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(54) **HAT AND MONITORING SYSTEM**

HUT UND ÜBERWACHUNGSSYSTEM

CHAPEAU ET SYSTÈME DE SURVEILLANCE

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## Description

**[0001]** The present invention relates to a hat for a neonate, and a monitoring system for a neonate, in particular the physiological condition of a neonate including but not limited to heart rate; breathing rate; and Oxygen Saturation (SpO<sub>2</sub>).

**[0002]** Newborn babies and those up to 28 days of life (neonates) in the UK are generally given a bonnet or hat immediately following birth, to help them maintain an appropriate body temperature.

**[0003]** A number of commercially produced hats for neonates are available as part of continuous positive airway pressure (CPAP) systems. Makers include Carefusion, Fisher and Paykel, and Intersurgical. Such hats are available in a range of sizes. One difficulty with a number of existing hats is in conveniently obtaining access to the neonate's head, for instance to perform a cranial ultrasound procedure. A further problem arises with the interaction of the hat and a CPAP mask and associated tube(s). It is necessary for the CPAP mask to be supported in the correct position on the neonate's head, for instance by a connection to a hat. Injuries can be inflicted on neonates (e.g. on the nasal septum) by an inappropriately fitted CPAP mask, so it is important to ensure that such systems are fitted appropriately..

**[0004]** In the UK, around 10% of newborn babies need some form of resuscitation at birth: 85,000 per year in the UK, 400,000 in the USA and at least 13,500,000 worldwide. Accurate monitoring of heart rate is vital to guide such interventions: both to identify when intervention is required, and to monitor how the newborn (neonate) is responding to the resuscitation. The stethoscope is the current standard of care for monitoring the neonate heart rate in the key moments following birth. However, the stethoscope's use is subject to delays and errors, which can ultimately have a severe impact on the future wellbeing of the child.

**[0005]** Each of US2004/0267104 and US2010/0249557 discloses a hat for a neonate that includes a pulse oximeter, for monitoring the heart rate of a neonate. US8,768,424 describes a photoplethysmography device for measuring heart rate. US2011/0098593 describes a head harness and monitoring system.

**[0006]** According to a first aspect of the invention, there is provided a hat for a neonate comprising: a central portion; a first side portion and second side portion attached to opposite sides of the central portion; a first fastener; a top flap and a second fastener;

wherein the hat has an unfolded configuration in which the first and second portions extend away from each other from the central portion in opposite directions; and a worn configuration in which the hat wraps a neonate's head with the central portion in contact with the back of the neonate's head, the first portion wrapped around a first side of the neonate's head and the second portion wrapped around a second

side of the neonate's head;

the first and second portions being configured to be fastened together in the worn configuration by the first fastener so that the first portion, central portion and second portion together define a hat rim encircling the neonate's head; and

the top flap is configured to cover the top of the neonate's head in the worn configuration, with the top flap being configured to be fastened to at least one of the first, central and second portions by the second fastener.

**[0007]** The term neonate may refer to an infant that is less than four weeks old.

**[0008]** The unfolded configuration of the hat makes it easy to put on a neonate, for example by placing the neonate's head on the central portion (with the hat in an unfolded configuration) and wrapping the hat around the head.

**[0009]** In some embodiments the central portion can be pulled backwards to reveal the fontanelle to allow access for scanning and other medical procedures.

**[0010]** The hat may be substantially T-shaped when in an unfolded configuration, with the top flap being connected to the central portion.

**[0011]** The first and second portions may be configured to overlap on the neonate's forehead when fastened together by the first fastener.

**[0012]** The first fastener and/or the second fastener may comprise a hook and loop fastener. Hook and loop fasteners are quick and easy to fasten and unfasten, and provide reliable and secure attachment (especially, but not exclusively, in the context of a single use item).

**[0013]** In some embodiments the loop portion of the first fastener and/or second fastener may be provided by a fabric from which the hat is made, rather than by a patch of loop material attached to the fabric. This may give more flexibility in where the fastener can be attached.

**[0014]** The first fastener may be configured to provide a plurality of fastening positions so as to allow a range of adjustment of the length of the hat rim, so as to accommodate a range of neonate head sizes.

**[0015]** The range of adjustment may be at least 1 cm, or at least 0.5cm, or 2cm.

**[0016]** The hat may further comprise a strap for supporting a continuous tube (e.g. a continuous airway pressure or CPAP tube) adjacent to the neonate's forehead when the first, central and second portions encircle the neonate's head.

**[0017]** The strap may comprise an elastic fabric material. The strap may comprise a strap fastener, for fastening the strap to at least one of the first and second portions.

**[0018]** The strap may be fixed at one end to one of the first or second portion, and the other end of the strap may be securable to the other of the first or second portions using the strap fastener. The detachable strap may be securable to either the first or second portions via hook

and loop attachments.

**[0019]** The strap may comprise a friction enhancing lining on an inner surface thereof. The friction enhancing lining may comprise silicone rubber.

**[0020]** The hat may comprise a first plurality of eyelets in the first portion adjacent to the hat rim, and a second plurality of eyelets in the second portion adjacent to the hat rim. The first and second plurality of eyelets may be for securing a CPAP mask to the neonate's face using CPAP cords that thread into the eyelets. The plurality of eyelets in each of the first and second portion may provide a range of CPAP mask securing locations or endotracheal tube securing locations, or securing locations for other fittings.

**[0021]** The eyelets may be strengthened by stitching a hem around each eyelet. This may provide a firm fixation point for the securing tethers of either a CPAP mask or endotracheal tube.

**[0022]** The hat may comprise at least one external loop through which a tube (such as a CPAP tube, or an intubation tube) may be supported adjacent to the exterior of the hat.

**[0023]** The at least one external loop may comprise a first and second external loop, arranged to be positioned on either side of the neonate's forehead when the hat is worn.

**[0024]** The hat may comprise a first dart between the first and central portion and a second dart between the second and central portion. A third dart may be provided in the central portion, the third dart arranged to improve the conformation of the central portion with the back of the neonate's head.

**[0025]** The first and second dart may extend substantially toward the rim from a top edge of the hat, the top edge being on the opposite side of the hat to the hat rim.

**[0026]** The second fastener may comprise a plurality of fastening locations spaced around the perimeter of the top flap.

**[0027]** The first, second, and central portions, and the top flap, may be substantially formed from a fabric material.

**[0028]** The fabric material may be stretchable substantially in one direction only. The direction may be along the circumference. This enables the hat to provide a comfortable fit, while accommodating a range of head sizes and shapes.

**[0029]** The fabric may have at least an inner ply and an outer ply. The inner ply may be larger in extent than the outer ply (or the outer ply may be larger than the inner ply). The outer ply may be provided in regions of the inner ply.

**[0030]** According to an aspect of the invention, there is provided a hat for a neonate comprising an inner fabric ply and an outer fabric ply, a first hole through the inner fabric ply at a first location and a second hole through the outer fabric ply at a second location, wherein, when the hat is worn by a neonate, the first location is adjacent to the forehead and the second location is adjacent to

the rear of the head, the first and second hole allowing an optical physiological sensor lead to be threaded through a space between the inner and outer plies between the first and second holes. The inner ply may be larger in extent than the outer ply (or the outer ply may be larger than the inner ply). The outer ply may be provided in regions of the inner ply.

**[0031]** The inner ply may comprise a material that is stretchy in a single direction. The outer ply may comprise a hook accepting material (for a hook and loop fastener).

**[0032]** The optical physiological sensor may comprise at least one of: an optical heart-rate sensor, a pulse oximeter, and optical breathing sensor, an optical blood flow sensor, or any other optical physiological sensor.

**[0033]** The hat of the first aspect may further comprise an inner hole through the inner fabric ply at a first location and an outer hole through the outer fabric ply at a second location. The first location may be in one of the first portion and second portion. The second location may be in the central portion or the other of the first and second portion. The inner and outer hole may allow an optical physiological sensor lead to be threaded through a space between the inner and outer plies between the inner and outer holes.

**[0034]** The inner hole may be a first inner hole, and the hat may further comprise a second inner hole through the inner fabric ply, spaced apart from the first inner hole by 0.5cm to 3cm.

**[0035]** The inner holes may be through the inner fabric ply and not the outer fabric ply.

**[0036]** The outer hole may be a first outer hole, and the hat may further comprise a second and third outer hole disposed between the inner hole and the first outer hole.

**[0037]** The outer holes may be through the outer fabric ply and not the inner fabric ply.

**[0038]** The second and third outer holes may be spaced apart from each other by between 0.5cm and 3cm.

**[0039]** The second and third outer holes may be arranged to allow an optical physiological sensor lead to be threaded between the second and third outer holes, so as to enable the optical physiological sensor lead to be cut between the second and third outer holes while the hat is worn. The physiological sensor may then be conveniently removed from the hat.

**[0040]** According to a second aspect of the invention, there is provided an optical physiological sensor comprising: a flexible circuit board, a light emitter and a light detector;

the flexible circuit board having:

a sensor portion to which the light emitter and light detector are connected;

a module portion including contacts for electrically connecting the light emitter and light detector to a readout module; and

an elongate lead portion between the sensor portion

and module portion.

- [0041]** The elongate lead portion may be flexible.
- [0042]** The light emitter may comprise a plurality of light emitting elements.
- [0043]** The sensor portion may comprise a package that includes both the light emitter and light detector.
- [0044]** The light emitter may comprise a light emitting element with a first output wavelength, and a light emitting element with a second, different output wavelength.
- [0045]** The light emitter may further comprise a light emitting element with a third output wavelength, different from the first and second output wavelengths. The light emitter may further comprise a light emitting element with a fourth output wavelength, different from the first, second and third output wavelengths.
- [0046]** The flexible circuit board may include a tang extending away from the sensor portion in a different direction to the lead. The tang may extend in a direction at 180 degrees to the lead, or at another angle.
- [0047]** The light detector may be a single photodetector or an array of detectors in the form of a multi-pixel camera. The light detector may be operable to detect wavelengths within and/or outside the visible spectrum.
- [0048]** The tang may be an elongate member. The tang may extend away from the sensor portion at an angle of between 135 and 155 degrees from the lead, or between 170 and 190 degrees from the lead (e.g. at substantially 180 degrees from the lead)..
- [0049]** The tang may comprise at least one lateral projection or recess configured to assist in preventing withdrawal of the tang through a hole (e.g. the second inner hole). The tang may comprise a barbed or hammerhead shaped structure, with a sloped edge to enable the tang to be inserted through a hole (e.g. the second inner hole), and a lateral edge (substantially perpendicular to a direction of insertion) for inhibiting withdrawal of the tang from the hole in which it is inserted. The tang may comprise a substantially circular or spherical 'blob' for assisting in retaining the tang in the hole. The applicant has found that a curved feature (e.g. a curved projection) may make removal of the tang easier, at the same time as providing an acceptable degree of retention within the hole (e.g. second inner hole)
- [0050]** The width of the lead may be less than 1cm. The thickness of the lead may be less than 0.5mm.
- [0051]** The module portion may comprise a substantially rigid planar element for supporting the contacts.
- [0052]** The module portion may comprise a ferromagnetic element.
- [0053]** The hat of the previous aspects may further comprise the optical physiological sensor of the second aspect.
- [0054]** At least part of the elongate lead portion of the optical physiological sensor may be disposed between an inner and an outer ply of the hat.
- [0055]** The sensor portion may be supported by the hat at an inner surface of the hat near the rim of the first

portion or the second portion, such that the sensor portion is positioned on a neonate's forehead when the hat is worn.

- [0056]** The sensor portion may be supported between the first inner hole and the second inner hole, the first inner hole receiving the elongate lead portion, and the second inner hole receiving the tang.
- [0057]** The elongate lead portion may be threaded between the second and third outer holes, so as to enable the lead to be cut between the second and third outer holes while the hat is worn. The sensor portion may then be conveniently removed from the hat.
- [0058]** The sensor portion may comprise a transparent element, arranged to be between the light emitter and light detector, and the skin, in use (i.e. covering the light emitter and light detector). The transparent element may be less than 1mm thick. The transparent element may comprise silicone. The transparent element may be transparent at the wavelengths emitted by the light emitter. The thickness of the transparent element may be less than 1mm, or less than 0.5mm.
- [0059]** The transparent element may comprise a region that is adhesive or tacky to skin.
- [0060]** The light emitters and detectors may be separated from each other by a baffle to avoid light shunting.
- [0061]** The sensor portion may further comprise at least one electrode for making an electrical connection to the skin of a neonate. The at least one electrode may be a wet electrode, or may be configured for coupling to skin via a hydrogel or by capacitive coupling. The at least one electrode may be suitable for performing an ECG measurement.
- [0062]** The sensor portion may comprise an array of sensors, the array of sensors comprising at least one optical sensor and at least one electrode.
- [0063]** According to a third aspect, there is provided a readout module for an optical physiological sensor, wherein the readout module comprises:
- an electrical power store for powering the readout module;
  - an electronic circuit for providing a drive signal to a light emitter of the physiological sensor and for receiving the signal from a light detector of the physiological sensor;
  - a processor for processing the signal from the light detector to produce data; and
  - a wireless transmitter, configured to wirelessly transmit the data from the readout module to a base station.
- [0064]** The readout module may be further configured to obtain an ECG measurement from the at least one electrode of the sensor module. The processor may be configured to process a signal derived from the at least one electrode to produce ECG data, and the wirelessly transmitted data may comprise ECG data.
- [0065]** The readout module may further comprise: a

housing containing the electrical power store, the electronic circuit and the wireless transmitter, and a cradle configured to receive the housing and a module portion of an optical physiological sensor (e.g. according to a previous aspect).

**[0066]** The readout module may further comprise a permanent magnet for attaching a module portion of an optical physiological sensor to the readout module by attracting a ferromagnetic element of the module portion.

**[0067]** The readout module may further comprise a connector for engaging a plurality of electrical contacts of a module portion of an optical physiological sensor.

**[0068]** The connector may comprise a plurality of pogo pins.

**[0069]** The readout module may comprise a status indicator configured to display an indication of the status of the readout module. The status indicator may be a light emitting element. The light emitting status indicator may be configured to emit at least two different colours. The status indicator may be configured to indicate an amount of charge in the electrical power store. The status indicator may be configured to indicate a fault status.

**[0070]** The readout module may be waterproof according to the IPX-7 standard.

**[0071]** The processor may encrypt the signal from the light detector to produce encrypted raw sensor data for transmission. Alternatively the processor may be configured to process the raw data locally (e.g. in real time, or with a delay of less than 1 second) to determine at least one of: heart rate, breathing, SpO2 and other relevant physiological signals. This may allow a reduced bandwidth of data to be transmitted thereby saving power in the module.

**[0072]** According to a fourth aspect, there is provided a monitoring system for a neonate, comprising a readout module according to the third aspect, and the optical physiological sensor of any previous aspect.

**[0073]** The system may include the hat of any previous aspect.

**[0074]** According to a fifth aspect, there is provided a receiving station comprising a display and a docking portion for receiving a readout module of an optical physiological sensor, wherein:

the receiving station is configured to wirelessly receive data from a readout module of an optical physiological sensor, and to display an indication of a physiological parameter (e.g. heart rate, breathing rate, SpO2, blood flow etc) of the neonate on the display;

the docking portion comprises charging contacts by which the receiving station is operable to charge the readout module.

**[0075]** The receiving station may further comprise a ferromagnetic element in the docking portion, to enable a readout module to be fixed in place in the docking portion using a permanent magnet of the readout module.

**[0076]** The docking portion may be a first docking portion, and the receiving station may comprise a second docking station for receiving and charging a second readout module.

5 **[0077]** The receiving station may further comprise an indicator operable to provide a visual indication every 6 seconds.

**[0078]** The indicator may comprise a light source (e.g. an LED) configured to flash or change state every 6 seconds. For example, the indicator could stay on for 6 seconds, then go off for 6 seconds, or briefly illuminate every 6 seconds.

