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(54) Title: DEVICE FOR NEONATAL MONITORING

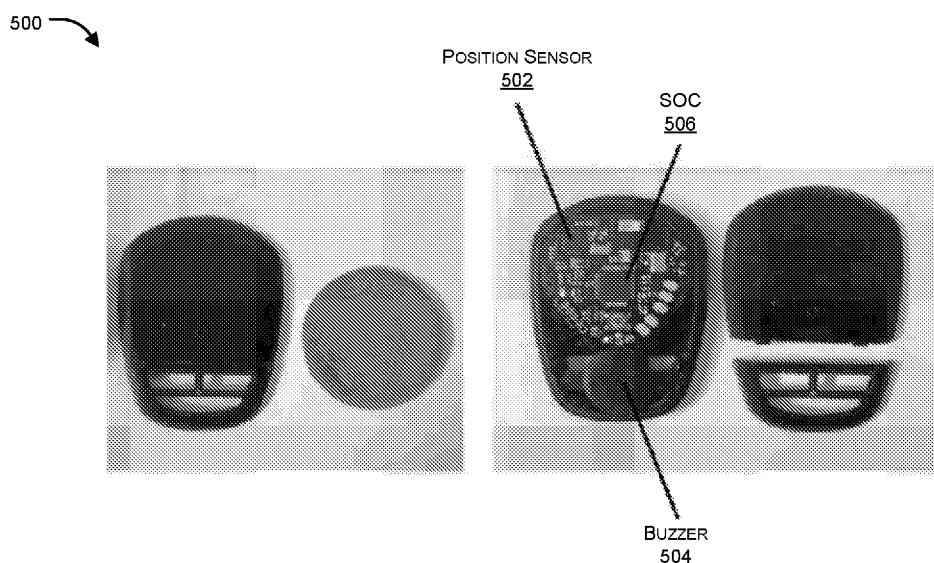


FIG. 5

(57) Abstract: A device for monitoring of neonates is disclosed. The device relies on determining whether a caregiver is holding a neonate with skin to skin contact such as during Kangaroo Mother Care treatment; and responsive to such determination, determines parameters such as temperature, activity level, breathing rate, angle of rest etc. of the neonate. The device incorporates touch sensors and temperature sensors on its two opposite surfaces and can be placed between the caregiver and the neonate to determine if a skin to skin contact is established or not. It does away with use of invasive sensors and thus safe for sensitive skin of neonates. Disclosed device can raise alarms when pre-defined threshold levels are exceeded or not met and can minimize false readings. It can be interfaced with other devices for enhanced monitoring abilities.



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DEVICE FOR NEONATAL MONITORING

TECHNICAL FIELD

[0001] The present disclosure relates generally to field of wearable biomedical sensors. In particular, it pertains to a system for physiological monitoring process of Kangaroo Mother Care.

BACKGROUND OF THE DISCLOSURE

[0002] The background description includes information that may be useful in understanding the present invention. It is not an admission that any of the information provided herein is prior art or relevant to the presently claimed invention, or that any publication specifically or implicitly referenced is prior art.

[0003] A newborn baby is medically termed a neonate and the neonatal period is the first 4 weeks of a child's life. It is a time when changes are very rapid. Many critical events can occur during this period such as establishment of feeding patterns, bonding between parents and infant. However, the period is also marked by higher risk of serious infections and it is this period during which any birth or congenital defect is first noticed. For this reason fatality during this period, referred to as neonatal deaths, is also high.

[0004] Global neonatal deaths today account for more than 40% of all child deaths before the age of five and is estimated to be more than 8 million (Oestergaard and Inoue, 2011). More than 95% of these deaths occur in developing nations like regions of Africa and South Asia. Reports (Global Health, 2010) have shown that India has about 10 times higher NMR compared to the western world. NMR in India was 31 as of 2011, a 33% decrease in NMR since 1990, yet taking into account its burgeoning population, approximately 1 million newborn died in 2010, nearly 30% of the global neonatal deaths(WHO,2012).

[0005] Recent research indicates that hypothermia is increasingly considered as a major cause of neonatal morbidity and mortality, especially in rural resource constrained settings(Kumar et al., 2009)(Kumar et al., 2008). Hypothermia for neonates is defined as an aberrant thermal state of diminution of their body's temperature below 36.5 degree centigrade. Further decrease in body temperature causes respiratory depression, acidosis,

decreases the cardiac output, decreases the platelet function, increases the risk of infection and may even lead to fatality without pre-emption (Macfarlane, 2006).

[0006] Prematurely born infants are at much greater risk of neonatal morbidity as generally having low birth weight. Such infants require delicate and continuous care and monitoring to survive and are kept in a Neonatal intensive care unit (NICU) if possible. A neonatal intensive care unit, also known as an intensive care nursery (ICN), is an intensive care unit specializing in the care of ill or premature newborn infants.

[0007] In an NICU setting neonates are kept under radiant warmers to regulate their body temperature. To achieve this, a neonates' body temperature is constantly monitored by employing conventional temperature probes, attached to their skin with adhesive tape. The skin of neonates is extremely delicate and vulnerable to environmental stress. Research (Susan et al., 2001) has shown that increase in microbial growth under temperature probe can be harmful. Medical tape causes irritation and when it is removed it causes skin abrasion and damage (Rutter, 2000). Risk of the damage of internal organs involved with the tympanic and rectal temperature measurement limits their use for continuous monitoring. Thus the primary concern in an NICU is protection of neonates and their non-invasive monitoring.

[0008] Kangaroo Mother Care (KMC) method, also known as skin-to-skin contact method, has been proposed as an alternative to conventional neonatal care for low birth weight (LBW) prematurely born infants. This method was developed and first implemented by Edgar Rey Sanabria and Hector Martinez in 1979, at the Maternal and Child Institute of Bogotá, Colombia, and it received this name because it shares similarities to marsupial care giving. Dr. Sanabria (Sanabria, 1982) found that holding the premature infant very closely, with skin to skin contact to the caregiver, resulted in very dramatic improvements in the prognosis for the premature infant. It was used for the early hospital discharge of LBW infants due to a critical lack of incubators, cross infections, lack of technological resources, early weaning, high neonatal mortality rates and infant abandonment. The new home care program for LBW infants was based on the following principles: a) early hospital discharge regardless of weight provided that the infant has stable clinical conditions; b) no use of formulas, only breast milk; c) encouragement of early skin-to-skin contact between mother and neonate; the neonate is

positioned on the mother's chest, and d) the neonate is maintained in an upright position. This initiative was supported by UNICEF, which widely advertised the results of the study, especially with regard to the reduction in mortality rates, to psychological benefits and low cost. During the last few decades, several health services have adopted KMC method, both in industrialized and developing countries, thus showing that it is possible to adapt this practice in different contexts of neonatal care. Accordingly, there is also need to monitor this treatment so that its administration may be regulated in scientific manner.

[0009] Various systems exist for monitoring of a neonate. Patent Application PCT/US2005/010064 discloses a neonate health monitoring device wherein skin temperature sensor is connected to a microprocessor for mathematically converting the sensed temperature to corrected skin temperature. Also included is a movement sensor, a display screen and a means for communicating with a computer. The device may include a humidity sensor or sound sensor as well as other types of sensors. While the device proposed non-invasively measures temperature and other data, it is continuously on and so requires high and continuous supply of energy. Also, it does not monitor parameters specific to the Kangaroo Mother Care method.

[00010] Patent Application PCT/NL2010/050224 provides a solution for monitoring a sleeping infant, which generates a warning signal in the event of insufficient heat dissipation from the infant as well as in the event of a too high body temperature of the infant. While the device proposed non-invasively measures temperature and other data, it is continuously on and so requires high and continuous supply of energy. Also, it does not monitor parameters specific to treatment per Kangaroo Mother Care method.

[00011] Application US20050245839 discloses a monitoring system that may comprise either a one or a multi component embodiment which includes at least a temperature module. The module may be provided with a display for output of temperature and other data as well as a variety of input capabilities. The module is particularly sized and shaped to conform to and interface with the skin of the wearer, typically in one of several preselected preferred locations. While the device proposed non-invasively measures temperature and other data, it is continuously on and so requires

high and continuous supply of energy. Also, it does not monitor parameters specific to treatment per Kangaroo Mother Care method.

