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(54) **SINGLE USE PULSE OXIMETER**

PULSOXIMETER ZUR EINMALIGEN VERWENDUNG

SPHYGMO-OXYMETRE A USAGE UNIQUE

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EP 1 948 010 B1

## Description

### Field of the Invention

**[0001]** The present invention relates to oximeters and more particularly to a single use oximeter that is self-contained in a patch, such as for example a self-adhesive bandage. The present invention further relates to a disposable patch oximeter having telecommunication capabilities.

### Background of the Invention

**[0002]** Oximeters are well known. Prior to the instant invention, self-contained oximeters come in the form of bulky housings that clip onto the finger of a patient, such as that disclosed in U.S. patent 5,792,052. Another example of a self-contained oximeter is that disclosed in U.S. patent 6,654,621, assigned to the assignee of the instant application. In these prior art self-contained finger oximeters, electronics are contained in housings that pivotally grasp the finger of a patient ('052 patent) or a housing that forms an opening to which the finger of the patient is inserted ('621 patent). Once the oxygen saturation level of the patient is determined, these finger oximeters may be removed from the patient and used on other patients, as these finger oximeters are reusable devices.

**[0003]** There is also in the market a bandage that has embedded therein the light emitter and sensor of an oximeter. The electronics for operating the light emitter and sensor and to which the bandage is connected is located remotely from the bandage. This device is disclosed in U.S. patents 6,735,459, 6,721,585, 6,684,091, 6,519,487, 6,343,224, 6,321,100 and 5,144,868. Only the bandage is disposable in this device.

**[0004]** US 5,511,553 discloses a device, system and method for monitoring continuously and simultaneously multiple physiological parameters from a patient, comprising a precordial strip-patch having first and second surfaces and multi-layer flexible structure permitting telemetering data. US 2005/131,288 discloses an apparatus and method for the transduction, acquisition, and processing of physiologic variables. The apparatus is a self-contained, patient-worn device consisting of a flexible substrate, a transduction means, a power generation means, and a signal acquisition and processing means, and a data transmission means.

**[0005]** DE100 15 928 A1 discloses a carrier of a medicament or some other active substance administrable to its recipient via skin comprising a protective layer which is provided with an electric conductor strip running over a separable section of the protective layer.

### Summary of the Present Invention

**[0006]** A first aspect of the invention provides a one piece self-contained disposable patch, as defined in claim 1.

**[0007]** The present invention is a self-contained, fully disposable, single use pulse oximeter that activates when the backing paper for its adhesive is peeled off. All of the components for the oximeter are mounted, integrated, or embedded to a multi-layered patch, or bandage. In addition to the light or radiation emitter that outputs a multifrequency light to the patient, be it the digit or the forehead of the patient, and the sensor or detector that senses the light passing through, or reflecting from, the patient for obtaining data from the patient and then calculating the oxygen saturation level of blood (SpO2) from the acquired data, the other components for the pulse oximeter are also mounted to the patch. This includes the oximetry circuitry, an optional display, an optional alarm possibly in the form of a piezoelectric transducer (audible) and/or an optical indicator on the display (visual) and the power source. The circuitry may be integrated to an application specific integrated circuit (ASIC) platform or chip, and is embedded to a layer of the bandage that is protected by at least two thin barrier layers that are immune to moisture and prevent the ASIC from being exposed to the environment. The power source may be a thin conventional button battery, or a fuel cell battery, that may also be embedded in the same layer as the ASIC chip. The same layer of the bandage may also include the optional display and alarm. Alternatively, the display and the alarm may be formed at a layer of the bandage that is above the ASIC platform layer and beneath a protective membrane layer that may include preprinted graphics. Membrane switches may also be provided under the protective membrane to provide the user the capability to activate a limited number of functions, as for example turning on/off the alarm and/or display.

**[0008]** The bandage is a sterile bandage with a peel off sheet covering its lower most adhesive layer that allows the bandage to be removably attached to the patient. To provide additional sterility, the bandage may be stored or housed in a sterile package that may have a removable cover.

**[0009]** The light emitter and detector are positioned onto the patch depending on whether the patch is to be used in a transmissive mode in which the patch, or bandage, is wrapped around a digit or an earlobe of a patient, or in a reflective mode whereby the patch is adhesively secured to the forehead, or another substantially flat surface, of the patient.

**[0010]** For the patch oximeter of the instant invention the most convenient way in which to attach the bandage to the patient is by means of an adhesive layer, as is conventionally done in conventional bandages that are used to cover cuts on an individual. However, other attachment mechanisms may also be used for the instant invention patch oximeter or bandage. Such attachment mechanisms may include for example velcro or snaps that would allow the bandage to be securely attached to the patient. Instead of a full layer of adhesive, only portions of the lower most layer of the bandage need to be

provided with the adhesive in order to enable the bandage to be removably attachable to a patient.

**[0011]** Electrodes may also be added to the bandage oximeter of the instant invention, so that physiological parameters other than the oxygen saturation level of the arterial blood of the patient, for example EEG, ECG, EKG, etc., may be obtained from the patient, at the same time that the SpO2 is being obtained from the patient. For measuring additional physiological parameters from the patient, additional electronics that enable the patch oximeter to perform additional measurement functions are either integrated to the ASIC circuit, or mounted to the electronics layer of the patch as separate additional circuits.

**[0012]** A power source remote from the patch, which would supply power to the patch when the patch comes within a predetermined or given distance from the remote power source, may be used. For this radio frequency identification (RFId) equipped embodiment, an antenna coil, as well as an RF power receiver, are added to the oximeter patch, so that power may be retrieved from the remote power source when the bandage comes within communication distance from the remote power source. For this embodiment, the display and/or the alarm may not be needed on the patch.

**[0013]** The present invention is therefore a one-piece disposable flexible patch or bandage adaptable to be attachable to a patient for measuring at least the oxygen saturation level of arterial blood of the patient. This disposable patch has mounted thereto a light emitter and a light detector to detect the light from the light emitter that passes through the patient so that data relating to at least the SpO2 of the patient is acquired. Also mounted to the disposable patch is an electronic circuit for effecting operation of the light emitter and the light detector, and to calculate from the data acquired at least the SpO2 of the patient. An attachment mechanism is also provided at the patch to enable the patch to be removably attached to the patient.

**[0014]** The present invention also relates to an oximeter that comprises a patch that is adapted to be attached to the patient. The oximeter includes a light emitter and a light detector each mounted to the patch, with the light detector detecting the light from the light emitter that passes through the patient. An electronic circuit also mounted to the patch operates the light emitter and the light detector, and calculates from the data acquired by the light detector at least the oxygen saturation level of arterial blood of the patient. Means is provided at the patch to enable the patch to be removably attached to the patient.

**[0015]** The instant invention further relates to a method of making a disposable oximeter, as defined in claim 12.

## Brief Description of the Figures

**[0016]** The instant invention will become apparent and will best be understood by reference to the following description of the invention taken in conjunction with the accompanying drawings, wherein:

Fig. 1 is a block diagram of the oximeter patch or bandage of the instant invention, with the light emitter and the light detector being positioned on the patch to operate in a transmissive mode to measure the oxygen saturation level of arterial blood of the patient when the patch is wrapped around a digit or an earlobe of the patient;

Fig. 2 is a block diagram of the patch oximeter of the instant invention in which the orientation of the light detector and light emitter as mounted to the patch is such that the oximeter is adaptable to operate in a reflective mode, with the patch being adhesively attached to the forehead, or another substantially flat surface, of the patient;

Fig. 3 is a block diagram of the patch oximeter of the instant invention in which a transmitter or transceiver, and appropriate electronics for operating the same, are added to the patch to enable the patch oximeter to wirelessly communicate with a remote device;

Fig. 4 is a block diagram of a wireless patch oximeter with no power source provided on the patch, but with an antenna and a coil added to the patch to retrieve and utilize power provided from a remote power source;

Fig. 5 is a different embodiment of the Fig. 4 wireless patch oximeter in which the display and alarm, in addition to their respective drivers, are removed from the patch;

Fig. 6 is a block diagram of a patch oximeter that has at least two electrodes added to the patch to enable the patch oximeter to obtain from the patient at least one other physiological parameter in addition to the SpO2, which is obtained in a transmissive mode;

Fig. 7 is a block diagram showing a patch oximeter that is the same as that shown in Fig. 6, but with the light emitter and the light detector oriented to operate in a reflective mode;

Fig. 8 is a block diagram illustrating a wireless patch oximeter configured with electrodes to obtain additional physiological parameters of the patient;

Fig. 9 is a block diagram of a wireless patch oximeter with electrodes mounted to the patch that is powered by a remote power source;

Fig. 10 is a block diagram of the patch oximeter of Fig. 9, but with the display and alarms removed;

Fig. 11 is an illustrated top view of an exemplar patch oximeter of the instant invention;

Fig. 12 is a cross-sectional view of the different layers of the patch or bandage strip of the patch oximeter of the instant invention;

Fig. 13 illustrates an exemplar sterile package of the disposable oximeter of the instant invention, and the removal of the oximeter from the sterile package;

Fig. 14 is a simplified diagram of a patch oximeter of the instant invention communicating with a remote monitoring system;

Fig. 15 is a simplified drawing showing a plurality of patch oximeters of the instant invention attached to different areas of a patient to provide a differential measurement of the SpO2 or perfusion of the patient, which may be indicative of whether the patient is in shock, to a remote monitor system; and

Fig. 16 is a flow diagram illustrating the processes of determining whether the patient shown in Fig. 15 is in shock.

**Detailed Description of the Invention**

**[0017]** With reference to Fig. 1, a flexible patch 2, in the form of a bandage or strip, has mounted thereto a light or radiation emitter 4 and a photodetector or sensor 6. As is well known, light emitter 4 may be made up of a number of LEDs each outputting a light at a different frequency, so that emitter 4 in essence outputs a multifrequency light to a part of the patient, be that part a digit, the bridge of the nose, an earlobe, the forehead or some other body part of the patient. Photodetector 6 then senses or detects the light that passes through the patient as data obtained from the patient.

**[0018]** Also mounted onto patch 2 is an application specific integrated circuit (ASIC) 8, possibly in the form of a flexible circuit platform or chip, in which the various electronic components for controlling emitter 4 and sensor 6, as well as for calculating from the data collected or acquired by sensor 6 at least the oxygen saturation level of arterial blood (SpO2) and the heart rate of the patient. As shown in Fig. 1, in accordance with the conventional processes for manufacturing an ASIC chip, representative electronic components required for the operation of a pulse oximeter are formed or integrated into the ASIC circuit 8. These include a processor 10, a memory 12, an electronic circuit 14 specifically designed for performing the oximetry functions, an emitter interface circuit 16, a sensor interface circuit 18, a display driver 20 and an alarm driver 22. Other electronics that may also be integrated to the ASIC circuit 8 are not shown for the sake of simplicity. For the oximeter embodiments discussed herein, ASIC circuit 8 is presumed to be in the form of a thin chip that may be flexible and/or is mounted or embedded in a particular layer of the patch, as will be discussed in more detail, *infra.*

**[0019]** The algorithm for performing the SpO2 analysis may be that described in U.S. patent 5,558,096, assigned to the assignee of the instant invention. The disclosure of the '096 patent is incorporated by reference herein. Other algorithms or software that may be needed for effecting the operation of emitter 4 and sensor 6 in a conventional way may also be stored in memory 12. Moreover, the software for operating other components or electronics that are to be discussed hereinbelow may also be stored in memory 12.

**[0020]** For the oximeter shown in Fig. 1, also mounted to the patch 2 is a display 24, an alarm 26, and a power source in the form of a battery 28. Display 24 may be a thin membrane LCD display while alarm 26 may be a piezoelectric transducer that conceivably could be integrated as a separate electronic component mounted on patch 2. Battery 28, for the instant invention oximeter, may be a conventional thin plate battery or a fuel cell battery that self activates when the patch is removed from its sterile packaging. A chemical light source that also self activates when the patch is removed from its sterile package, or having its adhesive backing strip removed, may be used as an illumination source for display 24. Using a chemical illumination source would extend the battery life. Self activation would eliminate the need for an "on" switch. Further, the illumination source could be automated to sense ambient lighting conditions to determine the need for the illumination source, thereby conserving battery power when self- illumination is not required. For the instant invention, the duration of the chemical light may be adjusted to mirror the life of the battery.

**[0021]** For illustration purposes, also provided at patch 2 are attached portions 30 and 32. Even though shown as separate portions, it should be noted that such attached portions may in fact be an adhesive layer at the face of the patch that comes into contact with the patient for adhesively attaching the patch to the patient. Attach portions 30 and 32 may also be made of velcro, so that the patch, in the form a bandage, may be wrapped around a digit or an earlobe of the patient. Other types of attach mechanisms such as clasps or snaps may also be used. This is particularly true insofar as emitter 4 and sensor 6, as shown in the Fig. 1 embodiment, are arranged or oriented to work cooperatively in a transmissive mode when the patch oximeter is wrapped around the digit, earlobe or bridge of the nose of the patient. A more detailed discussion of the various layers of the oximeter patch will be given below with respect to the discussion of Fig. 12.

**[0022]** Fig. 2 has the same components as those shown in Fig. 1. The same components in Fig. 2, as well as those same components in the other figures to be discussed, are accordingly labeled the same. The one difference between the patch oximeter shown in Fig. 2 from that shown in Fig. 1 is the placement of the emitter

4 and sensor 6 on the patch. As shown, emitter 4 and sensor 6 are mounted in defined proximity to each other on the patch, so as to enable the patch oximeter to measure the SpO2 of the patient reflectively. Thus, the reflective mode patch oximeter of Fig. 2 is best adapted to attach to the forehead, or another substantially flat skin surface, of the patient.

**[0023]** Fig. 3 shows another embodiment of the instant invention in which, in addition to having all of the components of the previously discussed embodiments, the patch oximeter further has electronic components mounted thereto that enable it to operate as a wireless patch oximeter. In particular, a transmitter or transceiver 34 is added to the electronics layer of the patch, and an antenna 36 coupled to transceiver 34 provides the means by which signals may be transmitted and/or transceived to or from the patch oximeter. To provide additional functionalities that are required for the operation of the transceiver 34, electronics in the form of a transmission circuit 38 is added to the electronics layer of the patch, either as a separate circuit or integrated to the ASIC circuit 8. The functionalities of the transceiver 34 and its associate transmission circuit 38 may be gleaned from assignee's U.S. patent 6,731,962, the disclosure of which being incorporated by reference herein.