**[0079]** The indicator may be used to improve the accuracy of a stethoscope reading of heart rate. At present, the clinician taking a stethoscope heart rate must count a 6 second interval at the same time as counting the heart beats (which can be cognitively challenging). The accuracy of a clinician's stethoscope reading may be improved with the use of the timing indicator.

20 **[0080]** The receiving station may further comprise non-volatile data storage. The receiving station may be configured to store data from the readout module of the optical physiological sensor and/or a time history of the physiological parameter.

25 **[0081]** The receiving station may be configured to process the data from the readout module of the optical physiological sensor to determine at least one of: heart rate, breathing rate, SpO2, and blood flow.

**[0082]** The receiving station may be configured to use the display to indicate at least one of: heart rate, breathing rate, SpO2, and blood flow.

**[0083]** According to a sixth aspect, there is provided a monitoring system for a neonate comprising the receiving station of the fifth aspect, and a readout module according to the third aspect. The monitoring system may include the hat of any previous aspect. Any of the features of any aspect may be combined with any other aspect, including the optional features. Only the first and second aspects are in accordance with the current invention.

40 **[0084]** Embodiments of the invention will be described, purely by way of example, with reference to the accompanying drawings, in which:

45 Figure 1 is a view of a system according to an embodiment;

Figure 2 is a view of a neonate wearing a hat according to an embodiment;

50 Figure 3 is an exploded diagram of a readout module according to an embodiment;

Figure 4 is a view of a hat according to an embodiment in an unfolded configuration from the exterior side of the hat;

55 Figure 5 is a view of the hat of Figure 4 in an unfolded configuration from the interior side of the hat;

Figure 6 is a view of the hat of Figure 4 with a neonate positioned on the central portion of the hat, ready for the hat to be wrapped around the neonate's head;

Figure 7 is a view of the hat of Figure 4 in a worn configuration on the head of a neonate, also showing an optical physiological sensor and associated readout module;

Figure 8 is a diagram of the inner side of a hat according to an embodiment;

Figure 9 is a diagram of the outer side of the hat of Figure 8;

Figure 10 is a diagram of the inner side of a hat according to a further embodiment;

Figure 11 is a diagram of the outer side of a hat according to the further embodiment

Figure 12 is a diagram of the inner side of a hat according to an embodiment;

Figure 13 is a diagram of the outer side of a hat according to an embodiment;

Figure 14 is a view of a hat according to an embodiment being worn by a neonate, and further including a CPAP mask and associated tubes;

Figure 15 is an exploded diagram of a module portion of a pulse oximeter according to an embodiment;

Figure 16 is an exploded diagram of a sensor portion of an optical physiological sensor according to an embodiment;

Figure 17 is a view of the module portion of the optical physiological sensor of Figure 14, with the module portion partly inserted into a cradle of a readout module;

Figure 18 is a view of the cradle of Figure 16 with the module portion fully engaged with the cradle, and with a readout module housing engaged with the cradle;

Figure 19 is view of a receiving station according to an embodiment, with a first and second readout module inserted in a first and second docking portion of the receiving station;

Figure 20 is a view of the receiving station of Figure 19 hanging from an edge of a resuscitaire.

**[0085]** Referring to Figure 1 a system 100 for neonatal physiological monitoring is shown, comprising: a hat 200,

optical physiological sensor 300, readout module 400 and base station 500.

**[0086]** The hat 200 is worn by a neonate 120, with the neonate lying on a resuscitaire 110. The optical physiological sensor 300 is supported by the hat 200 adjacent to the skin of the neonate 120, so as to monitor the physiological signals of the neonate 120. The optical physiological sensor 300 includes a lead, connecting a light emitter(s) and light detector(s) of the optical physiological sensor 300 to a readout module 400. The readout module 400 provides drive signals to the light emitter(s), and receives signals from the light detector(s). The readout module 400 comprises a wireless transmitter, configured to transmit data (either raw physiological or processed physiological data) derived from the light detector(s) signals (e.g. heart rate, breathing rate, SpO<sub>2</sub>, blood flow, etc) to the base station 500. The base station 500 is configured to receive the data from the readout module 300, and to display physiological signals of the neonate.

**[0087]** As shown in Figure 2 the hat 200 supports a sensor portion 302 of the optical physiological sensor 300 adjacent to the skin of the neonate 120, so as to enable a physiological signal measurement. The sensor portion 302 is preferably supported adjacent to the forehead of the neonate 120, which is a good location to perform measurements.

**[0088]** A pressure indicator may be woven into the fabric that indicates if the hat is too tight. The pressure indicator may comprise a region of zig zag stitching, the length of which indicates an amount of extension (strain) of the fabric. The pressure indicator may indicate that the hat is too tight when the pressure indicator exceeds a predetermined length (e.g. 1cm). This may ensure that the hat does not cause any facial congestion or oedema or worsen any existing facial oedema.

**[0089]** The elongate lead may be formed into a curved region, arranged to conform more easily with the curvature of the head.. This may ensure that the elongate lead follows the contours of the baby's head, reducing the likelihood of pressure damage.

**[0090]** The optical physiological sensor 300 (examples of which will be described in more detail later) includes an elongate lead 301 connecting a module portion of the sensor 300 (for connection to the readout module 400) to the sensor portion 302. The hat 200 may be configured to support the lead 301 against the opposite side of the neonate's head to the readout module 400, so that the lead 301 passes under the neonate's head on its way to the readout module 400. This configuration helps to limit any movement of the sensor portion 302 relative to the neonate's head, resulting in improved reliability and accuracy of performing the optical physiological measurement (e.g. a photoplethysmogram measurement).

**[0091]** Figure 3 is an exploded diagram of a readout module 400 according to an embodiment. In this example, the readout module 400 comprises: an upper housing 402a, a lower housing 402b, a seal element 403, fasteners 404, electrical power store/battery 405, readout

circuit board 406, readout circuit (including processor, power management, LED drive, detection circuit and wireless transmitter) 407 (on the reverse side of the readout circuit board 406), connectors 408, permanent magnets 409 and an optional semi-permeable membrane 410.

**[0092]** The upper housing 402a and lower housing 402b engage with each other (e.g. by a snap fit), and together define a housing of the readout module 400. The seal element 403 ensures that the housing is waterproof, for example to IPX7 standard. The optional semi-permeable membrane 410 may comprise a gas permeable hydrophobic membrane such as Gore-Tex®, so as to allow any undesirable chemical gases or vapours within the housing 402 to escape while maintaining a waterproof housing.

**[0093]** The readout circuit board 406 is secured to the lower housing 402b by two screw type fasteners 404. On one side of the readout circuit board 406 is an electrical power store 405, which may be re-chargeable. The power store 405 may comprise a re-chargeable battery (e.g. lithium-ion), or a supercapacitor. On the reverse side of the readout circuit board 406 is disposed an electrical circuit 407. The electrical circuit 407 is configured to provide output signals for driving a light emitter 310 of an optical physiological sensor 300, and to readout signals from a light detector 311 of the optical physiological sensor 300. In noise challenged environments the light emitter 310 can be driven in a modulated fashion and the detector 311 operated in a heterodyne lock in mode. There may be a plurality of light detectors 311 and light emitters 310.

**[0094]** The readout circuit 407 may be configured in accordance with the teaching of US8768424. In some embodiments, the readout circuit 407 may comprise a processor, configured to process signals from the light detector 311 to determine at least one of: heart rate and a level of blood oxygen saturation, breathing rate and blood flow. Alternatively, the readout circuit 407 may transmit data in a more raw form to the receiving station 500, and the receiving station may process the data to determine at least one of heart rate, a level of blood oxygen saturation, breathing rate, blood flow and ECG measurement.

**[0095]** Modulation of the light emitters may be necessary to avoid noise (both optical and electrical) but also to separate the different wavelengths deployed. To strengthen the selectivity a bandpass filter can be deployed before the ADC and subsequent digital lock in. Alternatively an analogue demodulator such as a Gilbert cell and low pass filter can be deployed in the analogue detection path.

**[0096]** In another electronic design implementation, the wavelengths can be transmitted in a time division multiplexing format (effectively DC version) and ambient background can be removed by the transmission of a null signal.

**[0097]** The readout module 400 may comprise a pair

of permanent magnets 409, which are used to maintain engagement between the readout module 400 and the receiving station 100 (e.g. during charging), and between the connectors 408 of the readout module 400 and contacts of a module portion 305 of the optical physiological sensor 300.

**[0098]** The connectors 408 may comprise at least one pogo-pin type connector. Pogo pin connectors comprise a telescopic sprung contact, for making reliable contact without the need for a plug type connector. The pogo-pins may be arranged in a rectangular or circular array.

**[0099]** The readout module 400 may be configured to obtain an ECG measurement from at least one electrode in contact with the skin of the neonate.

**[0100]** Figures 4 to 14 each show various views of hats according to embodiments of the invention. Although there are differences between the embodiment shown in Figures 4, 5 and 6, the embodiment shown in Figures 8 and 9, the embodiment shown in Figures 10 and 11, and the embodiment shown in Figures 12 and 13, a large number of features are common to each. The description below relates to each of the example embodiments unless otherwise noted.

**[0101]** The hat 200 is configured to wrap around a neonate's head, with the central portion 201 in contact with the back of the neonate's head. The first portion 202 is arranged to wrap around a first side and the forehead of the neonate's head, and is configured to carry a sensor portion 302 of an optical physiological sensor 300.

**[0102]** As can most clearly be seen in Figure 6, the hat 200 is arranged to bring the sensor portion 302 into contact with the forehead of a neonate 120 when the hat 200 is worn. The second portion 203 is arranged to wrap around the second side and the forehead of the neonate's head, overlapping with the first portion 202, so as to encircle the neonate's head with the first, central and second portions 201, 202, 203 (as shown in Figures 7 and 10).

**[0103]** The hat 200 comprises a first fastener 208 arranged to fasten the first and second portions 202, 203 together in the worn position. The first fastener 208 may be any suitable fastener (e.g. button, popper, etc), but preferably comprises a hook and loop type fastener. For instance, the first fastener 208 may comprise a hook portion 208a on an outer side of the first portion 202, and a loop portion 208b on an inner side of the second portion 203 (as shown in Figures 8 and 9).

**[0104]** In each example fastener described herein, the location of the hooks and loops can be reversed. For example, for the first fastener 208, a hook portion may be located on the first or second portion, and the corresponding loop portion may be located on the other of the first or second portion. In some embodiments a loop portion of a fastener may be provided by a fabric from which the hat is made, without the need for a patch of a specific loop material. For example, the first fastener 208 may comprise a hook portion 208a on an outer side of the second portion 203, and a corresponding loop portion

208b on an inner side of the first portion 202 (as shown in Figures 12 and 13).

**[0105]** The top flap 204 in each example embodiment is attached to the central portion 201 of the hat (although in other embodiments, could conceivably be attached to the first or second portion 202, 203), and is operable to cover the top of a neonate's head when the hat 200 is worn. The top flap 204 includes a second fastener 211, which conveniently comprises at least one hook portion. Figures 4 and 5 show an embodiment with a single central hook portion; Figures 8 and 9 show an embodiment with three hook portions, spaced apart along the inner edge of the top flap 204, and Figures 10 and 11 show an embodiment with three loop portions, spaced apart along the inner edge of the top flap 204. Figures 12 and 13 show an embodiment in which the second fastener 211 comprises two loop portions, on either side of the top flap 204. The loop portions of the second fastener 211 may be provided on protruding "ears" that extend outward from the top flap 204.

**[0106]** The second fastener 211 may further comprise complementary hook/loop portions, positioned on at least one of the first and second portions 202, 203, so as to secure the top flap 204 over the top of the head of the neonate 120, as shown in Figures 9 and 11 and Figures 12 and 13.

**[0107]** A hat 200 according to an embodiment may be advantageous over prior art neonatal hats, independent of it including any physiological sensor. An unfolded hat arrangement that is subsequently wrapped around a neonate's head is easier to put on. As illustrated in Figure 6, the neonate can simply be placed on the unfolded hat, then the hat wrapped around the neonate's head to provide an accurate and proper fit. The first fastener 208 may accommodate straightforward and simple adjustment of the size of the head, as it is being put on, in contrast to hats that do not unfold, where an incorrect judgement about the appropriate size hat can be remedied only by trying a different sized hat. In addition, the top flap 204 provides fast and easy access to the top of the neonate's head, enabling cranial ultrasound procedures to be performed without the need to disturb the hat 200.

**[0108]** The hat 200 shown in Figure 4 and 5 includes an optical physiological sensor 300 (and the hats shown in Figures 8 to 13 are likewise for use with an optical physiological sensor). The physiological sensor 300 comprises a lead portion 301, sensor portion 302, and module portion 305 (the module portion shown in Figure 10, but hidden by the readout module 400 in Figures 4 and 5). The sensor portion 302 of the physiological sensor 300 is held in position by the lead portion 301 being routed through the hat 200. In these example embodiments, the sensor portion 302 is further held in place using a tang 303 of the sensor 300 that is received in a hole in the hat 200, but this is not essential (e.g. alternative further support means may be provided for the sensor portion 302).

**[0109]** The hat 200 may comprise an inner and outer fabric ply. In some embodiments a first outer hole 210 may be provided through the outer ply (and not the inner ply) in the central portion 201, and a first inner hole 212 may be provided through the inner ply (and not the outer ply) in the first portion 202. The first inner and first outer hole are thereby configured to allow the lead 301 of an optical physiological sensor 300 to be supported/concealed between the inner and outer ply, from a suitable location for the sensor portion 302 of the sensor 300, to a location that is suitable for the lead 301 to exit the hat (e.g. in the central portion 201, the first portion 202, or the second portion 203).

**[0110]** A second inner hole 213 may be provided spaced apart from the first inner hole 212 (as shown in Figures 5 and 9), by a distance sufficient to accommodate the sensor portion 302 of the sensor 300. The distance between the first inner hole 212 and second inner hole 213 is preferably between 0.5cm and 3cm. The second inner hole 213 is arranged to receive a tang 303 of the sensor 300, so as to support the sensor portion 302 in the proper position within the hat 200. In other embodiments, alternative means may be used to secure the sensor portion 302 in position (e.g. a hook and loop fastener, or magnetic elements).

**[0111]** As shown in Figures 8 to 11, further outer holes may be provided to enable at least part of the sensor 300 to be removed from the hat 200 without disturbing the neonate 120. A second outer hole 216 and third outer hole 217 may be provided, between the first inner hole 212 and the first outer hole 210, where the lead 301 respectively enters and exits the gap between the inner and outer ply of the hat 200. The lead 301 may thereby be routed to the exterior of the hat 200 between the second and third outer holes 216, 217 on its way to the first outer hole 210. In addition to providing further support for the lead portion 301, this arrangement allows the lead 301 to be conveniently cut while the hat is being worn. Once the lead 301 is cut, the part of the lead 301 that is attached to the module portion 305 can easily be withdrawn from the hat 200 by gently pulling it. This then allows the sensor portion 302 to be removed thereby limiting the time that the sensor is in contact with the skin.

**[0112]** The second and third outer holes 216, 217 are preferably positioned on an exterior part of the first portion 202 that is not overlapped by the second portion 201 when the hat 200 is worn. The second and third outer holes 216, 217 are preferably closer to the first inner hole 212 than the first outer hole 210, so as to reduce the length of lead 301 remaining in the hat 200 if the lead 301 is cut between the second and third outer holes 216, 217. The lead 301a between the second and third outer holes 216, 217 can be seen in Figure 10.

