(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 December 2017 (14.12.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/214188 A1

(51) International Patent Classification:
*A61B 5/00* (2006.01)

(21) International Application Number:
PCT/US2017/036208

(22) International Filing Date:
06 June 2017 (06.06.2017)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/346,151 06 June 2016 (06.06.2016) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,

# (54) Title: SYSTEMS AND METHODS FOR PREVENTION OF PRESSURE ULCERS

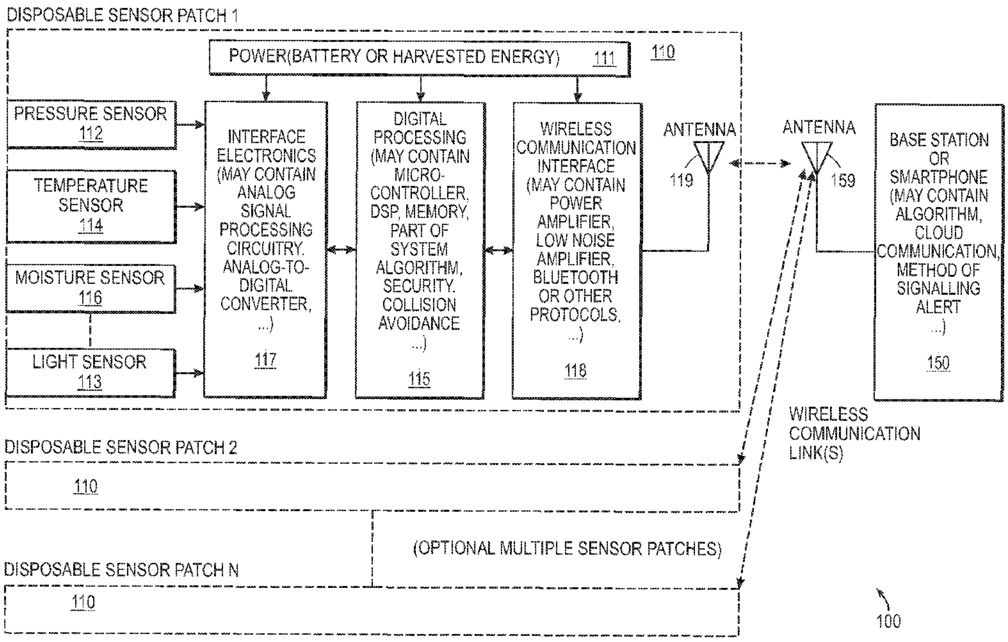


FIG. 1

(57) Abstract: Systems, devices, and methods of the present application relate to the diagnostic measurement of condition for pressure ulcers. Preferred embodiments utilize pressure measurements at body locations to determine a diagnostic pressure ulcer value. A pressure sensor device generates patient pressure data that is processed by a data processor which utilizes a diagnostic function to determine the diagnostic value that indicates whether corrective action is needed to prevent pressure ulcer formation. One or more sensor devices can be attached to a patient to measure to transmit data for further processing.

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TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

**Declarations under Rule 4.17:**
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

**Published:**
— *with international search report (Art. 21(3))*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

# SYSTEMS AND METHODS FOR PREVENTION OF PRESSURE ULCERS

## RELATED APPLICATION

This application claims priority to United States Provisional Application 62/346,151, filed June 6, 2016, the entire contents of which is incorporated herein by reference.

## BACKGROUND OF THE INVENTION

A pressure ulcer, commonly referred to as a bed sore, is defined as a breakdown of the skin due to a lack of blood flow and often results in an increase in pressure on boney prominences. The most common locations of pressure ulcers are on the back of the heels, the backbone, and the shoulder blades although pressure ulcers can form in nearly any location on the body. There are millions of cases of pressure ulcers in the world each year, and 2.4 million cases were recorded in the United States alone in 2007. There are substantial costs for the treatment of a single pressure ulcer, and, in some cases, insurers have indicated that they will no longer reimburse hospitals for the treatment of pressure ulcers as they are classified as a preventable problem.

Other than periodic patient movement, there are currently no methods in general use for preventing pressure ulcers. The current standard of care has clinicians taking preventative measures to help decrease the likelihood of forming pressure ulcers based on clinical practice guidelines. Existing approaches have utilized sensors integrated into patient supports such as tables or beds. However, when the patient is turned, the measurement is disrupted so that the cumulative impact of pressure over time is not considered. When these measures fail, ulcers are diagnosed and treated based on a scale of severity. All too often, the preventative measures are not effective enough to prevent pressure ulcers at an early stage thereby creating a need for costly and painful treatment of the ulcers. Further improvements in the diagnostic assessment of pressure ulcer formation are needed.

## SUMMARY OF THE INVENTION

The present invention relates to devices and methods for detecting the formation of pressure ulcers. Preferred embodiments utilized measured sensor data that is processed to determine a diagnostic value indicative of pressure ulcer formation. A sensor device in accordance with such embodiments can include at least one pressure sensor and a processing device that receives pressure data and processes this data using a diagnostic function to determine whether the patient or their caregiver should take action to avoid injury. As the conditions under which pressure ulcers will occur in a given patient depend on the specific condition of that patient, simply measuring the pressure applied at any instant to the skin of a patient does not provide meaningful information that is useful to the patient or caregiver. A particular pressure measurement at a particular time, for example, may indicate that no action is needed or that immediate corrective action is necessary both of which can be false depending on the circumstances. In conventional systems, time domain based measurements to determine the accumulated effects at a selected location on a patient's body are not available.

Preferred embodiments employ a number of patient specific attributes that are used to determine a diagnostic function for each individual patient. Patient attributes can include one or more body locations at which pressure is being measured, the weight or body mass of the patient as well as the age, medical condition, medical history, mobility, nutrition, blood oxygenation, blood pressure, temperature and other factors impacting diagnostic assessment. The diagnostic function provides a quantitative analysis to indicate to the user that a patient is at low or high risk of ulcer formation, for example. The diagnostic function can be the sum of weighted parameters, each parameter having a coefficient to define the weight given to the respective parameter, or other analytic expression that enables accurate computation of a quantitative diagnostic value over time. A location on the heel of a patient having peripheral vascular disease, for example, will have a substantially lower threshold than a location on a shoulder of a healthy child. In some embodiments, the diagnostic function can include a Bayesian statistical data integration algorithm.

A preferred embodiment can employ a conformable sensor patch that can be fixedly attached to one or more body locations of a particular patient. The device can include a wireless transmitter, a data processor, a power source such as a battery, and one or more sensor elements such as a pressure sensor or array of sensors, a temperature sensor, a moisture sensor and/or a light sensor. The processor can be programmed to determine a diagnostic value based on the measured data and communicate this value to the patient or other user. The sensor device is attached to the skin of the patient at specific body location(s) to perform time domain measurements to provide continuous or periodic measurements. The pressure sensor can be triggered to actuate device operation when a threshold pressure level is sensed for a preset time period or when the pressure reaches a level that could cause an impact injury, such as the patient falling. Pressure ulcer injury often occurs with the occlusion of microvasculature between a bone and a region of skin under pressure. Sustained oxygen deprivation of tissue arising from vascular occlusion over days or weeks can eventually cause ulcer formation. Triggering based upon pressure measurements can limit consumption of battery power by actuating device operation only during those times when a particular body location is subject to a pressure that can contribute to pressure ulcer formation. The device can also be activated by receipt of wired or wireless transmission of data by an onboard receiver that receives diagnostic data (e.g. blood pressure, blood oxygenation) from a separate sensor device.

Preferred embodiments can utilize the wireless communication of the sensor device to deliver the measured or processed data to a local communication device such as a cellular phone, a tablet or other computing device in proximity with the sensor. Alternatively, the device can directly communicate such data to a remote receiver, server or other networked computing device for further processing or storage as described herein. Data can be processed onboard the sensor device or on the local device, or remotely or combinations thereof.

For many patients, a plurality of locations on the body need to be monitored over time with each location having different criteria to measure and characterize risk. Thus, a preferred embodiment tracks different sensor units at different locations that integrate data over time for that specific patient for each of the body locations separately. Each location can have a sensor unit that comprises an array of pixel sensor elements distributed over a surface area of the skin. The pixel array can have sub-regions corresponding to sub-arrays of pixel elements that can be processed together as a unit, such as by averaging, or as individual pixel elements. Each pixel element can have a surface area in a range of 0.2 to 2.0 square centimeters, and preferably in the range of 0.5-1 square centimeter.

Embodiments can include a mobile device such as an internet enabled mobile phone or tablet that provides a handheld unitary interface for control of one or more sensor devices that are positioned on a patient. A tablet, for example, can include a near field sensing device or other machine code reader that detects a code, or communicates with a pressure sensor device or patch being activated for use with a particular patient. This both initiates the pressure sensor device and actuates the tablet user interface to record usage and display data. A patient identifier can be stored in a patch memory and a patch identifier can be stored in the tablet as being associated with a particular patient. The tablet has a plurality of pull down menus and fields for data entry and display including patient data entry fields and one or more display windows to display sensor data as it is recorded and/or processed. The display windows can separately display sensor device parameters, or within each sensor device display window can display parameter presets or user adjustable parameters such as thresholds for different sensor outputs. For example, the minimum sensor threshold for sensed pressure for each patch, or for selected pixel elements in a sensor array, can be separately operated by finger actuated touch gestures on the touch screen. Alternatively, a user can employ a mouse or other cursor control device to manipulate the graphical user interface of the tablet. The displayed data window for each patch can have separate touch actuated menus to display different data sets or graphical features for each body location. Different body locations can be individually controlled via the unitary control interface. Two or more locations can be linked, such as a first patch on the left heel and a second patch on a right heel of a patient, as they can be indicating similar conditions and have similar therapeutic indications. A plurality of patients can be monitored with a single device by selecting a particular patient to then display one or more patches that are operating on the selected patient at one time. Prior data sets can also be retrieved for each patient and data correlations computed for each dataset. For sensor arrays, pressure distributions can be displayed to identify particular regions requiring further monitoring or treatment. Image processing can be used to further characterize and quantify characteristics of a particular ulcer location.

## BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a schematic of a system for prevention of pressure ulcers in accordance with some embodiments of the present disclosure.

Figs. 2A and 2B illustrate top and side views of a sensor device in accordance with some embodiments of the present disclosure.

Fig. 3 illustrates a schematic flowchart of the calculation of a value indicative of pressure ulcer formation a schematic of a method for calculating a value indicative of pressure ulcer formation in accordance with some embodiments of the present disclosure.

Fig. 4 illustrates a schematic of a method for calculating a value indicative of pressure ulcer formation in accordance with some embodiments of the present disclosure.

Fig. 5 schematically illustrates a sensor device of some embodiments of the present disclosure affixed to a tissue of a patient.

Figs. 6A, 6B, and 6C illustrate schematic embodiments of systems for prevention of pressure ulcers in accordance with some embodiments of the present disclosure.

Fig. 6D illustrates an exemplary graphical user interface for a computing device connected to one or more sensor devices in accordance with some embodiments of the present disclosure.

Fig. 6E illustrates a schematic representation of a computing device for use with systems and methods described herein in accordance with various embodiments.

Fig. 7 illustrates a circuit diagram including a pressure sensor for use with some embodiments of the present disclosure.

Fig. 8 illustrates a plot of calibrated and uncalibrated pressure measurements obtained using a pressure sensor in accordance with some embodiments of the present disclosure.

Fig. 9 illustrates a portion of a system including a pressure sensor that can also act as an antenna in accordance with some embodiments of the present disclosure.

Fig. 10 illustrates a portion of a system including components to enable a service connection in accordance with some embodiments of the present disclosure.

Fig. 11 illustrates a system for prevention of pressure ulcers in accordance with some embodimetns of the present disclosure positioned on a heel of a patient.

Figs. 12A and 12B illustrate alternative embodiments of a pressure sensor in accordance with some embodiments of the present application.

## DETAILED DESCRIPTION OF THE INVENTION

Embodiments of the present invention relate to systems and methods for prevention or mitigation of pressure ulcers. The systems and methods taught herein include sensors attached to sites on a patient that may be prone to development of pressure ulcers. Data collected by the sensors can be used in combination with patient-specific data to determine the risk of development of a pressure ulcer at the site. In various embodiments, the data can be collected and processed directly by the sensors, by a local computing device such as a handheld tablet, internet enabled cellular phone or smartphone, or by a remote computing device.

A pressure ulcer is a localized injury to the skin and/or underlying tissue usually over a bony prominence as a result of pressure alone or in combination with shear and/or friction. Although direct measurements of pressure are an important component of determining risk to develop a pressure ulcer, the risk also strongly depends on other environmental variables such as temperature and humidity and patient-specific data such as age and mobility level. Systems and methods taught herein can adjust a diagnostic function, such as a risk model, based on historical measurements of environmental variables and patient-specific data. In some embodiments, the systems and methods taught herein can generate a patient-specific risk model from accumulated patient data using a neural network or support vector machine to create a supervised learning model. The diagnostic function can comprise a weighted combination of variables for a specific patient or for defined classes of patients.

As used herein, "integration of measurement data" includes computation of a mathematical integral of measurement data over time or alternatively, can include functional treatments of measurement data over time including nonlinear techniques, moving averages, apodization, interpolation, and discrete sampling.

Fig. 1 illustrates an embodiment of a pressure ulcer monitoring system 100 that includes one or more sensor devices 110 and a base station 150. The sensors 110 can be in communication with the base station 150 to transmit or receive data. Base station 150 can be a bedside monitoring system that monitors one or more sensors including blood pressure or blood oxygenation or can be a personal communication device of the patient.

The sensor devices 110 can include a one or more of a power source 111, a pressure sensor 112, a moisture sensor 116, a temperature sensor 114, a light sensor 113, interface electronics 117, digital processing 115, a communications interface 118, and an antenna 119. The sensor devices 110 can be attached to a patient at any location on the body or, more preferably, at locations on the body that are prone to developing a pressure ulcer. For example, sensor devices may be affixed to a patient that primarily uses a wheelchair on the heels of the feet, the sides of the legs, the buttocks, or any other place that commonly comes into contact with the wheelchair. The sensor device 110 may include an adhesive layer in some embodiments to enable fixation to the patient's body. The adhesive can include a biodegradable or bioabsorbable polymer, hydrogel or acrylate ester/vinyl pyrrolidone copolymers, dimethyl silicone polymers, and acrylate polymers, for example. In other embodiments, the sensor device 110 can be affixed to the patient using externally applied adhesive (*e.g.*, tape) or a fabric sleeve/sock that positions the sensor device or sensor array on a fixed tissue surface location such that movement of the patient does not alter the position of the sensor relative to the patient. In some embodiments, the sensor devices 110 are disposable or sterilizable. In some embodiments, the sensor devices 110 are waterproof or water-resistant to prevent damage to internal components of the sensor device 110 in a clinical setting. The patient can wear the sensor devices 110 without replacement in some embodiments for 1 to 14 days or more preferably for between 3 and 7 days. In some embodiments, the sensor device 110 can be a conformable patch that is disposable, or alternatively, utilizes a reusable electronic package positioned within a disposable sleeve.

The pressure sensor 112 can produce an output signal that is proportional to the pressure applied to the sensor device 110. The pressure sensor 112 can be adapted to measure pressures in a range from 0 mmHg to 350 mmHg in various embodiments. Each sensor device 110 can include more than one pressure sensor 112 in some embodiments. The use of more than one pressure sensor 112 can enable spatially-resolved pressure measurements within a single sensor device 110. The sensor device 110 can include interface electronics 117 to convert or calibrate the signal provided by the pressure sensor 112 to a format suitable for output by the communications interface 118. In some embodiments, the pressure sensor 112 can include a polymer thick-film device that exhibits a change in electrical resistance as the force applied to the device changes. In some embodiments, the pressure sensor 112 can include a capacitive sensor that produces a change in output signal when the capacitance between two surfaces across a dielectric material changes. Embodiments of the pressure sensor 112 are described in greater detail below.

