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(54) **BIOMETRIC READING APPARATUS, SYSTEM AND METHOD OF USE THEREOF**

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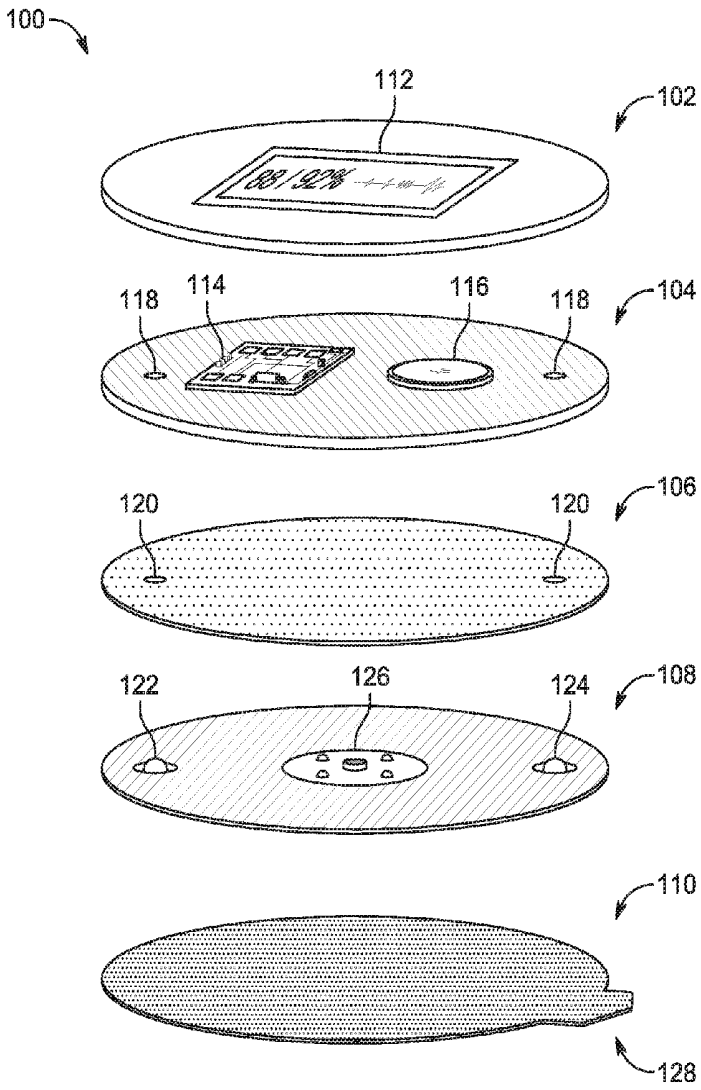
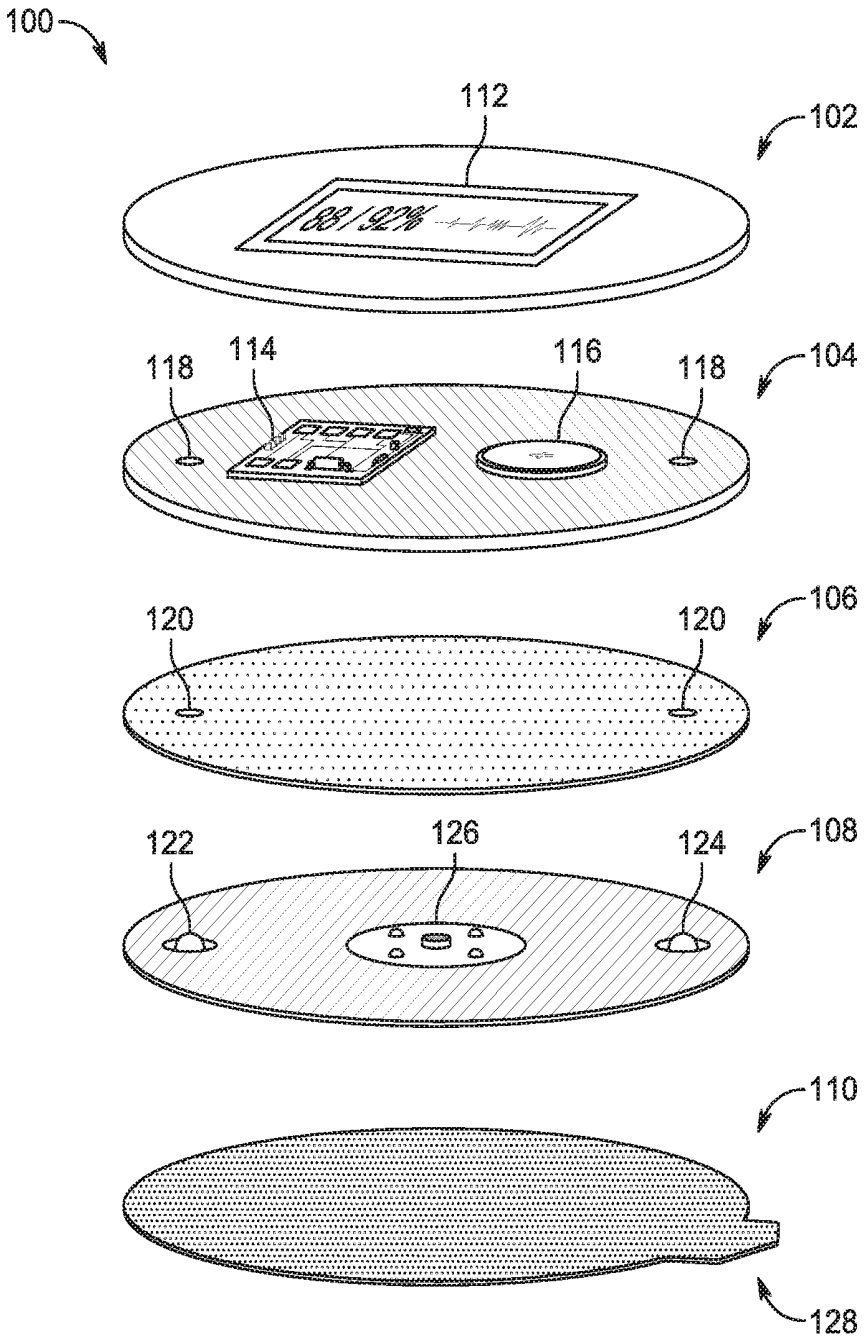
(57) **ABSTRACT**

Biometric sensor devices, systems and methods for obtaining biometric data and displaying biometric information based on the data on the sensor devices. The systems allow for additional biometric data collection and/or analysis through wireless communication capabilities. The devices and systems provide real-time information to the medical professional working on a patient. The information may be further based upon medical guidelines associated with the performed medical activity.




100
112
102
68192%
118
114
116
118
104
120
120
106
122
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124
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110
128