**[0113]** In more general terms, the hat 200 may be provided with a first sensor hole and second sensor hole for retaining the sensor within the hat 200. In the examples of Figures 8 to 11, the first and second sensor hole are the first and second inner hole 212, 213, which are con-

figured to receive the lead 301 and tang 303 of the sensor. In the example of Figures 12 and 13, the first and second sensor holes 222, 223 are through holes in the single-ply material 231, but not through the hook accepting second-ply 232. The distance between the first and second sensor hole 222, 223 may be between 0.5cm and 3cm. A first outer hole 210 may be provided in the hook accepting outer ply 232 to allow a sensor lead to exit the space between the inner ply (e.g. SPL) and the outer ply. Each of the first sensor hole 222, second sensor hole 223, and first outer hole 210 may be arranged on a substantially straight line on the fabric hat material (before darts 207 are sewn).

**[0114]** In Figures 8 and 9, dotted lines indicate stitching, dot-dash lines indicate overlocking and the solid line represents the outline. Single layer holes (through either the inner or outer ply only) are indicated by a concentric rectangles with a dotted outer rectangle, and double layer holes (through both inner and outer ply) are indicated by a solid line concentric rectangles. The rim 214 of the hat is indicated in Figures 8 to 11.

**[0115]** Figures 12 and 13 show an embodiment in which a single ply material is used to form the hat (such as a spun-bond-laminate, or SBL material). The outline of the single-ply material 231 is shown in Figure 12 and 13. A further layer 232 (e.g. a second ply) of hook accepting material may be attached to the single-ply material 231, in areas at which a loop fastener is intended to be attachable. In the embodiment of Figures 12 and 13, the completed hat 200 comprises a substantially continuous region of hook accepting material along the rim of the hat, for removably adhering to hook portions of the first and second fasteners 208, 211 and of the CPAP loop elements 209. The region of hook accepting material 232 along the rim of the hat provides a wide range of hook accepting area, improving the adjustability of the hat. The hook accepting material 232 may comprise multiple layers laminated together, for example a cotton/foam/velour layer structure, in which the velour is hook accepting.

**[0116]** The hat 200 may comprise at least one dart 207, to improve the fit of the hat on the head of a neonate particularly around the curvature of the occiput 120. There is preferably a dart 207 between the central portion 201 and the first portion 202, and between the central portion 201 and the second portion 203. The darts 207 preferably extends from the top edge of the hat (opposite the rim 214), to around halfway between the top edge and the rim 214. The darts 207 may be non-parallel, for example being angled so that the gap between them is smaller nearer to the rim 214. In Figures 8 and 9 the darts 207 are shown in a closed configuration, and in Figures 10 and 11 the darts 207 are shown before their edges have been drawn together. A dart 207 may be provided in the central portion 201, as shown in the embodiment of Figures 12 and 13. Drawing the darts 207 closed may comprise sewing together points 227 of the hat 200, which may be inward from the edge of the fabric 231.

**[0117]** The hat 200 is provided with a number of fea-

tures for securing/supporting CPAP apparatus or an intubation tube. The hat may include at least one of a strap 206, loop elements 209, and eyelets 205, for this purpose.

**[0118]** A plurality of eyelets 205 are provided in each of the first and second portion 202, 203, on either side of the central portion 201 of the hat 200. Three eyelets 205 may be provided on each of the first and second portion 202, 203, which enables lacing for a CPAP mask (or similar) to be secured at different locations to the hat 200, providing for an improved fit over a broader range of head shapes and sizes.

**[0119]** A strap 206 may be attached to the first portion 202 (as shown in Figures 10 and 11) or the second portion 203 (as shown in Figures 8 and 9) at one end (by sewing). A strap fastener 215 may be provided for securing the other end of the strap 206 to the first portion 202 or the second portion 203. The strap fastener 215 may comprise a hook and loop fastener. The strap fastener 215 may comprise a hook portion 215a at the end of the strap 206, and a corresponding loop portion on the exterior of the second portion 203, as shown in Figure 9. Alternatively, the strap fastener 215 may comprise a loop fastener 215a on the strap 206, and a hook fastener 215 on the first or second portion 203 (as in the embodiment of Figures 10 and 11). In the embodiment of Figures 12 and 13 the CPAP strap 206 may be a separate part that comprises hook fasteners at each end, which is attachable to the hook accepting fabric portion 231.

**[0120]** The loop element 209 may comprise a loop (or hook) region of hook and loop fastener material, so that a strip of hook material may be adhered to the loop element to secure a tube adjacent to the loop element (such a hook region 219 being shown in Figure 12). A loop element or region 209 is disposed on the exterior side, or at the edge of each the first and second portions 202, 203. The loop region 209 may comprise part of a larger continuous region of hook accepting material (e.g. as described above with reference to Figures 12 and 13). The strap 206 and/or the strips of material for adhering to the loop element 209 may comprise an elastic fabric material. The strap 206 and/or loops 209 may comprise a friction enhancing inner surface region, which may comprise a material such as silicone rubber.

**[0121]** All material that is to be sewed to the main hat material 200 is preferably of a form that is compatible.

**[0122]** Figure 14 illustrates the strap 206, loop elements 209 and eyelets 205 in use, with a CPAP mask 220 supported in the correct position on a neonate by the hat 200. The CPAP exhaust tube 220 is supported under the strap 206, and the two supply tubes are supported by adhering a hook fastener strip to each loop element 209. The strap/lacing of the mask is threaded through an appropriate pair of eyelets 205 at each of the first and second portion 202, 203.

**[0123]** The sensor 300 is shown in Figure 7 and 15 to 17, and comprises a flexible circuit board that includes the sensor portion 302, lead portion 301 and module por-

tion 305. Using a single flexible circuit board to define all of these parts of the sensor 300 eliminates connections between a sensor portion and lead, and between a lead and a subsequent connector, which are potential points of failure. Furthermore, this approach results in a very low profile arrangement: the thickness of the flexible circuit board may be less than 0.5mm.

**[0124]** Figure 15 shows the construction of the module portion 305 of the sensor 300 in more detail. The module portion 305 is arranged to engage with the readout module 400 and to provide an electrical connection between the sensor 300 and readout module 400.

**[0125]** The module portion 305 comprises: contacts 301, conducting tracks (not shown); a ferromagnetic element 307 and a rigidiser 306. The contacts 301 are exposed conducting regions that are connected to conducting tracks of the lead 301, that are in turn connected to the light emitter 310 and light detector 311 at the sensor portion 302. The ferromagnetic element 307 is a substantially planar sheet of a magnetic material such as steel. The rigidiser 306 is a substantially planar element (e.g. a plate) that is stiffer than the flexible circuit board, and which supports the contacts 301 from behind. The rigidiser 306 may fit in a recess or through hole in the ferromagnetic element 307.

**[0126]** Figure 16 shows the sensor portion 302, which comprises the light emitter 310, light detector 311, compressible element 308 and transparent element 309. The light emitter 310 may comprise a plurality of light emitting elements (such as light emitting diodes or LEDs). There may be more than one colour LED (e.g. infra-red, green, red etc). The light detector 311 may comprise a photodiode (or an array of photodiodes, or a multi-pixel camera chip not necessarily operating in the visible region). Where the light detector 311 comprises a plurality of light detecting elements, at least some of the light detecting elements may be configured with a different spectral response to the others (e.g. using a spectral filter), so that additional information may be obtained at the same time from more than one colour light emitter. Alternatively independent component analysis can be implemented on multi-detectors to separate out orthogonal components.

**[0127]** In the example shown, the light emitter 310 comprises a plurality of discrete LEDs, arranged around a central light detector 311. In other embodiments the light detector 311 and light emitter 310 may be disposed in a single package. In some embodiments the light emitter 310 and detector 311 may be separated by a baffle, which prevents light from the emitter 310 being directly detected by the detector 311. Or the LED's may be positioned at a lower level than the photodetector (relative to the transparent element 309) so that no direct light shunting occurs.

**[0128]** The compressible element 308 is formed of an elastic material, such as a closed cell foam, so that the optically transparent element 309 can conform to the skin of the neonate 120, minimising the potential for a pressure injury. The transparent element 309 may also be

relatively soft (e.g. compared to glass or polycarbonate), for instance being formed from optically clear silicone. The addition of an adhesive or tacky layer to the outer side of the transparent element 309 may help the sensor portion 302 to remain in contact with the skin and reduce slippage across the skin. Cross-polarisers can be placed between layers 308 and 309 to reduce internal reflection shunting.

**[0129]** In some embodiments, the sensor portion 302 may comprise at least one electrode for making electrical contact with the skin of the neonate, for example to perform an ECG measurement. The lead 301 may comprise at least one branch for connecting further electrodes at different positions on the neonate (for example, not on the head). The electrodes may be of any suitable type, including (but not limited to) wet electrodes, electrodes configured for capacitive coupling to the skin, and electrodes configured for connection to skin via a coupling gel (e.g. a hydrogel).

**[0130]** The tang 303 extends away from the sensor portion 302, in a different direction to the lead 301. In the example embodiment, the tang is at an angle of approximately 145 degrees to the lead 301, which results in the tang 303 being approximately parallel with the rim 314 of the hat 200 when the sensor portion 302 is between the first and second inner hole 212, 213. In some embodiments the tang 303 may extend away from the sensor portion at around 180 degrees from the lead 301.

**[0131]** Figures 17 and 18 illustrate how the module portion 305 of the sensor is connected to the readout module 400. A cradle 401 is provided, which assists in engaging and maintaining engagement between the module portion 305 and the readout module 400. The cradle 401 is configured to receive part of the housing base 402b, and has a wall that guides the housing into the proper location in the cradle 401. The cradle 401 further includes a slot in the base thereof, through which the module portion 305 of the sensor 300 can be inserted. The module portion 305 may subsequently be located within a slot of the cradle 401, with the lead portion 301 exiting the cradle 401 through the slot 401. The cradle 401 may be configured to require the cradle 401 to be initially moved relative to the module portion 305 in the direction of the lead 301 to disengage the module portion 305 from the slot. This helps to prevent the module portion 305 being disturbed in use, and helps maintain a secure connection between the readout module 400 and sensor 300.

**[0132]** As shown in Figure 18, when the readout module 400 is received within the cradle 401, the magnets of the readout module 400 may align with the ferromagnetic element 307 of the module portion 305, which urges the connector 408 into electrical contact with the contacts 304.

**[0133]** Figure 19 shows a receiver station 500, comprising a display 501 and a pair of docking portions 501.

**[0134]** The display 501 is for indicating the heart rate and other physiological variables of the neonate 120, based on data transmitted to the receiver station 500

wirelessly by the readout module 400. The receiver station 500 may be configured to show a time history of the pulse rate or blood oxygen saturation as a graph, the instantaneous pulse rate (e.g. as number indicating beats per minute), the breathing rate, an indication of battery status (e.g. for a charging module 400, or the transmitting module 400), the time, or any other information that may be appropriate.

**[0135]** Each docking portion is configured to receive a readout module 400. The receiver station 500 may be configured to charge each readout module 400 via each docking portion 502.

**[0136]** The receiver station (500) may contain adequate storage to collect all data from a recording session in a non-volatile format. This is useful for training purposes, medico-legal reasons and clinical records for example. Data can be accessed by removing the internal storage card, by wired or wireless connections.

**[0137]** The receiver station 500 may further comprise a hanger 504, by which the receiver station 500 can be secured to a sidewall of a resuscitaire, as shown in Figure 20.

**[0138]** The embodiments described above address a number of potential applications. In one use case, a clinician may identify a need for heart rate monitoring of a neonate, following an assessment of the neonate on delivery.

**[0139]** A prepared hat 200 may be positioned on a resuscitaire 110 in the unfolded configuration. The prepared hat 200 includes a sensor 300, as described above. The sensor 300 may be already connected to a readout module 400, which may already be in communication with the receiving station 500.

**[0140]** The neonate may be placed with their head on the central portion 201 of the hat 200, and the hat 200 wrapped around the head, so that the sensor portion 302 contacts the head (e.g. forehead) of the neonate 120. If a readout module 400 is not already engaged with the module portion 305, a readout module 400 may be taken from the docking portion 502 and engaged with the readout module 400 (e.g. by placing it in cradle 401).

**[0141]** The readout module 400 may subsequently transmit data derived from the output of the sensor 300 to the receiver station 500. As already discussed, the processing of the data from the sensor 300 to determine heart rate (and/or blood oxygen saturation, breathing rate etc) may take place at the readout module 400 and/or the receiver station 500. The receiver station subsequently displays the heart rate and/or blood oxygen saturation (e.g. an instantaneous indication and/or a time history in the form of a graph).

**[0142]** The hat 200 may be kept on the head of the neonate 120 while any treatment to remedy poor respiratory function and/or heart rate etc is given. An accurate time history of the heart rate etc made available at the resuscitaire will assist the treating clinician in determining whether their actions are having the desired effect. If it is determined that the neonate 120 needs to be trans-

ferred to a neonatal intensive care unit (NICU), the physiological signals of the neonate can continue to be monitored during transit of the resuscitaire to the NICU.

**[0143]** Once the neonate is stabilised, or has arrived at the NICU, the hat 200 may be removed, or the sensor removed from the hat 200. Removing the sensor can be achieved by cutting the lead 301 between the second and third outer hole, and then pulling the lead from the hat 200. In some embodiments (such as that of Figures 12 and 13), removing the sensor may comprise cutting the lead 301 outside the hat (e.g. not between second and third outer holes). The sensor element can subsequently be removed by briefly lifting the first portion 202 and detaching the sensor portion 302 from the interior. Each hat 200 and sensor 300 may be a single-use disposable item.

**[0144]** In another use-case, the hat may be applied as a matter of routine to each newborn, so that the physiological signals can be assessed to ensure that they are healthy before they leave the delivery suite.

**[0145]** A further use-case is for babies older than 4 weeks (e.g. for babies up to 6 months or even 1 year old), for instance to monitor for the onset of SIDS (sudden infant death syndrome). Although a hat for a neonate has been described, the same principles are also applicable to a hat for an older baby.

**[0146]** One issue present in the delivery room is the availability of ECG equipment for newborn monitoring. A device that is being used to monitor the fetal ECG could be transferred to continue to monitor the newborn ECG, simply by swapping the data receiving device from the electrodes used to monitor the mother and/or fetus to the electrodes on the sensor portion that are connected to the newborn baby (e.g. in the hat). Using the same interface to the cardiocogram printout mechanism could allow for data recording.

**[0147]** A number of examples have been described, which are not intended to limit the scope of the invention, which is limited only by the appended claims.

## Claims

1. A hat (200) for a neonate comprising: a central portion (201), a first side portion (202) and second side portion (203) attached to opposite sides of the central portion, a first fastener (208); a top flap (204) and a second fastener (211); wherein the hat has an unfolded configuration in which the first and second portions extend away from each other from the central portion in opposite directions; and a worn configuration in which the hat wraps a neonate's head with the central portion in contact with the back of the neonate's head, the first portion wrapped around a first side of the neonate's head and the second portion wrapped around a second side of the neonate's head; the first and second portions being configured to be

fastened together in the worn configuration by the first fastener so that the first portion, central portion and second portion together define a hat rim encircling the neonate's head; and  
 the top flap is configured to cover the top of the neonate's head in the worn configuration, with the top flap being configured to be fastened to at least one of the first, central and second portions by the second fastener;  
 the hat further comprising an optical physiological sensor (300) that comprises:  
 a flexible circuit board, a light emitter (310) and a light detector (311); the flexible circuit board having:

a sensor portion (302) to which the light emitter and light detector are connected;  
 a module portion (305) including contacts for electrically connecting the light emitter and light detector to a removable readout module; and  
 an elongate lead portion (301) between the sensor portion and module portion.

