



(51) International Patent Classification:

A61B 5/024 (2006.01) A61B 5/1491 (2006.01)

A61B 5/1455 (2006.01)

(21) International Application Number:

PCT/IB2019/056798

(22) International Filing Date:

09 August 2019 (09.08.2019)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/716,687 09 August 2018 (09.08.2018) US

(71) Applicant: 3M INNOVATIVE PROPERTIES COMPANY [US/US]; 3M Center, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US).

(72) Inventor: BEDINGHAM, William; 3M Center, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US).

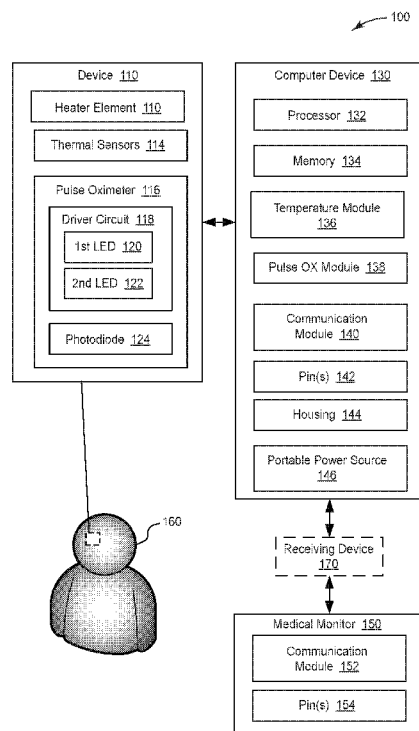
(74) Agent: SRY, Jonathan V. et al.; 3M Center, Office of Intellectual Property Counsel, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US).

(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, JO, 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, 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,

(54) Title: PULSE OXIMETRY AND TEMPERATURE DEVICE

FIG. 1



(57) Abstract: A device includes a plurality of thermal sensors that are arranged to sense a core body temperature of a patient, a pulse oximeter and a heater element. A non-zero difference between the temperatures of two thermal sensors can activate the heater element to heat a target tissue. The increased blood flow can in turn provide an enhanced optical signal for the pulse oximeter.

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))*
- *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*

PULSE OXIMETRY AND TEMPERATURE DEVICE

Background

The subject matter relates to a device for use in the estimation of deep tissue temperature (DTT) as an indication of the core temperature of humans or animals.

Deep tissue temperature measurement is the measurement of the temperature of organs that occupy cavities of human and animal bodies (core temperature). DTT measurement is desirable for many reasons. For example, maintenance of core temperature in a normothermic range during the perioperative cycle has been shown to reduce the incidence of surgical site infection; and so, it is beneficial to monitor a patient's core temperature before, during, and after surgery. Of course, noninvasive measurement is highly desirable, for the safety and the comfort of a patient, and for the convenience of the clinician. Thus, it is most advantageous to obtain a noninvasive DTT measurement by way of a device placed on the skin.

Pulse Oximeters are also placed on the skin. These pulse oximeters can be either transmission-based (meaning that light is transmitted through tissue such as a fingertip or earlobe) or reflective (meaning that light is bounced back from tissue). For example, transmission-based pulse oximeters can position an LED and a photodiode on opposite sides of a substrate. Reflectance-based oximeters position the LED and photodiode on the same surface.

Summary

Temperature devices that measure DTT may have power and device layout requirements that are additional to the pulse oximeter power and device layout requirements.

By adding a pulse oximeter to the temperature device, some power efficiencies and device layout efficiencies can be achieved. Further, components of the temperature device such as a heater element may also be used to improve determination of a pulse oximetry by the pulse oximeter.

Aspects of the present disclosure relate to a device. The device includes a plurality of thermal sensors that are arranged to sense a core body temperature of a patient. The device also includes a pulse oximeter and a heater element. Other aspects of the present disclosure relate to a system including the device and a first computing device. The first computing device is communicatively coupled to the heater element and the first and second thermal sensors. The first computing device includes one or more computer processors and a memory comprising instructions that when executed by the one or more computer processors cause the one or more computer processors to receive from the first thermal sensor a first electrical response and a second electrical response from the second thermal sensor. The one or more computer processors can also determine a first temperature from the first electrical response

can also determine whether a difference between the first temperature and the second temperature is non-zero and activate an electrical current to the heater element in response to the difference being non-zero.

In addition, the first computing device can be configured to apply a second electrical current to the driver circuit, receive a photodiode reading from the photodiode, and transmit a photodiode reading. The first computing device can also be configured to activate the electrical current prior to applying a second electrical current.

Although medical device constructions are described in terms of preferred embodiments comprising representative elements, the embodiments are merely illustrative. It is possible that other embodiments will include more elements, or fewer, than described. It is also possible that some of the described elements will be deleted, and/or other elements that are not described will be added. Further, elements may be combined with other elements, and/or partitioned into additional elements.

Brief Description of the Drawings

FIG. 1 illustrates a block diagram of a system using a medical device having a pulse oximeter, according to aspects of the present disclosure.

FIG. 2 illustrates a plan view of an electrical circuit of a medical device having a pulse oximeter, according to aspects of the present disclosure.

FIG. 3 illustrates a side cross-sectional view of a medical device having the electrical circuit of FIG. 2, according to aspects of the present disclosure.

FIG. 4 illustrates an exemplary construction of the medical device of FIG. 3, according to aspects of the present disclosure.

FIG. 5 illustrates an exemplary construction of a medical device, according to aspects of the present disclosure.

FIG. 6 illustrates a side cross-sectional view of the medical device of FIG. 5, according to aspects of the present disclosure.

FIG. 7 illustrates a plan view an exemplary construction of a medical device, according to aspects of the present disclosure.

FIG. 8 illustrates a side cross-sectional view of the medical device of FIG. 7 disposed on a patient, according to aspects of the present disclosure.

FIG. 9 illustrates an exemplary construction of a medical device disposed on a patient, according to aspects of the present disclosure.

FIG. 10 illustrates a perspective view an example of a pulse oximeter, according to aspects of the present disclosure.

FIG. 11 illustrates a perspective view of an example of a medical device with the pulse oximeter of FIG. 10, according to aspects of the present disclosure.

aspects of the present disclosure.

FIG. 13 illustrates a block diagram of a computing device, according to aspects of the present disclosure.

Detailed Description

Aspects of the present disclosure relate to a temperature or medical device with a pulse oximeter. More particularly, aspects of the present disclosure relate to a medical device with a heater element and a pulse oximeter. The pulse oximeter signals can be enhanced by components of the medical device (such as the heater element) and can enable the medical device to be placed in areas of the patient such as the arm pit or forehead. Further, by utilizing the heater element for other purposes, the power efficiency of the medical device can be increased.

Temperature devices can be useful in measuring core temperatures. The temperature device can have a thermal sensor useful in monitoring a temperature indicative of a core temperature and a thermal sensor useful in monitoring a temperature indicative of a skin temperature of a patient. Core temperature devices can be either invasive (such as esophageal or rectal thermometers) or non-invasive (which do not necessarily need to be inserted into any portion of the body). In at least one embodiment, the core temperature can be determined from a plurality of thermal sensors placed in multiple configurations and without the use of heaters (i.e., an unheated core temperature device). An unheated temperature device can differ from the zero-heat flux temperature device in that the zero-heat flux device uses a heater and the unheated temperature device may use a thermal-equilibrium method. Aspects of the present disclosure relate to a core temperature device that is either unheated or heated (e.g., zero-heat flux).

FIG. 1 discloses a temperature management system 100 for monitoring a core body temperature. The system 100 can have a medical device 110 and a temperature monitoring device (i.e., computing device 130). While the medical device 110 is preferably a heated, zero-heat flux temperature device, the medical device 110 can also be unheated and use multiple thermal sensors to measure a core body temperature described herein. The medical device 110 can be attached or coupled to a patient 160 in any position. In at least one embodiment, the medical device 110 can be attached to the forehead of the patient 160 proximate, adjacent, or bordering (i.e., close or very near) a temporal artery or carotid artery.

The medical device 110 can have an optional heater element 112. The heater element 112 can be a device that applies heat to a patient to form an isothermal tunnel. The heater element 112 can be polymeric or can be metallic (e.g., formed from a heater trace). Examples of a medical devices 110 with a heater element 112 can be similar to devices under the trade designation Bair Hugger Temperature Monitoring from 3M (Saint Paul, MN).

can be arranged to obtain a core body temperature of a patient. In one example, the thermal sensors 114 can be configured similar to a temperature device commercially available under the trade designation Bair Hugger Temperature Monitoring. For example, the device 110 can also include insulation and unheated portions to form an isothermal tunnel.

In at least one embodiment, the thermal sensors 114 can be substantially aligned. For instance, a first thermal sensor can be mounted directly above the second thermal sensor in an axis perpendicular to at least one of the planes of the first thermal sensor or the second thermal sensor. The second thermal sensor can be placed no greater than 5 mm, no greater than 4 mm, no greater than 3 mm, no greater than 2 mm, or no greater than 1 mm from the first thermal sensor.

The thermal sensors 114 can also be arranged in multiple levels to determine a temperature gradient without the use of the heater element 112. For example, at least 2 thermal sensors can be present on one plane and at least 2 temperature sensors can be present on another plane.

In at least one embodiment, a thermal mass (not shown) can be present between the thermal sensors 114 to create an isothermal tunnel. An example of a thermal mass can be commercially available under the trade designation Tcore from Draegerwerk AG (Germany). The thermal device can also include insulation between planes.

The thermal sensors can be based on a measured, temperature affected resistance of a material (e.g., a thermistor). Thermal sensors can also be based on a measured, temperature affected voltage of a material (e.g., Thermocouple from TE Connectivity, or Temperature Specialists, Inc. (Minnesota, USA). Examples of thermal sensors are commercially available from YSI Precision Temperature Group (Dayton, Ohio). Small surface mount thermistors are available from Vishay Intertechnology, TDK, TE Connectivity, Murata Manufacturing.

The device 110 can also include a pulse oximeter 116 which can be a device that measures a photoelectrical response to at least one wavelength of light. Complete commercially available oximeter sensors are available from Masimo (Irvine CA), Nellcor/Medtronic (Minneapolis, MN), and Nonin (Plymouth, MN). Components that can be used in an oximeter sensor are available from Maxim (San Jose, CA), Texas Instruments (Dallas, TX), OSRAM Opto Semiconductors Inc. (Sunnyvale, CA), Vishay Intertechnology (Malvern, PA). The pulse oximeter 116 can operated based on transmittance (where light is transmitted through tissue (biological) to a photodiode on the opposite side of the LED) or reflectance (where light is reflected off tissue to a photodiode on the same side as the LED) to determine the photoelectrical response.

As used herein, light can refer to electromagnetic radiation that has a wavelength in the range from about 1000000 nm to 10 nm. Some wavelengths of light, e.g., red, may perceived by the unaided, normal human eye. The pulse oximeter 116 can result in a determination of SpO₂ or oxygen saturation level of a patient. In at least one embodiment, the pulse oximeter 116 can be referred to as a sensor which responds to a physical stimulus and transmits a resulting impulse for interpretation or

producing light and can include LEDs as a class of light sources. Various other light sources can exist.

The pulse oximeter 116 can operate according to the pulse oximeter device described with greater detail in provisional application US 62/524,319, filed 6/23/2017 (attorney docket number 79580), which is incorporated by reference. For example, the pulse oximeter 116 can communicate with wireless communicative elements such as a wireless communication module. The pulse oximeter 116 can also include a driver circuit 118 which drives the LEDs in a particular timing pattern sufficient to determine the SpO₂ values of a patient 160 (or information relevant to/concerning pulse oximetry/SpO₂ values of a patient). In at least one embodiment, the information concerning pulse oximetry or SpO₂ values includes the R-value itself or the photodiode responses to the IR or red light (either AC or DC).

The driver circuit 118 can be electrically coupled to both a first LED 120, a second LED 122, and a photodiode 124. The photodiode can receive wavelengths of light from both the first and second LEDs. Even though LED is used, the term LED can be used to refer to additional lighting technologies that emit narrow bands of wavelengths of light such as lasers, halogen, LCD, etc. In at least one embodiment, the first LED 120 can emit mostly red light at approximately 620 nm to 750 nm. The second LED 122 can emit mostly infrared (IR) light at approximately 700 nm to 1 mm, particularly in the water band of 1400 nm to 15000 nm and/or the near IR band of 760nm to 1500 nm. The pulse oximeter 116 can optionally include a thermal sensor 114 which can be used to adjust the calibration of the pulse oximeter 116 and, optionally, provide skin temperature feedback to control the heater element 112.

The system 100 can also include a patient 160. The patient 160 is generally mammalian, and preferably human, and preferably, a statistically average adult patient. The term patient generally refers to a class of persons who can have the core body temperature measured (i.e., a patient population). The device 110 can be positioned over a target tissue. For example, the device 110 can specifically be removably attached (meaning adhered, mechanically clipped (e.g., using a spring), or banded (e.g., using elastic)) to a portion of the patient 160 such as the ear, fingertip, forehead, armpit region, across a foot, or combinations thereof.

