads of each of the sensors S1, S1', S2, S2' and terminate in conductive ground terminals CGT and CGT'. The form factor of DEDs used for data collection, transfer and/or analysis may vary in accordance with the desired location, size, and type of sensors, traces and/or terminals. It will be appreciated that sensor placement may vary depending on the types of sensors used and the activity being monitored, and that sensors may be provided in association with many different

types of garments. Sensor, lead and trace size, configuration, placement, and the like may vary depending on the application.

In yet another embodiment, multiple sensing garments may be electrically or electronically linked to one another, and optionally commonly linked to one or more DED(s). Terminals corresponding to e-textile sensors, and leads and traces associated with multiple independent garments may be interfaced with one another, providing signal flow along integrated pathways extending across multiple garments, and thereby integrating sensors provided in different garments, in different locations, with one or more DED(s). In one specific embodiment, for example, conductive terminals communicating with sensors, leads and traces located on a shirt-like garment may be provided in a hem-area of the shirt. Similar conductive terminals communicating with sensors, leads and traces located in leggings or shorts or pants or the like may be provided in the waist-band area of the leggings, shorts or pants. The conductive terminals provided on the different garments may interface in an electrically conductive fashion (using the conductive, magnetic components described below, for example), providing conductivity across garments, and providing the option of using one or more DED(s) across multiple garments. It will be appreciated that many different types and styles of garments, incorporating different configurations, sizes and types of sensors, may be linked in this fashion.

One embodiment of a signal transfer and signal receipt terminal configuration that detachably mates, mechanically and magnetically, is shown in Figs. 12A and 12B. This is a mechanical two-part interface device having mating male (Fig. 12A) and female (Fig. 12B) connector components, as shown. The male connector 20 comprises a central conductive pin element 21 surrounded by a non-conductive ring member 22 and having a magnetic perimeter portion 23. The female connector 25 comprises a central conductive pin receiving element 26 and contact that is electrically connected to the conductive area of the male connector when the connector portions are mechanically and/or magnetically connected to one another. Female connector 25 also comprises a non-conductive collar 27 and a magnetic collar 28 sized and configured to mate with corresponding components of the male connector. The components illustrated in Figs. 12A and 12B are shown in an exploded view; when assembled, the connector components nest to provide compact, highly functional connectors. The polarity of magnetic components 23, 28 may be arranged to provide male and female connectors that are connectable only when magnetically aligned in a predetermined orientation, which may facilitate user connection of the mating terminals. Although this exemplary mating terminal configuration is illustrated having a round configuration, it will be appreciated that other configurations, including oval, linear, polygonal, and the like, may be used.

Another embodiment of a signal transfer and signal receipt terminal configuration that detachably mates, mechanically and magnetically, is shown in Figs. 12C and 12D. In this embodiment, two electrically conductive, magnetically attractable and mating components 40, 45

are provided. One of the complementary components (40, 45) is mounted to a substrate and interfaced with a sensor (through appropriate leads, traces, etc.), while the other complementary component (45, 40) is mounted to a DED. In the embodiment illustrated schematically in Fig. 12C, component 40 may be mounted on (or otherwise associated with) a substrate at the termination or along conductive traces to provide a conductive terminal in electrical communication with one or more sensor(s). Interface component 40 shown in Fig. 12C includes a contoured (e.g., conical) projection 41 that is exposed for mating with a complementary interface component and may be mounted on/to/through the substrate, for example, using prongs 42 to penetrate the substrate. Prongs 42 are received in conductive retaining ring 43, which is positioned at an opposite surface of the substrate (e.g., an interior surface) to provide an electrical connection to conductive traces. Interface component 40, when mounted on a substrate, thus comprises conductive retaining ring 43 in electrical contact with one or more conductive trace(s) and contoured projection 41 exposed at an exterior location.

An exemplary receiving portion 45 of the mating signal transfer and receipt terminal configuration is shown in Fig. 12D. In this embodiment, receiving component 45 comprises a contoured (e.g., generally conical) depression 46 for receiving contoured (e.g., conical) projection 41 of the interface component 40 in a mating relationship. Contoured depression 46 is mounted to a base structure 47 for convenient mounting of this interface component in a DED or DED-like device. One of the contoured surface 41 and/or mating depression 46 comprises or is associated with a magnetic material, and the other comprises or is associated with a material that is attracted to a magnetic material. In some embodiments, mating depression 46 comprises a magnetic material, while contoured surface comprises a material that is attracted to the magnetic depression 46. The mating contoured (e.g., conical) surfaces presented by the complementary components provide convenient and reliable interfacing of the magnetically and electrically conductive components. While conical surfaces are illustrated, it will be appreciated that other contoured three-dimensional mating surfaces may be used.

Figs. 11A and 11B illustrate one exemplary embodiment of a dedicated electronic device (DED) 40 having signal receipt terminals RT1, RT2, RT3, RT4 that mate mechanically with conductive terminals such as CT1-CT4 to provide signal and/or data transfer from the sensor/lead/traces associated with the sock substrate to the DED. DED 40, as illustrated in Figs. 11A and 11B, comprises a curved housing or case enclosing an interior space containing processing, memory and/or communications components. In this embodiment, DED 40 may be installed on the exterior of a sock in the ankle or lower leg area of the user, as illustrated in Fig. 13. DED 40 preferably provides a protective and watertight housing or case protecting the electronic components provided within the housing. The housing may be provided as a substantially rigid or a substantially flexible component and a variety of DED form factors may

be provided, depending on the type and arrangement of underlying substrate and signal transfer terminals.

Figs. 11C and 11D illustrate another exemplary embodiment of a DED 42 having a slightly different design. In this embodiment, a curved housing or case encloses an interior space containing memory, processing and/or communications components and multiple terminals are provided on an inner surface in a keyed configuration, as shown in Fig. 11D. The keyed terminal configuration may be provided in any configuration that permits mating with corresponding terminals only in a pre-determined order or format. So, while a “W” configuration of keyed terminals is shown in Fig. 11D, it will be appreciated that many different keyed terminal configurations may be provided, including serpentine geometrical configurations, various asymmetrical configurations, triangular configurations, irregularly spaced configurations, and the like.

Conductive terminals CT1, CT2 and CT3 are provided on DED 42 for signal and/or data transfer from sensors associated with a substrate (e.g., sock, anklet, shirt, etc.). Ground terminals GT1 and GT2 are provided and interface with ground terminals provided on the underlying substrate to provide grounding of the device and, if desired, auxiliary features. One of the ground terminals may also serve as a DED connection detector and DED on/off actuator, such that the DED is automatically actuated when its ground terminal(s) is engaged by a mating ground terminal of the sensing substrate and the DED is automatically inactivated when its ground terminal(s) is dis-engaged with a mating ground terminal of the sensing substrate. A user-perceptible indicator (e.g., light, sound, vibration, or the like) may be provided to indicate when the DED is activated, or to provide indications of various status, operations or the like. In the embodiment illustrated in Fig. 11C, contrasting band 44 is provided with one or more underlying LED devices (shown as circles in band 44) that may illuminate upon activation of the DED by connection to terminals in an underlying substrate. In some embodiments, an indicator on the DED may provide feedback to the user based on analysis of the signals collected. It will be appreciated that many different types of indicators, read-out windows or screens, or the like may be provided in connection with the DED.

Fig. 11E schematically illustrates yet another exemplary embodiment of a DED in the form of a curved segment having a segmented, flexible design. The outer housing 46 is provided as a pliable material that accommodates bending. Inner segments 47A-47G may be provided as segmented, hinged modules movable relative to one another. In the embodiment shown, the terminals CT1, CT2, CT3, GT1 and GT2 are provided in a keyed configuration, as described above, and each of the conductive terminals is mounted in a separate, hinged module. LED indicators and a contrasting band may be provided in connection with one hinged module, and a battery and battery case 48 may be provided in connection with another hinged module. The battery is preferably rechargeable and may additionally be replaceable.

Flexible DED module components, as described herein, may comprise hybrid flex or fully flex circuits, as is known in the art, providing electrical connectivity between and among the constituent modules, which are movable and bendable with respect to one another. The DED housing and/or module components may also incorporate memory effect features that allow the DED housing to remain in a desired curved or bent configuration, and to allow configuring of the DED housing in a variety of curved or bent configurations. In one embodiment, for example, flexible copper (or other memory effect) wire(s) or band(s) may be provided extending along the bendable length of the DED housing. Other types of memory effect features may also be used.

Fig. 11F illustrates an exemplary charging device 45 for a DED as shown in Figs. 11A-11E. Charging device 45 incorporates a plurality of charging terminals ct1, ct2, ct3, gt1, gt2 (such as magnetically attractable terminals as used on the sensing device, described above) for mating with complementary conductive (and ground) terminals of the DED. The charging terminals (ct, gt) are arranged on a charger face having a configuration (e.g., curved) corresponding to that of the DED surface bearing the conductive and ground terminals so that a mating, nested charging condition is easily achieved with the conductive and ground terminals electrically connected to the complementary charging terminals. Charging may take place upon connection of the charging device to an electrical outlet via direct contact electrical connection or via inductive coupling. The charging device may have a generally stirrup-shaped configuration, as illustrated, with a curved connector body 47 and charger face formed as a cross-bar connecting the ends of the connector body. A central recess provided in this design, and shown in the exemplary embodiment as a generally semi-circular central recess, facilitates handling and placement of the charger device.

The DED incorporates processing, memory and/or communications functionalities within the housing. A schematic diagram illustrating exemplary DED components and interfaces is shown in Fig. 14. The DED has signal receipt terminals (shown as “snap connectors”) that feed analog input signals to appropriate processing means, such as analog filters, A/D converters, and to a processing component. Optional manual control input(s) and one or more optional output display(s) may be provided in or on the DED, as shown. Local memory may also be provided, and means for communicating signals and/or data externally via wired or wireless protocols may be provided, as shown. Signals and/or data is communicated from the DED to an external computing facility or device, such as a computer, base station, smartphone, or another bridge device, such as a gaming console, another game controller or interface, a remotely controlled device, such as a remotely controlled toy, exercise equipment etc., and/or to a centralized, hosted facility in a remote location, such as in the Cloud or at a centralized data processing and analysis facility. Data from other sources, such as other external sensors, sensors incorporated in the computer, base station, smartphone, or other bridge device, may also be collected and used. Following data analysis using data collected from the DED alone or in combination with data

collected from other sources in accordance with predetermined and/or pre-programmed instructions, data output, analysis, notifications, alerts, and the like are communicated from the centralized hosted facility to one or more bridge device(s), and/or the DED, as shown. It will be appreciated that this is one exemplary data flow scheme, and that many other work flows may be advantageously used in connection with sensing systems of the present invention.

Although specific embodiments have been illustrated and described with reference to the wearable substrate having a sock form factor, it will be appreciated that the sensors, leads, traces and terminals, as well as different types of DEDs may be adapted for use in other types of garment and non-garment applications. Similar types of flexible e-textile sensors may be applied to or associated with a wide variety of non-conductive underlying flexible substrate materials, including woven and non-woven materials, and incorporated in a variety of sensor systems. Additional exemplary systems are described below, and are non-limiting.

Wrap, band and sheet sensor applications

In additional applications, flexible sensors and sensor systems of the present invention may be fabricated as independently positionable sensor components and used in a variety of applications. Fig. 15 schematically illustrates an independently positionable sensor system comprising a flexible pressure sensor S1 electrically connected, via leads (not visible), to conductive traces T1 and T2, which are in turn electrically connected to conductive signal transfer terminals CT1 and CT2. The pressure sensor S1, leads, and/or conductive traces may be mounted to or associated with an underlying non-conductive flexible substrate to provide mechanical integrity to and enhance the durability of the system. It will be appreciated that this type of independent flexible sensor system may be fabricated using a wide variety of sensor sizes, and sensor functions, trace lengths, configurations, underlying substrates, and the like, and that additional and different types of sensors may be incorporated in such independent flexible sensor systems, as described above.

One or more of these types of independently positionable flexible sensor systems may be positioned by a user, caretaker and/or clinician at a desired body site and anchored at the site using bands, wraps, or other anchoring devices. Figs. 16A and 16B schematically illustrate the use of an independently positionable sensor system on the surface of or within a bandage wrapped around a foot. Fig. 16A shows the sensor S1 positioned as desired at a location near the bottom of the foot. The sensor S1 may be anchored to the desired sensing location, if desired, using a variety of non-conductive anchoring means such as hook and loop and other types of fasteners. Fastening means, such as hook and loop fasteners, may be mounted on or associated with a surface (or partial surface) of the sensor S1. Conductive leads are associated with sensor S1 and conductive traces T1, T2, which transmit signals/data to conductive signal transfer terminals CT1, CT2 positioned or positionable at an accessible external location, such as at the

top of the foot or at an ankle or lower leg position, as shown in Fig. 16B, providing access for connection of a DED and data downloading. Wraps, bands, bandages, or other anchoring systems may be wrapped around the sensor system following placement to secure the sensor system, and sensor, in place at the desired sensing location and to maintain external access to the signal transfer terminals.

Fig. 17 illustrates a foot wrap 50 having an integrated sensor system, or employable in combination with an independently positionable sensor system such as that illustrated in Figs. 16A and 16B positioned inside the wrap 50, between the interior surface of wrap 50 and the foot (or another body surface). The sensor is located at a desired sensing site on the foot and the conductive signal transfer terminals CT1, CT2 are positioned outside wrap 30 at a location that is accessible to a complementary DED. It will be appreciated that while this type of wrap system is shown and described with reference to a foot wrap, it may be embodied in various types of wraps, bandages, wound and/or ulcer dressing materials and the like having a variety of sizes, configurations, and sensing capabilities. The location of the sensor(s) and conductive signal transfer terminals, and the path of the conductive traces, is highly flexible and may be adapted for sensing in many different types of applications.

Figs. 18A and 18B illustrate one exemplary embodiment in which one or more protective layers or materials may be provided to protect one or more sensor(s) and, optionally the associated leads, and all or portions of conductive traces, from contact with liquids, body fluids or other solutions, while preserving the core resistive features and functions of the sensor(s). A protective barrier may comprise a liquid impervious or substantially liquid impervious material, such as a generally thin plastic sheet material or a composite sheet material, that doesn't interfere with the sensing capacity of the sensor. By "substantially" liquid impervious we mean that liquid penetration of the material is insubstantial enough to affect the features and functions of the sensor(s). The protective barrier may optionally be breathable and/or gas permeable. Many such liquid impervious barrier materials are known. In some embodiments, a protective barrier may be provided on one surface of the sensor; in some embodiments, a sandwich- or envelope-type barrier that substantially seals the sensor in a substantially liquid impermeable envelope or pouch may be used.

In the embodiment shown in Figs. 18A and 18B, barrier 30 comprises a thin, flexible sheet material and extends over and around sensor S, enclosing the sensor in a liquid impervious barrier or envelope. In the embodiment shown, surfaces or edges of barrier 30 are sealed, forming a pouch around the perimeter of sensor S at seal 31. An adhesive band 32 may be provided on one face (or both faces) of the protective barrier for mounting the sealed sensor component to an underlying surface or substrate (such as a garment, the skin of the user, or the like). Although adhesive band 32 is shown forming a peripheral band outside seal 31, it will be appreciated that adhesive components, as well as other types of mounting mechanisms, may be

applied to or used in connection with protected sensor components. In the embodiments shown in Figs. 18A and 18B, sensor S and leads L1 and L2 are encased within protective barrier 30; conductive traces T1 and T2 exit barrier 30 for attachment to conductive signal transfer terminals (not shown). Additional material layers may be provided inside and/or outside the barrier as shown in Fig. 18B to provide any desired functionality.

Fig. 19 schematically illustrates flexible pressure sensors S having conductive leads L1, L2 electrically connected to conductive traces T1, T2 in place on a flexible bandage 35 or on a wrap or another substrate for placement on or near wounds. The signal transfer terminals (not shown) are located on opposite sides of the bandages and may be connected to independently positionable signal receiving terminals for signal transfer. This system provides flexibility as to placement of the bandages having different sizes and configurations on different body surfaces and on body surfaces of different sizes and configurations, while permitting convenient and flexible signal transfer.

Fig. 20 schematically illustrates a plurality of pressure sensors (S1-S6) mounted to/in/on, or associated with, a substrate sheet material 36 that's flexible and non-conductive. Each of the sensors S1-S6 has conductive leads electrically connected to conductive traces that terminate in signal transfer terminals located at the edge of the substrate 36. The signal transfer terminals are connectible to mating signal receiving terminals of one or more DED(s), also mountable at the edge of the substrate. In this embodiment, the DED may have a strip-like form factor for connecting to aligned signal transfer terminals. This type of sensor arrangement and system may be used, for example, in connection with various types of garments, bed sheets, chair pads, or the like, to provide data regarding pressure and/or shear at locations where a user sits, lies, or the like.

Fig. 21 schematically illustrates exemplary computer- and/or firmware- and/or software-implemented processes used by a medical monitoring system of the present invention. In some embodiments, patient setup and (optional) device authentication, program selection and the like are provided, as well as a user and/or clinician dashboard providing data output and analysis in accordance with the program selection. One specific example of output returned to the user and/or clinician is illustrated as patient offloading data, expressed as excess pressure, which provides information to the user and/or clinician as to pressure conditions (and conditions of the underlying skin and tissue) at the site of any of the pressure sensors provided in the system.

In one exemplary methodology of the present invention, a garment having one or more sensing systems as described herein is positioned on a user with sensor(s) positioned in proximity to a body area desired to be monitored, or an independently positionable sensing band, or bandage, or substrate is positioned relative to one or more body surface areas of a user desired to be monitored. A dedicated electronic device is mounted to/on or associated with exposed signal transfer terminals of the sensing system and an authentication protocol is initiated to match the garment/sensing system to the user. The authentication protocol optionally loads user data,

profile information, and the like, to one or more hosted systems, such as a centralized data processing and analysis facility, a medical records facility, a caretaker system, clinician dashboard, or the like. Sensor calibration may then be conducted based on user specific information, conditions, and the like, and thresholds, limits or specific ranges, monitoring protocols, notifications, alerts, and the like may be selected by the user, a caretaker, clinician, or by the system to apply user-specific monitoring routines, parameters, and the like. Intermittent or substantially continuous user monitoring may then be initiated, with monitoring data and results provided to the user, a centralized data processing and analysis facility, a medical records facility, a caretaker system, clinician dashboard, and the like. Changes and updates to monitoring protocols may be implemented based on monitoring feedback, changes in user condition, etc.

Figs. 22A-22L schematically illustrate exemplary device set up, calibration and monitoring criteria input, along with an exemplary clinician dashboard, a graphical representation of patient offloading data, and an exemplary sample of acquired pressure data. Processing systems and means for executing device set up and calibration, and for monitoring and reporting sensed data may reside at a computing facility that is remote from the sensing device or means and the dedicated electronic device and may comprise computer implemented systems and methods at a host computer system, a medical facility computer system, in a computing environment such as the Cloud, or the like. Reports may be displayed at the computing facility, or at any display device (e.g. a monitor, smartphone, computer, electronic healthcare system, or the like) that is capable of communicating with the computing facility.

Fig. 22A schematically illustrates an exemplary setup and calibration protocol involving a patient information setup routine, a device information set up routine, a monitoring criteria set up routine and a calibration routine. A variety of different routines are available for patients having different conditions, for different device configurations, sensor types and locations, monitoring protocols, and the like. Various routines may be programmed or programmable and selectable by a user and/or by medical personnel. The routines may reside in the DED, a computing device or another bridge device, in cloud services, or the like.

Fig. 22B schematically illustrates an exemplary patient data collection protocol forming part of the patient information setup. In this example, a doctor or another medical professional can collect and input data to associate to the specific patient/device pair. Patient identification, patient-specific information like weight, height, condition, physician, ulcer location and condition, as well as procedures undergone, hospital admissions, notes, and the like not only add information related to the specific case, but can also be used as guidance for the device calibration procedure. This information also provides meaningful data to use in aggregated views of the overall patient data.

Figs. 22C-22F schematically illustrate exemplary device setup protocols including a sensor activation selection menu. In this exemplary device setup routine, the system model

number and identification is provided, along with the type of data collection. Real-time alerting and notification features may be selected. Various sensors and sensor locations may be selected and activated, while others may remain inactivated, as shown in Figs. 22C and 22D. Fig. 22D illustrates an exemplary sensor activation menu for a sock type sensor surface, where the doctor or medical assistant can activate specific sensors in a set of 5 available for the specific example. Fig. 22E illustrates an exemplary sensor activation menu for a dressing/wrap type sensor surface, where the doctor or medical assistant can specify which type of sensor (A, B, C in the specific example) will be used for any specific patient. Fig. 22F illustrates an exemplary sensor activation menu for an insole type sensor surface, where the doctor or medical assistant can activate specific sensors in a set of 5 available for the specific example.

Fig. 22G schematically illustrates monitoring criteria selection menus, including a monitoring threshold selection menu and a notification selection and activation menu. Fig. 22H schematically illustrates in more detail the monitor thresholds and notification selection and activation menu. In this example, the doctor or medical assistant can define different thresholds to monitor before and after the first 72 hours post medical procedure or post sensor activation. The exemplary monitor thresholds define two levels of severity: yellow and red. In one embodiment, the yellow threshold can be surpassed for a limited period of time (for example 5 minutes every hour) without consequence: after this time-based threshold has been surpassed, the system will alert the patient or caregiver according to a notification or alert protocol. This embodiment also allows the use and selection of a red threshold that, if it is surpassed at any time, the system alerts the patient or caregiver immediately. Thresholds are managed through a hysteresis cycle, to avoid multiple alerts to be raised when the pressure level is averaging around the threshold level. The threshold levels can be preset by the parameters input for the patient and based on historical data, or defined/tuned by the doctor or medical assistant. Notifications may include vibration of the device, e-mails sent to specific addresses, text messages sent to specific phone numbers, robo-calls from an automated speech system, or the like, and the notification type, frequency, etc. may be set by the user or a medical professional as part of the monitoring routine, as shown. In some embodiments, daily reports may be sent to the doctor or caregiver for each patient using such a sensor system.

Fig. 22I schematically illustrates a sample calibration protocol for automatic set up of parameters such as filter thresholds, signal gain, voltage-to-pressure formulae, e.g., voltage to kPa to evaluate weight, and the like, based on user-specific criteria. In this calibration, background data may be collected while the user is in various positions or doing various activities, such as sitting, standing, walking, or the like, to collect patient-specific data so that various parameters of the sensing system may be normalized to, or standardized against patient-specific "normal" parameters.

Fig. 22J illustrates an exemplary clinician dashboard displaying diabetic patient data by patient name, medical condition, foot ulcer location and condition, medical procedural history, monitoring sensor device and location, substantial real-time monitoring information, and patient status based on monitoring information. In the clinician dashboard shown, patients are categorized in red, yellow or green status based on monitoring information so that clinicians may contact and check on patients having conditions categorized in the red status and avert more serious conditions. The doctor or medical assistant can pivot the data on different “dimensions”, such as type of offloading device, medical condition, ulcer location, etc. The doctor or medical assistant can also filter and sort data based on the same dimensions, to extract a view of the data aggregated for specific area of interest, both for ease of access as well as statistical purpose. For example, by analyzing this data as aggregate, specific types of offloading devices, coupled with specific types of monitoring devices used, might show a better outcome for patients with ulcers in the metatarsal area.