2. The hat of claim 1, wherein the hat is substantially T-shaped when in an unfolded configuration, with the top flap being connected to the central portion; and wherein the first and second portions are configured to overlap on the neonate's forehead when fastened together by the first fastener.
3. The hat of any preceding claim, wherein:
  - i) the first fastener and/or the second fastener comprise a hook and loop fastener; and/or
  - ii) the first fastener is configured to provide a plurality of fastening positions so as to allow a range of adjustment of the length of the hat rim, so as to accommodate a range of neonate head sizes.
4. The hat of any preceding claim, further comprising a strap for supporting a tube adjacent to the neonate's forehead when the first, central and second portions encircle the neonate's head; and wherein the strap optionally:
  - i) comprises an elastic fabric material;
  - ii) comprises a strap fastener, for fastening the strap to at least one of the first and second portions;
  - iii) is fixed at one end to one of the first or second portion, and the other end is securable to the other of the first or second portions using the strap fastener; and/or
  - iv) comprises a friction enhancing lining on an inner surface thereof.
5. The hat of any preceding claim, comprising a first plurality of eyelets in the first portion adjacent to the

hat rim, and a second plurality of eyelets in the second portion adjacent to the hat rim, the first and second plurality of eyelets for securing a CPAP mask to the neonate's face using CPAP cords that thread into the eyelets, the plurality of eyelets in each of the first and second portion providing a range of CPAP mask securing locations, and/or  
 at least one hook or loop element against which a tube may be supported adjacent to the exterior of the hat, wherein the at least one hook or loop element optionally comprises a first and second external hook or loop element, arranged to be positioned on either side of the neonate's forehead when the hat is worn.

6. The hat of any preceding claim, comprising a first dart between the first and central portion and a second dart between the second and central portion; wherein the first and second dart extend substantially toward the rim from a top edge of the hat, the top edge being on the opposite side of the hat to the hat rim.
7. The hat of claim 1, wherein the first, second, and central portions, and the top flap, are substantially formed from a fabric material, and the fabric material is stretchable substantially in one direction only, wherein the direction is preferably along the circumference.
8. The hat of claim 1, wherein the first, second, and central portions, and the top flap, are substantially formed from a fabric material, and wherein:
 

the fabric has at least an inner ply and an outer ply; and  
 the hat further comprises an inner hole through the inner fabric ply at a first location and an outer hole through the outer fabric ply at a second location; the inner and outer hole allowing an optical physiological sensor lead to be threaded through a space between the inner and outer plies between the inner and outer holes.
9. The hat of claim 8, wherein:
  - i) the inner hole is a first inner hole, and the hat further comprises a second inner hole through the inner fabric ply, spaced apart from the first inner hole by 0.5cm to 3cm; and/or
  - ii) the outer hole is a first outer hole, and the hat further comprises a second and third outer hole disposed between the inner hole and the first outer hole.
10. The hat of any preceding claim, wherein the sensor portion comprises a transparent element covering the light emitter and light detector and the transparent element optionally comprises a region that is ad-

hesive or tacky to skin; and/or wherein the sensor portion further comprises at least one electrode for making an electrical connection to the skin of the neonate.

11. The hat of any preceding claim, wherein the light emitter comprises a first light emitting element with a first output wavelength, and a second light emitting element with a second, different output wavelength.
12. The hat of any preceding claim, wherein the flexible circuit board includes a tang extending away from the sensor portion in a different direction to the lead, wherein the tang optionally:
- i) is an elongate member and the tang extends away from the sensor portion at an angle of between 170 and 190 degrees from the lead; and/or
  - ii) comprises at least one lateral projection or recess configured to assist in preventing withdrawal of the tang through a hole in the hat.
13. The hat of any preceding claim, wherein the module portion comprises a substantially rigid planar element for supporting the contacts; and/or a ferromagnetic element.
14. The hat of any preceding claim, wherein at least part of the elongate lead portion of the optical physiological sensor is disposed between an inner and an outer ply of the hat and the sensor portion is supported by the hat at an inner surface of the hat near the rim of the first portion or the second portion, such that the sensor portion is positioned on a neonate's forehead when the hat is worn.
15. The hat of claim 14, wherein the hat includes the features of claim 9i), the optical physiological sensor includes a tang extending away from the sensor portion in a different direction to the lead, and the sensor portion is supported between the first inner hole and the second inner hole, the first inner hole receiving the elongate lead portion, and the second inner hole receiving the tang, wherein the elongate lead portion is optionally threaded between the second and third outer holes, so as to enable the lead portion to be cut between the second and third outer holes while the hat is worn, so that the sensor portion can subsequently be withdrawn from the hat.

### Patentansprüche

1. Hut (200) für ein Neugeborenes, umfassend: einen mittleren Abschnitt (201), einen ersten Seitenabschnitt (202) und einen zweiten Seitenabschnitt (203), die an gegenüberliegenden Seiten des mitt-

leren Abschnitts angebracht sind, ein erstes Befestigungselement (208), eine obere Lasche (204) und ein zweites Befestigungselement (211);

wobei der Hut eine entfaltete Auslegung aufweist, in der sich der erste und der zweite Seitenabschnitt von dem mittleren Abschnitt in entgegengesetzte Richtungen voneinander weg erstrecken; und eine getragene Auslegung, in der der Hut den Kopf eines Neugeborenen umwickelt, wobei der mittlere Abschnitt mit dem Hinterkopf des Neugeborenen in Kontakt ist, der erste Abschnitt um eine erste Seite des Kopfes des Neugeborenen gewickelt ist und der zweite Abschnitt um eine zweite Seite des Kopfes des Neugeborenen gewickelt ist;

wobei der erste und der zweite Abschnitt dazu ausgelegt sind, bei der getragenen Auslegung durch das Befestigungsmittel derart aneinander befestigt zu werden, dass der erste Abschnitt, der mittlere Abschnitt und der zweite Abschnitt zusammen einen Hutrand definieren, der den Kopf des Neugeborenen umschließt; und

die obere Lasche dazu ausgelegt ist, den oberen Bereich des Kopfes des Neugeborenen in der getragenen Auslegung abzudecken, wobei die obere Lasche dazu ausgelegt ist, durch das Befestigungsmittel an mindestens einem des ersten, des mittleren und des zweiten Abschnitts befestigt zu werden; wobei der Hut ferner einen optischen physiologischen Sensor (300) umfasst, der umfasst:

eine flexible Leiterplatte, einen Lichtemitter (310) und einen Lichtdetektor (311); wobei die flexible Leiterplatte aufweist:

- einen Sensorabschnitt (302), mit dem der Lichtemitter und der Lichtdetektor verbunden sind;
- einen Modulabschnitt (305), der Kontakte zum elektrischen Verbinden des Lichtemitters und Lichtdetektors mit einem entfernbaren Auslesemodul umfasst; und

- einen länglichen Leitungsabschnitt (301) zwischen dem Sensorabschnitt und dem Modulabschnitt.

2. Hut nach Anspruch 1, wobei der Hut im Wesentlichen T-förmig ist, wenn er sich in einer entfalteten Auslegung befindet, wobei die obere Lasche mit dem mittleren Abschnitt verbunden ist; und wobei der erste und der zweite Abschnitt dazu ausgelegt sind, sich an der Stirn des Neugeborenen zu überlappen, wenn durch das erste Befestigungsmittel aneinander befestigt.

3. Hut nach einem vorhergehenden Anspruch, wobei:

- i) das erste Befestigungsmittel und/oder das zweite Befestigungsmittel ein Klettverschluss ist; und/oder

- ii) das erste Befestigungsmittel dazu ausgelegt

- ist, eine Vielzahl von Befestigungspositionen bereitzustellen, um einen Einstellbereich für die Länge des Hutrandes zuzulassen, um verschiedene Kopfgrößen eines Neugeborenen aufzunehmen.
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4. Hut nach einem vorhergehenden Anspruch, ferner umfassend einen Riemen zum Halten eines Schlauchs an der Stirn des Neugeborenen, wenn der erste, der mittlere und der zweite Abschnitt den Kopf des Neugeborenen umschließen; und wobei der Riemen optional:
- 10
- i) ein elastisches Gewebematerial umfasst;  
 ii) ein Riemenbefestigungselement zum Befestigen des Riemens an mindestens einem des ersten und des zweiten Abschnitts umfasst;  
 iii) an einem Ende mit einem des ersten oder des zweiten Abschnitts fixiert ist und das andere Ende mit dem Riemenbefestigungselement an dem anderen des ersten oder des zweiten Abschnitts befestigt werden kann; und/oder  
 iv) eine reibungserhöhende Auskleidung an einer Innenfläche davon umfasst.
- 15
5. Hut nach einem vorhergehenden Anspruch, umfassend eine erste Vielzahl von Ösen in dem ersten Abschnitt neben dem Hutrand und eine zweite Vielzahl von Ösen in dem zweiten Abschnitt neben dem Hutrand, die erste und die zweite Vielzahl von Ösen zum Befestigen einer CPAP-Maske am Gesicht des Neugeborenen mithilfe von CPAP-Kabeln, die in die Ösen gefädelt werden, wobei die Vielzahl von Ösen in jedem des ersten und des zweiten Abschnitts eine Reihe von CPAP-Maskenbefestigungsstellen bereitstellt, und/oder  
 mindestens ein Klettverschlusselement, an dem ein Schlauch an der Außenseite des Hutes gestützt werden kann, wobei das mindestens eine Klettverschlusselement optional ein erstes und ein zweites externes Klettverschlusselement umfasst, das dazu angeordnet ist, auf beiden Seiten der Stirn des Neugeborenen positioniert zu werden, wenn der Hut getragen wird.
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6. Hut nach einem vorhergehenden Anspruch, umfassend einen ersten Abnäher zwischen dem ersten und dem mittleren Abschnitt und einen zweiten Abnäher zwischen dem zweiten und dem mittleren Abschnitt;  
 wobei sich der erste und der zweite Abnäher im Wesentlichen von einer Oberkante des Hutes in Richtung Hutrand erstrecken, wobei sich die Oberkante auf der gegenüberliegenden Seite des Hutes am Hutrand befindet.
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7. Hut nach Anspruch 1, wobei der erste, der zweite und der mittlere Abschnitt und die obere Lasche im Wesentlichen aus einem Gewebematerial gebildet sind und das Gewebematerial im Wesentlichen in nur eine Richtung gedehnt werden kann, wobei die Richtung vorzugsweise entlang des Umfangs verläuft.
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8. Hut nach Anspruch 1, wobei der erste, der zweite und der mittlere Abschnitt und die obere Lasche im Wesentlichen aus einem Gewebematerial gebildet sind und wobei:
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- das Gewebe mindestens eine innere Lage und eine äußere Lage aufweist; und  
 der Hut ferner ein Innenloch durch die innere Gewebelage an einer ersten Stelle und ein Außenloch durch die äußere Gewebelage an einer zweiten Stelle umfasst; wobei das Innen- und das Außenloch ermöglichen, dass eine optische physiologische Sensorleitung durch einen Raum zwischen der inneren und der äußeren Lage zwischen dem inneren und dem äußeren Loch durchgefädelt werden kann.
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9. Hut nach Anspruch 8, wobei:
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- i) das Innenloch ein erstes Innenloch ist und der Hut ferner ein zweites Innenloch durch die innere Gewebelage umfasst, das um 0,5 cm bis 3 cm von dem ersten Innenloch beabstandet ist; und/oder  
 ii) das Außenloch ein erstes Außenloch ist und der Hut ferner ein zweites und drittes Außenloch umfasst, das zwischen dem Innenloch und dem ersten Außenloch angeordnet ist.
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10. Hut nach einem vorhergehenden Anspruch, wobei der Sensorabschnitt ein transparentes Element umfasst, das den Lichtemitter und den Lichtdetektor abdeckt und das transparente Element optional eine Region umfasst, die auf der Haut haftend oder klebend ist; und/oder wobei der Sensorabschnitt ferner mindestens eine Elektrode zum Herstellen einer elektrischen Verbindung mit der Haut des Neugeborenen umfasst.
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11. Hut nach einem vorhergehenden Anspruch, wobei der Lichtemitter ein erstes lichtemittierendes Element mit einer ersten Ausgangswellenlänge und ein zweites lichtemittierendes Element mit einer zweiten, anderen Ausgangswellenlänge umfasst.
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12. Hut nach einem vorhergehenden Anspruch, wobei die flexible Leiterplatte eine Zunge umfasst, die sich von dem Sensorabschnitt in eine andere Richtung der Leitung weg erstreckt, wobei die Zunge optional:
- 55
- i) ein längliches Element ist und sich die Zunge von dem Sensorabschnitt in einem Winkel zwi-

- schen 170 und 190 Grad von der Leitung weg erstreckt; und/oder  
 ii) mindestens zwei Vorsprünge oder Ausnehmungen umfasst, die dazu ausgelegt sind, das Verhindern des Zurückziehens der Zunge durch ein Loch in den Hut zu unterstützen.
13. Hut nach einem vorhergehenden Anspruch, wobei der Modulabschnitt ein im Wesentlichen starres Flächenelement zum Lagern der Kontakte umfasst; und/oder ein ferromagnetisches Element.
14. Hut nach einem vorhergehenden Anspruch, wobei mindestens ein Teil des länglichen Leitungsabschnitts des optischen physiologischen Sensors zwischen einer inneren und einer äußeren Lage des Hutes angeordnet ist und der Sensorabschnitt des Hutes nahe des Randes des ersten Abschnitts oder des zweiten Abschnitts gelagert ist, sodass der Sensorabschnitt an der Stirn des Neugeborenen positioniert ist, wenn der Hut getragen wird.
15. Hut nach Anspruch 14, wobei der Hut die Merkmale nach Anspruch 9i) umfasst, der optische physiologische Sensor eine Zunge umfasst, die sich von dem Sensorabschnitt in eine andere Richtung der Leitung weg erstreckt und der Sensorabschnitt zwischen dem ersten Innenloch und dem zweiten Innenloch gelagert ist, wobei das erste Innenloch den länglichen Leitungsabschnitt aufnimmt und das zweite Innenloch die Zunge aufnimmt, wobei der längliche Leitungsabschnitt optional zwischen dem zweiten und dem dritten Außenloch eingefädelt ist, um zu ermöglichen, dass der Leitungsabschnitt zwischen dem zweiten und dem dritten Außenloch geschnitten werden kann, während der Hut getragen wird, sodass der Sensorabschnitt anschließend aus dem Hut entnommen werden kann.