The medical device 110 and pulse oximeter 116 can be communicatively coupled to the computing device 130. In at least one embodiment, one or more elements of the computing device 130 can be co-located with the medical device 110 in the same housing. For example, the medical device 110 can be wireless with the computing device elements located in the medical device 110 housing (not shown). In another example, a local processor can be used to control the timing of the pulse oximeter.

In at least one embodiment, the computing device 130 can be present in a separate housing 144 where the computing device 130 and the various electronics sufficient to allow reading of pulse oximetry and a core temperature from the patient 160. In at least one embodiment, the computing device 130 can perform functions of the control mechanization described herein. The computing device 130 can also provide control to the various thermal sensors in the device 110 and the pulse

element 112 either based on the thermal sensors 114 or independently to warm the region around the pulse oximeter 116.

The computing device 130 can include a processor 132 which processes the stored instructions in memory 134 and enables the control and coordination of the heater element 112, the pulse oximeter 116, and/or the thermal sensor 114. The computing device 130 can also be described further herein.

The computing device can include a temperature module 136. The temperature module 136 can enable measurement of the core body temperature of a patient 160. The temperature module 136 can also control the activation and deactivation of the heater element 112 and thermal sensors 114. In at least one embodiment, the temperature module 136 can be configured to measure a plurality of thermal sensors 114 in the absence of the heater element 112 such as those commercially available under the trade designation Tcore by Draegerwerk (Germany) or Temple Touch Pro by Medisim (Israel).

The temperature module 136 can utilize switches including a heater switch communicatively coupled to the computing device 130 and operative to switch a pulse-width-modulated drive signal through the probe signal interface cable to the heater element of the temperature device. The first computing device 130 includes probe control logic, and the zero-heat-flux temperature system further includes an information switch having a first state in which the information switch is operative to connect thermal sensor signals from the probe signal interface cable to the probe control logic and a second state in which the information switch is operative to connect programmable memory device information from the probe signal interface cable to the control logic. The heater switch can be operative to switch a pulse-width-modulated drive signal through the probe signal interface cable to the heater.

In at least one embodiment, the temperature module 136 can synchronize the activation of the heater element 112 with the activation of the pulse oximeter 116. For example, the temperature module 136 can activate a heater element 112 at a particular duty cycle such that the heater element 112 heats tissue. The frequency of pulses can correspond to any heartbeat frequency of the patient and be timed based on either the pulsatile or non-pulsatile blood.

In at least one embodiment, the heater element 112 can increase skin temperature of the patient 160 such that local blood flow is increased under the device 110. The increased blood flow can provide an enhanced optical signal for the pulse oximeter 116 (e.g., larger changes in arterial vasculature with each blood pressure pulse can causes larger optical absorption changes with each pulse). The enhanced optical signal can improve the accuracy and reliability of the reading from the pulse oximeter 116 and also reduce “false alarms” caused by low blood flow or “loss of signal” events.

first thermal sensor a first electrical signal and from a second thermal sensor a second electrical signal. The temperature module 136 can determine a first temperature from the first electrical signal and a second temperature from the second electrical signal and determine whether a difference between the first temperature and the second temperature is zero. As used herein, an electrical signal conveys information about the attributes of an electronic sensor. An electrical signal can refer to a digital signal or an analog signal. An analog signal is any continuous signal for which the time varying feature (variable) of the signal is a representation of some other time varying quantity, i.e., *analogous* to another time varying signal. Thus, an electrical signal can refer to a voltage value, a current value, or a resistance value.

If the temperature difference is zero (or within a range of zero such as plus or minus 3 degrees, 2 degrees, 1 degree, or 0.5 degree), then the temperature module 136 can perform at least one operation such as turning the heater element off or lowering the duty cycle of heater element pulses. If the temperature difference is non-zero, then the temperature module 136 can cause the computing device 130 to apply a current to the heater element 112 in response to the difference being non-zero.

The computing device 130 can also have a pulse oximetry module 138. The pulse oximetry module can enable measurement of the blood oxygen content of the patient 160 by comparing the physiological response of the patient 160 to a red light with a physiological response to an IR light.

For example, absorption of light at these wavelengths differs significantly between blood loaded with oxygen and blood lacking oxygen. Oxygenated hemoglobin absorbs more infrared light and allows more red light to pass through. Deoxygenated hemoglobin allows more infrared light to pass through and absorbs more red light. The pulse oximetry module 138 can cause the driver circuit 118 to sequence LEDs through their cycle of one on, then the other, then both off about 100 - 1000 repetitions per second which allows the photodiode 124 to respond to the red and infrared light separately and adjust for the ambient light baseline. The amount of light that is transmitted (in other words, that is not absorbed) is measured, and separate normalized signals are produced for each wavelength. These signals can fluctuate in time because the amount of arterial blood inside the optical interrogation field increases and decreases in response to the arterial pressure pulse from the patient 160. The optical signal can be normalized by dividing the peak-to-peak signal (ac or pulsatile signal) by the mean signal (dc or non-pulsatile absorption). ...

The ratio of the red light measurement to the infrared light measurement is then calculated by the processor. For example, the red light (600nm) absorption spectra and the infra-red light (940nm) absorption spectra can have small differences. The ratio of the normalized red signal (AC_{red}/DC_{red}) can be divided by the normalized IR signal (AC_{ir}/DC_{ir}), and then be converted to SpO_2 by the pulse oximetry module 138.

The patient's heart rate can also be computed from either the red or infrared pulsatile optical signal or plethsmogram (e.g. peak detection, autocorrelation, frequency decomposition).

wirelessly communicate the photodiode response (i.e., an electrical signal produced from an optical signal) to a receiving device 170 or medical monitor 150 as described in provisional application US 62/524,319, filed 6/23/2017 (attorney docket number 79580), which is incorporated by reference.

The computing device 130 can be communicatively or electrically coupled to a signal connector jack (e.g., pins 142) disposed at least partially inside the housing 144. The computing device 130 can also include a probe signal interface cable with first and second ends disposed at least partially outside of the housing 144.

The probe signal interface cable can also include a first connector attached to the first end of the probe signal interface cable for detachably connecting to a tab (described herein). The probe signal interface cable can also include a second connector attached to the second end of the probe signal interface cable for being inserted into and removed from the signal connector jack in the first computing device. In at least one embodiment, the probe signal interface cable and the first and second connectors are a single integrated element separate from the probe.

The computing device 130 can have a communication module 140 (e.g., using radio frequency to communicate) that is communicatively coupled to the computing device 130. Although a portion of the module 140 is disposed in the housing 144, the module 140 can also have an external antenna that is disposed outside of the housing 144. The module 140 can communicate with a medical monitor 150. In at least one embodiment, the module 140 can transmit a core body temperature of a patient using one or more radio frequencies. Various wireless communications protocols can be used such as those based on IEEE 802.11x, or Bluetooth. If the temperature difference is zero, then the temperature can be provided to the radio frequency communication module, wherein the temperature is packetized and transmitted. In addition, if the temperature difference is zero, then the temperature can be displayed by a display.

The computing device 130 can also have a portable power source 146. The portable power source 146 can be configured to be used so that the computing device 130 is untethered to a power source. The portable power source 146 can be a battery, capacitor, or an inductive power source where the inductive coupling is separate from the device 110. The portable power source 146 can be a battery or batteries having a capacity no greater than 2000 milliampere hour, no greater than 1500 milliampere hour, no greater than 1000 milliampere hour, no greater than 800 milliampere hour, no greater than 500 milliampere hour, no greater than 200 milliampere hour, no greater than 150 milliampere hour, no greater than 120 milliampere hour, no greater than 110 milliampere hour, no greater than 100 milliampere hour, no greater than 90 milliampere hour, no greater than 80 milliampere hour, no greater than 70 milliampere hour, no greater than 60 milliampere hour, or no greater than 50 milliampere hour. In at least one embodiment, the portable power source 146 can have a variety of chemistries such as zinc-air, nickel-cadmium, or lithium ion.

device 110 can use (at steady-state) no greater than 200 mW. In at least one embodiment, the medical device 110 can cause the portable power source 146 to discharge no greater than 200 mW at steady-state. In at least one embodiment, the medical device 110, when coupled with the computing device 130, can cause the computing device 130 to have an operational power of no greater than 200 mW, no greater than 190 mW, no greater than 180 mW, no greater than 170 mW, no greater than 160 mW, no greater than 150 mW, no greater than 140 mW, no greater than 130 mW, no greater than 120 mW, no greater than 110 mW, no greater than 100 mW, no greater than 90 mW, no greater than 80 mW, no greater than 70 mW, no greater than 60 mW, or no greater than 50 mW, when the medical device 110 placed on a forehead of a patient, proximate to a temporal artery, at standard ambient conditions. In at least one embodiment, the medical device 110 is proximate to the temporal artery when heat from the temporal artery affects a thermal sensor. For example, the medical device 110 can be proximate to the temporal artery when within 10 mm, within 9 mm, within 8 mm, within 7 mm, within 6 mm, or within 5mm of the (e.g., lower) thermal sensor of the medical device 110. The operational power can refer to a steady state where a heater element 112 is activated.

In at least one embodiment, the system 100 optionally includes a receiving device 170. The receiving device 170 can act as an intermediary between the computing device 130 and the medical monitor 150. The receiving device 170 can receive both a signal related to SpO₂ (such as that described in provisional application US 62/524,319, filed 6/23/2017) and a signal related to the core temperature value from the computing device 130. The transmission of both the SpO₂ signal and the core temperature value can be wireless and using radio waves. The receiving device 170 can also include a housing, with a computing device, and radio frequency communication module at least partially disposed in the housing. The computing device can be communicatively coupled to the communication module.

The receiving device 170 can optionally include one or more pins that are electrically coupled to the pins 154 of the medical monitor 150. The medical monitor 150 (or patient monitor) can be a device that is configured to receive biological measurements from a variety of sensors such as SpO₂, ECG, Blood Pressure, and temperature. Examples of medical monitors are commercially available from General Electric Medical, or Philips. The pins 154 can correspond to the temperature input or the SpO₂ input. The temperature input can be YSI-400 analog input. Thus, the pins 154 can be coupled to a digital-to-analog circuitry. In at least one embodiment, the receiving device 170 can be a separate device that is attached to the medical monitor 150. In at least one embodiment, the receiving device 170 can also integrated into the medical monitor 150. For example, the medical monitor 150 can integrate elements of the receiving device 170 to be able to receive a core temperature value and SpO₂-related signal wirelessly.

In at least one embodiment, computing device of the receiving device 170 or medical monitor can comprise one or more computer processors and a memory comprising instructions that when

receive the first temperature from the computing device 130, and provide the first temperature to the medical monitor 150 and the medical monitor circuitry.

In at least one embodiment, the computing device 130 comprises memory comprising instructions that, when executed by the one or more computer processors of the computing device 130, cause the one or more computer processors to transmit a pairing request message to a communication module on the receiving device or medical monitor 152, receive a confirmation message unique to the communication module 152 or the receiving device 170, and transmit the first temperature value based on the confirmation message.

In at least one embodiment, the computing device 130 comprises memory comprising instructions that when executed by the one or more computer processors cause the one or more computer processors to determine a signal strength between the communication module 140 and the communication module 152 and perform at least one operation responsive to the signal strength. For example, the computing device 130 can increase power usage of the communication module 152 responsive to a weak signal strength. In another example, the computing device 130 can store multiple temperature values in response to the signal strength being at a first level and transmit the multiple temperature readings in response to the signal strength being at a second level.

In at least one embodiment, the computing device 130 comprises a memory 134 comprising instructions that when executed by the one or more computer processors cause the one or more computer processors to receive a pairing request message from the communication module 140, providing a message on a display of the receiving device 170 or medical monitor 150 responsive to the pairing request message, receive a confirmation of the message (e.g., from a button or user interaction device), and establish a secure connection with the communication module 140. The message can be a symbol or unique code that is confirmable by a user interacting with the receiving device.

FIG. 2 illustrates a layout of an electrical circuit 200 for a device. Electrical circuit 200 can form device 300 shown in FIG. 3 which is an embodiment of device 110 in FIG. 1. The device 300 can be configured to use a heating element to form an isothermal tunnel. When two thermal sensors are within a temperature range of each other (i.e., the difference between a first thermal sensor and a second thermal sensor are around zero), then the heater element can deactivate.

The electrical circuit 200 can be disposed on a substrate (e.g., a flexible substrate) to adapt or conform the physical configuration of the temperature measurement device to differing contours encountered at different temperature measurement locations.

Preferably, but not necessarily, the electrical circuit 200 is constructed or fabricated to have a plurality of contiguous sections. For example, the electrical circuit 200 has four contiguous sections 202, 204, and 206. The first, or center, section 202 is substantially circular in shape. The second section (or “tail”) 204 has the shape of a narrow, elongate rectangle that extends in a first radial

at intersection 205 (which represent the beginning of the tail section), the periphery of the center section has a straight portion and the width of the tail section may be reduced (not shown). The third, or tab, section 206 has the shape of a broad, elongate rectangle that extends in a third radial direction from the periphery of the center section 202. Preferably, at least one tail section, and tab section are aligned along a diameter of the center section. In at least one embodiment, the tail section and tab section are separated by an arc of less than or equal to 180° on the periphery of the center section.