**[0024]** As the patch oximeter is equipped with a transceiver 34, not only could the patch oximeter transmit information to a remote device, it could likewise receive information from the remote device. For example the patch oximeter may ordinarily be in a sleep mode, and may be awakened by a signal from the remote device that awakens the patch oximeter to begin its monitoring or measurement. By way of another example, the last transmission of the patch oximeter may not have been correctly received by the remote device and hence the remote device could request the patch oximeter to resend the data.

**[0025]** Even though the light emitter 4 and sensor 6 of the wireless patch oximeter embodiment are shown to be arranged for operating in the transmissive mode, it should be appreciated that the wireless patch oximeter could likewise work in the reflective mode by simply rearranging the respective positions of emitter 4 and sensor 6 as shown per the Fig. 2 embodiment.

**[0026]** With the wireless functionalities, the patch oximeter of Fig. 3 is capable of at least transmitting the calculated SpO2 of the patient to a remote device, for example a monitor system such as the assignee's Vital Sign monitor equipped with the appropriate telecommunication transceiver such as for example an RF transmitter with its RF link, for displaying and/or recording the patient's SpO2 at the remote device. With transceiver 34 being integrated to the patch oximeter, the information or data acquired by sensor 6, or by the to be discussed electrodes added to the patch oximeter, may be transmitted to a similar wireless patch oximeter, so that a mini telecommunication network may be established among a plurality of wireless patch oximeters to enable the medical personnel to closely monitor the different physiological parameters of the patient. Such monitoring will be discussed in more detail, *infra,* with respect to Fig. 15.

**[0027]** Fig. 4 illustrates another embodiment of the instant invention in which the battery power source has been removed from the patch oximeter. Instead, power for the patch oximeter is obtained remotely by the incorporation of an antenna 40 and a coil 42. Antenna 40 is optional, as coil 42 is the component that allows the patch oximeter to receive power from a remote power source. The electronics that may be required to provide the functionalities to retrieve power remotely is added to the patch by way of a remote power circuit 44. The operation of the remote power grab is similar to the conventional RFID (radio frequency identification) technology that is being used for identifying goods. One example of the use of such RFID technology is in the miniaturized electronic circuit labels that are placed on items, for example, that would identify the items when they are sold. If perchance the customer had not paid for an item, when the item is taken past the cash register or out the store, an alarm is triggered. The electronic circuit that operates to trigger the alarm gets its power from a remote power source. The same scenario may be used with the Fig. 4 wireless patch oximeter, with the proviso that the power required for operating the patch oximeter embodiment such as that shown in Fig. 4 be increased by at least two fold, so that a sufficient level of power is provided for the operation of emitter 4.

**[0028]** For the Fig. 4 embodiment, even though display 24 and alarm 26 remain, it should be appreciated that those components may not necessarily be needed, especially when there is no need for the patient to look at the display, as for example when the patient wears the patch oximeter because she is in a sleep study involving for example sleep apnea, whereby the readings from the patient are displayed remotely on a remote monitor. A patch oximeter that does not include the display and alarm components, and their respective drivers, is shown in Fig. 5. As was mentioned previously, for all of the disclosed embodiments, it is assumed that the patch oximeter is adapted to work in both the transmissive mode and the reflective mode, irrespective of how the emitter 4 and sensor 6 are shown to be positioned in the figures.

**[0029]** Another aspect of the instant invention is illustrated by the block diagram of the strip or bandage shown in Fig. 6. As shown, the disposable patch oximeter of Fig. 6 has added thereto two electrodes 44 and 46, and their respective interface circuits 44a and 44b, which may be integrated to the ASIC circuit 8, or as additional electronics mounted separately to the electronics layer of the patch 2. Additional electronics represented by electrode circuit 48 may also be integrated to the ASIC circuit 8, or be mounted as an individual component on the electronics layer of the patch 2. In either event, electrodes 44 and 46 are conventional bioelectric electrodes (without limitation for example silver-silver chloride, possibly prejelled electrodes) that, when positioned at a distance from

each other (or formed concentrically), are able to measure additional physiological parameters of the patient, such as for example EKG, ECG, etc. EKG and ECG are well known physiological parameters associated with the electrical stimuli of the heart. The addition of electrodes to measure bioelectric events permits the determination of time differences between the ECG QRS complex and the patient's plethysmograph waveform which has been shown to correlate withnon-invasive blood pressure (NIBP).

**[0030]** In addition to the above mentioned physiological parameters that involve the pulse, the heart rate and the SpO2 of the patient, an electrode or sensor in the form of a temperature probe may also be added to the patch, along with the appropriate electronics, to measure the temperature of the patient. Thus, with the patch oximeter of Fig. 6, in addition to SpO2 and heart rate, other types of physiological parameters such as temperature, blood pressure, in the form of a non-invasive blood pressure (NIBP) could be continuously monitored, or obtained.

**[0031]** Fig. 7 shows in block diagram format the possible different placements of electrodes 44 and 46, as well as the placement of emitter 4 and sensor 6 on the patch, in the event that the SpO2 to be obtained from the patient needs to be done on the patient's forehead, or another substantially flat surface of the patient, via the reflective mode.

**[0032]** Fig. 8 shows a wireless patch oximeter with ECG electrodes 44 and 46, and the electrode circuit 48 for acquiring the data measured by the electrodes. For the Fig. 8 embodiment, in addition to the SpO2 and data collected by sensor 6 for calculating at least the SpO2, data relating to other physiological parameters of the patient, as collected by electrodes 44 and 46, may likewise be transmitted to a remote device, such as the previously mentioned Vital Signs monitor for display and/or recording. It should be appreciated that even though separate telecommunications circuit 38 and electrode circuit 48 are shown, those circuits may in fact be incorporated into the main electronic circuit 14 of the ASIC circuit 8 mounted to the electronics layer of patch 2.

**[0033]** Fig. 9 illustrates in block diagram format the embodiment of the wireless patch oximeter of the instant invention where SpO2, heart rate and other physiological parameters may be measured from the patient. The Fig. 9 embodiment is similar to the Fig. 4 embodiment in that the power for the operation of the patch oximeter is retrieved from a remote power source when the patch oximeter comes within a given distance from the remote power source. Thus, for the patch oximeter of Fig. 9, as well as for the remote power access patch oximeters described in Figs. 4 and 5, the patch oximeter attached to the patient may not be activated until the patient gets within a given distance from the remote power source, in which case the electronic circuit, for example circuit 14, would awake to activate the remaining electronic circuits to perform their respective functions, and power up emitter 4. If sufficient power is accessed from the remote power source, the patient may also be able to view, per display 24, her SpO2 and heart rate, as well as the ECG and possibly a strength bar graph. Membrane switches, not shown, may be provided on the top layer of the patch to activate/deactivate alarm 26, and/or display 24.

**[0034]** Fig. 10 shows the patch oximeter of Fig. 9 but without any display or alarm. Such wireless oximeter/electrode combination patch may be used where there is no need for the patient to view any readings or hear any alarms, as for example in the above-discussed sleep apnea study where the patient is asleep while measurement of the various physiological parameters of the patient takes place.

**[0035]** Fig. 11 is an illustration of the patch oximeter of the instant invention in the form of a bandage. As shown, display 24 of the bandage shows both the heart rate and the SpO2 of the patient.

**[0036]** Fig. 12 shows in a cross-sectional view the different layers of the patch of the oximeter of the instant invention. It should be appreciate that the various layers shown in Fig. 2 are not drawn to scale or in proportion to their respective thicknesses. As shown, starting with the peel off sheet 50, the layer 52 that comes into contact with the patient is an adhesive layer. In any event, adhesive layer 52 is prevented from being exposed to the environment by the peel off sheet or paper 50. Above adhesive layer 52 is a foam layer 54 that provides comfort to the patient and also compensates for movements of the patient. On top of foam layer 54 is a barrier layer 56, which may be a plastic sheet or a polyimide sheet that acts as a moisture resistant and electrically insulation layer.

**[0037]** Protected by barrier layer 56 on its lower side and another barrier layer 58 on its upper side is the electronics layer 60 whereby the various electronic components including the ASIC circuit and the other circuits mentioned previously are embedded or mounted. The electrical interconnections among the various components and/or the ASIC circuit with emitter 4 and sensor 6 are represented by the electronics layer 60 being in direct contact therewith. Emitter 4 and sensor 6 each are shown to be extending from electronics layer 60 to be flush with, or slightly above, adhesive layer 52. The optional electrodes 44 and 46 likewise are shown to extend from electronics layer 60 to adhesive layer 52. Although shown as being flush with adhesive layer 52, to operate more efficiently, the surfaces of the electrodes may in fact extend slightly beyond adhesive layer 52 and may be pre-gelled. In any event, each of the contact surfaces of emitter 4, sensor 6 and electrodes 44, 46 are protected by peel off sheet 50.

**[0038]** As noted above, the electronics layer is sandwiched by two protective barrier layers 56 and 58. As shown in Fig. 12, display 24 extends from electronics layer 60 to be flush with the top surface with barrier layer 58. Alternatively, display 24 may be mounted within electronics layer 60, as barrier layer 58, similar to barrier layer

56, may be a clear plastic moisture resistant and electrically insulating sheet that allows the display to be seen from the top of the patch. Also shown are optional switches 61 that may be a part of barrier layer 58 or be embedded in electronics layer 60. Barrier layer 58 is topped with a protective membrane layer 62 that may have graphics printed thereon and appropriate clear window areas, so that display 24 may be viewed, per shown in Fig. 11. With the appropriate graphics printed on protective membrane layer 62, if optional switches 61 are provided, the patient can readily determine which switch to push in order to activate/deactivate the operation of those components to which the caregiver/patient is allowed to control, for example optional display 24 and/or alarm 26, which are not shown in the Fig. 12 patch layers.

**[0039]** Fig. 13 illustrates the packaging of the patch oximeter of the instant invention. Patch 2 may be housed or stored in a package 63 that includes a clear top wrap 64 and a bottom wrap 66. Bottom wrap 66 may be the peel off sheet 50 shown in Fig. 12 which may have the additional function of activating battery 28 when peeled off, if battery 28 is a fuel cell type battery that utilizes the zinc/air chemistry to operate. Such battery, when stored in air tight environment, is inactive. But as soon as the sheet, for example 50, is peeled off from the patch, the battery becomes activated due to its exposure to air. This feature is advantageous in that it allows the patch oximeter to be stored for an extended length of time. The battery should have sufficient power to operate the oximeter for an appropriate length of time, for example 8-10 hours. Battery 28 may also be a photovoltaic type battery in which power is supplied when the battery is exposed to light. When a photovoltaic battery is used, the placement of the battery on the patch is such that light is allowed to reach the photovoltaic cell via a clear window provided at the membrane layer 62. The peeling off of sheet 50 from the adhesive layer may also be used to activate the above-mentioned chemical light source, which presumably begins its chemical reaction when exposed to air or light.

**[0040]** Fig. 14 illustrates the telecommunication functionalities of the wireless embodiment of the patch oximeter of the instant invention. Patch oximeter 2 retrieves power from a remote power source 68 when it is within a given distance therefrom (for the non-self powered wireless patch oximeter), and then transmits data collected from the patient and/or the calculated SpO2 to the monitor system 70 via the latter's receiver 72. The operation of the transmission of the data from patch oximeter 2 to the monitor system is similar to that given in the above incorporated by reference '962 patent, which discloses the use of an RF link for transmitting data packets from the oximeter to the monitor system 70, and the unpacking of the packets by the monitor system 70.

**[0041]** Fig. 15 illustrates the use of a plurality of patch oximeters of the instant invention, in their wireless form, for transmitting information to a remote device for informing the medical personnel whether the patient is in shock. As shown, a patch oximeter 2 is attached to the forehead of patient 74. Another patch oximeter 2' is attached to an extremity, for example a finger digit of the patient. As each of the patch oximeters measures the SpO2 of the patient at their respective locations, the respective rates of blood perfusion at the forehead and at the extremity of the patient are also measured and the differential between the measurements is determined. This is important insofar as when a person goes into shock, for example hypovolemic shock, the extremities of the patient would tend to shut down the blood perfusion before the brain. Thus, by comparing the difference in the perfusion measurements between an extremity and the forehead of the patient, a determination could be made on whether the patient is about to go into shock, or is in shock due to potential bleeding. With the patch oximeter of the instant invention, if appropriate electrodes which are adaptable to measure the temperature or other physiological parameters of the patient are added, septic or systolic shock may also be measured. As is known, perfusion is conventionally represented by an index, calculated as the ratio of the peak-to-peak red transmission signal to the peak-to-peak infrared transmission signal. See for example U.S. patent publication 2003/0236452, the disclosure of which being incorporated by reference herein.

**[0042]** A flow diagram illustrating the method of determining whether a patient is in shock or at the onset of shock is provided in the flow chart of Fig. 16. Specifically, the process of determining shock in the patient begins with the attachment of a plurality of the patch oximeters of the instant invention to the patient, per step 76. Perfusion measurements are obtained from the oximeter per step 78. A determination is made, per step 80, on whether there is a perfusion differential between the measurements at for instance the forehead and an extremity of the patient. If there is a differential, such differential is compared with a predetermined condition range, for example a predefined 1-10, that has been pre-calibrated to determine whether the patient is okay, at the onset of shock, or already in shock. For the exemplar 1-10 scale, assume that 1-4 correspond to normal, 5-8 correspond to possible onset and 9-10 correspond to the patient being in shock. The comparison of the measured perfusion differential with the predetermined scale takes place in decisional steps 84 and 86. If the measured perfusion differential is within the shock range, then a shock status is sent out per step 88. On the other hand, if the measured differential is within the range that the patient is at the onset of shock, such on the verge status is sent out per step 90. If the patient appears to be stable and not in shock, the process returns to the monitor phase whereby the differences in the measurements between the at least two areas of the patient where the patch oximeters of the instant invention are attached are continuously monitored and calculated. As with the different patch oximeter embodiments of the instant invention, the patch oximeters, once used, are disposed of.

## Claims

1. A one piece self contained disposable patch (2) having multiple layers including an electronics layer (60) adapted to be attached to a patient for measuring at least the oxygen saturation level of blood ($SpO_2$) of the patient, comprising:

   a light emitter (4) mounted to said patch;
   a light detector (6) mounted to said patch to detect the light from said light emitter passing through or reflected from the patient so as to acquire data relating to at least the oxygen saturation level of blood of the patient;
   an electronic circuit (8) mounted to the electronics layer (60) of said patch for effecting operation of said light emitter (4) and said light detector (6), and to calculate from the data acquired at least the oxygen saturation level of blood of the patient, said light emitter (4) and said light detector (6) each extending from said electronics layer;
   one moisture resistant and electrically insulated barrier layer (56) on the lower surface of the electronic layer (60) and another moisture resistant and electrically insulated barrier layer (58) on the upper surface of the electronics layer (60) sandwiching and protecting the electronics layer (60) from the environment:

      power source providing means (28; 40, 42) mounted to said patch for supplying power to said electronic circuit and said light emitter;
      a peel off sheet (50) attached to an adhesive layer (52) of the patch that comes into contact with the patient to protect the adhesive layer (52) that comes into contact with the patient and the respective patient contact surfaces of said light emitter (4) and said light detector (6); and the adhesive layer (52) provided at the patch to enable said patch to be attachable to the patient wherein the patch is activated when the peel off sheet (50) is removed from the patch.