The power source 111 of the sensor device 110 can include a battery in some embodiments. The battery can be single-use or rechargeable. In embodiments where the battery is rechargeable, the sensor device 110 may include additional circuitry to receive inductive or RF power from an external source to recharge the power source 111. In some embodiments, the power source 111 can include an energy-harvesting mechanism to recharge the power source 111 by capturing kinetic energy produced by patient movement. The energy-harvesting mechanism can include MEMS accelerating weights in some embodiments. The power source 111 can provide power to the electrical components of the sensor device 110 such as the digital processing 115, communications interface 118, or interface electronics 117.

The temperature sensor 114 and moisture sensor 116 can provide output signals correlated to temperature and relative humidity, respectively. In some embodiments, the sensor device 110 can include interface electronics 117 to convert or calibrate the signals from the temperature sensor 114 or the moisture sensor 116 to a format suitable for output by the communications interface 118. In some embodiments, the output from the temperature sensor 114 can be used to calibrate the output signal obtained from the pressure sensor 112.

The sensor device 110 is not limited to including the sensor types described thus far. In some embodiments, the sensor device 110 can include additional sensors to measure other physical or chemical properties in the patient. For example, the sensor device 110 can include a light sensor 113 (*e.g.*, photodiode or other photosensor) or other suitable sensor to detect light reflected or emitted from the skin of the patient. In embodiments with a light sensor 113, the sensor device 110 can also include a light source such as an LED or LED array having one or more emission wavelengths. The light sensor 113 can generate colorimetric data corresponding to a color of the skin of the patient. Hyperemia can be an early prognosticator of formation of a pressure ulcer and can manifest as a reddening of the skin. Blue, black, or green coloration of tissue can also be indicative of imminent or ongoing damage to the tissue. In some instances, colorimetric data may be indicative of restricted or altered blood flow in the tissue and thus can be predictive of risk for pressure ulcer development. In some embodiments, the light sensor 113 can be a component of a pulse oximeter.

In some embodiments, the sensor device 110 can include sensing elements for any suitable chemical or physical parameter of tissue or the surrounding environment. For example, the sensor device 110 can include a component to directly measure blood flow in tissue such as an ultrasound transducer device or a laser Doppler device.

The communications interface 118 of the sensor devices 110 can include appropriate electronics to transmit and receive data including power amplifiers or low-noise amplifiers. In various embodiments, the communications interface 118 can communicate through a wired or wireless interface. In wireless embodiments, the communications interface 118 can communicate using protocols or standards associated with 802.11x (wi-fi), BLUETOOTH®, or any other suitable wireless technology standard.

In some embodiments, the sensor device 110 can include digital processing 115 to perform various functions. For example, the digital processing 115 can include a microcontroller, a data processor, a digital signal processor, ASIC, memory, security architecture to encrypt data in accordance with patient data privacy protocols, collision avoidance architecture, or at least a portion of processor-executable code to generate a pressure ulcer diagnostic value indicative of a risk assessment using measurement data and patient-specific data. The memory can be used in some embodiments to store processor-executable code to control device operation or process the measured data. In some embodiments, the sensor device 110 can store measurement data in the memory and specifically if the connection between the communications interface 118 of the sensor device 110 and an external device is interrupted. The stored measurement data can be transmitted at a later time when the connection is re-established. In some embodiments, the digital processing module(s) 115 of the sensor device 110 can self-diagnose the sensor device's readiness state and report (using the communications interface 118) if one or more components of the sensor device 110 have failed or not functioning in accordance with specifications. Alternatively, the device can have a simplified configuration to automatically stream data to an external device by wired or wireless connection.

The pressure ulcer monitoring system 100 also can include a base station 150. In some embodiments, the base station 150 can be a computing device or mobile communications device such as a tablet or smartphone. The base station 150 can include a processor, memory, communications interface, an alert module, an antenna 159, and at least a portion of processor-executable code to generate a pressure ulcer risk assessment using measurement data and patient-specific data. In some embodiments, the base station 150 can be located within range of wireless communication with the sensor devices 110 or can be located distantly. In some embodiments, the base station 150 can communicate with the sensor devices 110 through an intervening communications network such as the internet or a local area network (LAN).

Figs. 2A and 2B illustrate top and side views of a sensor device 110 according to some embodiments of the present disclosure. The sensor device 110 can include a printed circuit board 120 onto which various components are mounted. The sensor device 110 can include the pressure sensor 110, the temperature sensor 114, interface electronics 117 such as a pressure readout circuit 122 or a temperature readout circuit 124, the power source 111, communications interface 118, and the antenna 119. The sensor device 110 can include a layer of adhesive 126 to enable the device to be affixed to a patient. In some embodiments, the printed circuit board 120 is a flexible printed circuit board (flex-PCB).

Because the sensor device 110 can be situated between the patient and bearing surface that threatens to create a pressure ulcer (for example, affixed directly to the tissue surface of the patient), it is important that the sensor device 110 itself not contribute to causing a pressure ulcer. In some embodiments, the sensor device 110 can include a cover 125. In certain embodiments, the cover 125 can have a uniform or flat external surface to prevent concentration of pressure or force on the patient due to the size and rigidity of certain internal components of the sensor device 110 such as the discrete components or chips. In some embodiments, the cover 125 can be molded onto the flex-PCB 120. In some embodiments, the cover 125 can seal the sensor device 110 to prevent moisture infiltration. The cover can provide a thin, pliable, conformable sensor device in which the opposite sides are aligned and the thickness is less than 4mm, and preferably less than 3 mm and further preferably less than

2mm. The sensor device or patch has an area less than $4cm^2$ and will preferably be rectangular circular or oval in shape.

Fig. 3 illustrates a schematic flowchart of a procedure to evaluate risk of pressure ulcer formation using current and historical measurement data and patient-specific data in accordance with various embodiments of the present disclosure. The procedure can process 330 integrated and historical measurement data such as pressure measurements 302, temperature measurements 304, and humidity measurements 306, measured physiological states such as blood oxygenation or blood pressure, and other patient-specific data 320. The procedure uses the processed data to calculate one or more pressure ulcer diagnostic values indicative of pressure ulcer formation 332. The procedure can manipulate the pressure measurement data by optionally calibrating the data using the temperature data, the humidity data, or both 310 or by filtering the pressure measurement data over time using a filter to eliminate anomalous pressure data or noise 312. The procedure can integrate the pressure data over different time periods 315a…315n. The procedure can display the pressure ulcer diagnostic value indicative of pressure ulcer formation 335 at each location. If the pressure ulcer diagnostic value is greater than a threshold value, for example, the procedure can signal an alert 336.

In some embodiments, the pressure ulcer diagnostic value indicative of pressure ulcer formation can be a probability value. In some embodiments, the probability value can be provided with confidence intervals.

In some embodiments, signaling the alert can include activating an alarm or displaying a warning on a display. In some embodiments, the alert can include actionable information including, but not limited to, suggestions to offload pressure from the area, move the patient, alter a movement regimen, change patient bedding, or other appropriate information.

Patient-specific data 320 can include any data that may impact diagnostic assessment for development of a pressure ulcer. Examples of patient-specific data include, but are not limited to, patient age, mobility level, weight, nutrition level, history of smoking, medication history (type, dosage, and schedule), medical history (*e.g*, heart disease, hypertension, or peripheral vascular disease), and blood pressure. In some embodiments, patient-specific data can include prior evaluations of a patient's risk for developing a pressure ulcer (*e.g.,* output from a patient evaluation using the Braden, Waterloo, or Norton scales). Some patient-specific data is also specific to a measurement site such as location of the measurement site (*e.g.*, heel, buttocks, back, leg, etc.), blood oxygenation level, and/or skin temperature.

As shown in Fig. 4, the patient-specific data can be processed along with the integrated measurement data and the historical measurement data. In some embodiments, processing the patient-specific data can include binning the patient-specific data. For example, a patient's age or weight may be provided to the calculation step as a range. Different patient-specific data can impact the calculation of the value indicative of pressure ulcer formation in different ways. For example, high values of age and weight and low mobility for a patient can indicate a greater likelihood of pressure ulcer formation, and the calculated pressure ulcer diagnostic value may accordingly be indicative of greater risk of pressure ulcer formation for this patient.

Systems and methods described herein can use the real-time physiological patient data stream measured by the sensor device as inputs to a Bayesian statistical data integration algorithm. In some embodiments, the patient data are combined with user-entered inputs, such as skin and tissue conditions, weight, blood pressure, or others that are patient-specific. In some embodiments, these data (e.g., blood pressure) can be automatically acquired by the system. The data integration algorithm can yield estimates of the probability that the patient or caregiver must take proactive actions to reduce or eliminate the external pressure applied on the body part where the sensor is located to avoid further tissue damage leading to a pressure ulcer. If the probability is higher than a pre-determined threshold, an alarm can be triggered indicating that there is a potential risk of developing a pressure ulcer.

Methods and systems taught herein can process the measurement data before inputting the data into the calculation of the pressure ulcer diagnostic value indicative of formation of a pressure ulcer. In some embodiments, the pressure measurements can be calibrated using the value of temperature measurements. For example, a pressure sensor that has a resistivity value associated with it may experience temperature-dependent changes in resistance. The temperature measurement can be used to calibrate the resistance value in these embodiments. In some embodiments, the pressure measurement data can be integrated over time to generate an accumulated pressure measurement. The area over which pressure is applied to a tissue can be indicative of the potential for formation of a pressure ulcer. For example, the body can have a greater capacity to repair a pressure insult applied to a small area than a similar insult applied to a large area. In that scenario, the large area would be at greater risk for formation of a pressure ulcer. In some embodiments, the pressure measurement data can be integrated over time and space (*e.g.,* the size of the sensor) to create an accumulated force measurement.

Methods and systems taught herein can use historical measurement data to calculate the value indicative of pressure ulcer formation. For example, a site on a patient that has recently been under adverse pressure conditions without full recovery may be more disposed to developing a pressure ulcer. In some embodiments, pressure, temperature, or humidity measurements can be stored in a memory and can be provided as inputs to the calculation of the pressure ulcer diagnostic value indicative of pressure ulcer formation.

A large pressure applied to a tissue even for a short time can predispose the tissue to formation of pressure ulcers (*i.e.*, the effect of pressure on tissue need not saturate at a specific value). Although a pressure of 35 mmHg can be sufficient to occlude blood flow in the capillaries of a tissue, higher pressures can create additional impacts that can increase the chances of forming a pressure ulcer. Systems and methods taught herein can measure the pressure applied to an area of tissue over time and weight the measurement appropriately during calculation of the pressure ulcer diagnostic value indicative of formation of a pressure ulcer.

In some embodiments, calculating the pressure ulcer diagnostic value indicative of pressure ulcer formation can include determining a functional representation such as a diagnostic function using weighted values of patient specific data, integrated measurement data, and historical measurement data. In some embodiments, the determined diagnostic function can incorporate historical measurement data directly into the representation rather than accessing historical data in a memory. For example, the historical data can be incorporated into the representation coupled with a decaying function that slowly de-weights the data's importance over time. An important purpose of the diagnostic function is to measure the time dependent effects of the pressure exerted at a particular tissue site. The diagnostic function preferably depends substantially on the accumulated pressure over time. The occurrence of repetitive injury at a particular body location where blood flow has been restricted periodically due to excessive pressure can substantially increase the risk of pressure ulcer formation. Different body locations, however, will respond differently for given levels of pressure over time. Thus, different locations on a particular patient will employ different diagnostic functions.

Fig. 5 illustrates a schematic of the sensor device 110 placed at an anatomical site of the patient in accordance with various embodiments of the present disclosure. The sensor device 110 can be placed on any tissue of the patient but is most preferably positioned on at-risk tissue 170 proximate to a bony prominence 175. In some embodiments, the sensor device 110 can be placed on or near the patient's ischium, sacrum, trochanter, heel, malleolus, knee, iliac crest, elbow, pretibial crest, pinous process, occiput, chin, scapula, or any other suitable location. When the anatomical site is placed into contact with a bearing surface 160, the tissue 170 located between the bony prominence 175 and the bearing surface 160 can be compressed. If the compression pressure is high enough, blood flow in the capillaries 172 can be occluded. This reduced blood flow (and concomitant reduction in blood oxygenation) can lead to tissue damage or necrosis that the body is unable to repair in a timely fashion. In some embodiments, the sensor device 110 can detect reductions in blood flow or other changes in the tissue 170 such as temperature, color, or oxygenation level.

Figs. 6A-6C illustrate schematic representations of systems for prevention or monitoring of pressure ulcers in accordance with various embodiments of the present disclosure. In Fig. 6A, the system 100 includes one or more sensor devices 110. The sensor devices 110 may be similar to those described above with reference to Figs. 1-2B. In some embodiments with a plurality of sensor devices 110, the sensor devices 110 can each include a communications interface 118 to allow the sensor devices 110 to communicate with one another. The communications interface 118 can non-exclusively include the capability to communicate using a variety of standards such as 802.11x, BLUETOOTH®, near-field communications (NFC) or RFID device, or any other suitable communications standard. In some embodiments, at least one of the sensor devices 110 can include a data processing and modeling code 300 that can receive measurement data from sensors in the one or more sensor devices 110. The data processing and modeling code 300 can process the measurement data, patient-specific data, and historical measurement data to calculate the pressure ulcer diagnostic value indicative of the formation of a pressure ulcer.

Fig. 6B shows a system 100 for preventing formation of pressure ulcers including one or more sensor devices 110 and the base station 150. The base station 150 can include a mobile communications device or a computing device. The base station 150 can be located locally or remotely with respect to the one or more sensor devices 110. In some embodiments, the base station 150 can include data processing and modeling code 300. In some embodiments, the base station 150 can be a mobile communications device such as a smartphone. In such an embodiment, the smartphone can provide an alert to the patient or a provider that action is needed to prevent formation of a pressure ulcer (*e.g.*, an alarm to awaken the patient if they are sleeping in one position for too long). The mobile devices can include an electronic display utilizing a graphic user interface (GUI). The GUI can have expandable menus from a toolbar to access patient data entry, diagnostic function profile as well as display real time and/or historical data.

Fig. 6C shows a system 100 for preventing pressure ulcers including one or more sensor devices 110, the base station 150, a network 400, a database 402, a user terminal 404, and a server 406. The system 100 can also optionally include a neural network or support vector machine (SVM) 408 that can be connected to the network 400 or directly to the server 406. In some embodiments, the server 406 or neural network 408 can include data processing and modeling code 300. In some embodiments, the neural network/SVM 408 can include a learning capability that can use a dataset (such as found in database 402, for example) including measurement data, patient-specific data, and patient outcomes to train a model including a functional representation such as a diagnostic function using weighted values of the data. In some embodiments, the SVM 408 can identify correlations between patient-specific data, measurement data, and patient outcomes. Correlations identified by the SVM 408 can be used to revise and improve the weighted values in the diagnostic function or can be used to revise the diagnostic function itself. In some embodiments, the SVM 408 can communicate with the server 406 to revise the data processing and modeling code 300 with improved diagnostic functions which can be functional represented as a plurality of variable with weighting parameters.

Fig. 6D illustrates an exemplary graphical user interface (GUI) 602 for a computing device or mobile communications device such as a tablet 600 that is connected to one or more sensor devices 110 in accordance with embodiments of the present disclosure. In some embodiments, the GUI 602 can be divided into portions 610a-610d that correspond to different sensor devices 110. Each portion 610a-610d can include textual or graphical information. Although Fig. 6D illustrates a device having four portions 610a-610d, it will be apparent to one of ordinary skill in the art that the GUI 602 could be divided into a greater or lesser number of portions. In some implementations, the user can reduce the number of portions shown on the GUI 602 to focus on data from one or more specific sensor devices 110 or increase the number of portions shown on the GUI 602 to get a broad overview of the status system wide. In some implementations, the GUI 602 can dynamically change the number of portions 610a-610d that are displayed in response to initializing additional sensor devices 110 or losing communication or de-registering sensing devices 110.