The elements of the electronic circuit 200 can be disposed on a single surface, on a first side 208 of the flexible substrate. A first thermal sensor 220 is positioned inside the outer perimeter 225 of the center section 202, preferably, near or at the center of the center section 202.

The heater element, as described herein, can be an area of active heating preferably through electrical means. In at least one embodiment, an electrically conductive heater trace 222 defines a heater element with a shape that surrounds, encompasses, or encircles a zone 221 in which the first thermal sensor 220 is located. Thus, the heater trace 222 is an embodiment of a heater element. Other forms of heater elements include ceramic or polymeric heaters. In at least one embodiment, the zone 221 can be thermally isolated/insulated from the heater trace such that the thermal sensor is substantially thermally unaffected by the heater trace 222. The heater trace 222 is shown as having an annular shape that includes a circular array of wedge-shaped heater zones 224 that surround or encircle the zone 221 and the first thermal sensor 220 which is disposed in the zone 221. A second thermal sensor 226 is positioned on the tail section 204. In at least one embodiment, the second thermal sensor 226 can have an insulation 227 disposed thereon to prevent thermal interference from the outside environment.

A plurality of electrical connection pads 230 is in the tab section 206. The heater trace 222 includes two electrically conductive trace sections that terminate in the connection pads 230 *a* and 230 *b*. For illustrative purposes, only one of the electrically conductive traces is shown. More connection pads for a sensor can be possible. An electrically conductive trace extends between mounting pads on which the first thermal sensor 220 is mounted and the connection pad 230 *e*. An electrically conductive trace extends between the second thermal sensor 226 is mounted and the connection pad 230 *d*.

In at least one embodiment, the thermal sensor 226 in the tail section 204 can be spaced-apart from a portion of the perimeter 225 of the center section (e.g., from 205) at standoff distance 223. The standoff distance 223 can be sufficient for the thermal sensor 226 to be substantially aligned (e.g., 202 discussed herein) with thermal sensor 220 when in a folded-together configuration with an insulative layer.

In addition, there may also be a standoff distance 229 between the thermal sensor 220 and the thermal sensor 226. In at least one embodiment, the standoff distance 229 is at least twice a radial

also be at least twice a radial dimension from the thermal sensor 220 to a point of the perimeter 225.

In the specific layout shown in FIG. 2, the path of the heater trace 222 crosses the paths of the two traces for the second thermal sensor 226. In this case, the continuity of the heater trace is preferably, but not necessarily, maintained by an electrically conductive zero-ohm jumper which crosses, and is electrically isolated from, the two traces for the thermal sensors 220 and 226. In other embodiments, the continuity of the heater trace 222 can also be maintained by vias to the second side of the flexible substrate, by running the thermal sensor traces around the periphery of the first side of the flexible substrate, by a jumper wire instead of the zero-ohm resistor, or by any equivalent solution. In at least one embodiment, the heater trace 222 is concentric with the center section 202 meaning that the heater trace 222 generally is circular. In at least one embodiment, the heater trace 222 follows a serpentine path that follows the outline of the periphery (including the tabs) and reunites through the center section and returns beside an original output path.

The flexibility or conformability of the flexible substrate can be enhanced by a plurality of slits 233 that define zones which move or flex independently of each other. In the preferred embodiment, the slits 233 are made in the center section 202 in a pattern that follows or accommodates the layout of the heater trace 222. The pattern at least partially separates the heater zones 224 to allow any one of the heater zones 224 to move independently of any other heater zone. The pattern of slits can be a radial pattern in that each slit is made along a respective radius of the circular center section 202, between adjacent heater zones, and extends along the radius from the periphery of the center section 202 toward the center of the circular shape of the section. In at least one embodiment, the pattern of slits 233 can define a space where the heater trace 222 occupies. The heater trace 222 can also be multi-zone meaning that the heater trace 222 is divided into separate heating zones. This is not meant to exclude other possible slit configurations determined by the different shapes of the heater trace layout and the flexible substrate sections.

In addition, the circuit 200 can include a pulse oximeter 216 disposed thereon. The pulse oximeter 216 can be an embodiment of pulse oximeter 116 from FIG. 1. The pulse oximeter 216 can be positioned so that it is separate from the heater trace 222 and the thermal impact of the heater element on the oximeter 216 can be reduced. As shown in FIG. 2, the pulse oximeter 216 is formed in an area outside of a heater zone 224.

At least one portion of the pulse oximeter 216 can have a stand-off distance 235 with respect to the thermal sensor 220. In at least one embodiment, the LED of pulse oximeter 216 can define the stand-off distance 235. In at least one embodiment, the outer perimeter of a housing for the pulse oximeter 216 can define the stand-off distance 235.

In at least one embodiment, sections of the flexible substrate can be brought or folded together about an insulator to provide thermal resistance between the first and second thermal sensors 220 and 226 in a configuration that is preferred for DTT measurement. For example, at least the

insulative layer. Preferably, the first and second thermal sensors 220 and 226 are thereby disposed on respective sides of a thermal insulator. As shown in FIG. 3, the center section 202 and tail section 204 are folded together about a flexible layer of insulative material 340. The layer 340 provides thermal and electrical resistance between the thermal sensors; it also supports the thermal sensors in a spaced-apart configuration having a vertical distance 341 between the sensors. In at least one embodiment, the thermal sensors can be at least 1mm, at least 2 mm, or at least 3mm from each other.

A flexible temperature measurement device construction includes an electrical circuit 200 laid out on a side of a flexible substrate as shown in FIG. 3. With two sections of the flexible substrate brought or folded together to sandwich a flexible insulative layer, the construction has a multilayer structure as best seen in FIG. 3. Thus, a temperature measurement device 300 includes the electrical circuit 200 laid out on the surface of the first side 208 of the flexible substrate. The central and tail sections 202 and 204 are brought or folded together about the flexible insulative layer 340 to provide a thermal resistance between the first and second thermal sensors 220 and 226. The flexible insulative layer 340 also maintains the first and second thermal sensors disposed in a spaced-apart relationship described herein.

As shown in FIG. 3, the device 300 can be arranged in a plurality of layers. For example, the thermal sensor 226 and the tail section 204 can form a first layer/section, the insulation can form insulative layer 340, the layer of substrate with the thermal sensor 220 can form a third layer/section, and an insulative layer 308 can form a fourth layer.

In at least one embodiment, the insulative layer 340 can have one or more regions on a side facing the patient 160. The regions can indicate a indented region (e.g., having surfaces beside the nadir of the indented region) formed from the body of the insulative layer 340. The indented region is a region that is depressed relative to the plane of a surface of the insulative layer. The indented region can be formed from a compressed portion of the insulative layer or can be In at least one embodiment, at least a portion of the pulse oximeter is disposed in a portion of the indented region. In at least one embodiment, the region can indicate a cutout portion 324 where part of the insulative layer 340 is removed to create at least two major surfaces (e.g., the nadir, and a side wall). A portion of the pulse oximeter 216 can protrude through the cutout portion 324 to contact the patient 160. The pulse oximeter 216 can also have a stand-off distance 235 from the axis 302 or the skin-facing thermal sensor 226. The stand-off distance 235 can be measured along an axis defined by the longitudinal dimension of the device 300 (e.g., by the axis formed by the tab section 206) or any other axis of the device 300.

The insulative layer 340 can also be substantially symmetrical and have a center portion that is defined at least in part by the electrical circuit center section 202. In at least one embodiment, the center portion of the insulative layer 340 can also be defined by the region that is not covered by the heater element (i.e., zone 221). Thus, a peripheral portion can be any zone that is not aligned with the

in FIG. 2 but other configurations are described herein.

The second thermal sensor 226 can be aligned with the first thermal sensor 220. For example, both the thermal sensors 226, 220 can be within the zone 221 formed from the absence of a heater element. In at least one embodiment, the axis 302 can pass through both thermal sensors and perpendicular to the plane of the electrical circuit 200. In at least one embodiment, the axis 302 can pass through only one of the sensors 220 and 226. For example, a sensor (220 or 226) can be no greater than 5 mm, no greater than 4 mm, no greater than 3 mm, no greater than 2 mm, or no greater than 1 mm from the other sensor measured along a plane perpendicular from the axis 302 (e.g., horizontal alignment).

The temperature measurement device further can also include a flexible insulative layer 308 attached to a portion of first side 208 of the circuit 200 and/or a portion of the stiffener 304, over the center section 202. In at least one embodiment, the zone 221 is thermally isolated from the heater trace such that the heater trace does not induce heat via induction or conduction to the first thermal sensor 220.

Another benefit of the layout shown in FIG. 2 is that the first thermal sensor 220 is physically removed from the heater, in a zone 221 of zero vertical heat flux that is surrounded or encircled by the heater trace 222, and not stacked under it as in the Fox/Solman and Togawa systems. When the temperature measurement device is activated, the heater is turned on and the heat produced thereby travels generally vertically from the heater to the patient, but only medially to the first thermal sensor. As a result, the jump in temperature that occurs when the heater is activated is not immediately sensed by the first thermal sensor, which improves stability of the temperature measurement without requiring an increase in thermal mass of the temperature measurement device. Thus, the first thermal sensor 220 is preferably located in the same plane, or on the same surface, as the heater trace 222 (and can even be elevated slightly above the heater trace), and substantially in or in alignment with the zone 221 of zero heat flux.

It is desirable that the temperature measurement device support a pluggable interface for convenience and for modularity of a patient vital signs monitoring system. In this regard, and with reference to FIGS. 2 and 3, the tab section 206 is configured with the array of electrical pads 230 to be able to slide into and out of connection with a plug. To provide a physically robust structure capable of maintaining its shape while being connected and disconnected, the tab section 206 is optionally stiffened. In this regard, a flexible stiffener 304 is disposed on the second side 209 of the flexible substrate. The stiffener extends substantially coextensively with the tab section 206 and partially over the center section 202, at least to the location of the first thermal sensor 220.

As best seen in FIG. 3, the stiffener 304 is disposed between the second side 209 of the flexible substrate and the flexible insulative layer 308. A key to align the tab section 206 with an electrical connector (not shown) and to retain the connector on the tab section may be provided on the

stiffener and tab section. In operation, the opening 249 would receive and retain a retractable, spring-loaded pawl on the casing of a plug.

The temperature measurement device 300 is mounted on a region of skin 160 where temperature is to be measured with the second thermal sensor 226 closest to the skin 201. A layer of adhesive 322 is disposed on the second side 209, on the layer of insulation 340 and the portion of the tail section 204 where the second sensor 226 is located. The adhesive can attach the device 300 to the patient's 160 skin. The adhesive 322 can avoid contact with the pulse oximeter 216 as shown. In at least one embodiment, the adhesive 322 can be optically clear such as that commercially available from 3M (St. Paul, MN).

A release liner (not shown in this figure) may be peeled from the layer of adhesive 322 to prepare the device 300 for attachment to the skin. When deployed as shown in FIG. 3, a pluggable signal interface between the electrical circuit 200 on the device 300 and a temperature control mechanization is provided through the plurality of electrical connection pads 230 located in the tab section 206. The signals transferred therethrough would include at least heater activation and thermal sensor signals.

Use of an electrical circuit 200 disposed on a flexible substrate greatly simplifies the construction of a disposable medical device for estimating deep tissue temperature, and substantially reduces the time and cost of manufacturing such a device. In this regard, manufacture of a temperature measurement device incorporating an electrical circuit 200 laid out on a side of the flexible substrate with the circuit elements illustrated in FIG. 2 may be understood with reference to FIG. 4.

For example, FIG. 4 shows the layers used in the construction of the device 400 which is like the device 300. In at least one embodiment, the insulative layer 308 (with a side wall thickness 310) can be configured to have a region 410 which corresponds to a region of lower insulative properties that can improve the thermal properties of the sensor. The region 410 can be further described in paras. [0034] to [0040] in U.S. provisional application no. 62/665,892, filed May 2, 2018, which is incorporated by reference. The adhesive 322 is covered with a release liner 326.

FIGS. 5 and 6 illustrate an example of a device 500 that measures both the pulse oximetry and core body temperature. The device 500 is an embodiment of device 110 and similar to the device 300 except that the pulse oximeter 516 is in a geometric center of the device 500. The pulse oximeter 516 is an embodiment of pulse oximeter 116. In at least one embodiment, the pulse oximeter 516 can also have a thermal sensor embedded therein. The device 500 can also include a thermal sensor 520 roughly aligned along axis 602 with the thermal sensor in the pulse oximeter 516. This construction can improve a profile of the device 500 by reducing the number of components.

The pulse oximeter 516 and the thermal sensor 520 can be located within an inner perimeter 530 of the device 500. The inner perimeter 530 can be defined by a heating zone. The heating zone can be defined by the lack of heating by a heater element relative to the surrounding area. In at least

surrounded or encompassed by the heater element.

The inner perimeter 530 can correspond to a cutout portion of an insulative layer. For example, layer 340 can have a cutout portion where the pulse oximeter 516 is seated. The layer 308 can also have a cutout portion or region of lower insulative value relative to another portion. The components such as the thermal sensor 520, and pulse oximeter 516 can further be disposed on a substrate 508 (such as a flexible substrate) and be electrically connected with one another. In at least one embodiment, the pulse oximeter 516 can also be roughly aligned with the center of the device 500 as shown by axis 602.