2. The patch of claim 1, further comprising a display (24) mounted thereto for displaying at least the calculated oxygen saturation level of blood of the patient; and
   a protective top membrane layer (62) at top of the patch;
   wherein the protective top layer has graphics printed thereon and a clear window area to enable the display to be viewed.

3. The patch of claim 1, wherein said electronic circuit comprises an ASIC circuit integrally mounted to said electronics layer of said patch.

4. The patch of any one of the preceding claims, wherein said patch comprises a bandage that is adaptable to wrap around at least a digit or an ear lobe of the patient; wherein the attachment means comprises an adhesive (52) at the surface of the patch that comes into contact with the patient and which is protected by the peel off sheet.

5. The patch of any one of claims 1-3, wherein said patch comprises a bandage that is adaptable to be adhesively attached to the forehead or another substantially flat surface of the patient; wherein the attachment means comprises an adhesive (52) at the surface of the patch that comes into contact with the patient and which is protected by the peel off sheet (50).

6. The patch of any one of the preceding claims, further comprising at least two electrodes (44, 46) mounted to said patch and additional electronics mounted to said patch or integrated to said electronic circuit to effect operation of said electrodes to measure at least one other physiological parameter of the patient.

7. The patch of any one of the preceding claims, further comprising an alarm (26) mounted to said patch that sends out an alarm signal when the oxygen saturation level of blood is deemed not to be within an acceptable range.

8. The patch of any one of the preceding claims being an oximeter.

9. The patch of claim 2, further comprising a chemical light source that is activated when the peel off sheet is removed from the patch or when the patch is removed from its storage package for illuminating said display.

10. The patch of any one of the preceding claims, wherein said power source providing means comprises a battery (28).

11. The patch of any one of the preceding claims, wherein said power source providing means comprises electronics (40, 42) to retrieve power from a remote power source (68), wherein when the power is retrieved from the remote power source, the patch is activated when it gets within a given distance from the remote power source.

12. A method of making a disposable oximeter, comprising the steps of:

    a) obtaining a flexible patch having multiple lay-

ers including an electronics layer adaptable to be attached to a patient;
b) mounting a light emitter (4) and a light detector (6) to said patch such that said light emitter (4) and said light detector (6) extend from said electronics layer (60);
c) ensuring said light detector and said light emitter are arranged on said patch to work cooperatively with each other so that said light detector detects the light from said light emitter passing through or reflected from the patient and acquires data relating to at least the oxygen saturation level of blood of the patient;
d) mounting an electronic circuit to the electronics layer of said patch for effecting operation of said light emitter and said light detector and to calculate from the acquired data at least the oxygen saturation level of blood ($SpO_2$) of the patient;
e) sandwiching the electronics layer (60) with one moisture resistant and electrically insulated barrier layer (56) on the lower surface and another moisture resistant and electrically insulated barrier layer (58) on the upper surface of said electronics layer (60) to protect said electronics layer (60):

f) mounting power source providing means (28; 40, 42) to said patch for supplying power to said electronic circuit and said light emitter;
g) providing an adhesive layer (52) at the surface of the patch that comes into contact with the patient to enable said patch to be removably attachable to the patient;
h) attaching a peel off sheet (50) to the adhesive layer of the patch to protect the the adhesive layer (52) that comes into contact with the patient and to protect the respective contact surfaces of said light emitter (4) and said light detector (6), the patch being activated when the peel off sheet is removed from the patch.

**13.** Method of claim 12, wherein said patch is a bandage, and wherein said step c further comprises the step of:

arranging said light emitter and light detector on said bandage to operate in a transmissive mode when said bandage is wrapped around a digit or an ear lobe of the patient.

**14.** Method of claim 12, wherein said step c further comprises the step of:

arranging said light emitter and light detector on said patch to operate in a reflective mode when said patch is attached to the forehead or another substantially flat area of the patient.

**15.** Method of any one of claims 12 to 14, wherein said oximeter is effected to measure additional physiological parameters of the patient by:

adding at least two electrodes 44, 46) to said patch; and
adding additional electronics to said electronics layer of said patch or to said electronic circuit to operate said electrodes to measure at least one other physiological parameter of the patient.

**16.** Method of any one of claims 12 to 15, further comprising the step of:

mounting a display (24) on said patch for displaying at least the calculated oxygen saturation level of blood of the patient.

**17.** Method of any one of claims 12 to 16, further comprising the step of:

providing a chemical light source to the patch to illuminate said display, the light source activated when the peel off sheet is removed from the patch or when the patch is removed from its storage package.

**18.** Method of any one of claims 12 to 17, further comprising the step of:

using said power source providing means (40, 42) to retrieve power from a remote power source (68), the patch being activated when the patch gets within a given distance from the remote power source.

**Patentansprüche**

**1.** Einstückiges abgeschlossenes Einwegpflaster (2) mit mehreren Schichten einschließlich einer Elektronikschicht (60), das dazu eingerichtet ist, an einem Patienten zum Messen von wenigstens dem Sauerstoffsättigungspegel des Blutes ($SpO_2$) des Patienten angebracht zu werden und das Folgendes umfasst:

einen Lichtemitter (4), der an dem Pflaster montiert ist;
einen Lichtdetektor (6), der an dem Pflaster montiert ist, um das Licht von dem Lichtemitter zu detektieren, das durch den Patienten hindurchläuft oder von diesem reflektiert wird, so dass Daten erfasst werden, die wenigstens mit dem Sauerstoffsättigungspegel des Blutes des Patienten in Zusammenhang stehen;

einen elektronischen Schaltkreis (8), der auf der Elektronikschicht (60) des Pflasters zum Bewirken eines Betriebs des Lichtemitters (4) und des Lichtdetektors (6) montiert ist, und um aus den erfassten Daten wenigstens den Sauerstoffsättigungspegel des Blutes des Patienten zu berechnen, wobei sich der Lichtemitter (4) und der Lichtdetektor (6) jeweils von der Elektronikschicht erstrecken;
eine feuchtigkeitsbeständige und elektrisch isolierte Barriereschicht (56) auf der unteren Oberfläche der Elektronikschicht (60) und eine andere feuchtigkeitsbeständige und elektrisch isolierte Barriereschicht (58) auf der oberen Oberfläche der Elektronikschicht (60), die die Elektronikschicht (60) umschließen und vor der Umgebung schützen;
ein Leistungsquellenbereitstellungsmittel (28; 40, 42), das an dem Pflaster zum Liefern von Leistung an den elektronischen Schaltkreis und den Lichtemitter montiert ist;
ein Abziehblatt (50), das an einer Klebschicht (52) des Pflasters angebracht ist, die mit dem Patienten in Kontakt kommt, um die Klebschicht (52) zu schützen, die mit dem Patienten und den jeweiligen Patientenkontaktoberflächen des Lichtemitters (4) und des Lichtdetektors (6) in Kontakt kommt; und
die Klebschicht (52), die an dem Pflaster bereitgestellt ist, um zu ermöglichen, dass das Pflaster an dem Patienten anbringbar ist,
wobei das Pflaster aktiviert wird, wenn das Abziehblatt (50) von dem Pflaster entfernt wird.

**2.** Pflaster nach Anspruch 1, das ferner Folgendes umfasst: eine Anzeige (24), die zum Anzeigen wenigstens des berechneten Sauerstoffsättigungspegels des Blutes des Patienten an diesem montiert ist; und eine obere Schutzmembranschicht (62) an der Oberseite des Pflasters;
wobei die obere Schutzschicht Grafiken, die darauf gedruckt sind, und eine dursichtige Fensterfläche, um zu ermöglichen, dass die Anzeige betrachtet wird, aufweist.

**3.** Pflaster nach Anspruch 1, wobei der elektronische Schaltkreis einen ASIC-Schaltkreis umfasst, der integral an der Elektronikschicht des Pflasters montiert ist.

**4.** Pflaster nach einem der vorhergehenden Ansprüche,
wobei das Pflaster einen Verband umfasst, der dazu verwendbar ist, sich um wenigstens einen Finger oder ein Ohrläppchen des Patienten zu wickeln; wobei das Anbringungsmittel einen Klebstoff (52) an der Oberfläche des Pflasters umfasst, die in Kontakt mit dem Patienten kommt und die durch das Abziehblatt geschützt wird.

**5.** Pflaster nach einem der Ansprüche 1-3, wobei das Pflaster einen Verband umfasst, der dazu verwendbar ist, klebend an der Stirn oder einer anderen im Wesentlichen flachen Oberfläche des Patienten angebracht zu werden; wobei das Anbringungsmittel einen Klebstoff (52) an der Oberfläche des Pflasters umfasst, die in Kontakt mit dem Patienten kommt und die durch das Abziehblatt (50) geschützt wird.

**6.** Pflaster nach einem der vorhergehenden Ansprüche, das ferner wenigstens zwei Elektroden (44, 46), die an dem Pflaster montiert sind, und zusätzliche elektronische Elemente umfasst, die an dem Pflaster montiert sind oder mit dem elektronischen Schaltkreis integriert sind, um einen Betrieb der Elektroden zu bewirken, um wenigstens einen anderen physiologischen Parameter des Patienten zu messen.

**7.** Pflaster nach einem der vorhergehenden Ansprüche, das ferner einen an dem Pflaster montierten Alarm (26) umfasst, der ein Alarmsignal aussendet, wenn der Sauerstoffsättigungspegel des Blutes als nicht innerhalb eines akzeptablen Bereichs erachtet wird.

**8.** Pflaster nach einem der vorhergehenden Ansprüche, das ein Oxymeter ist.

**9.** Pflaster nach Anspruch 2, das ferner eine chemische Lichtquelle zur Beleuchtung der Anzeige umfasst, die aktiviert wird, wenn das Abziehblatt von dem Pflaster entfernt wird oder wenn das Pflaster von seiner Lagerungsverpackung entfernt wird.

**10.** Pflaster nach einem der vorhergehenden Ansprüche, wobei das Leistungsquellenbereitstellungsmittel eine Batterie (28) umfasst.

**11.** Pflaster nach einem der vorhergehenden Ansprüche, wobei das Leistungsquellenbereitstellungsmittel elektronische Elemente (40, 42) umfasst, um Leistung von einer fernen Leistungsquelle (68) abzurufen, wobei das Pflaster, wenn die Leistung von der fernen Leistungsquelle abgerufen wird, aktiviert wird, wenn es innerhalb eines gegebenen Abstands von der fernen Leistungsquelle gelangt.

**12.** Verfahren zum Fertigen eines Einwegoxymeters, das die folgenden Schritte umfasst:

a) Erhalten eines flexiblen Pflasters mit mehreren Schichten einschließlich einer Elektronikschicht, das dazu verwendbar ist, an einem Patienten angebracht zu werden;
b) Montieren eines Lichtemitters (4) und eines Lichtdetektors (6) an dem Pflaster, so dass sich

der Lichtemitter (4) und der Lichtdetektor (6) von der Elektronikschicht (60) erstrecken;
c) Sicherstellen, das der Lichtdetektor und der Lichtemitter auf dem Pflaster angeordnet sind, so dass sie zusammenwirkend arbeiten, so dass der Lichtdetektor das Licht von dem Lichtemitter, das durch den Patienten hindurchläuft oder von diesem reflektiert wird, detektiert und Daten erfasst, die wenigstens den Sauerstoffsättigungspegel des Blutes des Patienten betreffen;
d) Montieren eines elektronischen Schaltkreises an der Elektronikschicht des Pflasters zum Bewirken eines Betriebes des Lichtemitters und des Lichtdetektors und zum Berechnen des Sauerstoffsättigungspegels des Blutes ($SpO_2$) des Patienten aus den erfassten Daten;
e) Umschließen der Elektronikschicht (60) mit einer feuchtigkeitsbeständigen und elektrisch isolierten Barriereschicht (56) auf der unteren Oberfläche und einer anderen feuchtigkeitsbeständigen und elektrisch isolierten Barriereschicht (58) auf der oberen Oberfläche der Elektronikschicht (60), um die Elektronikschicht (60) zu schützen;
f) Montieren eines Leistungsquellenbereitstellungsmittels (28; 40, 42) an dem Pflaster zum Liefern von Leistung an den elektronischen Schaltkreis und den Lichtemitter;
g) Bereitstellen einer Klebschicht (52) an der Oberfläche des Pflasters, die mit dem Patienten in Kontakt kommt, um zu ermöglichen, dass das Pflaster entfernbar an dem Patienten anbringbar ist;
h) Anbringen eines Abziehblattes (50) an der Klebschicht des Pflasters, um die Klebschicht (52) zu schützen, die in Kontakt mit dem Patienten kommt, und um die jeweiligen Kontaktoberflächen des Lichtemitters (4) und des Lichtdetektors (6) zu schützen, wobei das Pflaster aktiviert wird, wenn das Abziehblatt von dem Pflaster entfernt wird.

**13.** Verfahren nach Anspruch 12, wobei das Pflaster ein Verband ist und wobei der Schritt c ferner den folgenden Schritt umfasst:

Anordnen des Lichtemitters und des Lichtdetektors auf dem Verband, um in einem Transmissionsmodus zu arbeiten, wenn der Verband um einen Finger oder ein Ohrläppchen des Patienten gewickelt wird.

**14.** Verfahren nach Anspruch 12, wobei der Schritt c ferner den folgenden Schritt umfasst:

Anordnen des Lichtemitters und des Lichtdetektors auf dem Pflaster, um in einem Reflexionsmodus zu arbeiten, wenn das Pflaster an der Stirn oder einem anderen im Wesentlichen flachen Bereich des Patienten angebracht wird.

**15.** Verfahren nach einem der Ansprüche 12 bis 14, wobei durch Folgendes bewirkt wird, dass das Oxymeter zusätzliche physiologische Parameter des Patienten misst:

Hinzufügen von wenigstens zwei Elektroden (44, 46) zu dem Pflaster; und
Hinzufügen von zusätzlichen elektronischen Elementen zu der Elektronikschicht des Pflasters oder zu dem elektronischen Schaltkreis, um die Elektroden dazu zu betreiben, wenigstens einen anderen physiologischen Parameter des Patienten zu messen.