[00012] Application PCT/US2000/005777 discloses a device for determination of non-human animal body temperature in order to determine sick animals prior to clinical pathology expression. It has a battery powered electrical device having a remote temperature probe adapted for sensing the body temperature of an animal. Based on preset temperature thresholds, visible or audible alarms indicating, for example, a raised temperature greater or equal to 104 °F / 40 °C, are actuated. The device is semi-permanently attached to a non-human animal, for example, a cow, and positioned such that body temperature is accurately and/or consistently determined by the temperature sensing probe that can be, in a preferred embodiment, adapted for semi-permanent insertion into the animal's ear canal. The device is "asleep" most of the time and consumes minimal battery power. Hence the device is invasive while it addresses the problem of requiring high and continuous supply of energy. Even this device does not monitor parameters specific to treatment per Kangaroo Mother Care method.

[00013] Indian Patent Application 4499/CHE/2014 discloses a method to save power by monitoring whether a device for monitoring physiological characteristics is in skin contact. However, device disclosed does not monitor parameters specific to treatment per Kangaroo Mother Care method.

[00014] A research paper titled "Low power remote neonatal temperature monitoring device" discloses design of a wearable temperature sensing device for remote neonatal monitoring. The device is designed for continuous and real-time monitoring of infants in remote rural areas, for first few days and is capable of sensing the neonate's skin temperature with 0.1 degree C accuracy to detect the early onset of hypothermia. The sensed data is transferred securely over bluetooth low energy radio to a nearby gateway, which then relays the information to a central database for real time monitoring. However the disclosure does not address the problem of monitoring parameters specific to treatment per Kangaroo Mother Care method.

[00015] It can be seen that, while KMC method is now well-established as a popular choice for treating low birth weight premature infants, there are currently no

existing devices to monitor the administration of this treatment such as to quantify the dosage and other related metrics with respect to this care methodology.

[00016] Therefore, there is a need in the art for a device that can monitor parameters specific to treatment per Kangaroo Mother Care method and that can quantify dosage and other related metrics of this care methodology so that the care and its result can be correlated, analyzed, evaluated and corrective actions taken when required.

[00017] All publications herein are incorporated by reference to the same extent as if each individual publication or patent application were specifically and individually indicated to be incorporated by reference. Where a definition or use of a term in an incorporated reference is inconsistent or contrary to the definition of that term provided herein, the definition of that term provided herein applies and the definition of that term in the reference does not apply.

[00018] In some embodiments, the numbers expressing quantities of ingredients, properties such as concentration, reaction conditions, and so forth, used to describe and claim certain embodiments of the invention are to be understood as being modified in some instances by the term “about.” Accordingly, in some embodiments, the numerical parameters set forth in the written description and attached claims are approximations that can vary depending upon the desired properties sought to be obtained by a particular embodiment. In some embodiments, the numerical parameters should be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of some embodiments of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as practicable. The numerical values presented in some embodiments of the invention may contain certain errors necessarily resulting from the standard deviation found in their respective testing measurements.

[00019] As used in the description herein and throughout the claims that follow, the meaning of “a,” “an,” and “the” includes plural reference unless the context clearly dictates otherwise. Also, as used in the description herein, the meaning of “in” includes “in” and “on” unless the context clearly dictates otherwise.

[00020] The recitation of ranges of values herein is merely intended to serve as a shorthand method of referring individually to each separate value falling within the range. Unless otherwise indicated herein, each individual value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g. “such as”) provided with respect to certain embodiments herein is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention otherwise claimed. No language in the specification should be construed as indicating any non-claimed element essential to the practice of the invention.

[00021] Groupings of alternative elements or embodiments of the invention disclosed herein are not to be construed as limitations. Each group member can be referred to and claimed individually or in any combination with other members of the group or other elements found herein. One or more members of a group can be included in, or deleted from, a group for reasons of convenience and/or patentability. When any such inclusion or deletion occurs, the specification is herein deemed to contain the group as modified thus fulfilling the written description of all Markush groups used in the appended claims.

OBJECTS OF THE INVENTION

[00022] It is an object of the present disclosure to provide a device to monitor skin to skin contact between a mother/caregiver and a neonate and determine its duration.

[00023] It is an object of the present disclosure to provide a device to monitor skin temperatures of a neonate and his/her caregiver simultaneously, or independently as required.

[00024] It is an object of the present disclosure to provide a device for skin to skin contact monitoring and temperature monitoring of a neonate in a safe, non-invasive fashion.

[00025] It is an object of the present disclosure to provide a device to monitor position of a neonate.

[00026] It is an object of the present disclosure to provide a device that uses various sensory inputs to robustly determine the dosage of skin to skin contact given to a neonate.

[00027] It is an object of the present disclosure to provide a device that raises an alarm if adequate skin to skin contact dosage has not been given to a neonate.

[00028] It is an object of the present disclosure to provide a device that uses various sensory inputs to determine activity levels of a neonate.

[00029] It is an object of the present disclosure to provide a device that uses various sensory inputs to determine the temperature of a neonate.

[00030] It is an object of the present disclosure to provide a device that uses various sensory inputs to reduce its energy requirements.

SUMMARY

[00031] The present disclosure relates to system and device for physiological monitoring of new born babies. In particular, it pertains to a system for physiological monitoring of a new born baby (interchangeably termed as a neonate herein) in accordance with parameters of Kangaroo Mother Care method.

[00032] In an aspect, disclosed device can determine whether a caregiver is holding a neonate and, responsive to such determination, can determine parameters such as duration of the skin to skin contact between the baby and mother/caregiver, skin temperature of the baby and mother/caregiver, and activity level, position, breathing rate, angle of rest of the neonate.

[00033] In an embodiment, the disclosed device can be configured in a thin form such as a strip or a thin block that has touch sensors on its two opposite surfaces. The device can be held (sandwiched) between the neonate and the caregiver in such a fashion that touch sensors on the two sides touch baby's skin and the caregiver's skin. When both sensors indicate touch i.e. simultaneous touch signal is received from the two touch sensors, it can be determined that skin of the neonate is in contact with that of the caregiver, i. e. the caregiver is holding the baby with skin to skin contact which is the core aspect of treatment by Kangaroo mother care Method.

[00034] In an aspect, duration of the KMC treatment can be ascertained by using a timer wherein the timer can start and pause based on presence or absence of the simultaneous touch signal and total duration of skin to skin contact can be obtained by suitably scaling the value of the timer to convert it to the units of hours.

[00035] In an embodiment, the device can further incorporate temperature sensors on both sides of the strip/thin block to collect skin temperature data of the baby and the caregiver. In an aspect data from the touch sensors can be used to avoid false temperature readings when skin touch has not happened to improve the quality of the temperature readings.

[00036] In an aspect, the device can also incorporate a 3-axis accelerometer wherein acceleration data from the three axes is used to get position information in respect of the baby. In an aspect, the acceleration data is suitably filtered to consider only low frequency components for position determination. Further the position data is used only if the baby touch sensor indicates a touch to avoid false readings.

[00037] In an aspect, the device can also incorporate a microcontroller/microprocessor, a storage module and a communication module. The microcontroller can process and interpret the data from different sensors and store useful information in the storage module as well as send it out via the communication module. The microcontroller can also activate alarms and indications using onboard buzzer and multi-color LED to alert caregiver and/or medical professionals in case the situation demands such as when adequate skin to skin contact dosage has not been given or KMC protocol is not complied to.

[00038] In an aspect, the communication module can connect the device with a gateway by a wireless connection so as to enable transmission of useful data compiled by the microcontroller.

[00039] In an aspect, the device can further incorporate a power module to power the device. The power module can consist of a battery or super-capacitor and may optionally have an energy harvesting module. In order to prolong period between charging, the power consumption by the device can be reduced by employing various means such as skipping turning on of the baby temperature sensor and position sensor if the baby touch sensor does not indicate touch, skipping turning on of the caregiver

temperature sensor if the caregiver touch sensor does not indicate touch, reducing the sampling frequency of all sensors when there is no wireless connection with a gateway, reducing frequency of connection with gateway if the sensor readings are within normal levels etc.

[00040] In an aspect, the disclosure also provides methods for determining if skin contact between the neonate and the caregiver is established and thereafter implementing the KMC protocol during KMC treatment.

[00041] Various objects, features, aspects and advantages of the present disclosure will become more apparent from the following detailed description of preferred embodiments, along with the accompanying drawing figures in which like numerals represent like features.