In at least one embodiment, the device 500 has an outer perimeter 510 which can correspond to the outside edge of the insulative layer 308 and/or the substrate 508.

FIGS. 7 and 8 illustrate a device 700 that is an embodiment of device 110 from FIG. 1. Device 700 shows a configuration where components of the pulse oximeter are separate. For example, the LEDs 718 are separate from the photodiode 724 in a spaced-apart configuration. In at least one configuration, the device 700 can have a standoff distance 713 between the photodiode 724 and the LEDs 718.

In at least one embodiment, one or both LEDs 718 and the photodiode 724 are positioned outside of the inner perimeter 712. The LEDs 718 are shown as being proximate the outer perimeter 710.

The LEDs 718 and the photodiode 724 can be generally separate from the thermal sensor 720, or 726. For example, the LEDs 718 can have a standoff distance 735 from the thermal sensor 720 or 726. Light 714 from at least one of the LEDs 718 can be transflected across the tissue of a patient 160 and onto the photodiode 724. The thermal sensors 720 and 726 can be generally aligned along a vertical axis. The construction of the device 700 can be similar to device 300 or device 500.

FIG. 9 illustrates a device 900 that is an embodiment of device 110 from FIG. 1. The device 900 is similar to device 700 except the LEDs 918 are proximate or adjacent to the photodiode 924. The LEDs 918 can have a standoff distance 913 with respect to the photodiode 924.

FIG. 10 illustrates an embodiment of a pulse oximeter 1000 described herein. The pulse oximeter 1000 can include a photodetector 1014, and a combination red and infrared LED 1018 within a housing 1010. The housing 1010 can include a perimeter 1020. The perimeter 1020 can have a lip portion 1022 that is generally parallel with the skin contact plane of the pulse oximeter 1000. The lip portion 1022 can contact a wall 1024 which extends perpendicularly from the lip portion 1022 and is generally perpendicular to the skin contact plane of the device. The lip portion 1022 can form a catch to prevent the housing 1010 from slipping out from an insulative layer, particularly when a hole is formed therein.

FIG. 11 illustrates an embodiment of a device 1100 which is an embodiment of device 110 in FIG. 1. The device 1100 is shown with the pulse oximeter 1000 from FIG. 10 and an insulative layer

example, the lip portion 1022 can abut a major surface of the insulative layer 1140 and a wall 1024 can abut a minor surface of the insulative layer. The pulse oximeter 1000 can be disposed in a position that is approximately in the midpoint 1112 of the device 1100. For example, at least a portion of the pulse oximeter 1000 can be disposed within a center portion of the first or second insulative layer. In at least one embodiment, the pulse oximeter 1000 is not proximate to the outer perimeter 1110 of the device 1100.

FIG. 12 illustrates an embodiment of a device 1200. The device 1200 is an embodiment of device 110 in FIG. 1. Device 1200 can be configured such that at least one a thermal sensor (e.g., 1214) is positioned outside of an inner perimeter 1212. The thermal sensor 1214 can be aligned with another thermal sensor that is stacked on top of the sensor 1214 as described herein.

The device 1200 can also include a pulse oximeter 1216. The pulse oximeter 1216 can be positioned at a stand-off distance 1210 from the thermal sensor 1214.

The device 1200 can have an inner perimeter 1212 and an outside perimeter 1213 which can be defined in part by a heater element (not shown). In at least one embodiment, the pulse oximeter 1216 is positioned within the inner perimeter 1222 and the thermal sensor is positioned outside of the inner perimeter 1212 and proximate to the outer perimeter 1214.

FIG. 13 illustrates a computing device 1300 which is an embodiment of computing device 130 in FIG. 1. FIG. 13 shows a detailed example of various devices that may be configured to execute program code to practice some examples in accordance with the current disclosure. For example, computing device 1300 may be a computing device that performs any of the techniques described herein. In addition to corresponding to the computing device 130, the computing device 1300 is as well as the computing circuitry within the medical monitor 960. In the example illustrated in FIG. 13, a computing device 1300 includes a processor 1310 that is operable to execute program instructions or software, causing the computer to perform various methods or tasks. Processor 1310 is coupled via bus 1320 to a memory 1330, which is used to store information such as program instructions and other data while the computer is in operation. A storage device 1340, such as a hard disk drive, nonvolatile memory, or other non-transient storage device stores information such as program instructions, data files of the multidimensional data and the reduced data set, and other information. The computer also includes various input-output elements 1350, including parallel or serial ports, USB, Firewire or IEEE 1394, Ethernet, and other such ports to connect the computer to external device such as a printer, video camera, surveillance equipment or the like. Other input-output elements may include wireless communication interfaces such as Bluetooth, Wi-Fi, and cellular data networks.

1. A device, comprising:
 - a plurality of thermal sensors; and
 - a pulse oximeter.
2. The device of embodiment 1, further comprising:
 - a substrate having a first section and a second section, wherein the plurality of thermal sensors comprises:
 - a first thermal sensor disposed within a portion of the first section;
 - a second thermal sensor disposed in a portion of a second section.
- 2a. The device of embodiment 2, wherein the substrate is continuous.
- 2b. The device of embodiment 1, wherein the pulse oximeter is configured to measure the SpO₂ of a patient by using optical signals.
- 2c. The device of embodiment 1 or 2, further comprising:
 - a processor communicatively coupled to the plurality of thermal sensors and the pulse oximeter, wherein the processor is configured to receive a temperature from at least one of the plurality of thermal sensors, determine a core body temperature of a patient from the temperature, and receive a plurality of values indicative of a biological response to light from the pulse oximeter, and determine the SpO₂ from the plurality of values.
- 2d. The device of any of embodiments 1 to 2c, wherein the device is a medical device or temperature device.
3. The device of embodiment 1 or 2, further comprising:
 - an insulative layer disposed between the first section and the second section, wherein the first section and the second section are connected.
- 3a. The device of embodiment 3, wherein the substrate is folded over such that the second section is in a first layer, and the first section is in a second layer, and the insulative layer is sandwiched between the first layer and the second layer.
4. The device of embodiment 3, wherein a portion of the pulse oximeter is disposed in a portion of the second section or the first section.
5. The device of embodiment 3 or 4, wherein the insulative layer has a indented region or cutout formed therein on a side facing the second section.
6. The device of embodiment 5, wherein a portion of the pulse oximeter is disposed in a portion of the indented region or cutout.
7. The device of any of embodiments 1 to 6, wherein the plurality of thermal sensors is arranged to measure a core body temperature of a patient.
8. The device of any of embodiments 1 to 7, further comprising a heater element.
- 8a. The device of embodiment 8, wherein the heater element is configured to provide heat sufficient to remove at least some noise from a photodiode signal from the pulse oximeter.

sufficient to increase the peak height of the red or IR signals from the pulse oximeter.

8c. The device of any of embodiments 8 to 8b, wherein a skin-facing surface of the pulse oximeter is substantially planar with at least one thermal sensor.

9. The device of embodiment 8, wherein at least part of the heater element contacts a portion of the insulative layer.

10. The device of any of embodiments 1 to 9, wherein the insulative layer is substantially symmetrical and having a center portion that aligns with the second section of the substrate.

11. The device of any of embodiments 1 to 10, wherein at least a portion of the pulse oximeter is disposed along a peripheral portion of the substrate.

12. The device of embodiment 10, wherein at least a portion of the pulse oximeter is disposed within the center portion of the of the insulative layer or the first or the second section of the substrate.

13. The device of any of embodiments 1 to 12, wherein the substrate is
a flexible substrate joining the plurality of thermal sensors; and,
an electrical circuit disposed on a surface of the flexible substrate, the electrical circuit comprising:

the plurality of thermal sensors; and
a plurality of conductive traces.

14. The device of embodiment 13, wherein the electrical circuit further comprises:

the heater element surrounding a first zone of the surface, wherein the first thermal sensor is disposed in the first zone and the second thermal sensor disposed outside of the heater element.

14a. The device of embodiment 14, wherein the electrical circuit further comprises:

a plurality of electrical pads disposed outside of the heater element, and
a plurality of conductive traces connecting the first and second thermal sensors and the heater element with the plurality of electrical pads.

14b. The device of embodiment 14, wherein the heater element surrounds a second zone of the surface, wherein the second zone is surrounded by the heater element and has the pulse oximeter disposed therein.

15. The device of embodiment 13 or 14, in which first and second sections of the flexible substrate are folded together to place the first and second thermal sensors in proximity to one another, between the sections.

16. The device of any of embodiments 13 to 15, wherein the flexible substrate comprises a center section, a tab section that is contiguous with the center section and extending from the center section in a first radial direction, and a tail section contiguous with the center section and extending from the center section in a second radial direction.

16a. The device of embodiment 16, wherein the center section is the first section and the tail section is the second section of the substrate.

thereon.

18. The device of any of embodiments 13 to 17, wherein a zone is encompassed by the heater element.

19. The device of any of embodiments 13 to 18, wherein a zone is an area thermally insulated from the heater element.

20. The device of any of embodiments 13 to 19, wherein a zone is thermally isolated from the heater element such that the heater element does not induce heat via induction or conduction to the first thermal sensor.

21. The device of any of embodiments 13 to 20, wherein the second thermal sensor is a first standoff distance from the center section.

22. The device of embodiment 21, wherein the first standoff distance is measured from a perimeter of the center section.

23. The device of any of embodiments 13 to 22, wherein the insulative layer is disposed between folded-together sections of the flexible substrate and separating the first and second thermal sensors.

24. The device of embodiment 23, wherein the first and second thermal sensors are positioned in a spaced-apart relationship.

25. The device of any of embodiments 1 to 24, wherein the first and second thermal sensors and the heater element are disposed on a first side of the flexible substrate, the device further comprising a second flexible insulative layer disposed on a second side of the flexible substrate, over the center section.

26. The device of embodiment 25, further comprising a flexible stiffener disposed on the second side of the flexible substrate, substantially coextensively with a tab section.

27. The device of embodiment 26, further comprising an electrical connector alignment key on the tab section.

28. The device of any of embodiments 16 to 27, further comprising a pattern of slits formed in the center section from the substrate therein.

29. The device of embodiment 28, wherein the pattern of slits defines a plurality of heater zones occupied by the heater element.

30. The device of embodiment 29, wherein the heater zones are wedge-shaped.

31. The device of embodiment 29, wherein each heater zone is flexible independently of any other heater zone.

32. The device of any of embodiments 16 to 31, further comprising a reduced width of the tail section where the center and tail sections are joined.

33. The device of any of embodiments 28 to 32, wherein the pattern of slits and the heater element define a multi-zone heater.

the center section has an annular shape, the heater element is concentric with the center section.

35. The device of any of embodiments 16 to 34, in which the heater element includes three terminal ends and a first electrical pad of the plurality of electrical pads is connected only to a first terminal end of the heater element, a second electrical pad of the plurality of electrical pads is connected only to a second terminal end of the heater element, and a third electrical pad of the plurality of electrical pads is connected only to a third terminal end of the heater element.

36. The device of embodiment 35, in which the center section has a substantially circular shape and the tail section and tab section are separated by an arc of less than or equal to 180° on the periphery of the center section.

37. The device of any of embodiments 16 to 36, wherein the heater element has an outer perimeter and an inner perimeter, the inner perimeter surrounding the first zone of the surface.

38. The device of embodiment 37, wherein the heater element has a first dimension defining the outer perimeter and a second dimension defining the inner perimeter, wherein a ratio of the first dimension to a second dimension is no greater than 2.1:1.

39. The device of any of embodiments 37 to 38, wherein the first dimension is defined by a largest linear dimension between two opposing points in the outer perimeter.

40. The device of embodiment 38, wherein the second dimension is defined by the largest linear dimension between two opposing points in the inner perimeter.

41. The device of embodiment 39, wherein the first dimension is defined by a largest dimension between the first sensor and a point on the outer perimeter.

42. The device of embodiment 41, wherein the second dimension is defined by the largest dimension between the first sensor and a point on the inner perimeter.

43. The device of any of embodiments 37 to 42, wherein the heater element has a zone of heating defined by the outer perimeter and the inner perimeter.

44. The device of embodiment 43, wherein the zone has a zone area and the ratio of the zone of heating to the zone area is no greater than 22:1.

45. The device of embodiment 44, wherein the device has an unheated area outside of the heater element and including the zone area, and the ratio of the zone of heating to the unheated area is no greater than 17:1.

46. The device of any of embodiments 8 to 45, wherein the heater element is a heater trace defined by wires.

47. The device of any of embodiments 8 to 46, wherein the heater element is a polymeric heater.

48. The device of any of embodiments 37 to 47, wherein a distance from the first thermal sensor to a point of the inner perimeter is at least 4 mm.

placed on a forehead of a patient, proximate to a temporal artery, and receiving a current is no greater than 200 mW at standard ambient condition.

50. The device of any of embodiments 1 to 49, further comprising a second flexible insulative layer disposed on a second side of the flexible substrate, over the first section.

51. The device of embodiment 50, wherein the second flexible insulative layer has a thermal resistance of at least 100 K/W.

52. The device of embodiment 50 or 51, wherein the second flexible insulative layer has a thickness of between 1 mm to 6 mm.