**16.** Verfahren nach einem der Ansprüche 12 bis 15, das ferner den folgenden Schritt umfasst:

Montieren einer Anzeige (24) auf dem Pflaster zum Anzeigen von wenigstens dem berechneten Sauerstoffsättigungspegel des Blutes des Patienten.

**17.** Verfahren nach einem der Ansprüche 12 bis 16, das ferner den folgenden Schritt umfasst:

Bereitstellen einer chemischen Lichtquelle an dem Pflaster, um die Anzeige zu beleuchten, wobei die Lichtquelle aktiviert wird, wenn das Abziehblatt von dem Pflaster entfernt wird oder wenn das Pflaster aus seiner Lagerungsverpackung entfernt wird.

**18.** Verfahren nach einem der Ansprüche 12 bis 17, das ferner den folgenden Schritt umfasst:

Verwenden des Leistungsquellenbereitstellungsmittels (40, 42), um Leistung von einer fernen Leistungsquelle (68) abzurufen, wobei das Pflaster aktiviert wird, wenn das Pflaster innerhalb eines gegebenen Abstands von der fernen Leistungsquelle gelangt.

**Revendications**

**1.** Timbre jetable autonome monobloc (2), possédant de multiples couches, incluant une couche à composants électroniques (60), adapté pour être attaché à un patient pour mesurer au moins le niveau de saturation en oxygène du sang ($SpO_2$) du patient, comprenant :

un émetteur de lumière (4) monté sur ledit timbre ;

un détecteur de lumière (6) monté sur ledit timbre pour détecter la lumière dudit émetteur de lumière passant à travers ou réfléchie à partir du patient afin d'acquérir des données concernant au moins le niveau de saturation en oxygène du sang du patient ;
un circuit électronique (8) monté sur la couche à composants électroniques (60) dudit timbre pour effectuer le fonctionnement dudit émetteur de lumière (4) et dudit détecteur de lumière (6), et pour calculer, à partir des données acquises, au moins le niveau de saturation en oxygène du sang du patient, ledit émetteur de lumière (4) et ledit détecteur de lumière (6) s'étendant chacun à partir de ladite couche à composants électroniques ;
une couche barrière résistante à l'humidité et électriquement isolée (56) sur la surface inférieure de la couche à composants électroniques (60) et une autre couche barrière résistante à l'humidité et électriquement isolée (58) sur la surface supérieure de la couche à composants électroniques (60), prenant en sandwich et protégeant la couche à composants électroniques (60) de l'environnement ;
des moyens de fourniture de source d'alimentation électrique (28 ; 40, 42) montés sur ledit timbre pour fournir une alimentation électrique audit circuit électronique et audit émetteur de lumière ;
une feuille décollable (50) attachée à une couche adhésive (52) du timbre, qui entre en contact avec le patient, pour protéger la couche adhésive (52), qui entre en contact avec le patient, et les surfaces respectives de contact avec le patient dudit émetteur de lumière (4) et dudit détecteur de lumière (6) ; et
la couche adhésive (52) étant prévue sur le timbre pour permettre audit timbre de pouvoir être attaché au patient,
dans lequel le timbre est activé lorsque la feuille décollable (50) est enlevée du timbre.

**2.** Timbre selon la revendication 1, comprenant en outre une unité d'affichage (24) montée sur celui-ci pour afficher au moins le niveau calculé de saturation en oxygène du sang du patient ; et
une couche membranaire supérieure de protection (62) par-dessus le timbre ;
dans lequel la couche supérieure de protection présente des graphismes imprimés sur celle-ci et une zone de fenêtre transparente pour permettre à l'unité d'affichage d'être vue.

**3.** Timbre selon la revendication 1, dans lequel ledit circuit électronique comprend un circuit ASIC monté de façon monobloc sur ladite couche à composants électroniques dudit timbre.

**4.** Timbre selon l'une quelconque des revendications précédentes, dans lequel ledit timbre comprend un pansement qui est adaptable pour entourer au moins un doigt ou un lobe d'oreille du patient ; dans lequel les moyens d'attache comprennent un adhésif (52) sur la surface du timbre qui entre en contact avec le patient et qui est protégé par la feuille décollable.

**5.** Timbre selon l'une quelconque des revendications 1 à 3, dans lequel ledit timbre comprend un pansement qui est adaptable pour être attaché de façon adhésive au front ou à une autre surface sensiblement plate du patient ; dans lequel les moyens d'attache comprennent un adhésif (52) sur la surface du timbre qui entre en contact avec le patient et qui est protégée par la feuille décollable (50).

**6.** Timbre selon l'une quelconque des revendications précédentes, comprenant en outre au moins deux électrodes (44, 46) montées sur ledit timbre et des composants électroniques supplémentaires montés sur ledit timbre ou intégrés dans ledit circuit électronique pour effectuer le fonctionnement desdites électrodes pour mesurer au moins un autre paramètre physiologique du patient.

**7.** Timbre selon l'une quelconque des revendications précédentes, comprenant en outre une alarme (26) montée sur ledit timbre qui envoie un signal d'alarme lorsque le niveau de saturation en oxygène du sang est estimé ne pas être au sein d'une plage acceptable.

**8.** Timbre selon l'une quelconque des revendications précédentes, étant un oxymètre.

**9.** Timbre selon la revendication 2, comprenant en outre une source de lumière chimique qui est activée, lorsque la feuille décollable est enlevée du timbre ou lorsque le timbre est enlevé de son emballage de stockage, pour éclairer ladite unité d'affichage.

**10.** Timbre selon l'une quelconque des revendications précédentes, dans lequel lesdits moyens de fourniture de source d'alimentation électrique comprennent une batterie (28).

**11.** Timbre selon l'une quelconque des revendications précédentes, dans lequel lesdits moyens de fourniture de source d'alimentation électrique comprennent des composants électroniques (40, 42) pour extraire une alimentation électrique d'une source d'alimentation électrique à distance (68), dans lequel, lorsque l'alimentation électrique est extraite de la source d'alimentation électrique à distance, le timbre est activé lorsqu'il est au sein d'une distance donnée de la source d'alimentation électrique à distance.

**12.** Procédé de fabrication d'un oxymètre jetable, comprenant les étapes de :

a) l'obtention d'un timbre flexible, possédant de multiples couches, incluant une couche à composants électroniques, adaptable pour être attaché à un patient ;
b) le montage d'un émetteur de lumière (4) et d'un détecteur de lumière (6) sur ledit timbre de telle sorte que ledit émetteur de lumière (4) et ledit détecteur de lumière (6) s'étendent à partir de ladite couche à composants électroniques (60) ;
c) l'assurance que ledit détecteur de lumière et ledit émetteur de lumière sont agencés sur ledit timbre pour fonctionner de façon coopérative l'un avec l'autre pour que ledit détecteur de lumière détecte la lumière dudit émetteur de lumière passant à travers ou réfléchie à partir du patient et acquière des données concernant au moins le niveau de saturation en oxygène du sang du patient ;
d) le montage d'un circuit électronique sur la couche à composants électroniques dudit timbre pour effectuer le fonctionnement dudit émetteur de lumière et dudit détecteur de lumière et pour calculer, à partir des données acquises, au moins le niveau de saturation en oxygène du sang ($SpO_2$) du patient ;
e) la prise en sandwich de la couche à composants électroniques (60) avec une couche barrière résistante à l'humidité et électriquement isolée (56) sur la surface inférieure et une autre couche barrière résistante à l'humidité et électriquement isolée (58) sur la surface supérieure de ladite couche à composants électroniques (60) pour protéger ladite couche à composants électroniques (60) ;
f) le montage de moyens de fourniture de source d'alimentation électrique (28 ; 40, 42) sur ledit timbre pour fournir une alimentation électrique audit circuit électronique et audit émetteur de lumière ;
g) la fourniture d'une couche adhésive (52) sur la surface du timbre qui entre en contact avec le patient pour permettre audit timbre de pouvoir être attaché de façon amovible au patient ;
h) l'attache d'une feuille décollable (50) à la couche adhésive du timbre pour protéger la couche adhésive (52), qui entre en contact avec le patient, et pour protéger les surfaces de contact respectives dudit émetteur de lumière (4) et dudit détecteur de lumière (6), le timbre étant activé lorsque la feuille décollable est enlevée du timbre.

**13.** Procédé selon la revendication 12, dans lequel ledit timbre est un pansement, et dans lequel ladite étape c comprend en outre l'étape de :

l'agencement desdits émetteur de lumière et détecteur de lumière sur ledit pansement pour fonctionner dans un mode transmissif lorsque ledit pansement entoure un doigt ou un lobe d'oreille du patient.

**14.** Procédé selon la revendication 12, dans lequel ladite étape c comprend en outre l'étape de :

l'agencement desdits émetteur de lumière et détecteur de lumière sur ledit timbre pour fonctionner dans un mode réfléchissant lorsque ledit timbre est attaché au front ou à une autre zone sensiblement plate du patient.

**15.** Procédé selon l'une quelconque des revendications 12 à 14, dans lequel ledit oxymètre est mis en oeuvre pour mesurer des paramètres physiologiques supplémentaires du patient par :

l'ajout d'au moins deux électrodes (44, 46) sur ledit timbre ; et
l'ajout de composants électroniques supplémentaires sur ladite couche à composants électroniques dudit timbre ou sur ledit circuit électronique pour faire fonctionner lesdites électrodes pour mesurer au moins un autre paramètre physiologique du patient.

**16.** Procédé selon l'une quelconque des revendications 12 à 15, comprenant en outre l'étape de :

le montage d'une unité d'affichage (24) sur ledit timbre pour afficher au moins le niveau calculé de saturation en oxygène du sang du patient.

**17.** Procédé selon l'une quelconque des revendications 12 à 16, comprenant en outre l'étape de :

la fourniture d'une source de lumière chimique au timbre pour éclairer ladite unité d'affichage, la lumière source étant activée lorsque la feuille décollable est enlevée du timbre ou lorsque le timbre est enlevé de son emballage de stockage.

**18.** Procédé selon l'une quelconque des revendications 12 à 17, comprenant en outre l'étape de :

l'utilisation desdits moyens de fourniture de source d'alimentation électrique (40, 42) pour extraire une alimentation électrique d'une source d'alimentation électrique à distance (68), le timbre étant activé lorsque le timbre est au sein d'une distance donnée de la source d'alimentation électrique à distance.

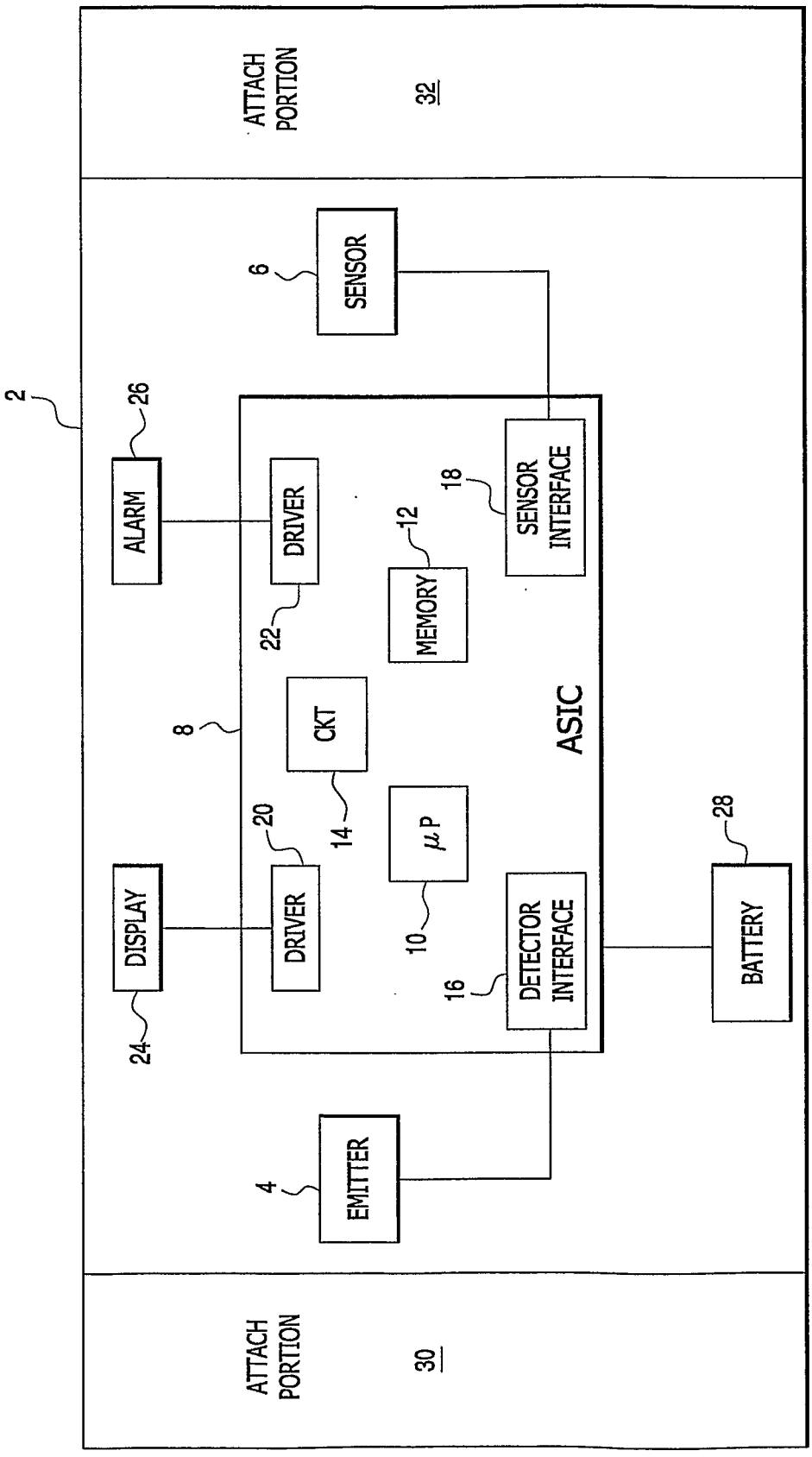
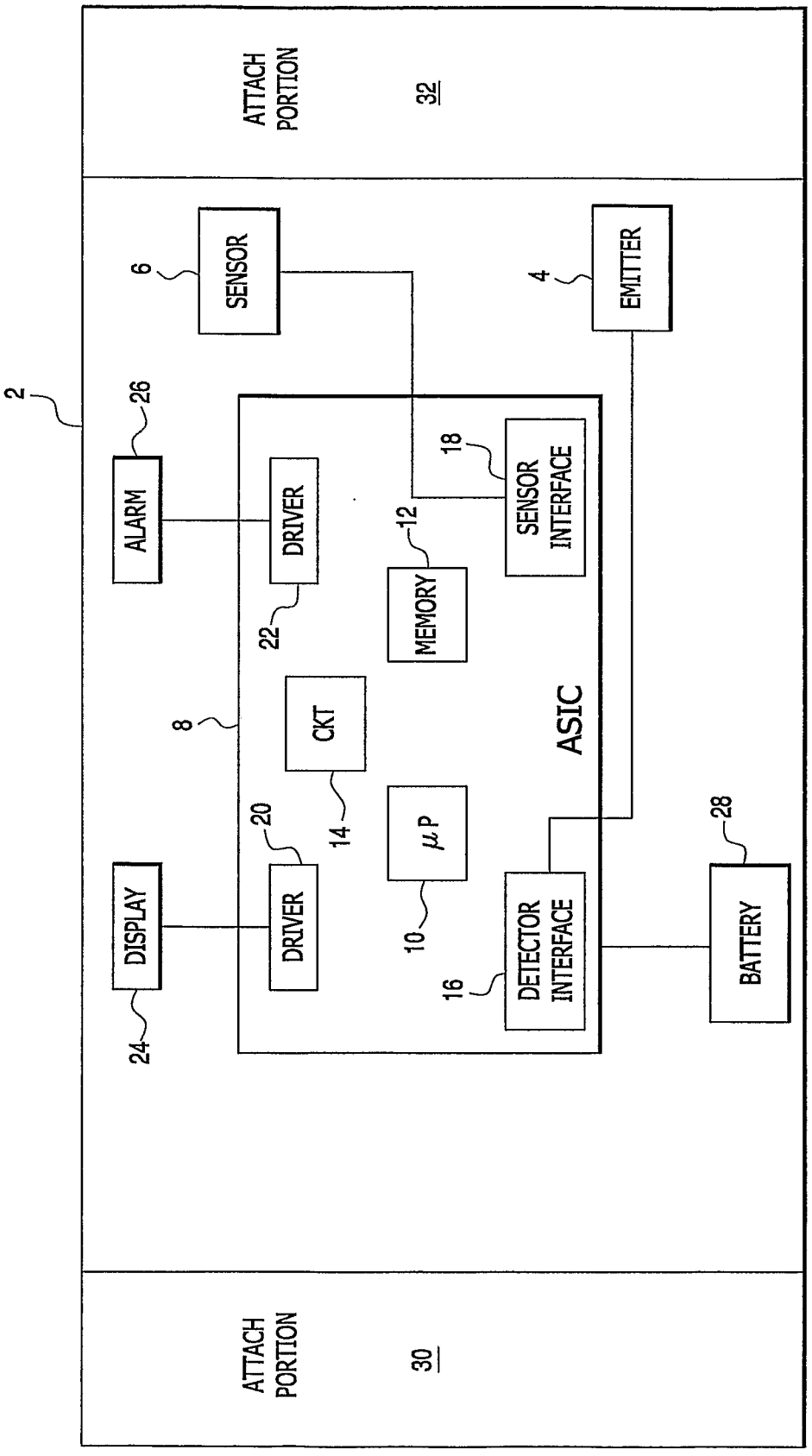