BRIEF DESCRIPTION OF DRAWINGS

[00042] The accompanying drawings are included to provide a further understanding of the present disclosure, and are incorporated in and constitute a part of this specification. The drawings illustrate exemplary embodiments of the present disclosure and, together with the description, serve to explain the principles of the present disclosure.

[00043] FIG. 1 illustrates an exemplary schematic arrangement of various components of a device for physiological monitoring of new born babies under Kangaroo Mother Care (KMC) in accordance with embodiments of the present disclosure.

[00044] FIG. 2 illustrates an exemplary installation of sensors on surface of the device of FIG. 1 in accordance with an embodiment of the present disclosure.

[00045] FIG. 3 illustrates an exemplary block diagram of the device of FIG. 1 indicating various functional parts and modules in accordance with embodiments of the present disclosure.

[00046] FIG. 4 illustrates exemplary graphs showing readings from both the baby and caregiver temperature sensors, touch sensors and orientation reading in accordance with embodiments of the present disclosure.

[00047] FIG. 5 illustrates an exemplary image of a prototype of the device for physiological monitoring of new born babies under Kangaroo Mother Care (KMC) in accordance with embodiments of the present disclosure. .

DETAILED DESCRIPTION

[00048] The following is a detailed description of embodiments of the disclosure depicted in the accompanying drawings. The embodiments are in such detail as to clearly communicate the disclosure. However, the amount of detail offered is not intended to limit the anticipated variations of embodiments; on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the present disclosure as defined by the appended claims.

[00049] Each of the appended claims defines a separate invention, which for infringement purposes is recognized as including equivalents to the various elements or limitations specified in the claims. Depending on the context, all references below to the "invention" may in some cases refer to certain specific embodiments only. In other cases it will be recognized that references to the "invention" will refer to subject matter recited in one or more, but not necessarily all, of the claims.

[00050] Various terms as used herein are shown below. To the extent a term used in a claim is not defined below, it should be given the broadest definition persons in the pertinent art have given that term as reflected in printed publications and issued patents at the time of filing.

[00051] The present disclosure relates to system and device for physiological monitoring of new born babies. In particular, it pertains to a system for physiological monitoring of a new born baby (interchangeably termed as a neonate herein) in accordance with parameters of Kangaroo Mother Care method.

[00052] In an aspect, disclosed device can determine whether a caregiver is holding a neonate and, responsive to such determination, can determine parameters such as duration of the skin to skin contact between the baby and mother/caregiver, skin temperature of the baby and mother/caregiver, and activity level, position, breathing rate, angle of rest of the neonate.

[00053] In an embodiment, the disclosed device can be configured in a thin form such as a strip or a thin block that has touch sensors on its two opposite surfaces. The device can be held (sandwiched) between the neonate and the caregiver in such a fashion that touch sensors on the two sides touch baby's skin and the caregiver's skin. When both sensors indicate touch i.e. simultaneous touch signal is received from the two touch sensors, it can be determined that skin of the neonate is in contact with that of the caregiver, i. e. the caregiver is holding the baby with skin to skin contact which is the core aspect of treatment by Kangaroo mother care Method.

[00054] In an aspect, duration of the KMC treatment can be ascertained by using a timer wherein the timer can start and pause based on presence or absence of the simultaneous touch signal and total duration of skin to skin contact can be obtained by suitably scaling the value of the timer to convert it to the units of hours.

[00055] In an embodiment, the device can further incorporate temperature sensors on both sides of the strip/thin block to collect skin temperature data of the baby and the caregiver. In an aspect data from the touch sensors can be used to avoid false temperature readings when skin touch has not happened to improve the quality of the temperature readings.

[00056] In an aspect, the device can also incorporate a 3-axis accelerometer wherein acceleration data from the three axes is used to get position information in respect of the baby. In an aspect, the acceleration data is suitably filtered to consider only low frequency components for position determination. Further the position data is used only if the baby touch sensor indicates a touch to avoid false readings.

[00057] In an aspect, the device can also incorporate a microcontroller, a storage module and a communication module. The microcontroller can process and interpret the data from different sensors and store useful information in the storage module as well as sends it out via the communication module. The microcontroller can also activate alarms and indications using onboard buzzer and multi-color LED to alert caregiver and/or medical professionals in case the situation demands such as when adequate skin to skin contact dosage has not been given or KMC protocol is not complied to.

[00058] In an aspect, the communication module can connect the device with a gateway by a wireless connection so as to enable transmission of useful data compiled by

the microcontroller.

[00059] In an aspect, the device can further incorporate a power module to power the device. The power module can consist of a battery or super-capacitor and may optionally have an energy harvesting module. In order to prolong period between charging, the power consumption by the device can be reduced by employing various means such as skipping turning on of the baby temperature sensor and position sensor if the baby touch sensor does not indicate touch, skipping turning on of the caregiver temperature sensor if the caregiver touch sensor does not indicate touch, reducing the sampling frequency of all sensors when there is no wireless connection with a gateway, reducing frequency of connection with gateway if the sensor readings are within normal levels etc.

[00060] FIG. 1 illustrates an exemplary schematic arrangement of various components of a device 100 for physiological monitoring of new born babies under Kangaroo Mother Care (KMC) in accordance with embodiments of the present disclosure. In an aspect, the device 100 can be of shape and size to enable its positioning between the baby under KMC treatment and the caregiver in skin contact with both of them. As can be appreciated, it has to be a thin and small device so as not to appreciably reduce area of skin contact between them. Therefore, it can be in form of a strip or a thin block of a non-conducting material and various functional parts and components of the device can be configured on its surface and inside the strip/thin block.

[00061] The two opposite surfaces of the device 100, illustrated in FIG. 1 as 102 and 104 can be in skin contact with neonate and his/her mother/caregiver. In an aspect, low distance between the surface 102 and 104 due to low thickness of the device can enable the device to be easily held between the neonate and his/her mother/caregiver without affecting skin contact in the surrounding area when the mother/caregiver is administering KMC treatment to the baby. The surface such as 102 that is in contact with the baby can be called baby side surface and the surface such as 104 that is in contact with skin of the mother/caregiver can be called the mother side surface.

[00062] In an aspect, the surfaces 102 and 104 can be embedded with various sensors for sensing different parameters of the KMC process. The sensors placed on the surface can be at least one touch sensor 106 and at least one temperature sensor 108 on

both surfaces 102 and 104. In an exemplary embodiment, as illustrated in FIG. 1, surface 102 can have a first touch sensor 106a and a first temperature sensor 108a. Likewise, surface 104 can have a second touch sensor 106b and a second temperature sensor 108b. In an embodiment, the touch sensors 106 can be used to ascertain if the corresponding surface is in contact with the baby or the caregiver as the case may be. And when signal from the touch sensors 106 on the two surfaces 102 and 104 is positive it can be concluded that skin to skin contact which is the core aspect of the KMC treatment has been established thus enabling assessment of time period for which the KMC treatment has been provided to the baby.

[00063] FIG. 2 illustrates an exemplary installation and constructional details of a touch sensor 106a/106b on surface of the device of FIG. 1 in accordance with an embodiment of the present disclosure. Two electrically conductive plates such as 202 and 204 can be embedded in the surfaces 102/104 to provide functionality of a touch sensor 106a/106b. One of these conductive plates say plate 202 (as shown in FIG. 2) can be exposed so that it can come in direct contact with skin, whereas other plate, say plate 204, can be covered with a thin electrical insulator 206 so that it does not make any contact with the skin. The two plates 202/204 are connected to the touch transducer 110 (FIG. 1) by conductive wires that can be connected to each of the plates 202/204 on the internal side. When the two plates 202/204 are placed next to skin, plate 202 comes in contact with skin but plate 204, being covered with the thin electrical insulator, does not make contact with the skin.

[00064] In an embodiment, the plate covered with thin insulator in the exemplary embodiment of FIG. 2, can act as one plate of a capacitance sensor which can be used for touch detection wherein body (of baby or caregiver as the case may be) in contact acts as the other plate of this capacitor with parasitic coupling to ground reference. In an embodiment, to improve sensitivity of capacitive touch sensor, capacitance can be measured between the insulated plate 204 and exposed or insulated plate 202. When the skin comes in contact with the external side of the surface, the capacitance between plates 202 & 204 changes due to the dielectric properties of human skin. This changed capacitance is used to signal a touch. To make the touch detection robust, the data from

the capacitance sensor can also be combined with data from other sensors to make the sensor more reliable.