53. The device of embodiment 52, wherein the second flexible insulative layer further comprises a reflective layer.

54. The device of any of embodiments 50 to 53, wherein the second flexible insulative layer has a first region with a lower thermal resistance relative to a second region of the second flexible insulative layer.

55. The device of any of embodiments 16 to 54, wherein the first region is defined by the zone and the second region is defined by the heater element.

56. The device of any of embodiments 1 to 55, wherein the pulse oximeter is positioned on the second layer.

57. The device of any of embodiments 1 to 55, wherein the pulse oximeter comprises a driver circuit and a photodiode, the driver circuit having at least one LED configured to provide at least two wavelengths of light, the photodiode configured to provide at least two photodiode readings to the at least two wavelengths of light from the at least one LED, wherein at least two photodiode readings is indicative of light absorption of arterial blood in a patient at each of the at least two wavelengths of light.

57a. The device of embodiment 57, wherein the driver circuit is disposed proximate to the periphery and the photodiode is disposed proximate to the periphery opposite from the photodiode.

58. The device of embodiment 57a, wherein the driver circuit is no greater than 9mm apart from the photodiode.

59. The device of any of embodiments 1 to 58, wherein the pulse oximeter comprises a housing, the driver circuit and the photodiode are disposed within the housing.

60. The device of any of embodiments 57 to 59, wherein the driver circuit comprises a red LED and an infrared LED.

61. The device of any of embodiments 1 to 60, wherein the pulse oximeter is positioned at least 3 mm apart from the first thermal sensor.

62. A system comprising

the device of any of embodiments 1 to 61;

a first computing device, wherein the first computing device is communicatively coupled to the heater element and the first and second thermal sensors, the first computing device comprising one or

more computer processors cause the one or more computer processors to:

- receive from the first thermal sensor a first electrical signal and a second electrical signal from the second thermal sensor;

- determine a first temperature from the first electrical signal and a second temperature from the second electrical signal;

- determine whether a difference between the first temperature and the second temperature is non-zero;

- activate an electrical current to the heater element in response to the difference being non-zero.

63. The system of embodiment 62, wherein the first computing device is configured to apply a second electrical current to the driver circuit, receive a photodiode reading from the photodiode, and transmit a photodiode reading.

64. The system of embodiment 63, wherein the first computing device is configured to activate the electrical current prior to applying a second electrical current.

65. The system of any of embodiments 62 to 64, wherein an operational power of the heater element when placed on a forehead of a patient, proximate to a temporal artery, and receiving the electrical current from the device is no greater 200 mW at standard ambient conditions.

66. The system of any of embodiments 62 to 65, further comprising a first housing, wherein the device and the first computing device are disposed in the first housing.

67. The system of any of embodiments 62 to 66, wherein the first computing device comprises:

- a first communication module, disposed at least partially inside of the first housing, communicatively coupled to the first computing device and configured to transmit a core body temperature of a patient using one or more radio frequencies;

- a portable power source, disposed at least partially inside of the first housing, electrically coupled to the first computing device having a capacity no greater than 2000 milliampere hour.

68. The system of any of embodiments 62 to 67, further comprising:

- a receiving device, comprising:

- a second housing;

- a second communication module at least partially within the second housing;

- a second computing device at least partially within the second housing and communicatively coupled to the receiving device, the second computing device comprising one or more computer processors and a memory comprising instructions that when executed by the one or more computer processors cause the one or more computer processors to:

- receive the first temperature and information concerning SpO₂ of a patient from the first computing device;

- provide the first temperature and information concerning SpO₂ of a patient to medical monitor circuitry.

electrically coupled to the receiving device.

70. The system of embodiment 68 or 69, wherein the first computing device is configured to:

receive at least two photodiode readings;

determine an AC component value and a DC component value of a first one of the at least two photodiode readings;

transmit the AC component value;

determine an R-value, corresponding to a ratio of an optical absorption of a first wavelength of light to an optical absorption of a second wavelength of light, for a first set of photodiode readings;

transmit the R-value for the first set of photodiode readings.

71. The system of embodiment 70, further comprising:

a pulse oximetry module communicatively couple to a pulse oximetry photodiode and a medical monitor; the pulse oximetry module comprising one or more processors configured to:

receive a first LED activation signal at a first time from a medical monitor,

receive a first wireless photodiode signal at a second time and an R-value at a third time;

determine a second photodiode signal based on the first wireless photodiode signal, the R-value, and the first LED activation signal;

determine the first photodiode signal current from a first photodiode signal and the second photodiode signal;

output the first photodiode signal current to the medical monitor.

72. The system of embodiment 71, wherein a difference between the second time and the first time is 10-20 ms.

73. The system of embodiment 71 or 72, wherein a difference between the first time and the third time is 1 to 5 seconds.

74. The system of any of embodiments 71 to 73, wherein an LED activation signal, a wireless signal, or photodiode signal correspond to at least one value.

75. The system of any of embodiments 71 to 74, wherein the LED activation signal corresponds to an on or off value.

76. The system of any of embodiments 71 to 75, wherein a first wireless photodiode signal corresponds to at least one numeric value corresponding to a portion of a photodiode current reading from a first LED.

77. The system of any of embodiments 71 to 76, wherein a second wireless photodiode signal corresponds to at least one numeric value corresponding to a portion of photodiode current reading from a second LED.

one numeric value corresponding to a ratio of a first ratio of AC component to DC component for a first wavelength of light to a second ratio of an AC component to DC component for a second wavelength of light.

79. The system of any of embodiments 71 to 78, wherein the LED activation signal, the wireless signal, or photodiode signal correspond to a plurality of values.

79a. The system of any of embodiments 62 to 79, further comprising a patient, wherein the device is disposed proximate to a temporal artery of the patient.

80. A device comprising:

- a heater element having a power output of at least 20 mW; and
- a pulse oximeter.

81. The device of embodiment 80, wherein the heater element does not interfere with measuring a photodiode reading from the pulse oximeter.

82. The device of any of embodiments 80 to 81, wherein the heater element is positioned at least 2 mm from a portion of the heater element.

83. The device of any of embodiments 80 to 82, wherein the heater element has a power output of at least 100 mW.

84. The device of any of embodiments 80 to 83, further comprising a plurality of thermistors.

85. The device of embodiment 84, wherein the plurality of thermistors is arranged to receive heat from a patient.

86. The device of any of embodiments 80 to 85, further comprising a computing device communicatively coupled to the heater element and the pulse oximeter.

87. The device of embodiment 86, wherein the computing device comprises a memory comprising instructions that, when executed by one or more computer processors of the computing device, cause the one or more computer processors to deactivate the heater element, activate an LED based on the deactivation of the heater element, and receive a photodiode response to the LED.

88. The device of embodiment 86 or 87, wherein the computing device is configured to activate the heater in response to a temperature from one of the plurality of thermistors.

89. A method comprising:

- activating a heater element in the device of any of embodiments 1 to 61;
- receiving a photodiode response to a light source from a pulse oximeter in the device in response to activating the heater element.

90. The method of embodiment 89, wherein activating the heater element comprises using an IR light of the pulse oximeter to warm a patient.

91. The method of embodiment 89 or 90, wherein activating the heater element comprises applying at least 20 mW of power to the heater element.

1. A device, comprising:
 - a plurality of thermal sensors;
 - a pulse oximeter; and
 - a heater element.
2. The device of claim 1, further comprising:
 - a substrate having a first section and a second section;
 - wherein the plurality of thermal sensors comprises:
 - a first thermal sensor disposed within a portion of the first section;
 - a second thermal sensor disposed in a portion of a second section;
 - wherein the heater element is disposed on the substrate.
3. The device of claim 1 or 2, further comprising:
 - an insulative layer disposed between the first section and the second section, wherein the first section and the second section are connected.
4. The device of claim 3, wherein the insulative layer has a indented region formed therein on a side facing the second section and a portion of the pulse oximeter is disposed in a portion of the indented region.
5. The device of any of claims 1 to 4, wherein the plurality of thermal sensors is arranged to measure a core body temperature of a patient.
6. The device of any of claims 1 to 5, wherein a skin-facing surface of the pulse oximeter is substantially planar with at least one thermal sensor.
7. The device of any of claims 3 to 6, wherein the insulative layer is substantially symmetrical and having a center portion.
8. The device of any of claims 1 to 7, wherein at least a portion of the pulse oximeter is disposed adjacent to a peripheral portion of the substrate.
9. The device of any of claims 1 to 8, wherein the substrate is a flexible substrate joining the plurality of thermal sensors; and,
 - an electrical circuit on a surface of the substrate, the electrical circuit comprising:
 - the plurality of thermal sensors;

a plurality of conductive traces connecting at least a thermal sensor with an electrical pad.

10. The device of claim 9, wherein the heater element surrounds a first zone, wherein a first thermal sensor is disposed in the first zone and a second thermal sensor disposed outside of the heater element,

the plurality of electrical pads disposed outside of the heater element, and

the plurality of conductive traces connecting the first and second thermal sensors and the heater element with the plurality of electrical pads;

wherein the heater element also surrounds a second zone, wherein the pulse oximeter is disposed within the first or second zone.

11. The device of any of claims 1 to 10, wherein a portion of the pulse oximeter is positioned at least 3 mm apart from the first thermal sensor.

12. The device of any of claims 1 to 11, wherein the pulse oximeter comprises a driver circuit and a photodiode, the driver circuit is separate from the photodiode.

13. The device of any of claims 1 to 11, wherein the pulse oximeter comprises a driver circuit and a photodiode in the same housing.

14. A system, comprising:

the device of any of claims 1 to 13;

a first computing device, wherein the first computing device is communicatively coupled to the heater element and the first and second thermal sensors, the first computing device comprising one or more computer processors and a memory comprising instructions that when executed by the one or more computer processors cause the one or more computer processors to:

receive from the first thermal sensor a first electrical signal and a second electrical signal from the second thermal sensor;

determine a first temperature from the first electrical signal and a second temperature from the second electrical signal;

determine whether a difference between the first temperature and the second temperature is non-zero;

activate an electrical current to the heater element in response to the difference being non-zero.

electrical current to a driver circuit, receive a photodiode reading from the photodiode, and determine information concerning SpO₂ of a patient.

16. The system of claim 14 or 15, wherein the first computing device comprises:

- a first communication module, disposed at least partially inside of a first housing, communicatively coupled to the first computing device and configured to transmit a core body temperature of a patient using one or more radio frequencies;

- a portable power source, disposed at least partially inside of the first housing, electrically coupled to the first computing device having a capacity no greater than 2000 milliampere hour.

17. The system of claim 16, further comprising:

- a receiving device, comprising:

- a second housing;

- a second communication module at least partially within the second housing;

- a second computing device at least partially within the second housing and communicatively coupled to the receiving device, the second computing device comprising one or more computer processors and a memory comprising instructions that when executed by the one or more computer processors cause the one or more computer processors to:

- receive the first temperature from the first computing device;

- provide the first temperature to medical monitor circuitry.

18. The system of claim 16 or 17, further comprising:

- a medical monitor having an input pin electrically coupled to the receiving device.

19. A method comprising:

- activating a heater element in the device of any of claims 1 to 13;

- receiving a photodiode response to a light source from a pulse oximeter in the device in response to activating the heater element.

20. The method of claim 19, wherein activating the heater element comprises using an IR light of the pulse oximeter to warm a patient.