ATTACH PORTION
32
6
SENSOR
2
26
ALARM
DRIVER
22
18
SENSOR INTERFACE
12
MEMORY
8
CKT
14
ASIC
20
DRIVER
DISPLAY
24
10
μP
16
DETECTOR INTERFACE
28
BATTERY
4
EMITTER
ATTACH PORTION
30

FIG. 1


ATTACH PORTION
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SENSOR
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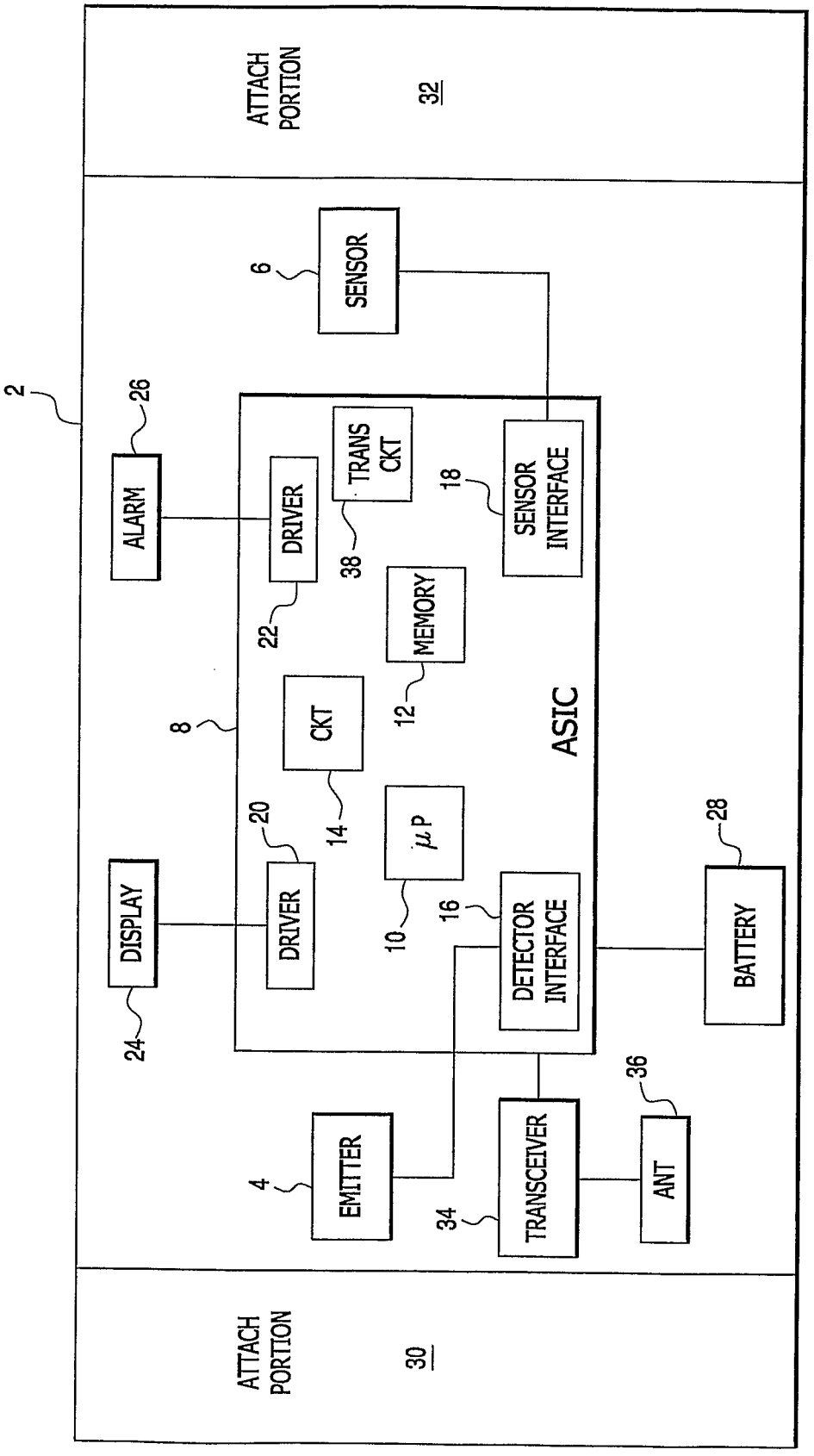
EMITTER
4
2
26
ALARM
DRIVER
22
18
SENSOR INTERFACE
12
MEMORY
8
CKT
14
ASIC
20
DRIVER
DISPLAY
24
μP
10
16
DETECTOR INTERFACE
28
BATTERY
ATTACH PORTION
30

FIG. 2


ATTACH PORTION
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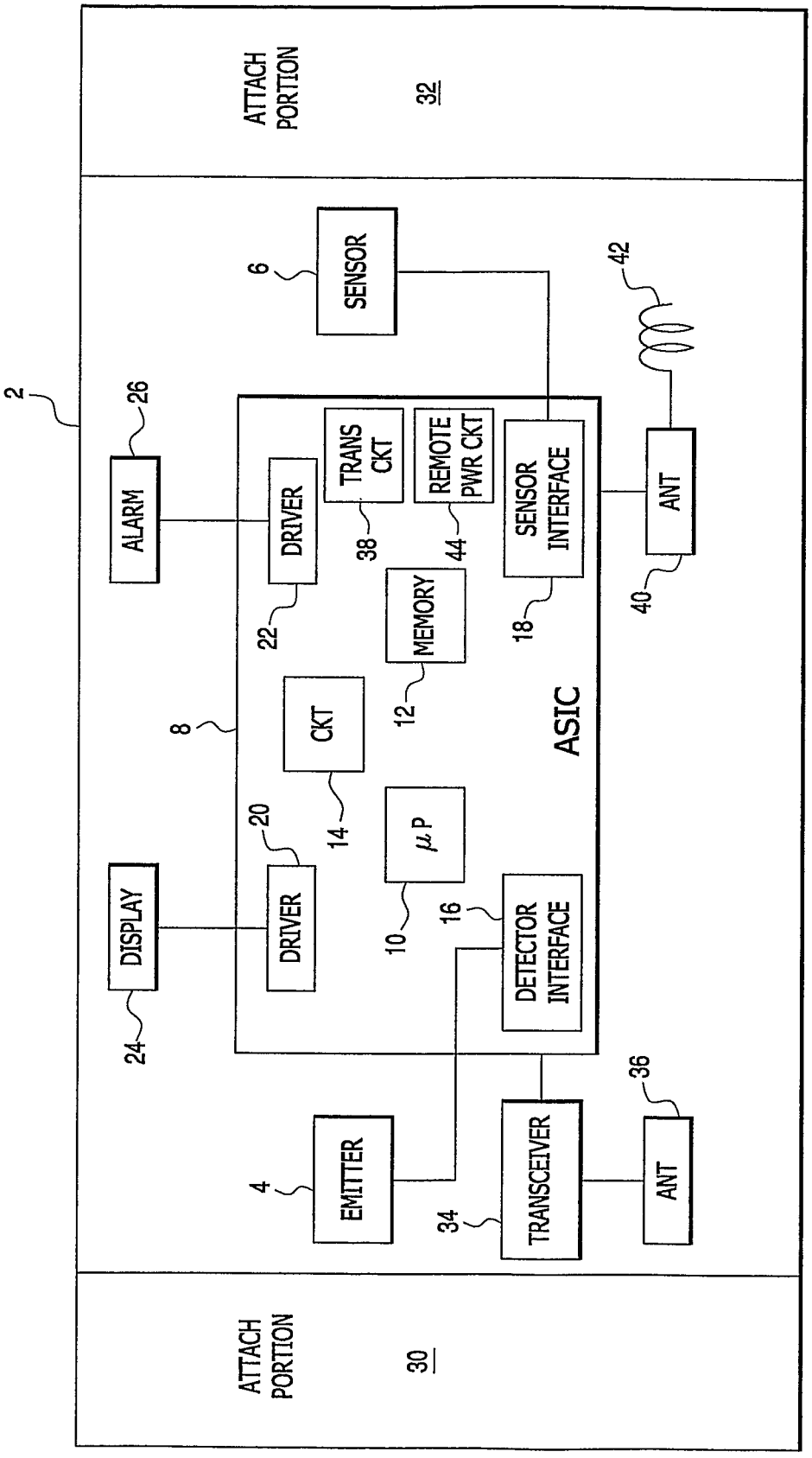
6
2
26
ALARM
DRIVER
TRANS CKT
18
SENSOR INTERFACE
38
22
MEMORY
12
8
CKT
14
ASIC
20
DRIVER
μP
10
16
DETECTOR INTERFACE
28
BATTERY
DISPLAY
24
4
EMITTER
34
TRANSCEIVER
36
ANT
ATTACH PORTION
30

FIG. 3


ATTACH PORTION
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SENSOR
6
42
2
26
ALARM
DRIVER
TRANS CKT
REMOTE PWR CKT
SENSOR INTERFACE
ANT
38
44
40
22
MEMORY
18
8
CKT
12
ASIC
20
14
μP
DISPLAY
DRIVER
10
16
DETECTOR INTERFACE
24
4
EMITTER
34
TRANSCEIVER
36
ANT
ATTACH PORTION
30

FIG. 4

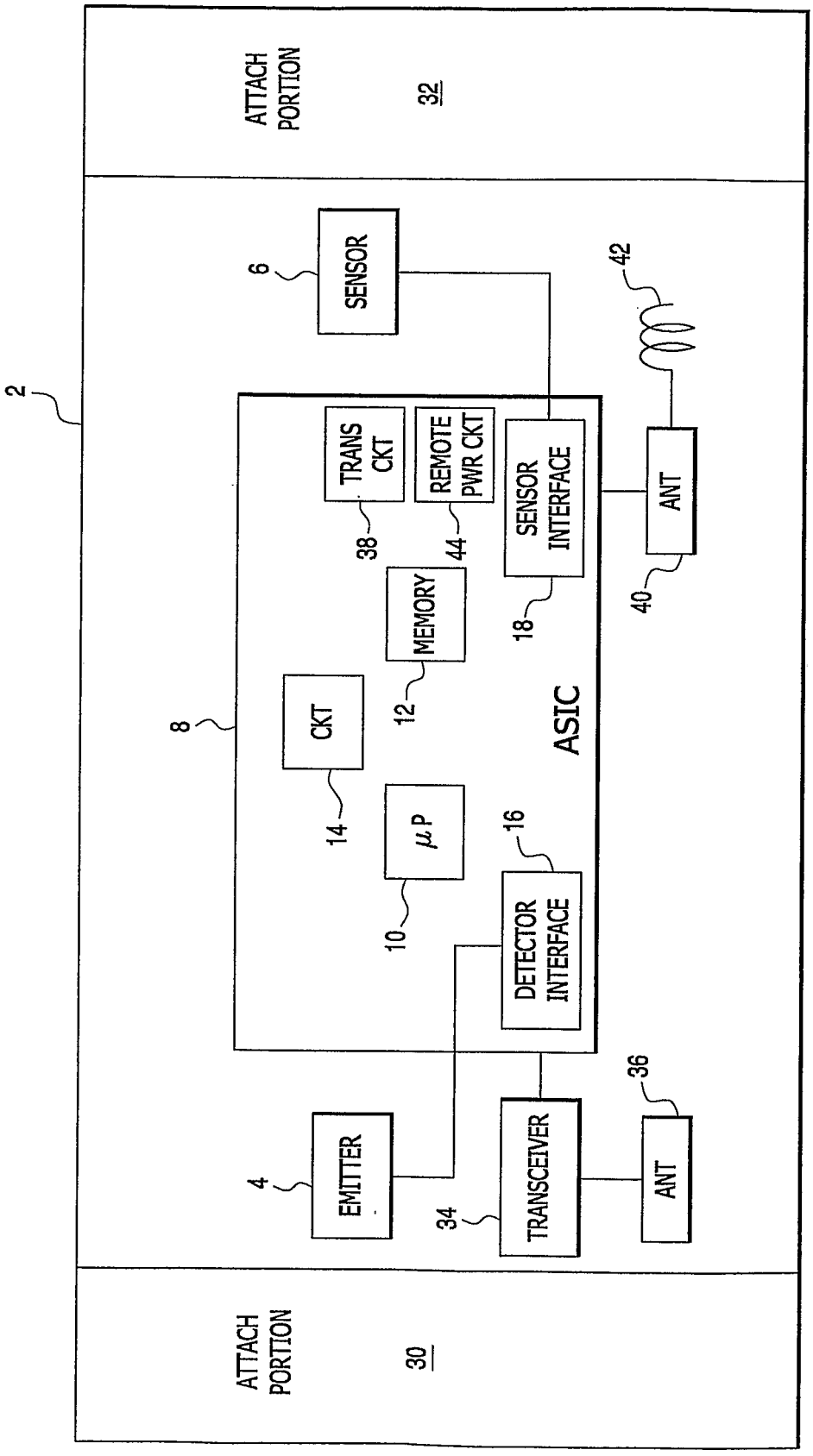

ATTACH PORTION
32
SENSOR
6
42
2
TRANS CKT
REMOTE PWR CKT
SENSOR INTERFACE
ANT
38
44
MEMORY
18
40
8
CKT
12
ASIC
14
μP
16
10
DETECTOR INTERFACE
36
4
EMITTER
34
TRANSCEIVER
ANT
ATTACH PORTION
30