## Revendications

1. Chapeau (200) pour un nouveau-né comprenant : une partie centrale (201), une première partie latérale (202) et une seconde partie latérale (203) fixées aux côtés opposés de la partie centrale, un premier élément de fixation (208) ; un rabat supérieur (204) et un second élément de fixation (211) ; le chapeau ayant une configuration dépliée dans laquelle les première et seconde parties s'étendent à distance l'une de l'autre à partir de la partie centrale dans des directions opposées ; et une configuration portée dans laquelle le chapeau enveloppe la tête d'un nouveau-né, la partie centrale étant en contact avec l'arrière de la tête du nouveau-né, la première partie étant enroulée autour d'un premier côté de la tête du nouveau-né et la seconde partie étant enroulée autour d'un second côté de la tête du nouveau-né ;
2. Chapeau selon la revendication 1, le chapeau étant sensiblement en forme de T lorsqu'il est dans une configuration dépliée, le rabat supérieur étant relié à la partie centrale ; et les première et seconde parties étant configurées pour se chevaucher sur le front du nouveau-né lorsqu'elles sont fixées ensemble par le premier élément de fixation.
3. Chapeau selon l'une quelconque des revendications précédentes,
- i) le premier élément de fixation et/ou le second élément de fixation comprenant un élément de fixation à boucles et crochets ; et/ou  
 ii) le premier élément de fixation étant configuré pour fournir une pluralité de positions de fixation afin de permettre une plage de réglage de la longueur du bord du chapeau, pour l'adaptation à une plage de tailles de têtes de nouveau-nés.
4. Chapeau selon l'une quelconque des revendications précédentes, comprenant en outre une sangle destinée à supporter un tube placé de manière adjacente au front du nouveau-né lorsque la première partie, la partie centrale et la seconde partie entourent la tête du nouveau-né ; et la sangle éventuellement :

- i) comprenant une matière textile élastique ;  
 ii) comprenant un élément de fixation de sangle, pour fixer la sangle à au moins une des première et seconde parties ;  
 iii) étant fixée à une extrémité de la première ou de la seconde partie, et l'autre extrémité pouvant être fixée à l'autre extrémité de la première ou de la seconde partie au moyen de l'élément de fixation de sangle ; et/ou  
 iv) comprenant un revêtement améliorant le frottement sur une surface intérieure de celle-ci.
5. Chapeau selon l'une quelconque des revendications précédentes, comprenant une première pluralité d'œillets dans la première partie adjacente au bord du chapeau, et une seconde pluralité d'œillets dans la seconde partie adjacente au bord du chapeau, les première et seconde pluralité d'œillets étant destinés à fixer un masque CPAP au visage du nouveau-né au moyen de cordons CPAP qui passent dans les œillets, la pluralité d'œillets dans chacune des première et seconde parties fournissant une plage d'emplacements de fixation de masque CPAP, et/ou au moins un élément à boucles et crochets contre lequel un tube peut être supporté en position adjacente à l'extérieur du chapeau, l'au moins un élément à boucles et crochets comprenant éventuellement des premier et second éléments à boucles et crochets externe, agencés pour être positionnés de chaque côté du front du nouveau-né, lorsque le chapeau est porté.
6. Chapeau selon l'une quelconque des revendications précédentes, comprenant une première pince entre la première partie et la partie centrale et une seconde pince entre la seconde partie et la partie centrale ; les première et seconde pinces s'étendant sensiblement vers le rebord à partir d'un bord supérieur du chapeau, le bord supérieur étant sur le côté du chapeau opposé au bord du chapeau.
7. Chapeau selon la revendication 1, la première partie, la seconde partie et la partie centrale, ainsi que le rabat supérieur, étant essentiellement constitués d'un matériau textile, et le matériau textile pouvant être étiré essentiellement dans une seule direction, la direction étant orientée de préférence le long de la circonférence.
8. Chapeau selon la revendication 1, la première partie, la seconde partie et la partie centrale, ainsi que le rabat supérieur, étant essentiellement constitués d'un matériau textile, et le tissu ayant au moins une couche intérieure et une couche extérieure ; et le chapeau comprenant en outre un trou intérieur à travers la couche de tissu intérieure au niveau d'un premier emplacement et un trou extérieur à travers
- la couche de tissu extérieure au niveau d'un deuxième emplacement ; le trou intérieur et le trou extérieur permettant de faire passer un conducteur de capteur physiologique optique à travers un espace entre les couches intérieure et extérieure entre les trous intérieur et extérieur.
9. Chapeau selon la revendication 8,
- i) le trou intérieur étant un premier trou intérieur, et le chapeau comprenant en outre un deuxième trou intérieur à travers la couche de tissu intérieure, espacé du premier trou intérieur de 0,5 cm à 3 cm ; et/ou  
 ii) le trou extérieur étant un premier trou extérieur, et le chapeau comprenant en outre des deuxième et troisième trou extérieurs disposés entre le trou intérieur et le premier trou extérieur.
10. Chapeau selon l'une quelconque des revendications précédentes, la partie capteur comprenant un élément transparent recouvrant l'émetteur de lumière et le détecteur de lumière, et l'élément transparent comprenant éventuellement une région qui est adhésive ou collante à la peau ; et/ou la partie capteur comprenant en outre au moins une électrode pour établir une connexion électrique avec la peau du nouveau-né.
11. Chapeau selon l'une quelconque des revendications précédentes, l'émetteur de lumière comprenant un premier élément électroluminescent avec une première longueur d'onde de sortie, et un second élément électroluminescent avec une seconde longueur d'onde de sortie différente.
12. Chapeau selon l'une quelconque des revendications précédentes, la carte de circuit imprimé souple comprenant un tenon s'étendant à distance de la partie capteur dans une direction différente de celle du conducteur, le tenon éventuellement :
- i) étant un élément allongé et le tenon s'étendant à distance de la partie capteur selon un angle compris entre 170 et 190 degrés par rapport au conducteur ; et/ou  
 ii) comprenant au moins une saillie latérale ou un évidement configuré pour aider à empêcher le retrait du tenon par un trou dans le chapeau.
13. Chapeau selon l'une quelconque des revendications précédentes, la partie module comprenant un élément plan sensiblement rigide pour supporter les contacts ; et/ou un élément ferromagnétique.
14. Chapeau selon l'une quelconque des revendications précédentes, au moins une partie de la partie de conducteur allongée du capteur physiologique opti-

que étant disposée entre une couche intérieure et une couche extérieure du chapeau et la partie capteur étant supportée par le chapeau au niveau d'une surface intérieure du chapeau près du bord de la première partie ou de la seconde partie, de telle sorte que la partie capteur est placée sur le front du nouveau-né lorsque le chapeau est porté. 5

15. Chapeau selon la revendication 14, le chapeau comprenant les caractéristiques selon la revendication 9 i), le capteur physiologique optique comprenant un tenon s'étendant à distance de la partie capteur dans une direction différente de celle du conducteur, et la partie capteur étant supportée entre le premier trou intérieur et le deuxième trou intérieur, le premier trou intérieur recevant la partie de conducteur allongée, et le deuxième trou intérieur recevant le tenon, la partie de conducteur allongée passant éventuellement entre les deuxième et troisième trous extérieurs, de manière à permettre à la partie de conducteur d'être coupée entre les deuxième et troisième trous extérieurs lorsque le chapeau est porté, de sorte que la partie capteur puisse ensuite être retirée du chapeau. 10  
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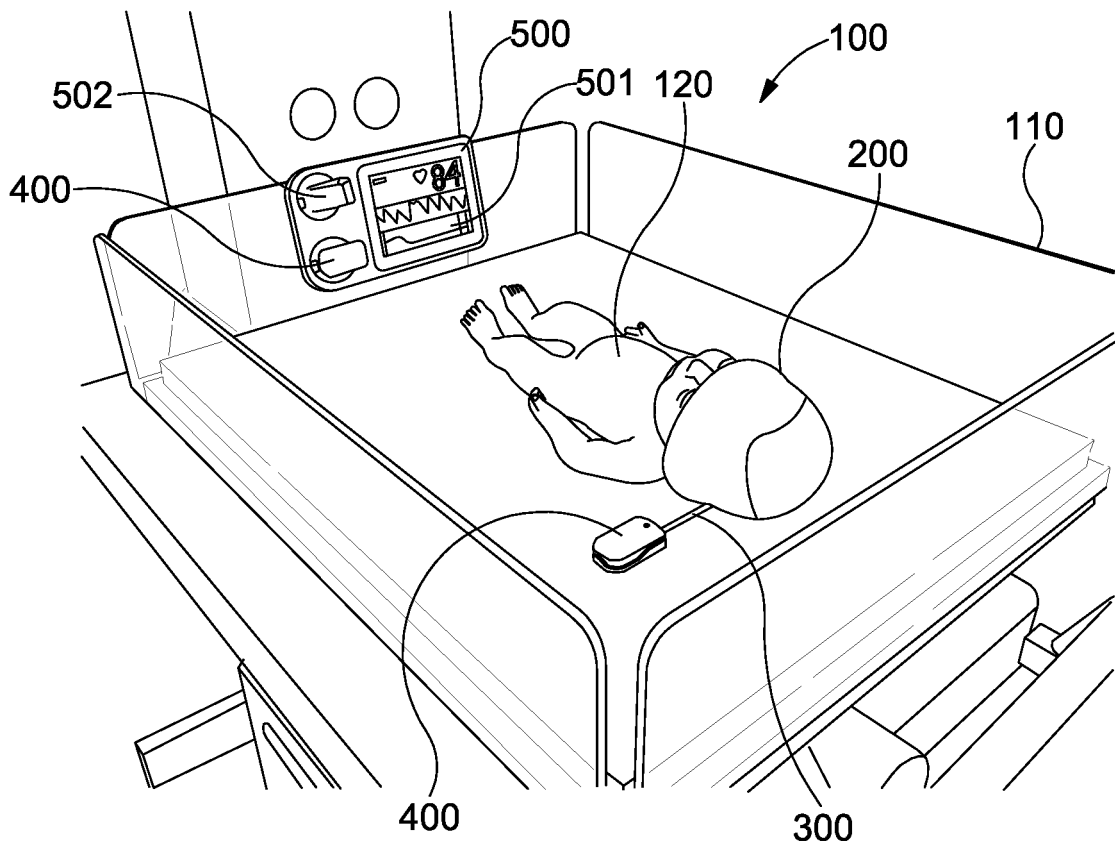


