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(54) **PHYSIOLOGICAL SENSOR COMBINATION**

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(60) Provisional application No. 60/347,047, filed on Jan. 8, 2002.

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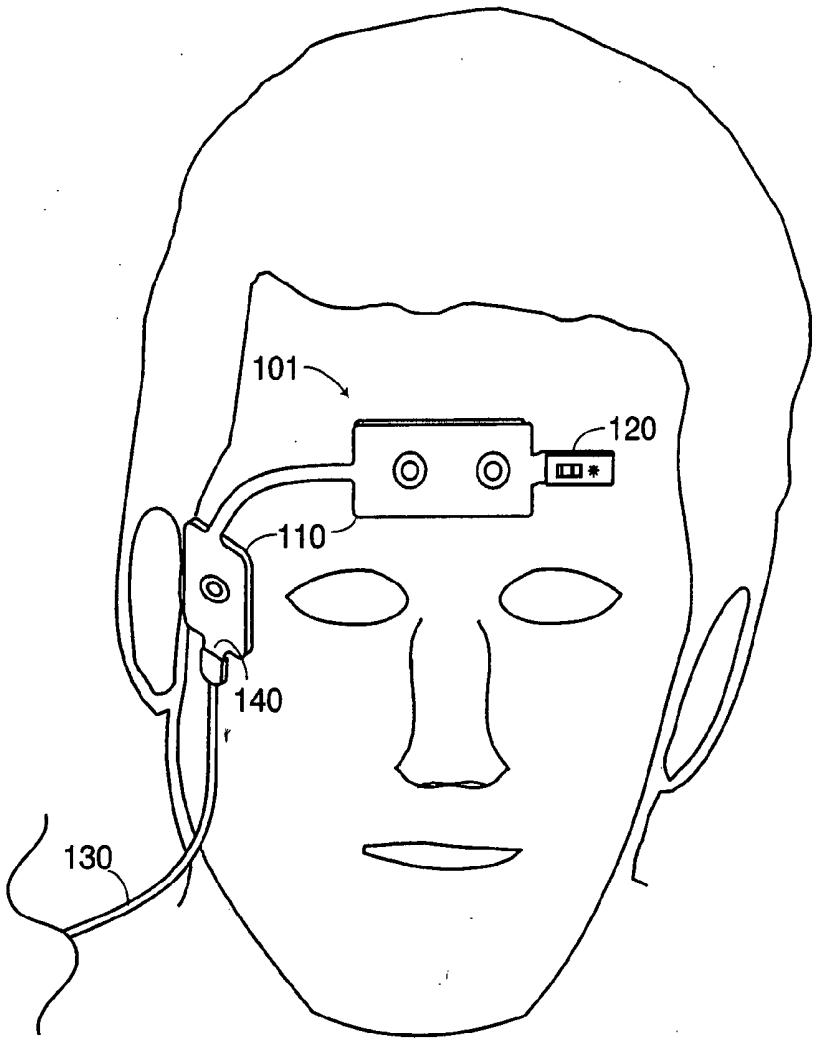
(57) **ABSTRACT**

A physiological sensor combination has a flexible substrate configured to attach to a tissue site. Multiple sensors are disposed on the substrate, which generate physiological signals. Each of the signals is responsive to a different physiological parameter. Conductors are carried on the substrate and routed between the sensors and at least one connector. The connector is configured to communicate the physiological signals to at least one monitor, which derives measurements of the parameters.