Fig. 22K schematically illustrates a patient offloading data display clearly showing excessive pressure exerted at sensing locations in real-time and historically, and providing a history of notifications and alerts provided. This data can be used by the doctor or medical assistant for the purpose of analyzing in detail the behavior of a patient, observing correlations and outcomes, as well as to provide the basis for honest conversations with patients about their behavior and how it affects the healing process. The same data can also be used to send reports to the patient, with emphasis on the good habits and positive reinforcement to improve the adherence and help the healing process.

Fig. 22L schematically illustrates sensed force/pressure data collected using a sensing system as described herein with sensors located at the heelbone and at a metatarsal area, with signals in areas A and B illustrating data collected while the user walked 10 steps; signals in area C corresponding to the user jumping, signals in area D corresponding to the user shifting his weight, and signals in areas E and F illustrating data collected while the user walks additional steps following the previous activity. It will be appreciated that many other types of input and output may be provided in connection with sensor systems of the present invention, and that these diagrams are provided for purposes of illustrating specific examples of useful input and output and do not limit the invention in any way.

Medical monitoring

The specific examples of sensors and sensor systems described herein are applicable to patients with multiple types of foot related problems such as flat foot, injuries from accidents or military personnel injured on the battle field or patients suffering from peripheral neuropathy, and more specifically diabetic neuropathic feet wherein portions of the foot may be insensitive to pressure. The user, caretaker and/or clinician may be alerted to lack of patient adherence to

offloading guidance, areas of excess pressure and/or shear, substantially in real-time, to facilitate prevention of ulcer formation and to promote ulcer and wound healing.

In another medical monitoring application, sensors and sensor systems described herein may be used with subjects who may be prone to falling, gait irregularities, or similar conditions that result in different pressure/force conditions and patterns at the foot or other body areas. Sensors and sensor systems may be used to monitor pressure/force exerted at sensing locations in real-time and detect various activities, such as walking, gait patterns, sitting or “foot off the ground” conditions, and the like. The signal processing and analytic protocols may provide capabilities such as fall detection, pre-fall detection, gait analysis and the like, and may facilitate diagnostic and preventative activities. The system may also provide substantially real-time alerts or notifications (to the user, a caretaker and/or healthcare provider) relating to gait irregularities, falls, pre-fall conditions, and the like based on analytics provided using pressure sensing systems as described herein.

In another medical monitoring application, e-textile sensing systems as described herein may be used and provided in association with prosthetic devices, or with body surfaces that contact (directly or indirectly) prosthetic devices, to detect and alert the user or a caregiver to pressure exerted on tissue contacting (directly or indirectly) prosthetic devices, which may be insensitive or less sensitive to pressure than normal tissue. In one embodiment, for example, a pliable substrate having one or more e-textile sensors with leads, traces and terminals may be placed between a prosthetic device and a subject's body surface, with terminals exposed for connection of a DED, as described herein. In some embodiments, a sensing system may be mounted to or incorporated in a prosthetic device, providing for connection of the DED to terminals provided on the prosthesis.

Fitness and athletic monitoring

Sensors and sensor systems described herein are also applicable to a wide range of fitness applications. Technology for measuring how far and how fast individuals run, hike, walk, etc., and for reporting various distance and velocity measurements, with mapping features, is available and in use. Pressure and/or force sensors as described herein may be used, for example, separately from or in combination with such systems, to detect how well individuals perform fitness activities such as running, walking, hiking, and the like. Pressure and/or force sensors, provided in a sock-like and/or garment form factor may be used, for example, to detect body position and length of time in a body position, various running and gait characteristics such as foot landing (e.g., heel striking, forefoot striking, pronation, supination, eversion), cadence, stride length, arm swing length and frequency, center of balance, and the like. Information and detection relating to environmental factors, such as terrain detection (e.g., soft, hard, uneven, etc.) may also be provided using sensing systems described herein.

In one scenario, a user/patient or an athlete or a person engaging in an activity wears one or two sock(s) incorporating a flexible sensing system, as described. In another scenario, a user may wear another garment, such as a shirt, shorts, gloves, or the like incorporating an e-textile sensing system, as described. The sensors may be activated by connection to (via appropriate leads, traces and/or terminals) or activation of one or more DED(s). The DED establishes a connection with one or more remote computing devices or services (e.g., via USB/Wi-Fi/Bluetooth/other medium), and pressure-related data is transferred to a remote computing device/service, where data processing and analysis takes place. Ranked recommendations related to patient adherence, performance and goal achievements, injury preventions, what/if analysis may be communicated and displayed to the patient, athlete, user and/or coach/caregiver in substantially real-time, allowing the patient, athlete, user and/or coach/caregiver to make changes to the patient's or athlete's behavior or activity in response to the sensed pressure and returned results.

In one fitness application, the user may employ one or two sensor-containing sock(s), with sensors in each sock communicating with a DED and, through the DED, communicating with one or more remote computing devices or services. The sock(s), or other garments or accessories may contain not only e-textile pressure sensors (as described), but one or more accelerometer(s) and other types of sensors. Data gathered from e-textile pressure sensors may be combined with data collected using one or more other device to provide comprehensive feedback to the user. A conceptual flow diagram illustrating exemplary fitness output data, graphical user interfaces, and the like, presenting data and analytics to the user based, at least in part, on data collected from sensing systems as described herein is shown in Figs. 24A and 24B.

In a diagnostic mode graphical user interface (GUI) shown in Figs. 24A, 24B and provided, for example, on a smart phone or tablet device or another electronic device having a display, essentially real-time pressure data collected by sensors provided in a sock substrate is provided, mapped on the bottom of each foot in graphical format, on the display. Different colors are used to indicate the amount of pressure, or force, exerted at different sensor locations, which may alert the user to pressure conditions that may produce discomfort or injury. Data from other sources may be used, and displayed, such as heart rate, distance, temperature (ambient and/or body), and the like. Useful analytical information, such as cadence, stride length, pronation, supination, and the like may also be displayed. Various activities may be displayed, with historical activity information and statistics available to the user. Warnings may be displayed on the GUI when predetermined parameter limits or ranges are detected; warnings may additionally or alternatively be communicated using other types of indications, such as audible and/or vibrational signals, or the like. Different display modes, including a coach mode, workout mode, statistics mode, and the like may display real-time and/or historical data of different types in different formats. The fitness GUIs may interface with and provide access to

other device features, such as music, other activity trackers, and the like, as shown. Figs. 25A-25D illustrate exemplary GUIs provided by systems as disclosed herein.

The systems and GUIs described above are used primarily in connection with running, walking, hiking and skiing activities, and the like, which involve repetitive foot planting, leg movement and weight shifting. In additional fitness applications, sensing systems as disclosed herein may be used in connection with monitoring and analyzing other types of activities, such as golfing, tennis, soccer, and the like. In golf and tennis applications, sensing systems provided in a sock-like form factor as described herein may be used alone, or with other data, to analyze golf swings, tennis strokes, and other types of movements that involve weight shifting from one foot to another, and across different surface areas of the foot. In soccer applications, sensors may be located in proximity to the bottom of the foot to track pressure/force in different areas on the bottom of the foot. Sensors may additionally or alternatively be provided (in a sock form factor, for example) in proximity to the top of the foot to track pressure/force exerted when kicking the ball, and the location of greatest pressure when kicking. These pressure/force measurements, alone and in combination with other types of data, provide useful analytical information and may be used to predict or prevent injuries, to improve swing and stroke effectiveness and efficiency, to log activities, and the like.

In another embodiment, data collected from auxiliary devices, exercise equipment, such as a treadmill, weight lifting machine, or the like, may be used in combination with data collected using sensing systems as described herein to provide detailed analytical information and user feedback. The DED may communicate directly with such auxiliary devices, exercise equipment, etc., and the GUI of the auxiliary device may display analytical information, notifications, recommendations, etc. generated by the sensing system to the user. In another embodiment, systems incorporating the DED and signal receipt terminals may be mounted to and/or incorporated in or associated with other types of intermediate dedicated electronic devices, such as a protective device (e.g., a shin guard or a helmet or other type of protective device). One version of this embodiment is illustrated in Fig. 23. In this embodiment, a substrate material in the form of a sock may be equipped with one or more sensors S1..Sn, leads and traces T1..Tn that provide signals and/or data to a set of terminals CT1..CTn. The terminals may comprise snaps, or connectors, mounted on the sock (male or female part) and on mating locations on a protective device, such as a shin guard device (female or male counterpart). The connectors on the sock may be located in areas where the shin guard usually overlies the sock, such that the counterpart connectors on the shin guard easily snap together and connect not only the terminals, but the sock and the shin guard. The shin guard can be manually positioned between the sock and the shin of the wearer, or be inserted in a proper fabric socket built-in the sock. In this embodiment, the shin guard is generally fabricated from a harder outer casing material and a shock absorber material on the inside. Electronic components of the dedicated electronic device (DED), as described earlier,

may be provided in a core area or recess within the shin guard, well protected from excessive impact. The DED gathers data from each sensor by means of direct connections between its inputs/outputs and mating terminals CT1..CTn and communicates signals and/or data to an external computing and/or bridge device, as described previously.

This type of arrangement may be used in a variety of sports that require leg and/or foot protection (e.g. soccer, hockey, football, etc.). Sensors may be placed in specific locations on a sock or another item of apparel, dependent on the type of sport and activity that is desired to be monitored. In one scenario, a soccer team may wear a sensor equipped (instrumented) sock and the shin guard with embedded DED to collect pressure data that can be processed in real-time or after the fact and extract useful statistical data for the individual and the team. For example, by placing specific sensors on the sides of the sock (foot), a software system receiving the data from the DED may be capable of determining whether the pressure signal spikes coming from the inner sensor are related to run, walk, a pass or a shot. The system may provide statistical data such as number of passes, number of shots, ball possession, etc. by means of data analysis and synthesis.

In another embodiment, e-textile sensors, leads, traces and terminals may be provided in connection with a substrate material in the form of helmet liner or another accessory associated with protective gear. The sensor terminals provided in connection with the liner device interface with mating terminals on the protective device, such as a helmet. In this embodiment, the protective device (e.g., helmet) is generally fabricated from a harder outer casing material with a shock absorber material on the inside, and the liner is generally provided contacting the user's head. Electronic components of the dedicated electronic device (DED), as described earlier, may be provided in a core area or recess within the protective device, well protected from excessive impact. The DED gathers data from each sensor by means of direct connections between its inputs/outputs and mating terminals of the protective device and communicates signals and/or data to an external computing and/or bridge device, as described previously. Sensors may thus be used to provide data relating to force and impact experienced by the underlying body surface, as well as the location of the force and impact. This is useful, e.g., for detection of injuries such as concussions, traumatic brain injuries, injury prevention, and the like,

Occupational and general health applications

In yet additional applications, sensing systems as described herein may be used to detect and assess general health, body positioning, weight bearing and the like, and to provide feedback to a user. A sensing system in a sock form factor may be used with a DED, as described above, for example, to detect how much time a user spends walking, running, sitting, resting without weight placed on the feet, and the like. Simple routines may be programmed or programmable in the DED, or in an accessory electronic device (smart phone, bridge device, etc.), to track user

activity, to notify or alert a user when a different activity is recommended. In one embodiment, for example, when the user's been sitting in one position for an extended period of time, changing position or walking or stretching may be recommended, and a notification or alert may be provided to the user recommending activity. Similarly, when the user's been resting without weight placed on the feet for a certain length of time, a notification or alert may be provided to wake the user and/or to recommend activity. The length of time a user spends in various body positions and activities may be tracked and analyzed.

In another embodiment, sensors provided in a shirt form factor, such as illustrated in Figs. 10A-10C, may be used in combination with a DED to detect spinal position, posture and postural changes (by detecting the pressure/force of spaced spinal surfaces against the sensors). Additional sensors may be positioned elsewhere in a shirt form factor, such as in the shoulder region, arm region, abdominal region, or the like, and may contribute data relating to postural condition for analysis. The user's postural condition may be tracked and analyzed based on data collected from the variously positioned sensors. Undesirable postures, such as slouching, may be detected and the user may be alerted or prompted to change position and improve his or her posture based on the data collected. A calibration routine may be provided to determine the user's "standard" postural condition, or a desired postural condition, and variance from the standard or desired posture may then be detected with notification provided to the user. Notifications may be provided in the form of visual notifications (e.g., light indicators, flashing lights, read-outs or other visual displays provided on the DED or an accessory device), acoustic indications, vibrations, or the like. The DED may be provided in various forms and adapted for interfacing with a sensing system at various locations, as described herein. This is an example of an application in which the DED may have signal processing and data analysis capabilities, and the DED may also provide notification (via lights, audible signals, vibrations or the like) directly to the user concerning postural conditions, changes, recommended changes, or the like.

In yet another embodiment, data is collected using sensing systems disclosed herein for purposes of detecting pressure/force exerted on sensed body surfaces during weight lifting and weight shifting activities or during activities that involve repetitive movements, such as those performed during freight transfer and delivery, during assembly line work, manual labor, and the like. The substrate form factor used, and the size, configuration and placement of sensors may be designed for acquisition of pressure/force data from affected body surfaces. The data analytics provided by such sensing systems during such activities may be used by the user and/or employer, medical professional or the like, for example, to enhance worker safety, reduce workplace injuries, improve worker training, postural and weight bearing activities.

Gaming and remote control applications

In yet additional applications, sensing systems as disclosed herein may be used in electronic gaming applications to provide an interface between the user (player) in the “real world” and the electronic game world and display. Sensing systems provided in a sock-like or ankle form factor may be used, for example, to detect the pressure/force at different areas of a user’s foot against a game interface element such as a foot pad, accelerator, or the like, in essentially real-time. The sensors provide pressure/force signals to an associated DED, which may be interfaced with electronic games and game consoles that support an accessory device, such as a USB device attachment that uses the human interface device (HID) standard or a similar standard. In this environment, the DED may be used as an input device to send commands (left, right, up, down, more, less, fire, etc.) to the gaming device or console based on the pressure/force exerted at various locations on a user’s body surface. A standard interface allows the DED to be used with existing gaming devices and consoles without requiring creation or installation of specialized drivers. While this gaming application has been described with reference to sensors provided in a sock-like form factor, it will be appreciated that sensing systems as described herein provided in other garment-type formats may be adapted for use as gaming device controllers and input devices. Sensing systems described herein may also be provided in non-garment formats, such as in mats or pads that a user contacts during game play, activities such as dancing, running (in place or on a treadmill, for example), or in objects such as punching or kicking bags, and the like.

A DED and sensing system, as described herein, may also be used to control remotely driven vehicles, toys, and the like. In some embodiments, such remotely operated vehicles, toys, etc. are controlled using commands provided as radio frequency (RF) signals. Using wireless interface protocols (e.g., Bluetooth), such devices may be controlled, remotely, using the DED and sensing system as the input device, much as described above with reference to gaming scenarios.

Footwear fitting

Throughout the footwear industry, there are multiple international sizing systems and, even more importantly, a lack of standardization in shoe sizing. Sensors and sensing systems of the present invention may also be used to assist in footwear fitting. When consumers buy or order footwear in a store or online, it’s difficult to assess proper fit, particularly given the large selections available and without the ability to try on footwear in their specific everyday scenario. Even when consumers shop in a store and have the ability to try footwear on, the location and the limited time and experience may not identify poorly fitting footwear. This results in lost sales opportunities and high return rates, which discourages consumers from making online purchases and significantly raises sales costs for online merchants. Being able to purchase and order footwear having confidence that it will fit well would provide substantial benefit. In 2010 three

hundred and fifty million shoes were sold online, however about a third got returned. E-commerce has seen tremendous growth in recent years; however, online footwear sales make up only 12% of the total footwear market (compared to 50% for computers and 60% for books). The reason is that consumers are less comfortable buying shoes online since they cannot try on footwear before purchasing.

Pressure sensor(s) incorporated in a sock form factor, or positioned as independently positionable sensors, may be used to detect pressure on different points and areas of the foot and identify areas of discomfort. Using databases and data analysis of pressure sensors positioned on a user's foot, analytics may find and display recommended fit options for shoes, insoles and/or orthotics for specific individuals, and the individual may be alerted in real-time as to recommended fit options. The device-collected sensor data can be augmented with individualized information provided directly by the user(s), such as requested shoe type, model, or other search criteria.

In another embodiment, pressure sensors incorporated in a sock form factor, or in independently positionable sensing systems, may collect comfort and anatomic data as well as data relating to humidity, temperature, and other parameters at one or more locations on an individual's foot. The collected data may be augmented with user provided information, such as requested shoe type, model, and other search criteria, which may be processed to provide output as individual-specific recommendations and alerts.

In another embodiment, a user may take a picture of a shoe and send the image to a computing device or service (e.g. via e-mail). The footwear image may be processed and matched to footwear metadata maintained in one or more database(s) to identify potential matching footwear. A selection of related shoes, including the matching one, may be presented to the user. The selection may take in account comfort zones and foot anatomy of the current user that share common features and needs, and may rank the returned selection according to various parameters or user preferences. In one embodiment, the DED control software collects data from a sensor system to determine the anatomy of the foot. Once wearer's anatomical foot data is processed and compared to footwear data maintained in one or more databases, footwear recommendations may be displayed to the wearer, ranked according to projected fit, or other user preference(s). These systems, or similar systems, may be used to find and display ranked recommended fit options for footwear, insoles and/or orthotics.

While the present invention has been described above with reference to the accompanying drawings in which particular embodiments are shown and explained, it is to be understood that persons skilled in the art may modify the embodiments described herein without departing from the spirit and broad scope of the invention. Accordingly, the descriptions provided above are considered as being illustrative and exemplary of specific structures, aspects and features within

the broad scope of the present invention and not as limiting the scope of the invention. The various embodiments described herein may be combined to provide further embodiments. The described devices, systems and methods may omit some elements or acts, may add other elements or acts, or may combine the elements or execute the acts in a different order than that illustrated, to achieve various advantages of the disclosure. These and other changes may be made to the disclosure in light of the above detailed description.

In the present description, where used, the terms "about" and "consisting essentially of" mean $\pm 20\%$ of the indicated range, value, or structure, unless otherwise indicated. It should be understood that the terms "a" and "an" as used herein refer to "one or more" of the enumerated components. The use of the alternative (*e.g.*, "or") should be understood to mean either one, both, or any combination thereof of the alternatives, unless otherwise expressly indicated. As used herein, the terms "include" and "comprise" are used synonymously, and those terms, and variants thereof, are intended to be construed as non-limiting. In general, in the following claims, the terms used should not be construed to limit the disclosure to the specific embodiments disclosed in the specification.

We Claim:

1. A sensing device comprising an electrically conductive e-textile sensor; at least two electrically conductive leads connected to the sensor; at least one electrically conductive signal trace connected to one of the conductive leads; at least one ground trace connected to one of the conductive leads; at least one signal transfer terminal electrically connected to the at least one signal trace; and at least one ground terminal connected to the at least one ground trace; wherein the sensor, the conductive leads, the signal trace, the ground trace, the signal transfer terminal and the ground terminal are associated with a flexible, non-electrically conductive substrate.
2. The sensing device of claim 1, comprising at least two electrically conductive e-textile sensors, wherein the flexible, non-electrically conductive substrate is provided in a sock or ankle-like form factor, at least one electrically conductive e-textile sensor is located in a heel region of the substrate, and at least one electrically conductive e-textile sensor is located in the forefoot area of the substrate.
3. The sensing device of claim 1, comprising at least two electrically conductive e-textile sensors, wherein the flexible, non-electrically conductive substrate is provided in a mat or pad form factor.
4. The sensing device of claim 1, comprising at least two electrically conductive e-textile sensors, wherein the flexible, non-electrically conductive substrate is provided in association with an item of sporting equipment.
5. The sensing device of claim 4, wherein the sporting equipment is a helmet.
6. The sensing device of claim 4, wherein the sporting equipment is three dimensional object intended to be contacted by a user.
7. The sensing device of claim 1, wherein the flexible, non-electrically conductive substrate is provided in association with a prosthesis.
8. The sensing device of claim 1, comprising at least two electrically conductive e-textile sensors, wherein the flexible, non-electrically conductive substrate is provided in a shirt form factor.
9. The sensing device of any of claims 1-8, in combination with a dedicated electronic device having at least one signal receipt terminal and at least one ground terminal that mate with the at least one signal transfer terminal and the at least one ground terminal of the sensing device

and additionally comprising a housing component with signal processing and communications components located within the housing component.

10. The sensing device of any of claims 1-8, in combination with a dedicated electronic device having at least one signal receipt terminal and at least one ground terminal that mate with the at least one signal transfer terminal and the at least one ground terminal of the sensing device and additionally comprising a housing component with signal processing and communications components located within the housing component, wherein terminals of the sensing device and the dedicated electronic device mate with one another both mechanically and magnetically.

11. The sensing device of any of claims 1-8, in combination with a dedicated electronic device having at least one signal receipt terminal and at least one ground terminal that mate with the at least one signal transfer terminal and the at least one ground terminal of the sensing device and additionally comprising a housing component with signal processing and communications components located within the housing component, wherein terminals of the sensing device and the dedicated electronic device are arranged in a complementary configuration and mate only when arranged in a pre-determined orientation.

12. A dedicated electronic device having at least one signal receipt terminal and at least one ground terminal that mate with the at least one signal transfer terminal and the at least one ground terminal of a sensing device and additionally comprising a housing component with signal processing and communications components located within the housing component and an indicator providing on/off status information to a user.

13. A dedicated electronic device having at least one signal receipt terminal and at least one ground terminal that mate with the at least one signal transfer terminal and the at least one ground terminal of a sensing device and additionally comprising a pliable housing component with signal processing and communications components located within the housing component, wherein the DED is bendable and incorporates a memory effect feature that allows the DED to be adjusted to and remain in a variety of curved, bent or flat configurations.

14. A battery charger for a DED of claim 12 having a plurality of charging terminals arranged on a charger face and having a generally stirrup-shaped configuration.

15. A method and a system for collecting data and monitoring conditions at or near a body surface, comprising placing a sensing device having an electrically conductive e-textile sensor, at least two electrically conductive leads connected to the sensor, at least one electrically conductive signal trace connected to one of the conductive leads, at least one ground trace connected to one

of the conductive leads, at least one signal transfer terminal electrically connected to the at least one signal trace, and at least one ground terminal connected to the at least one ground trace, wherein the sensor, the conductive leads, the signal trace, the ground trace, the signal transfer terminal and the ground terminal are associated with a flexible, non-electrically conductive substrate, in proximity to a body surface; interfacing a dedicated electronic device having at least one signal receipt terminal and at least one ground terminal that mate with the at least one signal transfer terminal and the at least one ground terminal of the sensing device with at least one signal transfer terminal and at least one ground terminal of the sensing device; acquiring signals from one or more locations in proximity to the body surface; communicating the signals or data generated by processing the signals to a communications component, and communicating the signals or data or notifications generated by processing the signals.

16. The method and system of claim 15, wherein the signals or data generated relates to pressure or force exerted on sensors in proximity to sensed body surfaces during weight lifting and weight shifting activities.

17. The method and system of claim 16, wherein the weight lifting and weight shifting activities include at least one selected from the group consisting of: walking, running, hiking, dancing, golf, tennis, occupational activities that involve weight lifting and weight shifting.

18. The method and system of claim 15, wherein the signals or data generated relates to pressure or force exerted on sensors in proximity to sensed body surfaces during postural changes.