FIG. 1

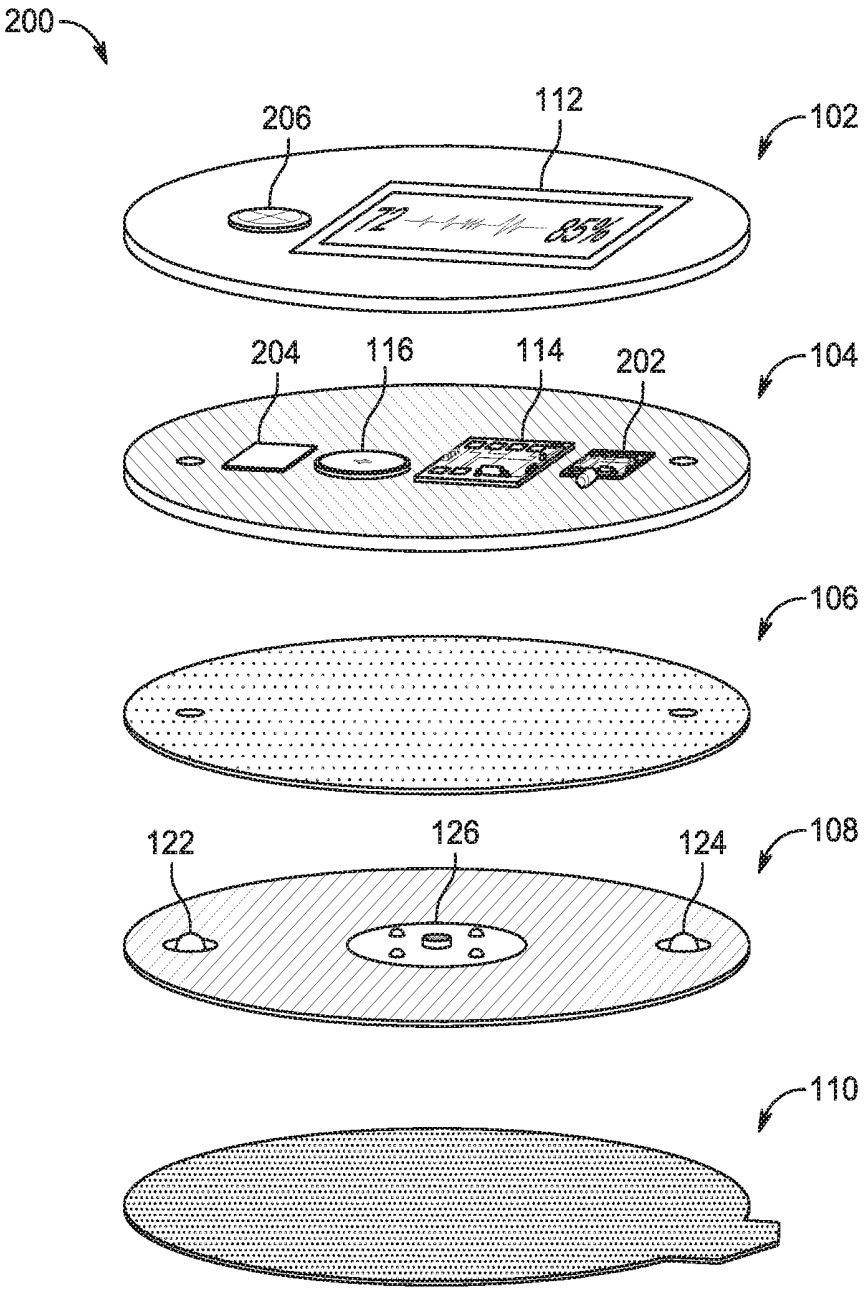

FIG. 2

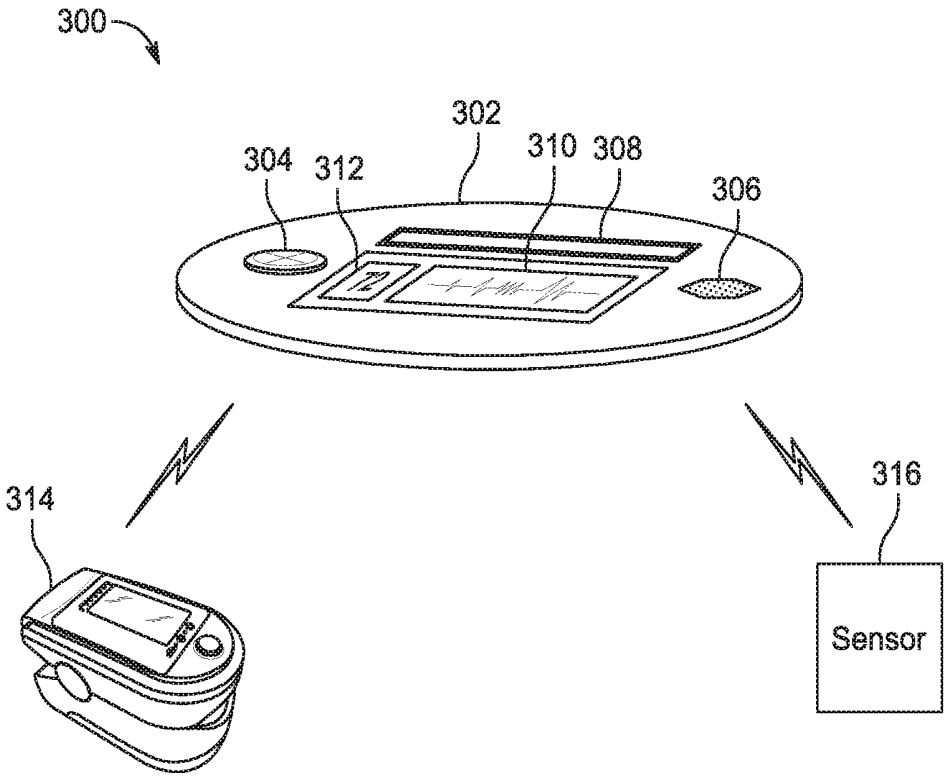

FIG. 3

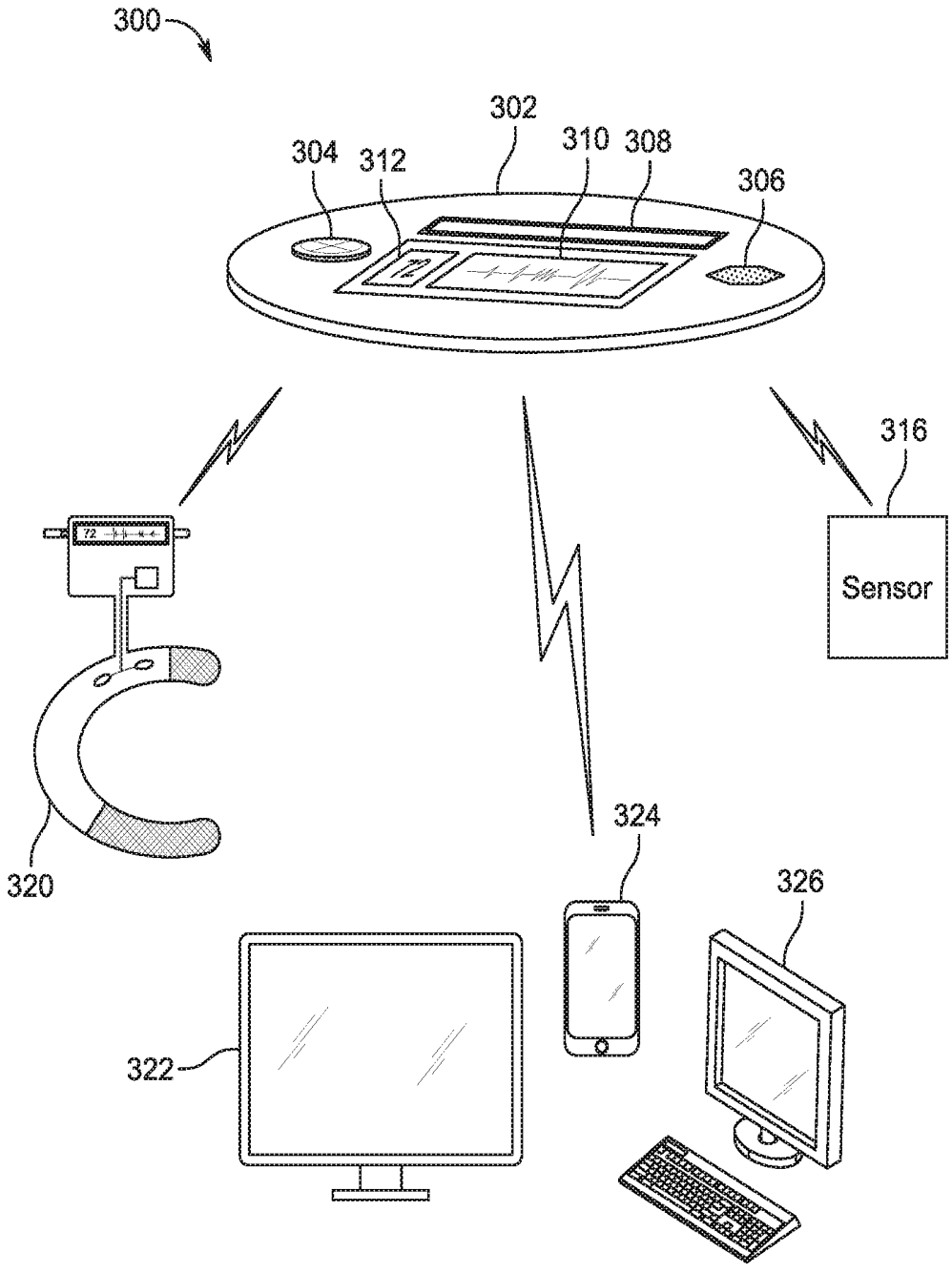

FIG. 4

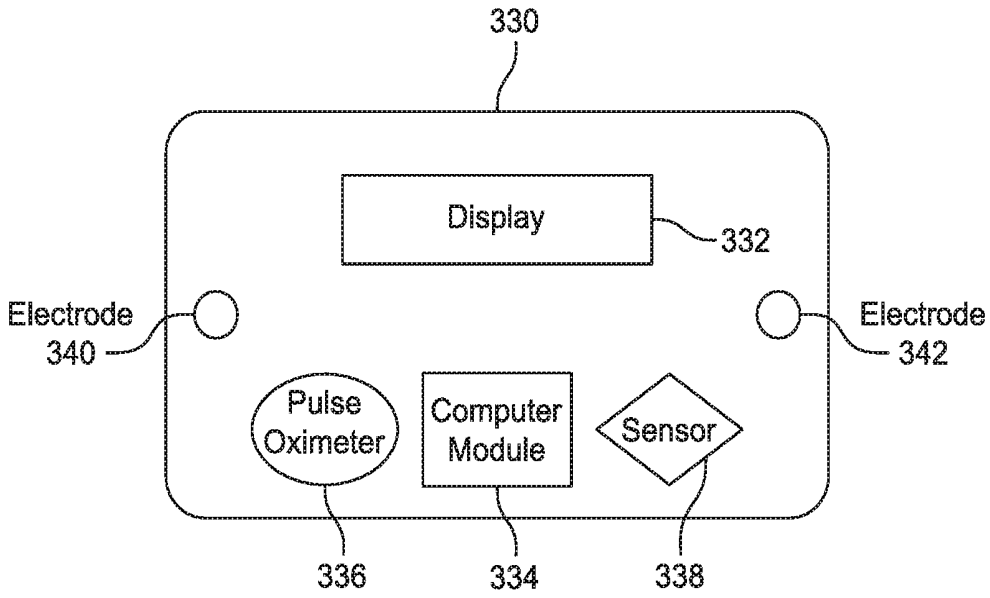
330
Display
332
Electrode
340
Electrode
342
Pulse
Oximeter
Computer
Module
Sensor
336
334
338