[00065] In an alternate embodiment, both the plates 202 and 204 can be exposed for contact with skin (i.e. without any thin insulation on any of the plate 202/204) so that both the plates 202/204 come in contact with the skin. In this case the two plates 202/204 form a resistive sensor which can be used to detect touch.

[00066] In an embodiment, the plate without insulation, such as 202, can also function as temperature sensor. For this a thermal transducer 112 (FIG. 1) can be attached underneath the plate 202 using a thermally conductive glue. The transducer wires can be connected to temperature sensor's analog front end. In an alternate embodiment, there can be third thermally conductive plate (not shown here) fixed in same way as plates 202/204 to the surface 102/104 to which the thermal transducer 112 can be attached to function as a temperature sensor 108a/108b.

[00067] Referring back to FIG. 1, in an embodiment, the device 100 can have positions for housing different functional parts. For example 110 and 112 can house temperature and touch transducers, 114 can house a microcontroller, an Analog to Digital Converter (ADC), and storage and communication modules. 116 can house a power source and 118 can house a position sensor.

[00068] In an embodiment, all surfaces of the device 100 can be made of bio-compatible and hypoallergenic materials and it can be affixed to the subjects i.e. the baby or the mother/caregiver via a belt, tape or a bandage such that a surface 102/104 touches his skin.

[00069] FIG. 3 illustrates an exemplary block diagram 300 of the device of FIG. 1 indicating various functional parts and modules in accordance with embodiments of the present disclosure. The device can incorporate temperature sensors 108, touch sensors 106, position sensor 310, a microcontroller/microprocessor 302, an ADC 304, a communication module 306, a data storage module 308, buzzer 312, LEDs 314 and a power module 316. In an embodiment, outputs from temperature sensors 108 and touch sensors 106 can be converted to electrical signals by respective transducers and further fed to the microprocessor 302 through ADC 304 for further processing.

[00070] In an embodiment, the position sensor 310 can consist of a 3-axes accelerometer and analysis of acceleration data from the three axes by the microcontroller 302 can yield position information. It can further provide activity levels and breathing rate of the baby.

[00071] In an embodiment, the processed information can be stored in the data storage module 308 for transmission using the communication module 306 that can transmit data to a gateway using wireless communication means. The power module 316 can meet necessary power requirement for functioning of different modules and parts.

[00072] In an embodiment, the device 100 can further include multiplicity of LEDs 314 of different colors to indicate various events or conditions to the user. For example, when the temperature goes out of normal range, the red colored LED 314 might be flashed to get the attention of the caregiver or the patient. The device can also include a speaker or buzzer 312 to emit various sounds upon different events or conditions.

[00073] In an embodiment, two opposite surfaces 102 and 104 of the device 100, when the device 100 is placed between the neonate and the caregiver, can be in contact with skins of the two subjects on respective sides. Under such condition the respective touch sensors 106 can detect touch (or skin) of the neonate on one side and touch of the mother/caregiver on the opposite side. When the touch sensors on the two sides detect touch it can be concluded that the mother/caregiver is holding the neonate and there is skin to skin contact between the neonate and the mother/caregiver. This time instant can be defined as an 'epoch' (event) of administering KMC treatment. Such epochs can be further accumulated, monitored, evaluated and used to trigger sensing and monitoring events etc. as elaborated in subsequent paragraphs. Microcontroller 302 can collect and store all such sensory data and use it for various purposes.

[00074] In an aspect, the device 100 can enable monitoring of duration of skin to skin contact that is a most critical aspect of administering KMC treatment. For the purpose, microprocessor 114 can accumulate 'epoch' of simultaneous contact signals from the touch sensors on the two opposite surfaces, wherein a 'epoch' signal is used to send a trigger to a timer to put the timer ON and OFF so as to accumulate the period of skin to skin contact. The timer can accumulate the touch epochs over a time window (a day, for example) and can provide a cumulative skin to skin contact period that can be

scaled in hours/minutes as required. Determination of simultaneous touch epochs can be optionally made more robust by analyzing historical data from both touch sensors and temperature sensors.

[00075] In another aspect, temperature sensors 108 can detect skin temperature of the neonate and caregiver, and for a reliable reading the sensing of temperature can be done only when the corresponding touch sensor 106 indicates a touch. In an aspect, monitoring of temperature of both the caregiver as well as neonate can help analyze how heat is being transferred from the caregiver to the baby and the information can be very useful for studies and refining the KMC treatment procedure. In an embodiment, historical record of the temperature of the baby along with record of touch sensors can also be used to assess quality of KMC treatment.

[00076] In an aspect, temperature sensors 108 on two surfaces of the device can be switched on only when the touch sensors 106 on both sides indicate a simultaneous touch epoch, and can remain on for only so long as the simultaneous touch epoch continues, thereby reducing energy consumption.

[00077] In an embodiment, device 100, in order to save on power consumption, can be configured to take readings of various sensors intermittently at regular time intervals. To manage energy consumption, various sampling intervals can be set, and samples taken only when touch sensor on neonate side indicates a touch, or when touch sensors on both sides indicate touch on their respective sides. Microprocessor 302 can be configured to set sampling intervals as required, send data using the communication module 306 through a gateway to external monitoring systems, as well as store such data within itself to provide historical data for comparison purposes. In another aspect, device 100 can be configured to store data at regular intervals in the storage module 308.

[00078] In another aspect, microprocessor 302 can be configured to compare historical data with current measurements in order to increase robustness of data measurement and reduce false alarms. For instance, there could be a situation when mother is not holding neonate for some time and temperature of the neonate sharply falls, which can normally be a cause of alarm. However, historical data of previous 6-7 readings of neonate temperature can indicate an expected value of neonate's temperatures, and touch sensor on mother side can indicate that she is no longer holding

the neonate. From the historical and current data, it can be concluded that the sudden drop in temperature is momentary and not a cause of concern. Microprocessor 302 can compare such data and not raise a false alarm. In an exemplary embodiment, the device 100 can store 30 hours of data generated at 6 minutes sampling intervals.

[00079] In another aspect, disclosed device can enable determination of position of a neonate while administering KMC treatment wherein position of the baby can be inferred based on signal from the position sensor 310. The position sensor can consist of a 3-axis accelerometer and acceleration data can be analyzed by the microprocessor 302 to generate position information. Acceleration data can be suitably filtered to consider only low frequency components for position determination. In an embodiment, position data can be used only when touch sensor on the neonate side indicates a touch to avoid any false readings.

[00080] In another aspect, position sensor 310 can be switched on only when the touch sensor on neonate side indicates a touch indicating presence of a neonate; and can remain on as long as the touch signal continues thereby reducing energy consumption of the disclosed device.

[00081] In an aspect, the device 100 can enable determination of quality of skin to skin contact by using data from the two touch sensors, timer and optionally from the two temperature sensors. Raw touch data (i.e. capacitance value) can be used to determine quality of attachment of the neonate to the caregiver. Raw touch data can also be used to determine tightness of fit when using a belt so as to avoid discomfort to the baby.

[00082] In another aspect, the device 100 can keep track of duration of skin to skin contact during a time period (also termed as a dosage window) and in case such contact period falls below a prescribed threshold, an alarm can be raised to notify the caregiver and other stakeholders.

[00083] In another aspect, the device 100, using the position sensor 310, can determine activity level of the neonate. Initially, position sensor can be turned on for a short duration to obtain a time sequence of samples for a period of a few minutes. This time sequence of samples can be transferred to another domain using a method like fast Fourier transform or a wavelet transform and next, energy of signals received from position sensor 310 in a range of frequencies can be mapped to determine activity levels.

In an alternate embodiment, rate of zero crossings of the time domain signal can be mapped to activity levels.

[00084] In another aspect, information from touch sensors from both neonate side and mother side can be used to discard false information. For example, if vigorous movements are indicated by position sensor 310, and touch sensor on the mother's side indicates that she is holding the neonate, it can be safely concluded that the movements being sensed by position sensor are being caused by the mother and not due to activity of the neonate.

[00085] In alternate exemplary embodiments the device 100 can be configured with sensors to monitor other physiological parameters like breathing rate of a neonate while being administered treatment as per KMC method.

