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(54) SINGLE USE PULSE OXIMETER

PULSOXIMETER ZUR EINMALIGEN ANWENDUNG

SPHYGMO-OXYMETRE A USAGE UNIQUE

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(73) Proprietor: **Smiths Medical ASD, Inc.**

Plymouth, MN 55442 (US)

(72) Inventors:

- **SWEITZER, Robert**
Wauwatosa, WI 53213 (US)
- **SMITH, Guy**
Waukesha, WI 53189 (US)

(74) Representative: **Tranter, Andrew David et al**

Barker Brettell LLP

100 Hagley Road

Edgbaston

Birmingham B16 8QQ (GB)

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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 6,144,868. 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. US 5,957,854 discloses a medical diagnosis and monitoring equipment has wireless electrodes, which are attached to the surface of the skin of the patient. US 2002/107,436 discloses a skin patch includes first and second layers of material and a telesensor sandwiched between the first and second layers.

[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 an apparatus, 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] Telecommunication capabilities are also added to the disposable patch oximeter of the instant invention. For the wireless patch oximeter, a transceiver is mounted to, or embedded in, the patch or bandage. The circuitry required for transmitting or transceiving the signals to/from the patch oximeter are either added or integrated to the ASIC chip, or is added as a separate circuit to the

electronics layer of the patch.

[0011] 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.

[0012] In addition to being able to wirelessly communicate with a host monitor system where at least the patient's oxygen saturation level of arterial blood (SpO₂) is remotely monitored, each patch oximeter may also be able to communicate with another similar patch oximeter that is attached to another location on the patient. With at least two oximeters attached to the patient, a differential of the SpO₂ of the patient may be obtained, so that a hypovolemic shock determination could be made on the patient, i.e., whether the patient is just bleeding, on the verge of going into shock, or in fact is in shock.

[0013] 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.

[0014] With respect to the wireless patch oximeter, instead of embedding the power source onto the patch, 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, and possibly other wireless embodiments of the inventive patch oximeter, the display and/or the alarm may not be needed on the patch.

[0015] The wireless one-piece disposable oximeter of the instant invention is a one-piece disposable patch that is adapted to be attached to a patient for measuring at the oxygen saturation level of arterial blood of the patient. The wireless patch oximeter includes a light emitter mounted to the patch, a light detector mounted to the patch to detect the light from the light emitter that passes

through the patient, or reflected back from the patient, so that data relating to at least the oxygen saturation level of the arterial blood of the patient may be acquired, an electronic circuit mounted to the patch for effecting operation of the light emitter and the light detector, and to calculate from the data acquired the oxygen saturation level of arterial blood of the patient, a transceiver mounted to the patch to at least transmit the calculated oxygen saturation level of arterial blood or data acquired of the patient to a remote device, and an attachment mechanism at the patch that enables the patch to be removably attached to the patient.

[0016] The oximeter of the instant invention furthermore includes a patch adaptable to be attached to the patient, a light emitter and a light detector each mounted to the patch, an electronic circuit mounted to the patch for effecting operation of the light emitter and the light detector, and to calculate from the data acquired by the light detector due to the light from the light emitter that passes the patient it senses, at least the oxygen saturation level of the arterial blood of the patient, a transceiver mounted to the patch to enable the patch to at least transmit the signal representing the oxygen saturation level of arterial blood of the patient or the data acquired by the light detector to a remote device, and means provided at the patch to enable the patch to be removably attached to the patient.

Brief Description of the Figures

[0017] 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 ear-lobe 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

[0018] 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.

[0019] 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*.

[0020] 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.

[0021] 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.

[0022] 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.

[0023] 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.

[0024] 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.

[0025] As the patch oximeter is equipped with a trans-

ceiver 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.

[0026] 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 re-arranging the respective positions of emitter 4 and sensor 6 as shown per the Fig. 2 embodiment.

[0027] 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.

[0028] 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.

[0029] 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.

[0030] 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 pre-jelled 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 with non-invasive blood pressure (NIBP).

[0031] 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.

[0032] 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.

[0033] 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.

[0034] 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.

[0035] 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.

[0036] 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.

[0037] Fig. 12 shows in a cross-sectional view the different layers of the patch of the oximeter of the instant invention. It should be appreciated 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 en-

vironment 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.

[0038] 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.

[0039] 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.

[0040] 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.

[0041] 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.

[0042] 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.

[0043] A flow diagram illustrating the method of deter-

mining 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. An apparatus comprising: a one piece patch (2) having a plurality of layers including an electronics layer (60) sandwiched by two protective layers (56, 58) adaptable to be attached to a patient, a light emitter (4) and a light detector (6) each mounted to said patch and extending from said electronics layer (60), said light detector (6) detecting the light from said light emitter (4) passing through or reflected from the patient and acquiring therefrom 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, the light emitter (4) and the light detector (6) being in electrical interconnection with and controlled by the electronic circuit (8) in the electronics layer (60) so that at least the oxygen saturation level of blood of the patient can be calculated from the data acquired by the light detector (6), a transceiver (34) mounted to the electronics layer (60) of said patch to enable said patch to at least transmit a signal representative of the oxygen saturation level of blood (SpO₂) or the acquired data of the patient to a remote device (72), power source providing means (28) mounted to said patch

for supplying power to said electronic circuit (8), said transceiver (34) and said light emitter (4), an adhesive layer (52) provided at the patch to enable said patch to be removably attached to the patient, and a sheet (50) protecting the adhesive layer (52) of said patch that comes into contact with the patient and the respective contact surfaces of said light emitter (4) and said light detector (6), wherein said patch is activated when said sheet (50) is peeled off from the adhesive layer (52), wherein said protective layers (56, 58) each are a moisture resistant and electrically insulation barrier layers, and wherein one (56) of said two barrier layers is on the lower side of said electronics layer (60) and the other (58) of the two barrier layers is on the upper side of said electronics layer (60) to protect said electronics layer (60) and said electronic circuit (8) and other components mounted to said electronics layer (60).

2. The apparatus of claim 1, wherein said power source providing means (40, 42) receives power from a remote power source (68) for at least said electronic circuit, said apparatus obtaining power from said remote power source to operate at least said electronic circuit when it comes within a given distance to said remote power source, and wherein when the power for the operation of said patch is retrieved from the remote power source, said patch may not be activated until the patient gets to within the given distance to the remote power source.
3. The apparatus of claim 1 or claim 2, further comprising at least one switch (61) on said patch embedded to a barrier layer (58) or the electronics layer (60) with graphics to enable selective activation or deactivation of at least one component of said patch by pushing the switch (61).
4. The apparatus of any one of the preceding claims, wherein said remote device comprises an other apparatus as claimed in any one of the preceding claims to establish a telecommunication network among the plurality of apparatuses to monitor the patient.
5. The apparatus of any one of the preceding claims, wherein said remote device comprises a monitor (70) for monitoring at least the oxygen saturation level of blood of the patient.
6. The apparatus of any one of the preceding claims, further comprising a display (24) mounted thereto for displaying at least the calculated oxygen saturation level of blood of the patient.
7. The apparatus of any one of the preceding claims, further comprising at least two electrodes (44, 46) mounted to said patch and additional electronics (48)

on 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.

8. The apparatus of any one of the preceding claims, wherein said patch comprises a bandage adaptable to be attached to the forehead or wrap around a digit of the patient.
9. The apparatus of any one of the preceding claims being an oximeter.

Patentansprüche

1. Einrichtung, die Folgendes umfasst: ein einstückiges Pflaster (2) mit mehreren Schichten einschließlich einer Elektronikschicht (60), die zwischen zwei Schutzschichten (56, 58) eingeschlossen ist, welches dazu verwendbar ist, an einem Patienten angebracht zu werden, einen Lichtemitter (4) und einen Lichtdetektor (6), die jeweils an dem Pflaster angebracht sind und sich von der Elektronikschicht (60) erstrecken, wobei der Lichtdetektor (6) Licht von dem Lichtemitter (4) detektiert, das durch den Patienten hindurchläuft oder von diesem reflektiert wird, und davon Daten erfasst, die wenigstens mit dem Sauerstoffsättigungspegel des Blutes des Patienten in Zusammenhang stehen, einen elektronischen Schaltkreis (8), der an der Elektronikschicht (60) des Pflasters montiert ist, wobei sich der Lichtemitter (4) und der Lichtdetektor (6) in elektronischer Zwischenverbindung mit dem elektronischen Schaltkreis (8) in der Elektronikschicht (60) befinden und durch diesen gesteuert werden, so dass wenigstens der Sauerstoffsättigungspegel des Blutes des Patienten aus den Daten berechnet werden kann, die durch den Lichtdetektor (6) erfasst werden, einen Sendeempfänger (34), der an der Elektronikschicht (60) des Pflasters montiert ist, um zu ermöglichen, dass das Pflaster wenigstens ein Signal, das den Sauerstoffsättigungspegel des Blutes (SpO_2) repräsentiert, oder die erfassten Daten des Patienten an eine ferne Vorrichtung (72) überträgt, ein Leistungsquellenbereitstellungsmittel (28), das an dem Pflaster montiert ist, zum Liefern von Leistung an den elektronischen Schaltkreis (8), den Sendeempfänger (34) und den Lichtemitter (4), eine Klebschicht (52), die an dem Pflaster bereitgestellt ist, um zu ermöglichen, dass das Pflaster entfernbar an dem Patienten angebracht wird, und ein Blatt (50), das die Klebschicht (52) des Pflasters schützt, die in Kontakt mit dem Patienten und den jeweiligen Kontaktflächen des Lichtemitters (4) und des Lichtdetektors (6) kommt, wobei das Pflaster aktiviert wird, wenn das Blatt (50) von der Klebschicht (52) abgezogen wird, wobei die Schutzschichten (56, 58) je-

weils feuchtigkeitsbeständige und elektrisch isolierte Barrierschichten sind und wobei sich eine (56) der zwei Barrierschichten auf der unteren Seite der Elektronikschicht (60) befindet und sich die andere (58) der zwei Barrierschichten auf der oberen Seite der Elektronikschicht (60) befindet, um die Elektronikschicht (60) und den elektronischen Schaltkreis (8) und andere an der Elektronikschicht (60) montierte Komponenten zu schützen.