19. A method and a system for operating a gaming system, comprising placing a sensing device in contact with a body surface or an object, wherein the sensing device has at least one electrically conductive e-textile sensor, at least one electrically conductive lead connected to the sensor, at least one electrically conductive signal trace connected to the at least one electrically conductive lead, and at least one signal transfer terminal electrically connected to the at least one signal trace, wherein the sensor(s), the conductive lead(s), the signal trace(s), and the signal transfer terminal(s) are associated with a flexible, non-electrically conductive substrate; interfacing a dedicated electronic device having at least one signal receipt terminal that mates with the at least one signal transfer terminal of the sensing device with the sensing device; moving one or more locations in proximity to the body surface; communicating signals or data generated by processing the signals from the sensing device to the dedicated electronic device and/or to an electronic gaming device, and thereby providing input to the gaming system.

20. A method and a system for operating a remotely controllable object, comprising placing a sensing device in proximity to a body surface, wherein the sensing device has at least one electrically conductive e-textile sensor, at least one electrically conductive lead connected to the sensor, at least one electrically conductive signal trace connected to the at least one electrically conductive lead, and at least one signal transfer terminal electrically connected to the at least one signal trace, wherein the sensor(s), the conductive lead(s), the signal trace(s), and the signal transfer terminal(s) are associated with a flexible, non-electrically conductive substrate; interfacing a dedicated electronic device having at least one signal receipt terminal that mates with the at least one signal transfer terminal of the sensing device with the sensing device; moving one or more locations in proximity to the body surface; using the sensing device to acquire signals from one or more locations in proximity to the body surface; and using signals or data generated by processing the signals acquired by the sensing device as input for controlling the remotely controllable object.