Figure 1

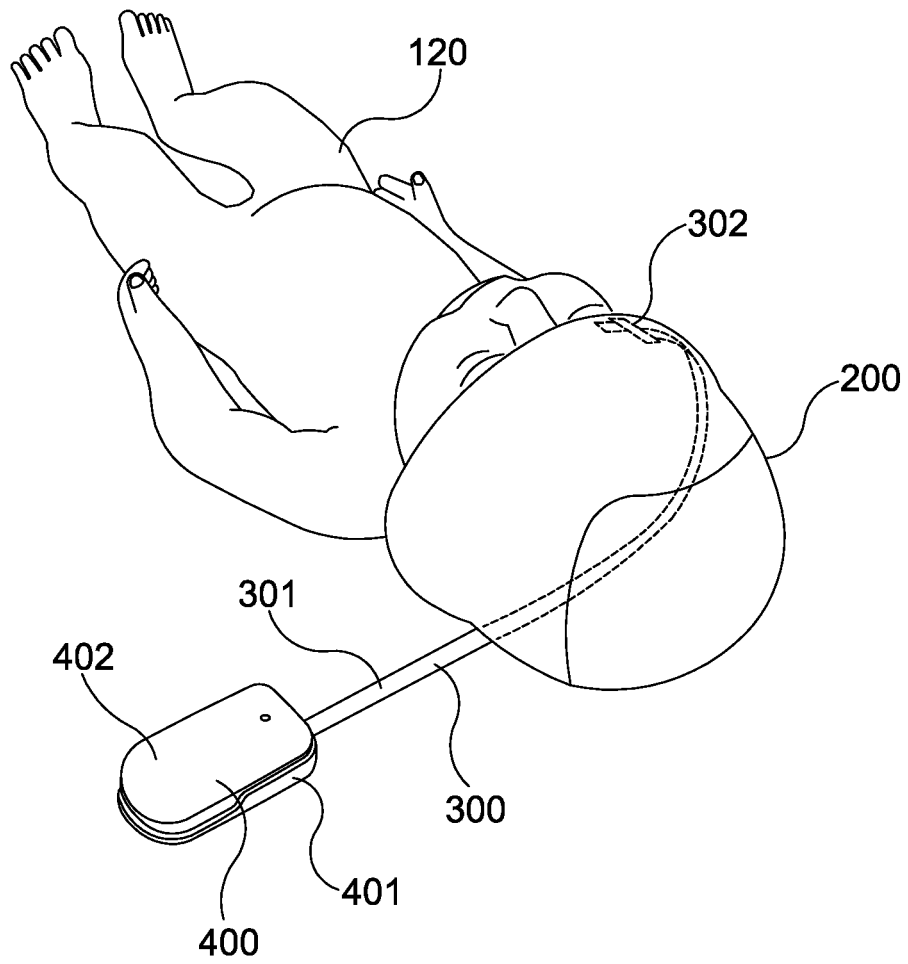


Figure 2

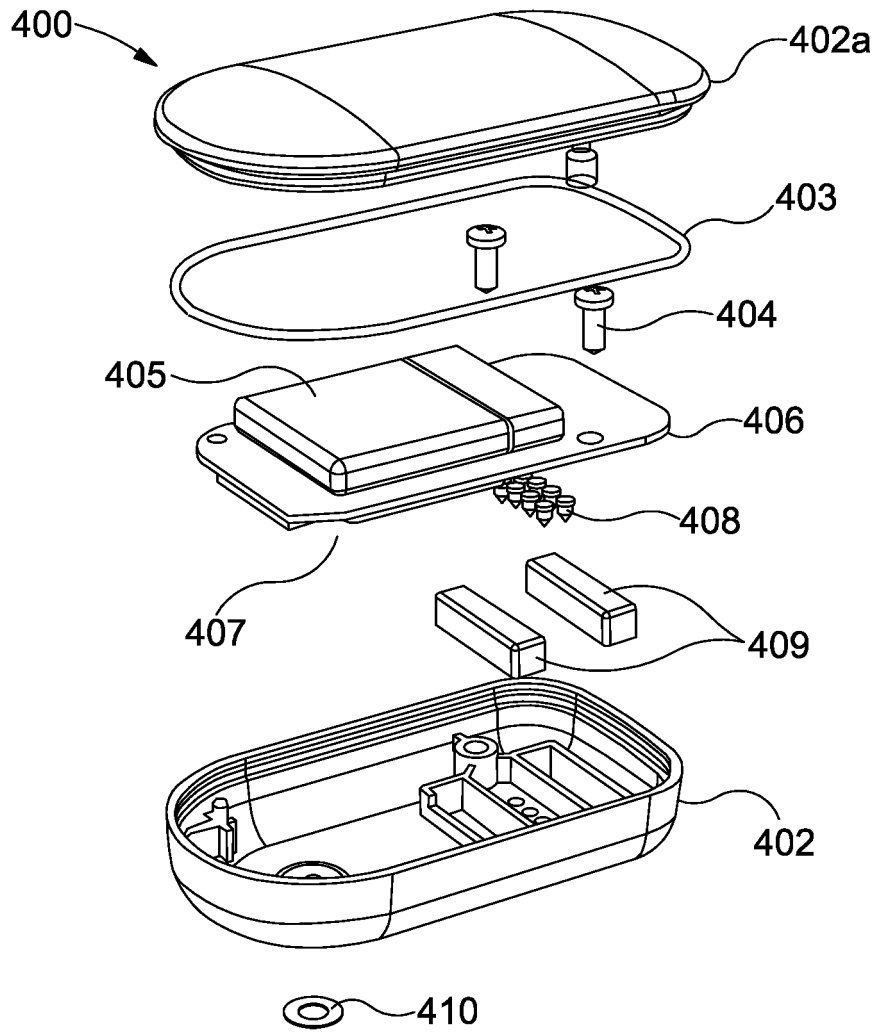


Figure 3

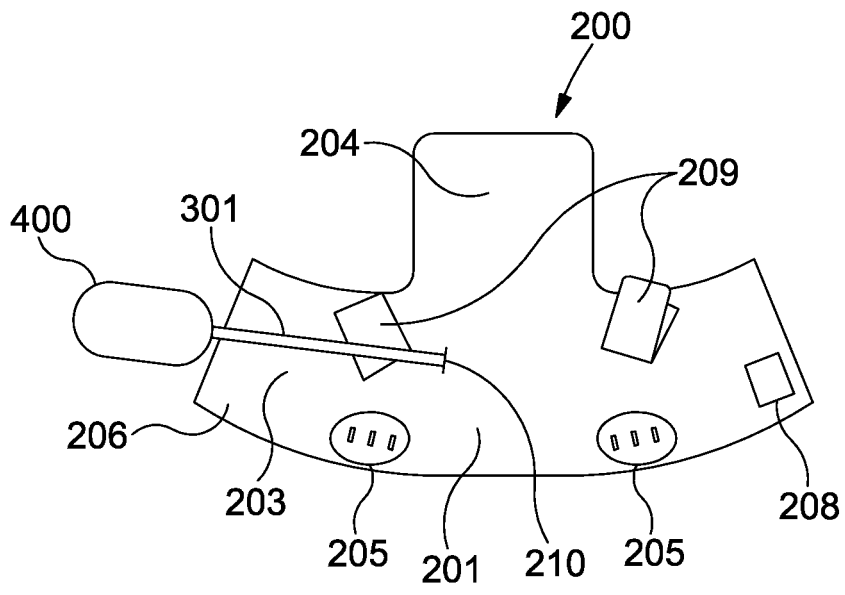


Figure 4

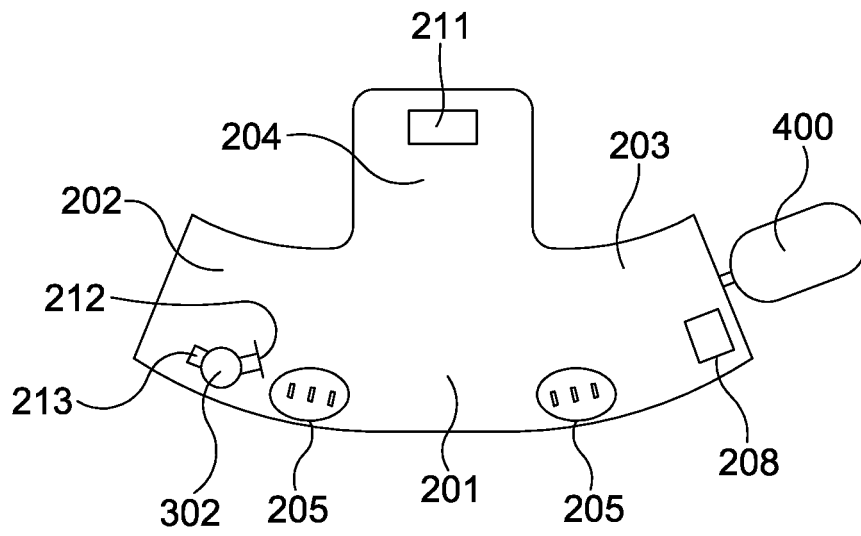


Figure 5

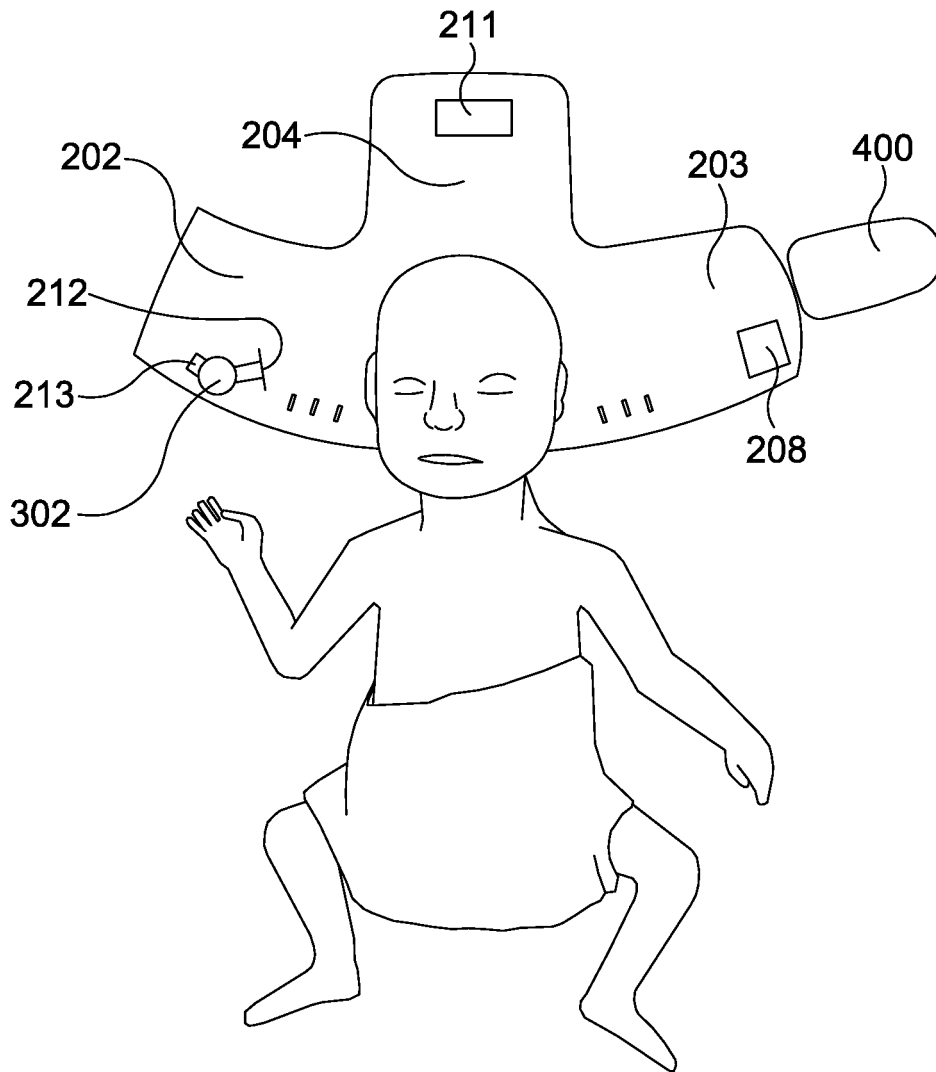


Figure 6

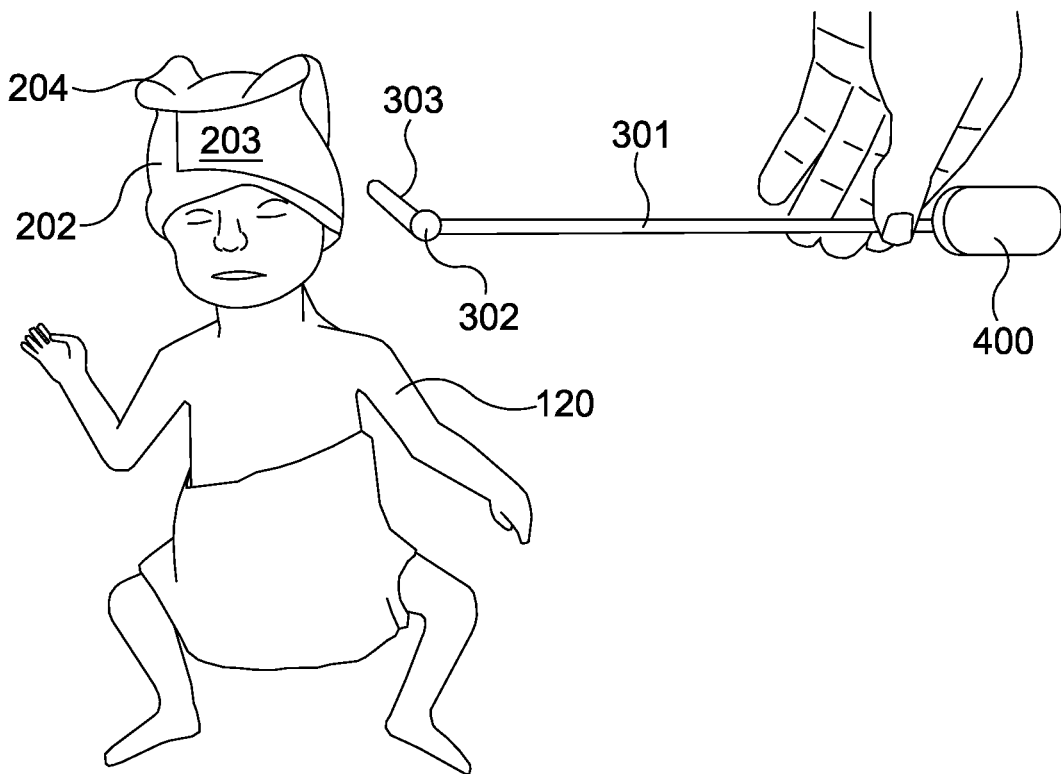


Figure 7

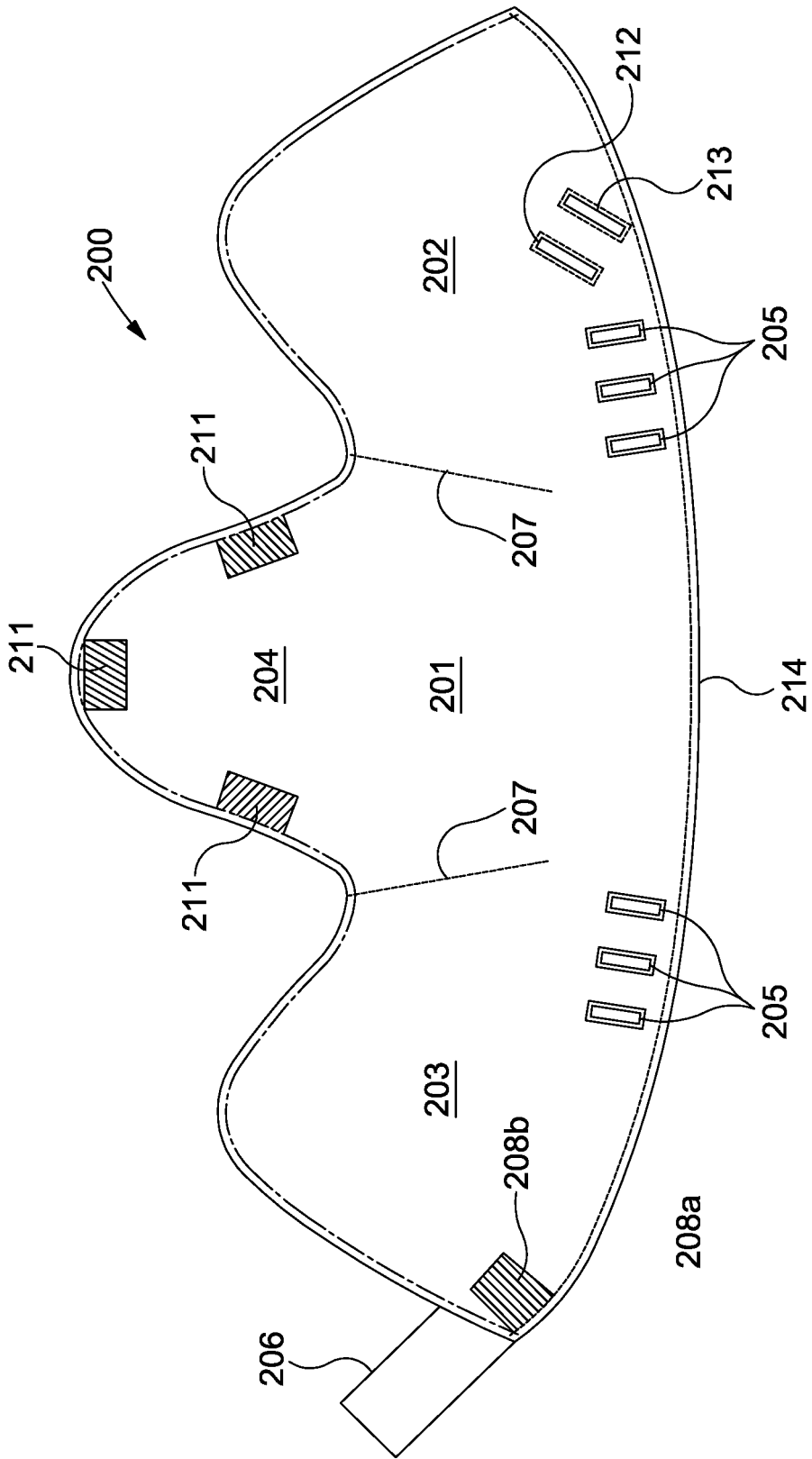


Figure 8

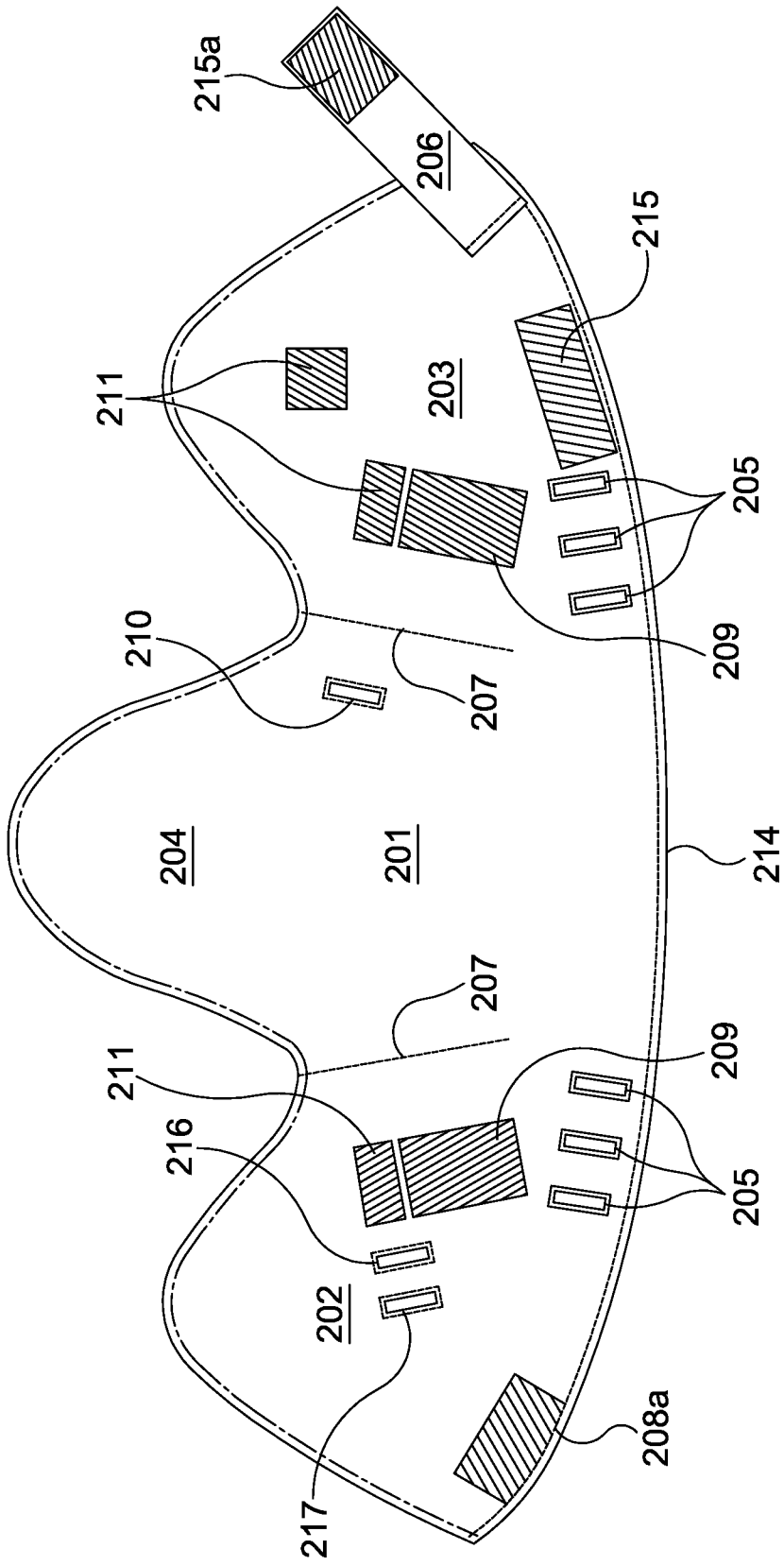


Figure 9

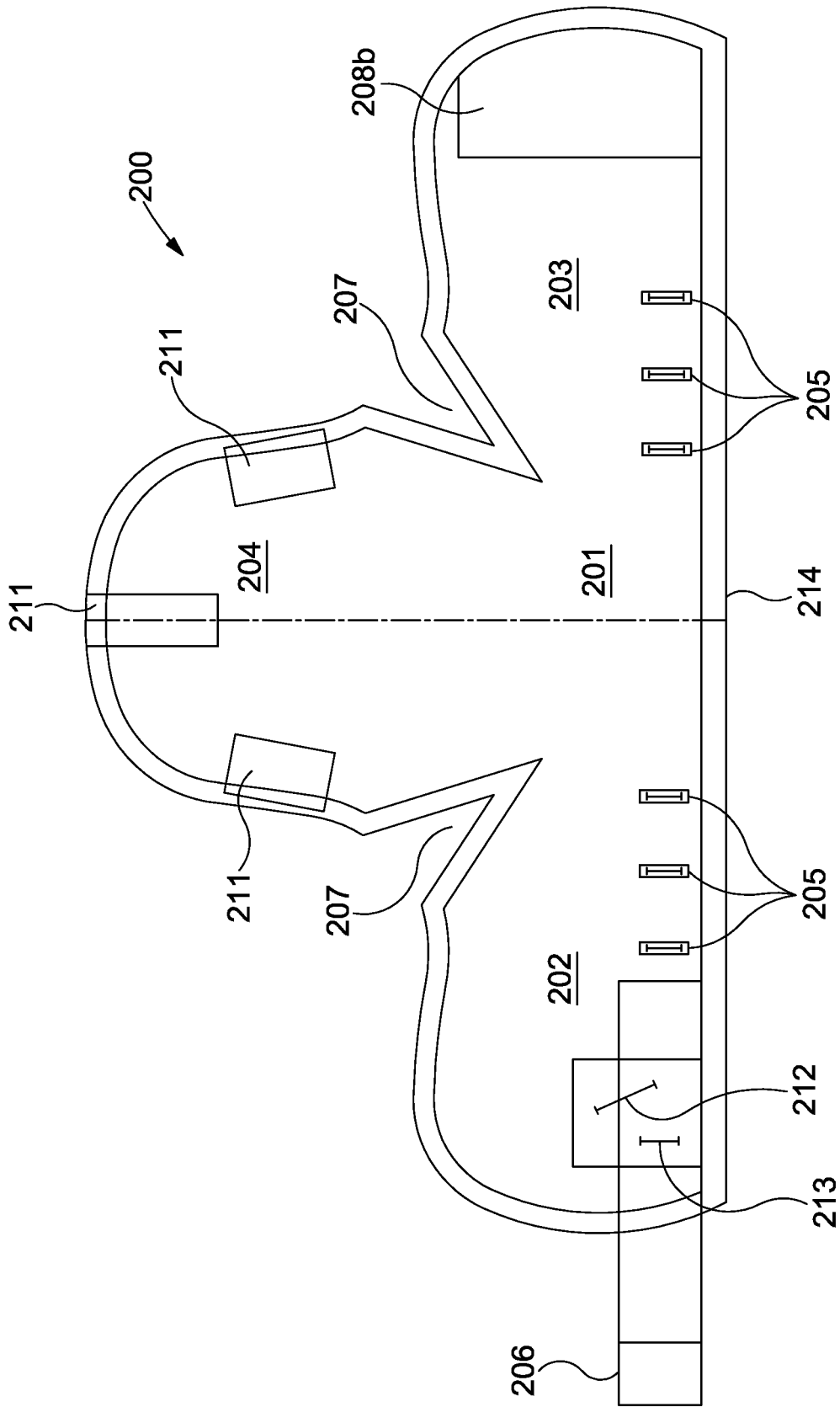


Figure 10

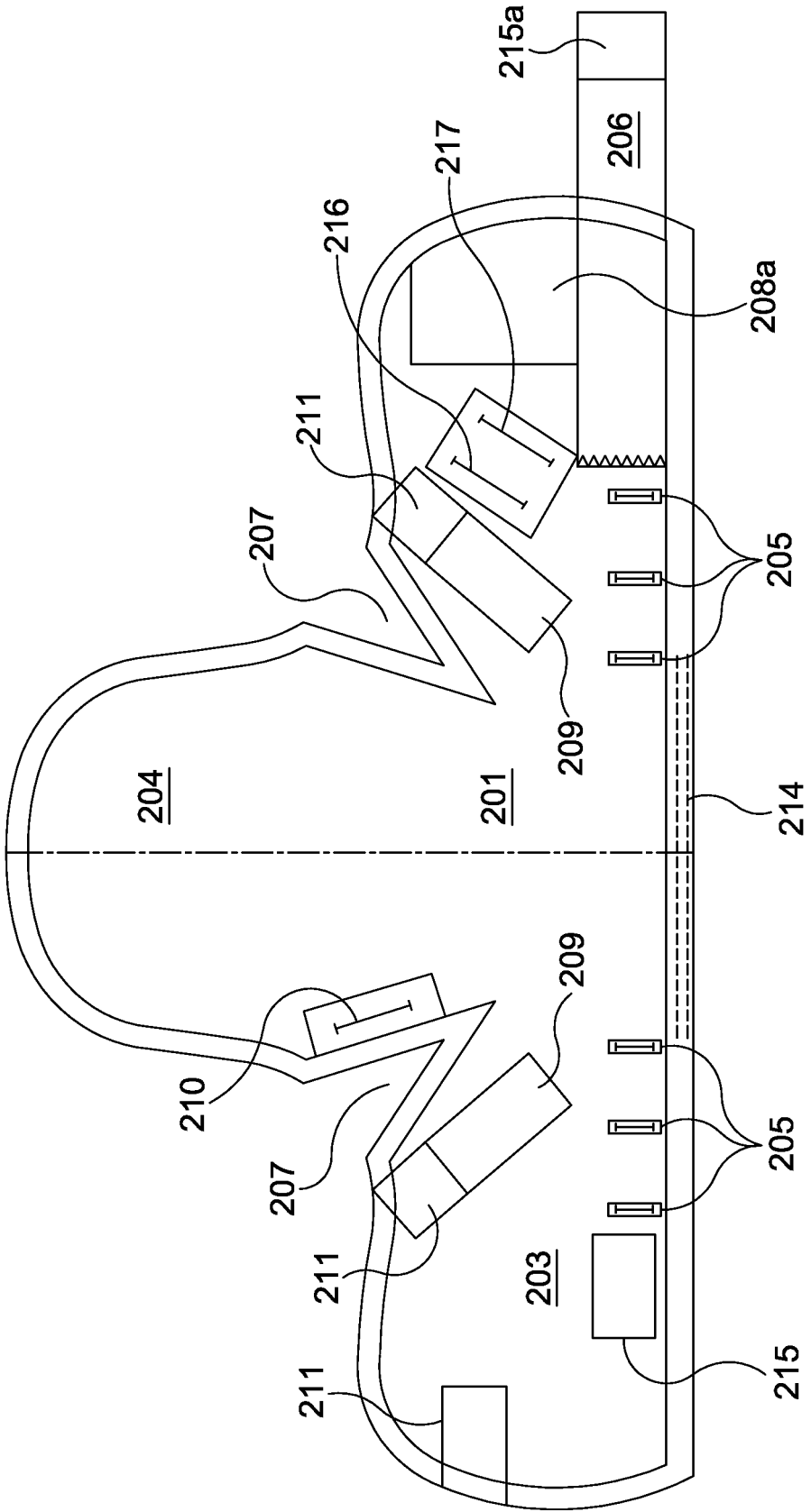


Figure 11

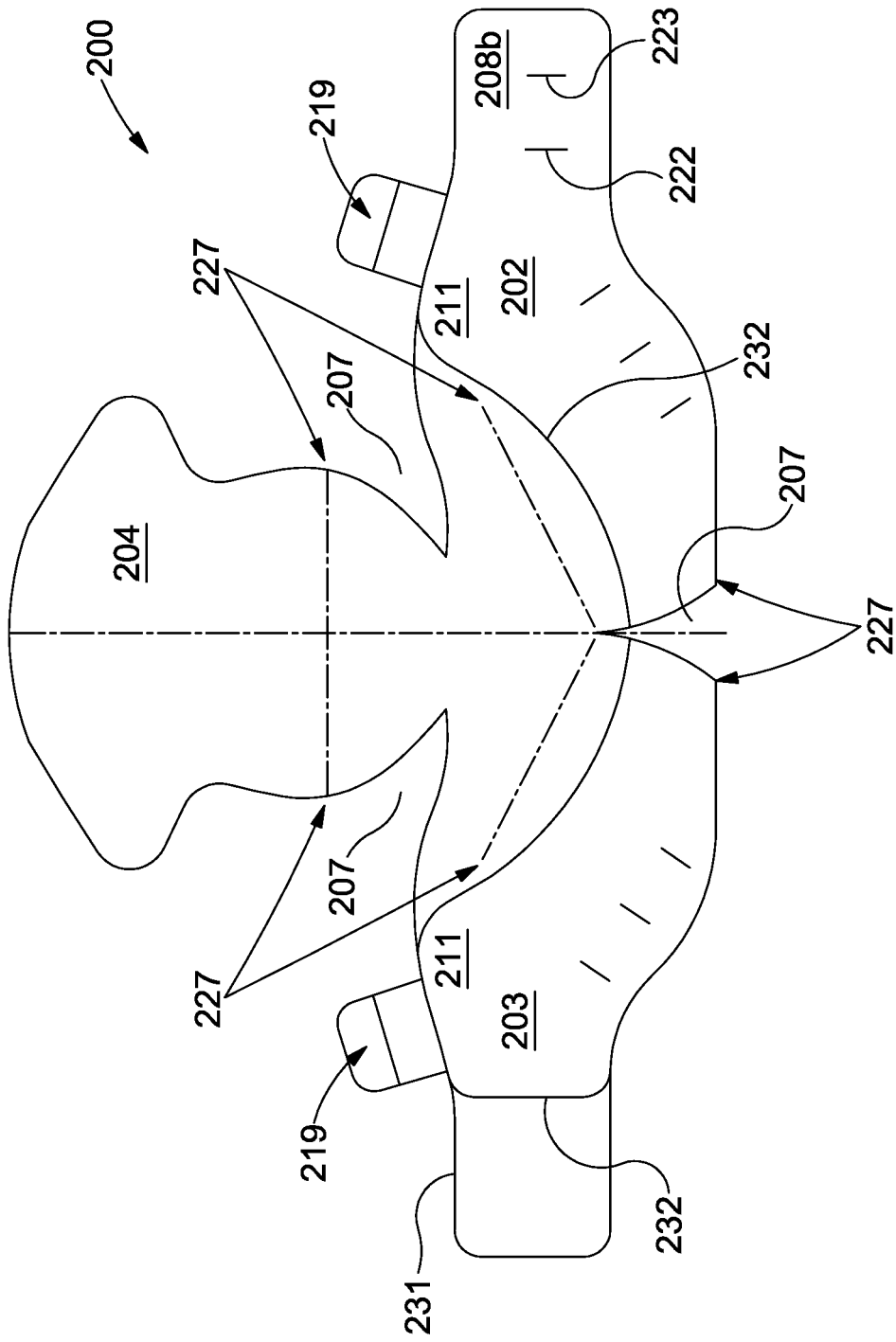


Figure 12

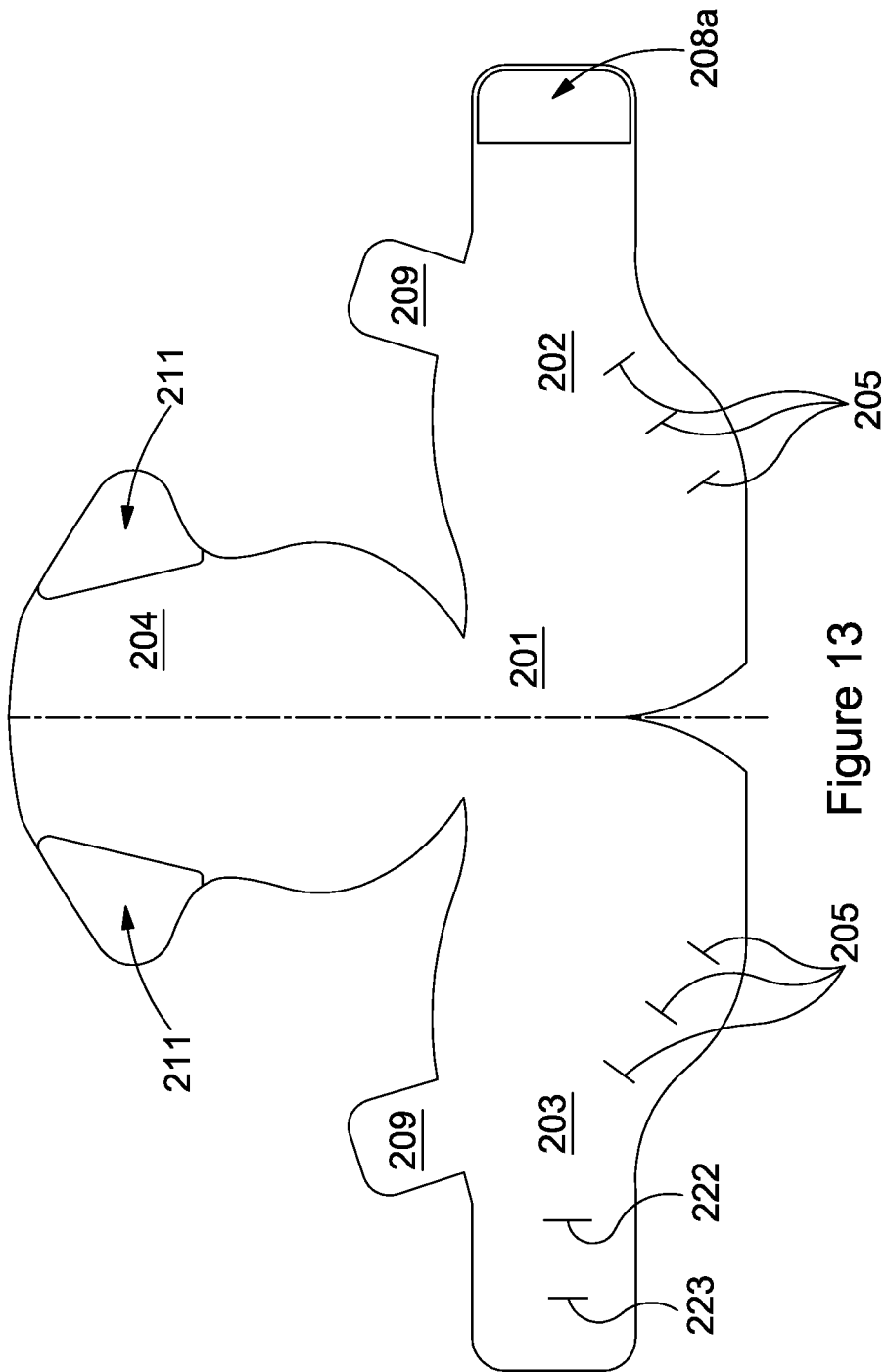


Figure 13

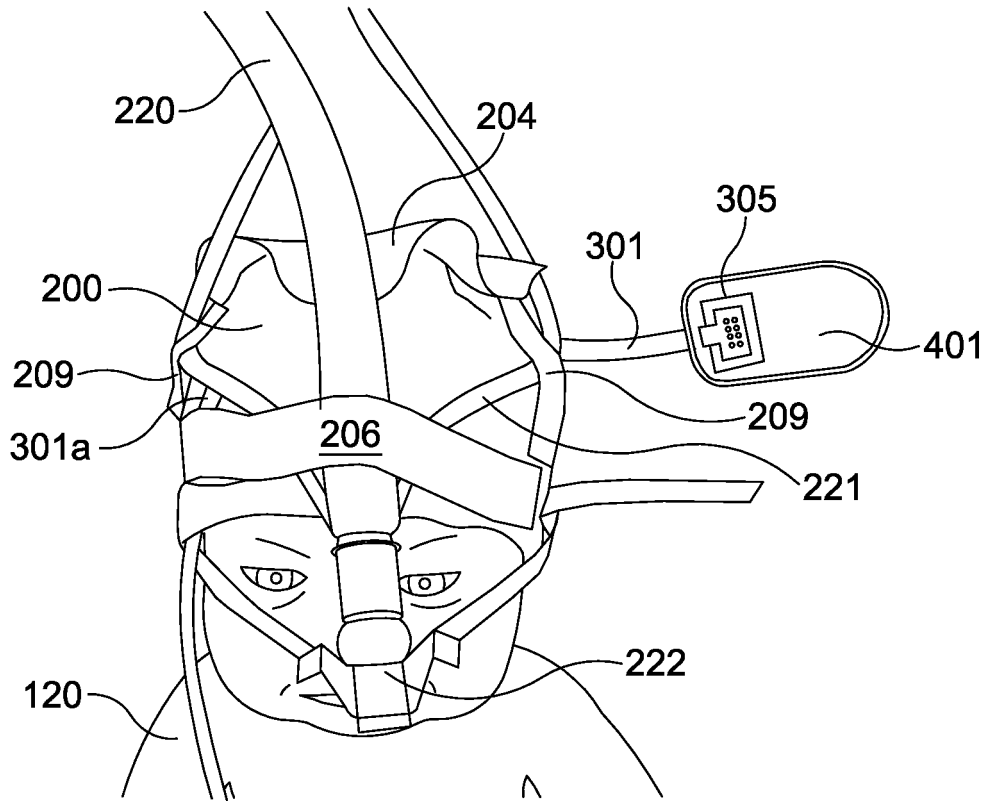


Figure 14

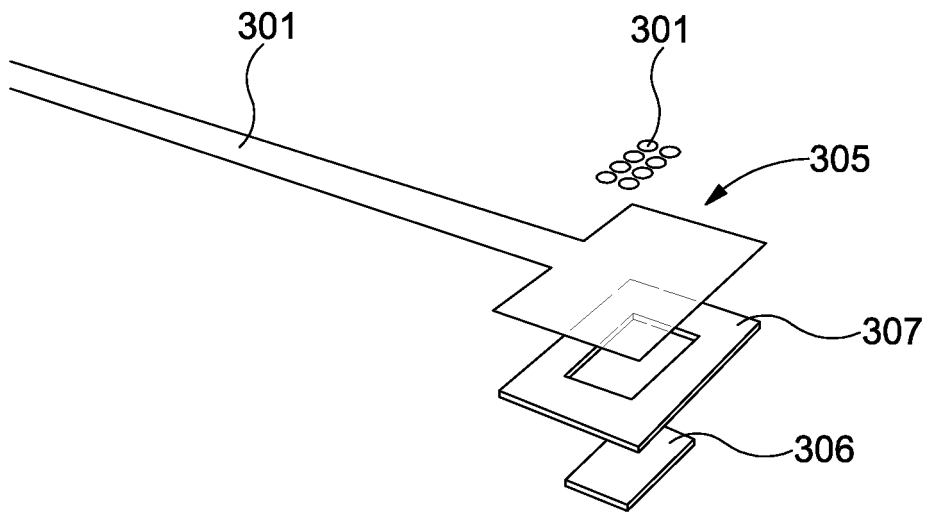


Figure 15

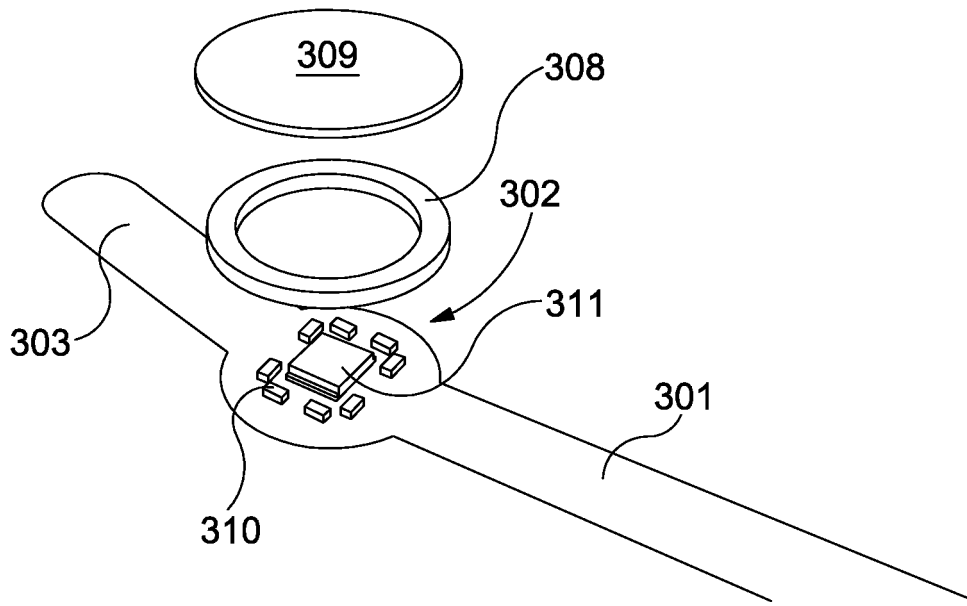


Figure 16

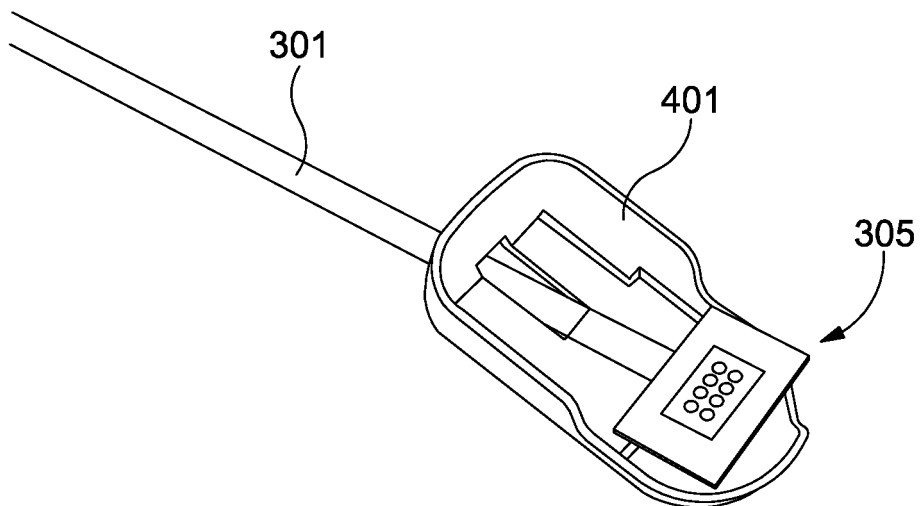