FIG. 5

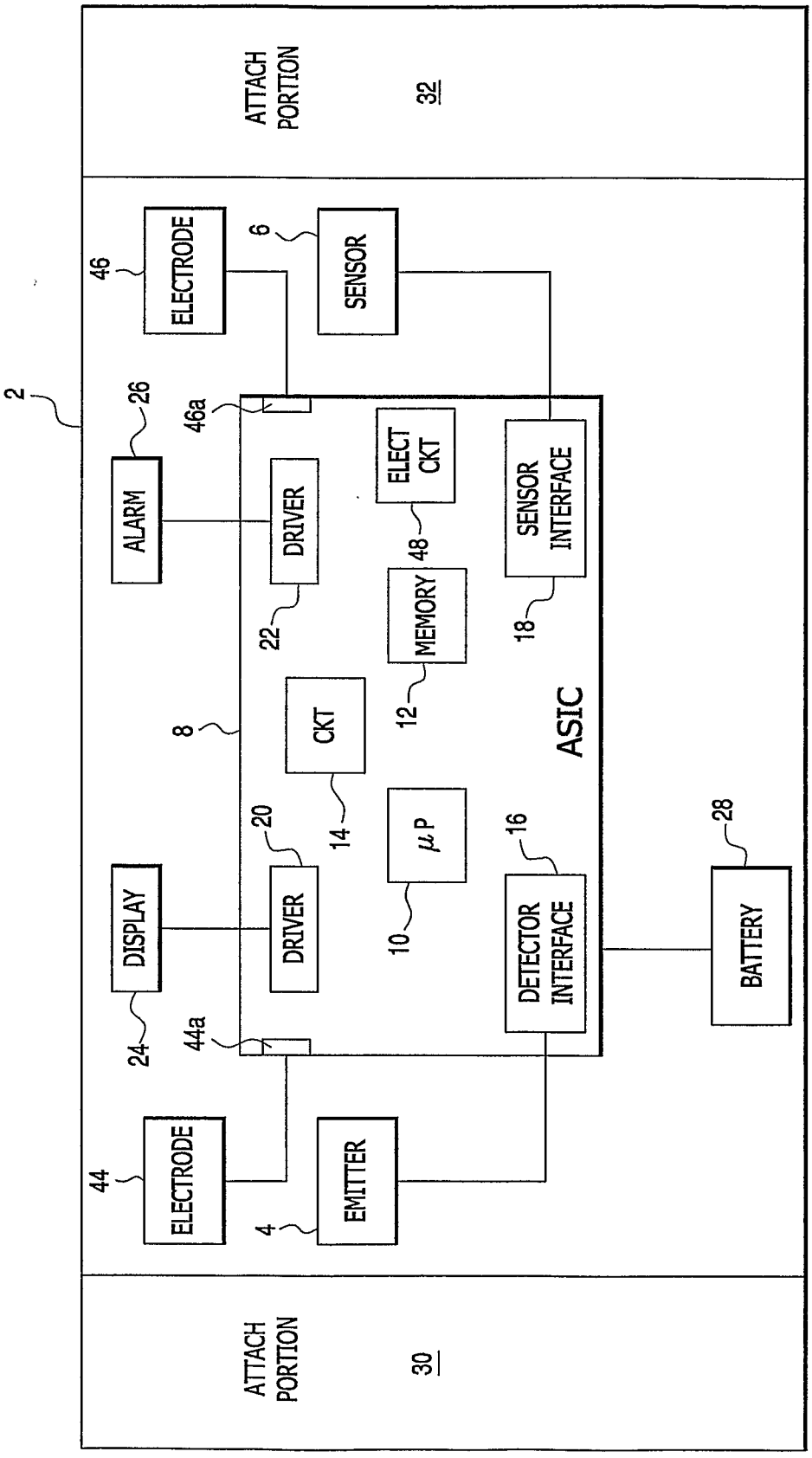
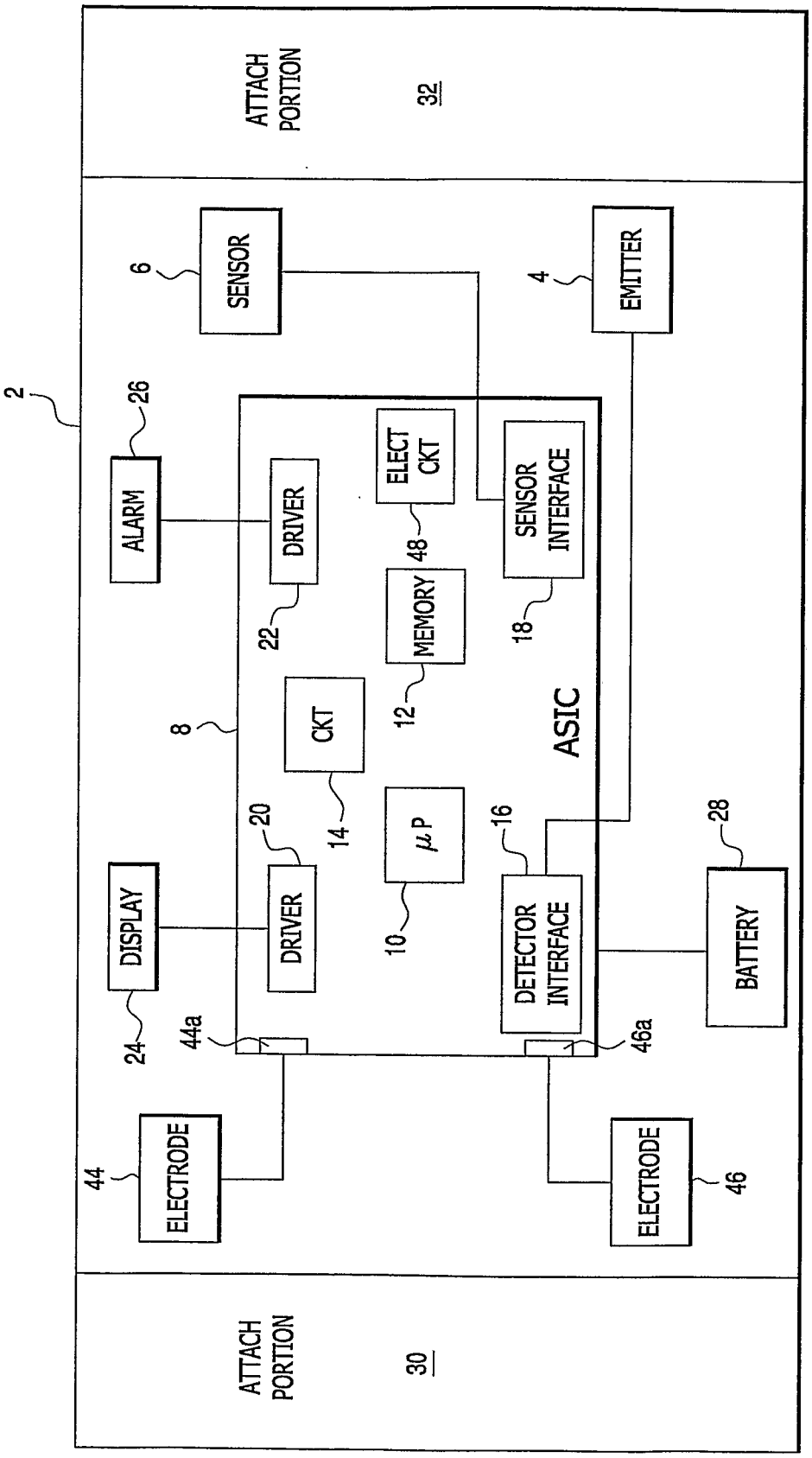

ATTACH PORTION
32
ELECTRODE
46
SENSOR
6
2
26
46a
ALARM
DRIVER
ELECT CKT
SENSOR INTERFACE
48
MEMORY
22
18
8
CKT
12
ASIC
20
14
μP
16
28
DISPLAY
DRIVER
DETECTOR INTERFACE
BATTERY
24
44a
44
ELECTRODE
EMITTER
4
10
ATTACH PORTION
30

FIG. 6


ATTACH PORTION
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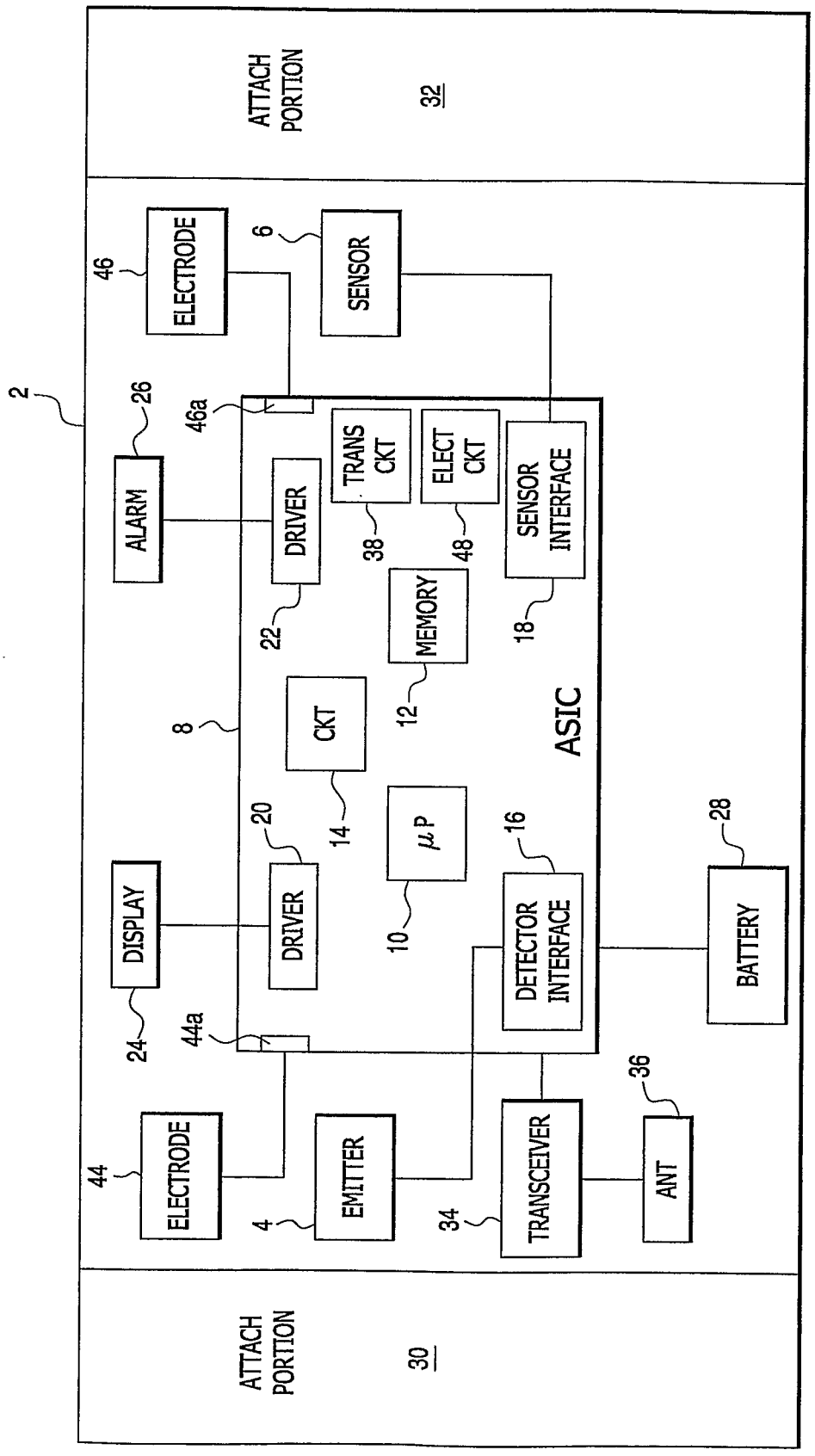
SENSOR
6
EMITTER
4
2
ALARM
26
DRIVER
22
ELECT CKT
48
SENSOR INTERFACE
18
MEMORY
12
8
CKT
14
ASIC
20
DRIVER
DISPLAY
24
44a
μP
10
16
DETECTOR INTERFACE
46a
28
BATTERY
44
ELECTRODE
ELECTRODE
46
ATTACH PORTION
30

FIG. 7


ATTACH PORTION
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ELECTRODE
46
SENSOR
6
2
26
46a
ALARM
DRIVER
TRANS CKT
ELECT CKT
SENSOR INTERFACE
38
48
22
MEMORY
18
8
CKT
12
ASIC
20
14
μP
16
28
DISPLAY
DRIVER
DETECTOR INTERFACE
BATTERY
24
44a
36
44
ELECTRODE
EMITTER
TRANSCEIVER
ANT
4
34
ATTACH PORTION
30
10