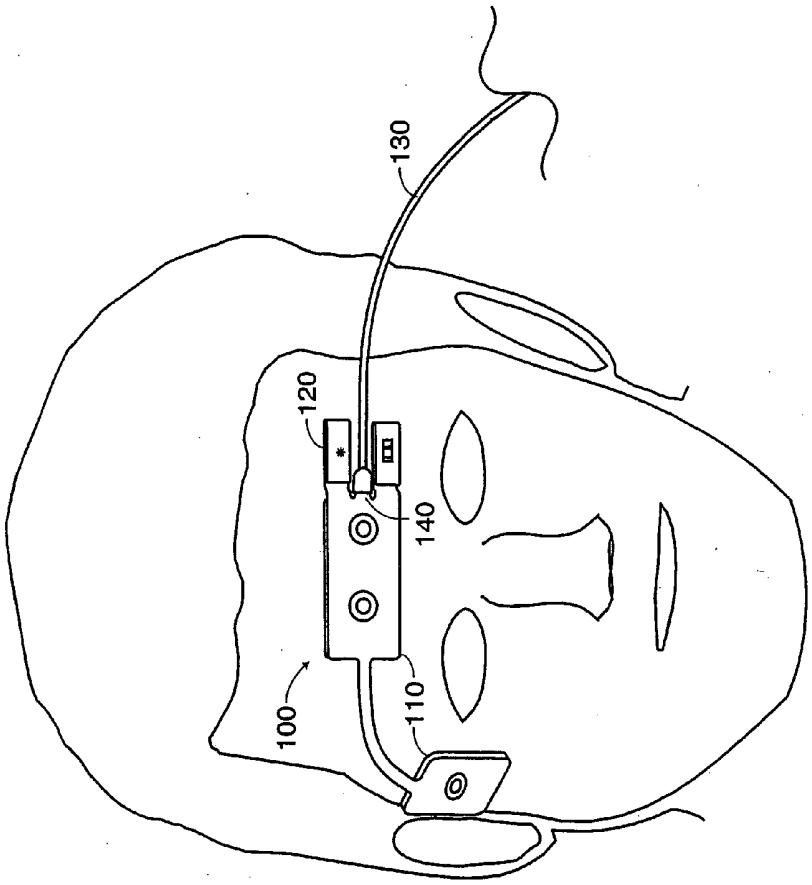


FIG. 1

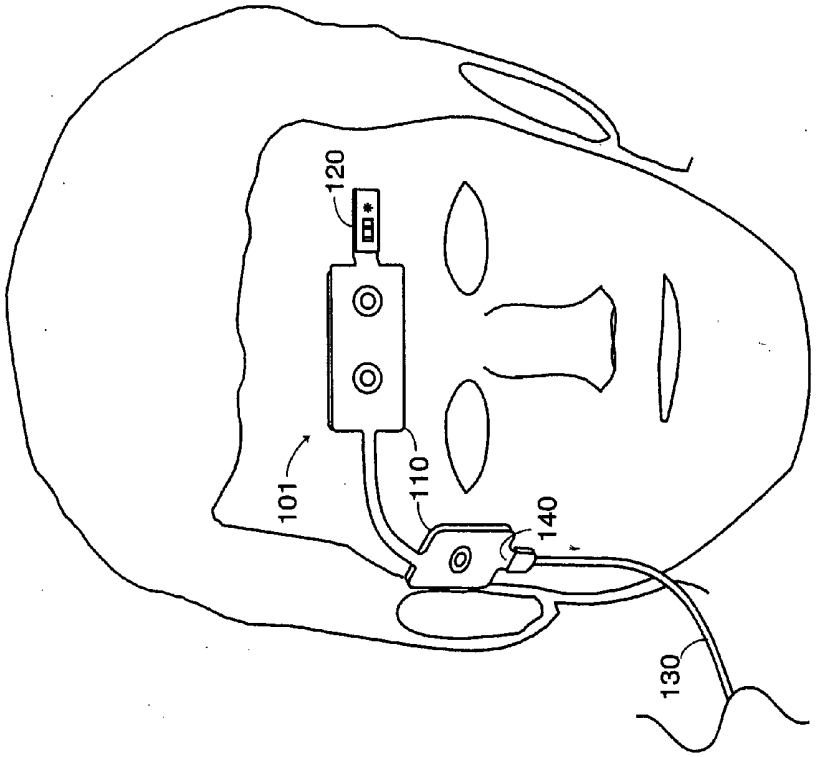


FIG. 2

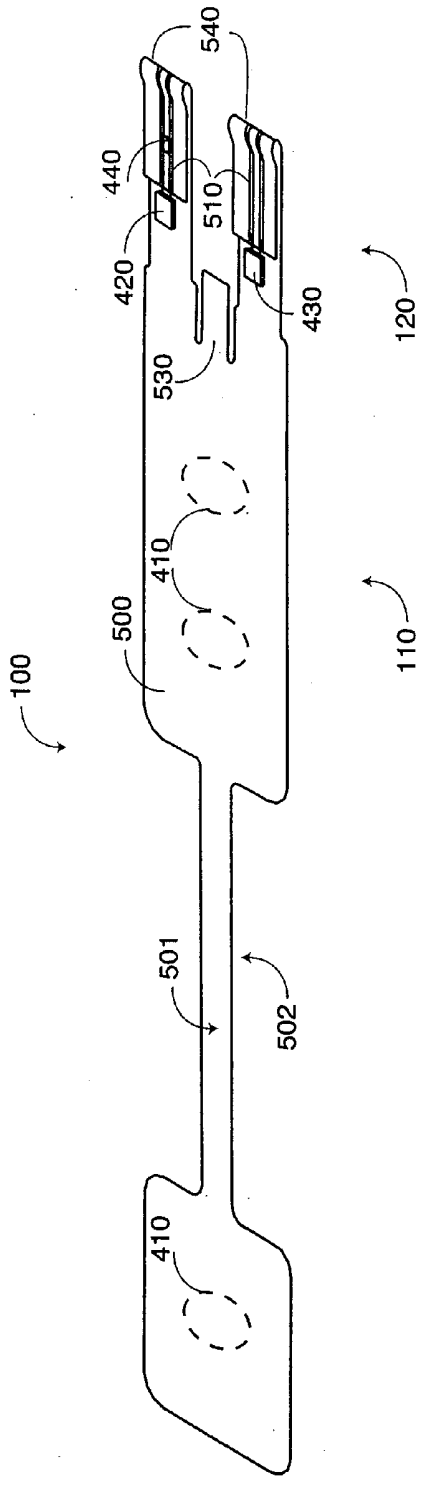

100
110
120
410
420
430
440
500
501
502
510
530
540

FIG. 3A

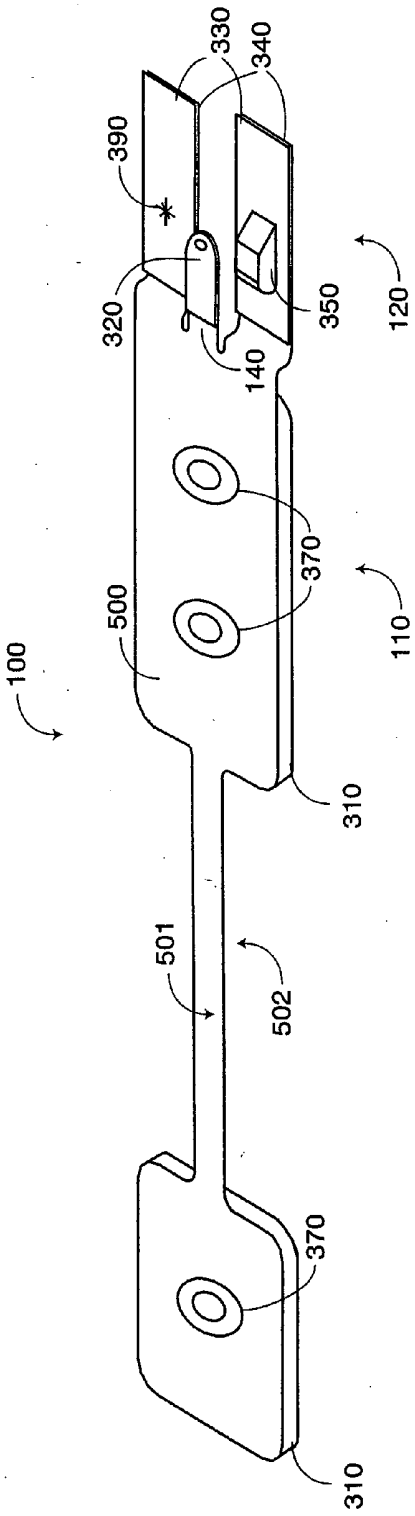