The tablet 600 can include a scanner 604 to read a unique identifier associated with each sensor device. For example, the scanner 604 can be a proximity scanner or machine reader such as an RFID scanner that can interface with an RFID tag on the sensor device. In another embodiment, the scanner 604 can include an imaging device or barcode scanner to read the unique identifier that is visually displayed on the sensor device. The tablet 600 is programmed to activate the sensor device, identify the data format to be provided by each device, perform the data analysis required by each device, and display the resulting diagnostic data for each device. As a user activates a particular sensor device, the user identifies the body location for that device for a particular patient. The patient's electronic medical record can be accessed along with sensor activation so that data retrieved from sensors applied sequentially to the same location can be utilized in the continuing monitoring of the patient's condition. The tablet or mobile communication device touchscreen operates as a unitary interface for operation of the one or more sensors activated for the patient.

Each portion 610a-610d can provide a user with information related to the operation of the sensor device and/or information related to data received from the sensor device. For example, the portion 610a can include a label 620 identifying the sensor device that corresponds to that portion. The label 620 can be provided by the computing system 150 or can be user-defined. In some embodiments, the label 620 can include a descriptive phrase corresponding to the location of the sensor device 110 on the body such as "heel," "left buttock," or "right leg." In some embodiments, the label 620 can include unique identifying information for the sensor device 110 such as, for example, a serial number. The portion 610a-610d can include a status indicator 630. The status indicator 630 can provide a status of the portion of the body adjacent to the relevant sensor device 110 as adjudged by the risk model. For example, the status indicator 630 can identify the adjacent body portion as not needing medical attention, soon to be in need of attention if pressure continues, or currently in need of medical attention. In some embodiments, the status indicatior 630 can include color such as red to indicate danger, yellow to indicate caution, and green to indicate that no problems are imminent.

Each portion 610a-610d can include a graphical pressure representation 640 of pressure sensed by the sensor device 110. In various embodiments, the graphical pressure representation 640 can illustrate instantaneous pressure values, current and historical pressure values, or a metric related to pressure value in combination with other measurement values. In some embodiments wherein the sensor device 110 includes an array of pressure-sensitive areas, the graphical pressure representation 640 can include a "pixelated" view showing the pressure values across the array of pressure-sensitive areas. For example, the graphical pressure representation 640 can include false-color or grayscale information correlated to the intensity of the pressure at a given point. The graphical pressure representation 640 can provide visual feedback to a user to illustrate which specific section of the body portion is receiving a particularly high or low level of pressure and to make adjustments to body position accordingly.

Each portion 610a-610d can include a plot 650 of pressure values. The y-axis of the plot can represent measured values of pressure, temperature, relative humidity, probability of pressure ulcer formation, or other relevant data in various embodiments. The x-axis of the plot can represent time in various embodiments. The user can select (e.g., by using a drop-down menu) the data to be displayed on each axis. The plot 650 can be updated continuously or at intervals (for example, every 5 seconds, 10 seconds, 30 seconds, 60 seconds, 120 seconds, or more). In some embodiments, the plot 650 can provide a quick assessment of the pressure history trend at the location of the sensor device 110.

The GUI 602 can include a pressure threshold setting 642 that can be adjusted by a user, for example, by touching or dragging the indicator. Depending upon the location of the associated sensing unit, the threshold pressure at which the system should trigger an alert for imminent formation of pressure ulcers can change. In various embodiments, the tablet 600 can automatically calculate a range of pressure thresholds appropriate to the location of the sensor unit 110 on the body of the patient. The tablet user can use the pressure threshold setting 642 to apply gross or fine adjustments to the pressure threshold. The decision to adjust the pressure threshold setting 642 can be based upon factors such as knowledge of ulcer formation on the analogous body part (e.g., knowledge that the patient's other heel has formed an ulcer) or either heightened circumstances.

Fig. 6E illustrates an schematic representation of a tablet 600 or computing device for use with various embodiments described herein. The tablet 600 can include any of a scanner 604, a battery 611, power regulation circuitry 631, a memory 614, a wireless transceiver 618, an antenna 159, a second data processor 635, a touch processor 616, a touchscreen display 618, a graphics processor 619, and a USB port 612. In such embodiments, a housing of the data processor 635 and other components can be a portable device such as a tablet 600.

As described above, the pressure sensor 112 of some embodiments can be a polymer thick-film sensor. One challenge associated with use of a polymer thick-film pressure sensor can be part-to-part variability of up to ±25%. In some embodiments, the interface electronics can employ a voltage-based resistance measurement technique. The pressure sensor can be placed in a voltage divider configuration with a reference resistance. With a known reference voltage applied, the voltage divider output can be digitized by an analog-to-digital converter (ADC). The resistance value of the pressure sensor can be inferred from the measured voltage using the voltage divider relationship. With the resistance value of the pressure sensor, Equation 1 can be used to determine force, and pressure can be determined using the sensor active area.

$$R_{SENSOR} = R_0 F^X \tag{1}$$

In some embodiments, a time-based resistance measurement technique can be used with the pressure sensor. Systems and methods taught herein can provide a calibration procedure to enable linear force measurement with accuracy approaching single-part repeatability of ±2%.

Fig. 7 illustrates an exemplary circuit for obtaining a time-based resistance measurement from the pressure sensor 112 in accordance with various embodiments of the present disclosure. For the output digital waveform DCLK, the frequency f and duty cycle $\delta = T_H/T$ (fractional "high" time $T_H$ relative to the waveform period $T$) are given by

$$f = \frac{1.44}{(R_A + 2R_B)C} \qquad \delta = \left(\frac{R_A + R_B}{R_A + 2R_B}\right) \tag{2}$$

Either expression in (2) can be used to determine resistance from a time domain measurement. In some embodiments, duty cycle can be used because it is independent of the capacitor value C. The duty cycle can be calculated by the microcontroller 135, which measures $T_H$ and $T$ in the digital domain over interval $T_{MEAS}$, covering many $T$ periods. The microcontroller can also implement the calibration algorithm described below in some embodiments. The resolution of the measurement can be improved in some embodiments by increasing the $T_{MEAS}$ time measurement interval.

In Fig. 7, the pressure sensor 112 is shown as force sensing resistor $R_{FSR}$ placed in parallel with resistor $R_{MAX}$, giving

$$R_A = R_{FSR} \| R_{MAX} = \frac{R_{FSR} R_{MAX}}{R_{FSR} + R_{MAX}} \tag{3}$$

This limits the maximum value of $R_A$, as $R_{FSR} \to \infty$ for zero force, which would result in a waveform period $T$ exceeding $T_{MEAS}$. A known reference resistance $R_{REF}$ is used for $R_B$.

Combining (1), (2), and (3) and solving for force F gives

$$F = \left[ R_0 \left( \frac{1}{R_{REF}} \left[ \frac{1-\delta}{2\delta - 1} \right] - \frac{1}{R_{MAX}} \right) \right]^{-1/x} \tag{4}$$

in which $R_{REF}$ and $R_{MAX}$ are known, and best-fit parameters $R_0$ and $x$ can be determined from initial measurements.

The embodiment of Fig. 7 was analyzed for accuracy over forces corresponding to a pressure range of 20 to 350 mm Hg. To assess tolerance of this approach to variation in the

FSR characteristic, four different sensors were used for measurements. System parameters and results are summarized in Table I. The upper plot in Fig. 8 shows calculated pressure from (4) as a function of the known applied pressure. Each of the four sensors is represented in a different color. The dashed lines indicate calculated pressure using the nominal FSR parameters of (1); the wide sensor-to-sensor variability of parameters is apparent. The solid lines show results after calibration, using a least-squares determination of best-fit values for $R_0$ and $x$ from (1) for each sensor. The lower plot in Fig. 8 shows the measurement error (the difference between the calculated pressure and actual applied pressure) as a fraction of the 350 mm Hg full scale. Despite the wide variation in initial uncalibrated performance, the model of (1) enables accuracy within ±3% for calibrated output.

In accordance with various embodiments, the calibration curve can be corrected for variation due to temperature. In some embodiments, the system can correct the slope or offset of the calibration curve itself as a function of temperature measured, for example, using a temperature sensor 114 as described above. In some embodiments, the system can apply a correction to the data based upon the measured temperature. For example, the system can apply an absolute or percentage shift in the obtained pressure values for each degree of temperature change with respect to the temperature at which the calibration occurred.

As shown in Fig. 9, the pressure sensor of certain embodiments of a sensor device 110 according to the present disclosure can be a capacitive sensor 132. In some embodiments, the capacitive sensor 132 can be used as an antenna to transmit and receive information. In these embodiments, the sensor device 110 can also include a multiplexing unit 134 that can switch the function of the capacitive sensor 132 from antenna-like (*i.e.,* transmitting and receiving information) to sensor-like (*i.e.*, measuring capacitance to determine pressure values). The multiplexing unit 134 can be under the control of a microprocessor 135. In some embodiments, the signal transmitted or received at the capacitive sensor 132 can be demodulated by the pressure sensor readout 122 or the multiplexing unit 134 to provide information indicative of the pressure on the capacitive sensor 132. The communications interface 118 can include a portion that senses the quality of impedence matching to the capacitive sensor 132 acting as an antenna. The quality of impedence matching can be correlated to the pressure applied to the capacitive sensor.

Fig. 10 illustrates a schematic of a portion of a sensor device including components to enable a service connection in accordance with some embodiments of the present application. In some embodiments, the use of a service connection or secondary communication method can enable communication with the sensor device even if the primary connection method is disabled. The sensor device can include a near field communications (NFC) component 128 that can be activated using an external service connection device 180 across the moisture barrier or seal. In some embodiments, the near field communications component can be an RFID or other sensor that is latent until powered by the external device. In some embodiments, the microcontroller 135 can receive or transmit data through the near field communications module 128 to the service connection 180. The sensor device can also include a power extraction module 121 that can extract power from the service connection 180 and deliver the power to a power conditioning unit 131 that may be connected to a power source 111 such as a battery.

Because the systems and methods described herein are often located at the position where a pressure ulcer is likely to occur (for example, at a bony prominence), the sensor device must be able to withstand large pressures over a period of time. However, the systems applied to these locations must be comfortable enough for long-term wear on a user's body to promote compliance in wearing the device. Fig. 11 illustrates an embodiment of a pressure ulcer monitoring system 1100 applied to a heel of a user. The pressure ulcer monitoring system 1100 can include a sensor device 1110, an electronics unit 1150, and a communication link 1160 (such as a cable or flexible band in some embodiments) between the sensor device 1110 and electronics unit 1150. In some embodiments, the sensor device 1110 can include sensors while the electronics unit 1150 can include the associated integrated circuit elements for the system 1100. By spatially separating the sensor device 1110 from the accompanying electronics unit 1150, the integrated circuit elements in the electronics unit 1150 are located outside the high-pressure zone (thus reducing the likelihood of damage) where the user is less likely to feel them during normal activities.

Similar to the sensor device 110 described above with relation to Fig. 1, the sensor device 1110 can include the pressure sensor 112, the temperature sensor 114, the moisture sensor 116, or the light sensor 113. In accordance with various embodiments, the sensor device 1110 can conform to the portion of the body to which it is affixed. To accommodate portions of the body that are highly curved such as, for example, the heel or elbow, the sensor device 1110 can flex or bend in one or two directions to conform to the curved body portion. In some embodiments, the sensor device 1110 can have a first maximum bend radius 1111 (i.e., minimum radius of curvature) with respect to a first dimension of the device and a second maximum bend radius 1113 (i.e., minimum radius of curvature) with respect to a second dimension of the device. When the sensor device 1110 is bent by less than the first bend radius along the first direction and less than the second bend radius along the second direction, the sensors included within the sensor device 1110 will still function properly. In certain embodiments, the sensor device is manufactured to have a surface area that is configured with a selected radius of curvature in one, two or more directions so that it confirms to a specific surface area of the skin of a patient. This is particularly advantageous in embodiments having a sensor array on an individual patch as each sensor element in the array then has uniform contact pressure to the skin surface. The radius of curvature can vary within a specific quantitative range for a particular body location. The heel, for example, has a first preferred range, the shoulder has a second range for the radius of curvature, a third body portion as described herein can have a third range of the radius of curvature, etc., where the sensor device is flexible within the indicated range for a given body portion, with each range being different. The system software can detect matrix sensor elements that generate data that indicate poor pressure contact with the skin surface and can remove data from those elements from the analysis. The system can verify that a threshold of operative sensor elements in the array is sufficient to provide accurate diagnostic analysis. The system can prompt the user to reapply the sensor device if the threshold is not reached within the entire array or a subset of elements in areas of the array.

In some embodiments, the electronics unit 1150 can include the power source 110, the interface electronics 117, the digital processing 115, the wireless communication interface 118, or the antenna 119. In various embodiments, the electronics unit 1150 can be affixed on the user’s body a short distance from the sensor device 1110. In some embodiments, the electronics unit 1150 can be located less than 5 cm, 10 cm, or 15 cm from the sensor device 1110. Some components in the electronics unit 1150 such as integrated circuits can have a thickness or shape that makes them prominent in the form factor of the unit even in the presence of surrounding cushioning. As such, pressure tends to focus on these elements and cause pre-mature breakage. Moreover, the user tends to find these “high points” in the electronics unit 1150 to be painful points. To mitigate these issues, the electronics unit 1150 can be located in an unobtrusive location on the body that experiences pressure only infrequently. For example, the electronics unit 1150 can be located in the depression in the hindfoot midway between the heel and the inner ankle.

The communication link 1160 can be wired or wireless in various embodiments of the present disclosure. For example, the communication link 1160 can utilize wireless communications methods such as near-field communications, BlueTooth™, or variants of 802.11 (wi-fi) to communicate. In some embodiments, the communication link 1160 can be facilitated through a network as described above with reference to Figs. 6B and 6C. The communications link 1160 can be a physical, wired connection in some embodiments. In some embodiments, a wire connecting the electronics unit 1150 and the sensor device 1110 can be insulated or otherwise treated to protect against moisture or friction that arise due to movement of the user.

Figs. 12A and 12B illustrate alternative embodiments of sensor devices 110 having pressure sensors 112 in accordance with some embodiments of the present application. In accordance with various embodiments, the pressure sensor 112 can include a single active area as shown above with reference to Fig. 1 or can include an array of pressure-sensitive areas as shown in Figs. 12A and 12B. In Fig. 12A, the pressure sensor 112 includes an array of pressure-sensitive areas 1212 wherein an area of each of the pressure sensitive areas is the same. In Fig. 12B, the pressure sensor 112 includes an array of pressure-sensitive areas 1212 wherein an area of the each of the pressure-sensitive areas is not necessarily the same. For example, the sensing area of the pressure-sensitive area 1212a at the edge of the pressure sensor 112 is lower than the sensing area of the pressure-sensitive area 1212b near the middle of the pressure sensor 112.

In some embodiments, the sensor device 110 can include a radio-frequency identification device (RFID) chip 1204. The RFID chip 1204 can communicate with a scanner 604 of the tablet 600 or computing system as described above with reference to Figs. 6D and 6E. The RFID chip can include unique identifying information for the sensor device 110 such as a serial number. In some embodiments, the scanner 604 of the tablet 600, such as a machine reader, can receive the unique identifying information and can transmit instructions to the sensor device 110 to initialize or power up to prepare to receive further instructions.

In some embodiments, the sensor device 110 can include a machine-readable pattern 1206 that encodes unique identifying information. For example, the machine-readable pattern 1206 can include a one-dimensional pattern such as a barcode or a two-dimensional pattern such as a quick response code. In various embodiments, the scanner 604 of the tablet 600 can scan the machine-readable pattern 1206 (e.g., by imaging the pattern using an imaging device) to gather the unique identifying information and identify the sensor unit 110.