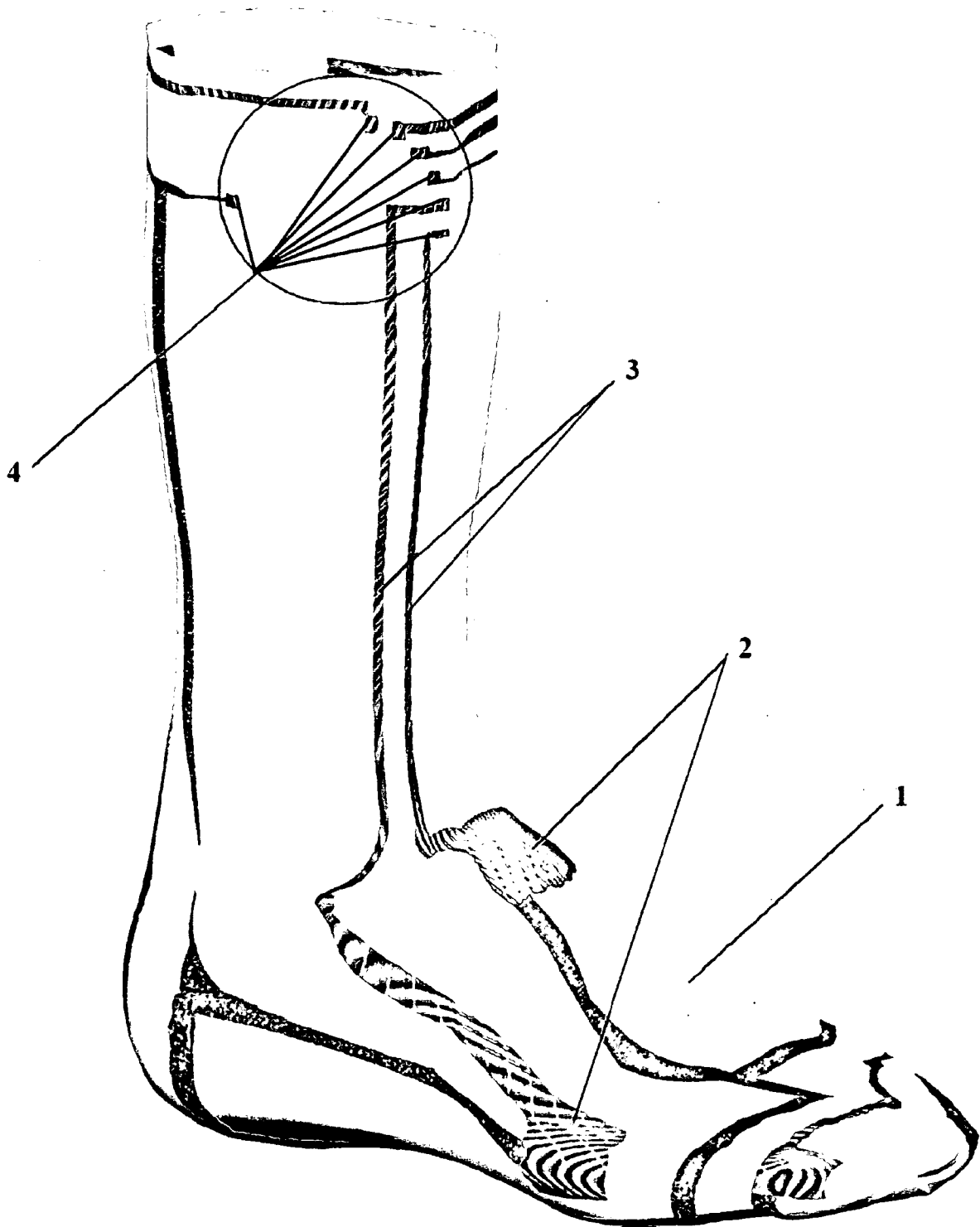


FIG. 1

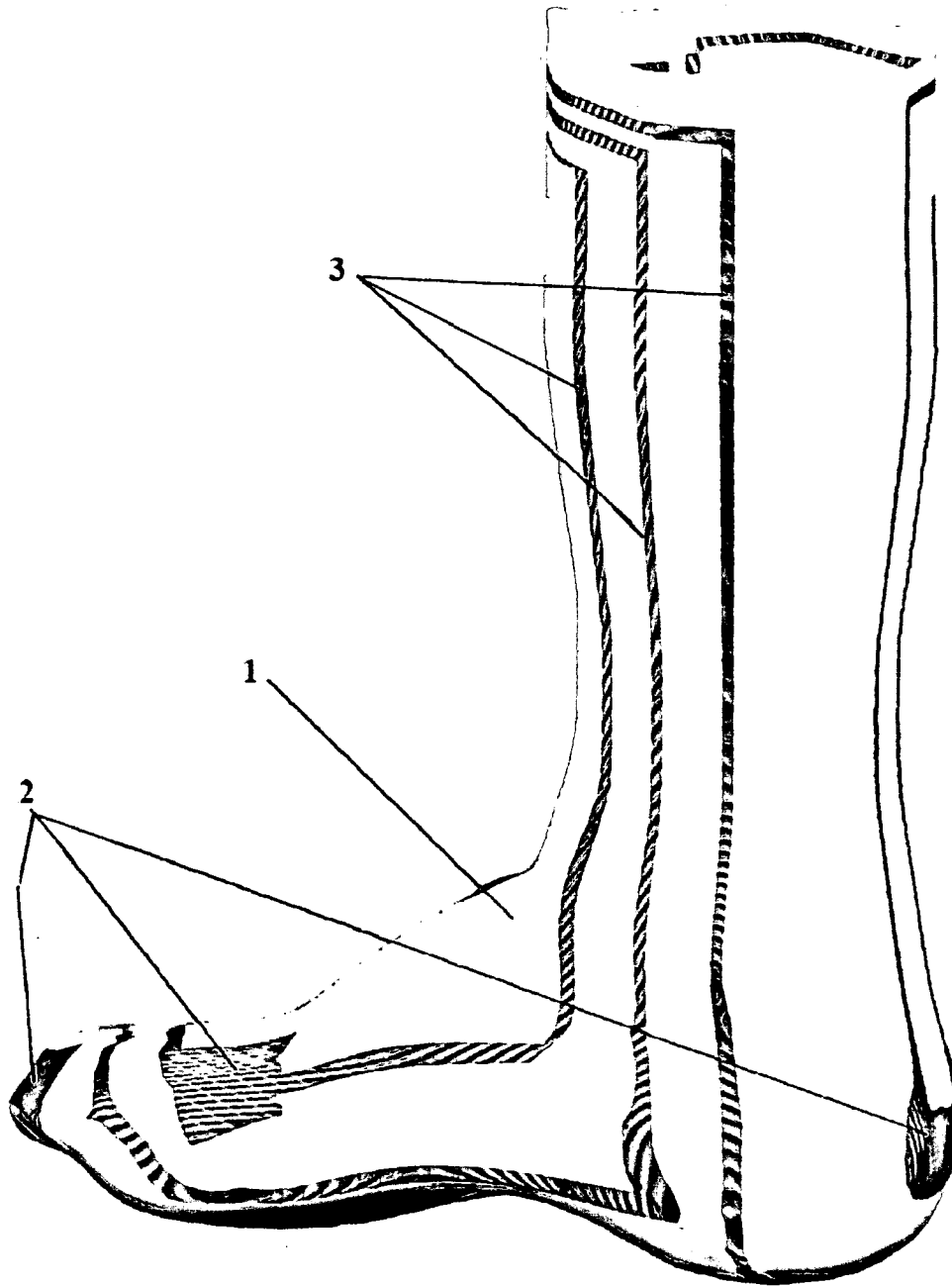


FIG. 2

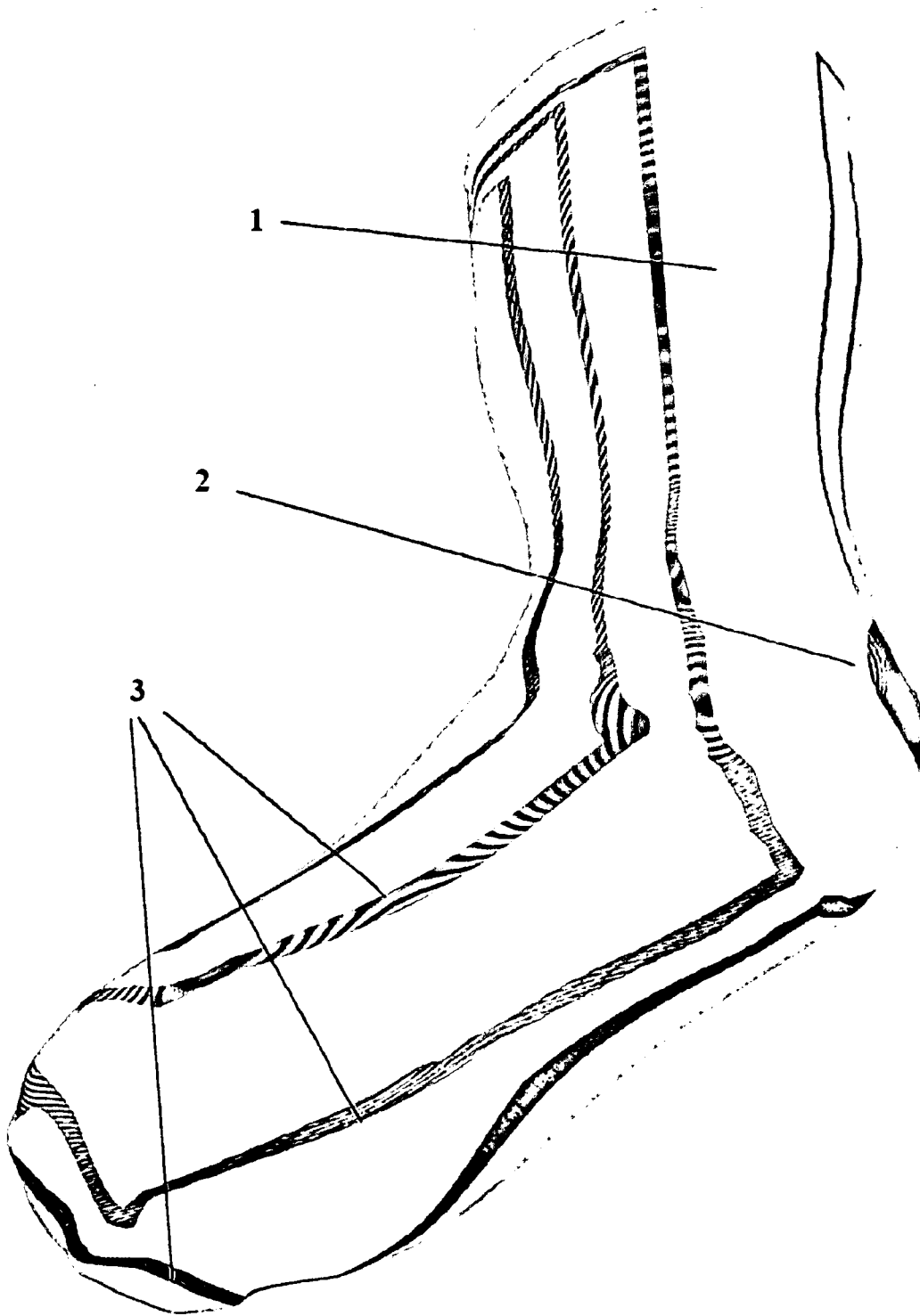


FIG. 3

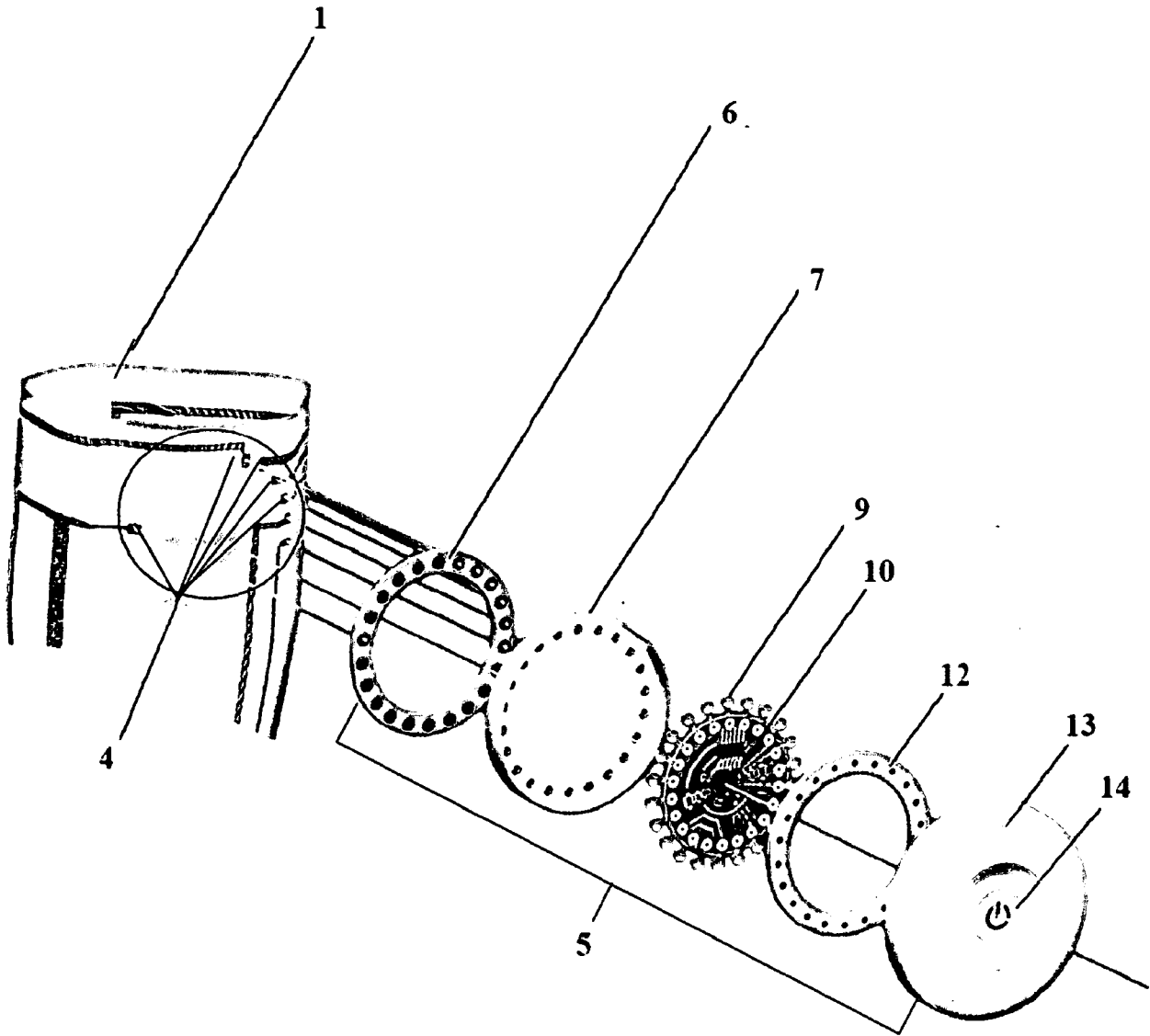


FIG. 4

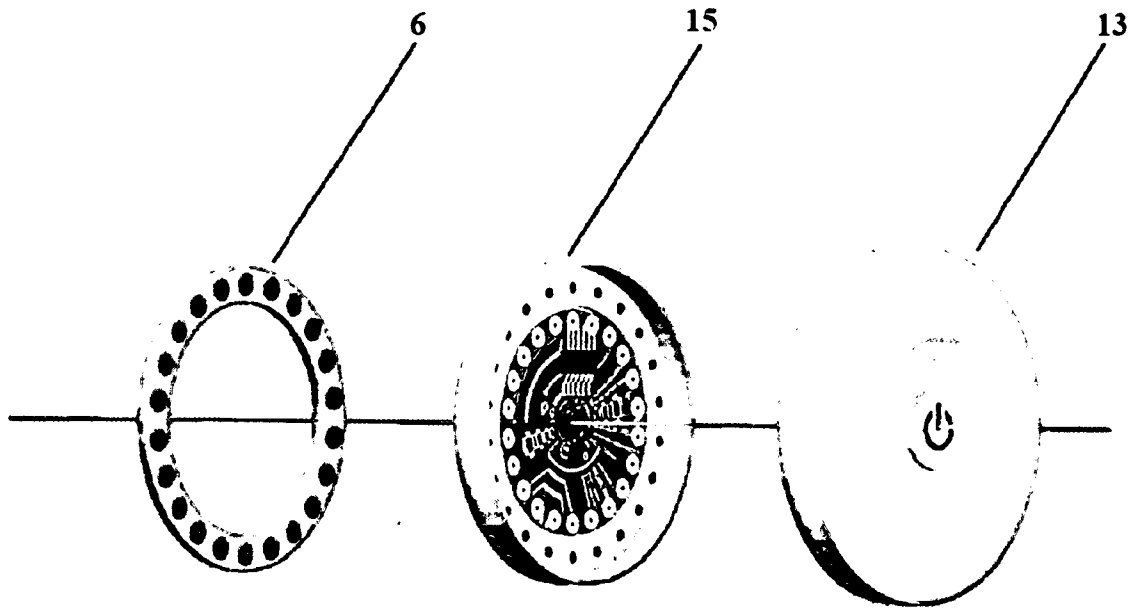


FIG. 5

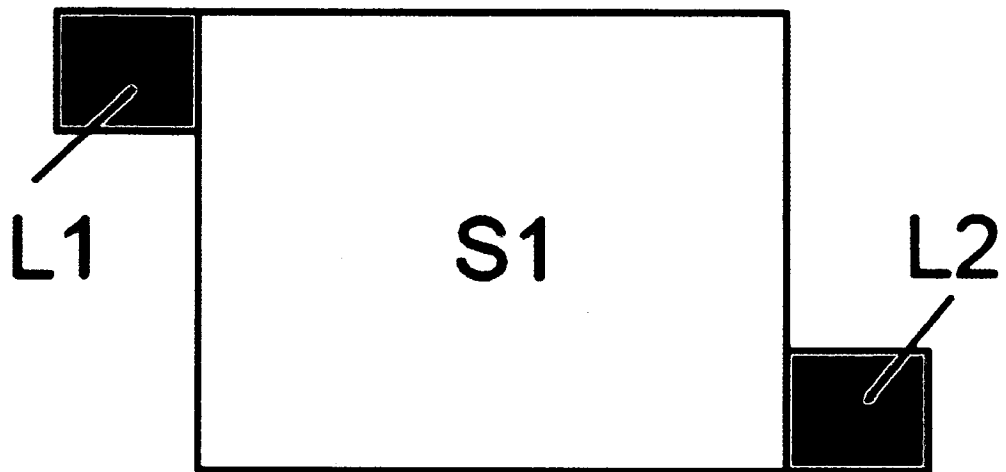


FIG. 6A

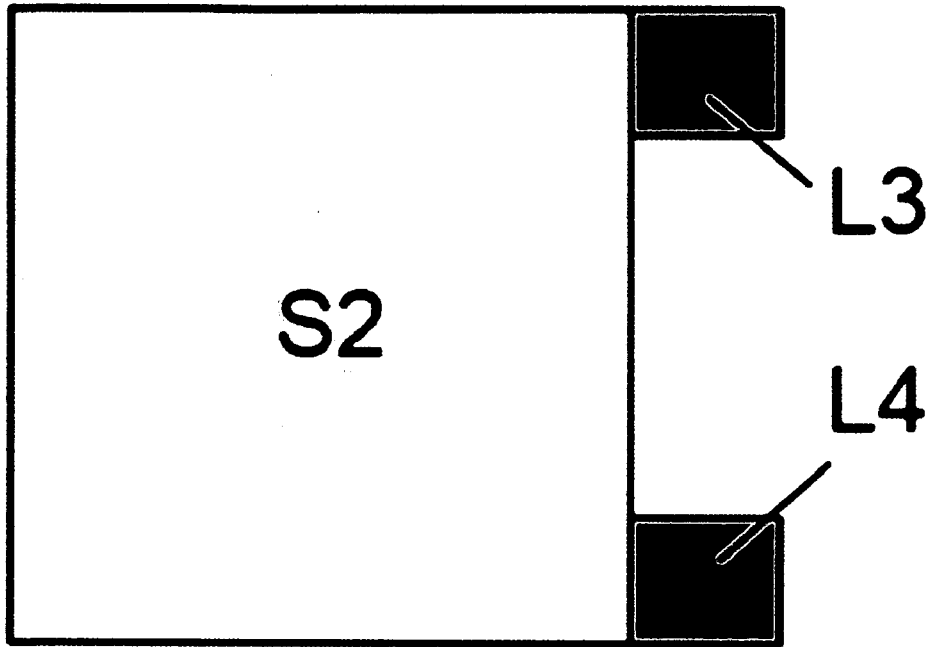


FIG. 6B

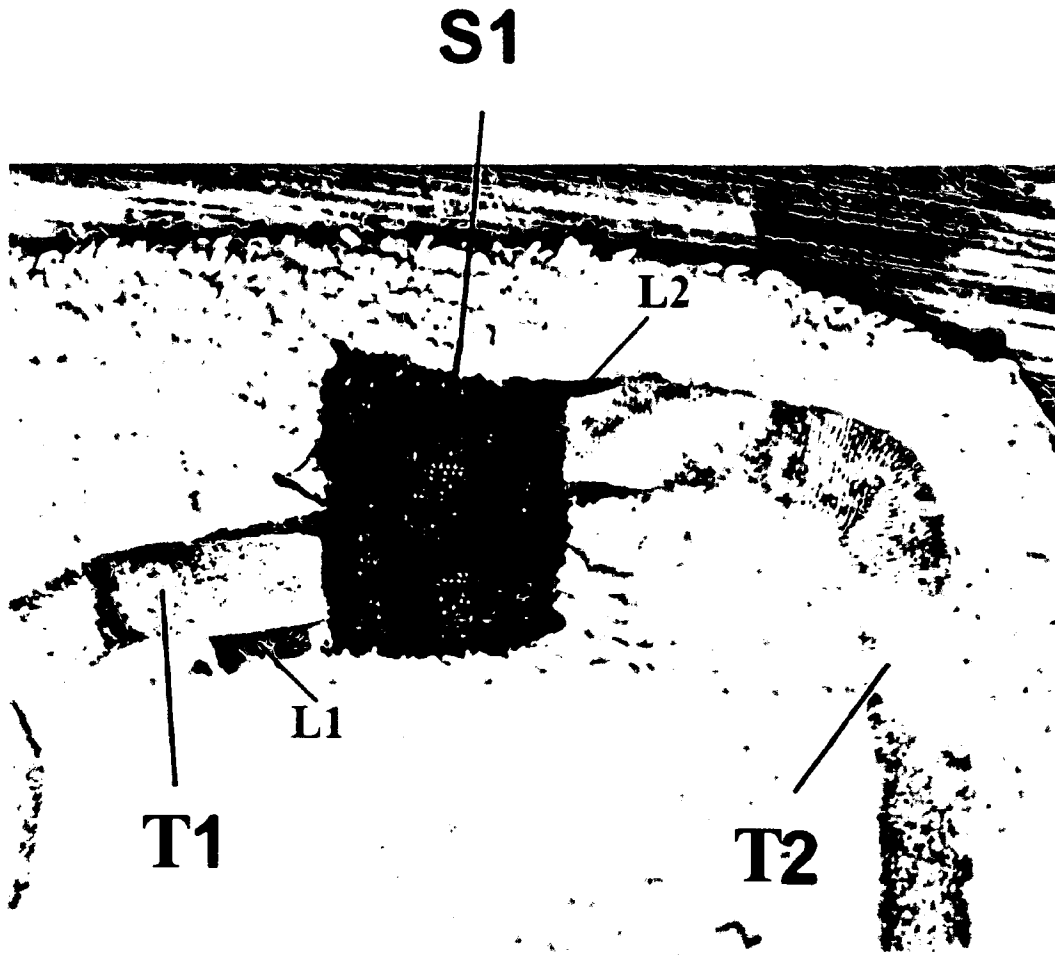


FIG. 7

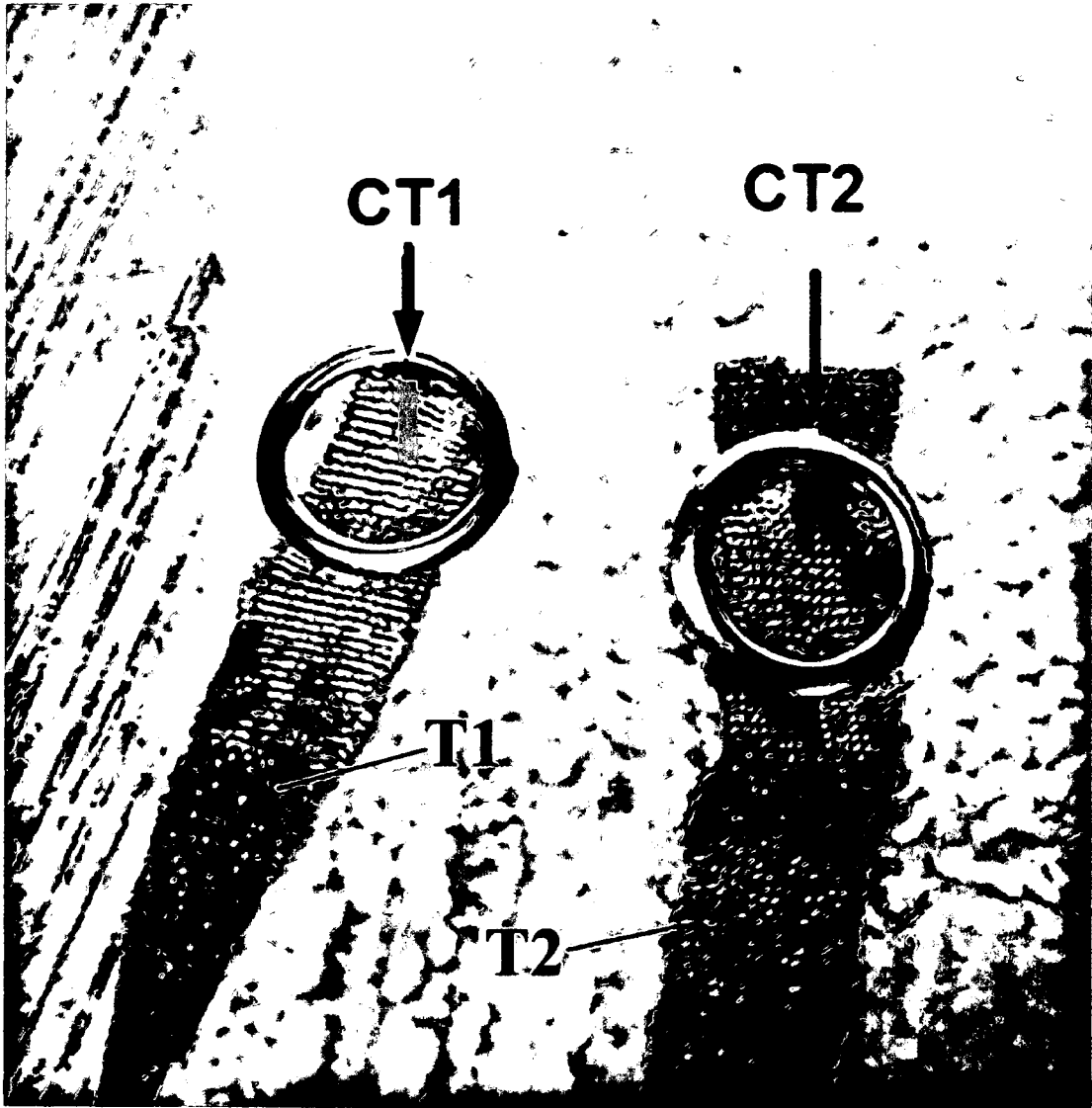


FIG. 8

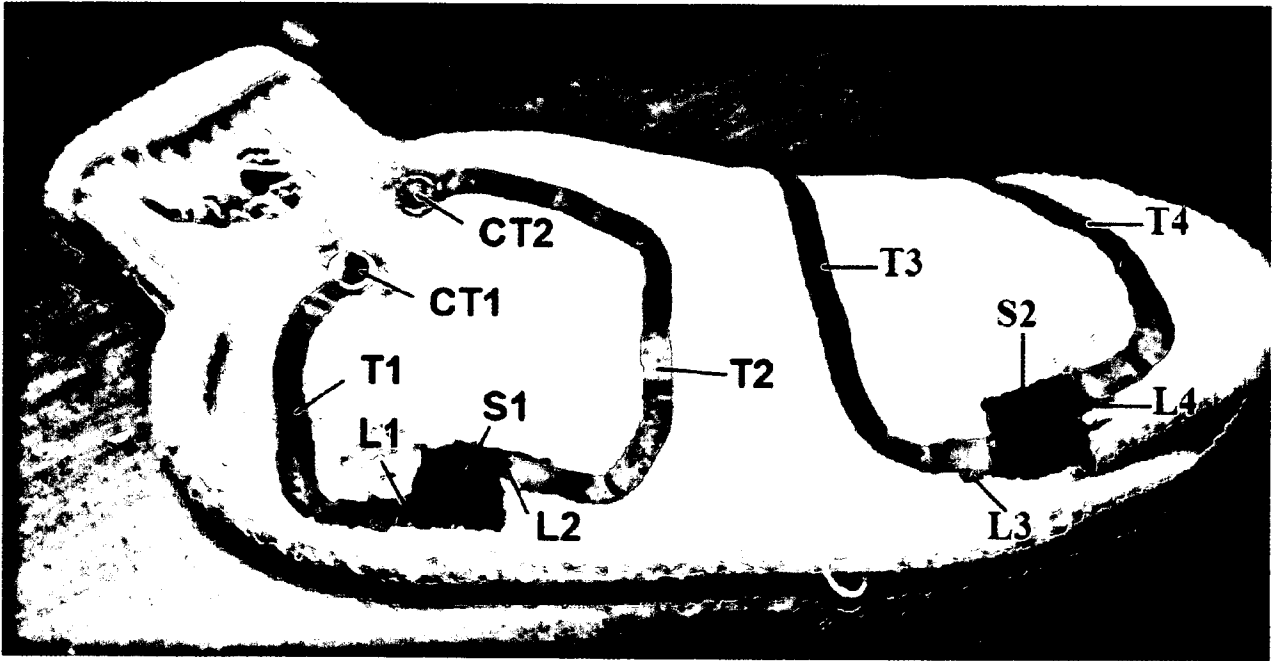


FIG. 9A

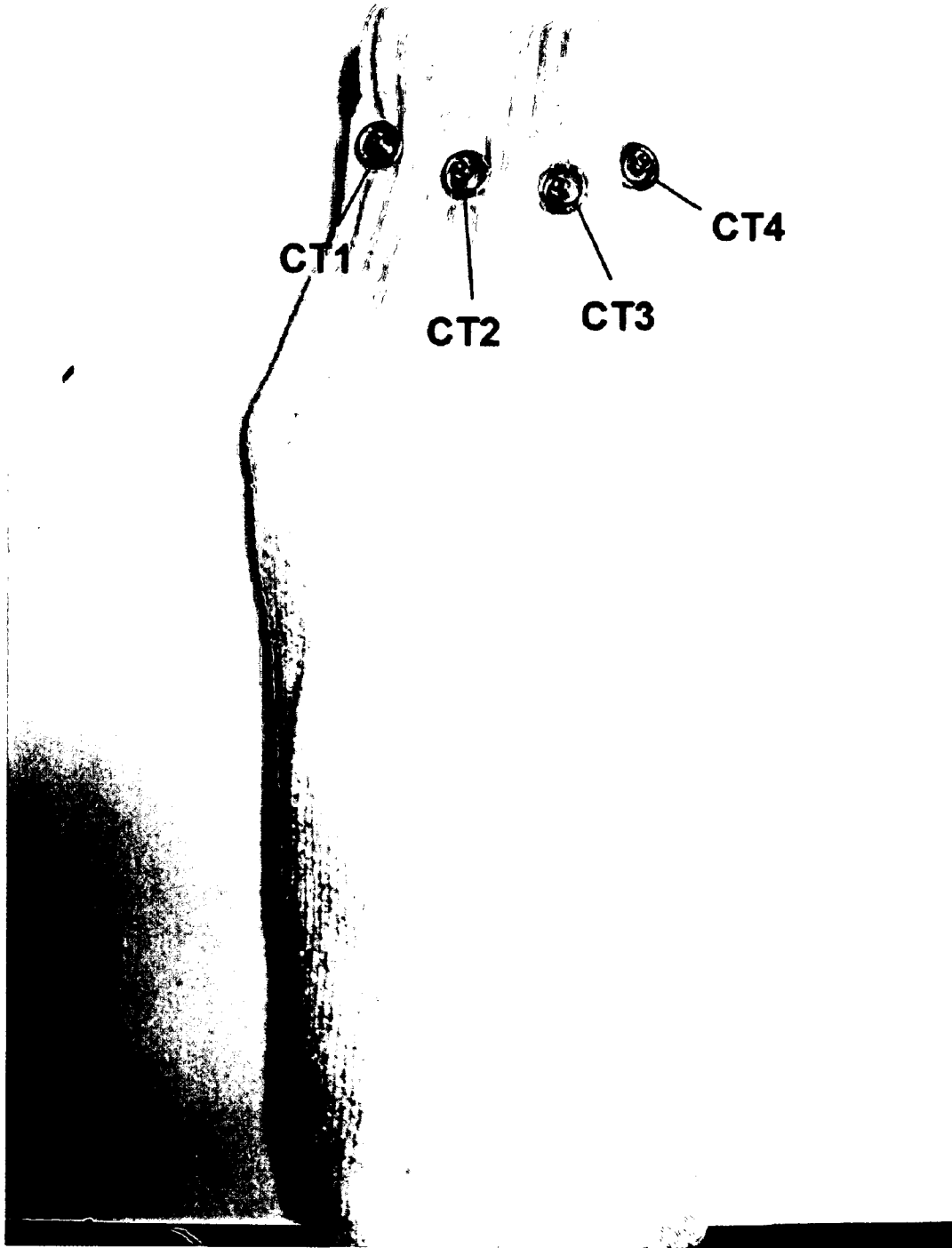


FIG. 9B

FIG. 9C

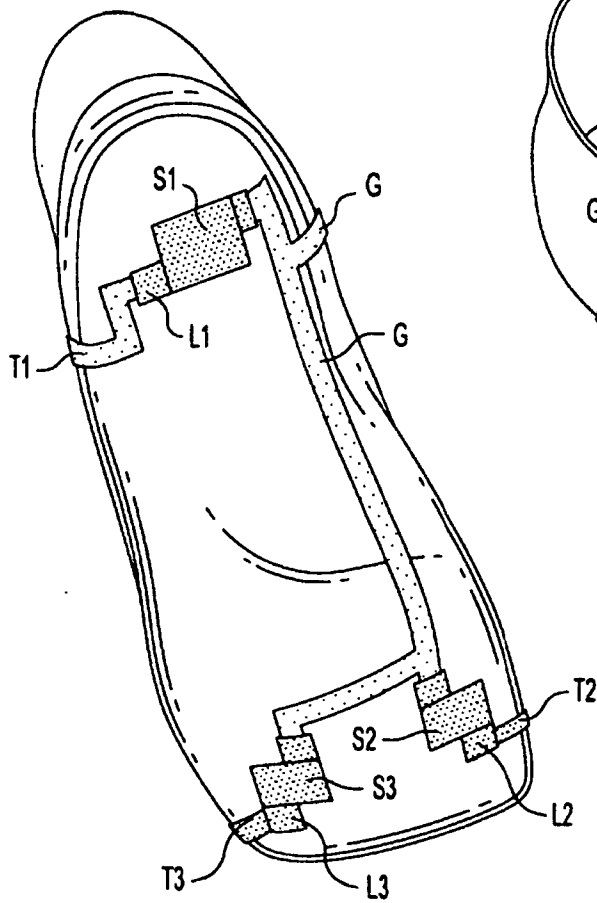


FIG. 9D

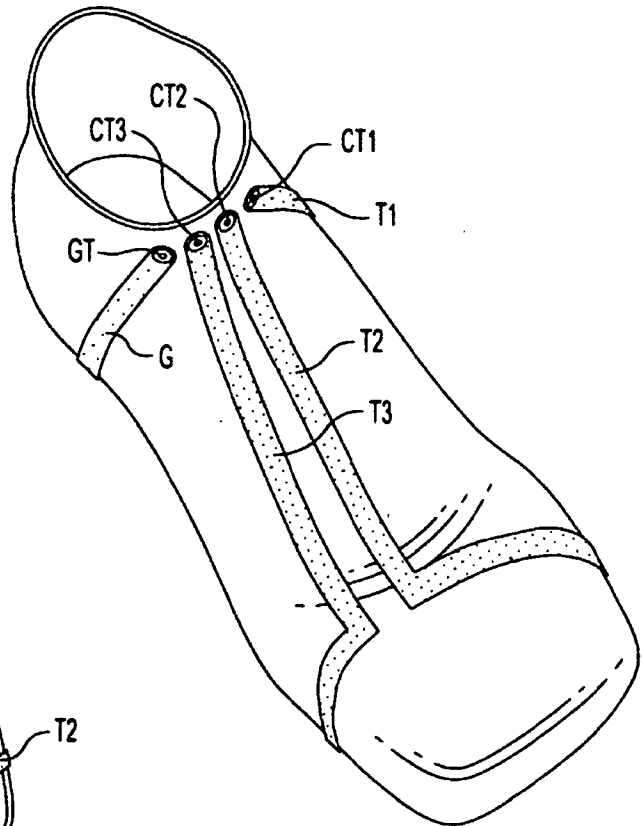


FIG. 10A

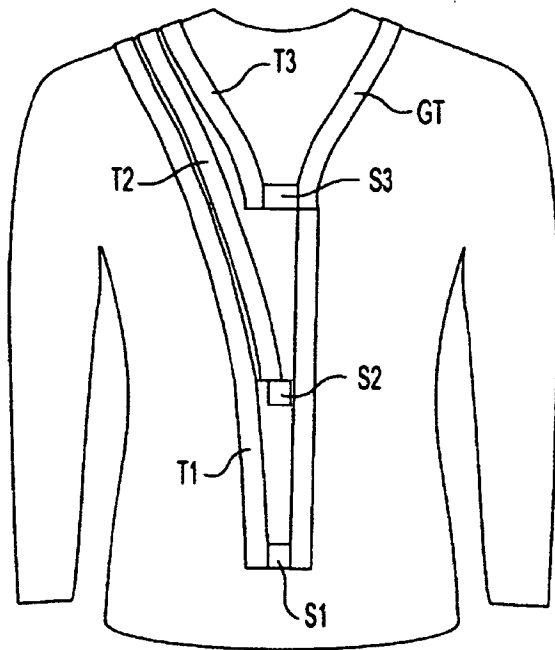


FIG. 10B

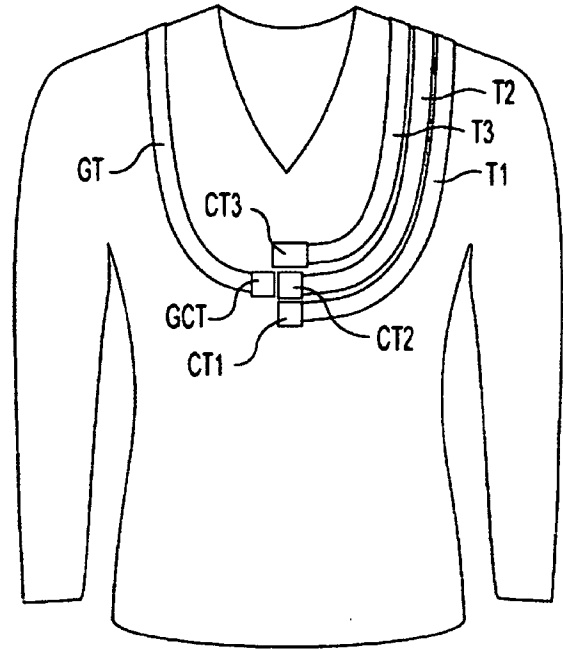


FIG. 10C

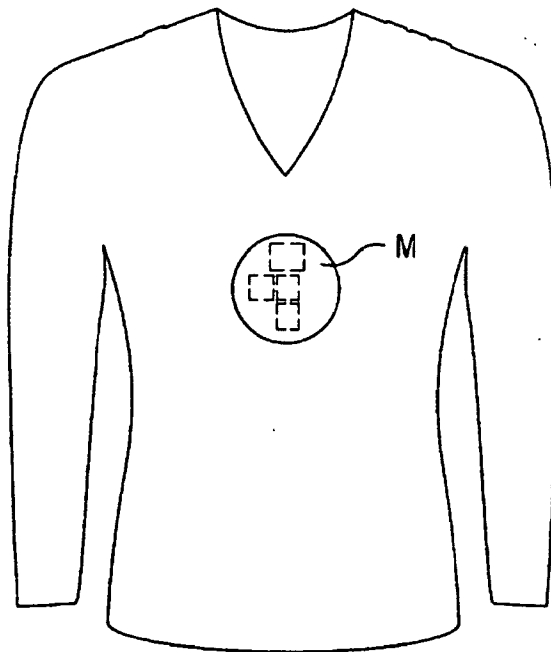


FIG. 10D

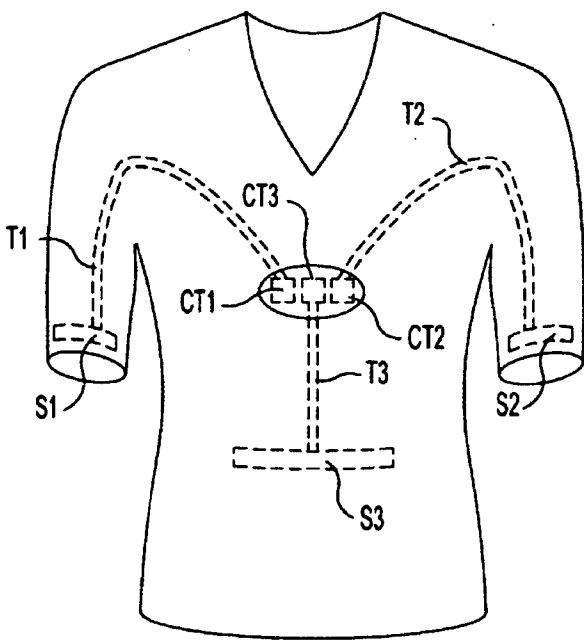
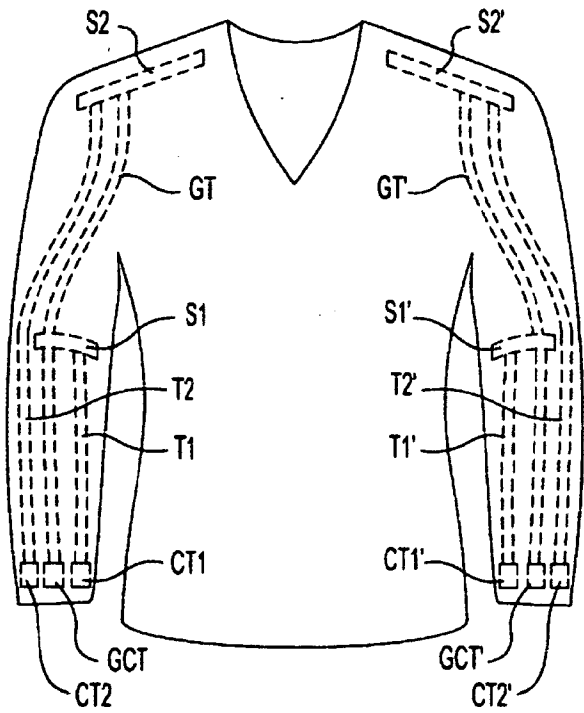