100
110
120
140
310
320
330
340
350
370
390
500
501
502

FIG. 3B

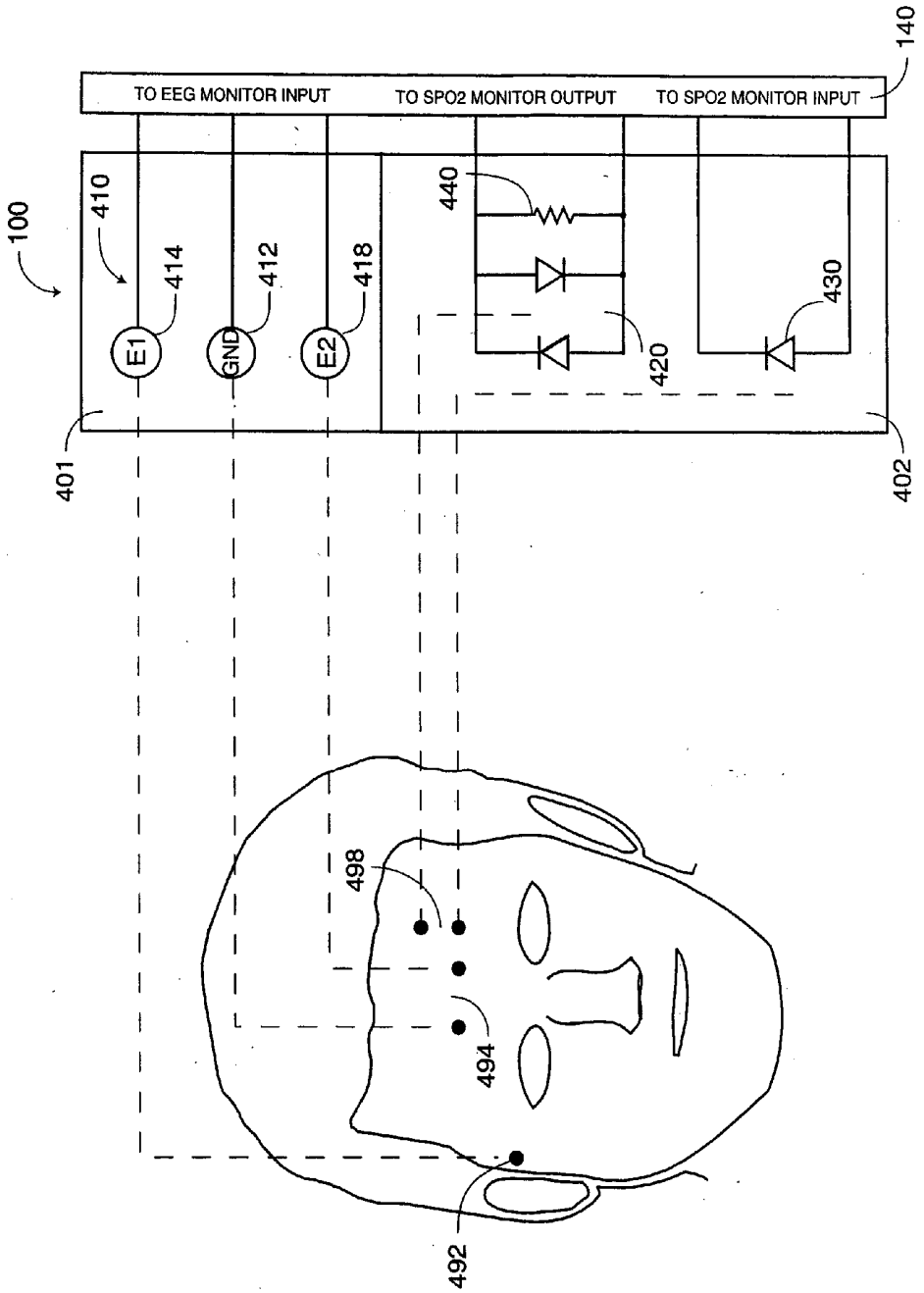

140
TO EEG MONITOR INPUT
TO SPO2 MONITOR OUTPUT
TO SPO2 MONITOR INPUT
100
410
414
412
418
440
430
420
E1
GND
E2
401
402
498
494
492