FIG. 5

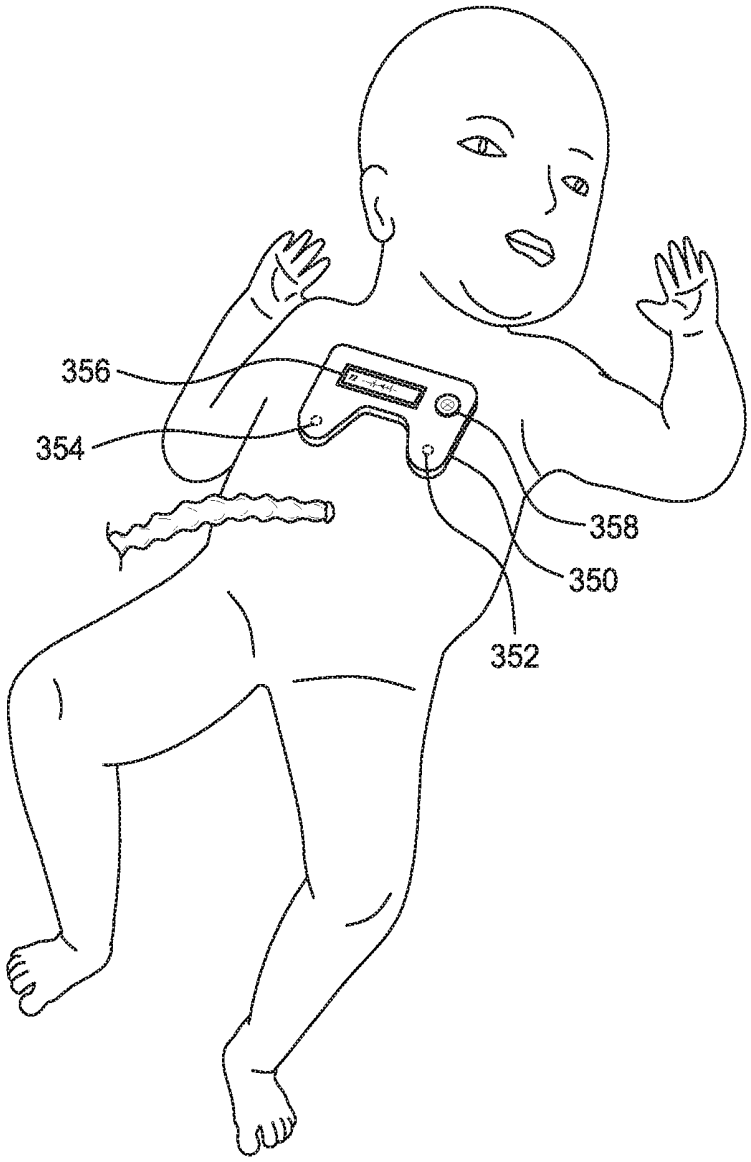

FIG. 6

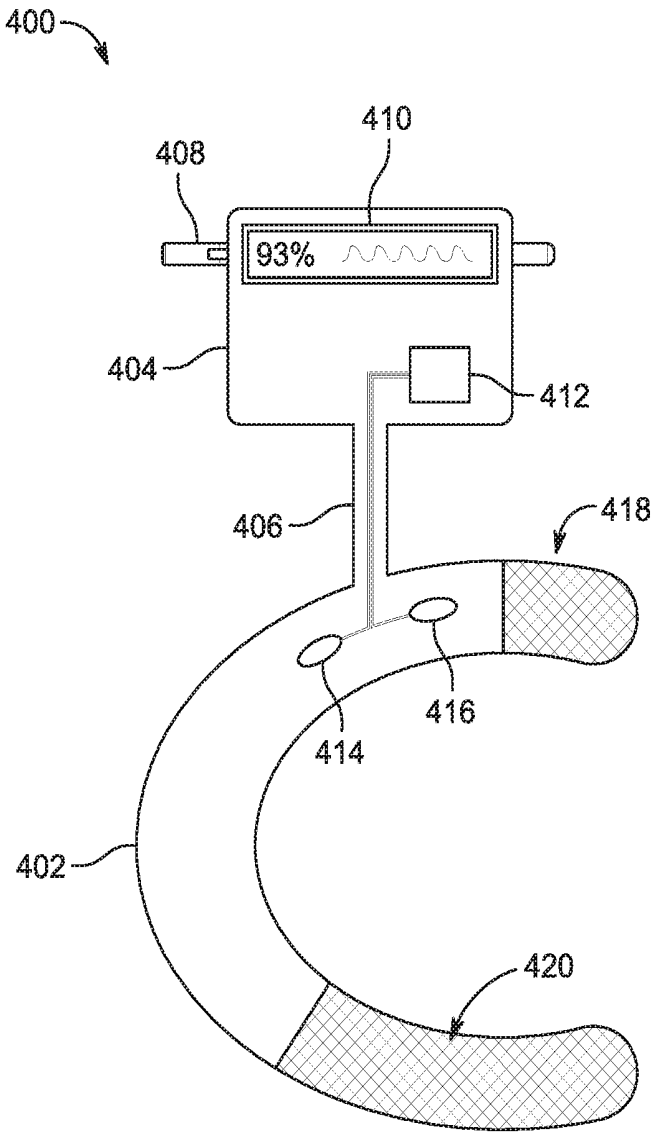

FIG. 7

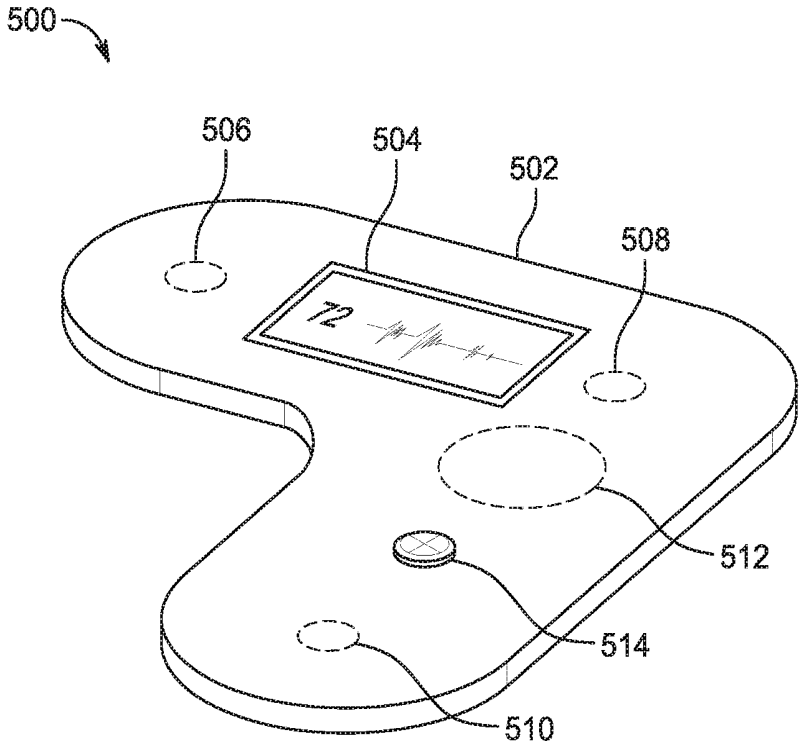

FIG. 8

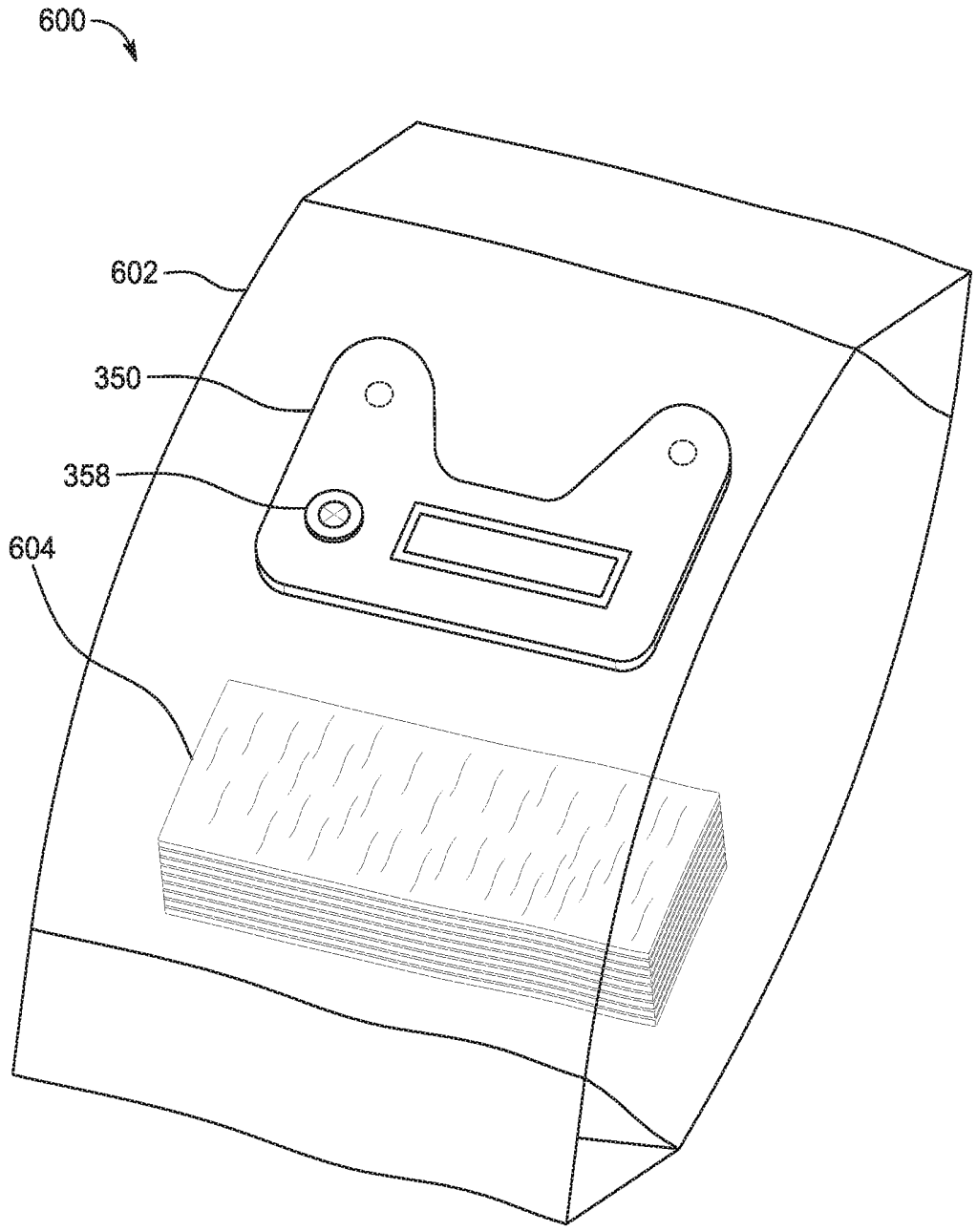

FIG. 9

BIOMETRIC READING APPARATUS, SYSTEM AND METHOD OF USE THEREOF

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of priority from U.S. Patent Application No. 62/396,458 filed on Sep. 19, 2016, which is incorporated herein by reference.

FIELD OF THE DISCLOSURE

[0002] The invention relates generally to the field of biometric sensing devices and systems.

BACKGROUND

[0003] In healthcare, patient biometric information is used to assist medical professionals in evaluating, diagnosing and caring for a patient. Often medical practice steps are influenced by specific biometric data. Wearable sensor devices are sometimes used to collect biometric information. U.S. Patent Publication No. 2014/0275932 titled "Disposable Biometric Patch Device" is an example of a wearable sensor. The sensor detects data and transmits the data wirelessly to a remote device.

[0004] Acquiring physiological data for newborn infants presents a number of challenges. The information needs to be as accurate as possible to ensure the proper procedures are being followed for the specific situation. In addition, the information needs to be obtained as quickly as possible to provide the best possible outcome for the baby and to ensure the procedures follow guidelines which are often based upon the time from birth.

[0005] Medical guidelines for neonatal resuscitation immediately following birth are tied to the heartrate of the baby. See American Heart Association, Web-based Integrated Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care—Part 13: Neonatal Resuscitation, p. 6 (2015) (hereinafter "Neonatal Resuscitation Guidelines"). For example, the guidelines teach specific actions for when the heartrate is (1) above 100 beats/min, (2) between 60 and 100 beats/min and (3) below 60 beats/min. Notably, certain steps in the guidelines should be occurring within the first minute of the baby's life. In addition, these guidelines call for the use of a pulse oximeter to evaluate oxygenation at specific times after birth. This guideline illustrates the anticipated oxygenation levels based upon the time from birth with expectations from 1 minute old.

[0006] Medical professionals have historically relied upon (1) intermittently auscultating the precordial pulse and/or (2) palpating the infant's umbilical cord pulse. In addition, some had attempted to acquire a heartrate using a pulse oximeter. The 2015 guidelines were updated to recommend using a 3-lead ECG (electrocardiogram) to acquire a heartrate because clinical assessment using auscultation and pulse oximetry was unreliable and inaccurate. See Neonatal Resuscitation Guidelines p. 3. In addition, "pulse oximetry more often displayed a lower rate in the first 2 minutes of life, often at levels that suggest the need for intervention." See Neonatal Resuscitation Guidelines p. 3. While the 3-lead ECG is recommended, application of a 3-lead ECG to a newborn takes time and often requires multiple wires connecting the leads on the child to a monitor located in the room.

[0007] Certain patents have presented devices that reduce or eliminate wiring for newborn ECG devices, such as U.S. Pat. Nos. 6,453,186 and 8,369,924. U.S. Pat. No. 6,453,186 is titled "Electrocardiogram Electrode Patch" and discloses a patch including a plurality of electrodes for attachment to an infant that includes a common connector to allow a single connection from a monitor in the room to each of the electrodes within the patch. Similarly, U.S. Pat. No. 8,369,924 is titled "ECG Leads System for Newborn ECG Screening" and discloses a chest strip ECG system having retractable limb leads for connecting to electrode leads to the infant's arms and legs. The ECG strip also may include a transceiver to transmit ECG signals to a receiver attached to an ECG machine located nearby.

[0008] Other patents and publications teach umbilical cord sensor systems for infant monitoring. For example, U.S. Patent Publication No. 2007/0276273 is titled "Periumbilical Infant ECG Sensor and Monitoring System" and discloses a combined ECG sensor and pulse oximetry sensor that attaches to the umbilical cord of the infant. The sensors are wired to the umbilical cord clamp then transferred to a monitor located nearby. Another example is U.S. Pat. No. 7,875,037 titled "Infant Umbilical Cord Cardiac Monitoring System and Method" which describes a monitoring device with a sensor attached to the umbilical cord clamp. The housing of the cord clamp includes an orifice to receive "a means for measuring physiological data" which is shown attached by a wire to a separate output device.

SUMMARY

[0009] The existing designs do not provide real-time information immediately following the birth of a baby for the efficient monitoring and use by a medical team working to provide immediate, emergency care to a newborn. Embodiments of the present disclosure provide relevant information in the immediate area of the medical team without requiring ancillary components. Embodiments of the design may also be used in other emergency situations to provide real-time data directly to the medical team working on a patient.

[0010] The present disclosure provides biometric reading devices, systems and methods of use. The devices may be designed as stand-alone products or as a system of networked components. Devices read one or more physiological features of a user and provide physiological data based on the collected information.

[0011] Embodiments of a device may include a patch that can be attached to a patient with one or more biometric sensors and one or more display features. The biometric sensor may include one or more electrodes used to determine a heartrate through an analysis of electrical signals detected in the user's body. In some embodiments, the biometric sensor is a pulse oximeter. The biometric sensor may include one or more of electrodes, pulse oximeters, a glucose sensor, a respiratory sensor, a thermometer or another sensor device.

[0012] Embodiments of the device may include one or more display features including an LED light strip, a display screen operable to show alpha-numeric data waveforms and/or other information. Display features may be incorporated into a single display element and/or multiple display elements. In some embodiments, the device also includes an audible output device.

[0013] Embodiments of the device may include a computer module to control the operation of the device, analyze

biometric data, store data and/or communicate data with another device. Some embodiments may include a user input to allow a user to start the device, control features of the device and/or stop operation of the device.

[0014] Some embodiments of the device may be part of a system that sends data to an external device. For example, embodiments of the device may transmit output signals to an external monitor and/or speaker for output. Some embodiments may send the data to a person's smart phone, tablet or other mobile device.

[0015] Embodiments of another device may include an umbilical cord biometric reading device. Embodiments of the umbilical cord device may include an umbilical cord strap that wraps around the infants umbilical cord, an output housing and a lead section that connects the strap to the housing. Sensor components may be located within the strap design such as pulse oximetry sensors, ECG electrode sensors and/or other sensors. The sensors may be connected to the housing through one or more wires within the lead section. Some embodiments of the housing include visual display features, such as colored lights, alpha-numeric outputs and/or waveform outputs. Within the housing, a computer module may be included some embodiments. The computer module may control the operation of the device, analyze biometric data, store data and/or communicate data with another device.