FIG. 10E



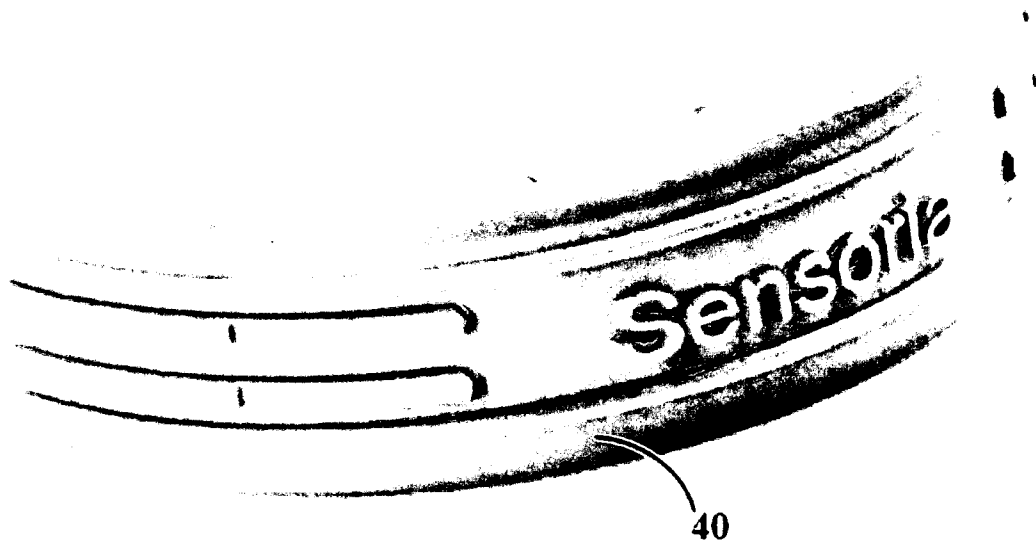


FIG. 11A

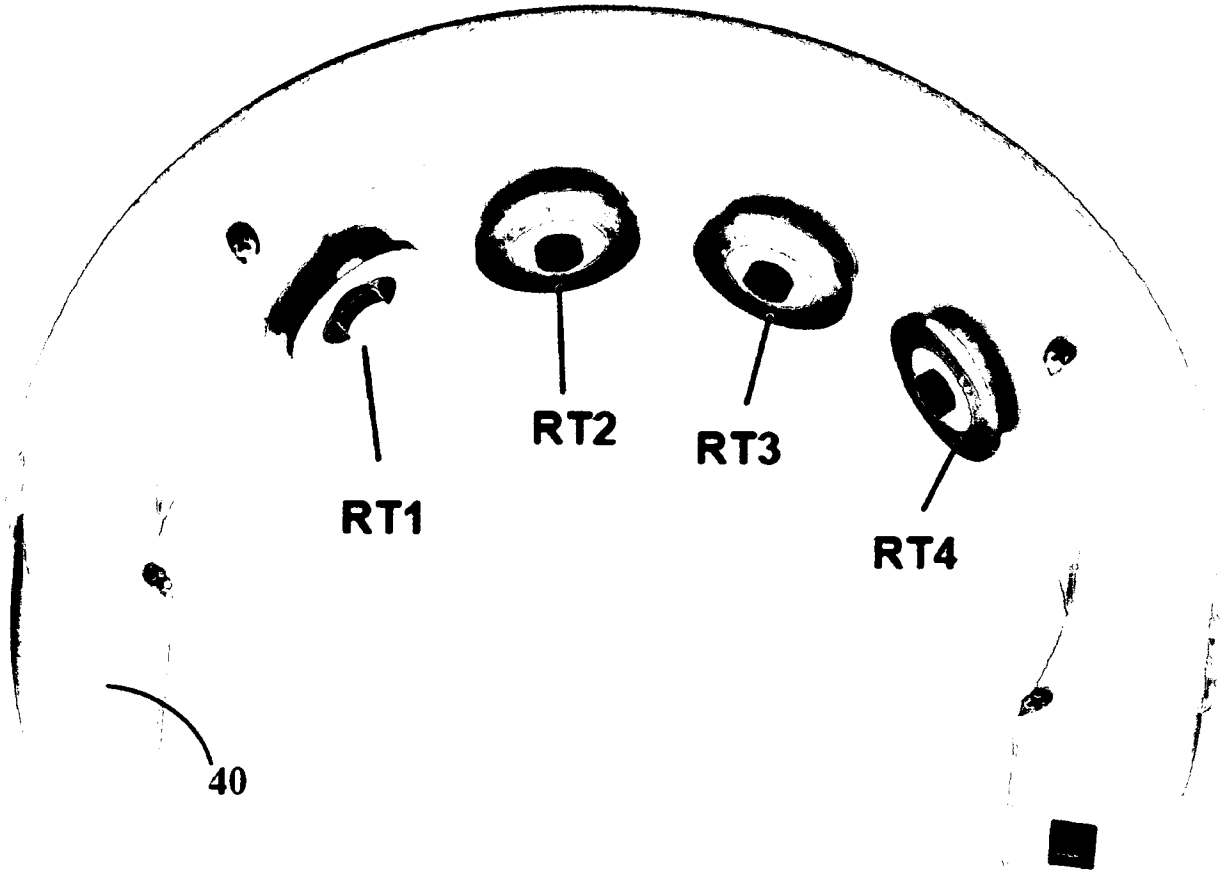


FIG. 11B

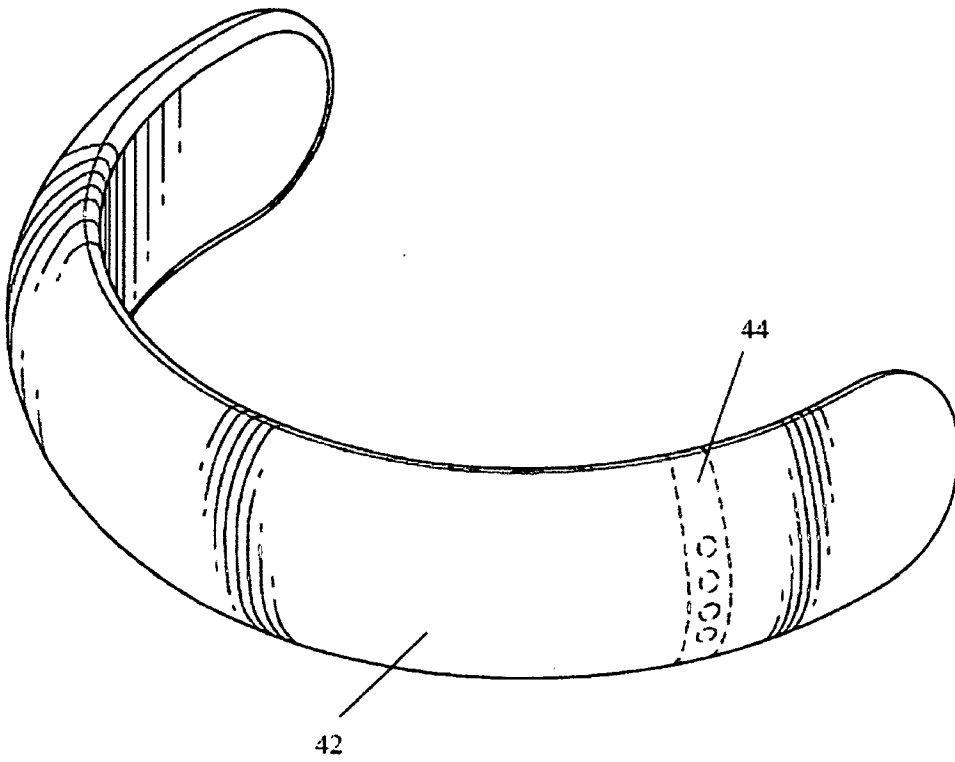


FIG. 11C

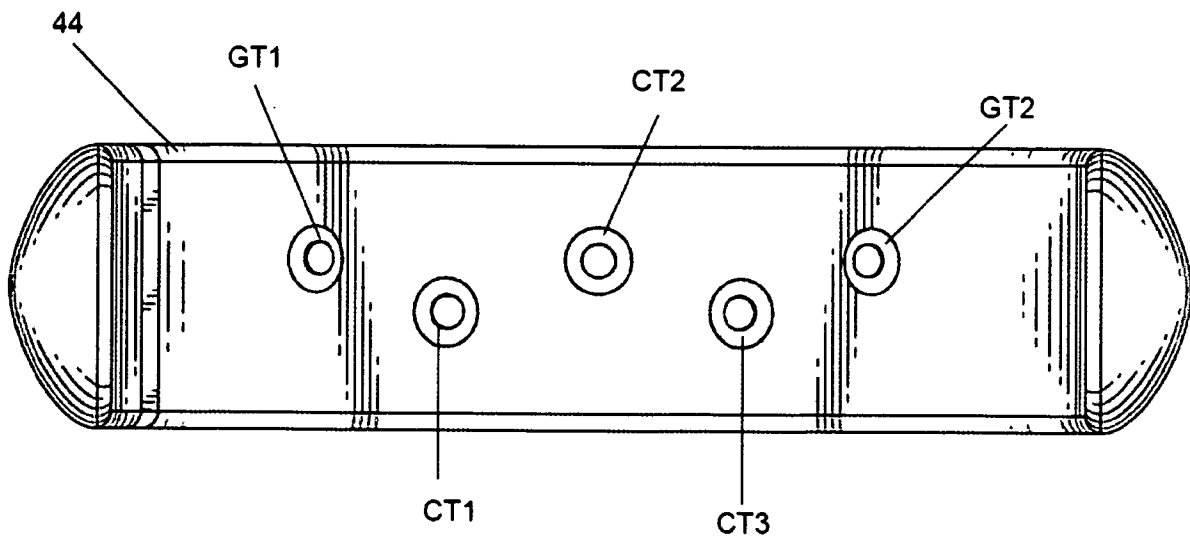


FIG. 11D

FIG. 11E

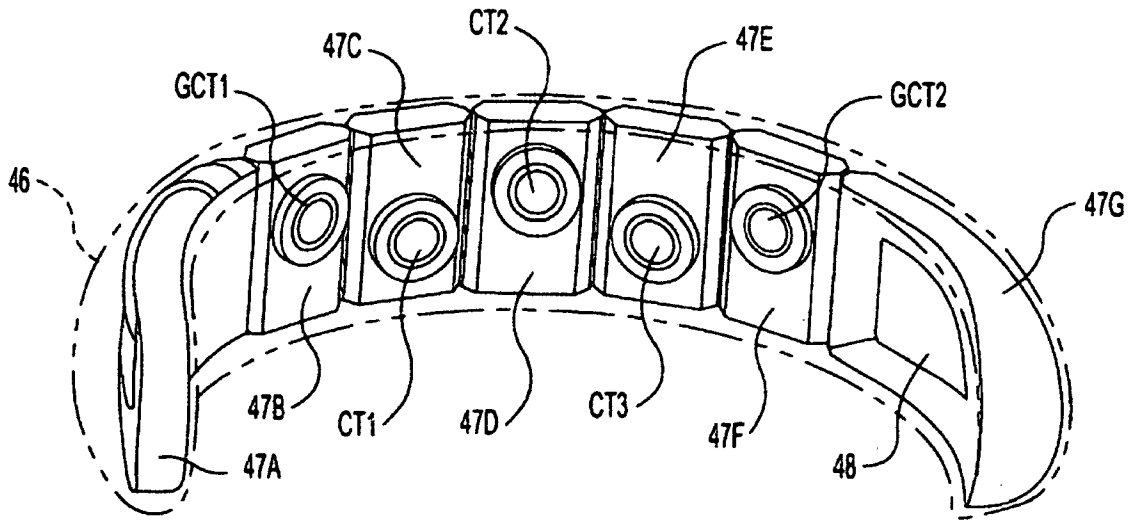


FIG. 11F

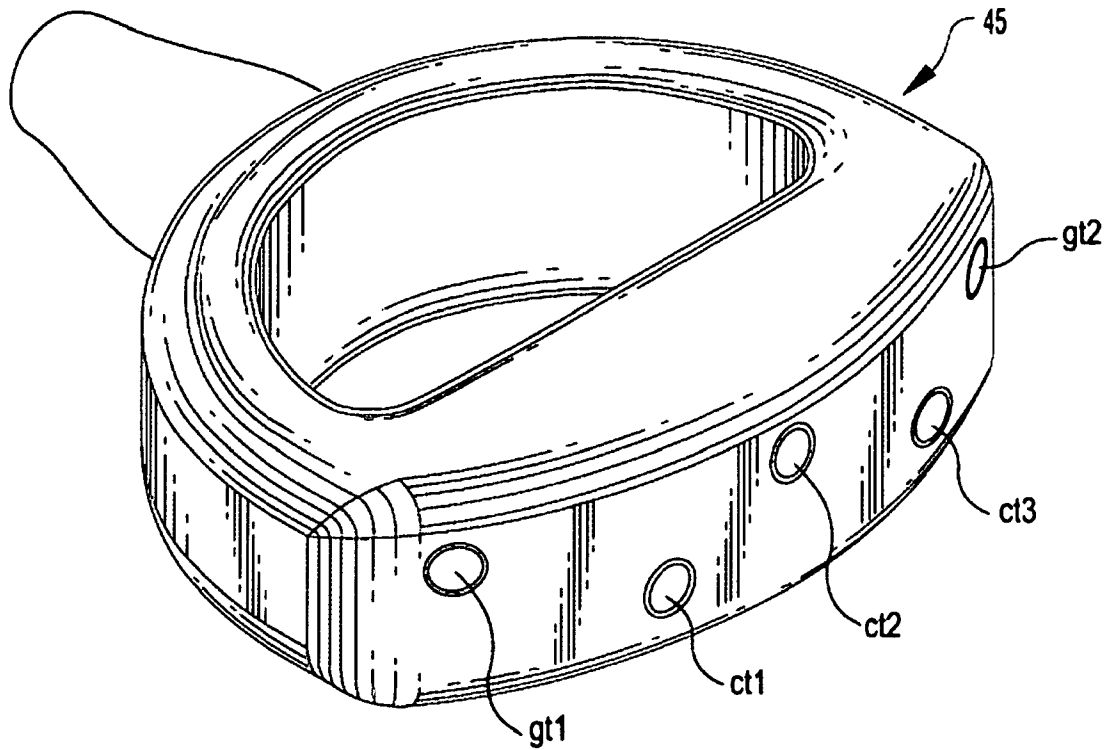


FIG. 12A

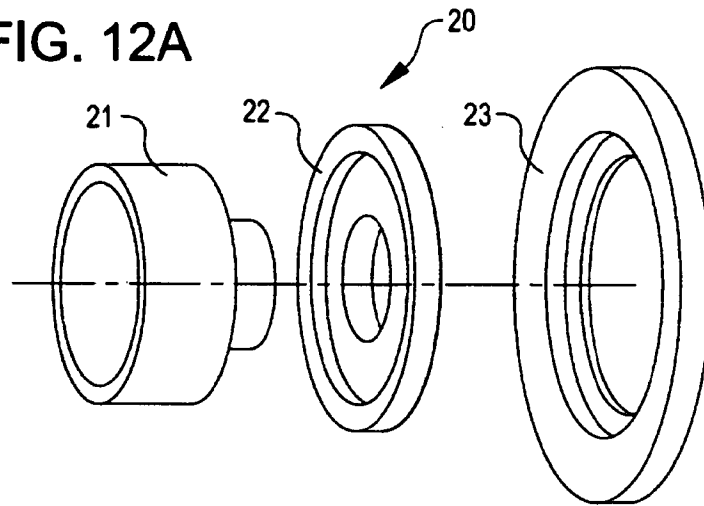


FIG. 12B

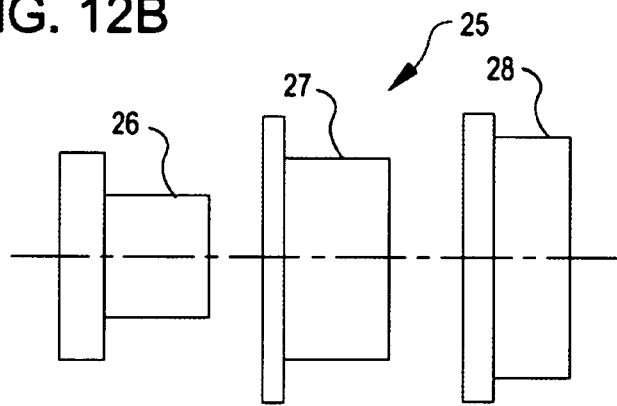


FIG. 12C

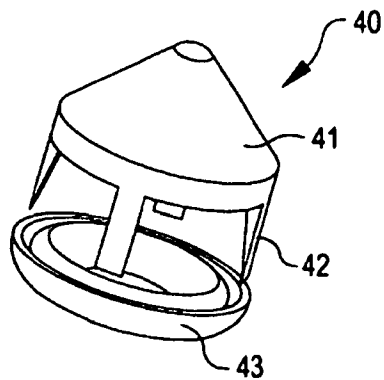
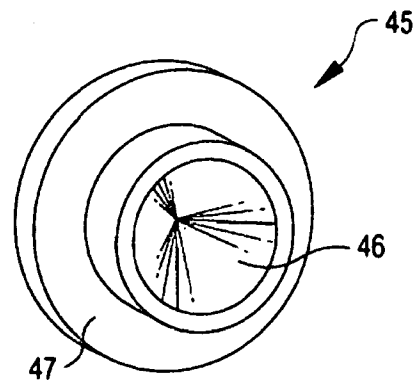