FIG. 4

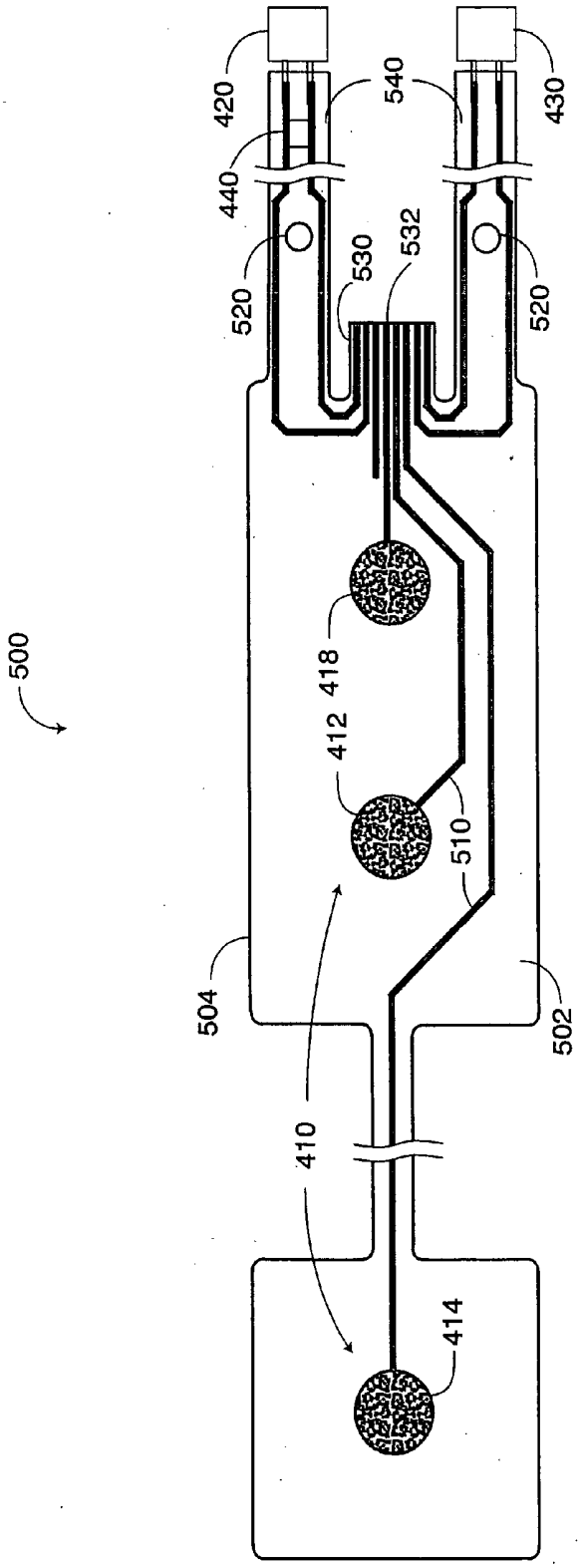


FIG. 5

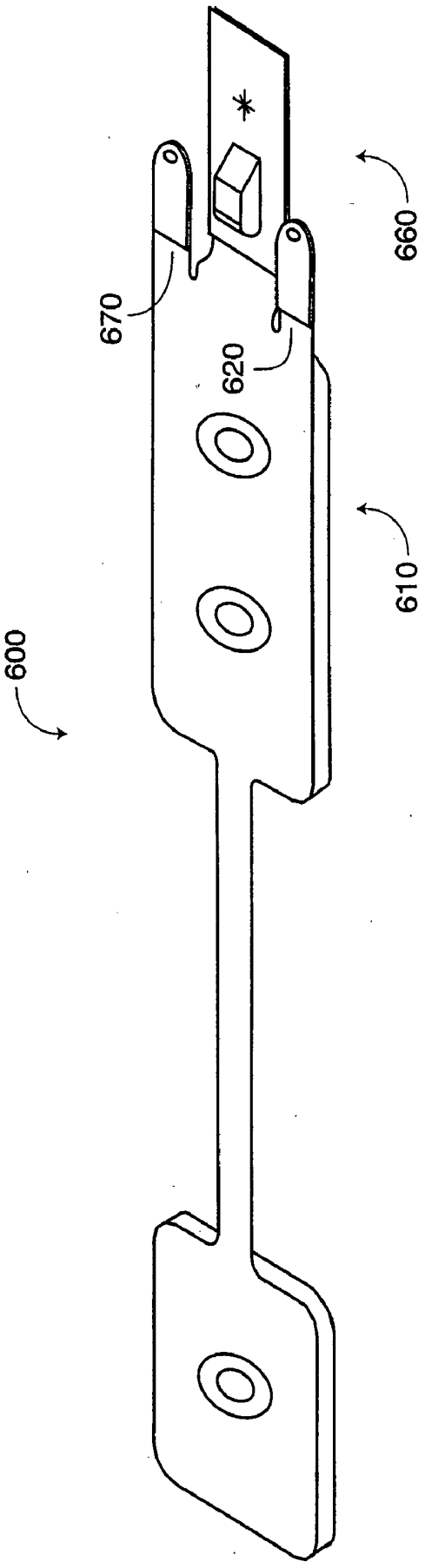


FIG. 6

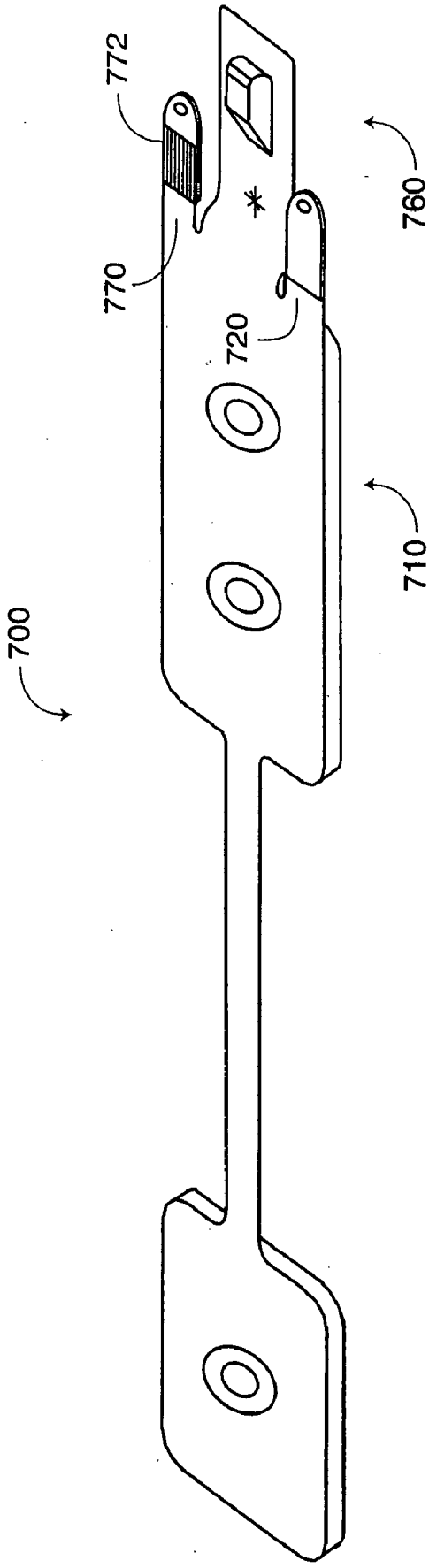


FIG. 7

PHYSIOLOGICAL SENSOR COMBINATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority benefit under 35 U.S.C. § 120 from, and is a continuation of U.S. patent application Ser. No. 10/325,699, filed Dec. 19, 2002, entitled "*Physiological Sensor Combination*," now U.S. Pat. No. 6,934,570, which claims priority benefit under 35 U.S.C. § 119(e) from U.S. Provisional Patent Application No. 60/347,047, filed Jan. 8, 2002, entitled "Physiological Sensor Combination." The present application incorporates the foregoing disclosures herein by reference.

BACKGROUND OF THE INVENTION

[0002] Pulse oximetry is a widely accepted noninvasive procedure for measuring the oxygen saturation level of arterial blood, an indicator of a person's oxygen supply. Early detection of low blood oxygen level is important in the medical field, for example in critical care and surgical applications, because an insufficient supply of oxygen can result in brain damage and death in a matter of minutes. A pulse oximetry system consists of a sensor applied to a patient, a pulse oximeter, and a patient cable connecting the sensor and the pulse oximeter. The pulse oximeter typically provides a numerical readout of the patient's oxygen saturation, a numerical readout of pulse rate, and an audible indication of each pulse. In addition, the pulse oximeter may display the patient's plethysmograph, which provides a visual indication of the patient's pulse contour and pulse rate.

[0003] Measuring a biopotential signal, such as an electroencephalogram (EEG) is also a widely accepted procedure for patient monitoring and diagnostic tests. An EEG measures cortical activity of the brain, which can reflect changes in cortical or subcortical cellular function due to insufficient oxygen or drugs, to name a few. For example, changes in EEG bandwidth and power can provide a measure of the effects of anesthetics on the brain. A biopotential measurement system consists of a bipotential sensor, a monitor and a patient cable connecting the sensor to the monitor. For example, an EEG monitor measures the potential difference between at least two well-spaced electrodes, using a separate ground electrode, and displays the resulting signal.

SUMMARY OF THE INVENTION

[0004] A physiological sensor combination has a flexible substrate configured to attach to a tissue site. Multiple sensors are disposed on the substrate, which generate physiological signals. Each of the signals is responsive to a different physiological parameter. Conductors are carried on the substrate and routed between the sensors and at least one connector. The connector is configured to communicate the physiological signals to at least one monitor, which derives measurements of the parameters. In one embodiment, the sensors comprise multiple electrodes disposed on the substrate. Each of the electrodes is adapted to be in electrical communication with the tissue site and electrically connect to at least one of the conductors. Further, an emitter and a detector are mounted to the substrate and electrically connected to at least one of the conductors. The emitter is adapted to transmit light into the tissue site, and the detector is adapted to receive reflected light from the tissue site.