[00086] In another aspect, historical and current data of temperature and touch can be used to determine and suppress erroneous readings. For example only that historical data can be considered as true when the corresponding touch sensor indicates a touch by corresponding person. To illustrate, only those temperature readings from thermal sensor on neonate side may be considered where the touch sensor on the neonate side also indicated touch. Any abnormal present reading can firstly be validated against touch, and thereafter against past record of "true" readings and an alarm raised only if a threshold is crossed.

[00087] In an aspect, the device 100 can determine if KMC method's protocol is being complied with. For the purpose, data from the two touch sensors, the two thermal sensors and the position sensor can be analyzed together to determine if all parameters fall in the specified range to achieve compliance with KMC method and duration for which KMC treatment was administered.

[00088] In another aspect, the device 100 can consume very little energy. Energy consumption can be reduced by operating different sensors in conjunction with the corresponding touch sensor. For example, neonate side thermal sensor and position sensor need not be ON until neonate side's touch sensor indicates touch. Similarly, caregiver side temperature sensor need not be ON until caregiver's side touch sensor indicates touch. In another aspect, sampling frequency of all sensors can be reduced if there is no wireless connection with a gateway. In yet another aspect, frequency of

connection with the gateway can be reduced if sensor readings are within normal levels. For example, when neonate's temperature is indicated as normal, sampling frequency of future readings can be lowered that can reduce overall energy consumption as well as frequency of connection with an external gateway. In an embodiment, the gateway can enable transfer of the data from the device 100 to a system such as a computing device that can use the data to create useful graphs.

[00089] In an aspect, the disclosure provides a method to monitor KMC treatment. The method can include steps of providing a thin flat device having a first surface and a second surface wherein the first surface and the second surface are opposite sides of the flat device; providing at least one touch sensor on each of the first surface and the second surface; placing the device between the baby and the caregiver such that the two opposite surfaces are in contact with skin of the baby and the caregiver respectively; ascertaining, by using signals from the touch sensor on the first surface, if the first surface is in contact with respective subject; ascertaining, by using signals from the touch sensor on the second surface, if the second surface is in contact with respective subject; activating a simultaneous touch signal when the touch sensors on both the first surface and the second surface indicate that the respective surface is in contact with respective subject, wherein occurrence of simultaneous touch signal from the touch sensors on both the first surface and the second surface indicates that a satisfactory skin to skin contact between the baby and the caregiver has been established.

[00090] In an aspect, the method can further include steps of accumulating duration of occurrence of simultaneous touch signal by means of a timer, wherein the simultaneous touch signal is used to start and pause the timer and the accumulated duration of occurrence of simultaneous touch signal can indicate duration of the skin to skin contact. Further, the total duration of skin to skin contact can be obtained by suitably scaling the value of the timer to convert it to the units of hours.

[00091] In an embodiment, the method can further include step of determining skin temperature of the baby and caregiver simultaneously, wherein the temperature of the baby and care is sensed by providing two temperature sensors connected to two heat conductive plates positioned on the first surface and the second surface each of which can be in contact with the baby's and caregiver's skin simultaneously. Further wherein the

current temperature can be estimated using historical data of the temperature readings and some statistical processing (like averaging). In addition, data from the touch sensor can be used to avoid false temperature readings when skin touch has not happened to improve the quality of the temperature readings.

[00092] In an embodiment, the method can further include step of determining position of the baby, wherein the position of the baby is determined by providing a position sensor, and wherein the position sensor can be the 3-axes accelerometer, and acceleration data for three axis is suitably filtered to consider only low frequency components to get position information. Further, baby touch sensor and the position sensor can be used to improve robustness of the result.

[00093] In an embodiment, the method can further include step of determining dosage quality of skin to skin contact by combining data from the two touch sensors, a timer and optionally the two temperature sensors, wherein raw touch data (e.g. Capacitance value) can be used to determine quality of attachment.

[00094] In an embodiment, the method can further include step of raising an alarm if adequate skin to skin contact dosage has not been given, wherein it is concluded that the skin to skin contact dosage is inadequate if the overall skin to skin contact duration during a dosage window falls below a threshold as prescribed by the medical practitioner

[00095] In an embodiment, the method can further include step of determining activity level of the baby, wherein activity level of the baby is determined by analyzing the accelerometer data for movement in conjunction with baby skin touch, wherein the accelerometer can be turned on for a short duration to obtain a time sequence of samples for a period of a few minutes can be transformed to another domain using a method like fast Fourier transform or wavelet transform. Energy of the signal in a range of frequencies can be mapped to determine activity levels. Alternatively, rate of zero crossings in the time domain signal can be analyzed and mapped to activity levels. Information from skin touch sensors from both the baby side and mother side can also be used to discard false information.

[00096] In an embodiment, the method can further include step of determining if KMC protocol is being complied to, wherein compliance to the KMC protocol can be ascertained by combining data from the two touch sensors, two temperature sensors and

accelerometer sensors to determine if all parameters fall in the specified range to achieve KMC compliance. Further duration for which KMC treatment is was administered can be determined..

[00097] In an embodiment, the method can further include step of reducing power consumption by skipping the turning on of the baby temperature sensor and position sensor if the baby touch sensor does not indicate touch, skipping the turning on of the caregiver temperature sensor if the caregiver touch sensor does not indicate touch, reducing sampling frequency of all the sensors when there is no wireless connection with a gateway, reduce frequency of connection with gateway if the sensor readings are within normal levels.

[00098] FIG. 4 illustrates exemplary graphs showing readings from both the baby and caregiver temperature sensors, touch sensors and orientation reading in accordance with embodiments of the present disclosure. While recording the data a sampling interval of 4 minutes was maintained and output from various sensors plotted against time on X-axis. Graph A comprising plots 406 and 408 indicates temperatures, wherein plot 406 pertains to temperature of the neonate and plot 408 pertains to temperature of the caregiver. Graph B comprising plots 402 and 404 indicates output of the touch sensors, wherein plot 402 pertains to neonate while plot 404 pertains to caregiver. Likewise, in graph C, plot 410 pertains to neonate angle.

[00099] As can be seen from Graph B, initially only neonate side touch sensor is showing an output i.e. skin contact, while touch sensor of the mother side is showing no touch. At point V, however, mother side sensor also starts showing skin contact and from that point onwards both mother side as well as neonate side touch sensors are showing skin contact as illustrated by a single line indicating that a simultaneous touch epoch has begun at point V; that is, starting from point V, the mother is holding the neonate and administering KMC treatment.

[000100] When the point V is extrapolated to the temperature graph A to a corresponding point U on the temperature plots, it be seen that prior to point U, mother side temperature plot 408 and neonate side temperature plot 406 are moving along different lines, that is, the two temperatures are different. However, from the time the mother starts holding the neonate,i.e. point U, the two temperatures start coming closer to

each other. This indicates heat transfer from the caregiver to the baby on account of their skin contact.

[000101] When the point V is extrapolated to a corresponding point W on the neonate angle graph C, it can be seen that prior to point W the neonate angle is about 350 indicating that neonate is supine. It shows a sharp change immediately prior to point W, indicating that the neonate is being lifted for administering KMC treatment by placing next to the caregiver.

[000102] FIG. 5 illustrates an exemplary image 500 of a prototype of the device for physiological monitoring of new born babies under Kangaroo Mother Care (KMC) in accordance with embodiments of the present disclosure. As can be seen the device 100 can be very compact for ease of placing between a caregiver and a neonate. FIG. 5 shows a position sensor 502, a buzzer 504 and a System on Chip 506. The functions of position sensor 502 and buzzer 504 are as elaborated above. System on Chip 506 can perform function of microcontroller as elaborated above and can incorporate additional functionalities such as wireless communication. Energy consumption of device can be very nominal. As illustrated, the device can be as small as a rupee coin.

[000103] It can readily be understood that the technique disclosed here for establishing skin to skin contact can have myriad applications, of which only one is elaborated above. For instance, a device as disclosed above can be worn on hand of a person, skin to skin contact determined on basis of his handshake with another person and, on such determination, digital business cards of both the persons (that may be stored either in the device itself or remotely), may be exchanged. All such applications using monitoring of skin to skin contact as elaborated herein are completely within scope of the present disclosure.

[000104] While the foregoing describes various embodiments of the invention, other and further embodiments of the invention may be devised without departing from the basic scope thereof. The scope of the invention is determined by the claims that follow. The invention is not limited to the described embodiments, versions or examples, which are included to enable a person having ordinary skill in the art to make and use the invention when combined with information and knowledge available to the person having ordinary skill in the art.