[0016] Embodiments of the system may include one or more embodiments of the biometric reading device and other external elements. Some embodiments of the system include a patch biometric reading device and an umbilical cord biometric reading device. The devices in some embodiments of the system operate to communicate in real time to share data. For example, the umbilical cord biometric reading device may transmit a heartrate and blood oxygenation reading to the patch device. In such embodiments, the patch device may take the data from the umbilical cord biometric reading device and analyze it with data obtained by the patch device to determine current biometric readings. In some embodiments, the patch may display the data on an integrated display or provide another output. Some embodiments may communicate with multiple external sensors and other devices to obtain additional data that may include redundant data to improve and/or confirm system accuracy in assessing biometric readings for a person.

[0017] In some embodiments, multiple external outputs and computer systems are integrated to output, review, assess and/or record the data from one or more biometric reading devices, such as a monitor, a smart phone, local or remote computer system and/or a server.

[0018] Some embodiments include a kit containing a biometric reading device and a wipe or other cleaning item to prepare a person's skin for application of the biometric reading device. The kit is sealed within a sanitary package prior to use in some embodiments.

[0019] Some embodiments of the method include placing a biometric sensor device on a newborn at the time of birth, sensing electrical signals produced by newborn, determining a heartrate of the newborn based on the sensed electrical signals, displaying an indication of the heartrate on the device. The display may provide a numerical indication, a wave form indication and/or a color coded indication. In some embodiments, the display is replaced with an audible output. A medical professional may use the heartrate indication as a factor in determining appropriate medical care for the newborn.

[0020] In some embodiments, the method may include utilizing a pulse oximetry sensor to determine blood oxygenation and displaying an indication of the blood oxygenation data. In addition, the pulse oximetry sensor in such an embodiment may be used to provide a secondary heartrate reading which may be used to evaluate an accurate heartrate of the baby.

[0021] Embodiments of the method may also include receiving additional data from other sensors placed on the newborn. The additional data may be used in evaluating the biometrics in some embodiments. In some embodiments, the additional data may be output on the display for the medical professional to see.

[0022] The data may be transmitted to another device for further analysis, storage and/or output in some embodiments. For example, the heartrate and oxygenation data may be transmitted to a nearby computer for evaluation.

A BRIEF DESCRIPTION OF THE DRAWINGS

[0023] Embodiments will now be described, by way of example only, with references to the accompanying drawings in which:

[0024] FIG. **1** is an exploded view of an embodiment of a biometric sensing patch;

[0025] FIG. **2** is an exploded view of another embodiment of a biometric sensing patch;

[0026] FIG. **3** depicts an embodiment of a biometric sensing system;

[0027] FIG. **4** depicts another embodiment of a biometric sensing system;

[0028] FIG. **5** is a block diagram of another embodiment of a biometric sensing patch;

[0029] FIG. **6** depicts another embodiment of a biometric sensing system placed on a newborn;

[0030] FIG. **7** depicts an embodiment of a biometric sensing device;

[0031] FIG. **8** depicts another embodiment of a biometric sensing patch; and

[0032] FIG. **9** is a perspective view of an embodiment of a kit including a biometric sensing patch.

DETAILED DESCRIPTION

[0033] While this invention may be embodied in many different forms, there will herein be described in detail preferred embodiments of the invention with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the broad aspects of the invention to the embodiments illustrated. It will be understood that the invention may be embodied in other specific forms without departing from the spirit or central characteristics thereof. The present embodiments, therefore, are to be considered in all respects as illustrative and not restrictive, and the invention is not to be limited to the details given herein.

[0034] The devices, systems and methods described herein may typically be used by a medical professional on a patient in a medical setting. For purposes of discussion, the user herein will often be referred to as a medical professional and/or patient as applicable; however, other users may also utilize the devices, systems and methods described herein. In

addition, users may utilize the devices, systems and methods described herein in non-medical settings without deviating from the scope of the disclosure.

[0035] FIG. **1** shows an embodiment of a biometric sensing patch **100** in an exploded view. In the embodiment shown, the patch **100** includes five layers including a display layer **102**, a substrate layer **104**, an insulation layer **106**, a sensor layer **108** and a liner layer **110**. Some embodiments of the biometric sensing patch **100** may include fewer or more layers. For example, the insulating layer **106** may be combined with the substrate layer **104** and/or the sensor layer **108** instead of being a separate layer. For another example, the substrate layer **104** and the display layer **102** may be combined in some embodiments. For yet another example, a top liner layer may be applied over the display layer **102**.

[0036] The layers of the patch **100** are constructed of flexible materials to allow the patch **100** to flex when applied to a patient and form to the patient. The flexibility of the patch **100** also allows the patch **100** to stay attached and operational while the patient is moving. Accordingly, one skilled in the art in view of this application will recognize that the display layer **102**, the substrate layer **104**, the insulation layer **106** and the sensor layer **108** combined will have the flexibility to fit intended patients and allow natural range of motion for the patient at the intended location for placement. For example, when the patch **100** is intended for use on a newborn's chest, the flexibility of the patch **100** will allow for a range of newborn body types and the natural movement of a newborn's chest. For another example, when the patch **100** is intended to be used on an adult female's chest, the flexibility of the patch **100** will allow for a range of women's body types and the natural movement of a woman's chest.

[0037] The layers of the patch **100** may be constructed from a variety of materials including foams, woven fabrics, rubbers, plastics, silicones and/or other materials. As discussed further herein most of the layers within the patch **100** will be constructed, at least in part, with non-conductive materials.

[0038] The upper layers of the patch **100** including the display layer **102**, the substrate layer **104**, the insulation layer **106** and the sensor layer **108** are combined to form the operational portion of the patch **100** while the liner layer **110** is designed to be removed prior to placement on a patient exposing the sensor layer **108** for contact with the patient's skin. The upper layers **102**, **104**, **106** and **108** of the patch **100** are attached and have a connection that allows the patch **100** to be fluid impermeable or at least fluid resistant. Alternative embodiments may include internal components that are safe to operate in a fluid environment obviating the need for the entire patch **100** to be fluid resistant. In some embodiments, all four of the display layer **102**, the substrate layer **104**, the insulation layer **106** and the sensor layer **108** may be connected. In some embodiments, the display layer **102** and the sensor layer **108** may be connected to each other with the substrate layer **104** and the insulation layer **106** fitted within the display layer **102** and the sensor layer **108**. The layers may be attached using mechanical techniques (e.g. press seals, heat seals, etc.), adhesives and/or other connections.

[0039] In addition, the patch **100** may include one or more gel layers applied to all or portions of a display layer **102**, a substrate layer **104**, an insulation layer **106**, a sensor layer **108** and a liner layer **110**. Some of the gel layers may include fluid repelling features and operate in conjunction with the connections to make the patch **100** fluid resistant. Some of the gels may be conductive to improve the electronic connections. For example, a conductive gel may be applied to the bottom of the sensor layer **108** to improve the sensor connections with the patient's skin.

[0040] The display layer **102** is the top outer layer of the patch **100** and includes a display **112** in this embodiment. The display **112** is depicted in this embodiment with an alpha-numeric output and a waveform output. The display **112** may be any type of visual output element, including but not limited to a digital display, an LED array, an analog display feature and/or any other display element or combination of elements. For example, the display **112** may be an array of LEDs that provide specific color outputs to indicate different information. In some embodiments, the display **112** is designed from flexible material that will flex with the patch **100**. In some embodiments, the display **112** may not have the same flexibility characteristics as the remainder of the display layer **102**.

[0041] In some embodiments, alternative designs of the display **112** may be used. For example, the display **112** may extend to the edges of the display layer **102**. For another example, the display **112** may include a secondary display element that extends from the frame of the illustrated digital display to the edge of the display layer **102**. In such embodiments, the digital display portion may show alpha-numeric and/or waveform outputs while the secondary display element shows colors indicative of medical guidelines associated with the biometric data identified by the device.

[0042] The substrate layer **104** includes a computer module **114** and a power source, shown as battery **116**. The computer module **114** includes elements of a computer including but not limited to a processor, memory and input/output elements. In some embodiments, the computer module **114** may include communication elements to receive and/or transmit signals with other external devices.

[0043] Passages **118** are also shown in the substrate layer **104** to illustrate optional passages for wiring or other elements to connect elements in the sensor layer **108** to the substrate layer **104** elements including the computer module **114** and battery **116**. While passages **118** are included for illustrative purposes, an assembled patch **100** would include wiring or other connections needed to operably connect the operational elements in to one another. One skilled in the art would further recognize in light of the application that the size of passages **118** may vary depending on the connections used. For example, the passages **118** may seal against wires passing through the passages **118**. In addition, while two passages **118** are shown, there may be fewer or more passages in some embodiments of the patch **100**.

[0044] The computer module **114** controls the operation of the patch **100** through receiving data from biometric sensor components, such as those located in the sensor layer, evaluating the received data to determine biometric information and providing the applicable output to the display **112** for communication to observer of the patch **100**. The actual output may be based upon standardized requirements stored in the memory of the computer module **114**. For example, the computer module **114** may direct the display **112** to provide specific color outputs correlated to the calculated heartrate of the patient, such as a red output for a heartrate under 60 beats per minute, a yellow output for a

heartrate from 60 to 100 beats per minute and a green output for a heartrate of 100 beats per minute or higher.

[0045] In some embodiments, the substrate layer **104** is a flexible backing material and the computer module **114** is a flexible circuit board attached to the backing material. The battery **116** may also be comprised of a semi-flexible material and attached to the backing material of the substrate layer **104**. In some embodiments, the computer module **114** is integrated into the material of the substrate layer **104** or placed on the backing material as a thin film.

[0046] In some embodiments, the battery **116** is designed to have a power capacity correlated to the intended use of the patch **100**. For example, when the patch **100** is a disposable device intended to stay on the patient for 24 hours, the capacity of the battery **116** may allow for the patch **100** to be operable for 24 hours. In some embodiments, the capacity may be designed to include additional capacity to allow operation for a specific amount of overuse. This additional capacity may also operate as a cushion to limit the likelihood of an underpowered device.

[0047] The insulation layer **106** includes passages **120** that correspond to the passages **118** in the substrate layer **104**. The passages **120** also illustrate optional passages for wiring or other elements to connect elements in the sensor layer **108** to elements in the substrate layer **104**. While passages **120** are included for illustrative purposes, an assembled patch **100** would include wiring or other connections needed to operably connect the operational elements in to one another. One skilled in the art would further recognize in light of the application that the size of passages **120** may vary depending on the connections used. For example, the passages **120** may seal against wires passing through the passages **120**. In addition, while two passages **120** are shown, there may be fewer or more passages in some embodiments of the patch **100**.

[0048] The insulation layer **106** provides insulation between the substrate layer **104** and the sensor layer **108**. In some embodiments, the insulation layer **106** limits the likelihood of interference between the elements of the substrate layer **104** and the sensing components located in the sensor layer **108**. For example, the insulation layer **106** prevents electrodes **122** and **124** from sensing electrical signals within the computer module **114**. In addition, the insulation layer **106** may prevent ancillary light from interfering with a light sensor within pulse oximeter **126** in some embodiments.

[0049] In some embodiments, the insulation layer **106** is integrated into one or both of the substrate layer **104** and the sensor layer **108**. For example, the backing material of the substrate layer **104** may also comprise an insulating material. For another example, the sensor elements in sensor layer **108** may be embedded in the bottom of an insulation material. In some embodiments, the sensor elements may not require additional insulation from other components, and the insulation layer **106** may not be included.

[0050] In this embodiment, the sensor layer **108** includes electrodes **122** and **124** and a pulse oximeter **126**. During operation, the electrodes **122** and **124** are used to detect electrical signals within the patient's body that indicate heart activity. The computer module **114** receives readings from the electrodes **122** and **124** and analyzes the readings to determine a patient's heartrate.

[0051] In this embodiment, the pulse oximeter **126** is shown as a reflective pulse oximeter with LEDs and an optical sensor to detect reflected light emitted from the LEDs. The detected light data is received by the computer module **114** and analyzed to determine oxygenation and/or a heartrate. In some embodiments, the pulse oximeter **126** may be another type of pulse oximeter.