2. Einrichtung nach Anspruch 1, wobei das Leistungsquellenbereitstellungsmittel (40, 42) Leistung von einer fernen Leistungsquelle (68) für wenigstens den elektronischen Schaltkreis empfängt, wobei die Einrichtung Leistung von der fernen Leistungsquelle erhält, um wenigstens den elektronischen Schaltkreis zu betreiben, wenn sie innerhalb eines gegebenen Abstands zu der fernen Leistungsquelle gelangt, und wobei das Pflaster, wenn die Leistung für den Betrieb des Pflasters von der fernen Leistungsquelle abgerufen wird, möglicherweise nicht aktiviert wird, bis der Patient innerhalb des gegebenen Abstands zu der fernen Leistungsquelle gelangt.
3. Einrichtung nach Anspruch 1 oder Anspruch 2, die ferner wenigstens einen Schalter (61) auf dem Pflaster, der in einer Barrierschicht (58) oder der Elektronikschicht (60) eingebettet ist, mit Grafiken umfasst, um eine selektive Aktivierung oder Deaktivierung von wenigstens einer Komponente des Pflasters durch Betätigen des Schalters (61) zu ermöglichen.
4. Einrichtung nach einem der vorhergehenden Ansprüche, wobei die ferne Vorrichtung eine andere Einrichtung nach einem der vorhergehenden Ansprüche umfasst, um ein Telekommunikationsnetz zwischen den mehreren Einrichtungen einzurichten, um den Patienten zu überwachen.
5. Einrichtung nach einem der vorhergehenden Ansprüche, wobei die ferne Vorrichtung einen Monitor (70) zum Überwachen von wenigstens dem Sauerstoffsättigungspegel des Blutes des Patienten umfasst.
6. Einrichtung nach einem der vorhergehenden Ansprüche, die ferner eine daran montierte Anzeige (24) zum Anzeigen von wenigstens dem berechneten Sauerstoffsättigungspegel des Blutes des Patienten umfasst.
7. Einrichtung nach einem der vorhergehenden Ansprüche, die ferner wenigstens zwei Elektroden (44, 46), die an dem Pflaster montiert sind, und zusätzliche elektronische Elemente (48) auf dem Pflaster oder integriert in den elektronischen Schaltkreis umfasst, um einen Betrieb der Elektroden zu bewirken,

um wenigstens einen anderen physiologischen Parameter des Patienten zu messen.

8. Einrichtung nach einem der vorhergehenden Ansprüche, wobei das Pflaster einen Verband umfasst, der dazu verwendbar ist, an der Stirn des Patienten angebracht zu werden oder sich um einen Finger von diesem zu wickeln.
9. Einrichtung nach einem der vorhergehenden Ansprüche, die ein Oxymeter ist.

Revendications

1. Appareil, comprenant: un timbre monobloc (2), possédant une pluralité de couches, incluant une couche à composants électroniques (60) prise en sandwich par deux couches de protection (56, 58), adaptable pour être attaché à un patient, un émetteur de lumière (4) et un détecteur de lumière (6), chacun montés sur ledit timbre et s'étendant à partir de ladite couche à composants électroniques (60), ledit détecteur de lumière (6) détectant la lumière dudit émetteur de lumière (4) passant à travers ou réfléchi à partir du patient et acquérant, à partir de celle-ci, 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, l'émetteur de lumière (4) et le détecteur de lumière (6) étant en interconnexion électrique avec et commandés par le circuit électronique (8) dans la couche à composants électroniques (60) pour qu'au moins le niveau de saturation en oxygène du sang du patient puisse être calculé à partir des données acquises par le détecteur de lumière (6), un émetteur-récepteur (34) monté sur la couche à composants électroniques (60) dudit timbre pour permettre audit timbre au moins de transmettre un signal représentatif du niveau de saturation en oxygène du sang (SpO_2) ou les données acquises du patient à un dispositif à distance (72), des moyens de fourniture de source d'alimentation électrique (28) montés sur ledit timbre pour fournir une alimentation électrique audit circuit électronique (8), audit émetteur-récepteur (34) et audit émetteur de lumière (4), une couche adhésive (52) prévue sur le timbre pour permettre audit timbre d'être attaché de façon amovible au patient, et une feuille (50) protégeant la couche adhésive (52) dudit timbre qui entre en contact avec le patient et les surfaces de contact respectives dudit émetteur de lumière (4) et dudit détecteur de lumière (6), dans lequel ledit timbre est activé lorsque ladite feuille (50) est décollée de la couche adhésive (52), dans lequel lesdites couches de protection (56, 58) sont chacune une couche barrière résistante à l'humidité et électriquement isolée, et dans lequel l'une (56) desdites

deux couches barrières est sur le côté inférieur de ladite couche à composants électroniques (60) et l'autre (58) des deux couches barrières est sur le côté supérieur de ladite couche à composants électroniques (60) pour protéger ladite couche à composants électroniques (60) et ledit circuit électronique (8) et d'autres composants montés sur ladite couche à composants électroniques (60).

2. Appareil selon la revendication 1, dans lequel lesdits moyens de fourniture de source d'alimentation électrique (40, 42) reçoivent une alimentation électrique d'une source d'alimentation électrique à distance (68) pour au moins ledit circuit électronique, ledit appareil obtenant une alimentation électrique de ladite source d'alimentation électrique à distance pour faire fonctionner au moins ledit circuit électronique lorsqu'il est au sein d'une distance donnée de ladite source d'alimentation électrique à distance, et dans lequel, lorsque l'alimentation électrique pour le fonctionnement dudit timbre est extraite de la source d'alimentation électrique à distance, ledit timbre peut ne pas être activé avant que le patient arrive au sein de la distance donnée de la source d'alimentation électrique à distance.
3. Appareil selon la revendication 1 ou la revendication 2, comprenant en outre au moins un interrupteur (61) sur ledit timbre incorporé dans une couche barrière (58) ou la couche à composants électroniques (60) avec des graphismes pour permettre l'activation ou la désactivation sélective d'au moins un composant dudit timbre en appuyant sur l'interrupteur (61).
4. Appareil selon l'une quelconque des revendications précédentes, dans lequel ledit dispositif à distance comprend un autre appareil selon l'une quelconque des revendications précédentes pour établir un réseau de télécommunication parmi la pluralité d'appareils pour surveiller le patient.
5. Appareil selon l'une quelconque des revendications précédentes, dans lequel ledit dispositif à distance comprend un moniteur (70) pour surveiller au moins le niveau de saturation en oxygène du sang du patient.
6. Appareil selon l'une quelconque des revendications précédentes, 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.
7. Appareil 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 (48) 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.