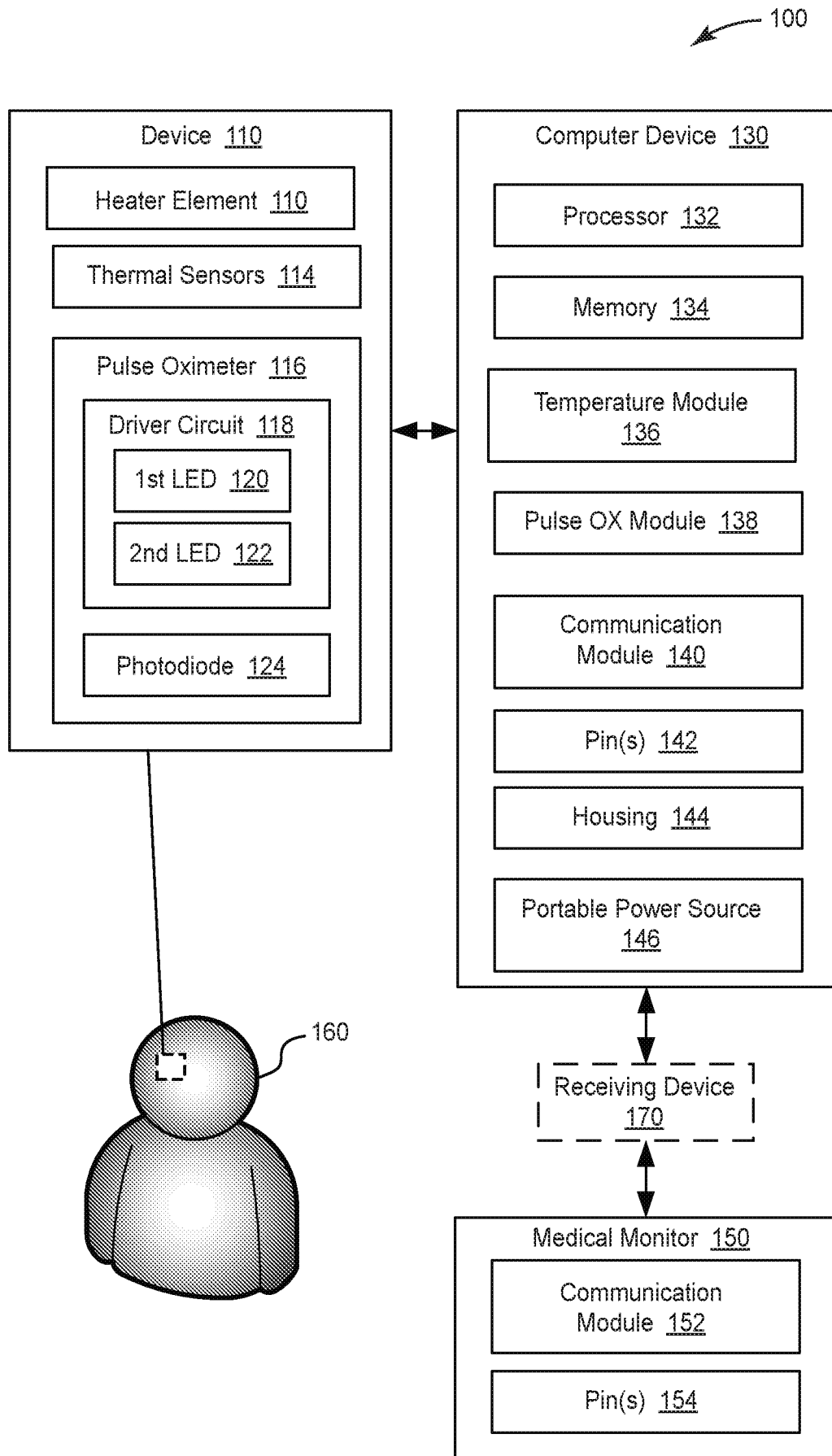


FIG. 1

2/12

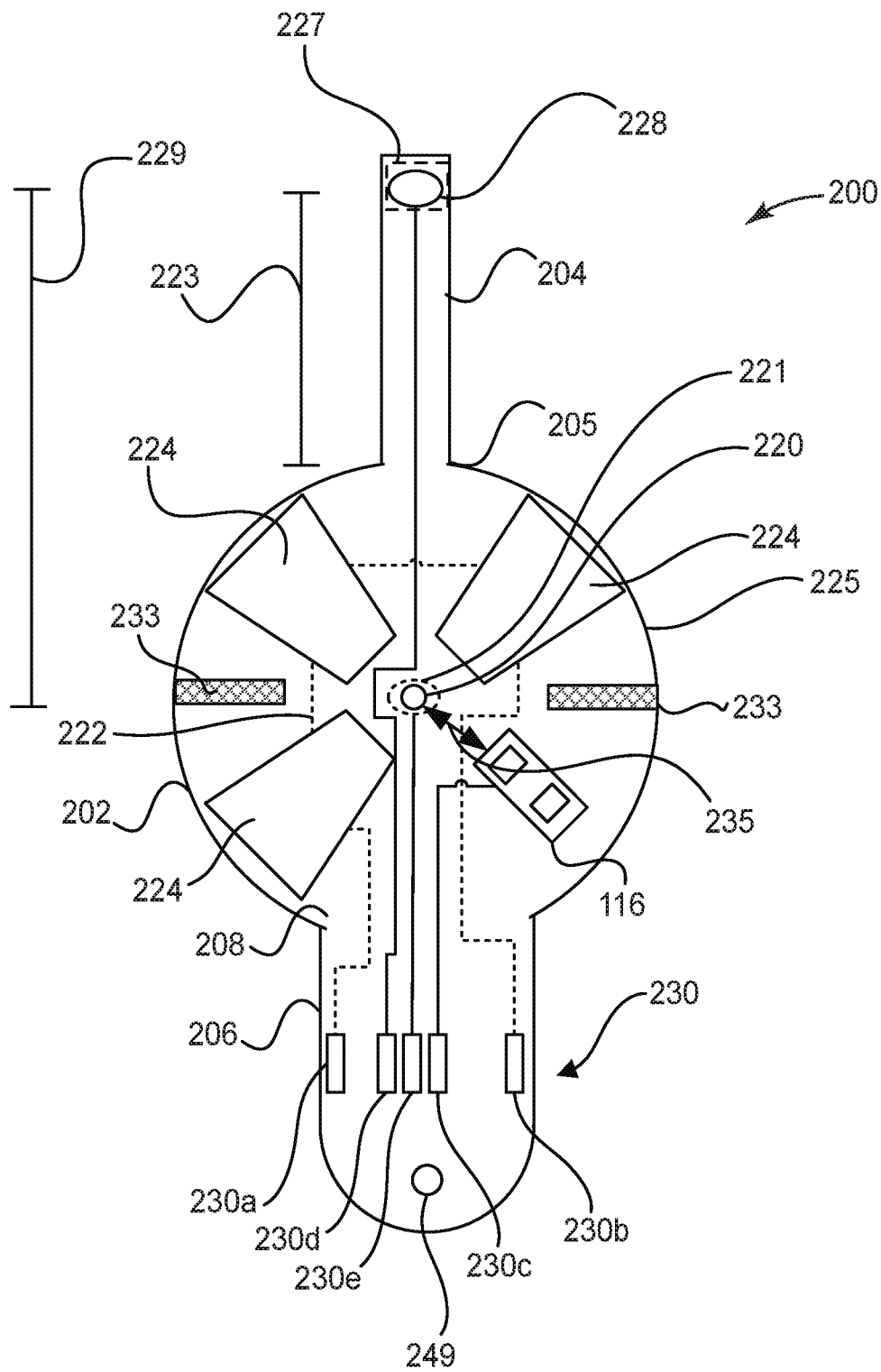


FIG. 2

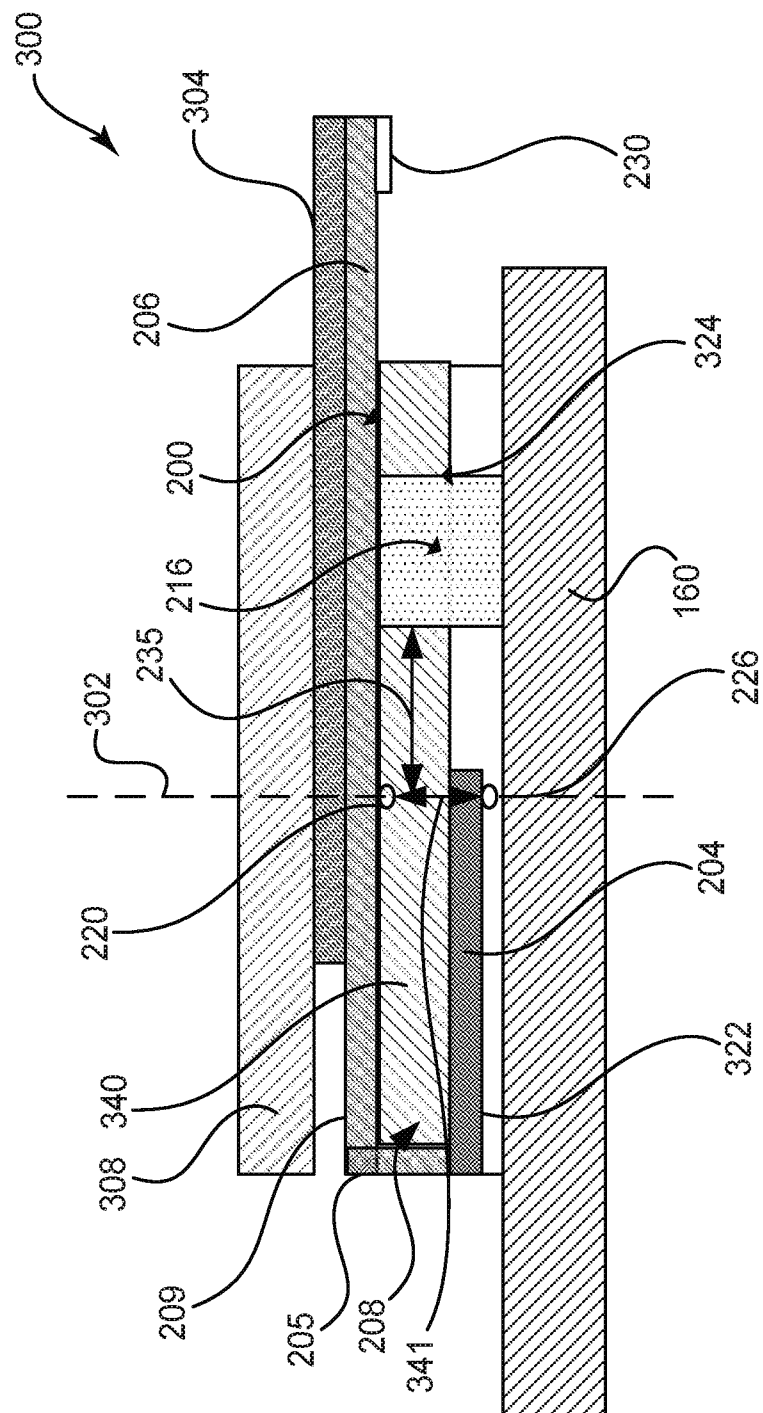


FIG. 3

4/12

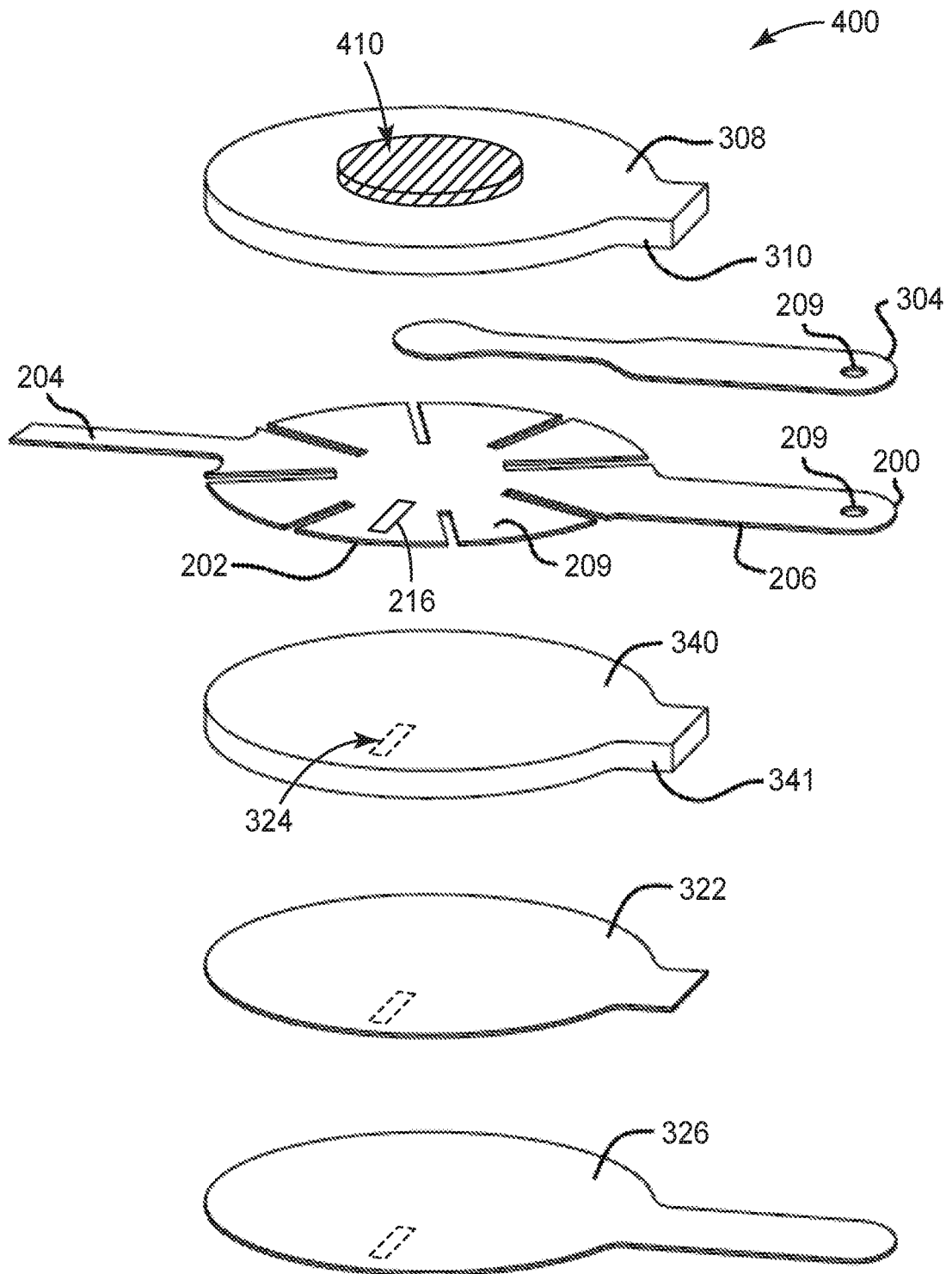


FIG. 4

5/12

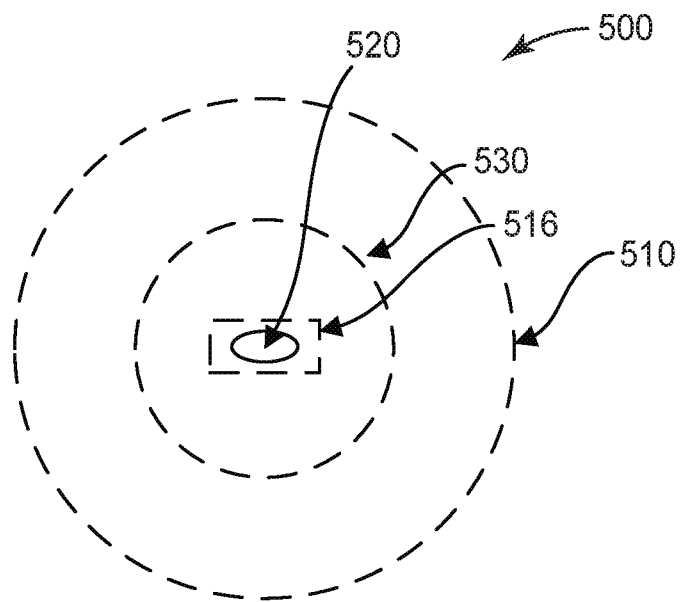


FIG. 5

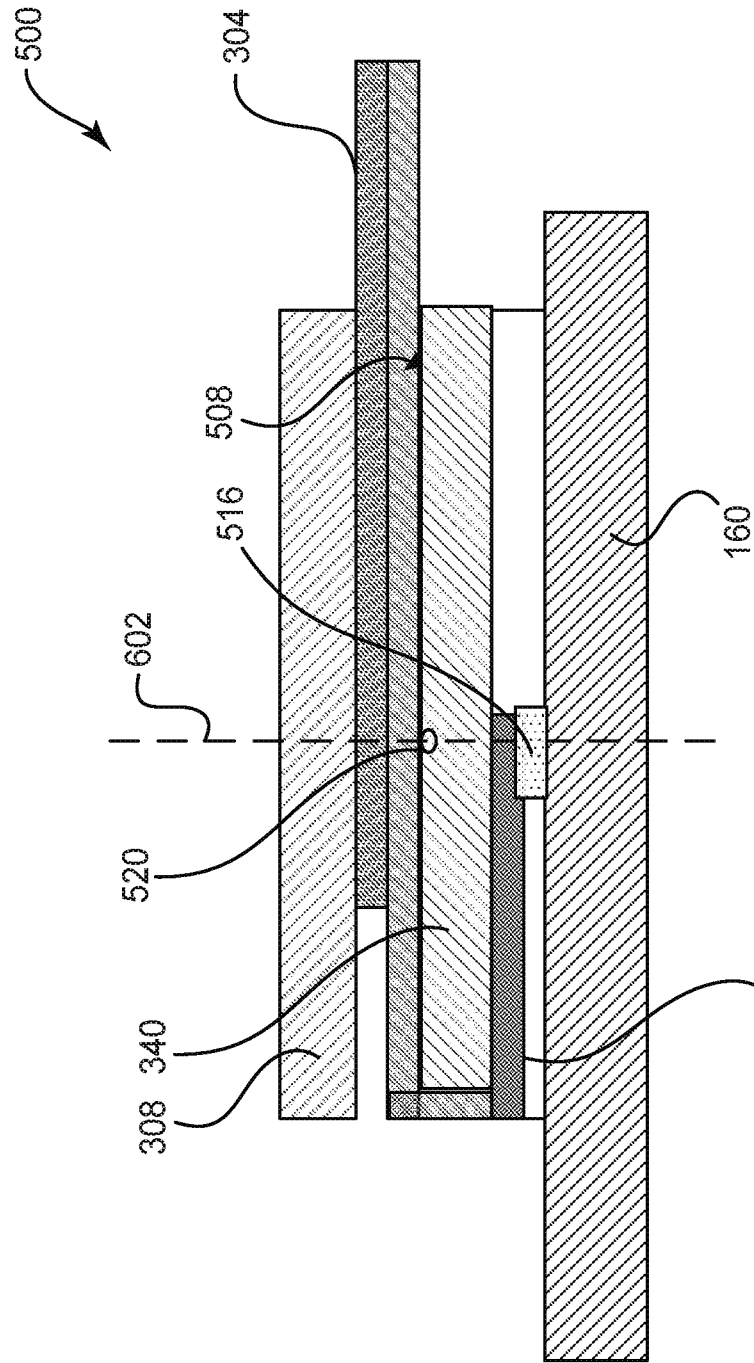


FIG. 6

7/12

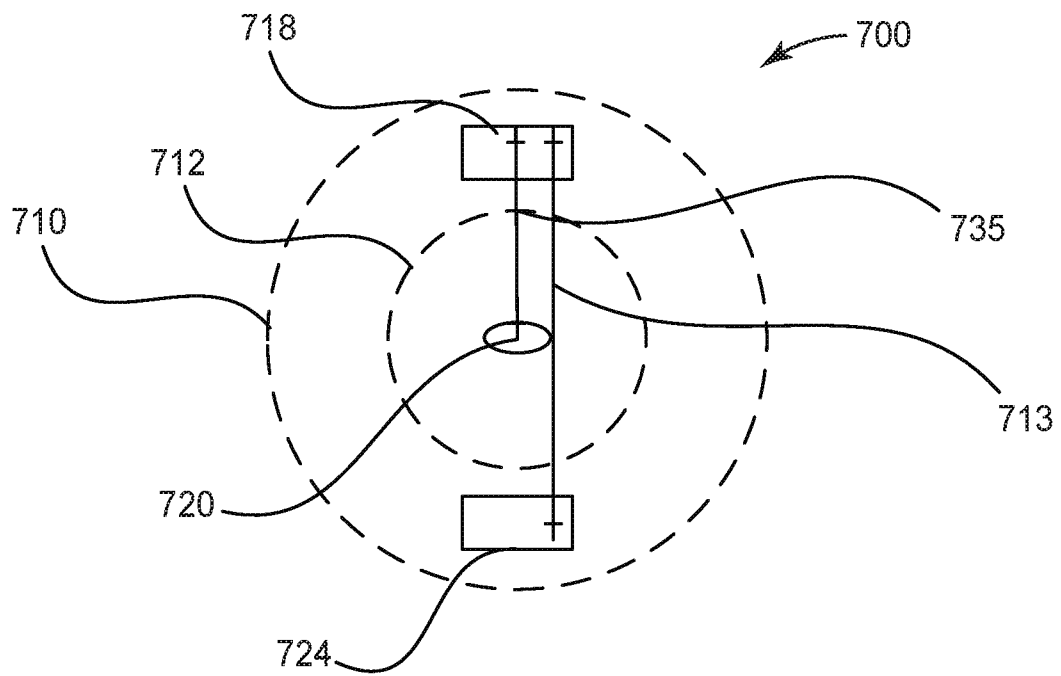


FIG. 7

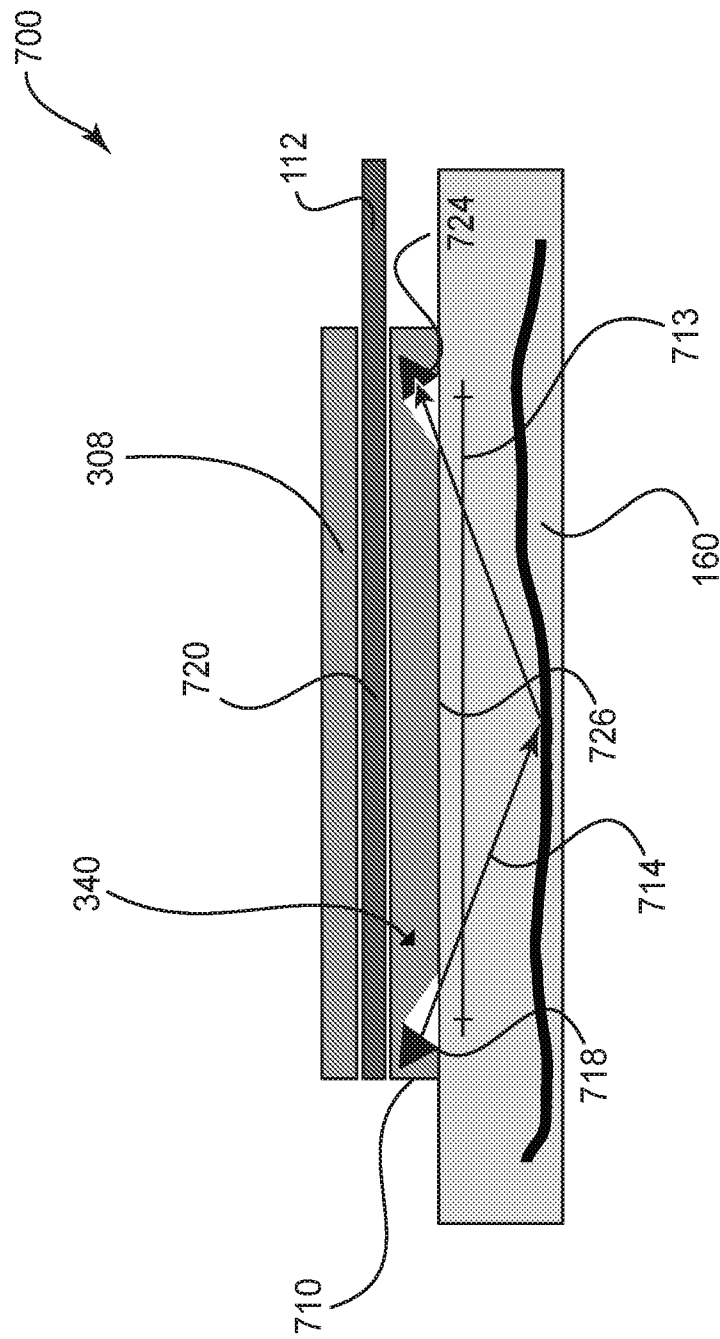


FIG. 8*

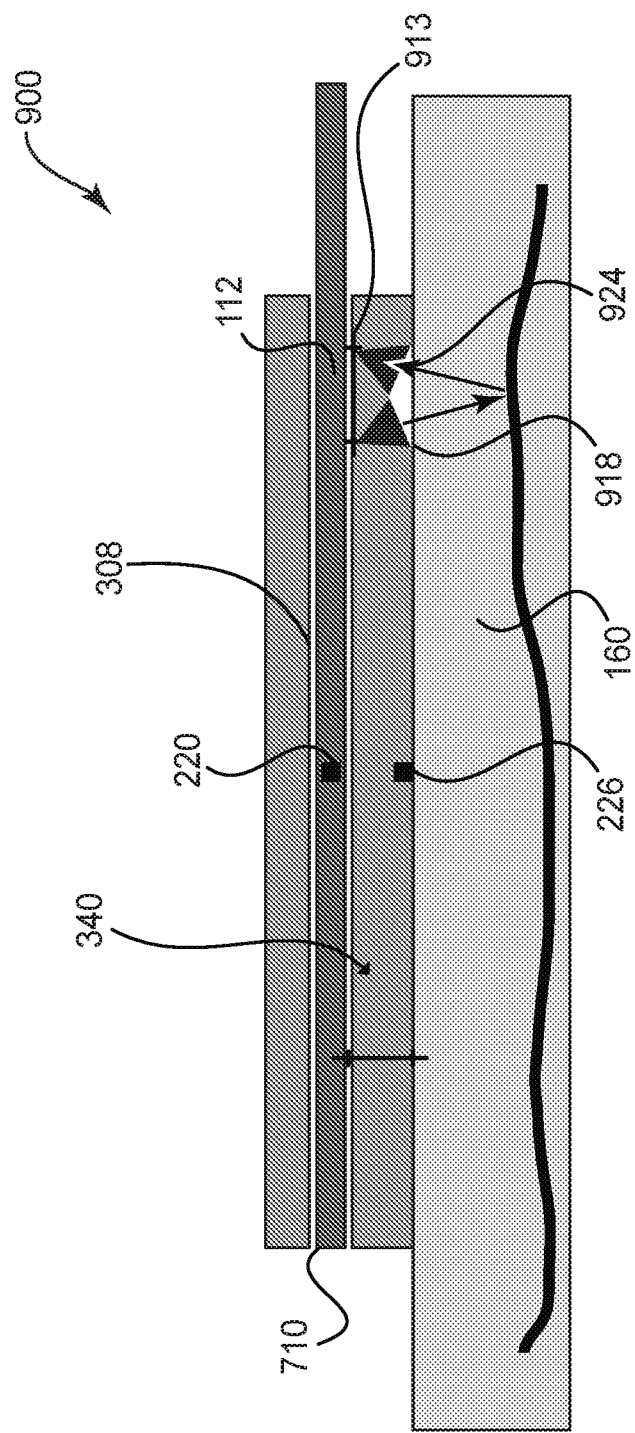


FIG. 9

10/12

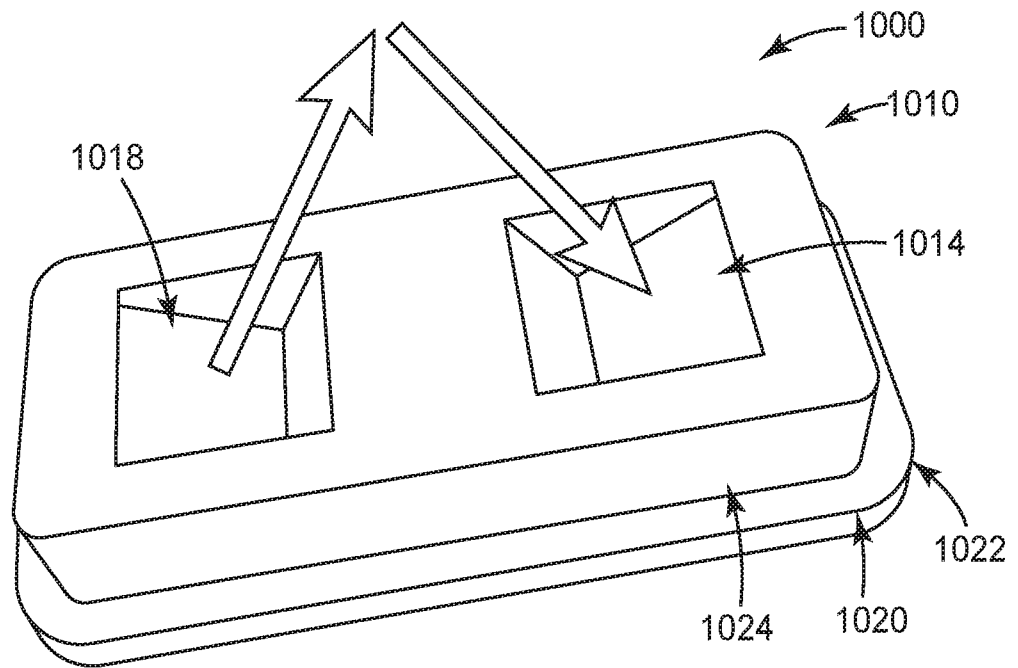


FIG. 10

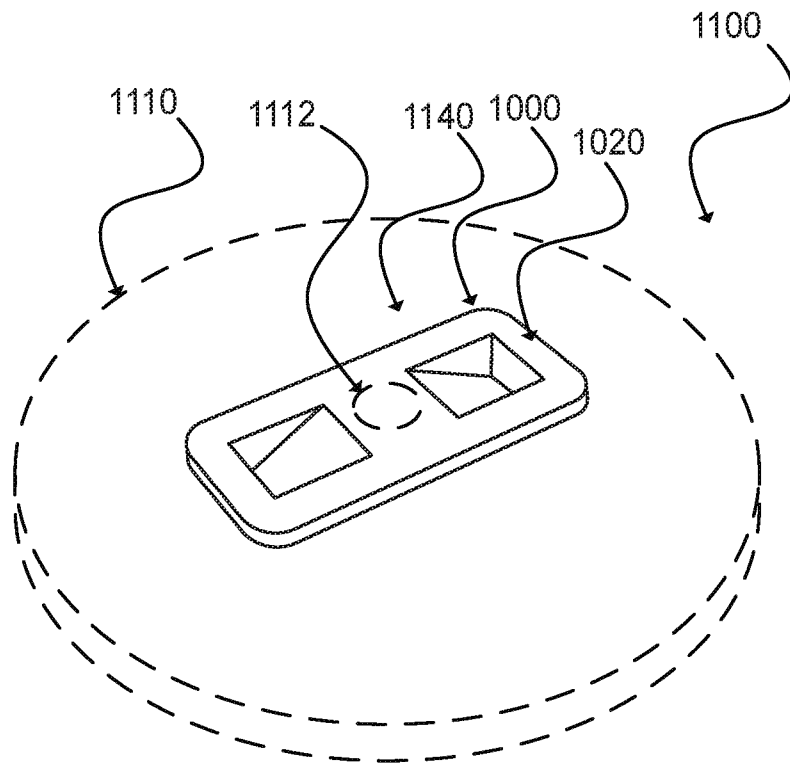


FIG. 11

11/12

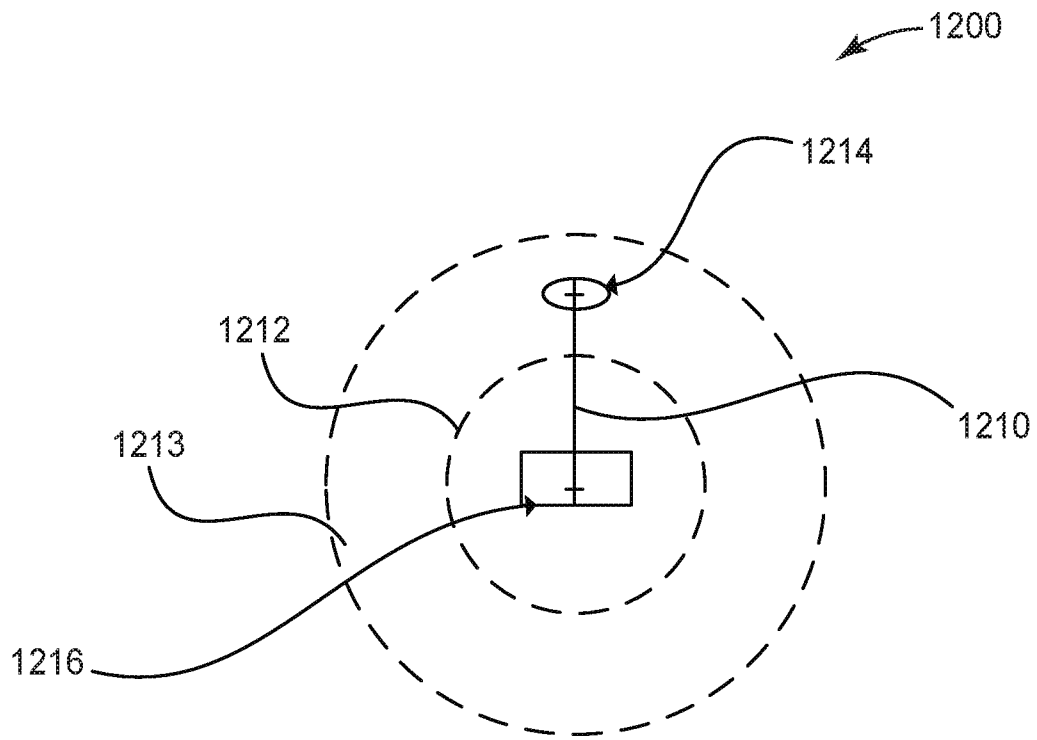


FIG. 12

12/12

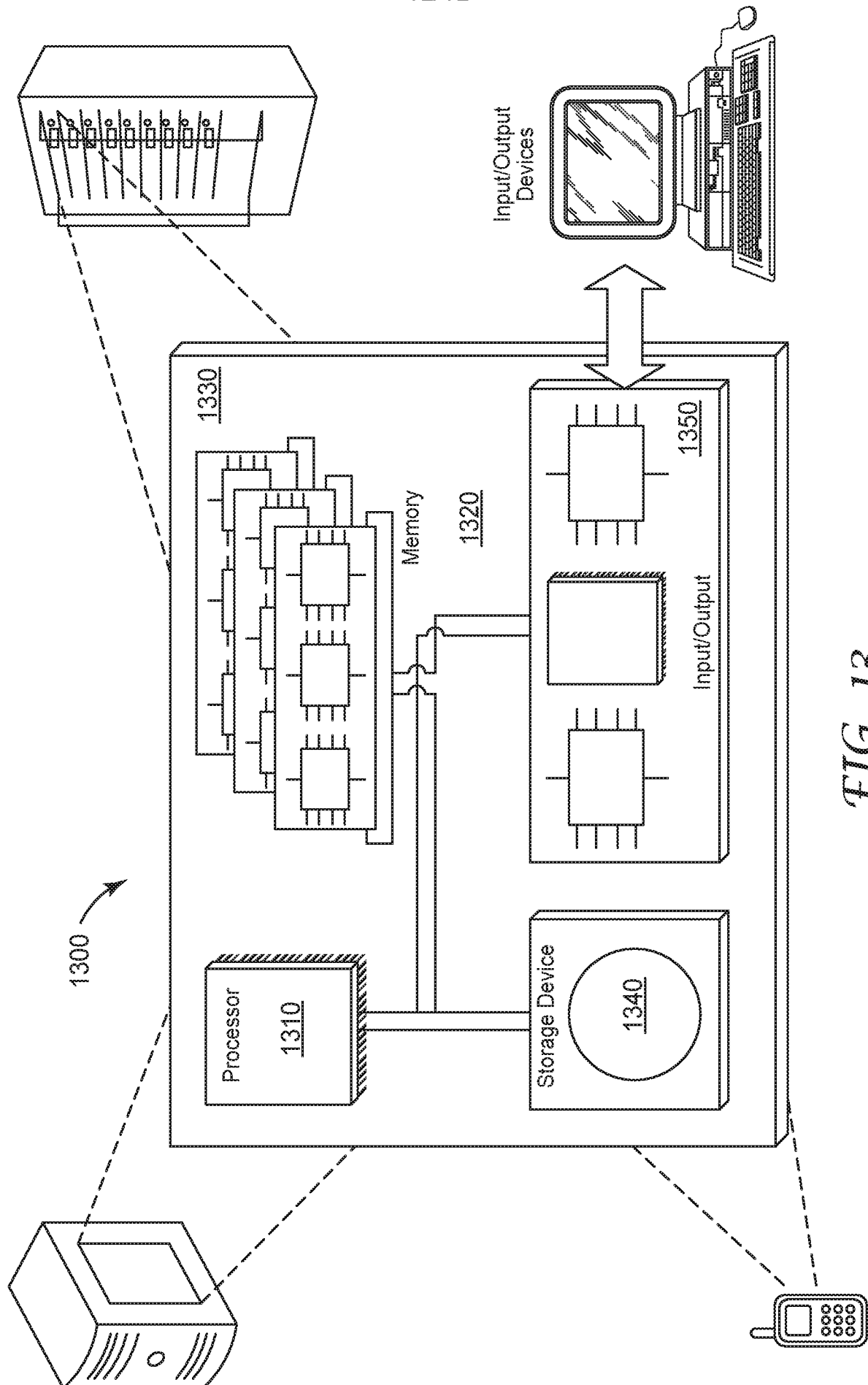


FIG. 13

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2019/056798

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/024 (2006.01) A61B 5/1455 (2006.01) A61B 5/1491 (2006.01)

According to International Patent Classification (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)