FIG. 12D



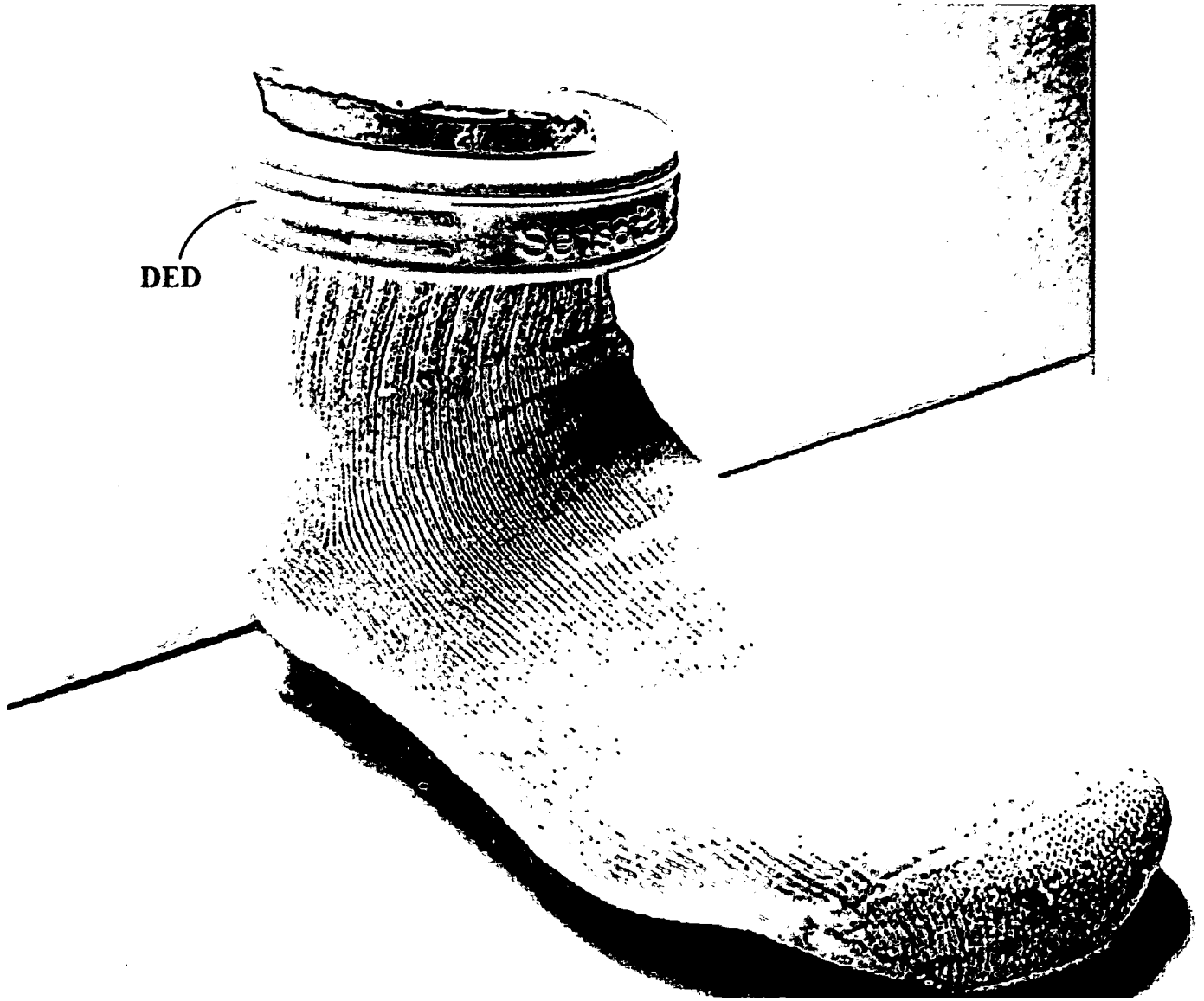


FIG. 13

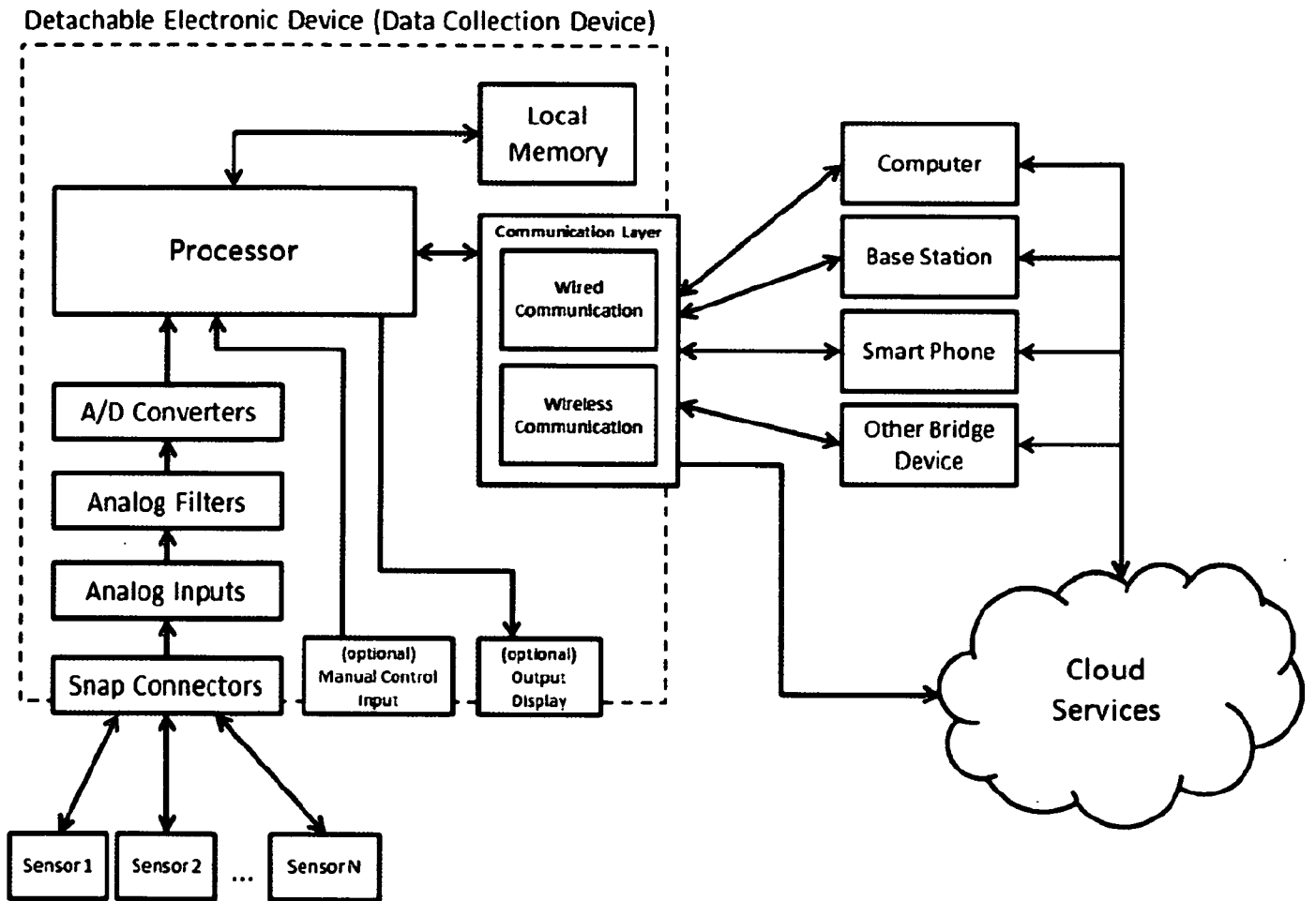


FIG. 14

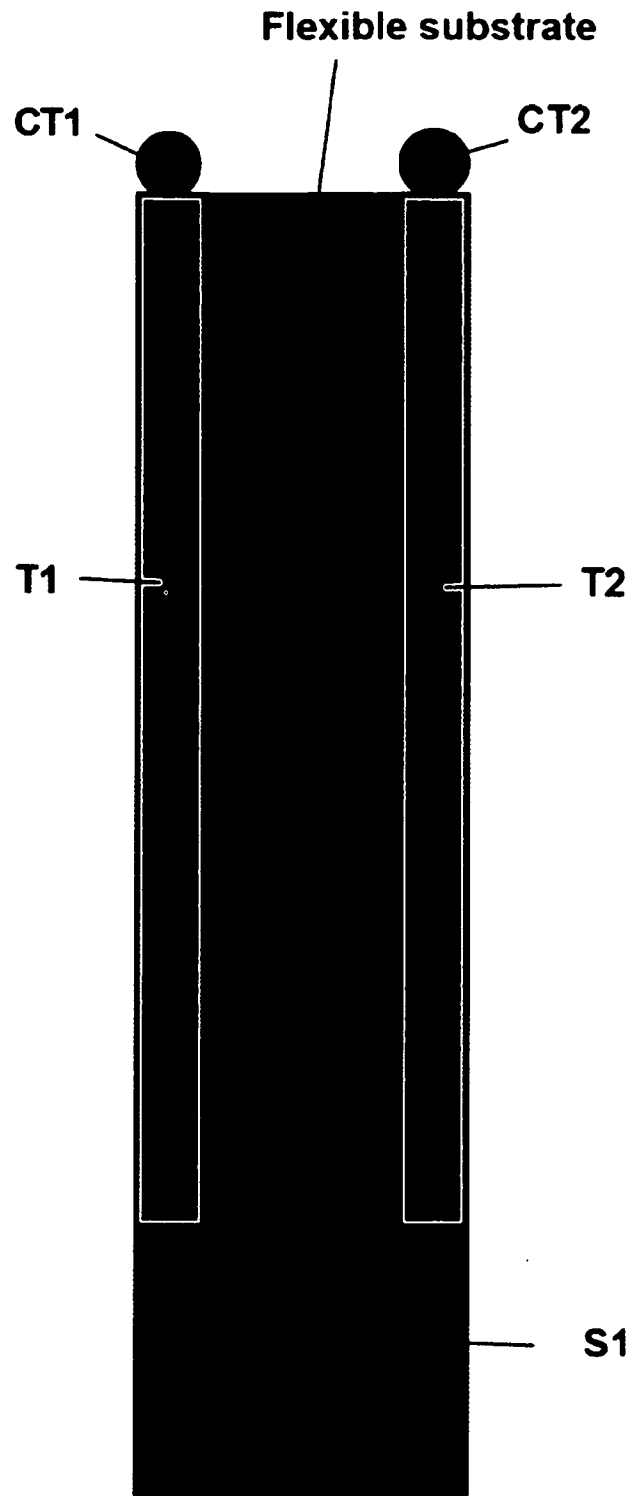


FIG. 15

FIG. 16A

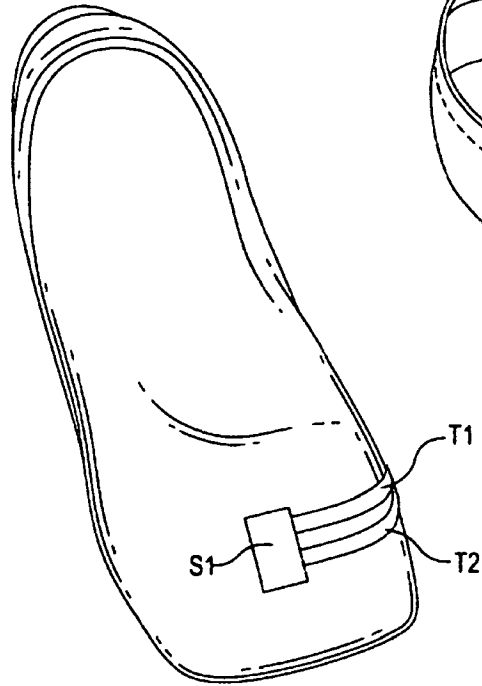


FIG. 16B

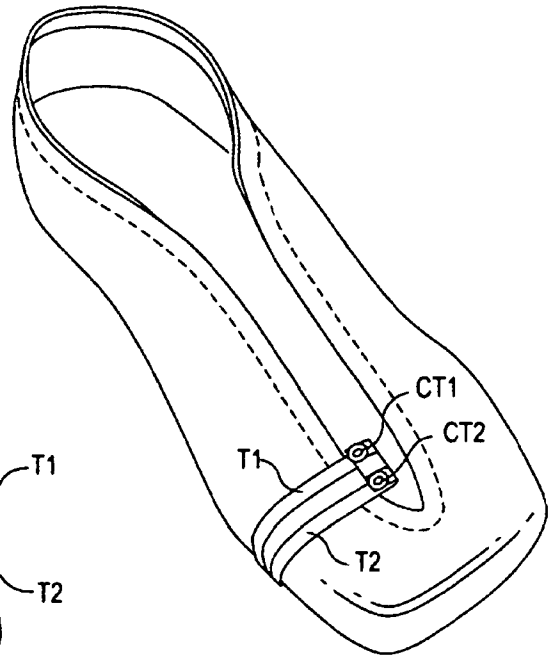
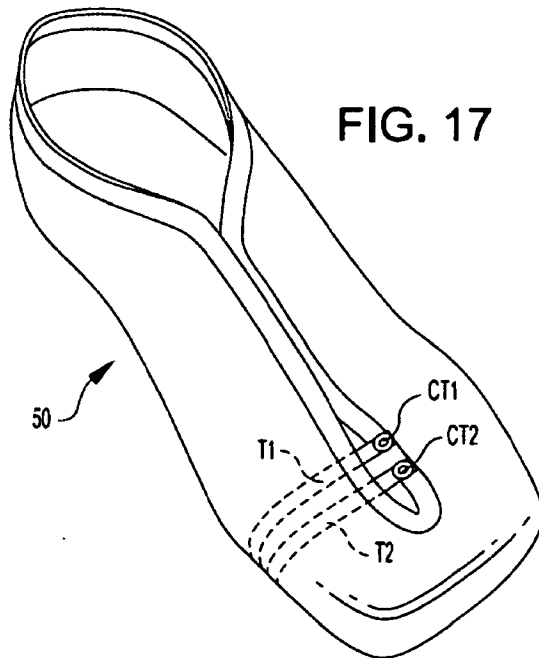


FIG. 17



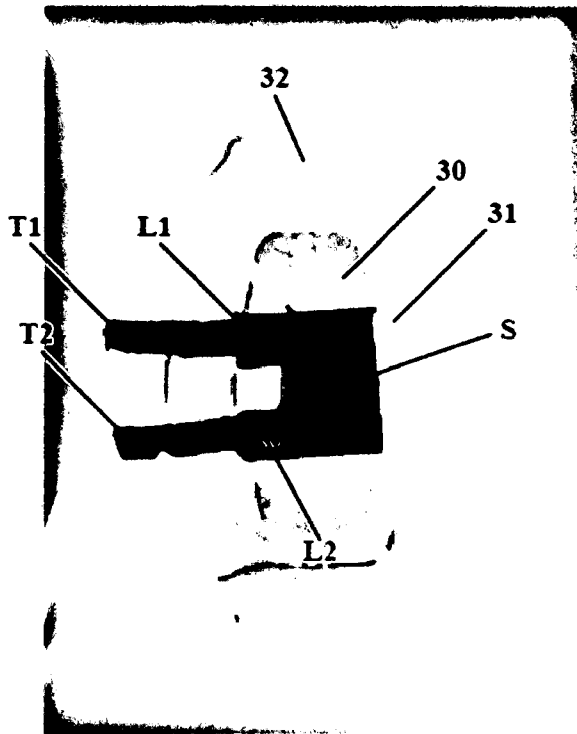


FIG. 18A

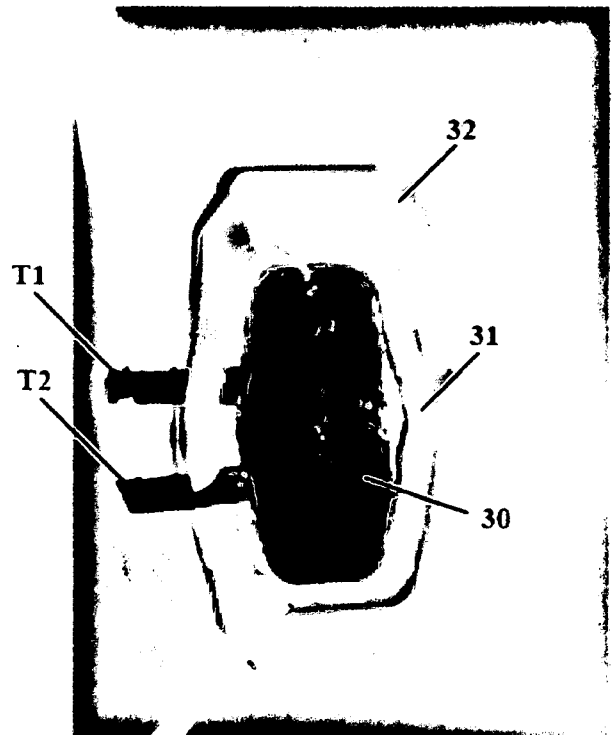


FIG. 18B

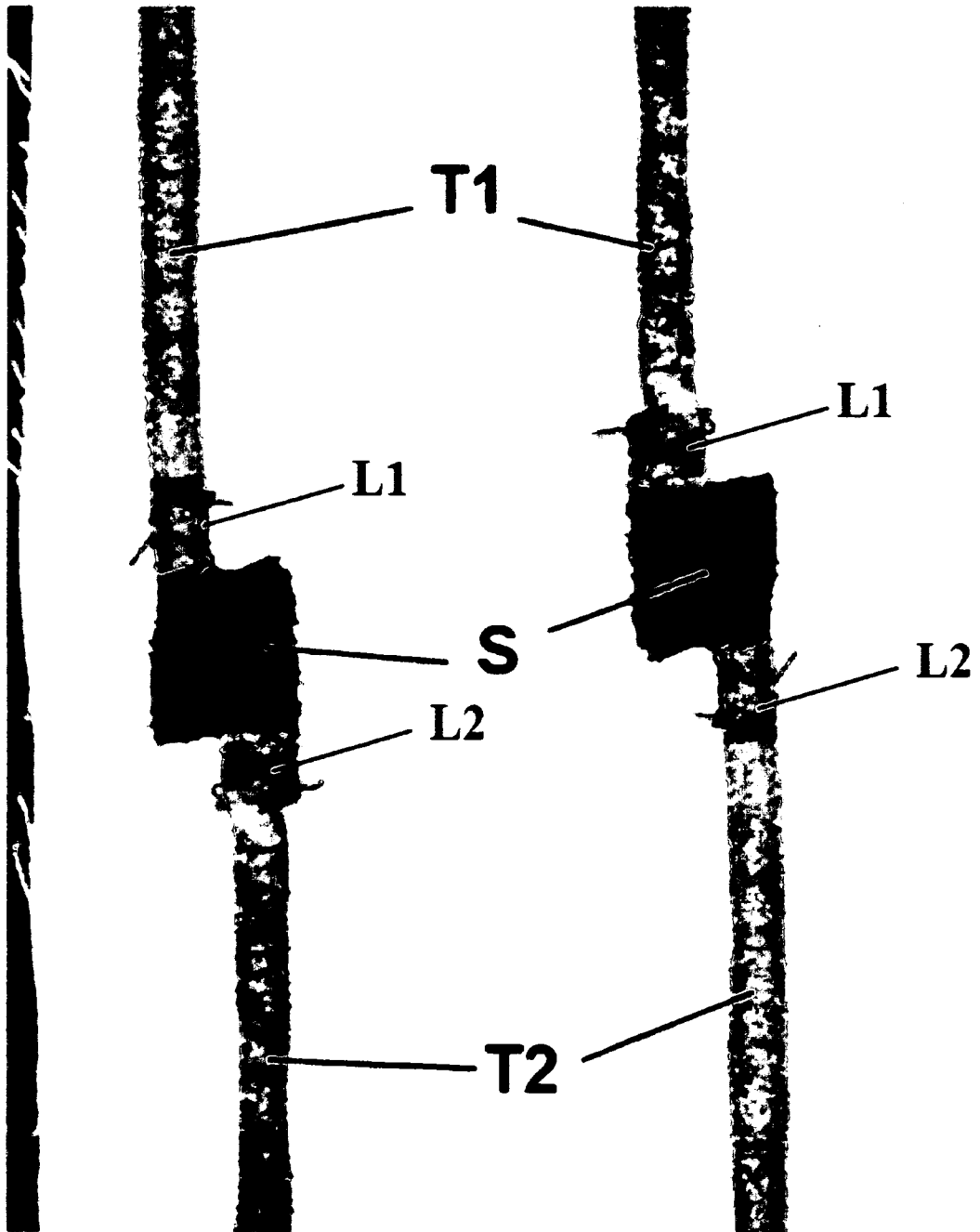


FIG. 19

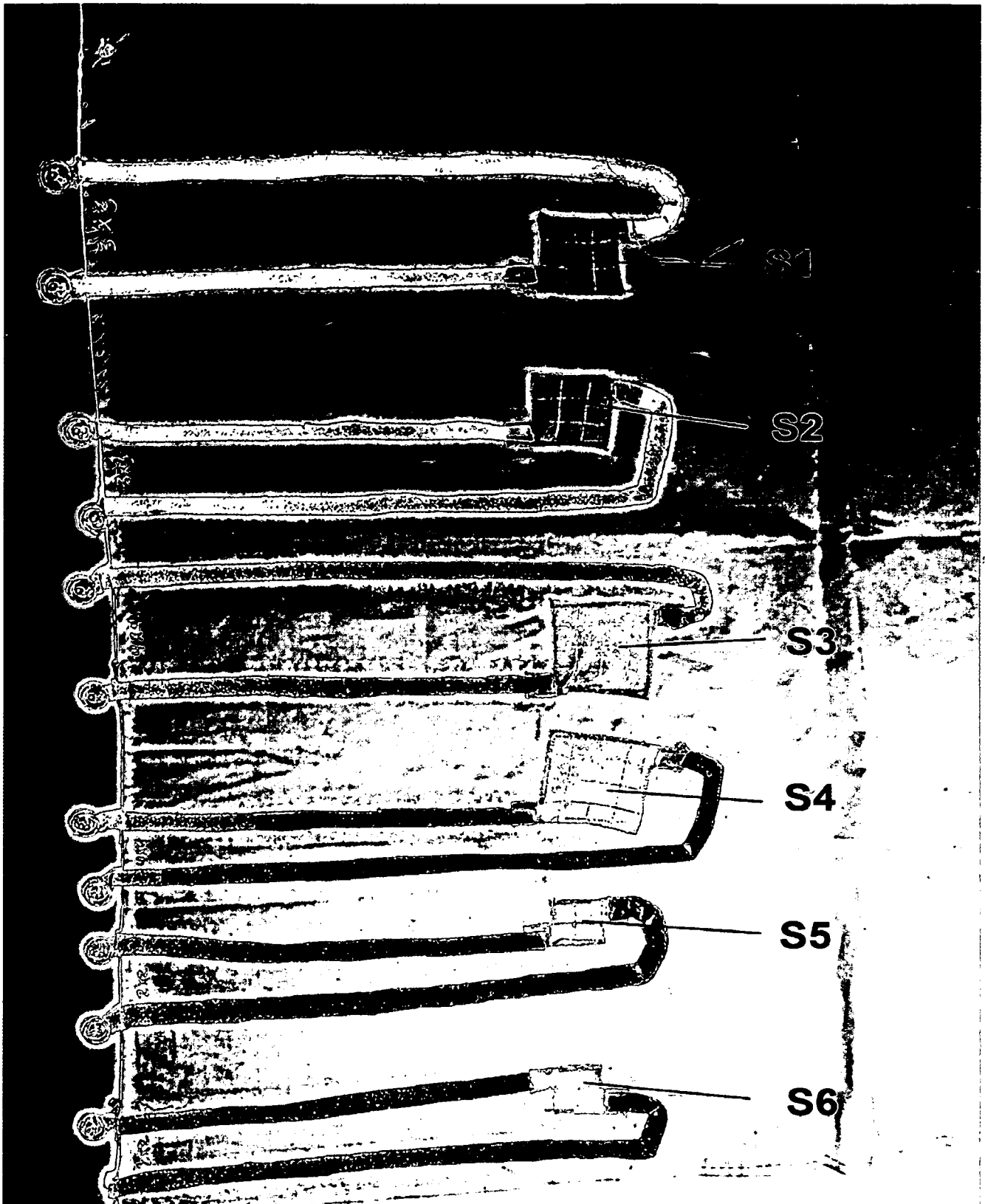


FIG. 20

DFU MONITORING & ALERTING

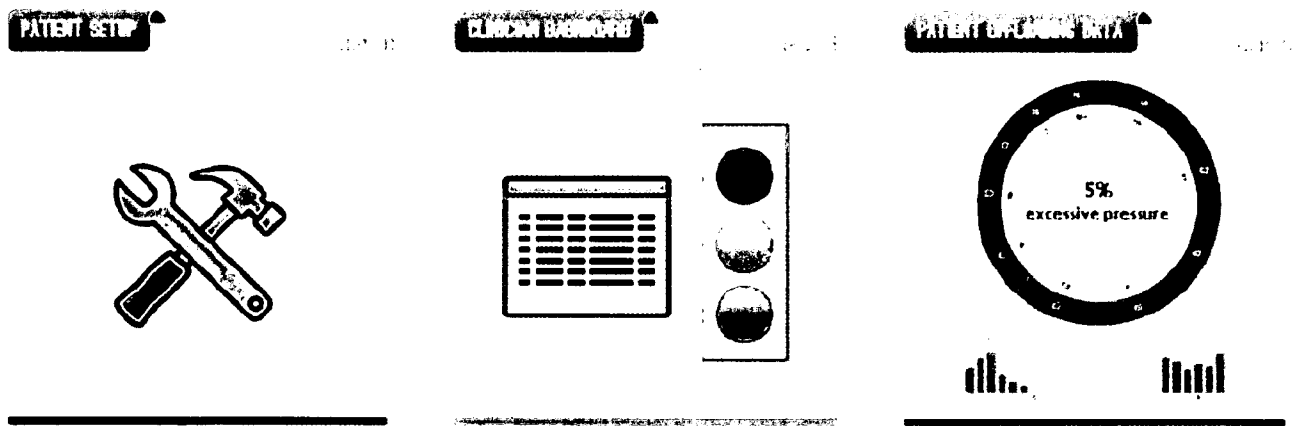


FIG. 21

28/46

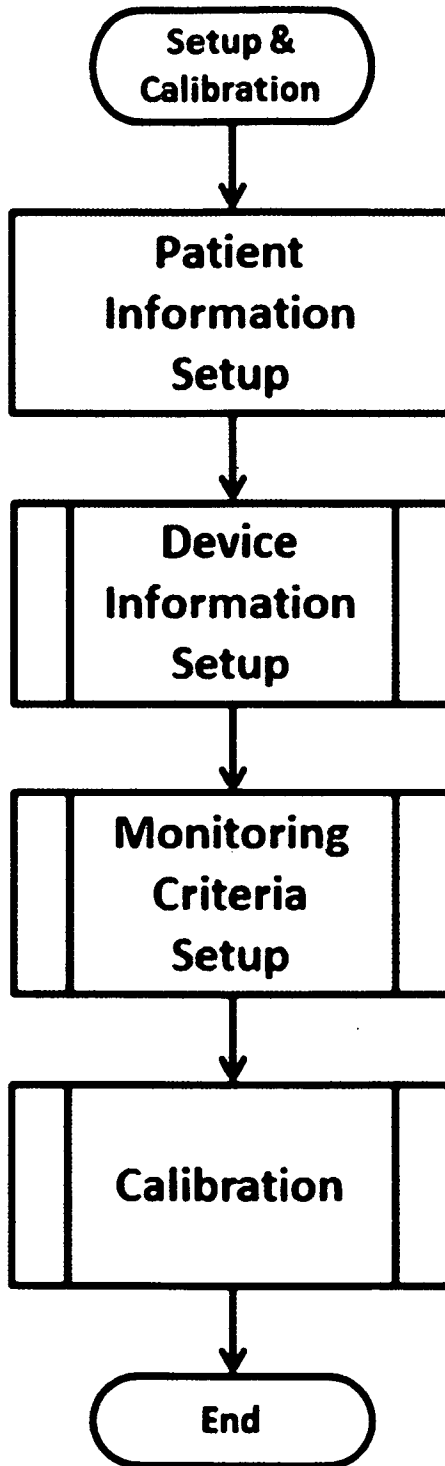


FIG. 22A

- Patient Data**
- Device Setup
- Monitoring



Patient Data

Enter patient data or click the yellow icon to select and populate patient data directly from your EMR system

Patient Name:

Date of Birth:

Weight: pounds

Height: feet
 inches

Condition:



Ulcer Information

Please enter information on existing ulcer requiring treatment and offloading

Interested foot:

Ulcer Location:

Ulcer Stage:

Notes:



Procedure Details

Please enter information on the procedure performed on the patient

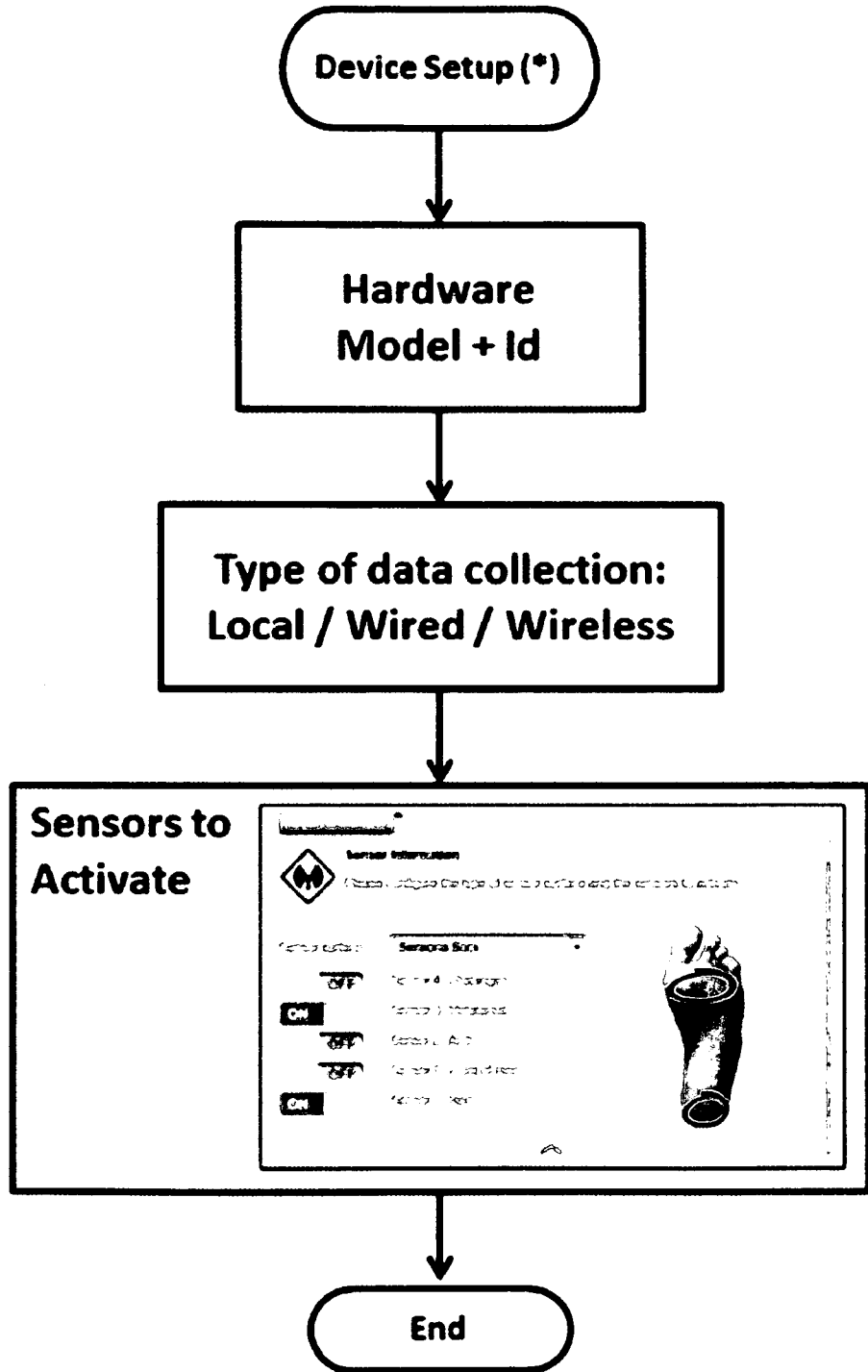
Admission date:

Type of Procedure:

Notes:

FIG. 22B

30/46



(*) User Assisted + Automatic

FIG. 22C

- Patient Data
- Device Setup**
- Monitoring



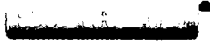
Device Information

Please connect the Sensaria device to your computer to automatically set it up. Alternatively you can enter the information manually below.