In various embodiments, the pressure-sensitive areas 1212 of the pressure sensor 112 can be implemented as separate devices or as neighboring areas integrated into a single device. As an example of the former, the pressure sensor 112 can include an array of discrete aligned sensing elements that individually output data values. Alternatively, the array of pressure-sensitive areas can be implemented as, for example, addressable portions of a larger sensing element. In some embodiments, the pressure sensor 112 can have between 12 and 128 pressure-sensitive areas or sensor elements, more preferably, between 50 and 70 pressure-sensitive areas. In some embodiments, a dimension (e.g., length or width) of each pressure-sensitive area or sensor element can be in a range from 0.5 to 1 cm. Data collected from arrayed pressure-sensitive areas such as those depicted in Figs. 12A and 12B can be displayed in a two-dimensional format to indicate locations on the body portion to which the sensor device 1110 is attached where pressure is higher or lower. A graphical representation of this “pixelated” pressure data is described above with reference to Fig. 6D.

In some embodiments, the system can separate data by subregion of pressure-sensitive areas or elements and treat the data differently by subregion. For example, the system can threshold different subregions differently. In some embodiments, the system can interrogate the sensor device 110 periodically and take action if no pressure has been measured for a period of time. For example, if no pressure has been measured over a period of several minutes, the system can conserve power by subsequently polling only a subregion of the array of pressure-sensitive elements rather than gathering data from all elements.

In some embodiments, systems and methods described herein can utilize the array of pressure-sensitive areas or pressure elements to optimize placement of the sensor device 110 on the patient. For example, if a particular subregion to the edge of the pressure sensor 112 senses pressure consistently while another region does not, the location of the sensor device 110 may need to be adjusted on the patient to position the peak pressure in the center of the pressure sensor 112. In some embodiments, the system can detect off-center pressure application and provide a notice to a user (for example, through the GUI 602) that the location of the sensor device 110 should be adjusted.

A preferred embodiment can utilize a neural network as an adaptive computational system whereby data is accumulated for a particular patient, and/or particular classes of patients and/or classes of body locations and/or therapeutic indications. Processors, such as graphics processors, available from Nvidia Corporation, Santa Clara California, are integrated into the tablet system, for example, or alternatively, can be connected by a communication network to a plurality of individual systems associated with a given network such as a hospital or group of networked hospitals, clinics or other patient treatment sites. Each sensor array can generate a two dimensional distribution or image of data that varies over time. The data can be integrated over time by the neural network processor.

While the present inventive concepts have been described with reference to particular embodiments, those of ordinary skill in the art will appreciate that various substitutions and/or other alterations may be made to the embodiments without departing from the spirit of the present inventive concepts. Accordingly, the foregoing description is meant to be exemplary and does not limit the scope of the present inventive concepts.

A number of examples have been described herein. Nevertheless, it should be understood that various modifications may be made. For example, suitable results may be achieved if the described techniques are performed in a different order and/or if components in a described system, device, or method are combined in a different manner and/or replaced or supplemented by other components or their equivalents. Accordingly, other implementations are within the scope of the present inventive concepts.

# CLAIMS

1. A pressure ulcer monitoring system comprising:

a sensor device including a pressure sensor that measures pressure at a tissue surface location on a patient; and

a data processor that receives pressure data from the pressure sensor, the data processor being configured to compute an accumulated pressure value during one or more time periods and, based on the computed accumulated pressure value and the location of the sensor device on the patient, a pressure ulcer diagnostic function.

2. The system of claim 1 further comprising a memory that stores patient data including the location of the pressure sensor on the patient.

3. The system of claim 2 wherein the patient data includes one or more of an age of the patient, a medication of the patient, a body mass of the patient, a blood oxygenation level of the patient and a blood pressure of the patient.

4. The system of any of claims 2-3 wherein the data processor is mounted on a flexible circuit board within the sensor device that determines a diagnostic function based on the patient data.

5. The system of any of claims 1-4 wherein the data processor further comprises a neural network that receives patient data from a plurality of patients and generates a diagnostic function such that the data processor determines the pressure ulcer diagnostic value with the diagnostic function.

6. The system of any of claims 1-5 wherein the monitoring system comprises a conformable patch having a uniform thickness, the patch being attachable to a body location on a patient, the patch including the sensor device, data processor, a power source, a wireless transmitter and an adhesive that attaches the patch to the tissue surface.

7. The system of any of claims 1-6 wherein the monitoring system comprises:

a first conformable patch having a uniform thickness and including the sensor device and an adhesive that attaches the patch to the tissue surface, the first conformable patch being attachable to a body location on a patient; and

a second conformable patch including the data processor, a power source, a wireless transmitter, and an adhesive that attaches the patch to a second surface near the tissue surface,

wherein the first conformable patch and second conformable patch are communicatively coupled.

8. The system of claim 7, wherein a distance between the first conformable patch and the second conformable patch is less than 15 centimeters.

9. The system of claim 7, wherein the first conformable patch and second conformable patch are communicatively coupled through a wireless connection.

10. The system of claim 7, wherein the first conformable patch and second conformable patch are communicatively coupled through a wired connection.

11. The system of any of claims 7-10 wherein the uniform thickness of the first conformable patch is less than 4 mm.

12. The system of claim 11, wherein the uniform thickness of the first conformable patch is less than 3 mm.

13. The system of claim 12, wherein the uniform thickness of the first conformable patch is less than 2 mm.

14. The system of any of claims 1-13, further comprising a second sensor device including a second pressure sensor that measures pressure at a second tissue surface on the patient.

15. The system of claim 14, wherein the first sensor device and the second sensor device are communicatively coupled to a computing device or a mobile communications device.

16. The system of any of claims 1-15, wherein the pressure sensor comprises an array of pressure-sensitive areas.

17. The system of any of claims 1-16, wherein the sensor device comprises a cover.

18. The system of either of claims 1 or 2, wherein the data processor filters at least one of the pressure data and the patient data to eliminate anomalous data or noise.

19. The system of any of claims 1-18, wherein the pressure sensor comprises a polymer thick-film device or a capacitive sensor.

20. The system of any of claims 1-19, wherein the sensor device further comprises a moisture sensor.

21. The system of any of claims 1-20, wherein the sensor device further comprises a temperature sensor.

22. The system of any of claims 1-21, wherein the sensor device further comprises a light source and a light sensor.

23. The system of any of claims 1-22, wherein the sensor device further comprises an antenna to send or receive communications with a computing device.

24. The system of any of claims 1-23, wherein the sensor device is water resistant.

25. The system of any of claims 1-24 wherein the sensor device has a surface area of less than 4 $cm^2$.

26. The system of any of claims 1-25, wherein the data processor is configured to display the accumulated pressure on a display of a computing device.

27. The system of any of claims 1-26, wherein the sensor device has a surface area that is configured with a selected radius of curvature in at least one direction such that the sensor device conforms to a specific surface area of the patient.

28. A method of determining a pressure ulcer condition of a patient comprising:

entering patient data to measure a pressure ulcer condition of a patient;

selecting, with a data processor, a pressure ulcer diagnostic function of the patient using the patient data;

detecting pressure data with a sensor device having a pressure sensor at a tissue surface location on the patient; and

computing a diagnostic value using the measured pressure data and the diagnostic function.

29. The method of claim 28 further comprising attaching a first conformable patch at the location on the patient, the patch comprising the sensor device and a flexible circuit device connected to the pressure sensor, the flexible circuit device including a wireless transmitter.

30. The method of claim 27, further comprising

attaching a first conformable patch at the location on the patient, the first conformable patch comprising the sensor device; and

attaching a second conformable patch at a second location near the location of the first conformable patch, the second conformable patch comprising a flexible circuit device including a wireless transmitter, the flexible circuit device communicatively coupled to the pressure sensor.

31. The method of claim 30, wherein the distance between patches once attached is less than 15 centimeters.

32. The method of claim 30, wherein the flexible circuit device is communicatively coupled to the pressure sensor through a wireless connection.

33. The method of claim 30, wherein the flexible circuit device is communicatively coupled to the pressure sensor through a wired connection.

34. The method of any of claims 29-33, wherein the first conformable patch has a uniform thickness that is less than 4 mm.

35. The method of claim 34, wherein the uniform thickness is less than 3 mm.

36. The method of claim 35, wherein the uniform thickness is less than 2 mm.

37. The method of any of claims 28-36, further comprising detecting pressure data with a second sensor device having a second pressure sensor at a second tissue surface location on the patient.

38. The method of claim 37, wherein the first sensor device and the second sensor device are communicatively coupled to a computing device or a mobile communications device.

39. The method of claim 38, further comprising displaying at least one of the pressure data or the diagnostic value on a display of the computing device or mobile communications device.

40. The method of any of claims 28-39, wherein detecting pressure data with a sensor device having a pressure sensor includes detecting pressure data from an array of pressure-sensitive areas or pressure elements of the pressure sensor.

41. The method of any of claims 28-40, further comprising filtering at least one of the pressure data and the patient data to eliminate anomalous data or noise.

42. The method of any of claims 28-41, wherein the pressure sensor comprises a polymer thick-film device or a capacitive sensor.

43. The method of any of claims 28-42, further comprising detecting relative humidity data with a moisture sensor of the sensor device.

44. The method of any of claims 28-43, further comprising detecting temperature data using a temperature sensor of the sensor device.

45. The method of any of claims 28-44, further comprising detecting colorimetric data using a light source and a light sensor of the sensor device.

46. The method of any of claims 28-45, further comprising sending or receiving communications to or from a computing device using an antenna of the sensor device.

47. The method of any of claims 28-46, wherein the sensor device is water resistant.

48. The method of any of claims 28-47 wherein the sensor device comprises a patch having a thickness of less than 2 mm and a surface area less than 4 $cm^2$.

49. The method of any of claims 28-48 further comprising actuating data storage and/or data transmission in response to a sensed pressure and time duration.

50. The method of any of claims 28-31 wherein the patient data includes one or more of an age of the patient, a medication of the patient, a body mass of the patient, a blood oxygenation level of the patient and a blood pressure of the patient.

51. The method of any of claims 28-50, further comprising selecting the sensor device having a surface area that is configured with a selected radius of curvature in at least one direction such that the sensor device conforms to a specific surface area of the patient.

52. A pressure ulcer monitoring system comprising:

a sensor device including a pressure sensor that measures pressure at a tissue surface location on a patient;

a first data processor connected to the pressure sensor, the data processor receiving pressure data from the pressure sensor, the data processor being configured to compute an accumulated pressure value during one or more time periods and, based on the computed accumulated pressure value and the location of the sensor device on the patient, a pressure ulcer diagnostic function; and

a processor housing having a wireless receiver that receives pressure sensor data from the sensor device, the processor housing having a second data processor connected to the wireless receiver, a battery, and a touchscreen display configured to display pressure data from one or more pressure sensors positioned on the patient.

53. The system of claim 52 further comprising a memory that stores patient data including the location of the pressure sensor on the patient and wherein the patient data includes one or more of an age of the patient, a medication of the patient, a body mass of the patient, a blood oxygenation level of the patient and a blood pressure of the patient.

54. The system of any of claims 52-53 wherein the data processor is mounted on a flexible circuit board within the sensor device that determines a diagnostic function based on the patient data.

55. The system of any of claims52-54 wherein the data processor further comprises a neural network that receives patient data from a plurality of patients and generates a diagnostic function such that the data processor determines the pressure ulcer diagnostic value with the diagnostic function.

56. The system of any of claims 52-55 wherein the monitoring system comprises a conformable patch having a uniform thickness, the patch being attachable to a body location on a patient, the patch including the sensor device, data processor, a power source, a wireless transmitter and an adhesive that attaches the patch to the tissue surface.

57. The system of any of claims 52-56 wherein the monitoring system comprises:

a first conformable patch having a uniform thickness and including the sensor device and an adhesive that attaches the patch to the tissue surface, the first conformable patch being attachable to a body location on a patient; and

a second conformable patch including the data processor, a power source, a wireless transmitter, and an adhesive that attaches the patch to a second surface near the tissue surface,

wherein the first conformable patch and second conformable patch are communicatively coupled.

58. The system of claim 57, wherein a distance between the first conformable patch and the second conformable patch is less than 15 centimeters.

59. The system of claim 57, wherein the first conformable patch and second conformable patch are communicatively coupled through a wireless connection.

60. The system of claim 57, wherein the first conformable patch and second conformable patch are communicatively coupled through a wired connection.

61. The system of any of claims 57-60 wherein the uniform thickness of the first conformable patch is less than 4 mm.

62. The system of claim 61, wherein the uniform thickness of the first conformable patch is less than 3 mm.

63. The system of claim 62, wherein the uniform thickness of the first conformable patch is less than 2 mm.

64. The system of any of claims 52-63, further comprising a second sensor device including a second pressure sensor that measures pressure at a second tissue surface on the patient.

65. The system of claim 64, wherein the first sensor device and the second sensor device are communicatively coupled to the tablet that comprises a computing device or a mobile communications device.

66. The system of any of claims 52-65, wherein the pressure sensor comprises an array of pressure-sensitive areas.

67. The system of any of claims 52-66, wherein the sensor device comprises a sensor array having a plurality of sensor elements.

68. The system of either of claims 52 or 53, wherein the first data processor filters at least one of the pressure data and the patient data to eliminate anomalous data or noise.

69. The system of any of claims 52-68, wherein the pressure sensor comprises a polymer thick-film device or a capacitive sensor.

70. The system of any of claims 52-69, wherein the sensor device further comprises a moisture sensor.

71. The system of any of claims 52-70, wherein the sensor device further comprises a temperature sensor.

72. The system of any of claims 52-71, wherein the sensor device further comprises a light source and a light sensor.

73. The system of any of claims 52-72, wherein the sensor device further comprises an antenna to send or receive communications with the processor housing, the processor being configured to provide a unitary interface to control one or more sensor devices being used to monitor a patient, each sensor device having a corresponding display window and threshold adjustment responsive to a touch gesture on the touchscreen display.

74. The system of any of claims 52-73, wherein the sensor device is water resistant.

75. The system of any of claims 52-74 wherein the sensor device has a surface area of less than 4 $cm^2$.

76. The system of any of claims 52-75, wherein the second data processor is configured to display the accumulated pressure on a display of a computing device.

77. The system of any of claims 52-76, wherein the sensor device has a surface area that is configured with a selected radius of curvature in at least one direction such that the sensor device conforms to a specific surface area of the patient.