8. Appareil selon l'une quelconque des revendications précédentes, dans lequel ledit timbre comprend un pansement adaptable pour être attaché au front ou entourer un doigt du patient. 5
9. Appareil selon l'une quelconque des revendications précédentes, étant un oxymètre. 10

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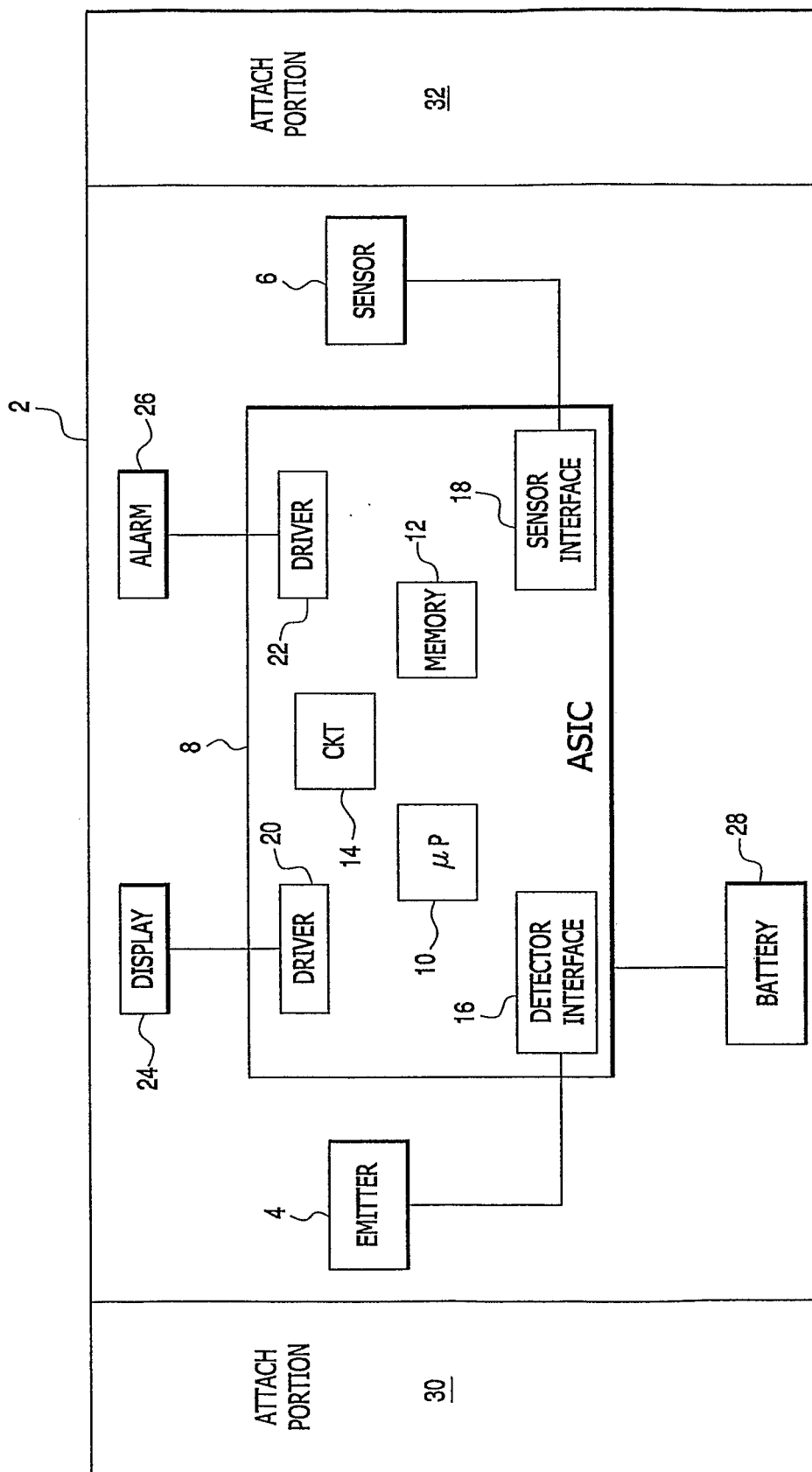