FamPat: thermal sensors, pulse oximeter, heater, insulative, temperature, skin, and related terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2018/0199872 A1 (ITO, K. & TSUCHIMOTO, H.) 19 July 2018 paras [0034]-[0035], [0039], [0041]-[0044], [0053], [0055], [0060]-[0065], figs 1-2, 4-6	1-20
X	US 5131391 A (SAKAI, H. & KOHMURA, S.) 21 July 1992 col 4 ln 9-19, col 5 ln 48-50, pg 6 ln 25-55, col 8 ln 43 – col 9 ln 10, fig 1	1-20
X	WO 03/022189 A1 (FISHER & PAYKEL HEALTHCARE LIMITED) 20 March 2003 pg 5 para 2 – pg 6 para 4, figs 1, 4	1-20

☒ 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

"D" document cited by the applicant in the international application

"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

21/11/2019

(day/month/year)

Date of mailing of the international search report

22/11/2019

(day/month/year)

Name and mailing address of the ISA/SG



Intellectual Property Office of Singapore

1 Paya Lebar Link, #11-03

PLQ 1, Paya Lebar Quarter

Singapore 408533

Email: pct@ipos.gov.sg

Authorized officer

Jie Xiao (Dr)

IPOS Customer Service Tel. No.: (+65) 6330 8660