78. The system of any of claims 52-77, further comprising a machine reader to read data from the sensor device.

79. The system of claim 78 wherein the machine reader reads an RFID chip of the sensor device.

80. The system of any of claims 52-79 wherein a housing of the data processor comprises a tablet.

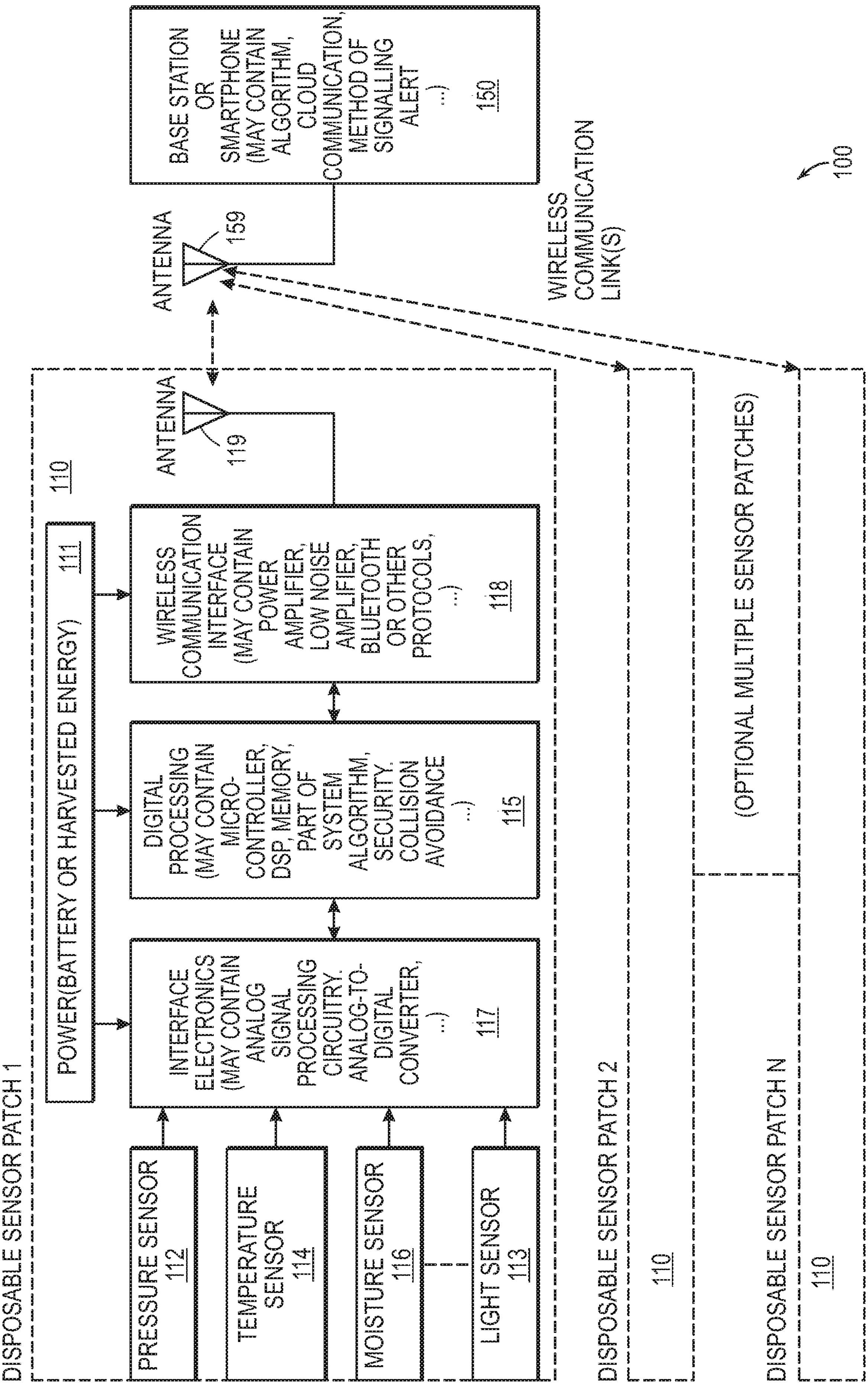
DISPOSABLE SENSOR PATCH 1
110
POWER(BATTERY OR HARVESTED ENERGY) 111
PRESSURE SENSOR 112
TEMPERATURE SENSOR 114
MOISTURE SENSOR 116
LIGHT SENSOR 113
INTERFACE ELECTRONICS (MAY CONTAIN ANALOG SIGNAL PROCESSING CIRCUITRY. ANALOG-TO-DIGITAL CONVERTER, ...) 117
DIGITAL PROCESSING (MAY CONTAIN MICRO-CONTROLLER, DSP, MEMORY, PART OF SYSTEM ALGORITHM, SECURITY, COLLISION AVOIDANCE ...) 115
WIRELESS COMMUNICATION INTERFACE (MAY CONTAIN POWER AMPLIFIER, LOW NOISE AMPLIFIER, BLUETOOTH OR OTHER PROTOCOLS, ...) 118
ANTENNA
119
ANTENNA
159
BASE STATION OR SMARTPHONE (MAY CONTAIN ALGORITHM, CLOUD COMMUNICATION, METHOD OF SIGNALLING ALERT ...) 150
WIRELESS COMMUNICATION LINK(S)
100
DISPOSABLE SENSOR PATCH 2
110
(OPTIONAL MULTIPLE SENSOR PATCHES)
DISPOSABLE SENSOR PATCH N
110

FIG. 1

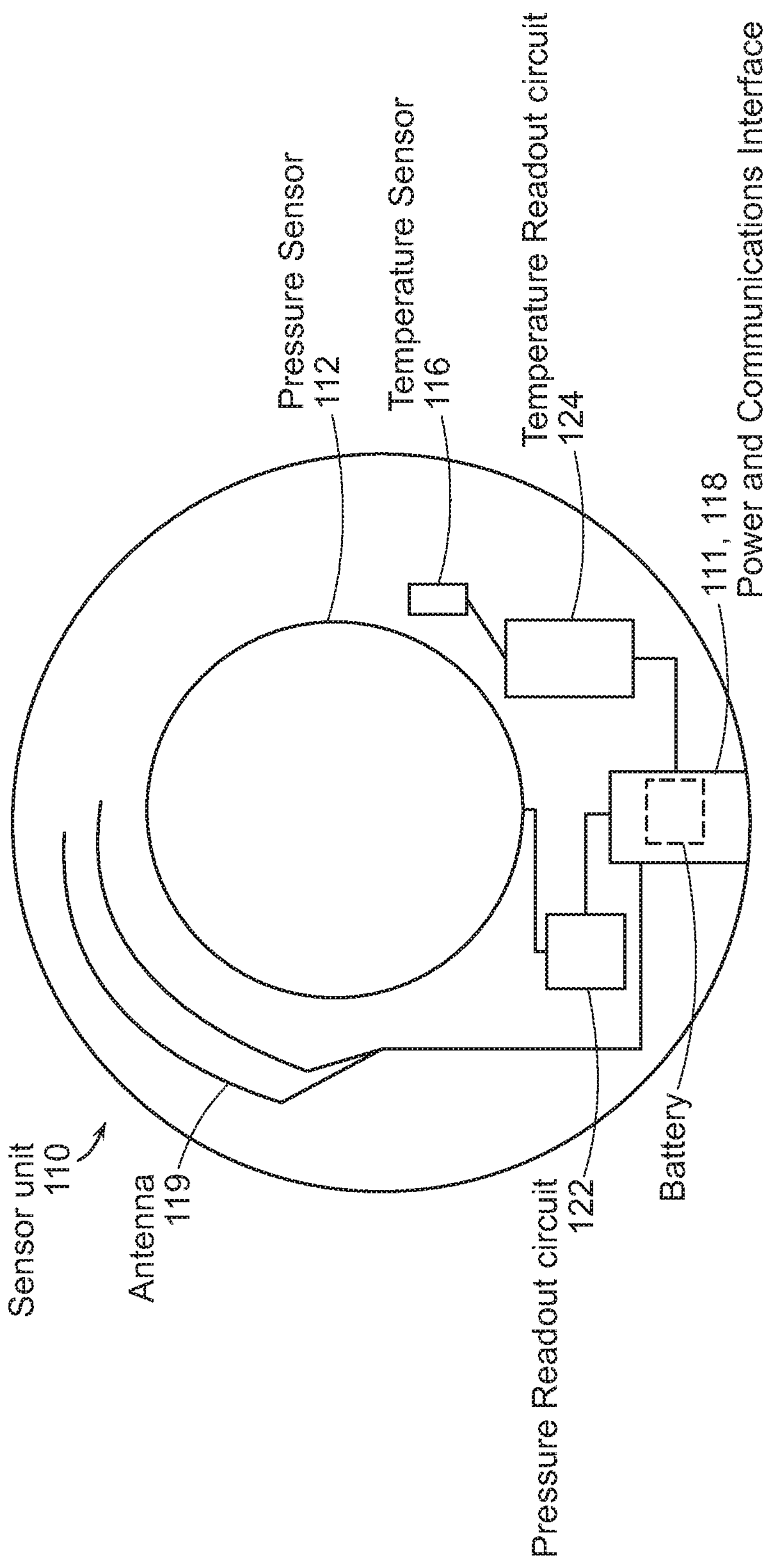
Pressure Sensor
112
Temperature Sensor
116
Temperature Readout circuit
124
111, 118
Power and Communications Interface
Sensor unit
110
Antenna
119
Battery
Pressure Readout circuit
122

FIG. 2A

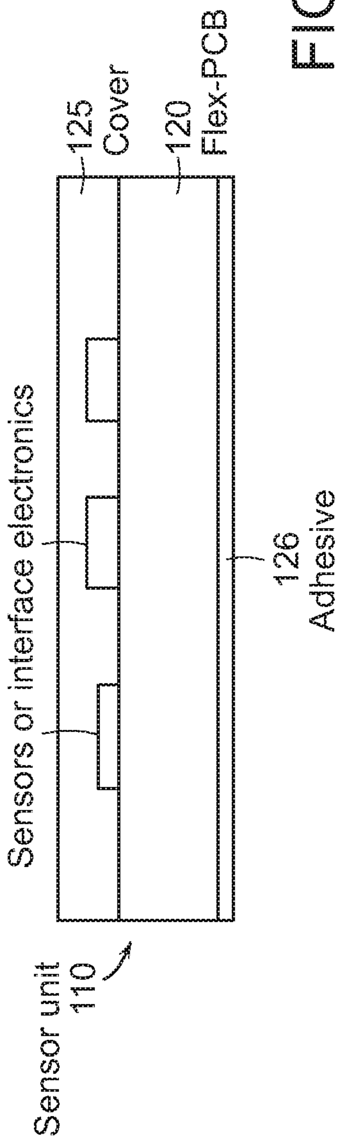
Sensors or interface electronics
125
Cover
120
Flex-PCB
126
Adhesive
Sensor unit
110

FIG. 2B

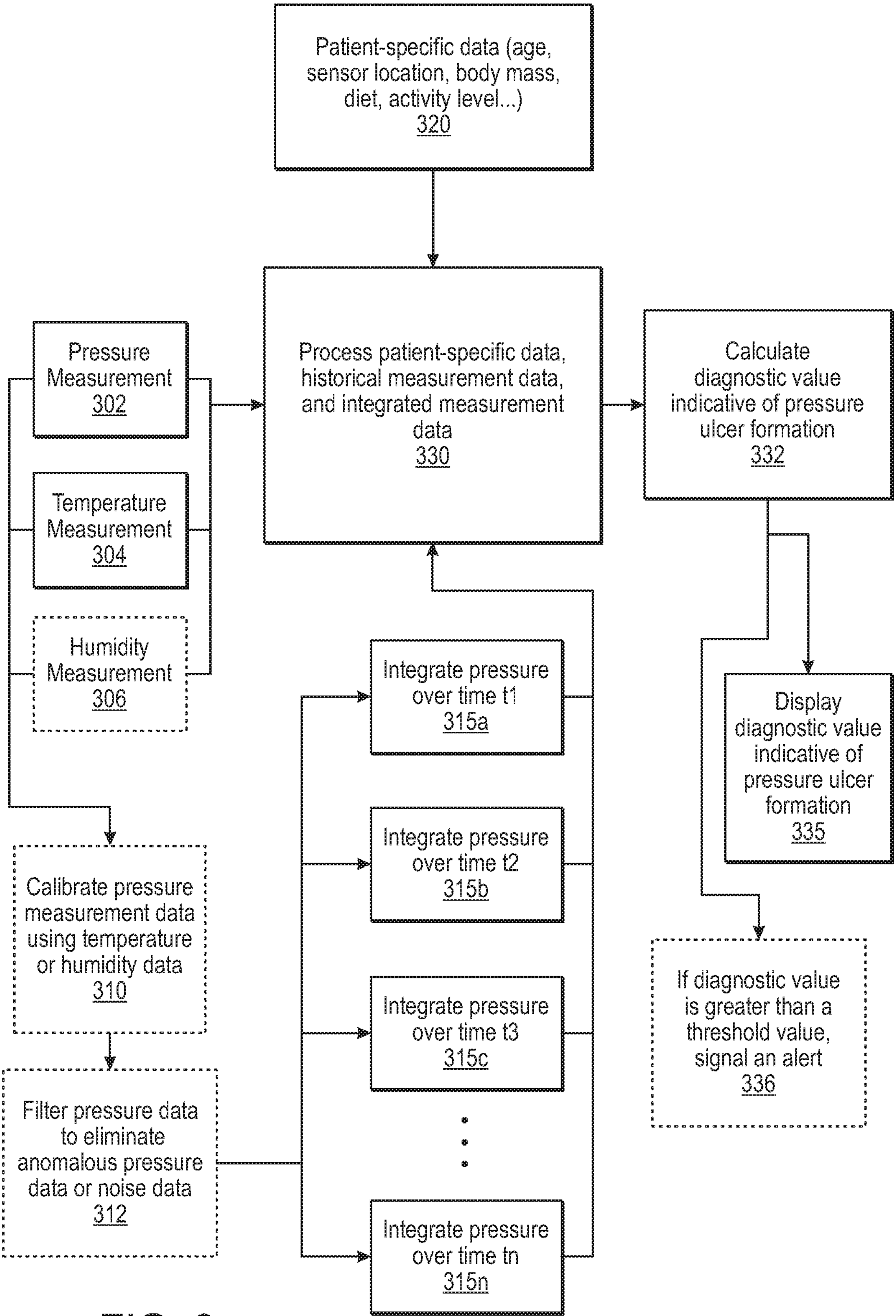
Patient-specific data (age, sensor location, body mass, diet, activity level...)
320
Process patient-specific data, historical measurement data, and integrated measurement data
330
Calculate diagnostic value indicative of pressure ulcer formation
332
Pressure Measurement
302
Temperature Measurement
304
Humidity Measurement
306
Display diagnostic value indicative of pressure ulcer formation
335
Integrate pressure over time t1
315a
Integrate pressure over time t2
315b
Calibrate pressure measurement data using temperature or humidity data
310
If diagnostic value is greater than a threshold value, signal an alert
336
Integrate pressure over time t3
315c
Filter pressure data to eliminate anomalous pressure data or noise data
312
Integrate pressure over time tn
315n

FIG. 3

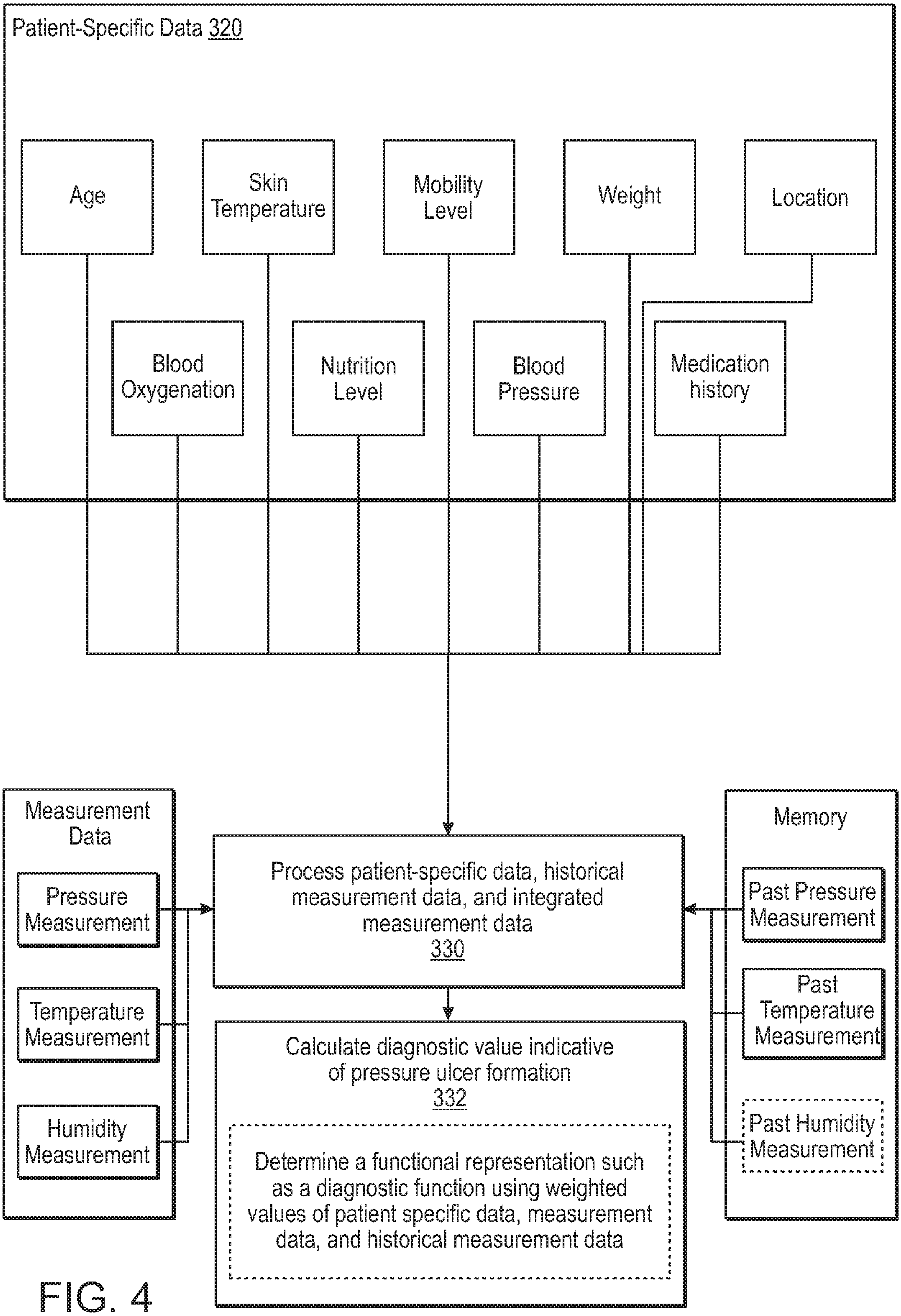
Patient-Specific Data 320
Age
Skin Temperature
Mobility Level
Weight
Location
Blood Oxygenation
Nutrition Level
Blood Pressure
Medication history
Measurement Data
Pressure Measurement
Temperature Measurement
Humidity Measurement
Process patient-specific data, historical measurement data, and integrated measurement data 330
Calculate diagnostic value indicative of pressure ulcer formation 332
Determine a functional representation such as a diagnostic function using weighted values of patient specific data, measurement data, and historical measurement data
Memory
Past Pressure Measurement
Past Temperature Measurement
Past Humidity Measurement