[0005] In a particular embodiment, the substrate has a first side adapted to face toward the tissue site and a second side adapted to face away from the tissue site, where the conductors and the electrodes are disposed on the first side and the emitter and the detector are mounted to the first side. The substrate may comprise a fold-over portion having a circuit side corresponding to the first side, where the fold-over portion is adapted to fold so that the circuit side is proximate the second side. Further, the emitter and the detector may be mounted to the fold-over portion. The substrate may define at least one aperture configured so that the emitter and the detector each align with a corresponding aperture when the fold- over is in a folded position.

[0006] In another particular embodiment, the physiological sensor combination comprises a plurality of biopotential sensor pinouts corresponding to the electrodes, a plurality of optical sensor pinouts corresponding to the emitter and the detector, and a common connector extending from the substrate. The biopotential sensor pinouts and said optical sensor pinouts are each disposed on the common connector.

[0007] Another aspect of a physiological sensor combination is a substrate means for combining a first sensor and a second sensor, a connector means for communicating signals from the first sensor and the second sensor to at least one monitor, and an identifying means of conveying information about each of the first sensor and the second sensor to the monitor. The physiological sensor combination may further comprise a fold-over means for positioning sensor components so as to extend away from a tissue site. The physiological sensor combination may additionally comprise an aperture means for providing light communications between sensor components and the tissue site.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] **FIG. 1** is an illustration of a physiological sensor combination applied to a patient and having a patient cable connected near the patient's forehead;

[0009] **FIG. 2** is an illustration of a physiological sensor combination applied to a patient and having a patient cable connected near the patient's temple;

[0010] FIGS. **3**A-B are perspective views of a circuit substrate and an assembled sensor, respectively, for a physiological sensor combination having a single-sided circuit substrate and a shared connector;

[0011] **FIG. 4** is a schematic diagram of a physiological sensor combination showing the location of applied sensor components;

[0012] **FIG. 5** is a layout diagram of a single-sided circuit for a physiological sensor combination;

[0013] **FIG. 6** is a perspective view of a physiological sensor combination having a single-sided circuit substrate and dual connectors; and

[0014] **FIG. 7** is a perspective view of a physiological sensor combination having a double-sided circuit substrate and dual connectors.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0015] **FIGS. 1-2** show a physiological sensor combination applied to a patient. **FIGS. 3-5** illustrate a physiological

sensor combination having a biopotential sensor and an optical sensor configured on a single-sided flexible circuit substrate with a shared patient cable connector. **FIG. 6** illustrates a physiological sensor combination also having a biopotential sensor and an optical sensor configured on a single-sided flexible circuit substrate. The biopotential sensor and the optical sensor, however, each have separate patient cable connectors. **FIG. 7** illustrates a physiological sensor combination having a biopotential sensor and an optical sensor configured on a double-sided circuit substrate, each sensor also having separate patient cable connectors.