FIG. 1

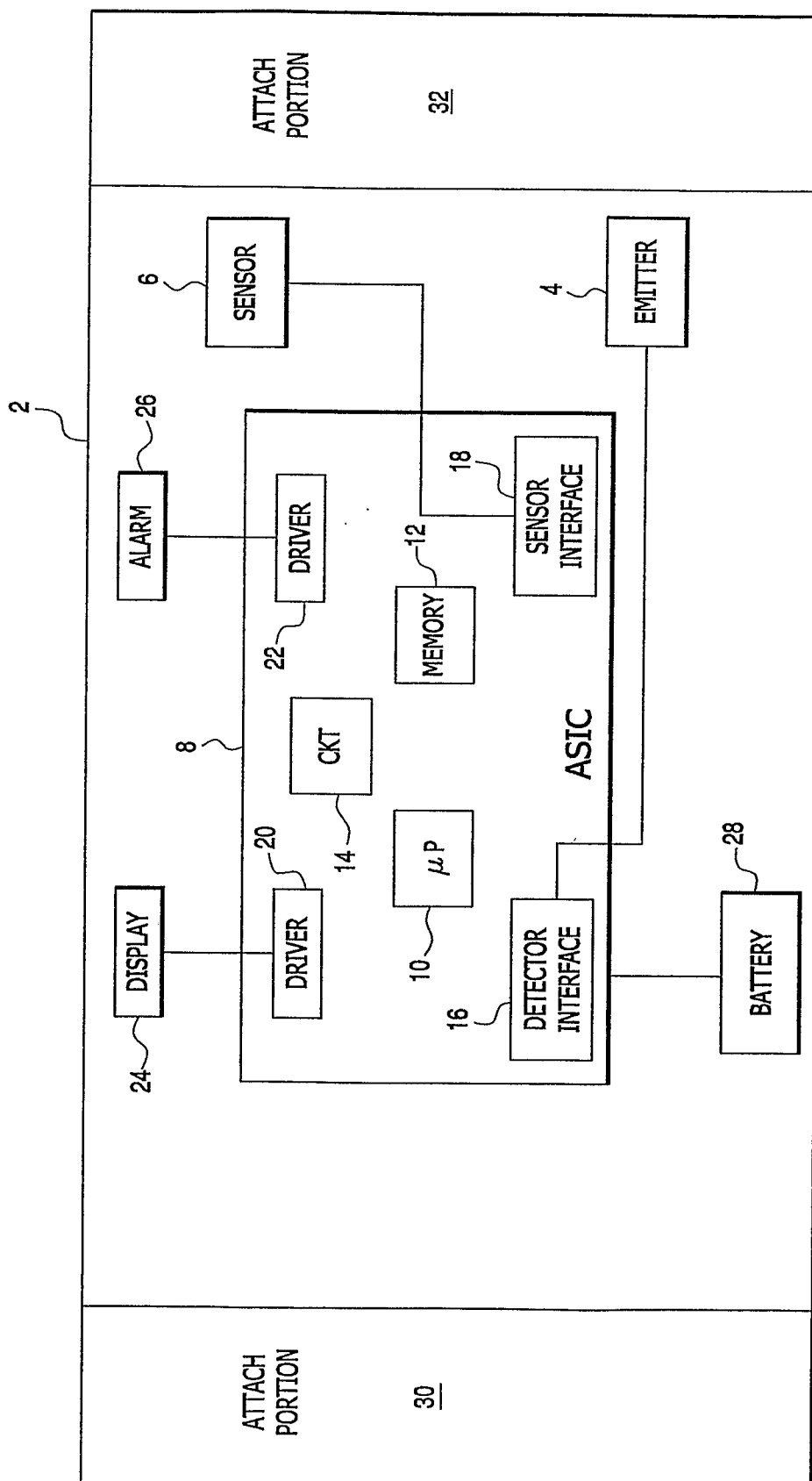


FIG. 2

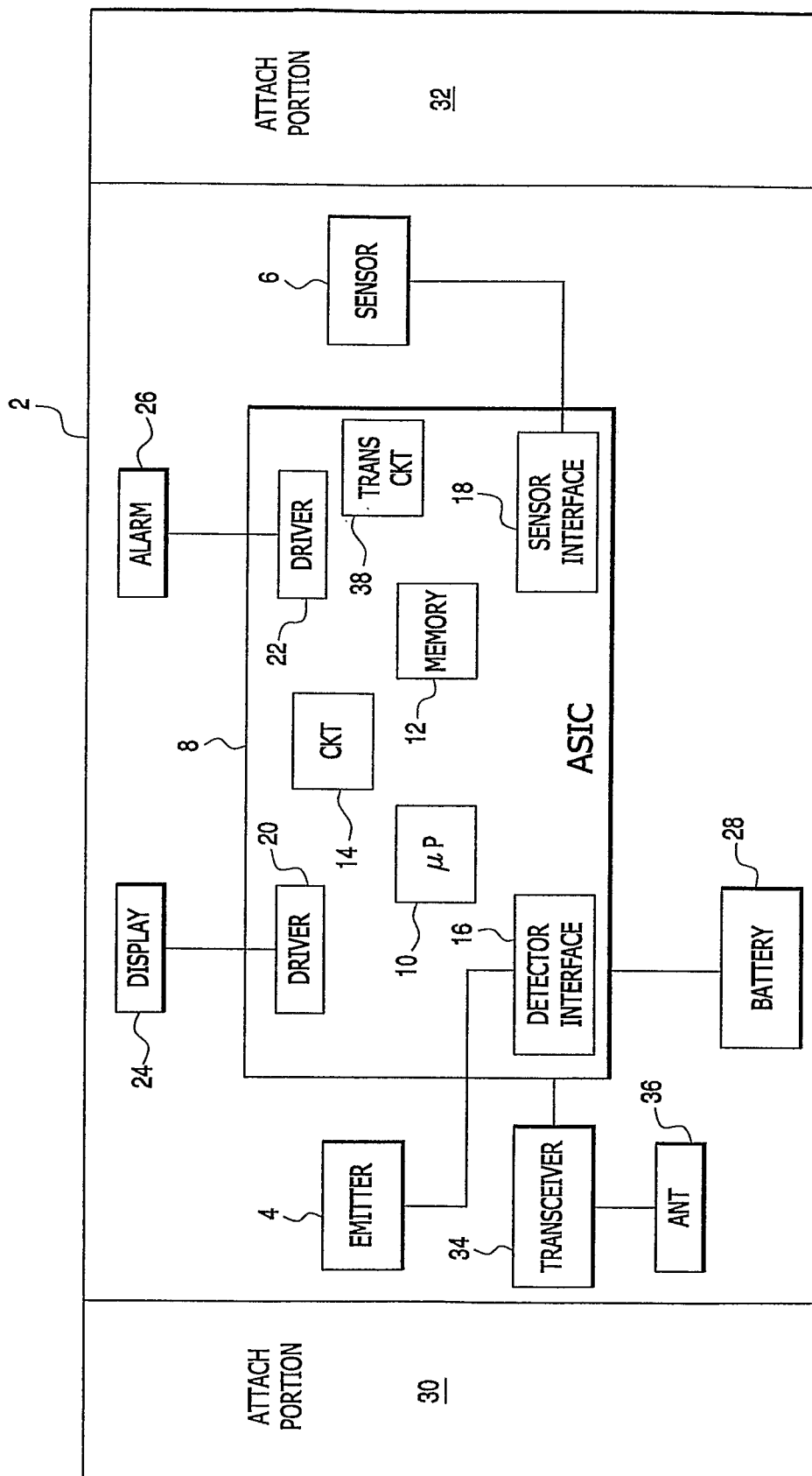


FIG. 3

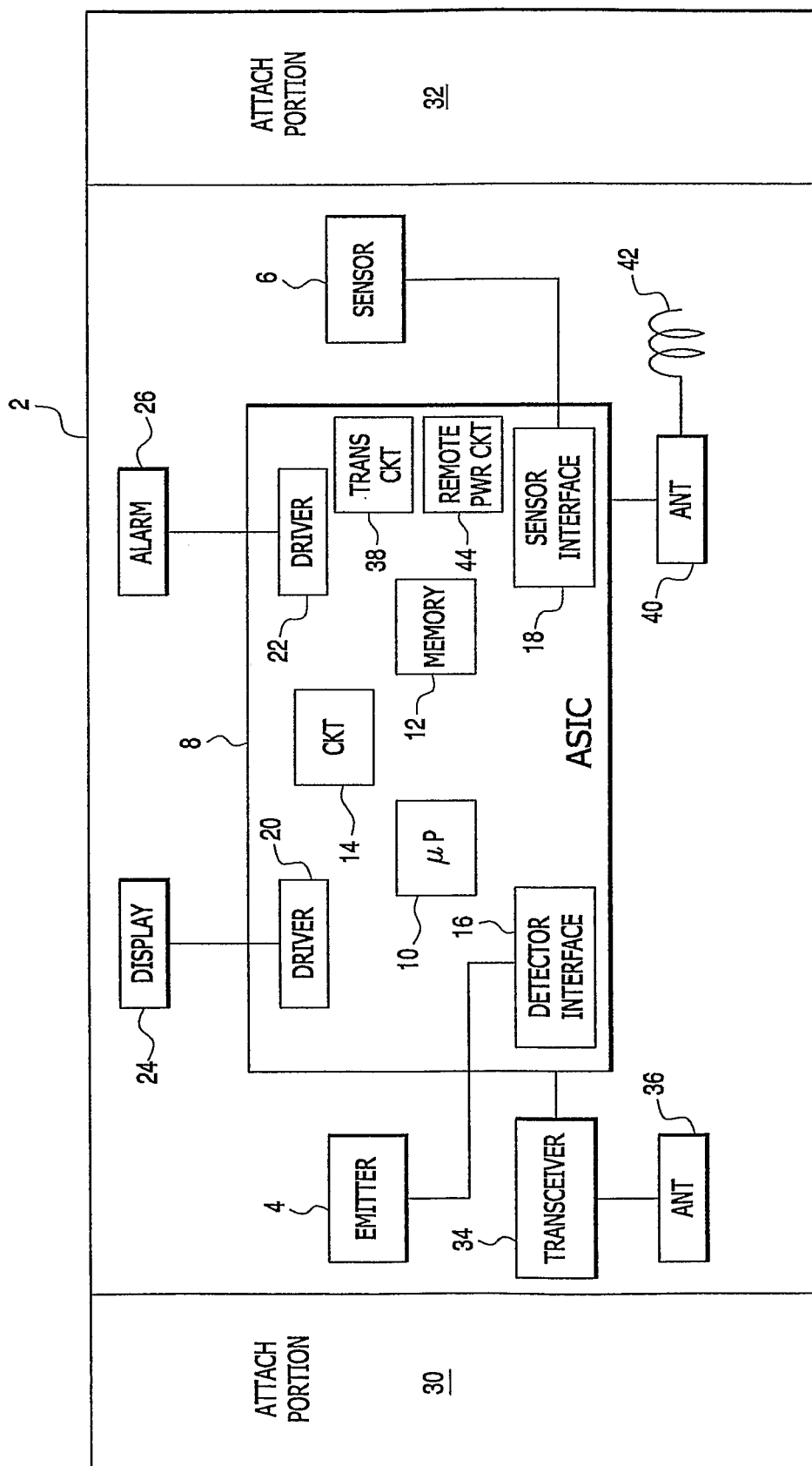


FIG. 4

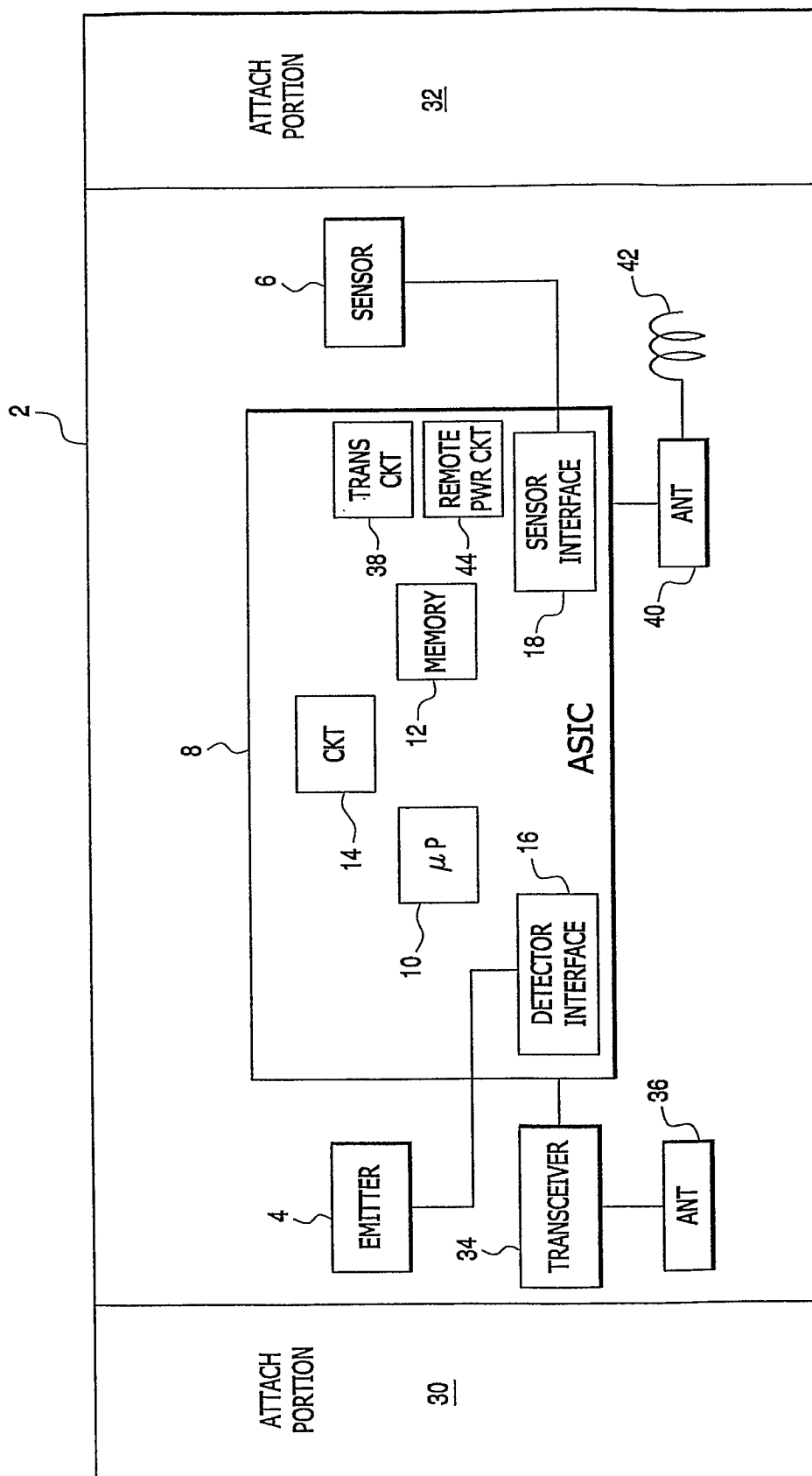


FIG. 5

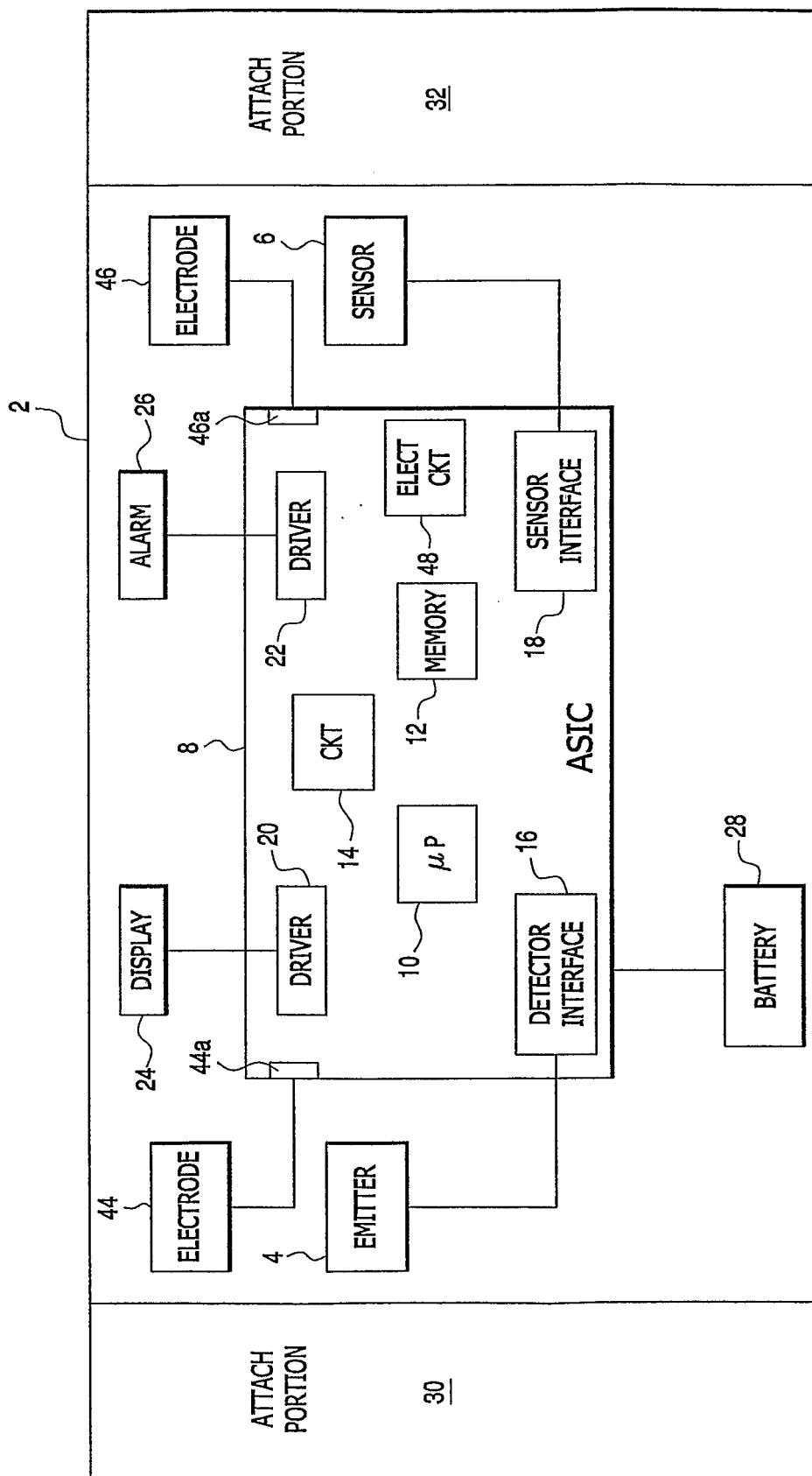