ADVANTAGES OF THE INVENTION

[000105] The present disclosure provides a device to monitor skin to skin contact between a mother/caregiver and a neonate and determine its duration.

[000106] The present disclosure provides a device to monitor skin temperatures of a neonate and his/her caregiver simultaneously, or independently as required.

[000107] The present disclosure provides a device for skin to skin contact monitoring and temperature monitoring of a neonate in a safe, non-invasive fashion.

[000108] The present disclosure provides a device to monitor position of a neonate.

[000109] The present disclosure provides a device that uses various sensory inputs to robustly determine the dosage of skin to skin contact given to a neonate.

[000110] The present disclosure provides a device that raises an alarm if adequate skin to skin contact dosage has not been given to a neonate.

[000111] The present disclosure provides a device that uses various sensory inputs to determine activity levels of a neonate.

[000112] The present disclosure provides a device that uses various sensory inputs to determine the temperature of a neonate.

[000113] The present disclosure provides a device that uses various sensory inputs to reduce its energy requirements.

We Claim:

1. A device for neonatal monitoring, the device comprising:
 - a thin and flat strip having a first surface and a second surface on two opposite sides of the flat strip;
 - a first touch sensor positioned on the first surface of the strip to generate a first signal on coming in contact with skin of a first subject;
 - a second touch sensor positioned on the second surface to generate a second signal on coming in contact with skin of a second subject; and
 - a microprocessor positioned within the strip and configured to receive the first signal and the second signal and determine simultaneous occurrence of the first signal and the second signal;wherein the strip is held between the two skins and the microprocessor determines contact between the first skin and the second skin based on simultaneous occurrence of the first signal and the second signal and provides outputs based on duration of skin to skin contact between the first subject and the second subject.
2. The device of claim 1, wherein one of the first subject and the second subject is a neonate and other of the first subject and the second subject is a caregiver administering Kangaroo Mother Care (KMC) to the neonate.
3. The device of claim 1, wherein the first touch sensor and the second touch sensor are capacitance sensors or resistance sensors.
4. The device of claim 1, wherein the device further comprises one or a combination of buzzers, speakers and LEDs for the device to provide the outputs, wherein the outputs are in form of any one or a combination of warning sounds and warning lights.
5. The device of claim 2, wherein the device further comprises a first temperature sensor positioned on the first surface and a second temperature sensor positioned on the second surface to sense temperature of the skin of the neonate and the caregiver.
6. The device of claim 2, wherein the device further comprises a 3-axes accelerometer, and wherein 3 axes acceleration data from the 3-axes accelerometer is used to get any one or combination of position information, breathing rate and activity level in respect of the neonate.

7. The device of claim 6, wherein the acceleration data is filtered to consider only low frequency components for position determination.
8. The device of claim 6, wherein the acceleration data is processed only if the touch sensor corresponding to the neonate indicates a touch to avoid false readings.
9. The device of claim 1, wherein the device further comprises a communication module to connect the device with a gateway by a wireless connection so as to enable transmission of useful data compiled by the microprocessor.
10. The device of claim 1, wherein the device further comprises a power module, wherein the power module can consist of a battery or super-capacitor.
11. A method of monitoring administration of Kangaroo Mother Care (KMC) treatment by a caregiver to a neonate; the method comprising steps of:
 - providing a thin flat device having a first surface and a second surface wherein the first surface and the second surface are opposite sides of the flat device, and wherein at least one touch sensor is positioned on each of the first surface and the second surface;
 - placing the device between the neonate and the caregiver such that the two opposite surfaces are in contact with skin of the neonate and the caregiver;
 - ascertaining, by using signals from the touch sensor on the first surface, if the first surface is in contact with respective subject;
 - ascertaining, by using signals from the touch sensor on the second surface, if the second surface is in contact with respective subject;
 - activating a simultaneous touch signal when the touch sensors on both the first surface and the second surface indicate that the respective surface is in contact with respective subject,
 - wherein occurrence of simultaneous touch signal from the touch sensors on both the first surface and the second surface indicates that a satisfactory skin to skin contact between the neonate and the caregiver has been established.
12. The method of claim 11, wherein the method further comprises step of accumulating duration of occurrence of simultaneous touch signal by means of a timer, wherein the simultaneous touch signal is used to start and pause the timer and the accumulated

duration of occurrence of simultaneous touch signal indicates duration of the skin to skin contact.

13. The method of claim 12, wherein the method further comprises steps of raising an alarm if adequate skin to skin contact dosage has not been given; wherein it is concluded that the skin to skin contact dosage is inadequate if the skin to skin contact duration during a dosage window falls below a threshold prescribed by a medical practitioner.
14. The method of claim 11, wherein the method further comprises step of determining skin temperature of the neonate and caregiver; wherein the skin temperature of the neonate and caregiver is sensed by providing two temperature sensors connected to two heat conductive plates positioned on the first surface and the second surface such that they are in contact with skin of the neonate and the caregiver.
15. The method of claim 14, wherein the skin temperature is estimated using historical data of the temperature readings and statistical processing like averaging; and wherein data from the touch sensor is used to avoid false temperature readings when skin touch has not happened.
16. The method of claim 11, wherein the method further comprises step of determining position of the neonate, wherein the position of the neonate is determined by providing a 3-axes accelerometer; and acceleration data for three axis is filtered to consider only low frequency components to get position information; and wherein the acceleration data is processed only if the touch sensor corresponding to the neonate indicates a touch to avoid false readings.
17. The method of claim 16, wherein the method further comprises step of determining activity level of the neonate; wherein the activity level of the neonate is determined by analyzing the acceleration data for movement in conjunction with neonate skin touch.