[**0016**] **FIGS. 1-2** illustrate a physiological sensor combination applied to the forehead and temple areas of a patient. A patient cable **130** connects the physiological sensor combination **100** (**FIG. 1**), **101** (**FIG. 2**) to one or more monitoring devices (not shown). As shown in **FIG. 1**, the patient cable **130** may connect near the patient's forehead. As shown in **FIG. 2**, the patient cable **130** may alternatively connect near the patient's temple. The biopotential sensor **110** and optical sensor **120** may share a common connector **140**. Alternatively, the biopotential sensor **110** and optical sensor **120** may each have a dedicated patient cable connector, as described in further detail with respect to **FIGS. 6-7**, below. The biopotential sensor **110** may be an EEG sensor for depth of consciousness monitoring, as described above. The optical sensor **120** may be a pulse oximetry reflectance sensor for oxygen saturation monitoring, also described above

[**0017**] FIGS. **3**A-B illustrate a physiological sensor combination **100** having a biopotential sensor **110** and an optical sensor **120** configured on a flexible circuit substrate **500**. As shown in **FIG. 3A**, the flexible circuit **500** is single-sided, having a blank side **501** and a circuit side **502** with printed conductive traces **510** on the circuit side **502**. The biopotential sensor **110** has electrodes **410** (not visible and shown as dashed lines) printed on the circuit side **502**. The electrodes **410** are configured so that one electrode is applied to the temple area and two electrodes are applied to the forehead, as further described with respect to **FIGS. 4-5**, below.

[**0018**] Further shown in **FIG. 3A**, the optical sensor **120** includes a fold-over **540**, an emitter **420**, a detector **430** and an information element **440**. The emitter **420**, detector **430** and information element **440** are each mounted to the circuit side **502** on the fold-over **540** and electrically connected to traces **510**, as described in detail with respect to **FIGS. 4-5**, below. The optical sensor **120** is configured so that emitter **420** and a detector **430** are applied over the forehead, also described with respect to **FIGS. 4-5**, below. The fold-over **540** is such that each of the emitter **420** and detector **430** align with corresponding apertures **520** (**FIG. 5**) so that light transmitted from the emitter **420** passes through an aperture **520** (**FIG. 5**) and into a patient's skin and that reflected light passes out of a patient's skin, through an aperture **520** (**FIG. 5**) and is received by the detector **430**. The substrate **500** has a stub **530** that contains pinouts **532** (**FIG. 5**), which connect to the electrodes **410** and also to the emitter **420**, detector **430** and information element **440**, also described in detail with respect to **FIGS. 4-5**, below. Emitters and a detector for a pulse oximetry sensor are described in detail in U.S. Pat. No. 6,256,523 entitled "Low Noise Optical Probe," which is assigned to Masimo Corporation and incorporated by reference herein. An information element for a pulse oximetry sensor is described in detail in U.S. Pat. No. 6,001,986 entitled "Manual And Automatic Probe Calibration," which is assigned to Masimo Corporation and incorporated by reference herein.

[**0019**] As shown in **FIG. 3B**, the biopotential sensor **110** has an adhesive foam layer **310** disposed around the electrodes **410** on the circuit side **502**. The foam layer **310** has an adhesive for patient skin attachment and cushions the biopotential sensor **110** against the skin. Further, the foam layer **310** forms cavities around the electrodes **410** that are filled with a conductive gel for electrical communication between a tissue site and the electrodes **410**. Printed electrode indicators **370** facilitate sensor application on a tissue site. Electrodes printed on a substrate, an associated foam layer, and gel-filled foam cavities are described in detail in U.S. Pat. No. 6,032,064 entitled "Electrode Array System For Measuring Electrophysiological Signals," assigned to Aspect Medical Systems, Inc. and incorporated by reference herein. One of ordinary skill in the art will recognize that various electrode configurations may be utilized as the biopotential sensor **110**.

[**0020**] Also shown in **FIG. 3B**, the optical sensor **120** has a face tape **330** and a base tape **340** that envelop the fold-over **540** along with the fold-over mounted components **420-440**. In one embodiment, the face tape **330** and base tape **340** attach together and to the fold-over **540** with PSA. Further, the base tape **340** has a backing (not shown) that is removed to expose an adhesive for skin attachment. The face tape **330** also secures the detector **430** within an optical cavity and cover **350**. A printed emitter indicator **390** facilitates sensor application on a tissue site. Emitters, detectors, optical cavities and corresponding covers are described in detail in U.S. Pat. No. 6,256,523, referenced above.

[**0021**] Further shown in **FIG. 3B**, the physiological sensor combination **100** has a tab **320** that attaches to the stub **530** (**FIG. 3A**) to complete the connector **140**. In one embodiment, the attachment is accomplished with pressure sensitive adhesive (PSA) between the tab **320** and stub **530**. The tab **320** provides a stiffener for the pinouts **532** (**FIG. 5**) and an insertion and locking mechanism for a mating patient cable connector, as described in U.S. Pat. No. 6,152,754 entitled "Circuit Board Based Cable Connector" and U.S. Pat. No. 6,280,213 entitled "Patient Cable Connector," each assigned to Masimo Corporation and incorporated by reference herein.