FIG. 6

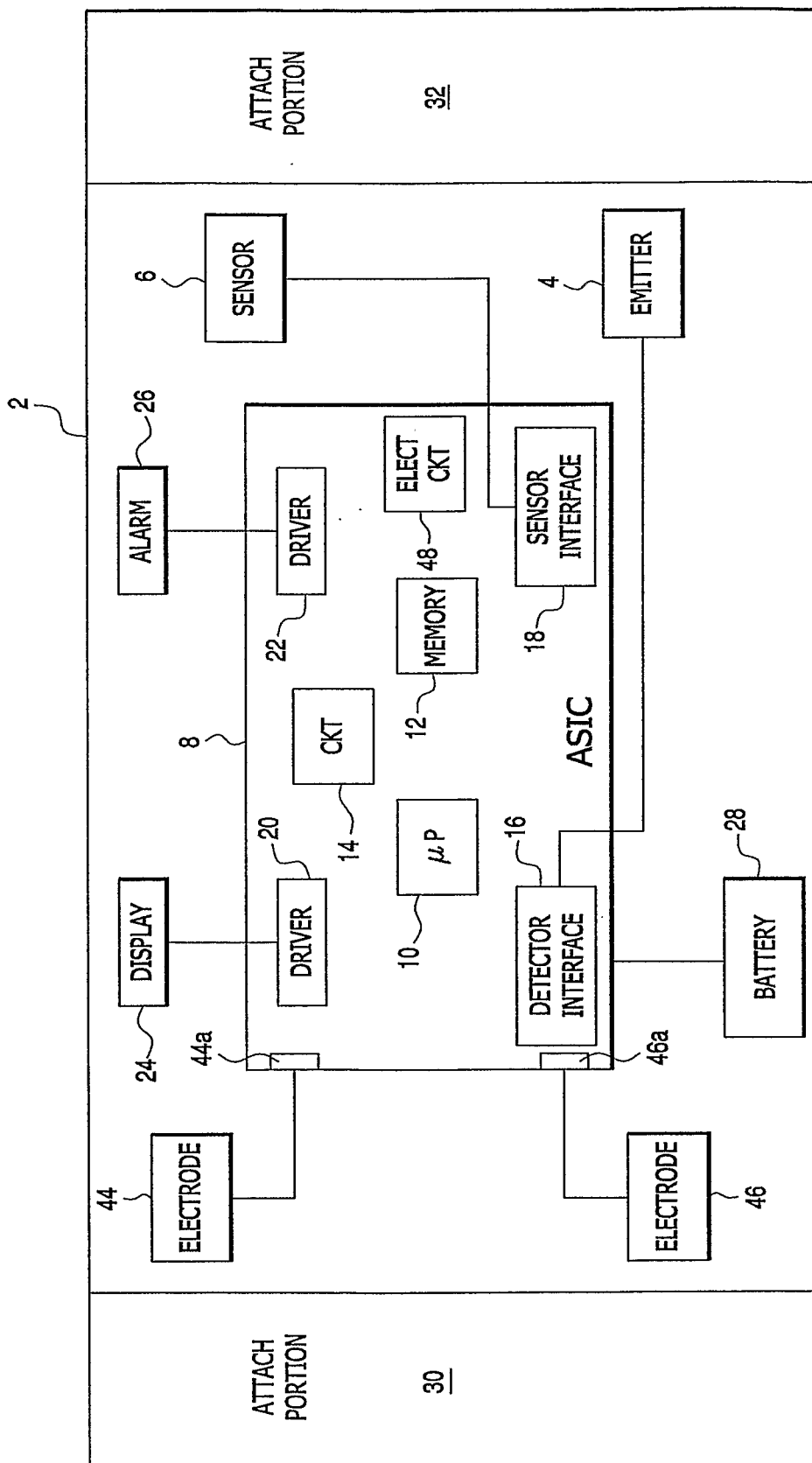


FIG. 7

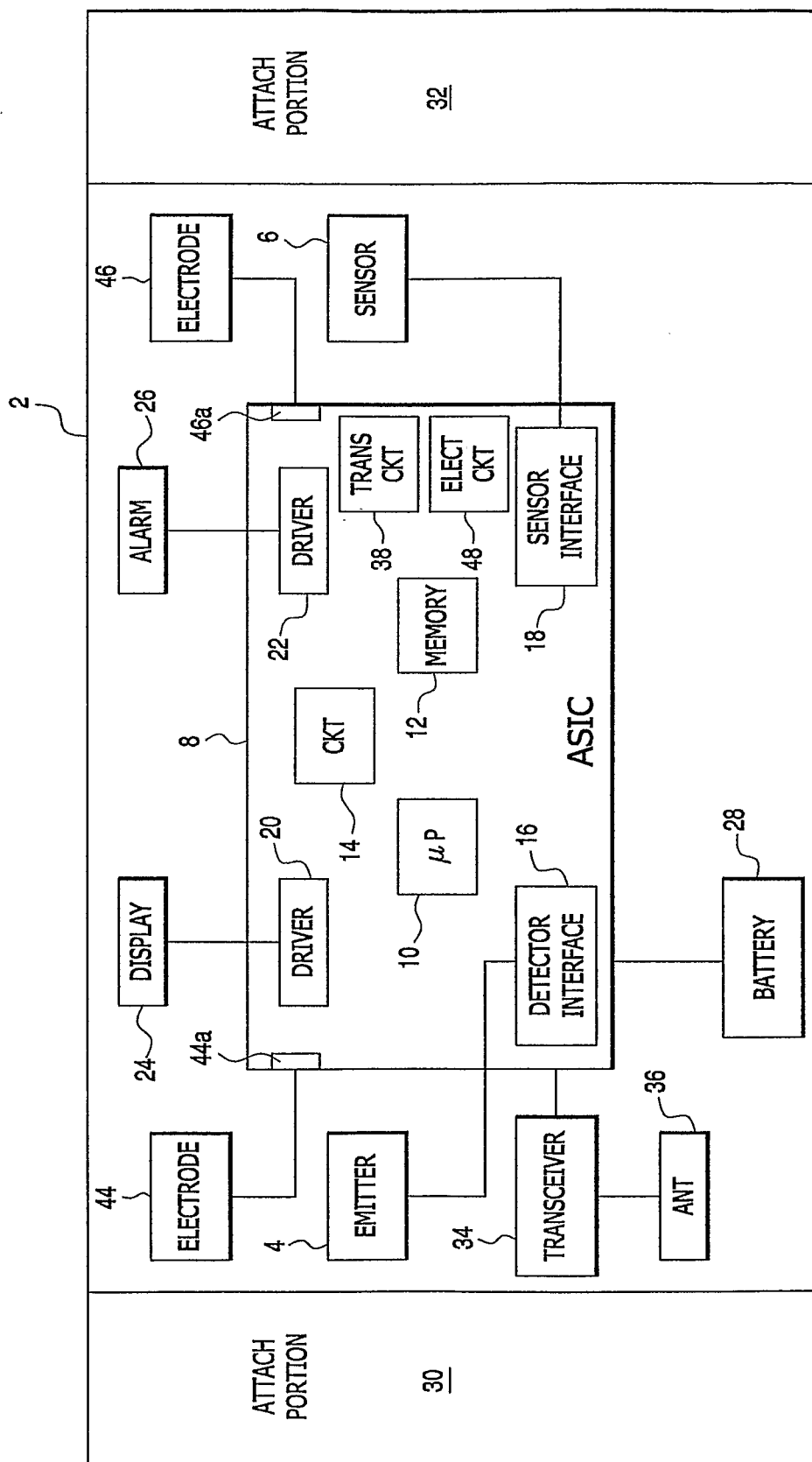


FIG. 8

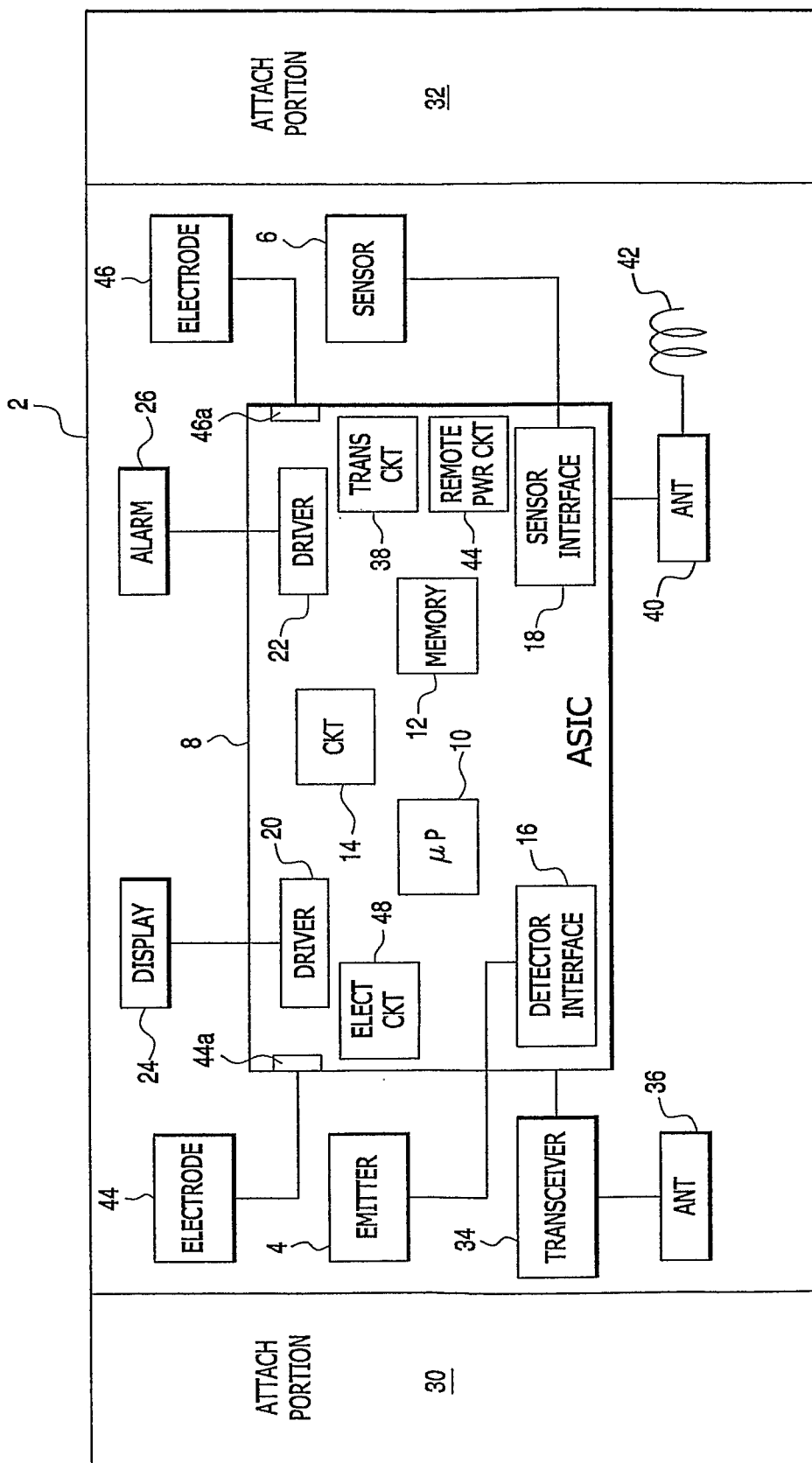


FIG. 9

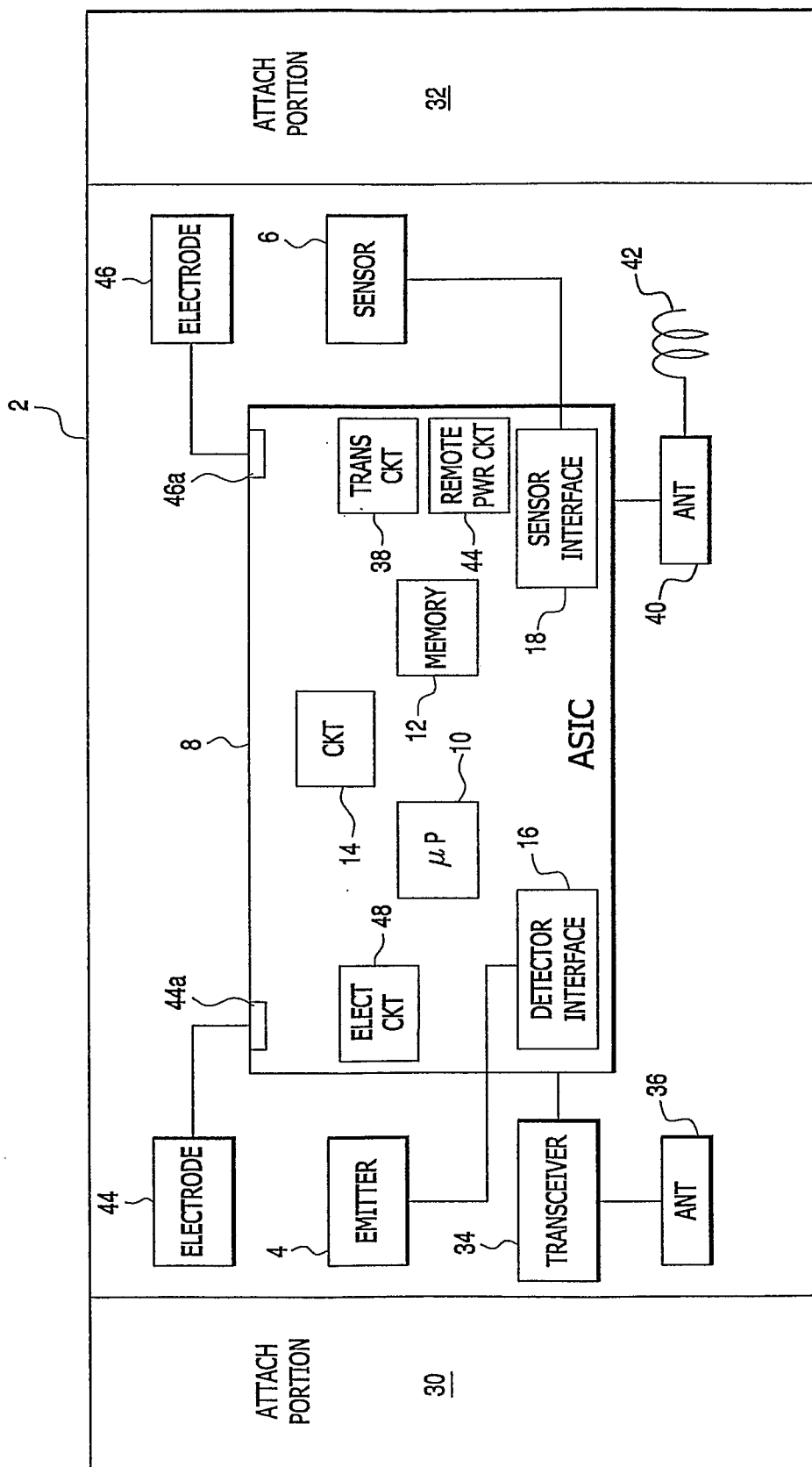


FIG. 10

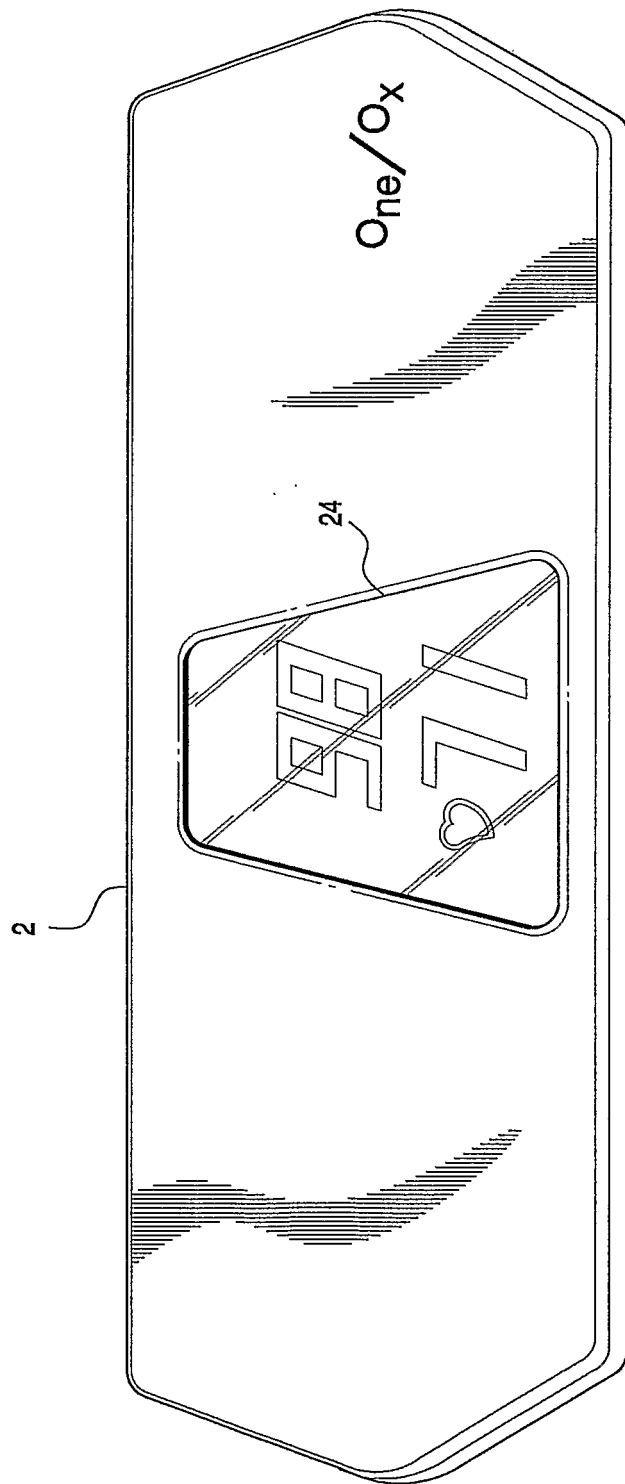