Figure 17

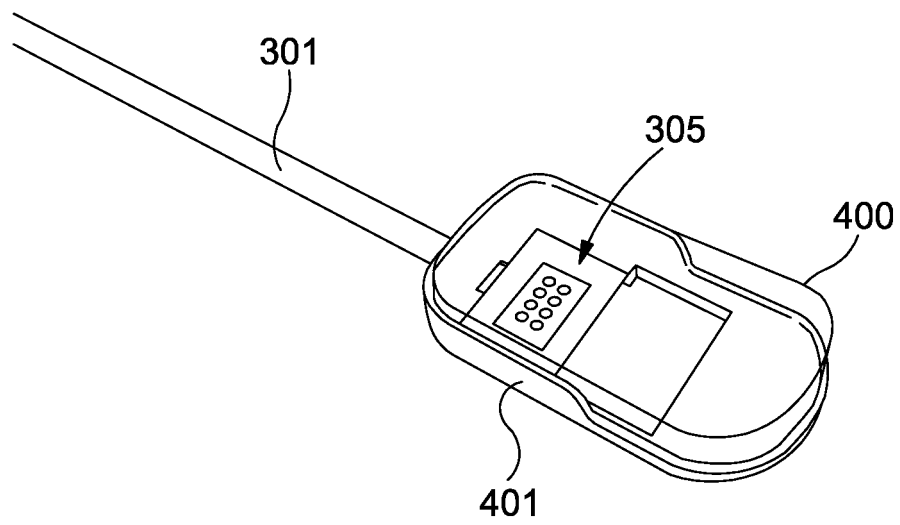


Figure 18

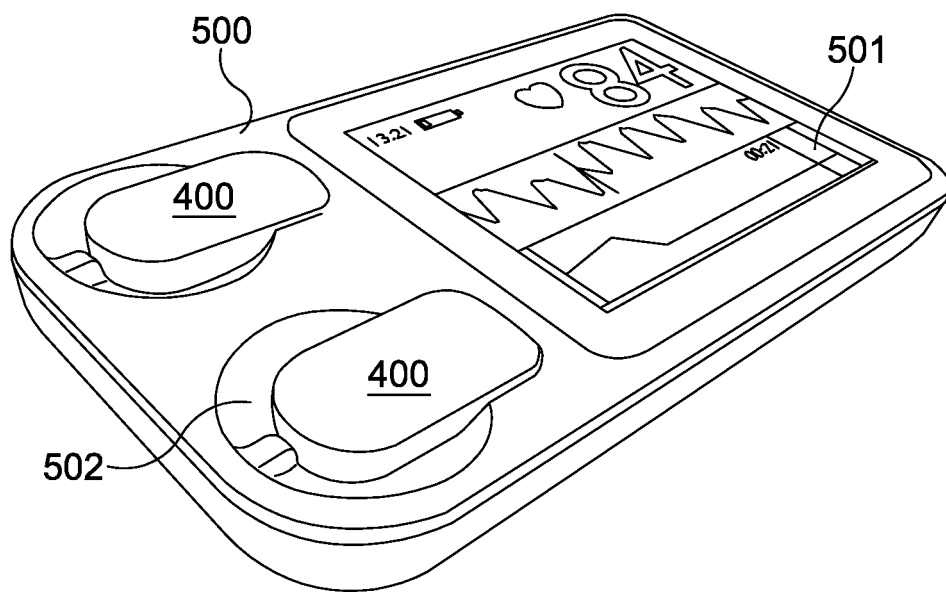


Figure 19

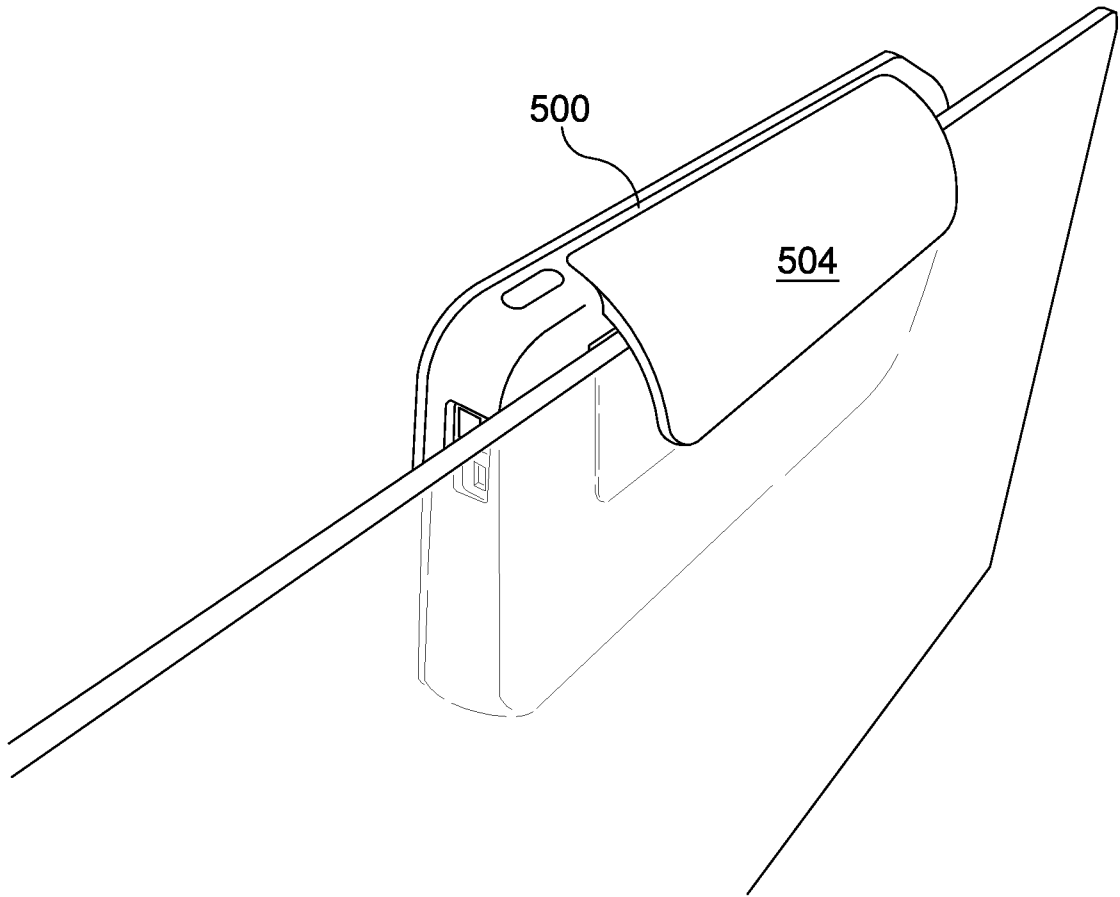


Figure 20

**REFERENCES CITED IN THE DESCRIPTION**

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- US 20040267104 A [0005]
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专利名称(译)	帽子和监控系统		
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申请号	EP2017709774	申请日	2017-03-03
[标]申请(专利权)人(译)	诺丁汉大学		
申请(专利权)人(译)	英国诺丁汉大学		
当前申请(专利权)人(译)	英国诺丁汉大学		
[标]发明人	CARPENTER JAMES HAYES GILL BARRIE HENRY CAROLINE SHARKEY DON SHIPLEY LARA		
发明人	CARPENTER, JAMES HAYES-GILL, BARRIE HENRY, CAROLINE SHARKEY, DON SHIPLEY, LARA		
IPC分类号	A61B5/024 A61B5/00		
CPC分类号	A61B5/02416 A61B5/14553 A61B5/6803 A61B5/6814 A61B2503/045		
代理机构(译)	BARKER BRETTELL LLP		
优先权	2016003793 2016-03-04 GB		
其他公开文献	EP3422932B1		