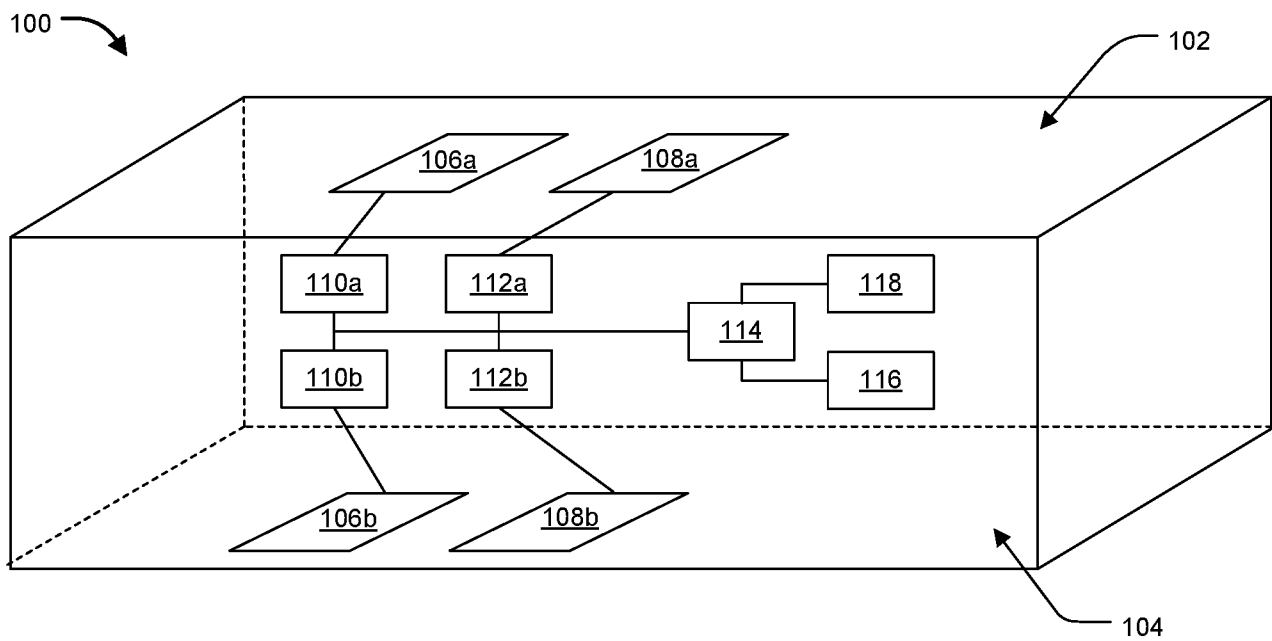


FIG. 1

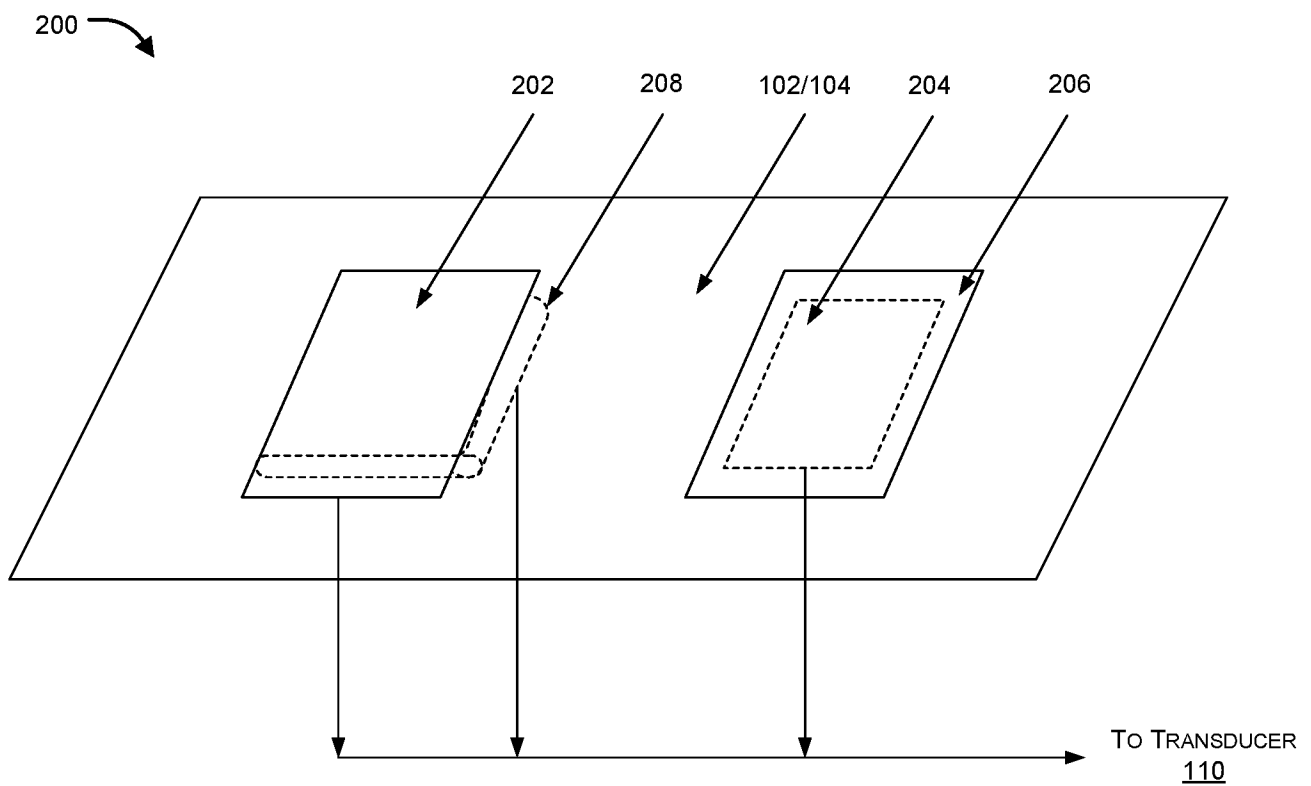


FIG. 2

300

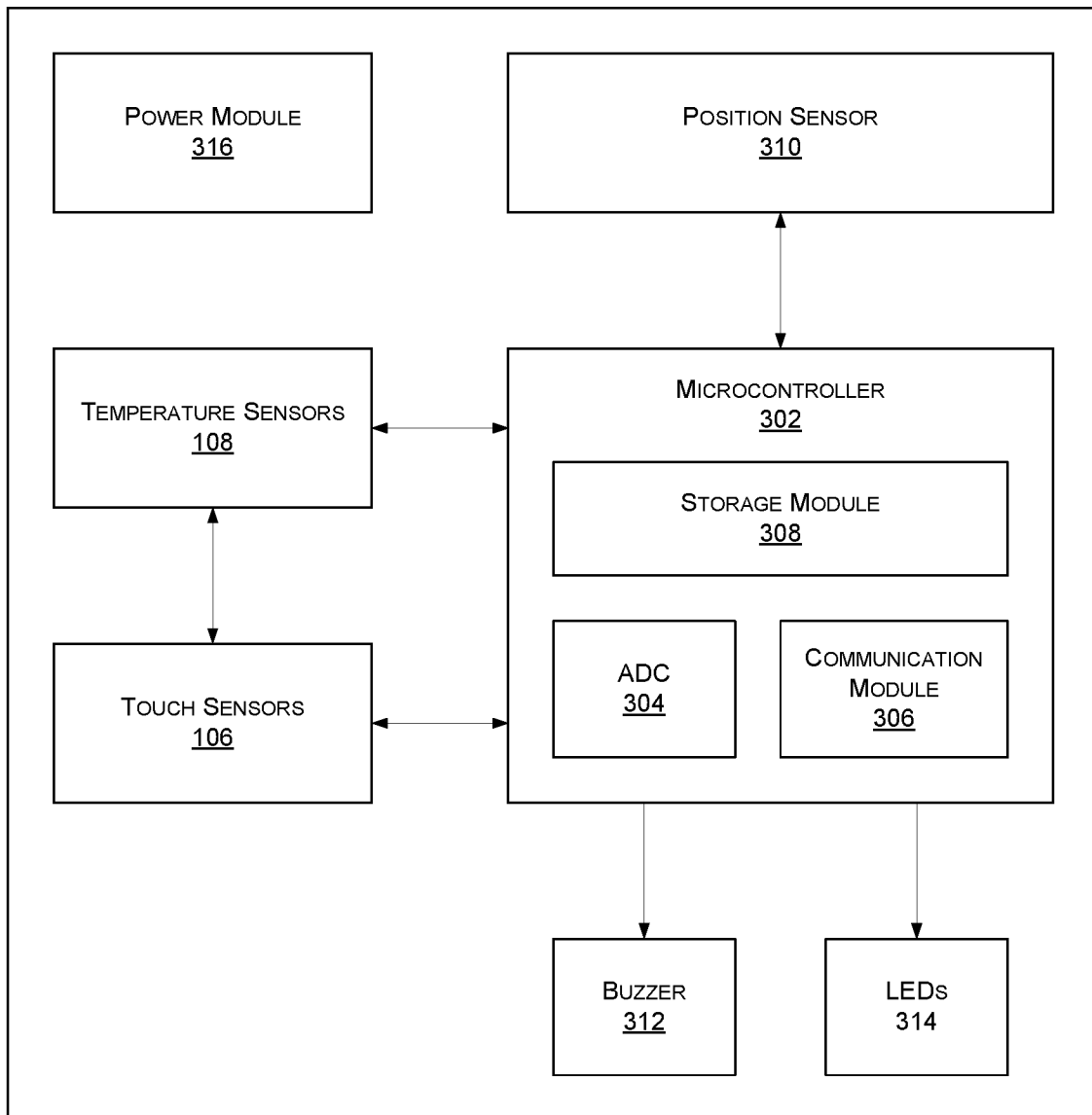


FIG. 3

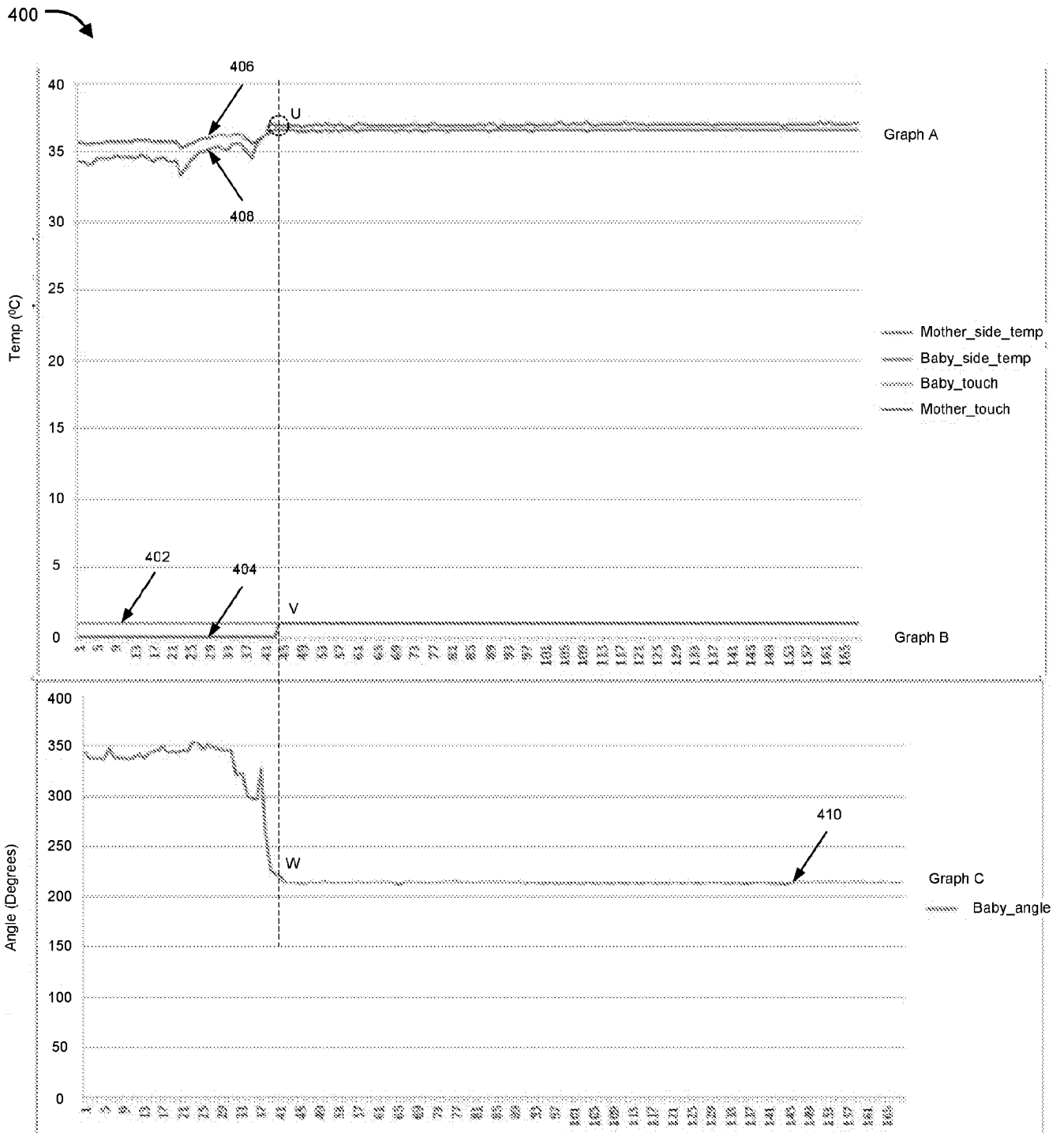


FIG. 4

500 →

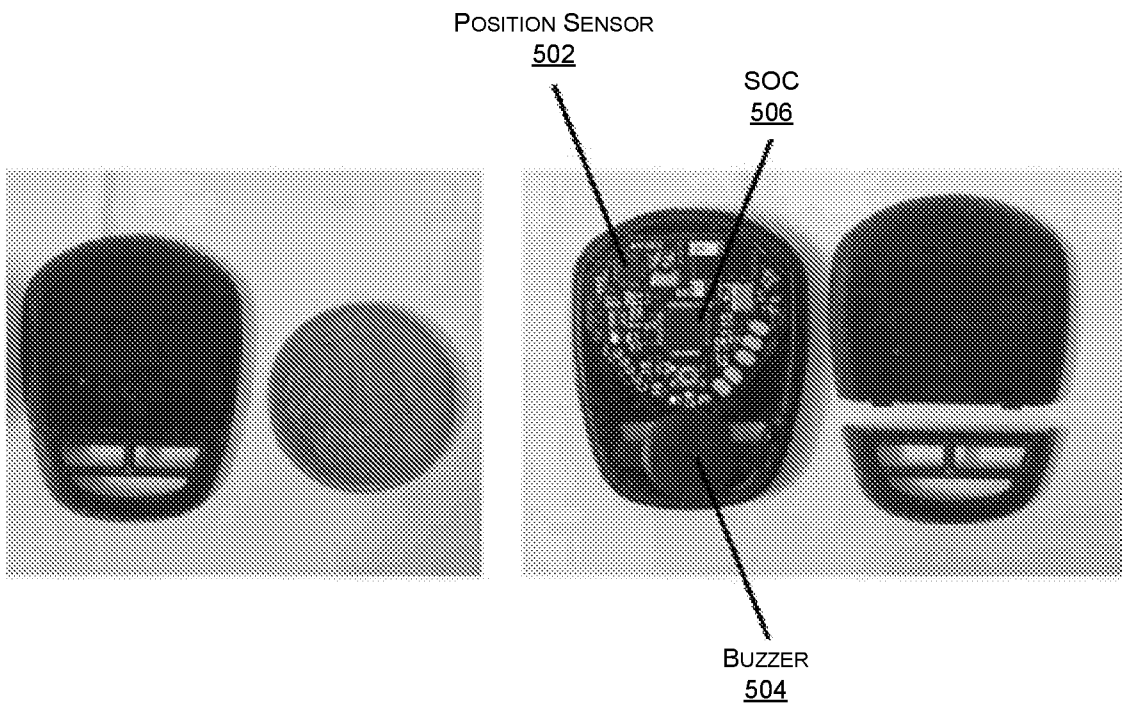


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2017/055265

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B5/01 A61B5/0205 A61B5/11 A61B5/113 ADD. A61B5/00														
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 <table border="1"> <thead> <tr> <th>Category*</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>X</td> <td>US 2005/245839 A1 (STIVORIC JOHN [US] ET AL) 3 November 2005 (2005-11-03) cited in the application abstract; figures 1,6-8, 11, 19-22 paragraphs [0050] - [0052], [0131] - [0138], [0154] - [0158] paragraphs [0167] - [0168], [0211] - [0219], [0234] - [0239] -----</td> <td>1-17</td> </tr> <tr> <td>X,P</td> <td>WO 2016/210334 A1 (RHYTHM DIAGNOSTIC SYSTEMS INC [US]) 29 December 2016 (2016-12-29) paragraphs [0052] - [0055] -----</td> <td>1-17</td> </tr> <tr> <td>A</td> <td>US 2006/056487 A1 (KURODA MASAO [JP] ET AL) 16 March 2006 (2006-03-16) abstract; figures 1-24 paragraphs [0009] - [0091] -----</td> <td>1-17</td> </tr> </tbody> </table>			Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	X	US 2005/245839 A1 (STIVORIC JOHN [US] ET AL) 3 November 2005 (2005-11-03) cited in the application abstract; figures 1,6-8, 11, 19-22 paragraphs [0050] - [0052], [0131] - [0138], [0154] - [0158] paragraphs [0167] - [0168], [0211] - [0219], [0234] - [0239] -----	1-17	X,P	WO 2016/210334 A1 (RHYTHM DIAGNOSTIC SYSTEMS INC [US]) 29 December 2016 (2016-12-29) paragraphs [0052] - [0055] -----	1-17	A	US 2006/056487 A1 (KURODA MASAO [JP] ET AL) 16 March 2006 (2006-03-16) abstract; figures 1-24 paragraphs [0009] - [0091] -----	1-17
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X	US 2005/245839 A1 (STIVORIC JOHN [US] ET AL) 3 November 2005 (2005-11-03) cited in the application abstract; figures 1,6-8, 11, 19-22 paragraphs [0050] - [0052], [0131] - [0138], [0154] - [0158] paragraphs [0167] - [0168], [0211] - [0219], [0234] - [0239] -----	1-17												
X,P	WO 2016/210334 A1 (RHYTHM DIAGNOSTIC SYSTEMS INC [US]) 29 December 2016 (2016-12-29) paragraphs [0052] - [0055] -----	1-17												
A	US 2006/056487 A1 (KURODA MASAO [JP] ET AL) 16 March 2006 (2006-03-16) abstract; figures 1-24 paragraphs [0009] - [0091] -----	1-17												
☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.														
* Special categories of cited documents : <table border="0"> <tr> <td> "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 </td> <td> "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 </td> </tr> </table>			"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										
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Date of the actual completion of the international search		Date of mailing of the international search report												
19 December 2017		03/01/2018												
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		Carta, Riccardo												

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2017/055265

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