FIG. 11

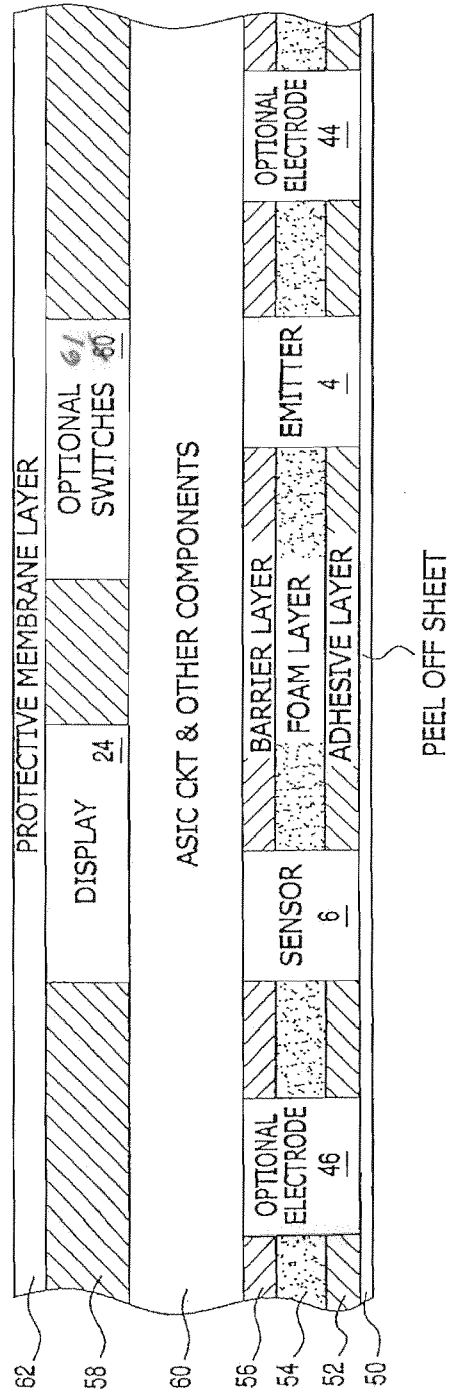


FIG. 12

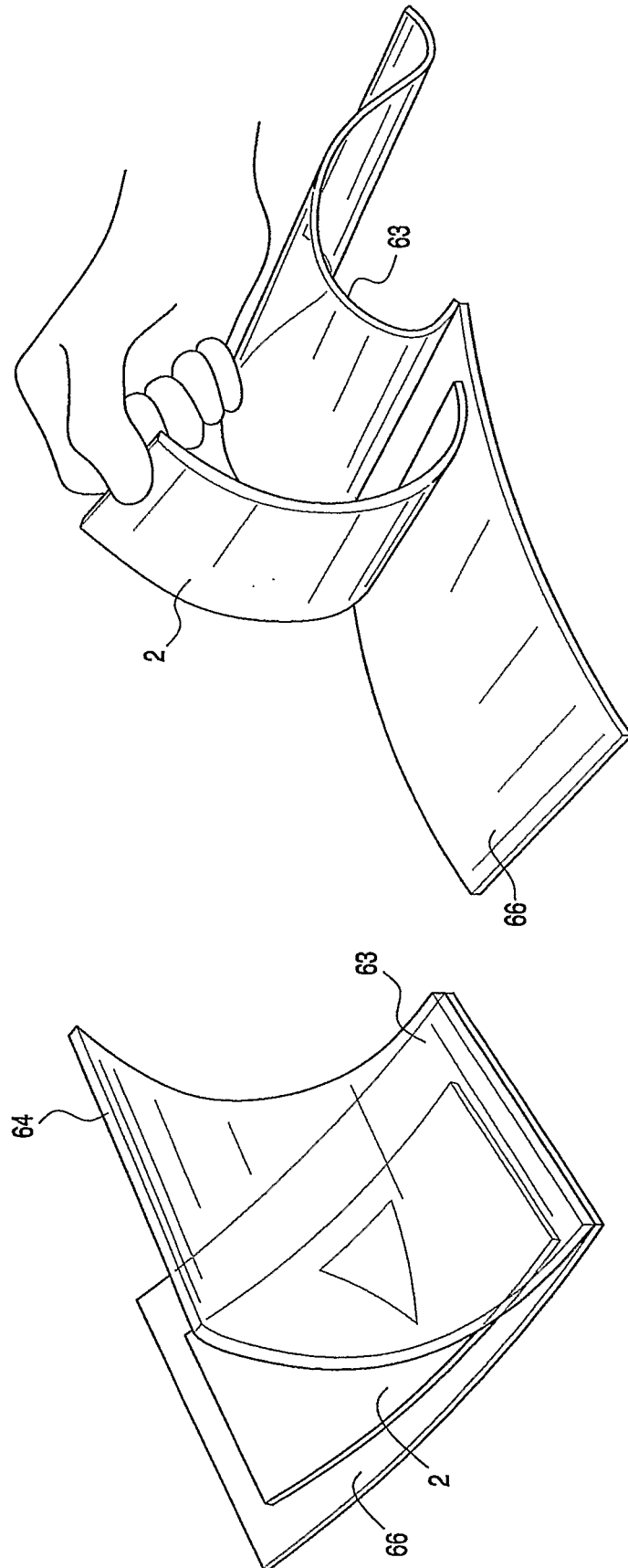


FIG. 13

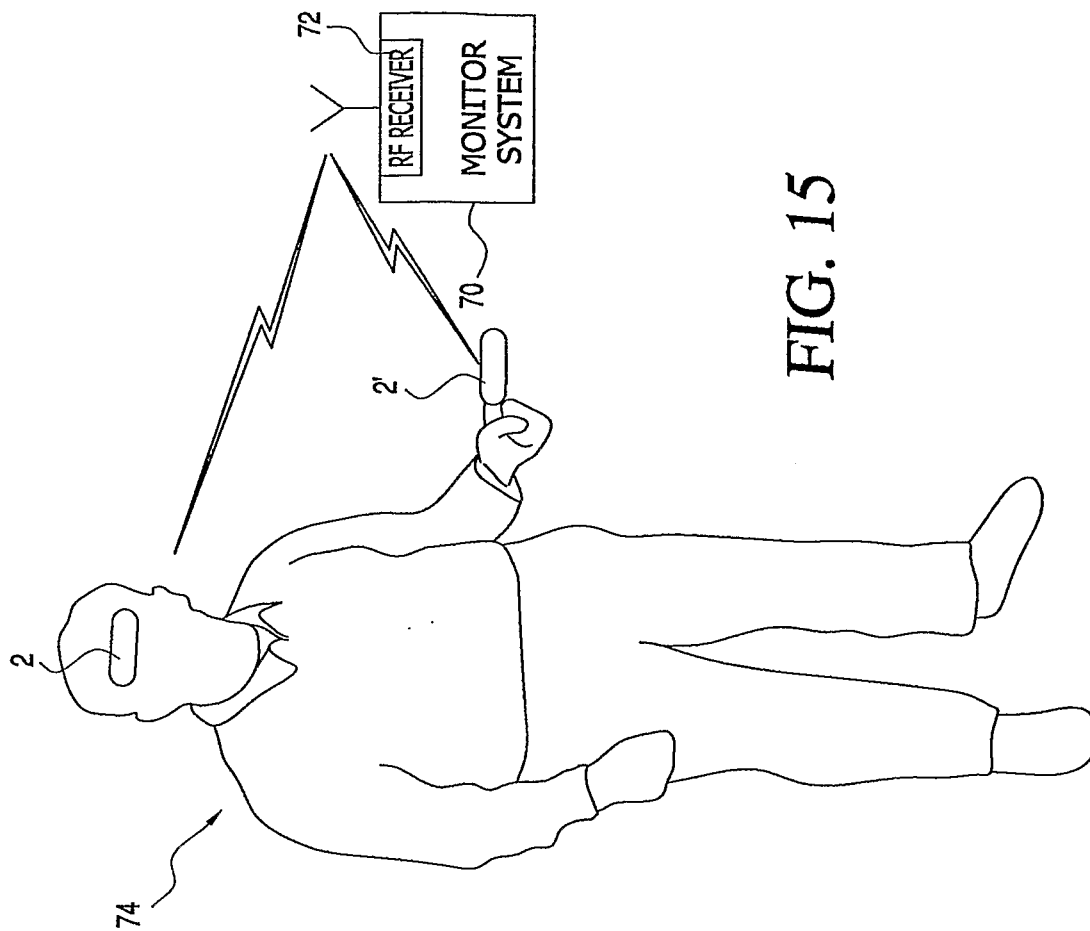


FIG. 15

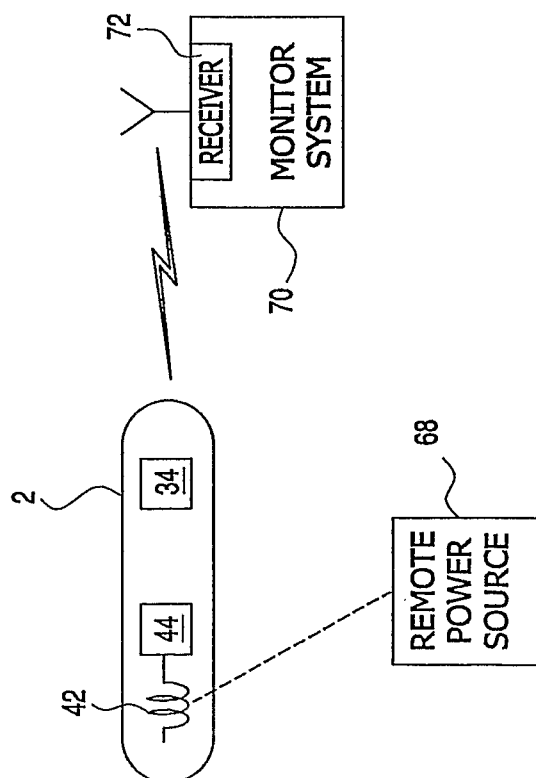