FIG. 4

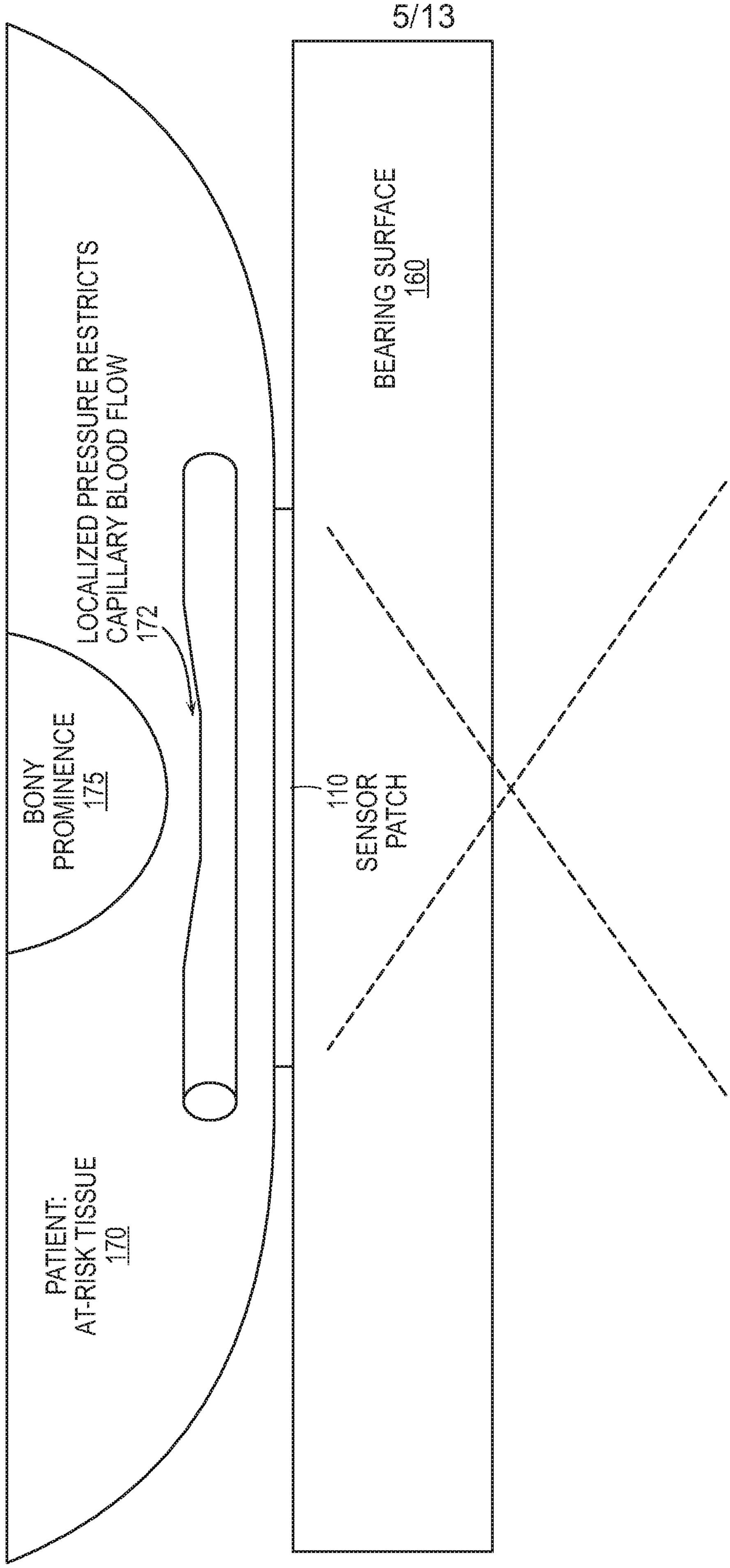
BEARING SURFACE
160
LOCALIZED PRESSURE RESTRICTS
CAPILLARY BLOOD FLOW
172
BONY
PROMINENCE
175
110
SENSOR
PATCH
PATIENT:
AT-RISK TISSUE
170

FIG. 5

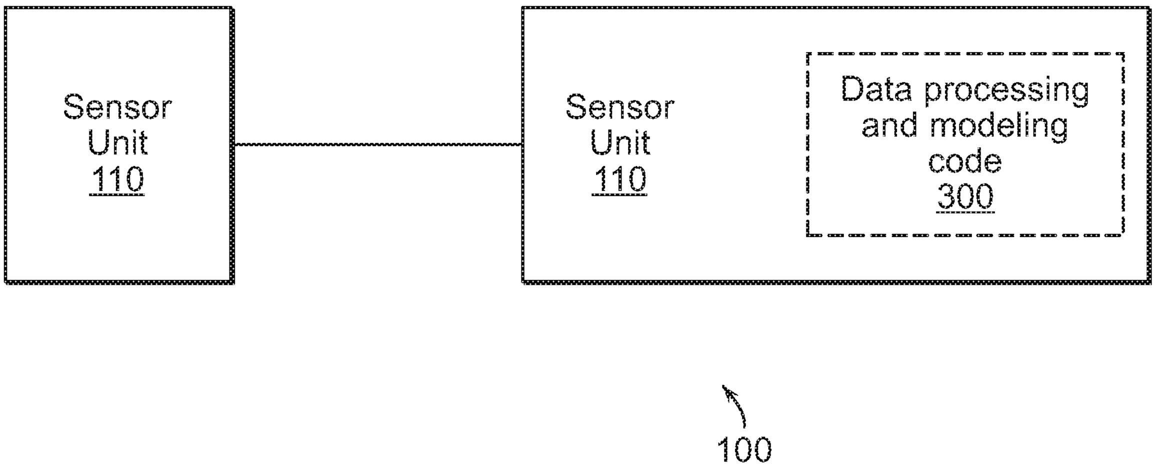
Sensor
Unit
110
Sensor
Unit
110
Data processing
and modeling
code
300
100

FIG. 6A

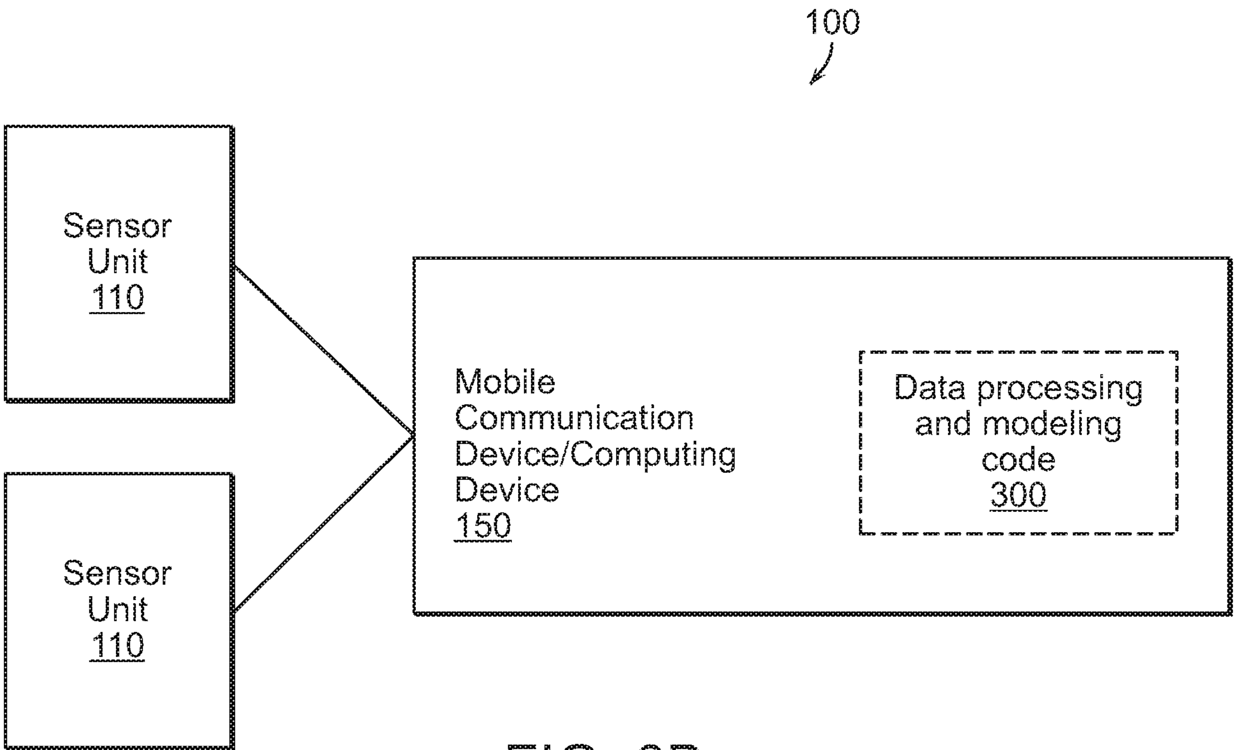
100
Sensor
Unit
110
Sensor
Unit
110
Mobile
Communication
Device/Computing
Device
150
Data processing
and modeling
code
300

FIG. 6B

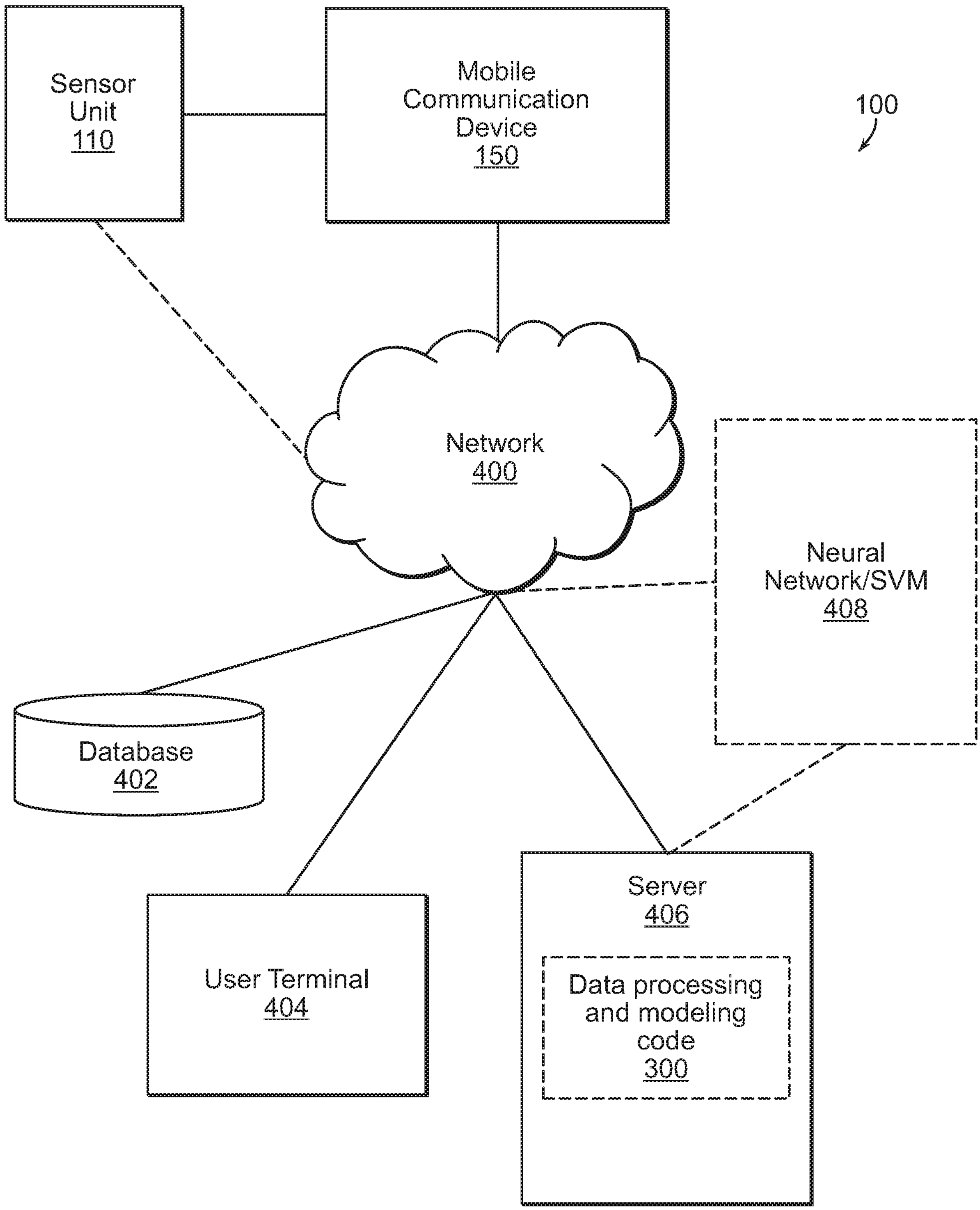
Sensor
Unit
110
Mobile
Communication
Device
150
100
Network
400
Neural
Network/SVM
408
Database
402
Server
406
Data processing
and modeling
code
300
User Terminal
404