FIG. 8

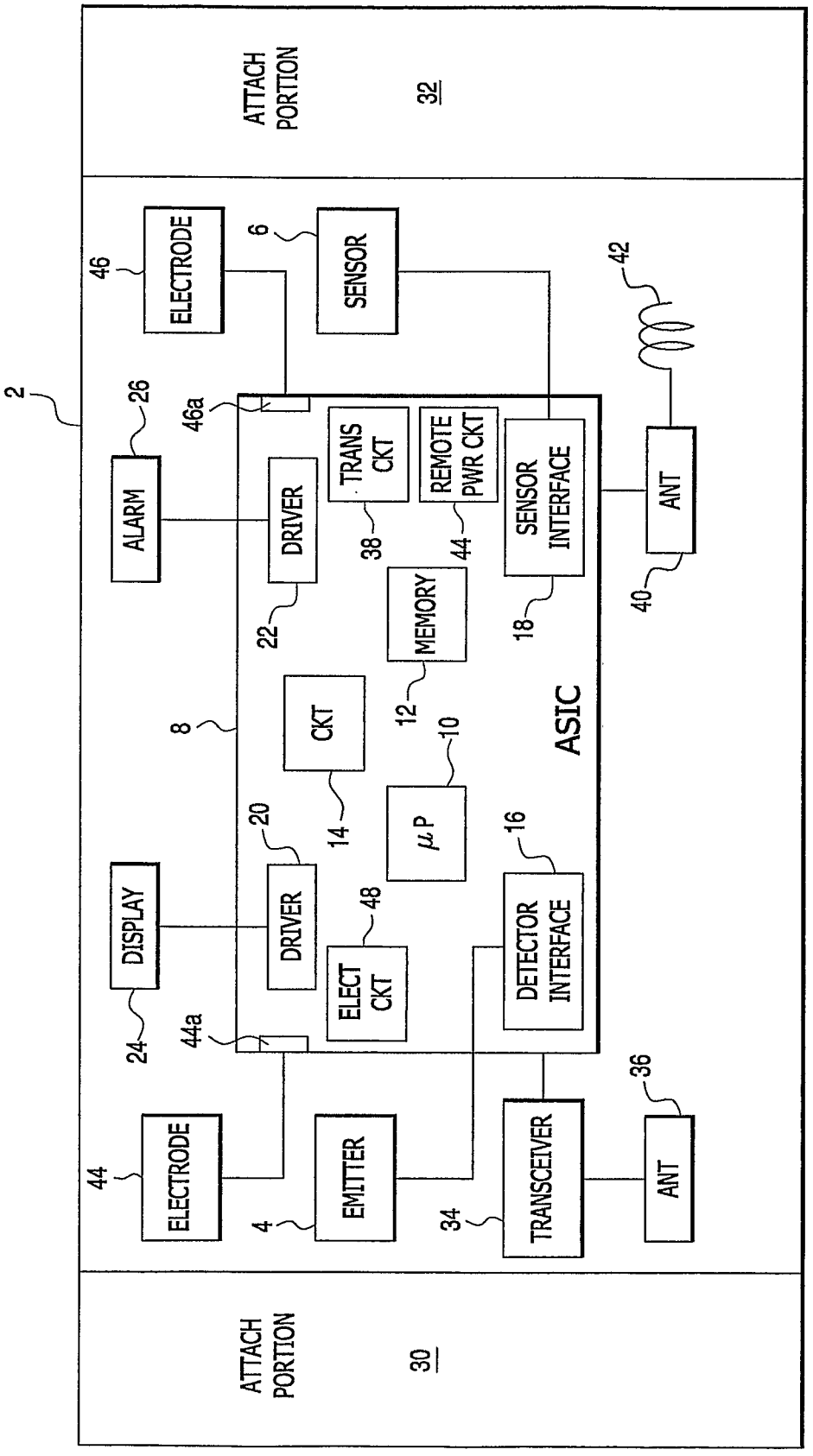

ATTACH PORTION
32
ELECTRODE
46
SENSOR
6
42
2
26
46a
ALARM
DRIVER
TRANS CKT
REMOTE PWR CKT
SENSOR INTERFACE
ANT
38
44
40
22
MEMORY
18
8
CKT
12
ASIC
10
14
μP
20
16
DISPLAY
DRIVER
48
ELECT CKT
DETECTOR INTERFACE
24
44a
44
ELECTRODE
EMITTER
TRANSCEIVER
ANT
36
4
34
ATTACH PORTION
30

FIG. 9

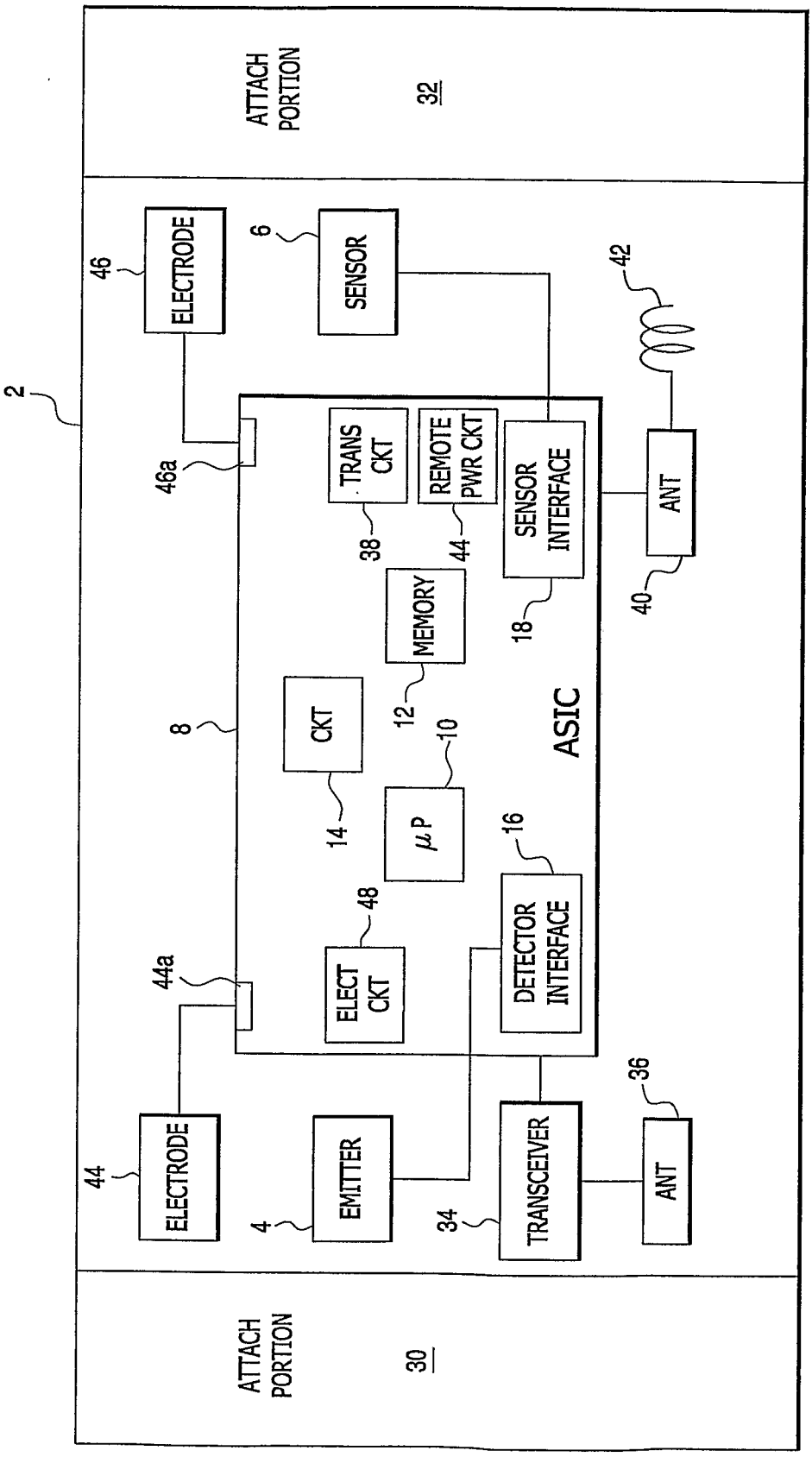

ATTACH PORTION
32
ELECTRODE
46
SENSOR
6
42
2
46a
TRANS CKT
REMOTE PWR CKT
SENSOR INTERFACE
ANT
38
44
40
MEMORY
18
12
8
CKT
ASIC
10
14
μP
16
48
ELECT CKT
DETECTOR INTERFACE
44a
36
ELECTRODE
44
EMITTER
4
TRANSCEIVER
34
ANT
ATTACH PORTION
30

FIG. 10

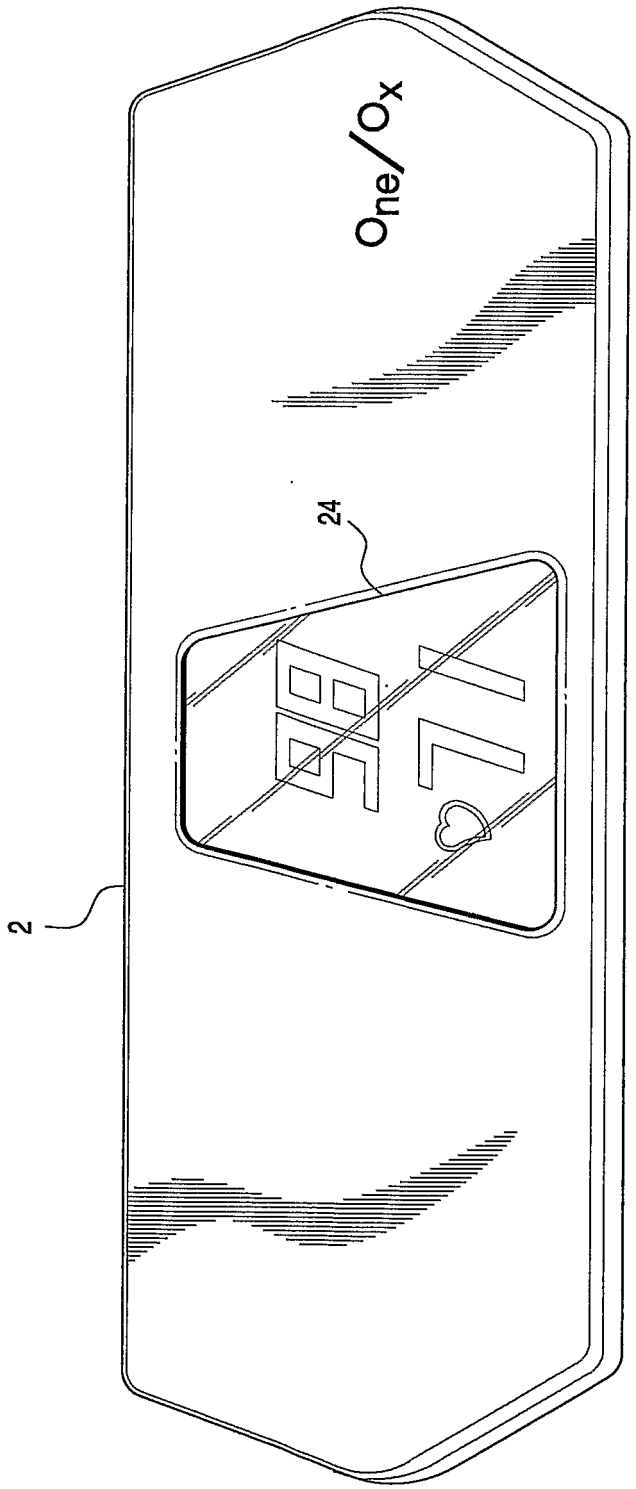



FIG. 11

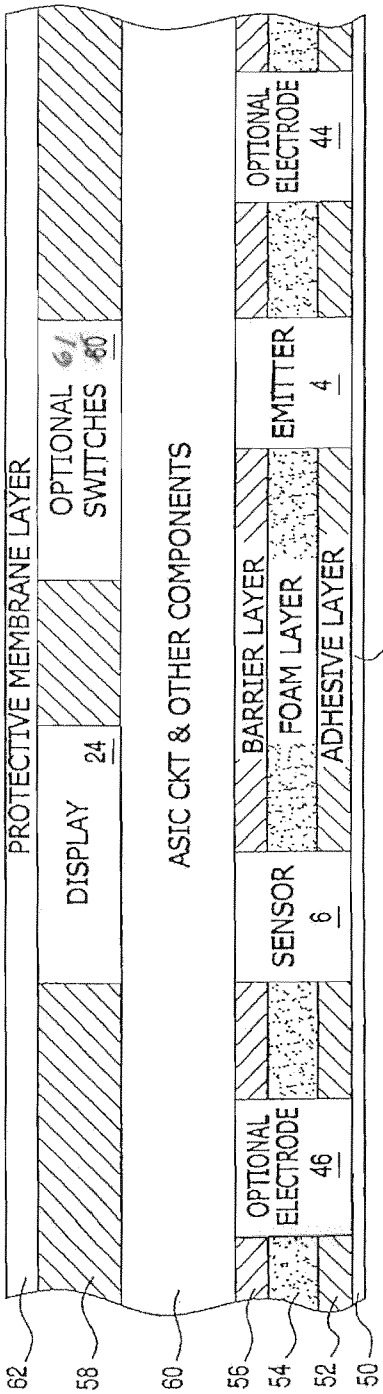

PROTECTIVE MEMBRANE LAYER
DISPLAY 24
OPTIONAL SWITCHES 60
ASIC CKT & OTHER COMPONENTS
OPTIONAL ELECTRODE 46
SENSOR 6
BARRIER LAYER
FOAM LAYER
ADHESIVE LAYER
EMITTER 4
OPTIONAL ELECTRODE 44
PEEL OFF SHEET
62
58
60
56
54
52
50