[0052] In some embodiments, the sensor layer **108** may include a different array of sensors. Some embodiments may only include one or more electrodes **122**, **124** to detect heart activity. Other embodiments may include the electrodes **122**, **124**, the pulse oximeter **126**, a thermometer, a glucose sensor, a respiratory sensor and/or other sensors.

[0053] The liner layer **110** covers the bottom of the sensor layer **108** prior to use of the patch **100**. In this embodiment, the liner layer **110** includes a tab **128** to provide place to grip when removing the liner layer **110** from the remainder of patch **100**. The liner layer **110** may help seal a gel against the bottom of the sensor layer **108** and prevent the gel from drying out prior to use.

[0054] When the patch **100** is used, the medical professional will grab tab **128** and remove the liner layer **110** from the bottom of the patch **100**. In some embodiments, removing the liner layer **110** may also turn on the patch **100**. Once the liner layer **110** is removed, the medical professional will place the bottom of the patch **100** (bottom of sensor layer **108**) against the patient's skin. For example, the patch **100** may be placed on the chest of a newborn immediately after birth. Once the patch **100** is placed on the patient, the computer module **114** will begin receiving data from the electrodes **122**, **124** and the pulse oximeter **126**. The computer module **114** will analyze the data received and determine a heartrate. Once the heartrate is determined, the computer module **114** will output the result to the display **112**. The computer module **114** may also output the heartrate waveform to the display **112**. In some embodiments, the computer module **114** will also determine an oxygenation level and output the oxygenation percentage result to display **112**.

[0055] During operation of the patch **100** on a newborn, medical professionals can review the relevant data on the display **112** which is located on the chest of the newborn on which the professional is attending. Providing the display **112** on the chest of the patient allows the medical professional to remain focused on the newborn while also monitoring the biometric data relevant to potential emergency situations. Accordingly, the patch **100** may allow the medical professionals to act faster in an emergency situation wherein every second can impact the life of the child because the medical professionals are not required to look away from the patient to receive the biometric data. In addition, the medical professionals would not have to include additional staff separately monitoring the biometric data and repetitively stating the relevant biometric data which may interfere with other emergency communications occurring at the same time.

[0056] Embodiments of the patch **100** may be placed at a variety of locations against the patient's skin, including the chest, forehead and other locations, that allow for the patch to operate as described herein. As discussed herein, the patch **100** may be placed at a location that allows the medical professional to remain focused on the patient while also monitoring the biometric data relevant to potential emergency situations. For example, the patch **100** may be placed on a patient's forehead and would be readily observable.

[0057] Additional data may also be evaluated and displayed on the display **112** in some embodiments. For illustrative purposes, the display **112** shows a heartrate of 88, an oxygenation of 92% and an electrical activity waveform. Alternative embodiments of the patch **100** may provide more or less information. In some embodiments, the computer module **114** may allow user control to select the preferred output options.

[0058] In some embodiments, the computer module **114** directs the display **112** to provide a color output indicative of the heartrate relative to medical guidelines stored in the memory of the computer module **114**. For example, the medical guidelines for neonatal resuscitation immediately following birth may be stored in the memory and an indicative color is assigned for each heartrate range provided in the guidelines. When the computer module **114** receives data from the electrodes **122**, **124** and/or the pulse oximeter **126**, the computer module **114** determines the heartrate and then compares the heartrate to each of the heartrate ranges defined by the stored medical guidelines. Once the applicable range is determined by the computer module **114**, the computer module **114** causes the display **112** to output the indicative color associated with the applicable heartrate range. For example, the display **112** may be red for a heartrate under 60 beats per minute, yellow for a heartrate from 60 to 100 beats per minute and green for a heartrate of 100 beats per minute or higher. In some embodiments using a color coded output, the computer module **114** will cause the display **112** to blink at the actual heartrate or otherwise indicate the actual heartrate within the given range.

[0059] In some embodiments, the patch **100** may also incorporate failsafe mechanisms. For example, the patch **100** may utilize redundant sensors to increase the likelihood of successfully obtaining a biometric readings and calculating the heartrate based upon each of the successfully obtained readings to provide increased accuracy in determining biometric characteristics of the patient.

[0060] In addition, some embodiments will provide error evaluation and notification features. For example, the patch **100** may include redundant and/or alternative sensors for obtaining readings associated with a characteristic of the patient. During an evaluation of the sensor readings, the computer module **114** may determine that one or more of the readings may be in error. If the correct result cannot be determined due to the error, the computer module **114** may output an error message and/or indication to ensure the medical professional can take appropriate steps in view of the error.

[0061] FIG. **2** shows another embodiment of a biometric sensing patch **200** in an exploded view. Similar to FIG. **1**, the patch **200** includes five layers including the display layer **102**, the substrate layer **104**, the insulation layer **106**, the sensor layer **108** and the liner layer **110**. Some embodiments of the biometric sensing patch **200** may include fewer or more layers. As discussed above, the layers of the patch **200** are constructed of flexible materials to allow the patch **200** to flex when applied to a patient and form to the patient. The layers of the patch **200** may be constructed from a variety of materials including foams, woven fabrics, rubbers, plastics, silicones and/or other materials. As discussed further herein most of the layers within the patch **200** will be constructed, at least in part, with non-conductive materials.

[0062] While aspects of the layers of patch **200** are described in further detail with regard to FIG. **1**, the embodiment shown in the patch **200** illustrates additional and/or alternative aspects of a biometric device. In addition to elements discussed elsewhere herein, the patch **200** includes a communication module **202**, a switch **204** and a button **206**. The patch **200** also illustrates another arrangement of the elements of in a biometric sensing device.

[0063] The display layer **102** of the patch **200** includes display **112** and a button **206** in this embodiment. The display **112** is depicted in this embodiment with an alphanumeric output and a waveform output. This display **112** shows the output of data in an alternative arrangement with the "72" indication on one side of a waveform and an 85% reading on the opposite side.

[0064] The substrate layer **104** includes the computer module **114** the power source (shown as battery **116**), communication module **202** and switch **204**. The button **206** in conjunction with switch **204** operates as a control of the patch **200**. In some embodiments of the patch **200**, the button **206** comprises a flexible material that may be compressed actuating the switch **204**. The flexible material of button **206** may be formed from the same piece of material as the display layer **102**.

[0065] In some embodiments, the button **206** and the switch **204** operate solely as an on/off control. In other embodiments, the button **206** and the switch **204** may also facilitate control of one or more features of the patch **200**. For example, pressing the button **206** may allow the user to select a preferred display option, such as only showing the heartrate and oxygenation level without any waveform.

[0066] As discussed above, the computer module **114** controls the operation of the patch **200** through receiving data from biometric sensor components, such as those located in the sensor layer **108**, evaluating the received data to determine biometric information and providing the applicable output to the display **112** for communication to observer of the patch **200**. The actual output may be based upon standardized requirements stored in the memory of the computer module. For example, the computer module **114** may direct the display **112** to provide specific color outputs correlated to the calculated heartrate of the patient, such as a red output for a heartrate under 60 beats per minute, a yellow output for a heartrate from 60 to 100 beats per minute and a green output for a heartrate of 100 beats per minute or higher.

[0067] In some embodiments, the computer module **114** may be off until the button **206** is pressed actuating the switch **204** and turning the computer module **114** on. When the computer module **114** is turned on, the computer module **114** will begin operation of the additional patch elements. In some embodiments, the computer module **114** will initiate an internal clock feature when the device is turned on. Some embodiments may include an option to display the clock data on display **112**.

[0068] The communication module **202** operates to transmit and/or receive (collectively "communicate") data wirelessly with external devices—such as a monitor, a smartphone, a tablet, another sensor, etc. Some embodiments of the communication module **202** are near field communication modules allowing communications with devices within a short range of the patch **200**. Near field communication modules may operate on the BLUETOOTH communication standard, the ZIGBEE communication standard, and/or any other near field communication standard.

[0069] Some embodiments of the communication module **202** may provide for communication beyond the range of a near field communication module. For example, the communication module **202** may be a WIFI communication module, a cellular communication module or another wide area communication module.

[0070] In some embodiments, the substrate layer **104** is a flexible backing material and the computer module **114**, switch **204** and the communication module **202** are flexible circuit boards attached to the backing material. The battery **116** may also be comprised of a semi-flexible material and attached to the backing material of the substrate layer **104**. In some embodiments, the computer module **114**, switch **204** and the communication module **202** are integrated into the material of the substrate layer **104** or placed on the backing material as a thin film.

[0071] In some embodiments, the communication module **202** communicates with other devices in real-time. Some embodiments of the communication module **202** may operate on a periodic basis. The operation of the communication module **202** may be managed or modified from a default setting by computer module **114**. For example, the computer module **114** may cause the communication module **202** to change from real-time communication to a periodic communication pattern to lower power consumption and thereby extend the life of battery **116**. For another example, the computer module **114** may cause the communication module **202** to transmit pairing signals periodically to identify whether another device is ready to pair with the patch **200** and will initiate real-time communication only upon receiving the corresponding pair signal from an external device. One having ordinary skill in the art will understand that a pairing process may include one or more security measures, such as authorization checks and/or encryptions, to ensure the data communicated is to and from an approved external device.

[0072] When the patch **200** is used, the medical professional may actuate the button **206** and remove the liner layer **110** from the bottom of the patch **200**. The patch **200** may begin operations, such as starting the display **112**, initiating communications through communication module **202** and/or other operations, as soon as the button **206** is pressed. Once the liner layer **110** is removed, the medical professional will place the bottom of the patch **200** (bottom of sensor layer **108**) against the patient's skin. Once the patch **200** is placed on the patient, the computer module **114** will begin receiving data from the electrodes **122**, **124** and the pulse oximeter **126**. In some embodiments, the computer module **114** may also receive additional data through the communication module **202**. The computer module **114** will analyze the data received and may determine a heartrate, oxygenation percentage and/or additional biometric data. Once the biometric data is determined, the computer module **114** will output the result to the display **112**. The biometric data may be displayed in an alphanumeric format, a waveform format and/or another format—e.g. a color coded format, a medical reference code, an estimated APGAR reference, etc.

[0073] In some embodiments, the patch **200** is designed for use on a newborn to evaluate the health characteristics of the child in the moments following birth. The device may be designed for operation beginning at the time of birth and for a period immediately following the birth. In the delivery room, a medical professional may press the button **206** at the time of birth to turn on the patch **200**. In addition, the button **206** may begin a clock feature within the computer module **114** to provide the time from birth. Some medical guidelines and procedures are based in part upon the time from birth. For example, the target oxygenation percentage is correlated to the time from birth within some medical guidelines.

[0074] In addition, a medical professional may observe the APGAR characteristics at specific times after the birth of a child. For example, the medical professional may evaluate the infant's APGAR score at the one minute, five minute and ten minute marks. In some embodiments, the computer module **114** may provide timing outputs to the display **112**, such as a warning light, a flashing time indicator, etc., to correspond with the selected times for evaluating the APGAR score or other trigger times.

[0075] As soon as practical following the birth of the child, a medical professional will remove the liner layer **110** from the bottom of the patch **200** and apply the patch to the child's chest. In some embodiments, a gel or other substance may be exposed on the bottom of the patch **200** that facilitates a connection to the child's skin. The gel or other substance located at the electrodes **122** and **124** may have conductive properties to allow the electrodes **122** and **124** to read electrical signals produced by the heart. In some embodiments, the gel or substance is designed to facilitate a connection prior to removal of a vernix coating or other biological material on the child. In some embodiments, a medical professional will first wipe vernix and/or other biological material from the location where the patch **200** will be placed.

[0076] Once the patch **200** is placed on the newborn, the patch **200** will gather data from the electrodes **122** and **124**, the pulse oximeter **126**, any additional sensors and/or any external data sources in communication with the patch **200**. The computer module **114** will evaluate relevant data to determine biometric information about the baby, such as a heartrate and an oxygenation percentage. The computer module **114** will output relevant results, or indications thereof, on the display **112**. In addition, the computer module **114** may transmit data and/or evaluation results to an external device via the communication module **202**.