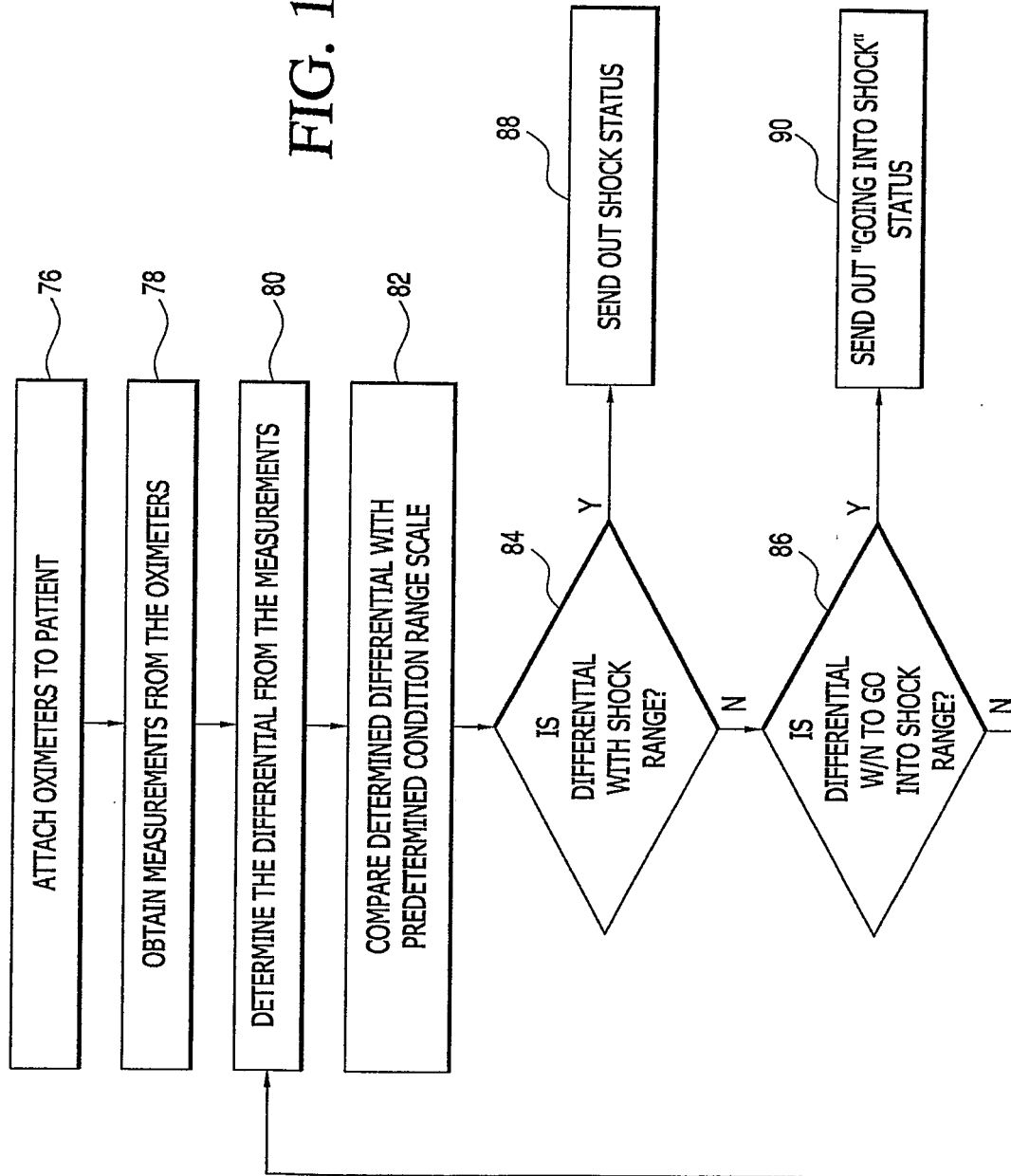


FIG. 14

FIG. 16



REFERENCES CITED IN THE DESCRIPTION

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[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 SMITH GUY		
发明人	SWEITZER, ROBERT SMITH, GUY		
IPC分类号	A61B5/00 H01R43/00		
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优先权	11/259093 2005-10-27 US		
其他公开文献	EP1948009B1 EP1948009A4		
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供电，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。