FIG. 12

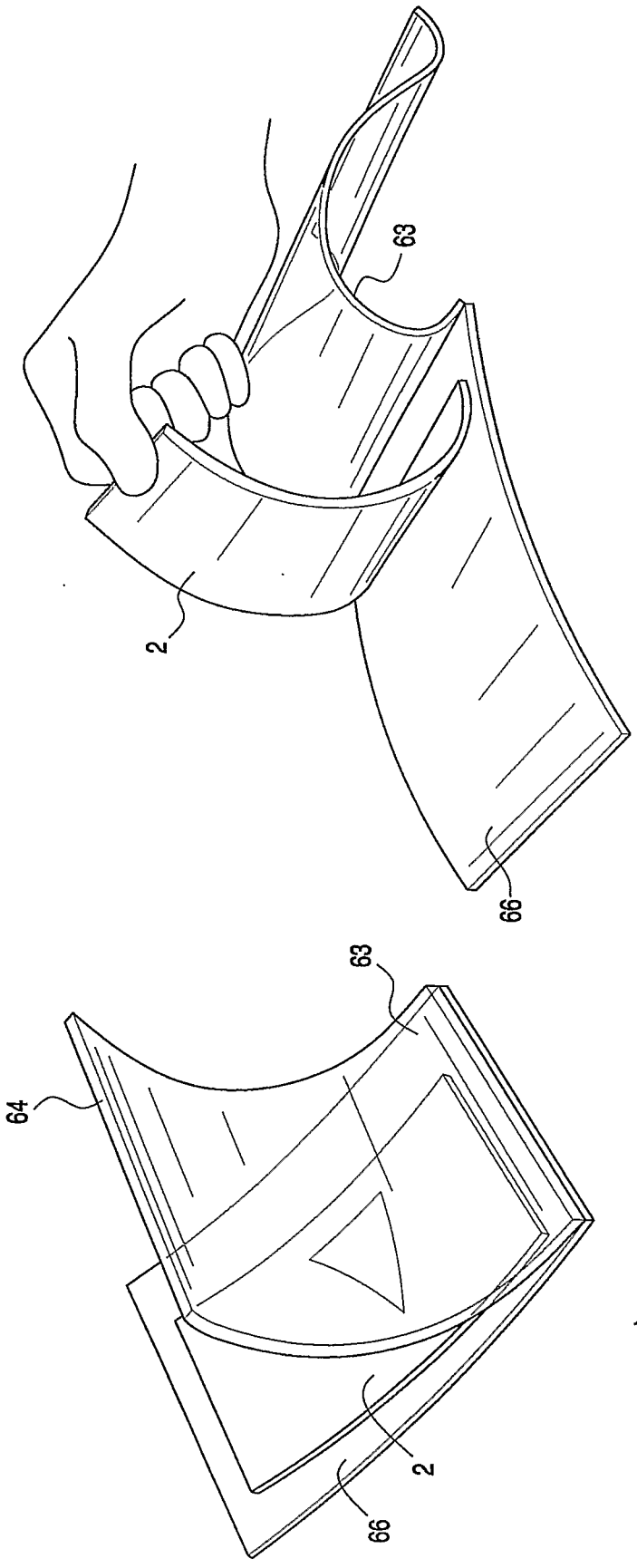



FIG. 13

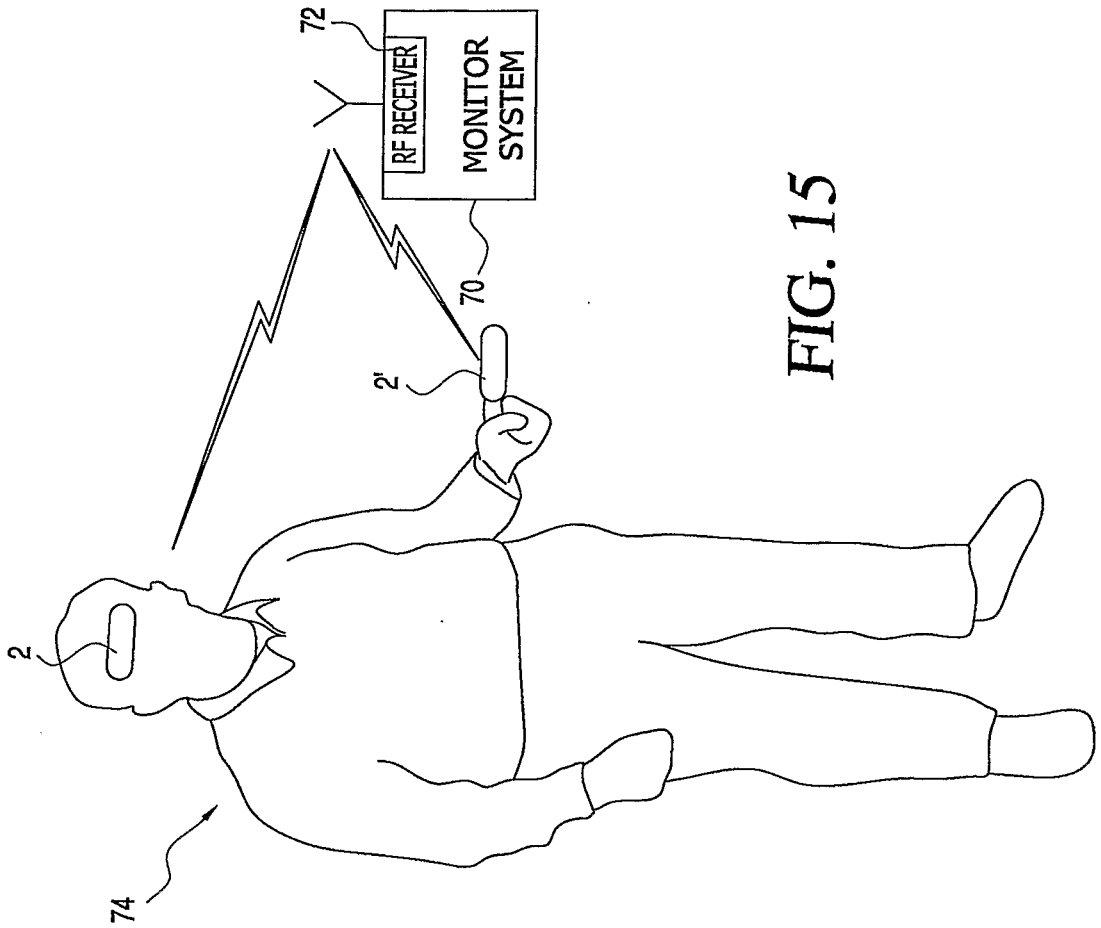

72
RF RECEIVER
MONITOR SYSTEM
70
2'
2
74

FIG. 15

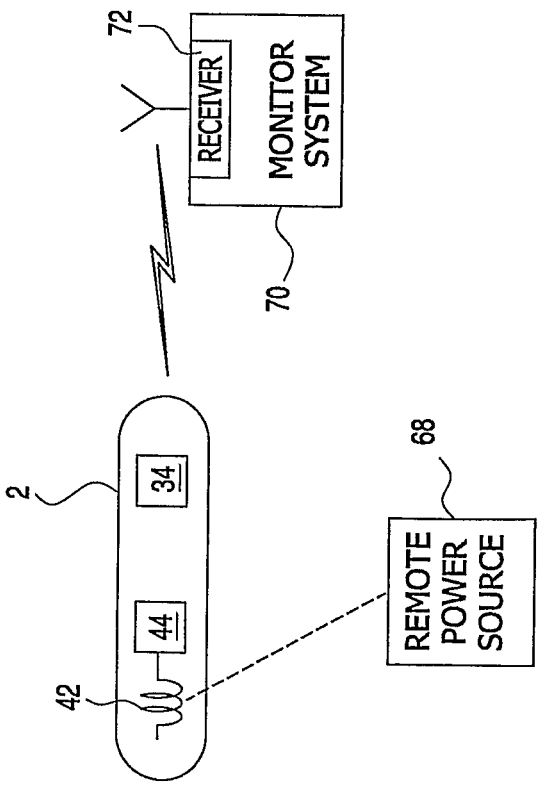
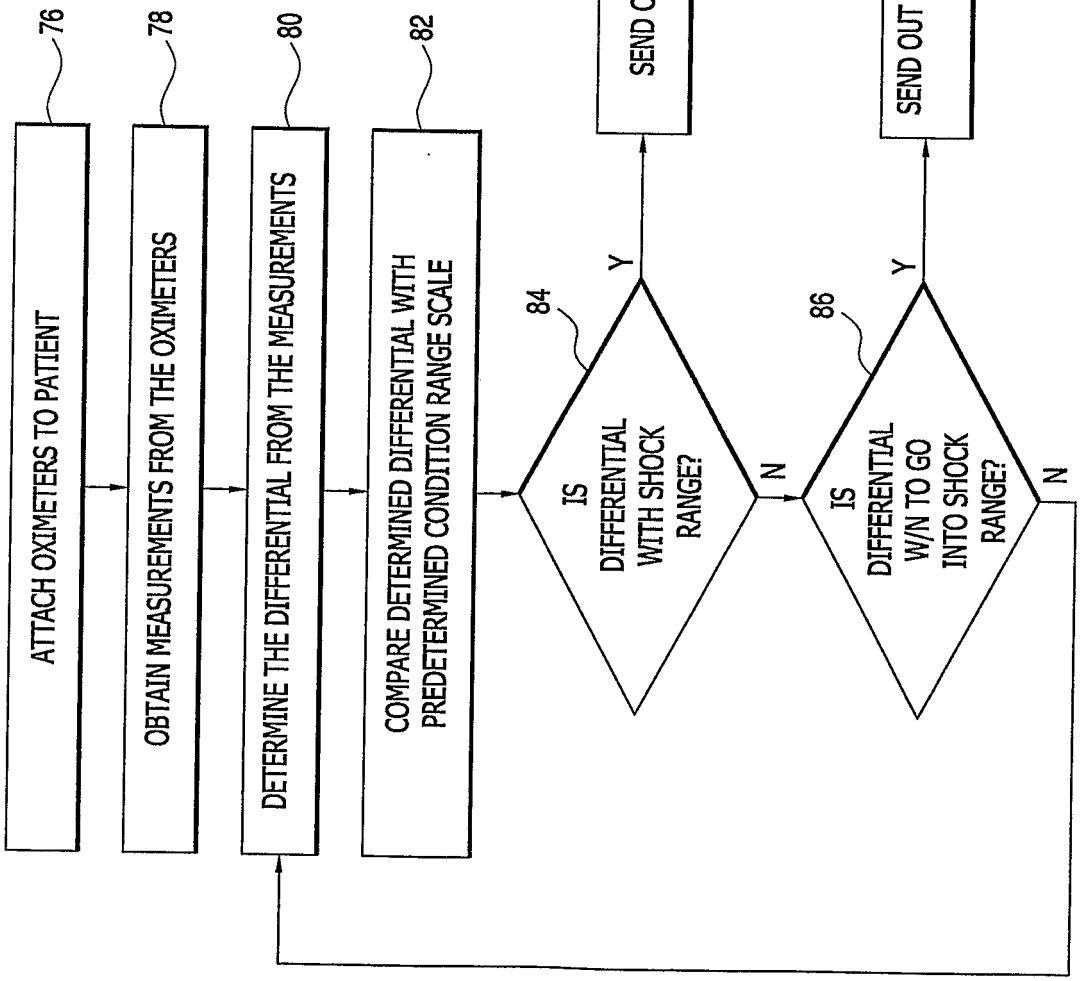

72
RECEIVER
MONITOR SYSTEM
70
2
34
44
42
68
REMOTE POWER SOURCE

FIG. 14

FIG. 16


76
ATTACH OXIMETERS TO PATIENT
78
OBTAIN MEASUREMENTS FROM THE OXIMETERS
80
DETERMINE THE DIFFERENTIAL FROM THE MEASUREMENTS
82
COMPARE DETERMINED DIFFERENTIAL WITH PREDETERMINED CONDITION RANGE SCALE
84
IS DIFFERENTIAL WITH SHOCK RANGE?
Y
N
88
SEND OUT SHOCK STATUS
86
IS DIFFERENTIAL W/IN TO GO INTO SHOCK RANGE?
Y
N
90
SEND OUT "GOING INTO SHOCK" STATUS

## REFERENCES CITED IN THE DESCRIPTION

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| | | | |
|---|---|---|---|
| 专利名称(译) | 一次性脉搏血氧仪 | | |
| 公开(公告)号 | EP1948010B1 | 公开(公告)日 | 2017-11-22 |
| 申请号 | EP2006825628 | 申请日 | 2006-10-10 |
| [标]申请(专利权)人(译) | 史密斯医疗PM公司 | | |
| 申请(专利权)人(译) | 史密斯医疗PM，INC. | | |
| 当前申请(专利权)人(译) | 史密斯医疗ASD，INC. | | |
| [标]发明人 | SWEITZER ROBERT<br>SMITH GUY | | |
| 发明人 | SWEITZER, ROBERT<br>SMITH, GUY | | |
| IPC分类号 | A61B5/00 H01R43/00 | | |
| CPC分类号 | A61B5/0002 A61B5/14551 A61B5/6833 A61B2560/0219 A61B2560/0285 A61B2560/0412 A61B2562/12 Y10T29/49117 | | |
| 优先权 | 11/259092 2005-10-27 US | | |
| 其他公开文献 | EP1948010A4<br>EP1948010A2 | | |
| 外部链接 | Espacenet | | |


摘要(译)

单个使用的，独立的，自供电的一次性血氧计，以贴片或绷带条的形式，在其上安装有光发射器和光传感器，它们一起至少测量患者的SpO2。安装到贴片的电子层是专用集成电路（ASIC），其具有集成在其中的电子器件，其控制光发射器和光传感器的操作，以及用于根据传感器收集的数据计算至少SpO2的算法病人可选地，显示器和警报器也可以安装或嵌入到贴片上，用于分别显示至少SpO2，并且用于通知护理人员/患者至少SpO2不在可接受的范围内，如果是这种情况。在贴片中还提供了电池，其为ASIC电路和发射器的操作提供动力，以及如果在贴片上提供这样的可选组件则显示和报警。贴片上还提供了连接机构。这种机构可以是粘合剂层的形式，其可以以透射模式或反射模式将贴片可移除地附接到患者。贴片血氧计还可以配备有收发器和适当的电子设备，用于向/从远程设备或另一无线贴片血氧计无线地收发信息。代替自备电源，可以从远程电源检索用于操作无线贴片血氧计的电源，条件是贴片血氧计在距离这种远程电源的给定距离内。


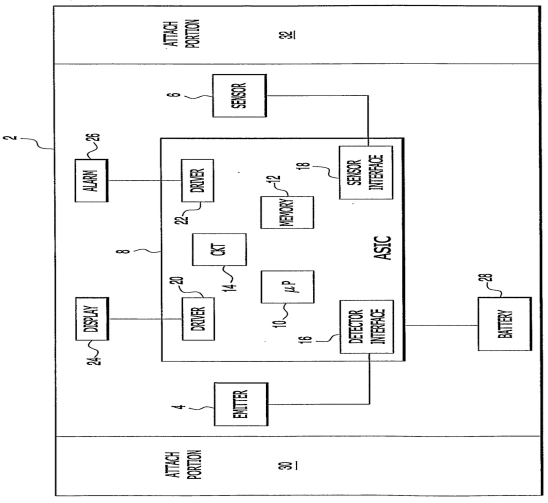


FIG. 1