[0077] During operation of the patch **200** on a newborn, medical professionals can review the relevant data on the display **112** which is located on the chest of the newborn on which the professional is attending. Providing the display **112** on the chest of the patient allows the medical professional to remain focused on the newborn while also monitoring the biometric data relevant to potential emergency situations.

[0078] In some embodiments, the display **112** may provide a color output indicative of the heartrate relative to medical guidelines stored in the memory of the computer module **114**. Providing the indicative color may allow the medical professional to recognize relevant information without modifying their focus from other medical activities for the newborn. For example, a medical professional may notice the display **112** change from yellow to green indicating that the newborns heartrate improved to a safer level.

[0079] In some embodiments, the display **112** or an external display connected wirelessly to the patch **200** via the communication module **202** may also show a number or indication correlated to one or more aspects of an APGAR score. One skilled in the art will recognize that APGAR scoring is a simple assessment to quickly gauge the status of a newborn and the newborn's response to resuscitation or

other procedures. The APGAR score is based upon a medical professional's review of five characteristics of the newborn, including the color, heartrate, reflexology, muscle tone and respiration. In some embodiments, the patch **200** may determine a preliminary result correlated to one or more characteristics of the APGAR score. For example, the patch **200** may provide a preliminary score for the heartrate, respiration and color based upon sensor analysis tied to the heartrate sensors, oxygenation sensors, respiration sensors and/or other sensors. The medical professional may use the preliminary score from the patch **200** along with observed scores for other characteristics to determine an APGAR score. The accuracy and completeness of an APGAR or other status indicator may be improved based upon scientific studies of data collected with one or more patches and correlated to various health outcomes.

[0080] FIG. **3** depicts an embodiment of a biometric sensing system **300** including a patch **302**, a pulse oximeter **314** and another sensor **316**. The patch **302** is similar to patches **100** and **200** discussed previously and includes similar internal features, such as electrode sensors, a computer module, a power source and/or other elements. The patch **302** may also include additional elements that are not shown in this view, such as alternative sensors.

[0081] The display surface of patch **302** in this embodiment includes a button **304**, an audible output **306**, a bar display **308**, a waveform display **310** and an alphanumeric display **312**. The button **304** may operate as an on/off control and/or a feature control. Embodiments of the button **304** may be similar to the button **206** described with respect to FIG. **2**.

[0082] The audible output **306** may be a speaker or any other audible output device. During operation the audible output **306** may be used to provide information to the user of the patch **302**. For example, the audible output **306** may provide an audible noise correlated to each heartbeat detected by the patch **302**. For another example, the audible output **306** may provide voice outputs stating relevant data. One having ordinary skill in the art will recognize that the audible output **306** may be used to provide information regarding the data obtained or received by the patch **302**, results of an analysis by the patch **302**, status information regarding the patch **302** or connected devices and/or other information.

[0083] In addition to the audible output **306**, this embodiment of the patch **302** includes multiple display features—a bar display **308**, a waveform display **310** and an alphanumeric display **312**. While this embodiment includes multiple separate display features, other embodiments, such as those described elsewhere herein, may only include one display feature. In addition, certain display features may be operable to provide multiple display types in separate sections of a single display.

[0084] The bar display **308** may provide an indication for biometric readings. In some embodiments, the bar display **308** may provide a color indication correlated to a medical guideline. For example, the bar display **308** may be red for a heartrate under 60 beats per minute, yellow for a heartrate from 60 to 100 beats per minute and green for a heartrate of 100 beats per minute or higher. In some embodiments using a color coded output, the bar display **308** will blink at the actual heartrate or otherwise indicate the actual heartrate within the given range. In some embodiments, the bar display **308** may light up from one end to the other to illustrate a gauge. For example, the lit portion of the bar display **308** may begin on the left and extend to a point in the bar display **308** representative of the current heartrate of the patient. The lit portion of the bar display **308** grows as the patient's heartrate increases and shrinks as the patient's heartrate decreases.

[0085] The waveform display **310** shows a heartrate waveform in this embodiment. In some embodiments, the waveform display **310** may provide alternative information. For example, the waveform display **310** may show pulse readings obtained by the pulse oximeter **314**. For another example, the waveform display **310** may show respiration patterns based upon data received from the sensor **316**.

[0086] The alphanumeric display **312** may show any alphanumeric output in this embodiment. For example, the alphanumeric display **312** may show the calculated heartrate of the patient. For another example, the alphanumeric display **312** may show an oxygenation percentage, a temperature and/or other information obtained by the patch **302**, the pulse oximeter **314**, the sensor **316** and/or another source of information.

[0087] The outputs including displays **308**, **310** and **312** and audible output **306** may provide information regarding the data obtained or received by the patch **302**, results of an analysis by the patch **302**, status information regarding the patch **302** or connected devices and/or other information. The outputs may be coordinated to provide the same or different information depending on settings of the patch **302**.

[0088] In some embodiments, the button **304** may be operable to facilitate the selection of settings for the patch **302**. In some embodiments, one or more of the bar display **308**, the waveform display **310** and the alphanumeric display **312** may be an input device, such as a touch screen control, that may be used to control one or more features of the patch **302**. In some embodiments, the audible output **306** may include a microphone to record sounds and/or facilitate voice activated controls for the patch **302**.

[0089] In this embodiment, the patch **302** is wirelessly connected to pulse oximeter **314** through wireless modules in patch **302** and pulse oximeter **314**. The pulse oximeter **314** is depicted as a fingertip or clip pulse oximeter in this embodiment. One having ordinary skill in the art will recognize that other types of pulse oximeters may be used in place of the fingertip design. During operation, the pulse oximeter **314** obtains data regarding an oxygenation level of the user and may also obtain data regarding the patient's heartrate. In some embodiments, the pulse oximeter **314** communicates the obtained data directly to the patch **302** in real-time or near real-time. In some embodiments, the pulse oximeter **314** may include a processor or other computer module to determine an oxygenation percentage and/or a heartrate and sends calculated information to the patch **302**.

[0090] In addition, the patch **302** is also wirelessly connected to another sensor **316** through wireless modules in patch **302** and the sensor **316**. The sensor **316** may be any type of sensor that may provide relevant data to the patch **302**, including one or more of electrode sensors, pulse oximeters, a glucose sensor, a respiratory sensor, a thermometer or another sensor device. The sensor **316** may be applied to the patient to obtain additional data that is distinct from the data obtained by the patch **302**. For example, the sensor **316** may be a temporal thermometer attached to the patient's head. For another example, the sensor **316** may be a glucose sensor attached to an infant's umbilical cord. In

addition, the sensor **316** may obtain data redundant to the data obtained by the patch **302**. For example, the sensor **316** may be another electrode sensor designed to obtain a heartrate whereby the patch **302** may compare data to ensure the results are properly correlated. If the redundant results are not properly correlated, the patch **302** may indicate a warning to let the medical professional know a potential error may have occurred.

[0091] During operation of the system **300**, one or more medical professionals may work together to properly apply the patch **302**, the pulse oximeter **314** and the sensor **316** to a patient. The medical professional(s) would ensure the devices are each turned on (e.g. button **304** is pressed to turn on the patch **302**) and may wait for an indication that the devices have all properly paired together. Once the devices are communicating and properly attached, data is received by the patch **302** and processed to determine and output information to the medical professional(s) via at least one of the outputs.

[0092] In some embodiments, the system **300** may be used to conduct a critical congenital heart disease screening using two of the pulse oximeters **314**. The first pulse oximeter **314** may be placed on the infant's right hand to acquire a preductal reading and the second pulse oximeter **314** may be placed on either one of the infant's feet to acquire a post-ductal reading. During operation for a critical congenital heart disease screening, the system **300** will acquire preductal and post-ductal heartrate and oxygen saturation data from the two pulse oximeters **314**. The data may be sent to the patch **302**. In some embodiments, the patch **302** will show the data directly on one or more of displays **308**, **310** and **312**. In other embodiments, the computer module within patch **302** will analyze the data and provide relevant results (such as the preductal oxygenation percentage, the post-ductal oxygenation percentage, the oxygenation percentage difference between the preductal and post-ductal readings, a pass/fail indication based upon screening guidelines and/or another relevant result) the on one or more of displays **308**, **310** and **312**. For example, the display **308** may light up with a color to indicate the results of the screening, such as green to indicate the preductal and post-ductal oxygenation levels are each at or above 95% and within 3% of each other, yellow to indicate the results are within a set deviation for a passing result (e.g. the preductal and/or post-ductal oxygenation levels are below 95% and at or above 90% and/or the preductal and/or post-ductal oxygenation levels are not within 3% of each other) and red to indicate the preductal and/or post-ductal oxygenation levels are below 90%.

[0093] FIG. **4** depicts another embodiment of the biometric sensing system **300**. In this embodiment, the biometric sensing system **300** includes the patch **302** and sensor **316** discussed above. In addition to these components, the biometric sensing system **300** includes a pulse oximeter **320** (illustrated as a different type of pulse oximeter than pulse oximeter **314**), a display monitor **322**, a smartphone **324** and a computer **326**. In the biometric sensing system **300**, each of the devices is wirelessly connected to the patch **302** and/or each other. In some embodiments, the system **300** may include a hub component to facilitate communications between devices. In such an embodiment, the hub may also facilitate relaying communications to other devices and/or systems that may be remote from one or more of the devices shown and beyond the range of their communication capabilities.

[0094] The pulse oximeter **320** is an umbilical cord pulse oximeter that includes its own output features. During operation, the pulse oximeter **320** obtains data regarding an oxygenation level of the user and may also obtain data regarding the patient's heartrate. In some embodiments, the pulse oximeter **320** communicates the obtained data directly to the patch **302** in real-time or near real-time. In some embodiments, the pulse oximeter **320** sends calculated information regarding the oxygenation percentage and/or the heartrate to the patch **302**. Additional elements of the pulse oximeter **320** are discussed further in the context of FIG. **7**.

[0095] The monitor **322** in this embodiment may operate as an additional and/or a redundant display for the patch **302**. The larger monitor **322** may be capable of providing more information and detail regarding the patient data and other potentially relevant data. For example, the monitor **322** may include a running clock to show the time from birth, the calculated heartrate and electrical waveform, the calculated oxygenation percentage and pulse waveform, the patient's temperature and other information. While the monitor **322** may be available for reference, the medical professional does not have to use the monitor **322** during emergency situations because the pertinent information is provided on the display outputs on the patch **302**.

[0096] This embodiment of the system **300** shows smartphone **324** as another connected element within the network of devices. One having ordinary skill in the art will recognize that alternative devices may be included in the network of devices of system **300** in addition to or instead of those shown in FIG. **4**, including tablet devices, laptop devices and/or any other mobile computing device. In some embodiments, analog devices, such as phones and pagers, may be able to operate within the system **300** through texting protocols. These options allow for the system **300** to be utilized in a wide variety of environments including those away from hospitals and other medical facilities. For example, a person working to help others in a remote village may be able to use the patch **302** with a smartphone **324** with limited additional supplies and/or equipment.

[0097] The smartphone **324** in this embodiment may also operate as an additional and/or a redundant display for the patch **302**. In addition, the smartphone **324** may provide additional medical information, such as applicable medical guideline information, that may be available as a reference for the medical professional. In some embodiments, the smartphone **324** may include application software that allows the app to identify relevant medical information and correlate the data to the medical information. The application may also allow a user to select relevant information to find out additional information supporting a diagnosis, a guideline or procedure.

[0098] The smartphone **324** may also facilitate additional outputs for data, warnings and/or other information. For example, the smartphone **324** may provide audible and/or mechanical outputs (e.g. vibration) to indicate a heartrate or other information. In addition, the smartphone **324** may use alternative communication means (e.g. cellular, WIFI, Internet connections, etc.) to communicate information to others in areas remote from the patient and patch **302**. For example, the smartphone **324** may be designed to communicate a WIFI signal to a medical professional in another area of a medical facility to call for assistance and/or to provide updates. The operation of the smartphone **324** may depend

on data thresholds. For example, the smartphone **324** may message a cardiologist in the event the heartrate is below a certain threshold.