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2019/056798**C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2015/0134297 A1 (SILVER, A. E. & FREEMAN, G. A.) 14 May 2015 paras [0022]-[0028], figs 3, 6	1-20
A	US 2002/0062070 A1 (TSCHUPP, A. ET AL.) 23 May 2002 Whole document, in particular paras [0046], [0049]-[0050]	-
A	WO 2016/210334 A1 (RHYTHM DIAGNOSTIC SYSTEMS, INC.) 29 December 2016 Whole document, in particular paras [0046], [0048]	-

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/IB2019/056798

Note: This Annex lists known patent family members relating to the patent documents cited in this International Search Report. This Authority is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2018/0199872 A1	19/07/2018	WO 2017/047402 A1	23/03/2017
US 5131391 A	21/07/1992	JP H0323846 A	31/01/1991
WO 03/022189 A1	20/03/2003	US 2003/0040783 A1 WO 03022189 A1 EP 1424969 A1 JP 2005501658 A	27/02/2003 20/03/2003 09/06/2004 20/01/2005
US 2015/0134297 A1	14/05/2015	NONE	
US 2002/0062070 A1	23/05/2002	HK 1059553 A1 AT 349948 T	29/06/2007 15/01/2007
WO 2016/210334 A1	29/12/2016	JP 2018518323 A CN 107735025 A EP 3313287 A1 CA 2983771 A1	12/07/2018 23/02/2018 02/05/2018 29/12/2016