[**0022**] The physiological sensor combination **100** is described above with respect to a fold-over that positions the optical sensor components **420-440** so that they extend away from the tissue site. This advantageously allows a smooth surface to be positioned against the tissue site for patient comfort. In another embodiment, however, there is no fold-over **540** and the components **420-440** extend from the substrate toward the tissue site. In yet another embodiment, there is no fold-over and the components **420** are mounted on the substrate side opposite the conductors and utilize substrate feed-throughs to connect with the flex circuit traces **510**. Further, the fold-over **540** is described above as positioning the emitter **420** and detector **430** over substrate apertures **520** (**FIG. 5**). In an alternative embodiment, the fold-over **540** is skewed so that the emitter **420** and detector **430** are positioned away from the substrate so that no apertures are necessary.

[0023] **FIG. 4** illustrates a circuit diagram for a physiological sensor combination **100** having a biopotential sensor circuit **401** and an optical sensor circuit **402**. The biopotential sensor circuit **401** has an electrode array **410**, which is placed on well-separated skin areas. In one embodiment, a first electrode **414** is placed on a temple area **492** and a second electrode **418** is placed on a forehead area **494**. A ground electrode **412** is also placed on the forehead area **494** near the second electrode **418**. Each electrode of the array **410** provides a pinout to a connector **140**. The connector **140** provides sensor input to a monitor. The electrodes placed on the patient's head transmit EEG signals to a monitor, which may include a separate digitizer located near the patient to reduce electrical noise. The difference in potential between the first electrode **414** and second electrode **418** reflects primarily a far-field electrical source, i.e. the EEG from the distant brain cortex, and not a near-field electrical source, such as transdermal nervous stimulation of muscle. The monitor filters the EEG data, analyzes it for artifact and extracts characteristic features from the complex signal to provide pattern recognition of changes over time.

[0024] Also shown in **FIG. 4**, the optical sensor circuit **402** has an emitter **420**, a detector **430** and an information element **440**. The emitter **420** includes both a red LED (light emitting diode) and an infrared (IR) LED in a back-to-back arrangement. In alternative embodiments, the red and IR LEDs are arranged in three-wire, common anode or common cathode configurations, as is well-known in the art. The detector **430** is a photodiode. The LEDs **420** and photodiode **430** are located on the skin in close proximity, such as on a forehead area **498**. In this manner, the LEDs emit light into the blood vessels and capillaries underneath the skin, and the photodiode **430** is positioned to detect the LED emitted light reflected from the skin tissues. The emitter **420** and detector **430** provide pinouts to the connector **140**, which provides a sensor input to a monitor. The monitor determines oxygen saturation by computing the differential absorption by arterial blood of the two wavelengths of light projected into the skin from the emitter **420**, as is well- known in the art. The monitor provides LED drive current, which alternately activates the red and IR LEDs. The detector **430** uses a single photodiode that responds to both the red and infrared emitted light and generates a time-division-multiplexed ("modulated") output signal to the monitor, corresponding to the red and infrared light energy attenuated by absorption and reflection from the patient's tissue. The monitor has front-end circuitry for amplification, filtering and digitization of the detector signal. The monitor also has a signal processor that calculates a ratio of detected red and infrared intensities, and an arterial oxygen saturation value is empirically determined based on that ratio.

[0025] Further shown in **FIG. 4**, the optical sensor circuit **402** may have an information element **440**, such as a resistor configured in parallel with the emitter **420** LEDs. The information element **440** can be read by the monitor and used to determine such things as LED wavelength, sensor type or manufacturer. Information elements and monitor reading of information elements are described in U.S. Pat. No. 6,011,986, referenced above. Advantageously, although associated with the optical sensor circuit **402**, the information element **440** can be used to designate information regarding the biopotential sensor portion of the physiological sensor combination **100**. For example, the information element **440** can specify the number of electrodes as well as the electrode locations on the head.

[0026] **FIG. 5** illustrates a flexible circuit **500** for a physiological sensor combination **100**. The flexible circuit **500** has a substrate **504**, traces **510**, electrodes **410**, pinouts **530** and apertures **520**. Conductors are deposited and/or etched on a circuit side **502** of the substrate **504** in a pattern to form the traces **510**, electrodes **410** and pinouts .**532**, as is well known in the art. In one embodiment, the substrate **504** is a flexible polyester film and the conductors are silver/silver-chloride. In another embodiment, the conductors are copper. The components **420-440** attach to the flexible circuit **500** and are electrically connected to the traces **510**, such as with solder. The fold-over **540** is configured so that the emitter **420** and detector **430** align with the corresponding apertures **520**.

[0027] **FIG. 6** illustrates a physiological sensor combination **600** having a biopotential sensor **610** and an optical sensor **660**. The biopotential sensor **610** is configured as described with respect to **FIGS. 3-5**, above, except that the physiological sensor combination **600** has a connector **620** that is dedicated to the biopotential sensor **610** rather than being shared with the optical sensor **660**. The optical sensor **660** also is configured as described with respect to **FIGS. 3-5**, above, except that a connector **670** is dedicated to the optical sensor **660** rather than being shared with the biopotential sensor **610**. Further, the optical sensor **660** has a single fold-over (not visible) on which is mounted the emitter **420** (**FIG. 4**) and detector **430** (**FIG. 4**) rather than having a separate fold-over **540** (**FIG. 3A**) for each.

[0028] **FIG. 7** illustrates a physiological sensor combination **700** having a biopotential sensor **710** and an optical sensor **760**. The biopotential sensor **710** is configured as described with respect to **FIG. 6**, above. The optical sensor **760** also is configured as described with respect to **FIG. 6**, above, except that the flexible circuit **500** (**FIG. 5**) is double-sided, i.e. the traces **510** (**FIG. 5**) associated with the biopotential sensor **710** are on the side facing the patient's skin when applied, and the traces **510** (**FIG. 5**) associated with the optical sensor **760** are on the side away from the patient's skin when applied. As a result, the connector **770** is dedicated to the optical sensor **760** and has pinouts **772** facing away from the patient's skin when applied. Further, the optical sensor **760** does not have a fold-over **540** (**FIG. 3A**). Rather, the optical sensor components **420-440** (**FIG. 4**) are mounted on the flexible circuit side away from the patient's skin.