[0099] This embodiment also includes the computer **326**. The computer **326** may be a desktop or laptop computer, a server or any other type of computing device sufficient to facilitate a selected operation. For example, a desktop or laptop computer may facilitate many of the display and information features discussed in connection with the smartphone **324**. For another example, a server may facilitate the aggregation, storage and/or analysis of data from multiple patients. In some embodiments, the server may be used to collect de-identified information from multiple patients for research and educational purposes.

[0100] In some embodiments, the computer **326** may receive and record data while the patch **302** is used. After the medical process is completed, the computer **326** may be used to conduct a review and analysis of the patient and the medical process. In addition, the computer **326** may be used for updating and completing a patient's medical records.

[0101] FIG. **5** shows a block diagram of an embodiment of a biometric sensing device **330**. The biometric sensing device **330** includes a display **332**, a computer module **334**, a pulse oximeter **336**, a sensor **338**, a first electrode **340** and a second electrode **342**. The biometric sensing device **330** may be a patch similar to those described elsewhere herein. In some embodiments, the biometric sensing device **330** may be part of a band or wrap. The biometric sensing device **330** may be embodied in other structural designs as well that may be tailored for a specific type of use.

[0102] The display **332** may operate in a similar manner to the other display elements described herein. The display **332** may be used to show data, calculated results and/or other information for the user of the biometric sensing device. In some embodiments, the display **332** may also operate as a user input element via touch screen operations or other control designs.

[0103] The computer module **334** includes elements of a computer including but not limited to a processor, memory and input/output elements. A power source may be included in the computer module **334** or separately within the biometric sensing device **330**. In some embodiments, the computer module **334** may include communication elements to receive and/or transmit signals with other external devices. The computer module **334** controls the operation of the biometric sensing device **330** through receiving data from biometric sensor components, evaluating the received data to determine biometric information and providing the applicable output to the display **332** for communication to observer of the biometric sensing device **330**. The actual output may be based upon standardized requirements stored in the memory of the computer module **334**. For example, the computer module **334** may direct the display **332** to provide specific color outputs correlated to the calculated heartrate of the patient, such as a red output for a heartrate under 60 beats per minute, a yellow output for a heartrate from 60 to 100 beats per minute and a green output for a heartrate of 100 beats per minute or higher.

[0104] The pulse oximeter **336** may be any type of pulse oximeter. For example, the pulse oximeter **336** may be a reflective pulse oximeter, a clip pulse oximeter or another type of pulse oximeter. The pulse oximeter **336** may operate to obtain data regarding the blood oxygenation levels, pulse patterns and/or heartrate information. The data obtained by the pulse oximeter **336** is sent to the computer module **334** for analysis.

[0105] The sensor **338** may be any type of biometric sensor, including but not limited to one or more of electrodes, a pulse oximeter, a glucose sensor, a respiratory sensor, a thermometer or another sensor device. The additional data obtained by the sensor **338** is sent to the computer module **334** for analysis. In some embodiments, the biometric sensing device **330** included additional sensors not shown herein.

[0106] The biometric sensing device **330** also includes the first electrode **340** and the second electrode **342**. The two electrodes **340** and **342** operate to detect electrical signals within the patient's body that indicate heart activity. The computer module **334** receives readings from the electrodes **340** and **342** and analyzes the readings to determine a patient's heartrate.

[0107] FIG. **6** shows another embodiment of a biometric patch **350** placed on the chest of a newborn. The patch **350** is similar to other embodiments of the patch discussed in conjunction with other figures herein. The patch **350** includes a first electrode **352** and a second electrode **354** (shown in dotted lines to indicate their placement on the bottom of the patch **350**) as well as a display **356** and a button **358**.

[0108] In this embodiment, the patch **350** has an alternative shape to the other embodiments shown. Specifically, the patch **350** includes two sections that extend separately away from the display **356**. In this embodiment, the sections extend downward—away from the infant's head—and look similar to an upside down set of rabbit ears. The upside-down, rabbit ear shape of the patch **350** may allow for an improved view of the infant's abdomen while keeping the display **356** in focus for a medical professional. Other embodiments may have the sections directed upwards—toward the infant's head—or to one of the sides. One having ordinary skill in the art will recognize that the patches described herein may vary in shape, size, thickness, weight and other characteristics.

[0109] The first electrode **352** is located in one of the sections and the second electrode **354** is located in the other section. The location of the electrodes **352** and **354** in the extended sections may allow for better placement of the electrodes **352** and **354** to obtain accurate signals without interfering with a medical professional observation and work with the infant. In addition, placing the electrodes **352** and **354** away from the other electrical components in the patch **350** may reduce the likelihood of electrical interference. This may reduce or eliminate the application of insulation within the patch **350** for the purpose of preventing electrical interference.

[0110] The display **356** and button **358** may operate in the same way as other displays and controls discussed elsewhere herein. Specifically, the display **356** may provide relevant medical data to the medical professional working with the infant including the heartrate, oxygenation percentage, waveforms and/or other information. In addition, the display **356** may provide the information or indications for the information in a variety of formats. The button **358** may operate as an on/off control or a feature control for the patch **350**.

[0111] FIG. **7** shows an embodiment of a pulse oximeter **400** that may be part of a biometric sensing system such as

those discussed above or operate as a stand-alone device. The pulse oximeter **400** includes a band **402** to wrap around an infant's umbilical cord and a housing **404** attached to the band **402** by a wire connection **406**.

[0112] In some embodiments, the housing **404** includes an umbilical cord clamp **408**. In some embodiments, the housing **404** is designed to connect to the umbilical cord clamp **408**. The housing **404** includes a computer module **412** and a display **410**. The display **410** may be any type of visual output device, including a light array, a digital display, etc. In this embodiment, the display **410** shows an oxygenation percentage (93%) and a pulse waveform. In some embodiments, the housing **404** may operate as a visual output also. For example, the housing **404** may comprise a transparent or semi-transparent material and an internal LED or other light source that operates to light up the material allowing the housing **404** to light up.

[0113] The computer module **412** includes elements of a computer including but not limited to a processor, memory and input/output elements. A power source may be included in the computer module **412** or separately within the biometric sensing device housing **404**. In some embodiments, the computer module **412** may include communication elements to receive and/or transmit signals with other external devices. The computer module **412** controls the operation of the pulse oximeter **400** through receiving data from biometric sensor components, evaluating the received data to determine biometric information and providing the applicable output to the display **410** for communication to an observer of the pulse oximeter **400**. The actual output may be based upon standardized requirements stored in the memory of the computer module **412**. For example, the computer module **412** may direct the display **410** to provide specific color outputs correlated to the calculated oxygenation percentage scaled from the time of birth of the patient, such as a red output for an oxygenation percentage under 67% at three minutes after birth, a yellow output for an oxygenation percentage between 67% and 72% at three minutes after birth and a green output for an oxygenation percentage above 72% at three minutes after birth.

[0114] The computer module **412** facilitates operation of the oxygen saturation sensor components including the light source **414** and the optical sensor **416**. The light source **414**, such as an LED, operates to provide light to the umbilical cord. The optical sensor **416** detects light that has passed through the umbilical cord. The computer module **412** calculates the oxygen saturation in the blood based upon the differences in the characteristics of the light emitted by the light source **414** and detected by the optical sensor **416**. In some embodiments, the pulse oximeter **400** may include multiple light sources **414** and/or optical sensors **416**. In addition, some embodiments may use light sources **414** that produce different light characteristics, such as a visible light source and an infrared light source.

[0115] The band **402** also includes attachment sections **418** and **420**. These sections **418** and **420** may include corresponding attachment elements to allow the band to be secured around an infant's umbilical cord, including hook and loop tape, adhesives, friction materials and/or other attachment mechanisms or materials. In this embodiment, the attachment section **420** covers more of the band **402** than attachment section **418**. This additional coverage by attachment section **420** allows for the band to vary in circumference and accommodate a variety of umbilical cord sizes.

[0116] Prior to attaching the pulse oximeter **400** to an infant, a medical professional may remove the pulse oximeter **400** from a sterile packaging, such as a TYVEK bag. In addition, the medical professional may turn on the pulse oximeter **400**, select settings, start a clock associated with the infant's time of birth, etc. Following any set-up steps that may or may not be necessary depending on the embodiment of the pulse oximeter **400**, the pulse oximeter **400** will be attached to the infant.

[0117] To attach the pulse oximeter **400**, a medical professional will attach a clamp **408** to the infant's umbilical cord. In embodiments which include the clamp **408** with the housing **404**, attaching the clamp **408** will also attach the housing **404**. In other embodiments, the housing **404** may be attached to the clamp **408** after the clamp **408** is in place. The clamp **408** will be applied to the umbilical cord at a distance from the infant's abdomen that is at least sufficient to allow attachment of the band **402** on the umbilical cord between the clamp **408** and the infant's abdomen. For example, a medical professional may attach the clamp **408** four inches from the infants abdomen. One having ordinary skill in the art will recognize that the distance may vary along the umbilical cord depending on the medical professional's assessment of the needs for the infant as long as the circulation through the umbilical cord provides an accurate correlation to the oxygenation and pulse readings for the sensor elements.

[0118] Once the housing **404** is in place, the medical professional will wrap the band **402** around the umbilical cord between the clamp and the infant's abdomen and connect the attachment section **418** to the attachment section **420**. When the attachment sections **418** and **420** are connected, the band **402** will be firmly wrapped around the umbilical cord without cutting off or inhibiting the circulation in the umbilical cord. In addition, the band **402** will hold the light source **414** and the optical sensor **416** in place for the pulse oximeter **400** to operate properly.

[0119] The band **402** may be placed in any location below the clamp **408** within the length of the connector **406**. The connector **406** may be any length. In order to limit unnecessary material that may impede care or may get tangled, the connector **406** will be short. In some embodiments, the connector **406** will be less than three inches. In some embodiments, the connector **406** may be between half an inch and two inches. In some embodiments, a medical professional may use bandages, wraps, tapes and/or other materials to hold the connector **406** and/or the other portions of the pulse oximeter **400** in place and limit the likelihood of tangles.

[0120] Once the pulse oximeter **400** is attached to the infant, the pulse oximeter **400** will gather data from the light source **414** and/or optical sensor **416**, any additional sensors and/or any external data sources in communication with the pulse oximeter **400**. The computer module **412** will evaluate relevant data to determine biometric information about the baby, such as a heartrate and an oxygenation percentage. The computer module **412** will output relevant results, or indications thereof, on the display **410**. In addition, the computer module **412** may transmit data and/or evaluation results to an external device.

[0121] Medical professionals can review the relevant data on the display **410** which is located on or near the abdomen of the infant on which the professional is attending. Providing the display **410** on the abdomen of the patient allows the

medical professional to remain focused on the newborn while also monitoring the biometric data relevant to potential emergency situations.

[0122] In some embodiments, the display **410** and/or the housing **404** may provide a color output indicative of the heartrate or oxygenation of the patient relative to medical guidelines stored in the memory of the computer module **412**. Providing the indicative color may allow the medical professional to recognize relevant information without modifying their focus from other medical activities for the newborn. For example, a medical professional may notice the display **410** and/or the housing **404** change from yellow to green indicating that the newborns oxygenation improved to a safer level.

[0123] In some embodiments of a biometric sensing system, other wirelessly networked components, such as other sensor devices, may provide additional data to the pulse oximeter **400**. In some embodiments, the computer module **412** may output relevant data to the display **410** and/or the housing **404**. In some embodiments, the computer module **412** may analyze the data to determine an output. During such an analysis, the computer module **412** may compare data or determined information to reference information stored in memory of the computer module **412** and provide an indication based upon the results of the comparison. Reference information may include medical guidelines, historical trends, prior patient or mother data points, custom references by the medical professional and/or other information.