FIG. 6C

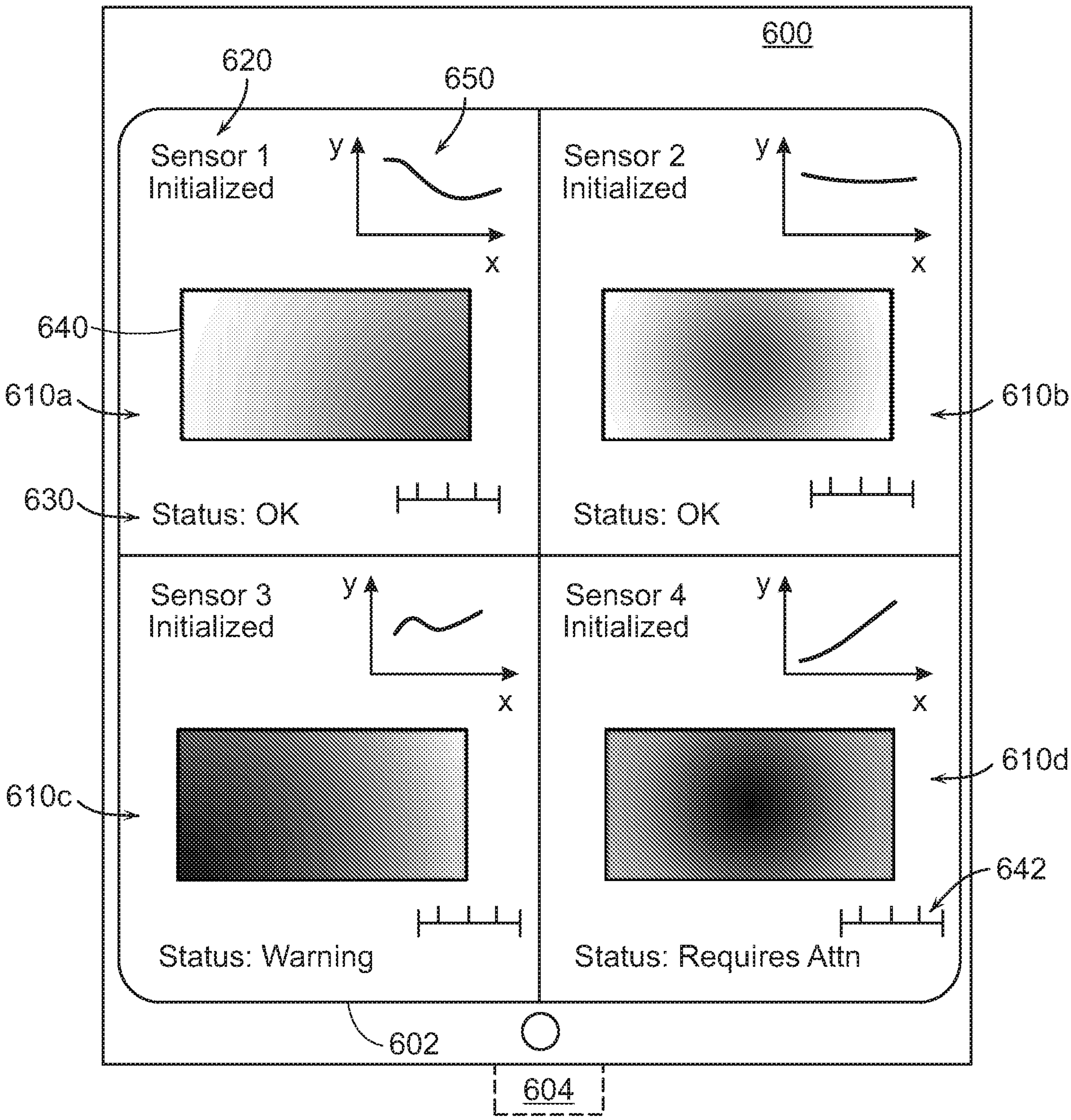
600
620
650
Sensor 1
Initialized
y
x
Sensor 2
Initialized
y
x
640
610a
610b
630
Status: OK
Status: OK
Sensor 3
Initialized
y
x
Sensor 4
Initialized
y
x
610c
610d
642
Status: Warning
Status: Requires Attn
602
604

FIG. 6D

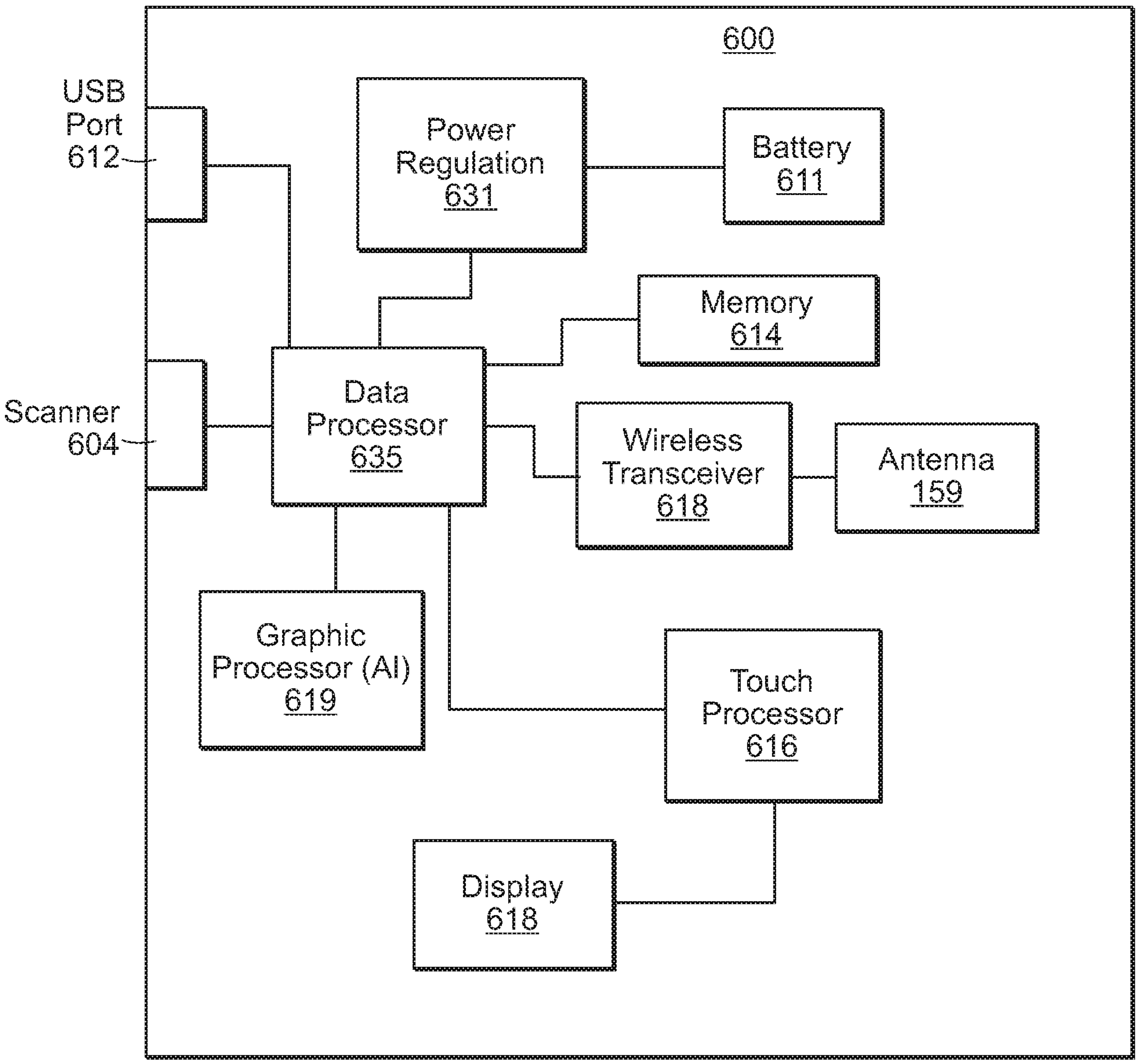
600
USB Port 612
Power Regulation 631
Battery 611
Memory 614
Scanner 604
Data Processor 635
Wireless Transceiver 618
Antenna 159
Graphic Processor (AI) 619
Touch Processor 616
Display 618

FIG. 6E

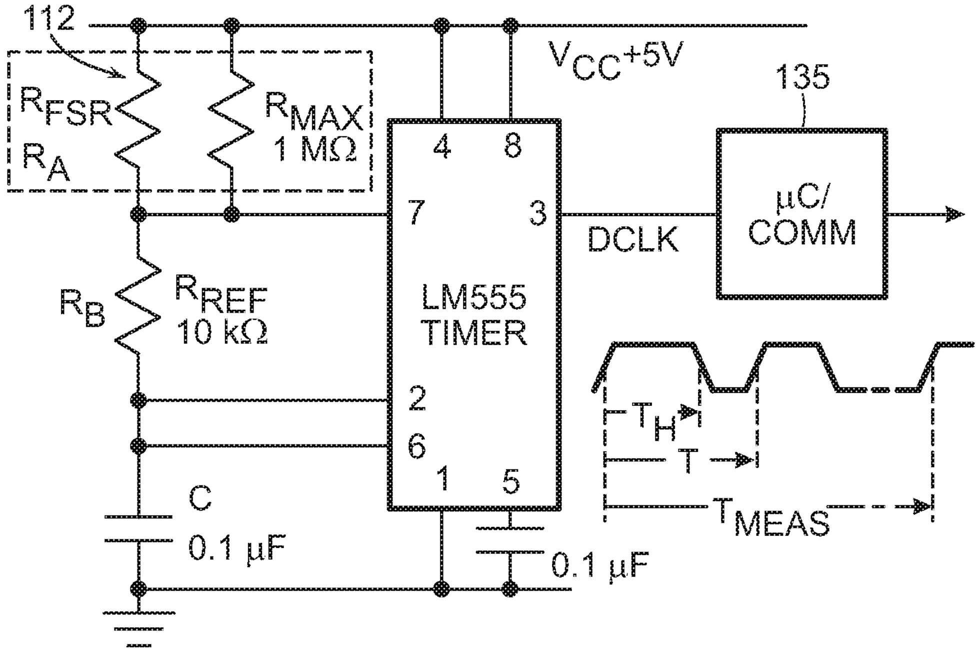
112
$V_{CC}$+5V
135
$R_{FSR}$
$R_A$
$R_{MAX}$
1 MΩ
4
8
7
3
DCLK
μC/
COMM
$R_B$
$R_{REF}$
10 kΩ
LM555
TIMER
2
6
1
5
$T_H$
T
$T_{MEAS}$
C
0.1 μF
0.1 μF

FIG. 7

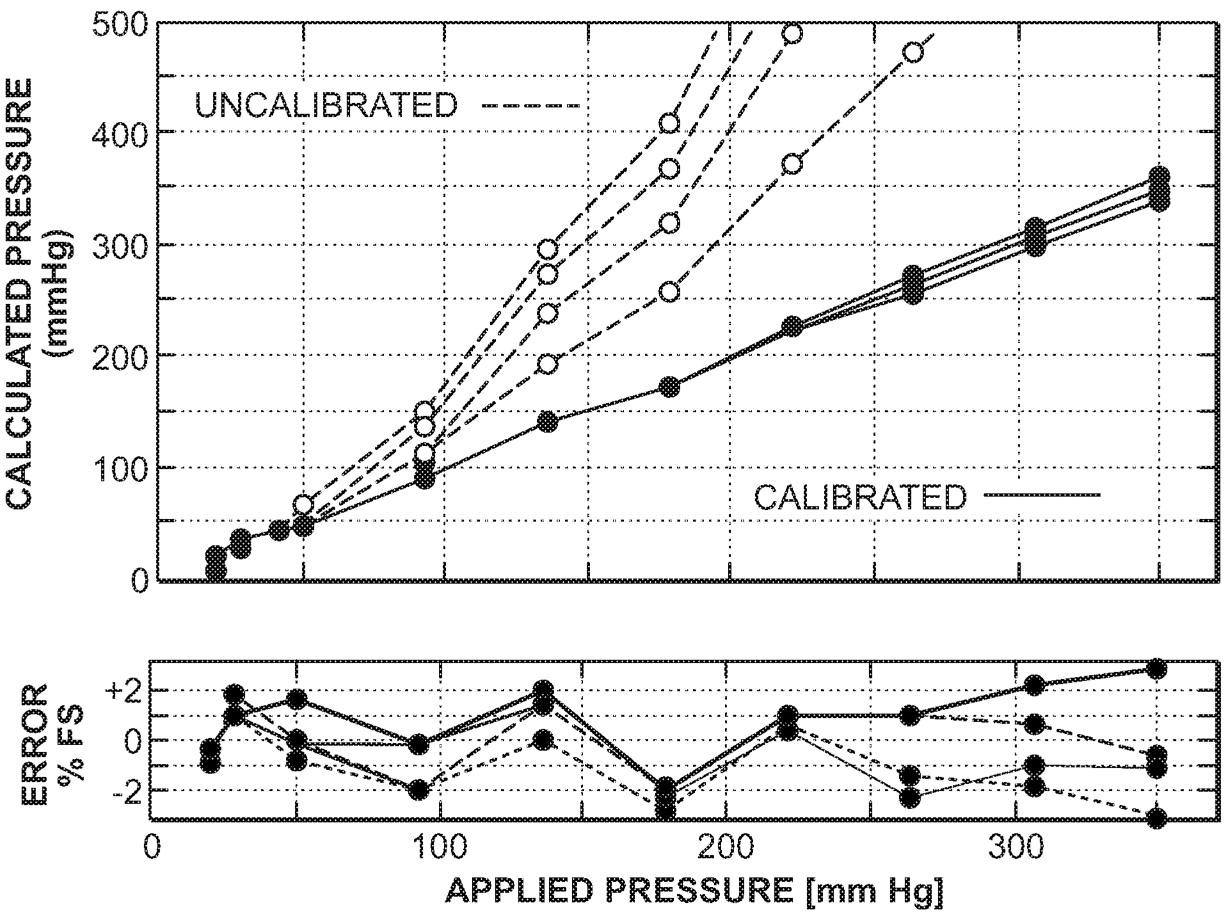
CALCULATED PRESSURE
(mmHg)
UNCALIBRATED
CALIBRATED
ERROR
% FS
APPLIED PRESSURE [mm Hg]

FIG. 8

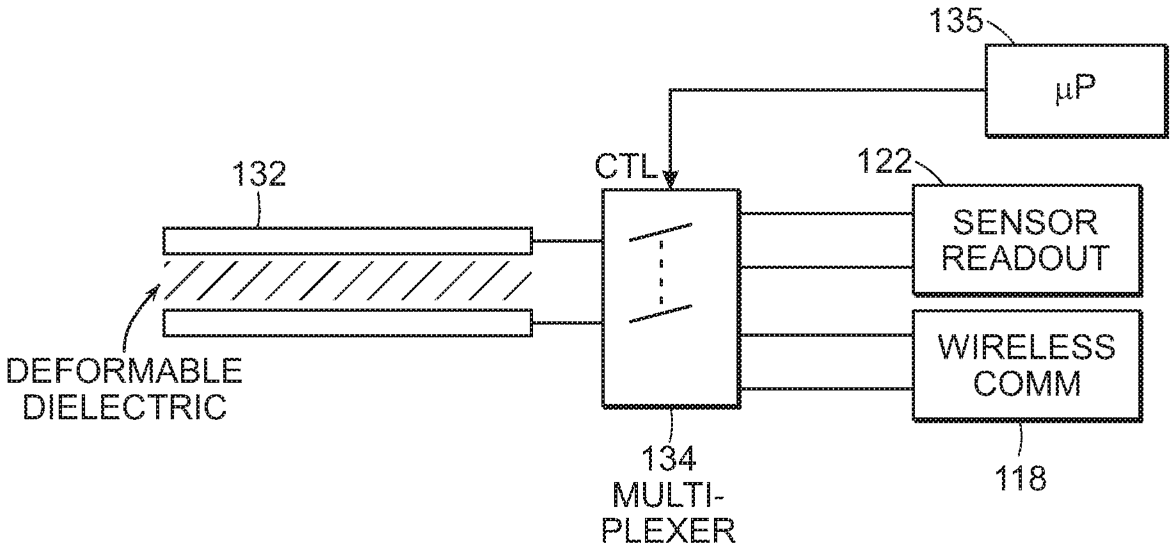
135
µP
CTL
122
132
SENSOR READOUT
WIRELESS COMM
DEFORMABLE DIELECTRIC
134
MULTI-PLEXER
118