Hardware Model:

Hardware Id:

Real-time alerting (requires smartphone)



Sensor Information

Please configure the type of sensor surface and the sensors to activate.

Sensor surface:

Sensor 4 (Phalanges)

Sensor 3 (Metatarsal)

Sensor 2 (Arch)

Sensor 1 (Front of Heel)

Sensor 0 (Heel)

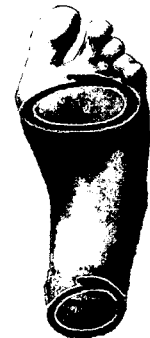


FIG. 22D

Patient Data

Device Setup

Monitoring



Device Information

Please connect the Sensona device to your computer to automatically set it up. Alternatively you can enter the information manually below.

Hardware Model:

Hardware Id:

Real-time alerting (requires smartphone)



Sensor Information

Please configure the type of sensor surface and the sensors to activate.

Sensor surface:

Type A

Type B

Type C

FIG. 22E

Patient Data

Device Setup

Monitoring



Device Information

Please connect the Sensona device to your computer to automatically set it up. Alternatively you can enter the information manually below.

Hardware Model

Hardware Id

Real-time alerting (requires smartphone)



Sensor Information

Please configure the type of sensor surface and the sensors to activate.

Sensor surface

Sensor 4 (Phalanges)

Sensor 3 (Metatarsal)

Sensor 2 (Arch)

Sensor 1 (Front of Heel)

Sensor 0 (Heel)



FIG. 22F

34/46

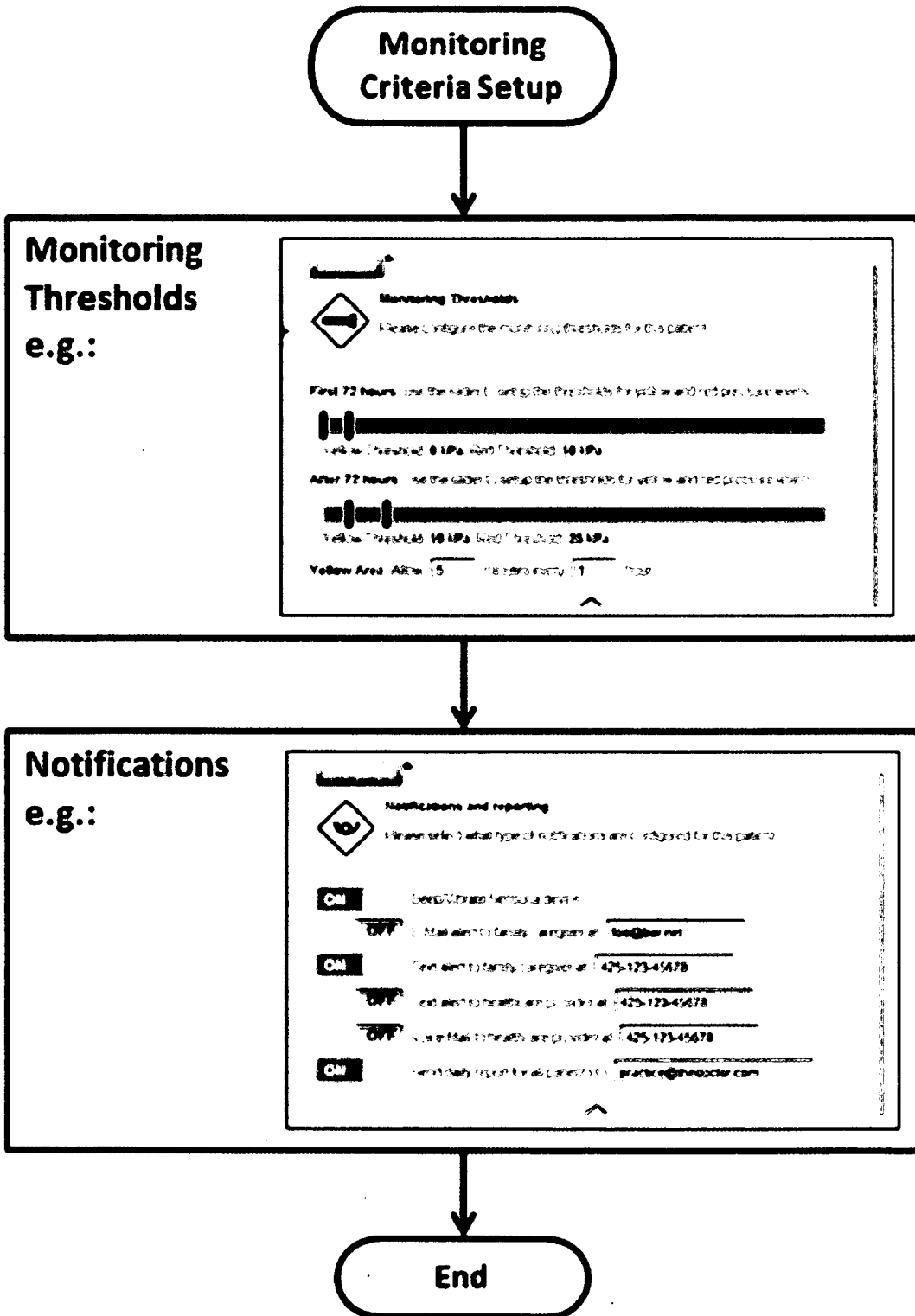


FIG. 22G

- Patient Data
- Device Setup
- Monitoring**



Monitoring Thresholds

Please configure the monitoring thresholds for this patient.

First 72 hours, use the slider to setup the thresholds for yellow and red pressure levels.



Yellow Threshold: 0 kPa Red Threshold: 10 kPa

After 72 hours, use the slider to setup the thresholds for yellow and red pressure levels.



Yellow Threshold: 10 kPa Red Threshold: 20 kPa

Yellow Area: Allow 5 minutes every 1 hour



Notifications and reporting

Please select what type of notifications are configured for this patient.

ON

Beep/Vibrate Serrana device

OFF

E-Mail alert to family caregiver at loo@bar.net

ON

Text alert to family caregiver at 425-123-45678

OFF

Text alert to healthcare provider at 425-123-45678

OFF

Voice Mail to healthcare provider at 425-123-45678

ON

Send daily report for all patients to practice@thedoctor.com



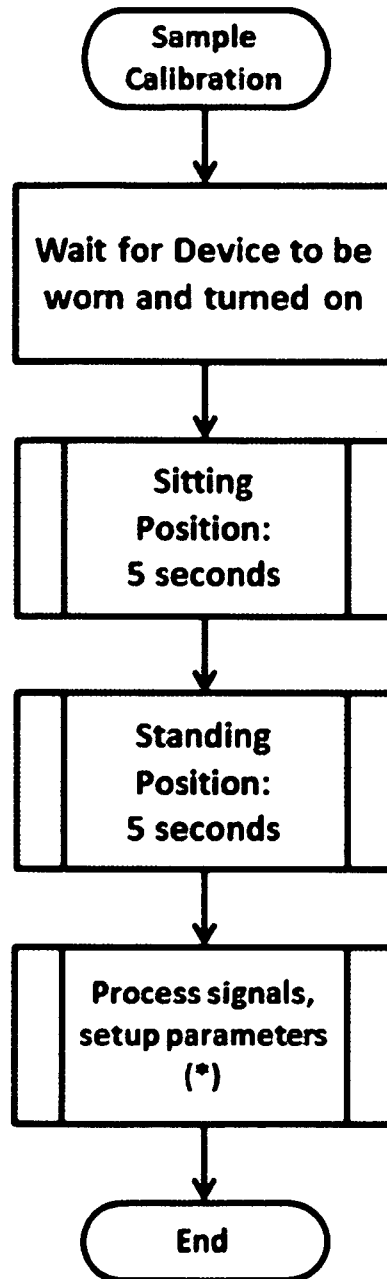
Calibration

When all the information above is correct, press the button to send the data to Serrana and initiate the calibration procedure.

UPDATE DEVICE

FIG. 22H

36/46



(*) Automatic setup of parameters like filter thresholds, signal gain, voltage-to-pressure formula, etc.

FIG. 22I

SENSORIA CLINICIAN DASHBOARD

Filter	25	Sort	sock						
Patient Status	Patient Name	Medical Condition	Involved Foot	Ulcer Location	Ulcer Stage	Admission Date	Type of procedure	Sensoria Device	Outfitting Device
⊕	Red	John Smith	Type II Diabetes	Right Foot	Metatarsal #1	3	11/12/2012	Sensoria Sock	Walker
⊕	Red	Bob Singer	Type I Diabetes	Right Foot	Calcaneus	3	11/13/2012	Sensoria Sock	Crutch
⊕	Red	Milo Johnson	Type II Diabetes	Right Foot	Metatarsal #3	2	11/14/2012	Sensoria Sock	TCC
⊕	Red	Allec Law	Type II Diabetes	Left Foot	Metatarsal #3	3	11/15/2012	Sensoria Sock	RCW
⊕	Red	Bob Franklin	Type II Diabetes	Right Foot	Metatarsal #3	2	11/18/2012	Sensoria Sock	Half Shoes
⊕	Red	Tyler Dale	Type II Diabetes	Left Foot	Dorsal Phalange #2	3	11/19/2012	Sensoria Sock	Half Shoes
⊕	Red	Jason Anderson	Type II Diabetes	Left Foot	Metatarsal #3	2	11/20/2012	Sensoria Sock	Foiled Feet
⊕	Red	Mary Williams	Type I Diabetes	Right Foot	Calcaneus	3	11/21/2012	Sensoria Sock	Therapeutic Shoes
⊕	Red	George Lambert	Type II Diabetes	Left Foot	Medial Calcaneus	3	10/24/2012	Sensoria Sock	Walker
⊕	Red	Maria Whitford	Type I Diabetes	Left Foot	Lateral Calcaneus	3	10/25/2012	Sensoria Sock	Walker
⊕	Red	Memo Stappert	Type II Diabetes	Left Foot	Cuboid	3	10/26/2012	Sensoria Sock	RCW
⊕	Red	Andrew Sycamore	Type II Diabetes	Left Foot	Metatarsal #4	3	10/27/2012	Sensoria Sock	Half Shoes
⊕	Green	Mark Travis	Type II Diabetes	Right Foot	Navicular	2	10/30/2012	Sensoria Sock	Healing Canes
⊕	Green	Anna O'Hara	Type II Diabetes	Right Foot	Navicular	2	11/1/2012	Sensoria Sock	Half Shoes
⊕	Green	John Gambino	Type II Diabetes	Left Foot	Metatarsal #3	3	11/2/2012	Sensoria Sock	TCC
⊕	Green	Derrick Gonzalez	Type I Diabetes	Left Foot	Calcaneus	3	11/2/2012	Sensoria Sock	Healing Canes
⊕	Green	Abra Mizer	Type II Diabetes	Right Foot	Medial Phalange #3	3	11/3/2012	Sensoria Sock	TCC
⊕	Green	Maria Kinsman	Type I Diabetes	Left Foot	Navicular	2	11/7/2012	Sensoria Sock	Walker
⊕	Green	Anna Parakova	Type II Diabetes	Right Foot	Navicular	2	11/1/2012	Sensoria Sock	Healing Canes
⊕	Green	John John	Type II Diabetes	Left Foot	Metatarsal #3	3	11/2/2012	Sensoria Sock	TCC
⊕	Green	DERRIA Dean	Type I Diabetes	Left Foot	Calcaneus	3	11/3/2012	Sensoria Sock	Walker
⊕	Green	Rick Stuchman	Type II Diabetes	Right Foot	Medial Phalange #3	3	11/3/2012	Sensoria Sock	TCC
⊕	Green	Karl Bauer	Type I Diabetes	Left Foot	Navicular	3	11/7/2012	Sensoria Sock	Walker

Showing 10 of 28 entries (sorted from 30 total entries)

FIG. 22J

PATIENT OFFLOADING DATA

November 2012
Su Mo Tu We Th Fr Sa
15 16 17
18 19 20 21 22

Alert Log

Text messages
Over max pressure limit on Sensor 1 11/15/2012
Over max pressure limit on Sensor 1 11/16/2012
Over max pressure limit on Sensor 1 11/17/2012

Calls
Exceeded loading time on Sensor 1 11/22/2012
Over max pressure limit on Sensor 2 11/22/2012
Exceeded loading time on Sensor 2 11/22/2012
Over max pressure limit on Sensor 3 11/22/2012
Over max pressure limit on Sensor 3 11/22/2012

Contact patient for follow up.