[0124] FIG. **8** shows another embodiment of a biometric sensing device **500** comprising a patch **502**. The patch **502** is similar to other embodiments of the patch discussed in conjunction with other figures herein. The patch **502** includes a first electrode **506**, a second electrode **508**, a third electrode **510** and a sensor **512** (shown in dotted lines to indicate their placement on the bottom of the patch **502**) as well as a display **504** and a button **514**.

[0125] In this embodiment, the patch **502** has an alternative shape to the other embodiments shown. Specifically, the patch **502** creates an "L" shape with a section extending downward from the display **504** on one side of the patch **502**. Other embodiments may have the extended section directed upwards or to one of the sides relative to the layout of the display **504**. One having ordinary skill in the art will recognize that the patches described herein may vary in shape, size, thickness, weight and other characteristics.

[0126] This embodiment also illustrates the patch with three electrodes **506**, **508** and **510**. One skilled in the art will recognize that the number and placement of the electrodes may vary depending on the application and needs for the biometric sensing device **500**. In an emergency situation, a design with fewer electrodes may be beneficial to avoid delays in attaching the device properly and time for the device to acquire and evaluate multiple data points. For example, acquiring an infant's heartrate provides sufficient information for an emergency resuscitation guidelines and a complete ECG screening with multiple specifically placed electrodes is unnecessary and introduces additional problems during the emergency situation.

[0127] In this embodiment, the first electrode **506** is located on one side of the display **504**, the second electrode **508** is located on the opposite side of the display **504** and the third electrode **510** is located in the downwardly extended section. The location of the electrodes **506**, **508** and **510** may allow for obtaining improved accuracy through additional signal interpretation based upon the data associated with each of the electrodes **506**, **508** and **510**.

[0128] The sensor **512** may be any type of biometric sensing element or elements, including one or more of a pulse oximeter, a glucose sensor, a respiratory sensor, a thermometer or another sensor device. The sensor **512** will obtain data regarding a patient's oxygenation, pulse patterns, glucose levels, respiration, temperature and/or other biometric data and send the data to a computer module (not shown) similar to those discussed elsewhere herein. The computer module may output the data to the display **504**, analyze the data and provide a result to the display **504**, store the data or calculated information and/or communicate the data to an external device.

[0129] The display **504** and button **514** may operate in the same way as other displays and controls discussed elsewhere herein. Specifically, the display **504** may provide relevant medical data to the medical professional working with the infant including the heartrate, oxygenation percentage, waveforms and/or other information. In addition, the display **504** may provide the information or indications for the information in a variety of formats. The button **514** may operate as an on/off control or a feature control for the patch **502**.

[0130] FIG. **9** shows an embodiment of a biometric sensing kit **600** including the biometric patch **350** described in further detail regarding FIG. **6**. As discussed, the patch **350** is similar to other embodiments of the patch discussed in conjunction with other figures herein.

[0131] In this embodiment, the kit **600** includes a sealed package **602** containing the patch **350** and wipes **604**. In some embodiments, the interior of the sealed package **602** provides a sterile environment to maintain sterility of the patch **350** and wipes **604**. The sealed package **602** is shown as a bag in this embodiment, such as a TYVEK bag, which may be constructed from a variety of materials, such as a plastic or polyester material. Alternative, structures for the sealed package **602** may also be used including clam shell packages, vacuum sealed packages, boxes and other packaging options for medical components. In some embodiments, the sealed package **602** may be partitioned to hold the contents separately. The sealed package **602** may also include design elements to make opening the package safe and efficient, such as perforations, weakened tear lines, tear-away strips, a zip-top connection and/or other easy open options.

[0132] In this embodiment, the sealed package **602** includes one or more wipes **604**. The wipes **604** may be used by a medical professional to clean the area of a patient for applying the patch **350**. For example, the medical professional may use the wipe **604** to clean the chest of a newborn immediately prior to the application of the patch **350**. For another example, a medic may wipe away dirt, blood and other material from a person's chest in the field prior to applying the patch **350**. In some embodiments, the wipes **604** may be tailored for the specific use. For example, the wipes **604** for use on a newborn may contain a specified cleaning mixture designed to safely remove the vernix covering as well as other biological materials while also being soft to protect the newborn's delicate skin. In some embodiments, alternative cleaning components may be

included instead of the wipes **604**, such as cloths, sponges, a container of a cleaning liquid, and/or other cleaning materials.

[0133] During the preparation time prior to use of the patch **350**, the medical professional may turn on the patch **350** by pressing the button **358** prior to removing the patch from the package. In addition, the button **358** may be used to select features for the patch **350** best suited for the anticipated medical use.

[0134] While patch **350** is shown in the kit **600**, any of the patches described herein may be included in the kit **600**. In addition, some kits **600** may include additional elements of a biometric sensing system. For example, an alternative kit **600** may include the patch **200** and the pulse oximeter **400** (each discussed above).

[0135] Embodiments of the kit **600** may be customized for specific applications. For example, a military medic's kit may include the patch **502**, a fingertip pulse oximeter and a series of wipes **604** designed from a strong material and containing a disinfecting chemical.

[0136] The devices, systems and/or kits may be tailored for specific purposes based on intended use in a variety of situations, including patient transport activities, emergency medical transport activities, medical triage activities, military medical activities, remote healthcare activates, neonatal activities and other activities.

[0137] The invention being thus described and further described in the claims, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention and all such modifications as would be obvious to one skilled in the art are intended to be included within the scope of the apparatuses, systems and methods described.

1. A biometric sensor patch comprising:

a patch body having a top layer and a bottom layer, wherein said patch body is configured to be suitable for application to a person's skin and wherein said top layer is configured to be facing away from said person when the patch is applied;

a sensor array in said bottom layer of said patch body comprising a first electrode and a second electrode configured to sense electrical activity in said person;

a display in said top layer of said patch body;

a power source within said patch body;

a computer module within said patch body that is operably connected to said sensor array, said display and said power source, wherein said computer module receives power from said power source, receives sensor data from said sensor array and provides an output to said display based on an analysis of said sensor data; and

wherein said display is configured to visually communicate said output to an observer.

2. The biometric sensor patch of claim **1** wherein said patch body is configured to be suitable for application to a newborn baby's chest.

3. The biometric sensor patch of claim **1** wherein said sensor array comprises a pulse oximeter.

4. The biometric sensor patch of claim **1** wherein said sensor array comprises at least one of a glucose sensor, a respiratory sensor and a thermometer.

5. The biometric sensor patch of claim **1** wherein said patch includes a communication module within said patch body.

6. The biometric sensor patch of claim **1** wherein said computer module comprises a processor that facilitates operation of said patch and analyzes said sensor data, and a memory that stores reference data for said analysis.

7. The biometric sensor patch of claim **6** wherein said analysis of said sensor data comprises said processor comparing said sensor data to said reference data stored in said memory.

8. The biometric sensor patch of claim **7** wherein said output is based upon said comparison of sensor data to said reference data.

9. The biometric sensor patch of claim **1** wherein said display visually communicates a heartrate based on said sensor data.

10. The biometric sensor patch of claim **1** wherein said display visually communicates a heartrate waveform based on said sensor data.

11. The biometric sensor patch of claim **1** wherein said sensor array comprises a third electrode configured to sense electrical activity in said person.

12. A biometric sensor system comprising:

a patch configured to be suitable for application to a person's skin comprising:

a top layer and a bottom layer, wherein said top layer is configured to be facing away from said person when the patch is applied,

a sensor array in said bottom layer of said patch comprising a first electrode and a second electrode configured to sense electrical activity in said person,

a display in said top layer of said patch that is configured to communicate

a visual output to an observer,

a power source within said patch,

a communication module within said patch configured to wirelessly communicate over a near-field communication standard,

a computer module within said patch that is operably connected to said sensor array, said display, said power source and said communication module, wherein said computer module receives power from said power source, receives sensor data from said sensor array, analyzes said sensor data and provides results for said visual output to said display, and wherein said computer module facilitates communication via said communication module;

an external device comprising

an external device communication module configured to wirelessly communicate over a near-field communication standard, and

an external device computer module configured to facilitate operation of said external device and communication via said external device communication module.

13. The biometric sensor system of claim **12** wherein said patch is configured to be suitable for application to a newborn baby's chest.

14. The biometric sensor system of claim **12** wherein said analysis determines a heartrate based on said sensor data.

15. The biometric sensor system of claim **12** wherein said sensor array comprises a pulse oximeter and said analysis determines a heartrate and an oxygenation percentage based on said sensor data.

16. The biometric sensor system of claim **12** wherein said external device is a sensor configured to obtain biometric

data from said person, wherein said sensor transmits said biometric data via said external device communication module, and wherein said patch receives said biometric data via said communication module and said analysis comprises analyzing said sensor data and said biometric data.

17. The biometric sensor system of claim **16** wherein said sensor is at least one of a pulse oximeter, a glucose sensor, a respiratory sensor and a thermometer.

18. The biometric sensor system of claim **16** wherein said sensor is an umbilical cord pulse oximeter.

19. The biometric sensor system of claim **18** wherein said umbilical cord pulse oximeter includes a housing configured to attach to an umbilical cord clamp, wherein said housing includes an umbilical cord display.

20. The biometric sensor system of claim **12** wherein said external device is at least one of a monitor, a computer and a mobile communication device, wherein said external device receives biometric information via said external device communication module from said patch.

21. The biometric sensor system of claim **20** wherein said external device compares said biometric information to reference information stored in said external device and provides an output based on results from said comparison.

22. The biometric sensor system of claim **20** wherein said external device processes said biometric information to remove identifying information to create de-identified information, stores said de-identified information and aggregates said de-identified information with additional de-identified information from other sources.

23. A method for acquiring a newborn's biometric information for emergency care of the newborn, comprising the steps of:

providing a biometric patch configured to be suitable for application to the newborn's skin, wherein the biometric patch comprises:

a sensor array in a bottom layer of said patch comprising a first electrode and a second electrode configured to sense electrical activity in said newborn,

a display in a top layer of said patch that is configured to communicate a visual output to an observer, and

a computer module within said patch that is operably connected to said sensor array and said display;

applying the biometric patch to said newborn's chest;

observing said visual output on said display and wherein said visual output is based on an analysis by said computer module of sensor data acquired by said sensor array and is configured to indicate heartrate data.

24. The method of claim **23** wherein said visual output is a color output correlated to the heartrate data, wherein the color output is based on a medical guideline for newborn heartrates.

25. The method of claim **23** further comprising the step of pressing a button on said biometric patch when the newborn is born to establish a time of birth and begin a timer for elapsed time from the time of birth.

26. The method of claim **25** wherein said analysis is based on medical correlations of biometric data tied to elapsed time from the time of birth.

* * * * *

专利名称(译)	生物识别阅读装置，系统及其使用方法		
公开(公告)号	US20180078163A1	公开(公告)日	2018-03-22
申请号	US15/654853	申请日	2017-07-20
[标]申请(专利权)人(译)	韦尔奇格雷戈瑞P		
申请(专利权)人(译)	韦尔奇GREGORY P.		
当前申请(专利权)人(译)	韦尔奇GREGORY P.		
[标]发明人	WELCH GREGORY P		
发明人	WELCH, GREGORY P.		
IPC分类号	A61B5/0404 A61B5/0452 A61B5/1455 A61B5/00 A61B5/01 A61B5/0245		
CPC分类号	A61B5/0404 A61B5/0452 A61B5/14551 A61B5/00 A61B5/0002 A61B5/01 A61B5/0245 A61B5/6802 A61B5/0006 A61B5/0015 A61B5/02055 A61B5/04085 A61B5/0816 A61B5/14532 A61B5/6823 A61B5/6833 A61B5/6838 A61B2503/045 A61B2560/0412 A61B2560/045 A61B2560/0468		
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摘要(译)

生物特征传感器设备，系统和方法，用于获得生物特征数据并基于传感器设备上的数据显示生物特征信息。该系统允许通过无线通信功能进行额外的生物统计数据收集和/或分析。这些设备和系统为在病人身上工作的医学专业人员提供实时信息。该信息可以进一步基于与所执行的医疗活动相关联的医疗准则。