FIG. 9

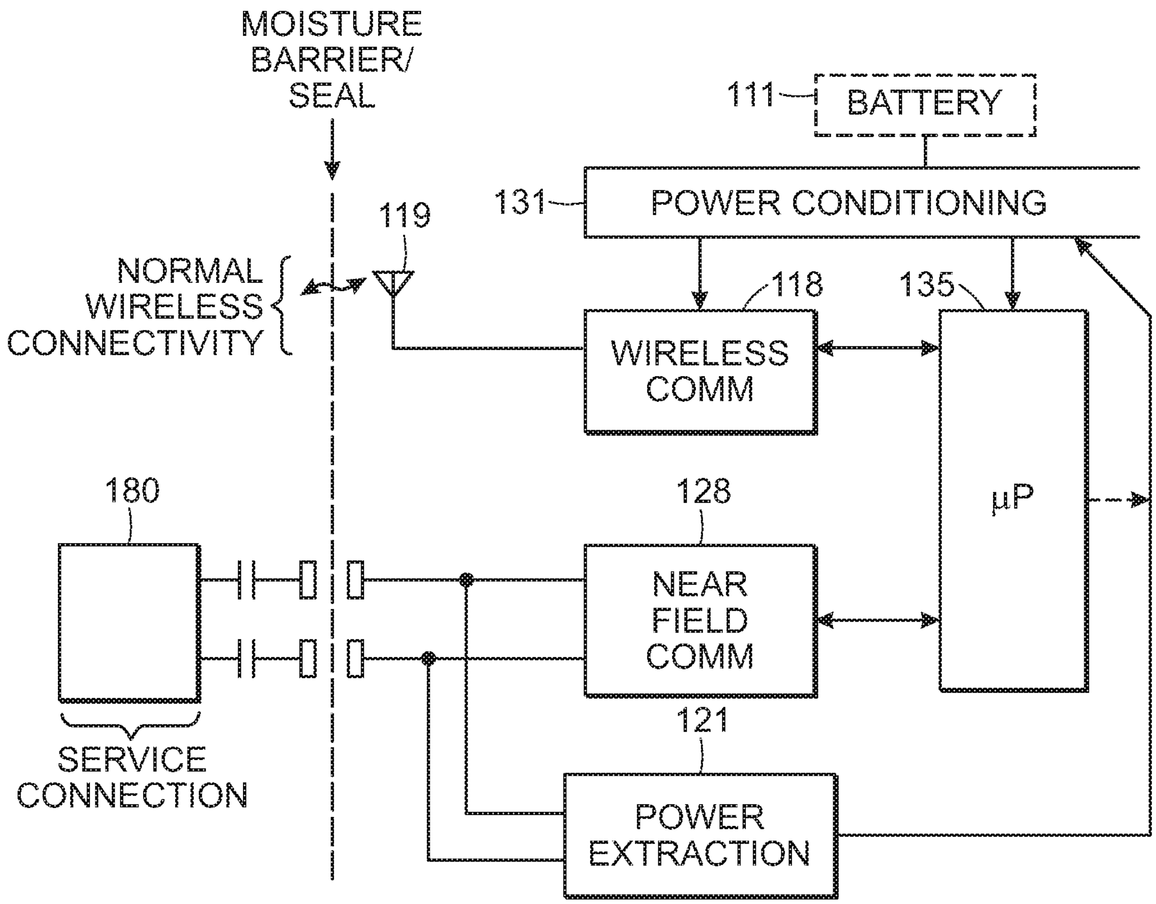
MOISTURE BARRIER/ SEAL
111
BATTERY
131
POWER CONDITIONING
119
NORMAL WIRELESS CONNECTIVITY
118
135
WIRELESS COMM
180
128
µP
NEAR FIELD COMM
121
SERVICE CONNECTION
POWER EXTRACTION

FIG. 10

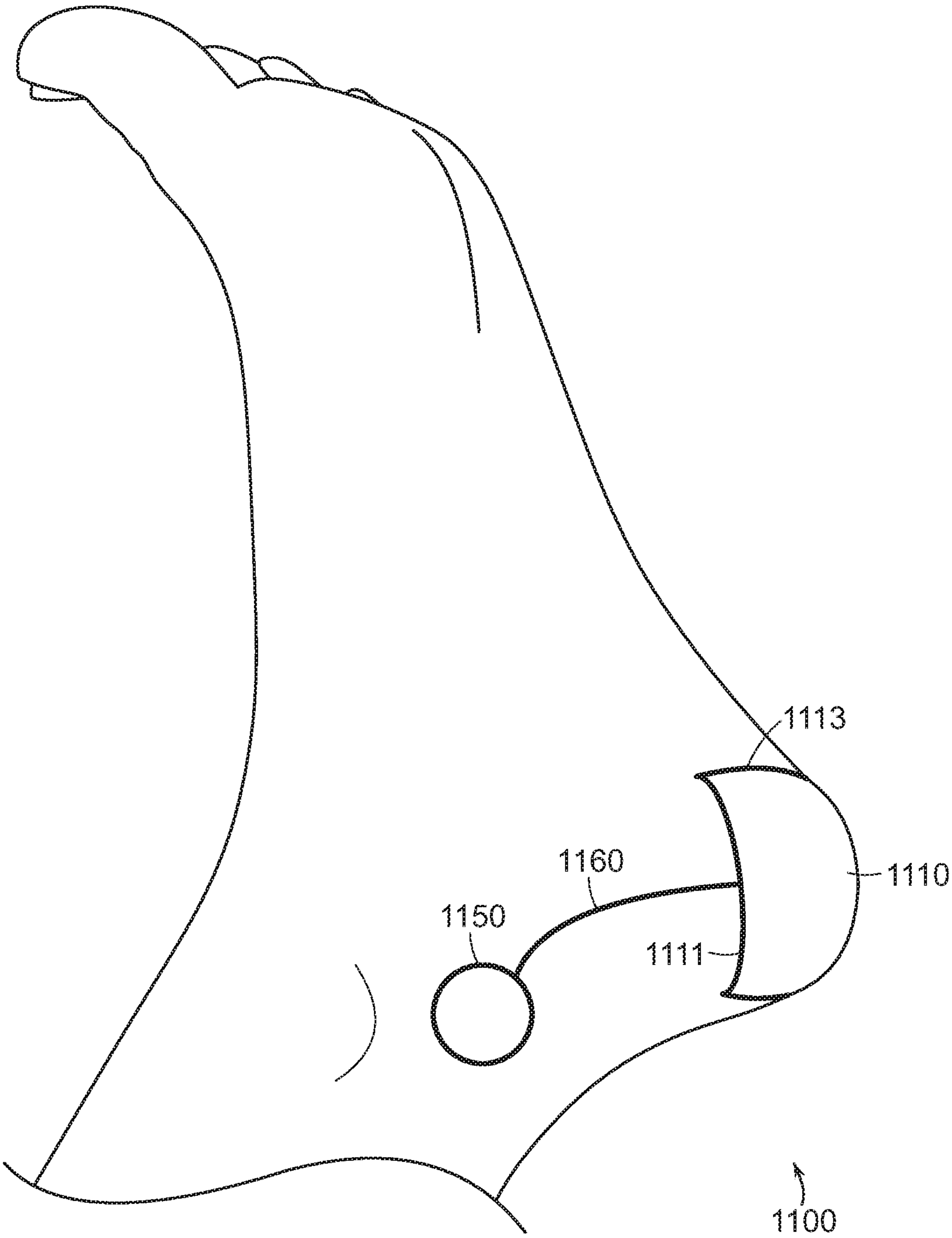


FIG. 11

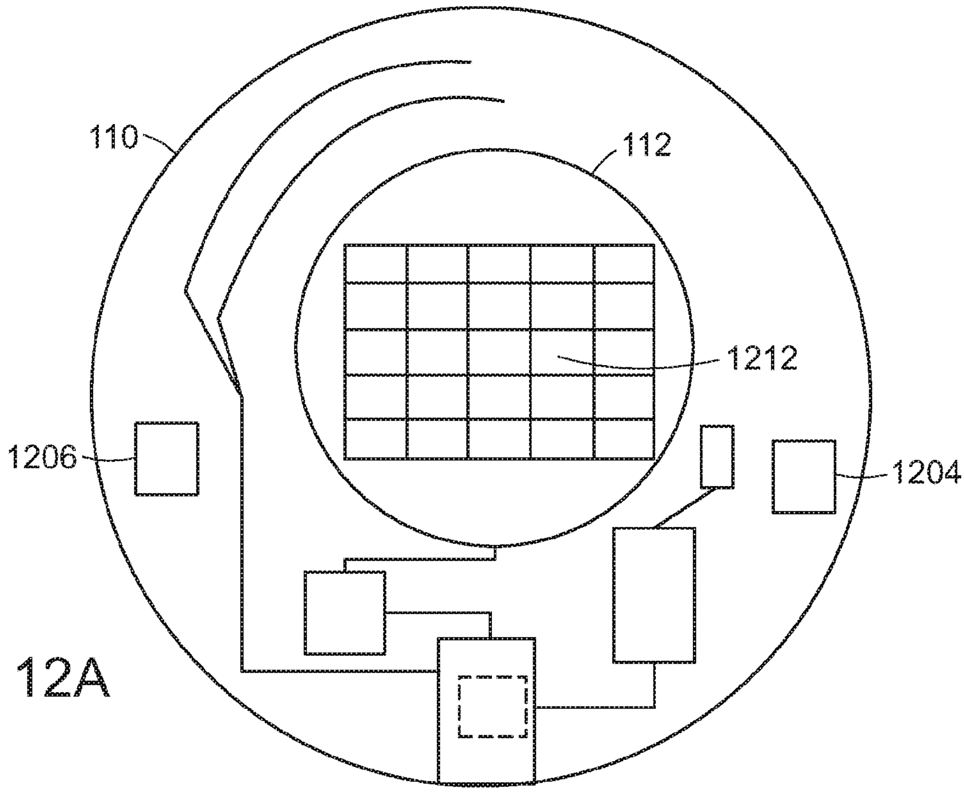


FIG. 12A

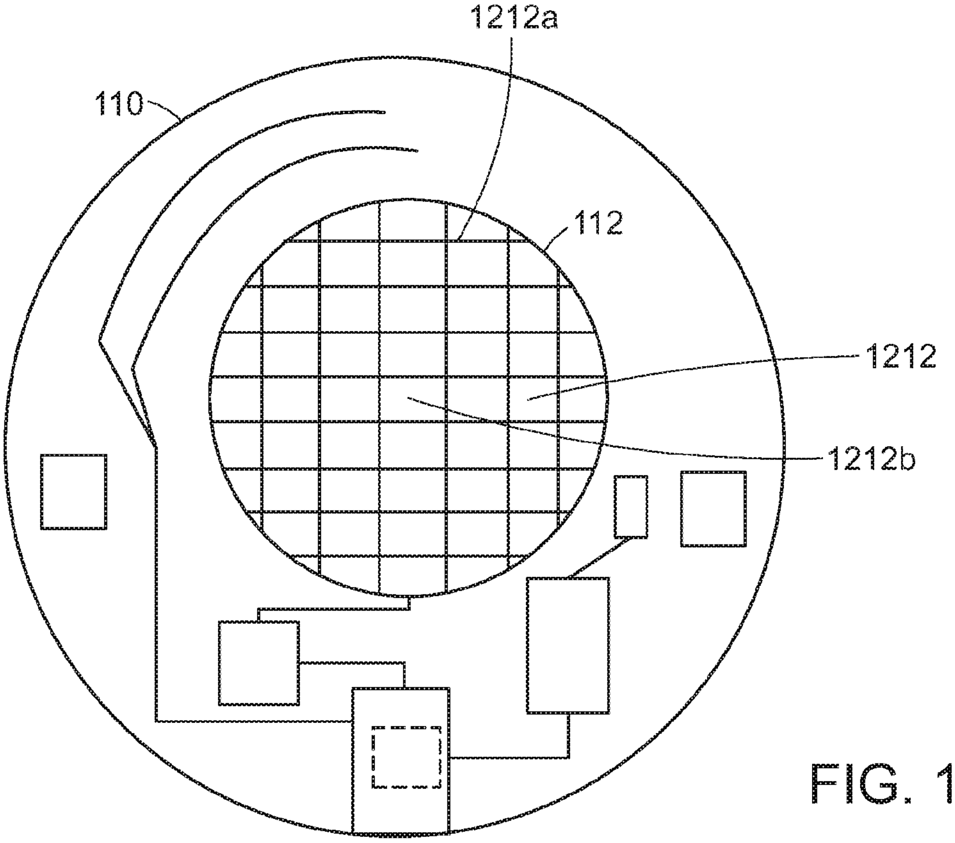


FIG. 12B

# INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/036208

**A. CLASSIFICATION OF SUBJECT MATTER**
INV. A61B5/00
ADD.

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)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | WO 01/00089 A1 (SABOLICH RES & DEV INC [US]) 4 January 2001 (2001-01-04)<br>the whole document<br>----- | 1-6, 14-27, 52-56, 64-80 |
| X | WO 2016/077310 A1 (DM SYSTEMS INC [US]) 19 May 2016 (2016-05-19)<br>figures 1,5,12<br>paragraphs [0043] - [0056], [0063], [0069], [0082], [0085], [0087], [0088]<br>----- | 1-27, 52-80 |
| X | US 2013/019408 A1 (JACOFSKY MARC C [US] ET AL) 24 January 2013 (2013-01-24)<br>figures 7-12,16<br>sentences 26-31,40-67,102-103<br>----- | 1-27, 52-80 |

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"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)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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

"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

"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

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 5 October 2017 | 11/10/2017 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Dhervé, Gwenaëlle |

2

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/036208

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 28-51
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Diagnostic method practised on the human or animal body

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

**Information on patent family members**

International application No
PCT/US2017/036208

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| WO 0100089 A1 | 04-01-2001 | AU 5636100 A | 31-01-2001 |
| | | CA 2376162 A1 | 04-01-2001 |
| | | EP 1207785 A1 | 29-05-2002 |
| | | US 6287253 B1 | 11-09-2001 |
| | | WO 0100089 A1 | 04-01-2001 |
| WO 2016077310 A1 | 19-05-2016 | AU 2015346555 A1 | 27-04-2017 |
| | | CA 2966221 A1 | 19-05-2016 |
| | | EP 3218867 A1 | 20-09-2017 |
| | | US 2016135731 A1 | 19-05-2016 |
| | | WO 2016077310 A1 | 19-05-2016 |
| US 2013019408 A1 | 24-01-2013 | EP 2734083 A2 | 28-05-2014 |
| | | JP 2014523332 A | 11-09-2014 |
| | | KR 20140049568 A | 25-04-2014 |
| | | RU 2014106359 A | 27-08-2015 |
| | | US 2013019408 A1 | 24-01-2013 |
| | | WO 2013016132 A2 | 31-01-2013 |

patsnap

| | | | |
|---|---|---|---|
| 专利名称(译) | 用于预防压疮的系统和方法 | | |
| 公开(公告)号 | EP3463053A1 | 公开(公告)日 | 2019-04-10 |
| 申请号 | EP2017740142 | 申请日 | 2017-06-06 |
| [标]申请(专利权)人(译) | 马萨诸塞大学<br>伍斯特理工学院 | | |
| 申请(专利权)人(译) | 马萨诸塞大学<br>伍斯特理工学院 | | |
| 当前申请(专利权)人(译) | 马萨诸塞大学<br>伍斯特理工学院 | | |
| [标]发明人 | DUNN RAYMOND<br>MCNEILL JOHN<br>MENDELSON YITZHAK | | |
| 发明人 | DUNN, RAYMOND<br>MCNEILL, JOHN<br>MENDELSON, YITZHAK | | |
| IPC分类号 | A61B5/00 | | |
| CPC分类号 | A61B5/0015 A61B5/0022 A61B5/021 A61B5/02416 A61B5/107 A61B5/14542 A61B5/1495 A61B5/447 A61B5/6829 A61B5/6833 A61B5/7203 A61B5/7264 A61B5/7275 A61B2562/0214 A61B2562/0247 A61B2562/0271 A61B2562/029 A61B2562/046 A61B2562/08 A61B2562/164 A61B2562/18 G16H40/67 G16H50/20 G16H50/70 A61B5/0064 A61B5/0531 A61B5/746 A61B2560/0214 A61B2560/0247 A61B2560/0252 | | |
| 优先权 | 62/346151 2016-06-06 US | | |
| 外部链接 | Espacenet | | |


摘要(译)

本申请的系统，装置和方法涉及压力性溃疡病症的诊断测量。优选实施例利用身体位置处的压力测量来确定诊断压疮值。压力传感器装置产生由数据处理器处理的患者压力数据，该数据处理器利用诊断功能来确定诊断值，该诊断值指示是否需要校正动作来防止压疮形成。可以将一个或多个传感器设备附接到患者以进行测量以传输数据以进行进一步处理。