外部链接	<a href="#">Espacenet</a>		

摘要(译)

用于新生儿 ( 120 ) 的帽子 ( 200 ) , 包括 : 中央部分 ( 201 ) , 第一侧面部分 ( 202 ) 和连接到中央部分 ( 201 ) 相对两侧的第二侧面部分 ( 203 ) , 第一紧固件 ( 208 ) ; 顶盖 ( 204 ) 和第二紧固件 ( 211 ) 。帽子 ( 200 ) 具有展开的构造和磨损的构造。在展开构造中, 第一和第二部分 ( 202、203 ) 从中央部分 ( 201 ) 沿相反的方向彼此远离延伸。在佩戴状态下, 帽子 ( 200 ) 包裹新生儿的头部, 而中央部分 ( 201 ) 与新生儿的头部的后部接触, 第一部分 ( 202 ) 包裹在新生儿头部的第一侧, 第二部分 ( 202 ) 203 包裹在新生儿头部的第二侧。第一部分 ( 202 ) 和第二部分 ( 203 ) 被构造成通过第一紧固件 ( 208 ) 以磨损的形式紧固在一起, 使得第一部分 ( 202 ) , 中央部分 ( 201 ) 和第二部分 ( 203 ) 一起限定帽子 ( 214 ) 的边缘环绕新生儿的头部。顶部襟翼 ( 204 ) 被配置为在佩戴状态下覆盖新生儿的头部的顶部。顶部折板 ( 204 ) 构造成通过第二紧固件 ( 211 ) 紧固到第一, 中央和第二部分 ( 202、201、203 ) 中的至少一个。帽子 ( 200 ) 还包括光学生理传感器, 该光学生理传感器包括: 柔性电路板, 发光器 ( 310 ) 和光检测器 ( 311 ) ; 以及光学传感器。柔性电路板具有: 传感器部 ( 302 ) , 光发射器 ( 310 ) 和光检测器 ( 311 ) 连接到该传感器部。模块部分 ( 305 ) 包括用于将光发射器 ( 310 ) 和光检测器 ( 311 ) 电连接到可移动读出模块 ( 400 ) 的触点 ( 304 ) ; 传感器部分302和模块部分305之间的细长引线部分301。