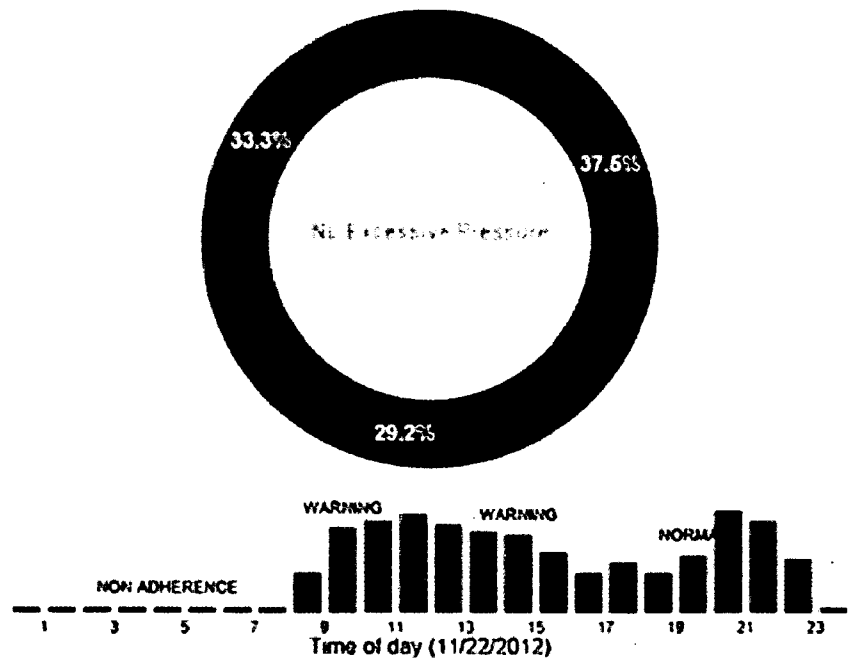


FIG. 22K

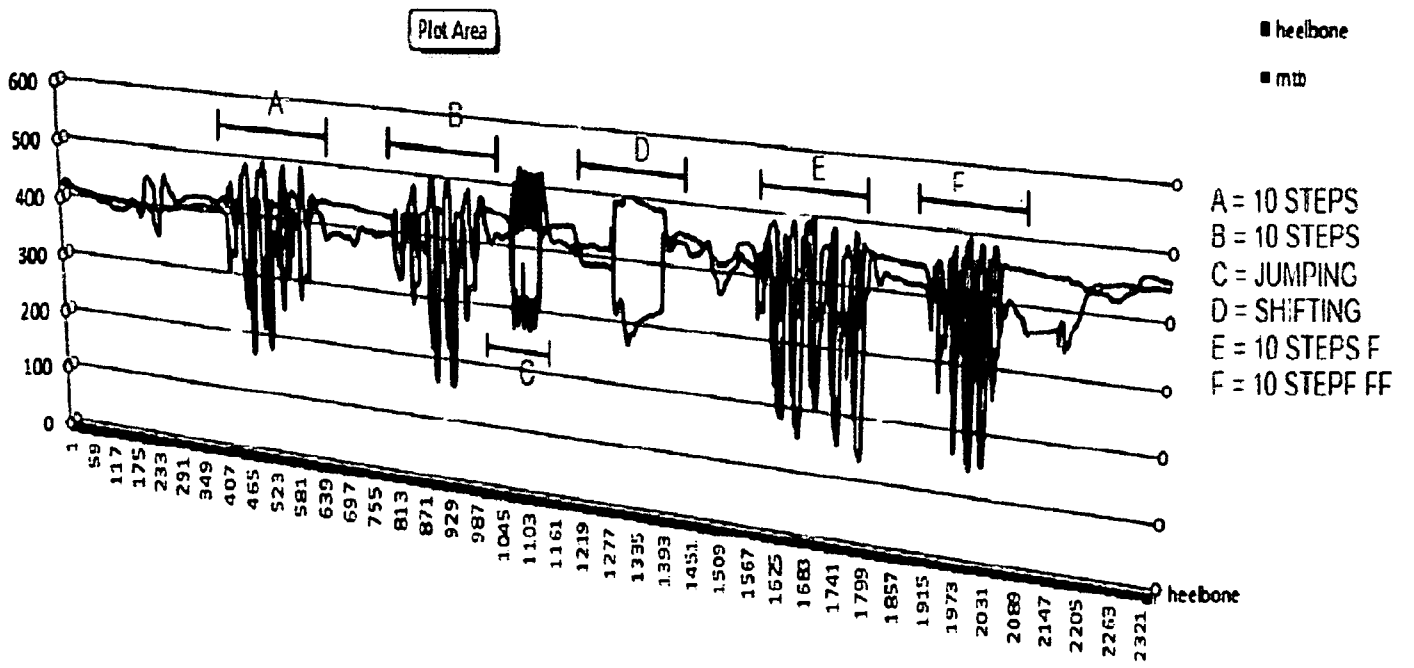


FIG. 22L

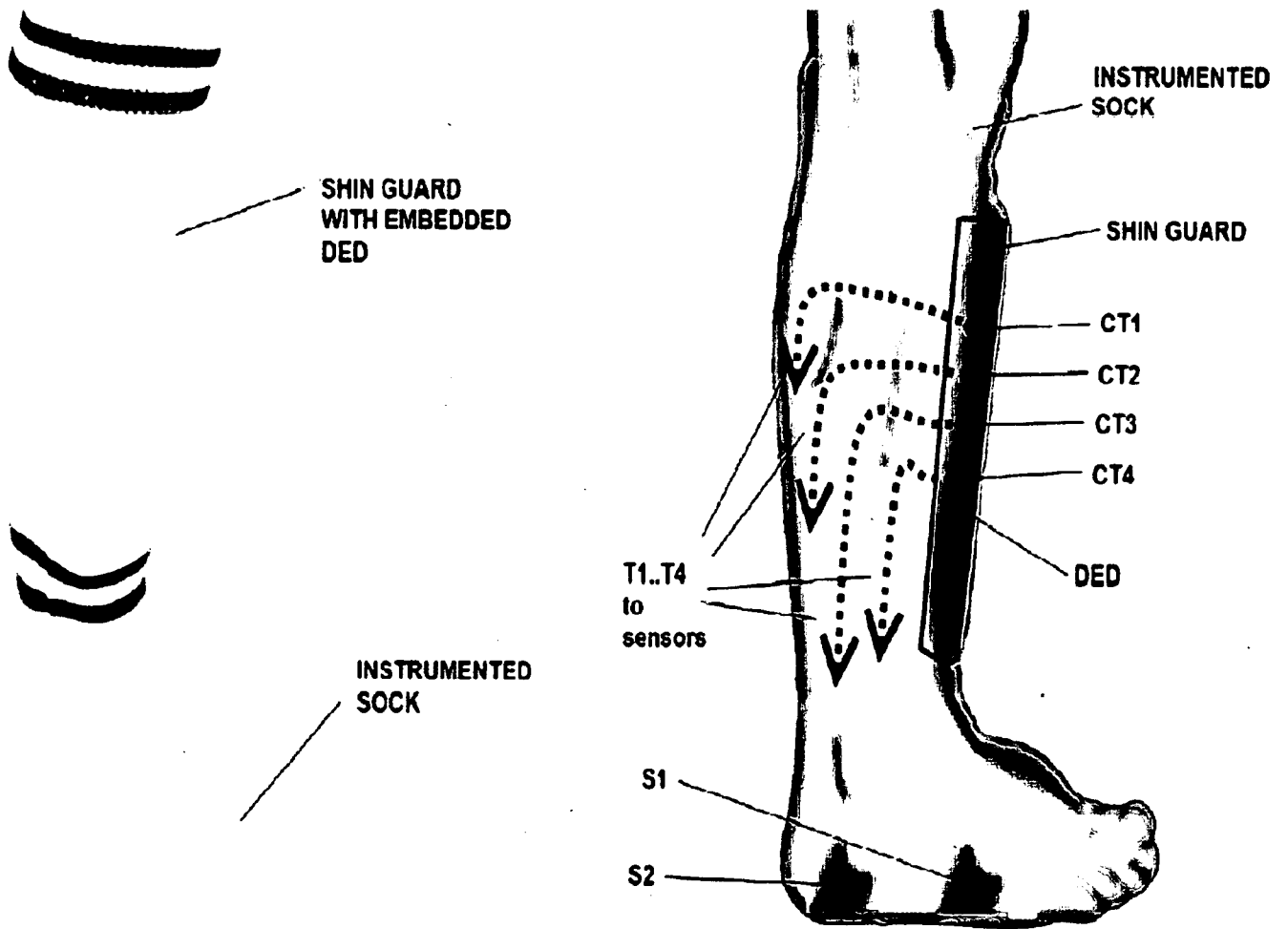


FIG. 23

FIG. 24A

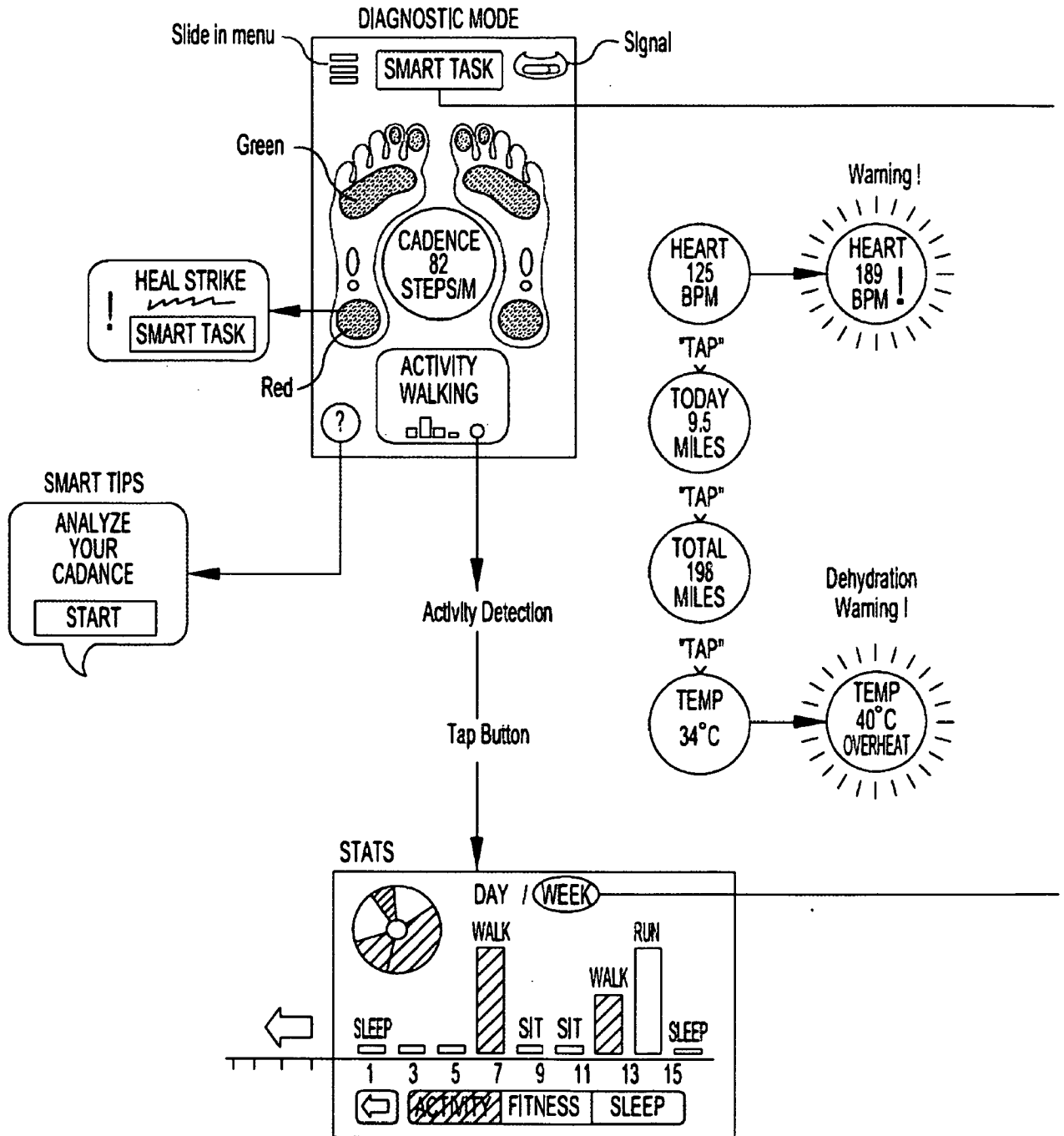


FIG. 24B

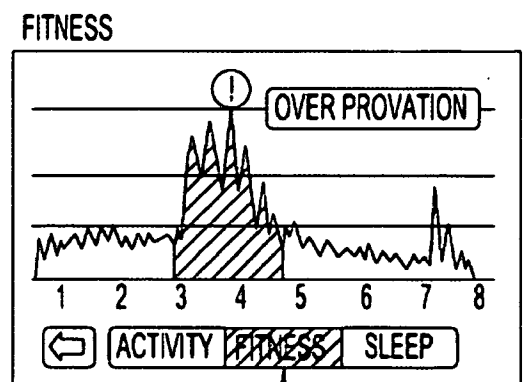
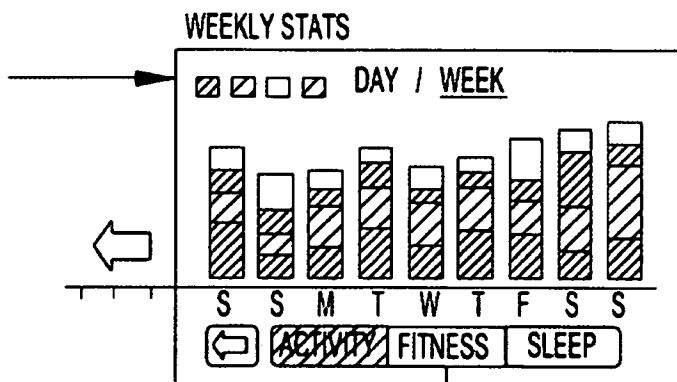
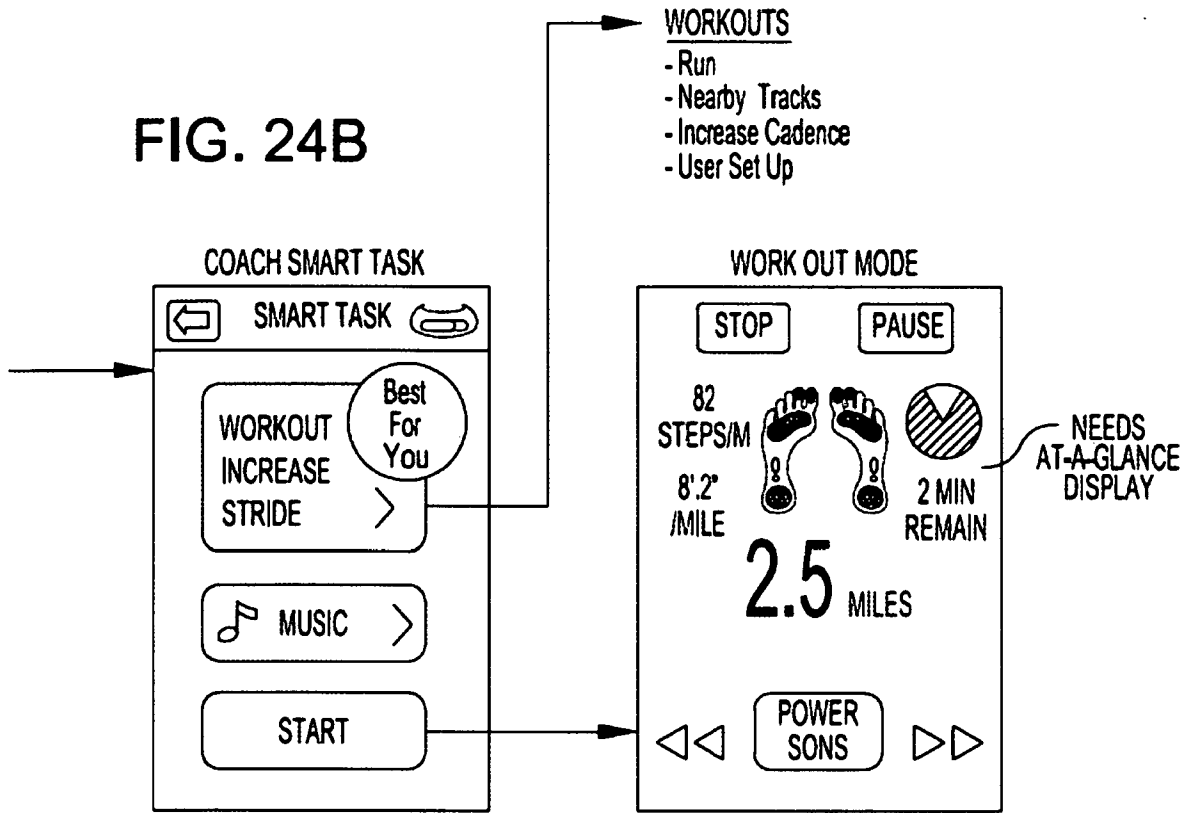


FIG. 25A

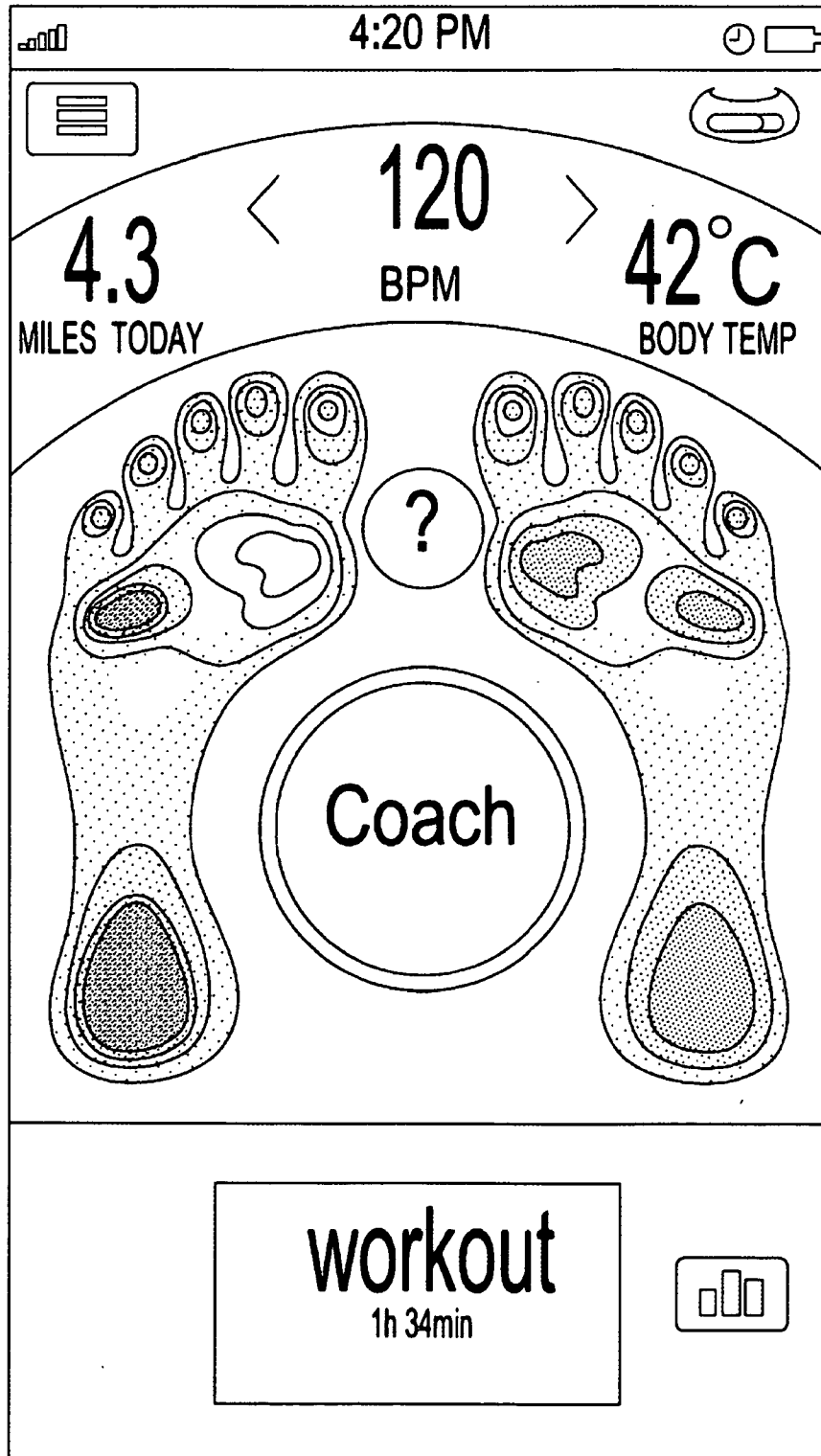


FIG. 25B

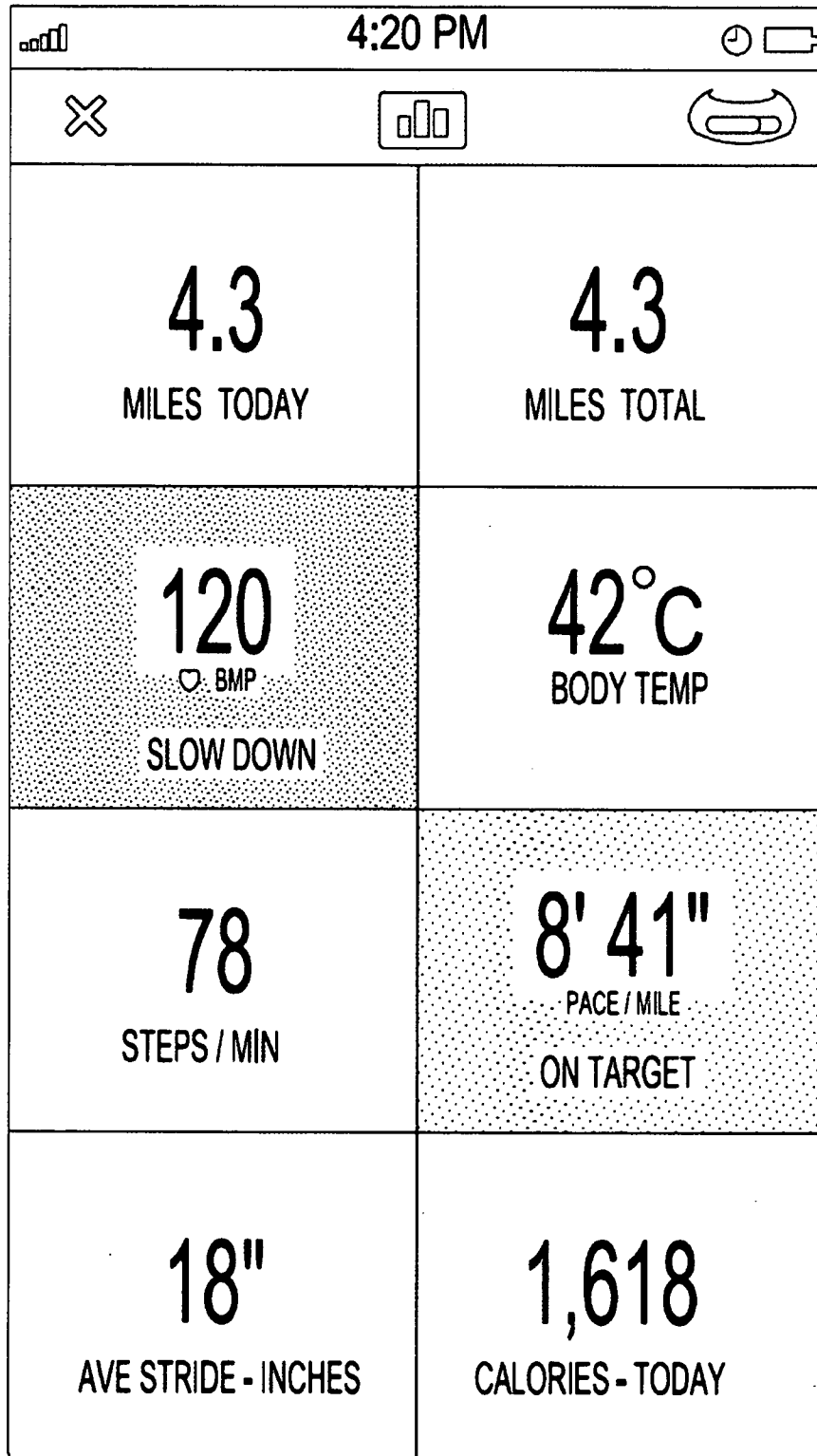
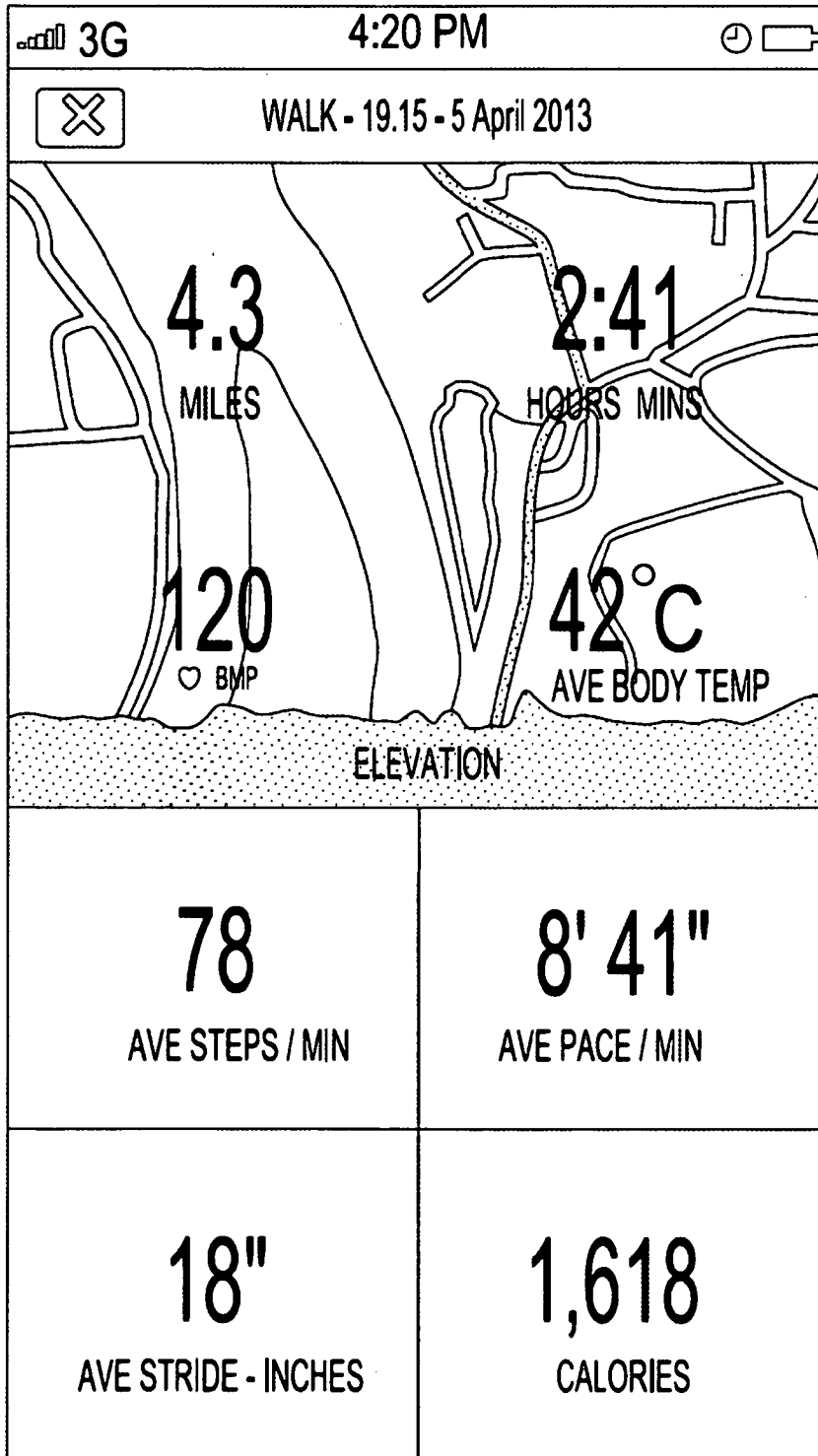


FIG. 25C



FIG. 25D



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 14/49263

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/04 (2014.01)
CPC - A61B 5/0022, A61B 5/0531, A61B 5/1455
 According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
 Minimum documentation searched (classification system followed by classification symbols)
IPC(8): A61B 5/04 (2014.01)
CPC: A61B 5/0022, A61B 5/0531, A61B 5/1455

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8): A61B 5/04 (2014.01); **CPC:** A61B 5/0022, A61B 5/0531, A61B 5/1455
USPC: 600/388, 382 (keyword limited, see terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
 PatBase, Google Patents, Google Scholar. Search terms used: wearable, textile, washable, clothing, sock, foot, feet, apparel, shirt, helmet, sensor, ground, terminal, return, guard, trace, lead, game, gaming, memory, effect, shape, substrate, pad, mat, pressure, weight, force, data, collection, analysis, formulation, user, specific, feedback, in

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/0014626 A1 (FENNELL et al.) 21 January 2010 (21.01.2010), para [0042], [0048], [0078], [0085], [0089]	12
Y		1-11, 13-18
Y	US 2011/0015498 A1 (MESTROVIC et al.) 20 January 2011 (20.01.2011), para [0001], [0016], [0040]-[0043], [0050]-[0056], [0059]-[0064], [0085], [0087], [0091], [0092], [0101]	1-11, 15-20
Y	US 2009/0149722 A1 (ABOLFATHI et al.) 11 June 2009 (11.06.2009), para [0102])	13
Y	US 2009/0045966 A1 (ROCZNIK) 19 February 2009 (19.02.2009), para [0023], [0024]	14
Y	US 2012/0083705 A1 (YUEN et al.) 05 April 2012 (05.04.2012), para [0003], [0155], [0214], [0249]	19, 20
Y	US 2012/0210498 A1 (MACK) 23 August 2012 (23.08.2012), para [0004], [0010], [0045], [0046]	5, 6
Y	US 2010/0063778 A1 (SCHROCK et al.) 11 March 2010 (11.03.2010), entire document, especially, para [0069]-[0074]	1-11, 13, 15-20
A	US 5,642,096 A (LEYERER et al.) 24 June 1997 (24.06.1997), entire document	1-20
A	US 5,678,448 A (FULLEN et al.) 21 October 1997 (21.10.1997), entire document	1-20
A	US 2011/0282164 A1 (YANG et al.) 17 November 2011 (17.11.2011), entire document	1-20
A	WO 2009/112281 A1 (HARMS et al.) 17 September 2009 (17.09.2009), entire document	1-20

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 22 October 2014 (22.10.2014)	Date of mailing of the international search report 26 NOV 2014
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Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 14/49263

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2010/0063365 A1 (PISANI et al.) 11 March 2010 (11.03.2010), entire document	1-20