[0029] A physiological sensor combination is described above with either a shared patient cable connector or a patient cable connector dedicated to each sensor. One of ordinary skill will recognize that either connector configuration will allow the sensor to communicate with a single monitor that analyzes and displays multiple physiological parameters or, alternatively, multiple monitors that are dedicated to analyzing only related physiological parameters, such as oxygen saturation and pulse rate.

[0030] The physiological sensor combination as described above can be cost effectively manufactured, advantageously allowing disposable use. One of ordinary skill in the art will recognize that, however, that the physiological sensor combination as disclosed herein can be similarly applied to construct a reusable sensor combination.

[0031] The physiological sensor combination was also described above with respect to a shared substrate. One of ordinary skill in the art will recognize that a physiological sensor combination can be constructed from, for example, a biopotential sensor configured on a first substrate and an optical sensor configured on a second substrate, where the first substrate and the second substrate are joined together during the manufacturing process to form a multilayer substrate or an otherwise integrated substrate incorporating multiple sensors.

[0032] Although a physiological sensor combination is described above with respect to a biopotential sensor combined with an optical sensor applied to a patient's head, one of ordinary skill in the art will recognize that a physiological sensor combination may be applied to other tissue sites and utilize other sensor combinations, where there is a need to combine two or more sensors in one to accommodate sensors competing for the same tissue site. For example, a physiological sensor combination may include a noninvasive blood pressure (NIBP) sensor and a pulse oximetry sensor or a NIBP sensor and a respiration rate sensor for monitoring on the forearm or the wrist. As another example, a physiological sensor combination may include two optical sensors and one biopotential sensor applied to the forehead and configured as a pulse oximetry sensor and a EEG sensor, as described above, in addition to a near infrared spectroscopy sensor for measuring cerebral tissue oxygenation.

[0033] A biopotential sensor as described above could be used in conjunction with a depth of anesthesia monitor that uses not just passive EEG, but also active EEG. That is an Evoked Potential EEG can be used, where some kind of sound is played and changes in EEG are observed as the patient goes into consciousness.

[0034] A physiological sensor combination has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

What is claimed is:

1. A physiological sensor combination comprising:

a flexible substrate configured to attach to a tissue site;

a plurality of sensors adapted to provide a corresponding plurality of physiological signals, each of said physiological signals responsive to at least one of a plurality of physiological parameters, wherein at least a first sensor of said plurality of sensors provides a physiological signal responsive to at least one parameter different from a second sensor of said plurality of sensors; and

an information element, accessible by a physiological monitor, adapted to provide said physiological monitor information about each of said plurality of sensors.

2. The physiological sensor combination of claim 1, wherein said first sensor comprises a noninvasive blood pressure sensor.

3. The physiological sensor combination of claim 1, wherein said first sensor comprises a pulse oximetry sensor.

4. The physiological sensor combination of claim 1, wherein said first sensor comprises a biopotential sensor.

5. The physiological sensor combination of claim 1, wherein said first sensor comprises a respiration rate sensor.

6. The physiological sensor combination of claim 1, wherein said first sensor comprises at least one of a noninvasive blood pressure sensor, a pulse oximetry sensor, a respiration rate sensor or a biopotential sensor, and said second sensor comprises another of said noninvasive blood pressure sensor, said pulse oximetry sensor, said respiration rate sensor or said biopotential sensor.

7. The physiological sensor combination of claim 1, further comprising a plurality of conductors between said first sensor, said second sensor, and one connector, wherein said one connector is configured to communicate said physiological signals to said physiological monitor for determination of a plurality of measurements of said physiological parameters.

8. The physiological sensor combination of claim 7, wherein at least said first sensor an at least some of said conductors are disposed on said flexible substrate.

9. The physiological sensor combination of claim 8, wherein at least said second sensor is disposed on said flexible substrate.

10. The physiological sensor combination of claim 1, further comprising a plurality of conductors between said first sensor and a first connector and another plurality of conductors between said second sensor and a second connector, wherein said first connector is configured to communicate physiological signals to or from said first sensor and said second connector is configured to communicate physiological signals to or from said second sensor.

* * * * *

专利名称(译)	生理传感器组合		
公开(公告)号	US20050277819A1	公开(公告)日	2005-12-15
申请号	US11/210128	申请日	2005-08-23
[标]申请(专利权)人(译)	Kiani曾MASSIê AL ALI AMMAR COVERSTON RONALD MASON基因 ROBERTSON FRED		
申请(专利权)人(译)	Kiani曾MASSIê AL-ALI AMMAR COVERSTON RONALD MASON基因 ROBERTSON FRED		
当前申请(专利权)人(译)	摩根大通银行，NATIONAL ASSOCIATION		
[标]发明人	KIANI MASSI E AL ALI AMMAR COVERSTON RONALD MASON GENE ROBERTSON FRED		
发明人	KIANI, MASSI E. AL-ALI, AMMAR COVERSTON, RONALD MASON, GENE ROBERTSON, FRED		
IPC分类号	A61B5/00 A61B5/0478 A61B5/04 A61B5/02		
CPC分类号	A61B5/0478 A61B2562/164 A61B5/6814 A61B5/14552		
优先权	60/347047 2002-01-08 US		
其他公开文献	US9364181		
外部链接	Espacenet USPTO		

摘要(译)

生理传感器组合具有柔性基底，其配置成附接到组织部位。多个传感器设置在基板上，其产生生理信号。每个信号响应于不同的生理参数。导体承载在基板上并在传感器和至少一个连接器之间布线。连接器被配置为将生理信号传送到至少一个监视器，该监视器导出参数的测量值。